

HCV Advocacy and Activism—More for 2004



Liz Highleyman

Chronic hepatitis C (HCV) has received much attention in recent years, as experts and the general public alike have become more aware of the extent of the epidemic. Expect more of the same in 2004, as well as an increased focus on hepatitis B (HBV) and HCV/HIV and HBV/HIV coinfection.

While no new drugs for hepatitis C are expected to hit the shelves, some innovative treatments are on the horizon, including HCV polymerase and protease inhibitors. A few to keep an eye on: Boehringer Ingelheim's BILN 2061, Schering's SCH-6, and Vertex's VX-950. At least a couple of new drugs should move out of the laboratory and into human trials.

Additional study results will also become available for existing treatments. Look for data on longer-term sustained response rates to pegylated interferon plus ribavirin, and more on treatment of non-

responders, relapsers, and patients with cirrhosis. As more people use pegylated interferon/ribavirin outside clinical trials, we'll get a better idea of how the drug works in "real world" settings. And, toward the latter part of the year, we may start to see preliminary results from the IDEAL trial comparing Pegasys and Peg-Intron.

In terms of HBV, expect more news about telbivudine (LdT) and emtricitabine (FTC, Emtriva, approved in

July 2003 for HIV treatment), both of which have shown promising results in clinical trials so far.

Another trend that will continue into the new year is the recent upsurge in

activism around HCV. As was the case with HIV/AIDS in the 1980s, people with HCV and their advocates are demanding more awareness and prevention

On December 4, 2003, more than 100 members of DECA, an association of marketing students, rallied on the steps of the Capitol building to raise awareness about the disease.

IN THIS ISSUE

AASLD Highlights:	
Part 3.....	2
HealthWise:	
Food for Thought.....	3
Ten Ways You Can Help.....	5
Writing Tips:	
Letters of Support.....	7

education, stepped up funding, increased research, and better access to treatment.

In a recent example of such grassroots mobilization, last month high-school students from Fairfax, Virginia, launched a hepatitis C campaign in Washington, DC. On December 4, 2003, more than 100 members of DECA, an association of marketing students, rallied on the steps of the Capitol building to raise awareness about the disease. The DECA students plan to lobby their local school board for hepatitis C education and survey local businesses to determine if HCV safety measures are being practiced for manicures, tattooing, and body piercing. The campaign was inspired by one of the students whose father has HCV.

Among the DECA students' main goals was supporting the **Hepatitis C Epidemic Control and Prevention Act** (HR 3539/S 1143).

continued on page 6

AASLD Conference

Highlights: *Part 3*



Alan Franciscus, Editor-in-Chief

AASLD Conference highlights part 3 will focus on an important study on sexual transmission as well as on current pegylated interferon therapies for the treatment of hepatitis C.

SEXUAL TRANSMISSION

Sexual transmission of hepatitis C is highly controversial due to prior study limitations, such as small sample size, exclusion of non-sexual routes (injection drug use) and failure to test for different serotypes (viral strain) of hepatitis C among the couples.

Norah Terrault and colleagues presented data on sexual transmission of hepatitis C in heterosexual monogamous couples from the HCV Partners Study.

This study included only monogamous heterosexual partners who were in a relationship for at least 3 years and reported no history of injection drug use. People with HIV and/or HBV infections were excluded. Partners were tested for antibody using EIA-2, RIBA-3, HCV RNA and HCV genotype/serotype. Partners with concordant serotype underwent phylogenetic analysis (pending). Detailed information on HCV risk factors and sexual practices were obtained by interviewing the partners separately.

Of the 2077 couples screened, 672 were eligible, 552 enrolled and 500 completed the study. The most common reasons for study ineligibility were lack of sexual partner

(40%), prior organ transplant (15%), HIV or HBV coinfection (10%), partnership < 3 years or non-monogamous (8%), and IDU in both partners (8%).

The median age of partners was 49 years old (range 27-79) and 75% were Caucasian.

The median duration of sexual contact was 16 yrs (range 3-52); the median number of sexual contacts per month per couple ranged from 0.3 to 24.4. The proportions of couples engaging in vaginal, anal, oral active and oral receptive sex were 98.3%, 12.5%, 77%, and 76%, respectively. Use of condoms was reported by 80%, but only 17% reported frequent or regular condom use.

