

HIV/HCV Coinfection Reports from the 2004 Retrovirus Conference

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Liz Highleyman

Hepatitis C coinfection was a major focus of the 11th Conference on Retroviruses and Opportunistic Infections, held February 8-11, 2004, in San Francisco, with more than 50 abstracts devoted to the topic.

PEGYLATED INTERFERON PLUS RIBAVIRIN: APRICOT, ACTG 5071, RIBAVIC

Among the major news: data from three studies of hepatitis C treatment in HIV/HCV coinfecting patients. Past studies have shown that while about half of people with hepatitis C alone achieve a sustained response to combination therapy with pegylated interferon plus ribavirin, response rates are lower in coinfecting patients—about 40-60% in those with genotypes 2 or 3, and less than 25% in those with genotype 1.

Douglas Dieterich presented 72-week results from the Roche APRI-COT study, the largest such trial to date (abstract 112). In this study, 860 subjects were randomly assigned to one of three arms: 3 million IU standard interferon three times weekly plus 800 mg ribavirin daily, 180 mcg pegylated interferon (Pegasys) once weekly plus placebo, or the same doses of pegylated interferon plus ribavirin, all for 48 weeks. The participants were about 81% male, about 79% Caucasian, the mean age

was 40, about 60% had HCV genotype 1, and about 16% had bridging fibrosis or cirrhosis. The participants had well-controlled HIV disease and 85% were on antiretroviral therapy.

Overall, 40% of patients treated with Pegasys/ribavirin achieved a sustained virological response (SVR; undetectable HCV RNA at the end of a 24-week post-treatment follow-up period), compared with 20% of those receiving Pegasys monotherapy and 12% of those receiving standard interferon/ribavirin. Among subjects with genotypes 2 or 3, the respective SVR rates were 62%, 36%, and 20%, while in genotype 1 patients the corresponding rates were 29%, 14%, and 7%. The higher SVR rates in the Pegasys/ribavirin arm compared with the Pegasys monotherapy arm suggest that ribavirin plays an important role in preventing HCV relapse. Adverse side effects or laboratory abnormalities were seen in about 15% in all three arms.

Raymond Chung presented final results from ACTG A5071 (abstract 110). This was the first randomized study looking at pegylated interferon/ribavirin in coinfecting patients. Interim (48-week) data was presented at the Retrovirus conference two years ago. A total of 133 participants were randomized to receive either standard interferon three times



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weekly or 180 mcg Pegasys once weekly, both for 48 weeks. Subjects in both arms also received daily ribavirin in escalating doses from 600 mg to 1000 mg. About 80% of the participants were men, about half were African-American, 75% had genotype 1, the median fibrosis score was 2.0, and the median HAI score was 5.0. Participants in this study also had well-controlled HIV.

After 48 weeks, an end-of-treatment response (ETR) was seen in 41% of patients in the Pegasys arm, compared with 12% in the standard interferon arm. Within the Pegasys arm, 80% with non-1 genotypes achieved an ETR, compared with 29% of genotype 1 patients. By 72 weeks, overall SVR rates were 27% in the Pegasys arm and 12% in the standard interferon arm. In the Pegasys arm, the SVR rates were 73% for

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A Patient Guide to Finding an HCV Support Group



Alan Franciscus, Editor-in-Chief

Many people with HCV feel isolated and find it difficult to cope with the effects of living with a chronic illness. Family and friends can be a great source of comfort and support, but support from people who have faced some of the same fears and challenges can be crucial in helping people understand, manage and live successfully with hepatitis C.

A support group can offer a safe space to discuss the emotional and practical issues of living with hepatitis C. In addition, the information shared by peer members can be helpful in making decisions about a wide variety of issues from disease stigma, disclosure, disease management and treatment options. Family members may also need help when they learn that a loved one has a potentially life-threatening disease, and in coping with a loved one undergoing treatment.

Many HCV peer-led support groups have begun to emerge to address the need for support and education in the hepatitis C population. In addition, people who have come together in support groups have been the same individuals who have emerged as HCV advocates/activists.

Support groups can be divided into two basic types: information (or educational) and emotional, although most support groups provide aspects of both, but may focus on one area or the other. Informational support group meetings typically have a lecture format that includes a guest speaker.

A wide variety of people seek out and attend support group meetings. People who have been recently diagnosed with HCV are usually interested in educating themselves about the disease and talking to other people living with chronic hepatitis C. Hepatitis C is a highly stigmatized disease and for some people a group is a "safe" place where they can talk and seek advice from people. People considering HCV therapy can receive help with their decision-making process and talk with others about what to expect and how to prepare for treatment. People currently undergoing HCV therapy can receive emotional support and learn coping strategies to help them deal with the physical and psychological side effects of treatment. Finally, people with symptomatic HCV can benefit from the emotional support and the chance to discuss the various issues that surround living with a chronic illness.

Support groups are usually led by hepatitis positive people who have not been professionally trained as therapists or counselors. It is very important that people seeking a support group explore different support groups to find well informed facilitators and to make sure that they are a "good fit" with the group.

The first step is finding a support group. HCV positive friends and acquaintances, healthcare providers, agencies that work with people and the internet are all good sources. Unfortunately, some people may not

have access to a support group in their area. These people may find internet resources, online HCV email lists or discussion groups beneficial. You can also check the local paper or call one of the organizations listed at the end of this article for referrals to support groups. If possible interview the support group leader. This will help you with deciding if an initial visit is warranted.

Some questions to ask:

- Is the support group facilitator knowledgeable about hepatitis C?
- What is the typical size of the support group?
- Is the support group leader a healthcare provider or is the group linked to a healthcare advisor?
- What is the focus of the group?
- What populations frequent the group? Is the group geared to one particular aspect such as treatment or primarily focused on one population?
- When does the support group meet?
- How often and at what time does the group meet?
- Is this a strictly emotionally focused group or are there informational meetings?
- Does the support group feature speakers? If so, how frequently?
- Are there membership fees or dues?
- Is the support group held in an area that is considered safe?
- Are family members/friends allowed to attend the group?
- How is confidentiality dealt with?

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HealthWise:

Hepatitis C and Aging



Lucinda K. Porter, RN, CCRC

*"To me, old age is always 15 years older than I am."
- Bernard M. Baruch*

According to the most recent census, there are more than 35 million adults age 65 and over in the United States. By the next census in 2011, Baby Boomers will push this growth to notable numbers as this group reaches the age of 65. The National Institutes of Health (NIH) Consensus Conference on the Management of Hepatitis C (HCV) reported that the highest prevalence of HCV occurred in persons age 40 to 59. This means that by the 2011 census, the U.S. population will have record numbers of aging adults living with HCV. This group includes a high prevalence of African Americans and Veterans, groups that already have unique health problems without the extra burden of an HCV diagnosis.

The aging process has an impact on every body system. Older adults experience eye, skin, and gastrointestinal problems. Immune and cardiovascular systems become affected. Bladder, bowel, and brain functions can become impaired. Arthritis, insomnia, depression and sexual dysfunction are reported more frequently in older adults. Our bodies are somewhat like automobiles. The better you take care of your car, the longer it is more likely to last. However, sooner or later various parts start to break down. In *Reader's Digest*, Gloria Pitzer sums up the process well when she said, "About the only thing that comes to us without effort is old age."

People living with HCV may report various symptoms that accompany this viral infection.

There are some similarities between the medical problems incurred by aging and those of chronic HCV infection. An area worth exploring is the relationship between aging and HCV.

At the American Association for the Study of Liver Diseases (AASLD) 2003 conference, Dominique Thabut and colleagues from Groupe Hospitalier Pitie-Salpetriere, Paris, France reported that in patients 65 years or older, chronic hepatitis C is more severe and presents with lower ALT levels than in younger patients. This report was based on data collected from 2,410 people living in France. The report also stated in the conclusion that treatment is effective and well-tolerated. Additionally, the use of biochemical markers may be useful as a non-invasive alternative to liver biopsy in this population.