A total of 20 (4%) partners tested positive for anti-HCV (EIA and RIBA) and 12 had detectable HCV RNA (viral load). The type and frequency of sexual contacts and frequency of sharing personal items (e.g., razors) did not differ between anti-HCV positive and negative partners (all $p > 0.05$).

Anti-HCV positive partners had higher rates of IDU (45% versus 1%, $P < 0.001$), tattoos (45% versus 15%, $P = 0.007$), blood brother rituals (37% versus 12%, $p = 0.0015$), bloody needlestick injury (60% versus 14% ($p = 0.005$), and total number of sex partners ($p = 0.005$).

In multivariate analysis, only IDU, tattoos and needlestick injury were independently associated

40% of partners had discordant types indicating lack of sexual transmission which would mean that the sexual transmission rate would be 2.2%.

with anti-HCV positivity in the partners. Genotypes/serotypes were discordant in 6 couples and concordant in 9 couples tested to date. Sexual contact rates of type concordant couples tended to be higher than type discordant couples (median 1 vs 0.25 contact per months, $p = 0.07$) but with no differences in types of sexual practices. The frequency of percutaneous risk factors for HCV in both partners tended to be higher in discordant than concordant couples (3/5 versus 1/9, $p = 0.09$).

The authors concluded that the prevalence of anti-HCV among sexual partners of persons with HCV was 4% (95% CI: 2.3%-5.7%) but 40% of partners had discordant types indicating lack of sexual transmission which would mean that the sexual transmission rate would be 2.2%. The majority of type concordant couples lacked percutaneous risk factors for HCV, suggesting sex may be the route of transmission but phylogenetic analysis of viral strains will ultimately determine whether sexual transmission occurred.

continued on page 4

HealthWise:

Food for Thought



Lucinda K. Porter, RN, CCRC

The holidays have passed and the next event that involves chocolate is not until Valentine's Day. Food is an essential part of life. Unfortunately, too much food or an excess of "empty calories" may have a negative impact on life expectancy and quality of life. The prevalence of overweight and obese Americans is on the rise. The Surgeon General estimates that 300,000 obesity-related deaths occur annually in the United States. Obesity is associated with an increased risk in a number of medical conditions including heart disease, stroke, high blood pressure, and type 2 diabetes. People living with chronic hepatitis C virus (HCV) infection may have additional reasons to be concerned about body weight. Obesity may be a negative-predictor for response to currently available HCV therapy. Obesity is a risk factor for cirrhosis-related death and may increase the risk for fibrosis.

The generally acceptable definitions of overweight and obesity are based on the Body Mass Index (BMI). BMI is a measurement based on the ratio of weight-to-height. Individuals with a BMI of 25 to 29.9 are considered overweight, while individuals with a BMI of 30 or more are considered obese. You can calculate your BMI by dividing your weight in kilograms by the square of your height in meters. The mathematical formula for BMI is: $BMI = Kg / (m)^2$. For those who prefer not to do the math, BMI calculators are available on the Internet.

Losing weight is a simple concept. The goal is to use more calories than you take in. This usually involves diet and exercise. However, simple does not mean easy. Opinions about various diets can be confusing. Exercise can be a huge challenge to those with physical limitations. The topic of exercise will be discussed in a future article. The rest of this article will focus on the topic of diet.

Weight loss is the subject of much debate. Between Atkins, L.A., South Beach, Weight Watchers, and the Zone diets, which diet is the best? First and foremost, talk to your primary care practitioner. It is

**MAKE THE GOAL
MEASURABLE AND
ACHIEVABLE. AN EXAMPLE
OF THIS IS TO AVOID
EATING DESSERTS FIVE
OUT OF SEVEN DAYS FOR A
WEEK**

important to choose a weight loss strategy that is healthy and fits your current medical condition. Second, choose a diet that you can live with and maintain. Look for a diet that has a record of long-term success. At best, deprivation can be maintained for the short term and can sabotage the best intentions. Choosing a diet is like shopping for clothes, you have to find something that fits and that you like. Find a diet that works with your food preferences and lifestyle. Third, identify resources. Consider if you want to work with a group, a nutritionist, a book, an online program, or a magazine. Dieting is a booming industry and there are many choices. Public and private agencies, such as insurance companies, sometimes offer assistance with weight loss. There are free resources available on the Internet and at the library. Magazines such as *Health* and *Prevention* usually have monthly weight loss articles as well as recipes.