The age at which HCV was acquired may have an impact on prognosis. A number of studies have reported that individuals who become infected with HCV at older ages tend to have a worse prognosis than those who acquire HCV while young. The NIH HCV Consensus report lists people over age 40 among those who are more likely to develop HCV-related liver cancer. Age can also have a negative impact on liver transplantation survival. In a study from Spain, Ignacio Herreroa and colleagues reported in the November issue of the *American Journal of Transplantation* that older liver transplant recipients have a significantly lower survival rate than younger patients.

Treatment for older adults living with HCV has dimensions that occur less frequently in younger adults. Some physicians are reluctant to treat elderly HCV patients. The current standard treatment of pegylated alpha interferon and ribavirin carries

There are some similarities between the medical problems incurred by aging and those of chronic HCV infection

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Questions to Ask Your Healthcare Professional



Kara Wright, PA-C

The diagnosis of hepatitis C can be overwhelming. Many people are shocked at the time of diagnosis and have difficulty understanding all of the implications at first. After adequate time to process the information, patients should do a little research to learn more about the disease. After this research, it is important to sit down with your healthcare provider to learn more about this diagnosis. To help you get started, here are some important questions you may want to ask.

GENERAL HEPATITIS C QUESTIONS

- How does my diet affect the hepatitis C virus?
- May I be referred to a dietitian or nutritionist for help with my dietary needs?
- How do my social habits (drinking alcohol, using drugs, and smoking) affect my liver or the hepatitis C virus?
- Do I need to stop drinking alcohol completely?
- If I want to stop using alcohol and/or other drugs, can you refer me to an alcohol and drug counselor?
- If I want to stop smoking, can you refer me to someone to help me quit?
- Do I have to change my sexual practices?
- Should my partner(s) be tested?
- What kinds of symptoms/signs can I expect now that I have been diagnosed with hepatitis C?
- What if I feel fine? Does that mean my liver is not damaged?
- Is there a support group in the area that I can attend?
- What are my liver function test levels? (Liver function tests are ALT/AST, ALP, and SGTP, bilirubin, albumin, and prothrombin time.)
- How often should I have liver function tests done?

QUESTIONS ABOUT A LIVER BIOPSY

- Do you recommend I have a liver biopsy?
 - If yes, why?
 - If no, why not?
- What is involved in getting a biopsy?
- What are the risks?
- How is the procedure performed?
- How long does the procedure take?
- What experience do you have, or does the doctor performing the procedure have in doing liver biopsies? (The more experience they have, the better.)
- If a liver biopsy shows that I have fibrosis or cirrhosis (scarring), how does that affect my treatment options?
- (If you have already gotten a biopsy) What are the results of my liver biopsy and what does it

OTHER INFECTIONS

- Do I need to be tested to see if I am immune to hepatitis A and/or hepatitis B?
- Am I immune to hepatitis A and/or hepatitis B? If not, do you recommend I be vaccinated for either or both the hepatitis A and B viruses?
- Should I be tested for HIV or other infections?

QUESTIONS ABOUT LABS

- What is my hepatitis C viral load?
- How often should I have my viral load checked?
- What is my hepatitis C genotype? (This is a one-time liver test.)
- How does my genotype affect my illness and possible treatment?

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Occupational Exposure to Hepatitis C



Alan Franciscus, Editor-in-Chief

Hepatitis C virus (HCV) is transmitted through blood-to-blood exposure. The most common transmission routes include sharing HCV infected needles and drug preparation tools, and receiving blood products/transfusions before 1992. Sexual transmission is less common but has been documented in studies. Tattooing, body-piercing and sharing personal items such as toothbrushes and razors are also possible transmission routes, but are not well-documented. Healthcare workers are at risk because of needlestick accidents and unavoidable situations that may result in direct contact with blood from an HCV infected individual.

Health-Care Workers

Healthcare workers or healthcare personnel are defined as people whose occupational activities involve contact with patients or with blood or other body fluids from patients in health-care, laboratory, or public-safety settings.

Occupational Exposure

It has been well-documented that transmission of hepatitis C in a healthcare situation can occur. However, the general rate of transmission is considered low - about 1.8%. The risk is primarily with needlestick accidents involving hollow-bore needles. Transmission from exposure to fluids or tissues other than HCV-infected blood can occur but it is uncommon.