Next, set a goal. Make the goal measurable and achievable. An example of this is to avoid eating desserts five out of seven days for a week. Trying to give up desserts forever is unrealistic. Finally, formulate a plan. "Failing to plan is a plan to fail," notes Pamela Peeke, MD, Assistant Clinical Professor of Medicine at the University of Maryland School of Medicine. Losing weight takes thought and commitment. Some find it easier to maintain the commitment if there is a plan in place. Hunger and temptation are harder to resist when there is no plan in place.

Losing weight and maintaining weight loss can be a slow process. It involves trial and error, commit-

continued on page 6

AASLD 2003

continued from page 2

Dr. Terrault commented that duration of exposure or condom use did not affect the rate of transmission. The next questions that need to be answered in this study are what types of sexual contact are more likely to transmit HCV and whether male or females are more susceptible to HCV transmission.

AFRICAN AMERICANS

There is growing evidence that response rates to interferon therapy appear to be lower in African American patients with chronic hepatitis C than in Caucasians. However, African Americans are under represented in HCV clinical trials and the majority of trials to date have been retrospective trials (looking back at completed trials) rather than prospective trials (carefully planned and conducted with treatment protocols) which are needed to form concrete conclusions.

Lennox J. Jeffers and colleagues presented data from a prospective clinical trial to determine the efficacy and safety of peginterferon alfa-2a (Pegasys) in combination with ribavirin (Copegus) in non-Hispanic African Americans patients infected with genotype 1 hepatitis C.

The trial enrolled patients in a 3:1 ratio of African Americans to Caucasian patients and was designed to estimate sustained virologic response rates in the African American group to within $\pm 10\%$ of a 95% confidence interval.

One hundred and six previously untreated genotype 1 patients with elevated ALT levels were treated with Pegasys 180 μg sc once weekly plus Copegus 1000 or 1200 mg

for 48 weeks, with a 24 week follow-up period. Sustained virological response was defined as undetectable HCV RNA (viral load) at week 72. Histologic responses were reported as Knodell HAI scores of liver biopsies obtained prior to treatment and within 4 weeks of completion of the 24-week untreated follow-up period.

The baseline characteristics of the African American patients were: mean age 46 years, 56 male (72%), mean ALT 63 U/L, high viral load (58%).

Baseline characteristics of Caucasian patients were: mean age 45 years, 17 male (61%), mean ALT 64 U/L, high viral load (43%).

Sixty-two of 78 (80%) African American patients and 22 of 28 (79%) Caucasian patients completed treatment; and 60/78 (77%) African American patients and 17/28 (61%) Caucasian patients returned at week 72. African Americans with a high viral load achieved a 20% sustained virological response rate compared with Caucasians who achieved a 25% sustained virological response rate.

The authors concluded that the sustained virological response rate in African Americans with genotype 1 is the highest response to combination therapy reported to date in this population. The authors also noted that the difference in the sustained virological response rates of African Americans versus Caucasians might be explained by the high viral load seen in African American patients and that this study would provide a basis for future efforts to increase the effectiveness of HCV treatment results in African Americans.

William Cassidy and colleagues reported data on a trial that looked at the effect of HCV therapy on hepatic histology (liver health) of

non-Hispanic African Americans compared to non-Hispanic Caucasians treated with pegylated interferon alfa-2a (Pegasys) plus ribavirin (Copegus).

All Patients received Pegasys 180 μg once weekly plus Copegus 1000 or 1200 mg for 48 weeks, with a 24 week follow-up period. Histologic responses based on the Knodell HAI score were determined from liver biopsies obtained prior to treatment and within 4 weeks of completion of the 24-week follow-up period. HAI activity scores range from 0-18 and fibrosis scores range from 0-4. The histology outcome was evaluated for patients with paired biopsies only. Improvement in necroinflammatory activity was defined as > 2 point decrease, and improvement in fibrosis as > 1 point decrease. The primary efficacy endpoint was sustained virologic response (SVR) with undetectable HCV RNA (< 50 IU/mL) at 72 weeks.

The intent-to-treat population included 106 patients. Paired biopsies were available for 53 of the 78 African American patients and 16 of the 28 Caucasian patients. These patients were representative of all patients with respect to Knodell HAI scores.

Mean baseline HAI activity scores were 7.2 ± 0.32 for African Americans and 6.9 ± 0.69 for Caucasian patients; mean baseline fibrosis scores were $1.8 + 0.14$ and $1.9 + 0.3$, respectively.

The sustained virological response rate for all African American patients was 20/78 (26%) and for all Caucasian patients was 11/28 (39%).

The majority of patients in both groups exhibited improvement in activity scores: 64% for the African American group and 69% for the

continued on page 8

Ten Ways You Can Help



Alan Franciscus, Editor-in-Chief

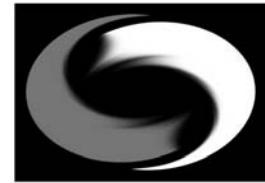
2003 was a watershed year for hepatitis C advocacy and activism. We are now on the brink of some major positive changes that will have a direct impact on each and every one of us. At the national level, the introduction of **The Hepatitis C Epidemic Control and Prevention Act** is moving its way through congress with an excellent chance that it will become law. However, we must all continue to do our part to support and make this law a reality. In addition, there is much movement at the local and state levels for providing testing, support and other services for the hepatitis C community.

It is of the utmost importance that we all pull together and work hard to make these positive changes a reality. In addition to supporting the national bill, there are many other areas that can be directly supported regardless of how much time or energy you may have at your disposal.

Below is a list of ideas to help you in your advocacy efforts. The list below is by no means exhaustive. Please let us know about any ideas that have worked for you and we will share them with our readers.

Please consider some of the following ideas:

1. Support the Hepatitis C Epidemic Control and Prevention Act. Some tips for writing an advocacy letter are included in this issue (see page 7).
2. Support local and state initiatives—check in with your representatives about pending legislation.
3. Educate individuals and the public about hepatitis C—we have seen remarkable strides in awareness from HCSP certified trainers who have taken their outreach efforts to new heights. They have made presentations, worked with local agencies and their clients to improve support and services.
4. Start a support group or help an existing support group leader in their efforts.
5. Help others with hepatitis C—this can be one of the most powerful acts of selflessness.
6. Get involved in your community—check-in with your local health department or other agencies affected by hepatitis C. Contact your CDC Hepatitis Coordinator.
7. Direct action—public demonstrations can have a huge impact on public education and awareness.
8. Enlist the help of the media—develop a press kit on hepatitis C that you can send to various news services in your area.
9. Distribute educational materials to local agencies and individuals. Make a commitment to keep them stocked with materials.
10. Start or work with a local Hep C task force.



**HEPATITIS C
SUPPORT PROJECT**

**Executive Director
Editor-in-Chief,
HCSP Publications**

Alan Franciscus
alanfranciscus@hcvadvocate.org

Managing Editor, Webmaster

C.D. Mazoff, PhD
cdmazoff@hcvadvocate.org

Contributing Authors

Liz Highleyman
Lucinda K. Porter, RN, CCRC

Design and Production

Paula Fener
Blue Kangaroo Design
blueroodesign@aol.com

Contact information:

Hepatitis C Support Project
PO Box 427037
San Francisco, CA 94142-7037

The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

Reprint permission is granted and encouraged with credit to the Hepatitis C Support Project.

© 2004
Hepatitis C Support Project

Advocacy & Activism

continued from page 1

This legislation, introduced in May 2003 by Senators Kay Bailey Hutchison (R-TX) and Edward Kennedy (D-MA), would require the federal government to develop a comprehensive national treatment and prevention plan for hepatitis C—the first federal response to the epidemic. The legislation would create HCV public awareness campaigns; implement screening, counseling, and surveillance programs; and fund professional training and HCV research. The bill is supported by the National Hepatitis C Advocacy Council, a new coalition comprising nearly two dozen organizations—including the Hepatitis C Support Project—spearheading the same kind of advocacy around HCV that successfully garnered more attention and funding for HIV/AIDS. The bill is currently pending in a congressional committee. Advocates are expected to renew their push to get the legislation passed when Congress reconvenes for the new year.

In addition to students, veterans and prisoners are also calling for more awareness of and better treatment for HCV. Last September, for example, veterans, active military members, and their dependents demonstrated at the Department of Veterans Affairs (VA) headquarters in Washington, DC, during the VA's annual National HCV Community Advisory Board meeting. The veterans are promoting another bill introduced in 2003, the **Comprehensive Hepatitis C Health Care Act for Veterans** (HR 73), which will help HCV positive veterans get better testing and care from the VA. A companion bill was introduced in the Senate by Jon Corzine (D-NJ) this past November.