If exposure does occur, testing should be initiated and an occupational exposure report should be filed.

Prevention

All healthcare workers should always follow standard universal precautions including the use of gloves and face and eye protection if appropriate. Properly dispose of or sterilize used equipment. Safely dispose of used bandages, and clean and disinfect spilled blood and body fluids. Unlike hepatitis B, there is no pre- or post-exposure vaccine or immunoglobulin (IG) to protect against HCV transmission.

Exposure

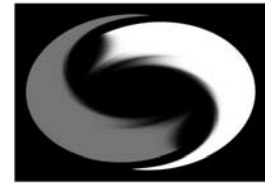
If exposure does occur the U.S. Public Health Service Guidelines for the management of HCV exposure include:

For the source of infection:

- Perform testing for anti-HCV (antibody)

For the person exposed to an HCV positive source:

- Perform baseline testing for anti-HCV and ALT activity; and
- Perform follow-up testing at 4-6 months for anti-HCV and ALT activity-if earlier diagnosis of HCV infection is desired, testing for HCV RNA (viral load) may be performed at 4-6 weeks.



**HEPATITIS C
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COINFECTION

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non-1 patients, compared with just 14% for genotype 1 patients; in the standard interferon arm, the corresponding rates were 33% and 6%. Notably, while the overall ETR and SVR rates were the same in the standard interferon arm, the response rate declined dramatically from week 48 to week 72 in the Pegasys arm. Dr. Chung suggested that the lower initial dose of ribavirin may have led to higher relapse rates, indicating that timing of ribavirin is important. Histological improvement was seen in about half of virological responders and about one-third of nonresponders who had repeated biopsies. The incidence of side effects was similar in both arms, and 12% in both prematurely discontinued therapy.

Finally, Christian Perronne presented 72-week results from the French RIBAVIC (ANRS HC02) study (abstract 117LB). This 412-person trial also compared standard and pegylated interferon, but used Peg-Intron instead of Pegasys. Participants were randomly assigned to receive 3 million IU standard interferon three times weekly plus 800 mg ribavirin daily, or 1.5 mcg/kg Peg-Intron once weekly plus 800 mg ribavirin daily. In this study, 74% of participants were male, the mean age was 40, 79% had a history of injection drug use, 58% had HCV genotypes 1 or 4, and 40% had stage F3 or F4 fibrosis. Here, too, the subjects had well-controlled HIV disease and 82% were receiving antiretroviral therapy.

Overall, at 72 weeks, 19% of participants receiving standard interferon achieved SVR, compared with 27% of those on Peg-Intron, using an intent-to-treat analysis. Among patients with genotype 1, SVR was seen in 5% of the standard interferon

arm and 15% of the pegylated interferon arm; among non-1 patients, the corresponding rates were 40% and 45%. About 40% discontinued therapy in both arms and about 30% experienced severe adverse events.

It is unclear why the sustained response rate was so much higher in the APRICOT study compared with the other two trials, but there were some important differences in the patient populations. ACTG 5071 included more African-Americans, a group that appears to respond less well to treatment. The RIBAVIC study included patients with more advanced liver damage, and drop-out rates and rates of severe adverse events were considerably higher. Also, RIBAVIC used Peg-Intron while the other two studies used Pegasys.

HOW LONG TO TREAT?

In patients with HCV alone, response to pegylated interferon/ribavirin after 12 weeks of therapy predicts the likelihood of achieving SVR. Data have been conflicting as to whether the same cut-off applies for coinfecting patients. In an analysis of medical records, Vincent Soriano and colleagues (abstract 819) found that while no coinfecting patients who failed to achieve an HCV RNA decrease of at least 2 logs after 12 weeks of treatment went on to achieve SVR, about 40% of those who did achieve ETR later relapsed, regardless of genotype. This relapse rate was surprisingly high, especially in patients with genotypes 2 or 3 (relapse is uncommon in HCV monoinfecting people with these genotypes), suggesting that coinfecting patients may respond more slowly than those with HCV alone, and thus may benefit from a longer course of treatment (12 months for genotypes 2 or 3; 18 months for genotypes 1 or 4).