A conference on the Management of Hepatitis C in Prisons held in San Antonio, Texas, in January 2003, and a report on HCV in prison released by the Centers for Disease Control and Prevention (CDC) the same month, have spurred activism by prisoners and their advocates. Class action lawsuits are pending in Oregon and Michigan—along with individual legal actions in several other states—demanding better access to testing and treatment in accordance with the CDC's new guidelines.

With the increased attention to chronic hepatitis, the National Institutes of Health (NIH) this past summer created a Liver Disease Research Branch (LDRB) within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The new branch will be headed by Dr. Jay Hoofnagle, a well known hepatitis expert who pioneered the use of interferon for HBV and HCV. The LDRB will help coordinate liver-related research conducted by the NIH and other federal agencies such as the CDC, the VA, and the Bureau of Prisons. As part of its mission, the branch will direct epidemiological studies and clinical trials, identify gaps in research, and set research and funding priorities. As one of its first efforts, the LDRB is preparing an Action Plan for Liver Disease Research. The plan will provide an overview of the current burden of liver disease in the U.S., the status of current research funding, challenges to advancing liver disease research, and major future research needs—and will prepare a tactical plan for meeting these needs.

The LDRB's action plan will be released in 2004 and—along with pending legislation—will hopefully help turn the increased HCV advocacy of recent years into concrete results.



Food for Thought

continued from page 3

ment, and knowledge. Successful weight loss requires a willingness to explore many avenues. Thomas Edison said, "The three things that are most essential to achievement are common sense, hard work and stick-to-it-iv-ness. Unfortunately, many of life's failures are experienced by people who did not realize how close they were to success when they gave up. If I find 10,000 ways something won't work, I haven't failed." Most of us do not achieve instant success with our first attempt to lose weight. Even if it takes 10,000 attempts, it is worth the effort.

Copyright, January 2004 Lucinda Porter, RN, and the Hepatitis C Support Project / HCV Advocate - All Rights Reserved.

Reprint is granted and encouraged with credit to the author and the Hepatitis C Support Project.



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.

Writing Tips: Letters of Support

Alan Franciscus, Editor-in-Chief

Every letter received by your senator and representative is very important to them. Writing your senator or representative is another example of democracy at work, allowing us all to have a voice in how our country is run. You may not think that just one letter can make a difference, but even one letter could be the ‘one’ that sways an opinion or vote. Some representatives lose touch with the issues—a letter from a constituent will inform them of the political climate back home. They may realize that by not supporting one bill they may lose many votes.

Writing a letter of support is relatively simple. It is important to remember that legislative assistants receive thou-

sands of letters and only have a fraction of time to read them, so it is very important that the letter is clear, concise and to the point.

1. Read the entire piece of legislation—pick out parts of the bill that you believe are important for later reference.

2. Before you compose the letter ask and answer some simple questions:

- *Why am I writing this letter?
- *What is the goal of this letter?
- *How does this legislation affect me?

3. Compose a first draft—make it clear

and easy to understand.

*Begin with how HCV has affected you:

*Use your own voice: **Example:** “As a person living with hepatitis C”, “As an African American living with hepatitis C”, “As a parent of someone living with hepatitis C”, “As a friend of someone with hepatitis C.” It should be passionate but the introduction should not ramble or become a ‘pity party’.

*Introduce the legislation—This can also be the first line of your letter. **Example:** “Please vote **YES** on **H.R. 3539**, the Hepatitis C Epidemic Control and Prevention Act...” **Example:** “.....I would like to encourage you to

continued on page 9

Help Us Reach More People with Hepatitis C!