FIBROSIS PROGRESSION AND IMPROVEMENT

Maribel Rodriguez-Torres and colleagues (abstract 813) presented data confirming that HIV appears to accelerate hepatitis C progression. The researchers detected fibrosis progression even in some younger coinfecting patients with shorter durations of HCV infection, and suggested that "Therapeutic interventions should be a priority in this population." Dr. Rodriguez-Torres (abstract 821) also reported that retreatment with Pegasys was associated with improved liver histology in coinfecting patients who did not respond previously to standard interferon alone. The researchers found that both Pegasys monotherapy and Pegasys/ribavirin led to decreased fibrosis grade and progression rate in patients who received at least 24 weeks of therapy even if they did not achieve SVR.

RENEWED HOPE

While HCV coinfection remains a significant cause of death in people with HIV, and while inconsistent results from different studies are perplexing, the news about HIV/HCV coinfection presented at the Retrovirus conference was generally encouraging. The APRICOT study produced the highest SVR rate ever seen in a coinfecting population, approaching rates achieved in patients with HCV alone, and its large number of participants gives added weight to the findings. In addition, research continues to show that interferon can reduce liver damage even in patients who do not achieve complete HCV clearance. Together, these results provide renewed hope for people with HIV/HCV coinfection.

For the 2004 Retrovirus conference program and abstracts, see www.retroconference.org/2004/home.htm.



Review:

Winning the Hepatitis C Battle by Dr. Schalla



Alan Franciscus, Editor-in-Chief

The book *Winning the Hepatitis C Battle* and its companion CD cover every topic related to hepatitis C in an easy to understand format sprinkled with patient anecdotes that help guide the reader through the difficult process of understanding the complexities of hepatitis C—the importance of your liver, maintaining a healthy lifestyle, making treatment decisions, preparing for treatment and getting through treatment. There is a

section devoted to helping a patient's loved ones understand hepatitis C, learn to accept and be supportive as well as assist and cope during treatment. The CD is jam-packed with information presented by a variety of speakers, and there are plenty of colorful graphics that make watching it a pleasurable and rewarding learning experience.

It is very apparent that the book and CD are a labor of love by someone who has a passion

for hepatitis C and cares deeply for his patients. I highly recommend the book and its companion CD to anyone with hepatitis C. It is also an excellent educational tool for helping hepatitis C affected families, medical providers, health service organizations as well as the general public learn more about hepatitis C.

To learn more about the book and companion CD please visit: <http://www.hepcbattle.com>



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QUESTIONS

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mean? Will the result affect my treatment?

- May I have a copy of the biopsy report for my records?

QUESTIONS ABOUT TREATMENT

- Do you feel I am a good candidate for interferon and ribavirin combination therapy? What about pegylated (peg-a-lated) interferon therapy?

- If so, why?
- If not, why?

- What are the pros and cons of beginning treatment?
- What are the potential side effects of interferon and ribavirin, or of pegylated interferon?
- How long do you think I will have to be on therapy?
- How is the treatment taken?
- How may the treatment affect my life and my lifestyle?
- What is the likelihood that the treatment will be successful?
- Should my partner or I practice birth control while on the medications?
- Can my partner (or I) get pregnant safely while I am on the medications?
- Do you exclude patients from interferon/ribavirin or pegylated interferon treatment if they have advanced liver scarring?

- If I have a history of mental health issues (depression/anxiety), will I be a candidate for hepatitis C treatment?

- How will my mental health be managed?
- What will be done if my mental health gets worse?

- If I am on methadone, how will this affect my eligibility for hepatitis C treatment?

- How do you feel about treatment for hepatitis C while a person is on methadone?

- Will you work together with my dispensing/treatment agency to coordinate my care?

- Are there new therapies that will soon be available, and do you think I should wait for them?

- While on treatment, how often will I need to return for follow-up?

- What should I do if my health gets worse between now and the next time I see you?

- Are you available by phone?
- What should I do if I have side effects? Is there anything I can take to help the side effects go away?

- Is there anything I can do on my own to help—such as changes to my diet, etc?

QUESTIONS ABOUT EMOTIONAL ISSUES

- Where can I find emotional support for my family and for me?
- How can I expect this to affect my marriage or other intimate relationships?

- How do I explain my diagnosis to friends and family?

- Are there any clinical trials I could participate in?

- Who from your office can I speak with if I have questions or concerns about my treatment?

QUESTIONS ABOUT A HEALTH CARE PROVIDER'S EXPERIENCE WITH HEPATITIS C:

- Do you have many other patients with hepatitis C?

- Do you feel up-to-date on all the latest changes and advancements in hepatitis C treatment?

Now that you are armed with some questions to ask, you may wonder how to ask these questions. Providers can sometime appear intimidating and may make you feel they are rushed. Be confident. Providers are usually more than happy to take the time to answer any questions or schedule time to answer questions later, perhaps by email or phone.



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.

AGING

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some risks. Couple the list of treatment side effects with the list of changes that occur during aging and the overall picture becomes more complicated. The NIH HCV Consensus report states that patients over the age of 60 years old should be managed on an individual basis.

Another consideration of HCV treatment for older adults is life expectancy. Just like certain models of cars, some individuals can expect to live longer. Further, a report in the medical press preliminarily suggests that life expectancy may be increased in chronic hepatitis C patients undergoing interferon therapy by preventing liver-related deaths.

Regardless of age, treatment decisions are always between the medical team and the patient. These decisions are individualized, based on multiple factors. The impact of age is a component of the decision-making process. Hopefully as new treatments develop, there will be more and easier to tolerate options available to aging persons living with HCV. Until that time, take good care of yourself. We all know that life is short. In the words of Maurice Chevalier, "Old age is not so bad when you consider the alternatives."

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SUPPORT GROUP

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If you are able to talk with someone "live" before sitting in on a support group you should also use your gut reaction. Is the person warm and fuzzy? Is the person too warm and fuzzy? It is pretty easy to tell after a couple of minutes if the support group leader is conducting a group that you would like to attend, or if you will just sit in on one session.

Once you have a chance to sit in on a group, ask yourself the following questions:

- Is the information and emotional support unbiased?
- How is the tone of the group—is it positive and upbeat?
- Is the group leader able to "leave" his or her ego at the door?
- Is the information just about treatment or does it include a broader range of topics?
- Is the time divided up evenly among the members?
- Is this a group in which you would feel comfortable talking about personal issues?
- Does the facilitator keep the group discussion moving?
- Does the facilitator allow time for all group members to talk?
- Are the group's members open-minded and not judgmental?
- Is the group a safe haven?
- Did you feel supported by the other group members?

This list of questions is by no means exhaustive, and once you get started you will probably think of more specific questions to ask.

Write down notes and questions that came up for you during the group session. Talk briefly with the support group facilitator or other members after the meeting about any concerns that may have been raised during the meeting.

If you do not find that the group is a good fit for you, try another support group, or, even better yet, start your own support group.



EXPOSURE

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- All anti-HCV results should be confirmed by enzyme immunoassay using supplemental anti-HCV testing (RIBA).
- Information on counseling, testing and medical follow-up should be given to individuals exposed to hepatitis C.

Antiviral Therapy for Post Exposure

There are currently no treatment recommendations for patients with acute hepatitis C, but recent data has shown that up to 98% of people treated with interferon monotherapy were able to rid their bodies of the hepatitis C virus. However, the best time to start antiviral therapy and who should be treated remain unknown.



Support Groups

For referrals to support groups, please contact one of the following organizations:

Hepatitis C Support Project
www.hcvadvocate.org

American Liver Foundation
800-223-0179
www.liverfoundation.org

Hepatitis Foundation International
800-891-0707
www.hepfi.org

Hep C Connection
800-522-4372
www.hepc-connection.org

L.O.L.A.
888-367-5652
www.lola-national.org

HepCBC
www.hepcbc.ca

For Living Positively. Being Well.



www.hcvadvocate.org

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