SUPPORT US THROUGH EITHER A PAID SUBSCRIPTION OR DONATION

YES! I'd like to subscribe

\$18 one year—12 issues

\$9 one year—12 issues
(for those with fixed incomes)

Renewal

NAME _____

ADDRESS _____

CITY _____

STATE _____ ZIP _____

Please make checks payable to: HCSP/The Tides Center

YES! I'd like to donate

Please mail form to:

\$10 \$25

\$100 other

Please mail form to:

HCV ADVOCATE

P.O. Box 427037

San Francisco, CA 94142-7037



The Hepatitis C Support Project does not share its mailing list with any individual or organization. All subscribers' names and addresses are strictly confidential

AASLD 2003

continued from page 4

Caucasian group. More importantly, the proportion of patients with worsening fibrosis was similar in both groups, while 13/53 (25%) African American patients and only 1/16 (6%) Caucasian patients showed fibrosis improvement. Mean changes in fibrosis scores were -0.4 ± 0.14 for African Americans and -0.1 ± 0.14 for Caucasian patients.

The authors concluded that therapy with Pegasys and Copegus improved necroinflammation and fibrosis in a substantial number of African American patients in this study. Even those patients without a sustained virological response showed an improvement in hepatic histology

GENOTYPE 2 & 3

Pegylated interferon alfa-2b (PEG-Intron) plus ribavirin (Rebetol) is currently FDA approved for treatment of genotype 2 and 3 patients for 48 weeks. A study by Zeuzem and colleagues compared the safety and efficacy of PEG-Intron plus Rebetol for genotype 2 and 3 treated for 24 weeks to the historical Manns clinical trial that treated all genotypes for 48 weeks.

Two hundred-twenty-four treatment-naive chronic HCV patients infected with genotype 2 or 3 received PEG-Intron 1.5 microgram/kg subcutaneously once weekly plus Rebetol 800-1400 mg/day based on body weight for 24 weeks.

Plasma HCV RNA was determined using quantitative PCR (Taq-Man, sensitivity 29 IU/ml). Genotype was determined by sequencing the PCR product.

The sustained virological response rate was 81% which is similar to the sustained virological response rate seen in the historical

group treated for 48 weeks. As expected, the overall drop-out rates and dose reductions were lower in the 24 week group compared with the 48 week group.

The authors concluded that 24 weeks of PEG-Intron plus Rebetol therapy for genotype 2 and 3 were similar in efficacy to the 48 week group in the historical study.

ACUTE INFECTION

Treatment of acute hepatitis C infection remains controversial. However, the few studies that have been conducted to date have shown a high efficacy rate using interferon monotherapy.

In a study conducted by Johannes Wiegand and colleagues (HEP-NET Acute HCV Study Group) the use of pegylated interferon alfa-2b (PEG-Intron) for the treatment of acute hepatitis C was examined.

In this study, 60 patients with symptomatic acute hepatitis C were recruited between February 2001 and May 2003 from 40 different sites in Germany. The peak ALT levels were at least ten times the upper limit in 51 patients (85%). The patient characteristics were 22 females/38 males, mean age 38 years old, Genotype 1 – 55%, Genotype 2 – 3%, Genotype 3 – 17%, and Genotype 4 – 2%. Genotype was not available in 23%. HCV RNA (viral load) was quantified before, during and after treatment.

Patients were treated with 1.5 mcg/kg pegylated interferon alfa-2b (PEG-Intron) for 24 weeks.

The interim results showed that a high percentage of patients with symptomatic acute hepatitis C achieved high response rates. However, there was a relatively high number of patient drop-out rates—underlining the importance of patient management, support, and ad-

herence to therapy. Final results of this trial are eagerly awaited.

GENOTYPE 4

Hepatitis C genotype 4 infection is uncommon in the United States. However, in other parts of the world such as the Eastern Mediterranean, genotype 4 is the predominant strain of hepatitis C. Clinical trials on the effectiveness of interferon therapy in this patient population have been limited.

O. A. Shobokshi and colleagues conducted a study in genotype 4 patients in Saudi Arabia to compare the safety and effectiveness of peginterferon alfa-2a (Pegasys) plus ribavirin (Copegus) with Pegasys monotherapy and interferon alfa 2b (Roferon) plus Copegus combination therapy.

This was an open label multi-center clinical trial in which 180 patients infected with chronic hepatitis C genotype 4 were treated for 48 weeks with a follow up period of 24 weeks. The patients were randomized into the following treatment groups:

Group A: Pegasys -180µg once weekly plus Copegus (400mg) twice daily

Group B: Pegasys 180µg once weekly

Group C: Roferon A 4.5 million units three times a week plus Copegus (400mg) twice a day.

The sustained virological response rates (week 72) were 50% (group A), 28% (group B) and 30% (group C). Among week 12 early responders the sustained virological responses were 65.2% and 47.2% in the two pegylated interferon groups. The negative predictive value observed among non-responders in all groups at week 12 was 100%.

Twelve patients (6.7%) dropped out of the study: group A, 7 patients

continued on page 9

AASLD 2003

continued from page 8

(11.7%), Group B, 4 patients (6.7%) and group C, 1 (1.7%).

The authors of this study concluded that pegylated interferon alfa-2a plus ribavirin is safe and effective in this patient population and, despite the use of a low dose ribavirin of 400mg twice a day, an enhanced sustained virological response rate of 50% (65% in early responders) was reported for the combination of peginterferon alfa-2a plus ribavirin.

Gamal H. Esmat and colleagues conducted a study on 200 patients (90% - genotype 4) in Egypt to assess the effectiveness of interferon alfa-2b (Intron A - 2 million units three times a week) and pegylated interferon alfa 2b (PEG-Intron-100 mcg/week) plus ribavirin (Rebetol - 800-1000 mg for both groups). This was a prospective, open-label, randomized trial. If HCV RNA viral load was detectable at week 24, treatment was discontinued, but if HCV RNA was undetectable at week 24 treatment was extended to 48 weeks with a follow up period of 24 weeks.

The sustained virological response rate (intent to treat analysis) was 55% in the PEG-Intron group compared to 40% in the Intron A group. Six patients dropped out of the study in the Intron A group and 11 patients in the Peg-Intron group.

The authors concluded that patients treated with PEG-Intron plus Rebetol achieved similar sustained response rates as those with genotype 1.

This concludes our coverage of AASLD 2003—visit our web site for additional coverage.



WRITING TIPS

continued from page 7

support **H.R. 3539**, the **Hepatitis C Epidemic Control and Prevention Act.**”

*Discuss the importance of the bill and how it can affect needed change.

Example: “Hepatitis C is the most common blood-borne infection in the United States. Approximately **4 million Americans** have been exposed to hepatitis C. This bill will help to address the hepatitis C epidemic” **Example:** “It is estimated that approximately 4 million Americans have been exposed to hepatitis C yet only about 20% of those infected know they have hepatitis C.

This bill will help to heighten awareness and provide services enabling people to seek care, which will save lives and reduce future medical costs.”

*Restate your objective: **Example:** Please vote **YES** on **H.R. 3539**, the Hepatitis C Epidemic Control and Prevention Act. If you would like to discuss this issue with me, please call me at . . .”

*Use only approved statistics and facts that have been issued by governmental sources.

*Once a draft is written walk away from the letter—come back to it with a clear mind.

*Let the second draft sit (overnight if necessary) and proof it the next day.

*Use spell and grammar check!

*Ask a member of the family, friend or business acquaintance to review the letter for content, grammar and punctuation.

*Don’t be afraid to rewrite or edit as necessary.

4. Handwritten or typed letters carry the most weight. Mail a hard copy of the letter to your representative and send a copy via email and fax.

5. Make a follow-up call to your representative and encourage her or him to support the bill.

HEPATITIS C: WORLDWIDE



Alan Franciscus, Editor-in-Chief

The World Health Organization estimates that 170 million people worldwide have been exposed to hepatitis C, which represents approximately 3% of the world’s population. Although it is difficult to accurately measure the rate of HCV infections in countries that do not routinely test, the currently available data appears to substantiate these numbers. Hepatitis C prevalence rates vary considerably from country to country but, as expected, lower prevalence rates are generally seen in developed countries and higher rates are seen in underdeveloped countries.

High:

· *Egypt* where an estimated 18% of population is infected with hepatitis C due to re-use of needles to treated schistosomiasis.

· *Rwanda; Cameroon; Mongolia*

Moderate:

· *Japan; Italy; Romania; Brazil; United States*

Low:

· *Scandinavia; Spain; Australia; Canada; England*

The modes of transmission are varied but the most common routes include the re-use of needles for medical procedures, medical procedures involving blood products, illegal injection drug use and blood ritual practices.

In the coming months, we will be reporting on the impact of hepatitis C in various countries around the world. We welcome any information that people in other countries would like to share with our staff.



For Living Positively. Being Well.



www.hcvadvocate.org

HCSP

P.O. Box 427037
San Francisco, CA
94142-7037