

HEPSQUADS

Making a Difference in Your Community.



a quarterly
training
newsletter from
the Hepatitis C
Support Project

HEPATITIS C
SUPPORT PROJECT

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HEPSQUADS NEWS ROUNDUP

Liz Highleyman

■ DDW CONFERENCE OVERVIEW

The annual Digestive Disease Week (DDW) conference—one of the major scientific meetings devoted to digestive conditions, including liver disease—took place May 15-20 in New Orleans. More than 70 abstracts dealt with viral hepatitis and its treatment.

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Researchers presented promising data on an experimental HCV polymerase inhibitor called NM286, and

on an herbal combination containing mistletoe and green tomato extracts. Researchers reported that in a small study, using Peg-Intron twice weekly (plus ribavirin) led to better sustained virological response (SVR) rates than once-weekly Peg-Intron injections for patients with genotype 1 HCV. And in the first large-scale study of its kind, a pharmaceutical industry research group examined clinical practice patterns and HCV treatment across the U.S. Among the results: about half of all HCV patients initiate some type of therapy, and about 75% of these stop treatment if a virological response is not seen after 12 weeks. For a summary of DDW HCV reports, see the June and July issues of the *HCV Advocate*. Abstracts from the DDW conference, as well as from the European Association for the Study of the Liver conference in April, are available in the "Conference Reports" section of the HCV Advocate website.

■ TREATMENT FOR NON- RESPONDERS

Treatment of nonresponders—people who do not achieve a sustained virological response to HCV therapy—has been a hot topic at conferences and in recent medical journal articles. In the April 2004 issue of *Gastroenterology*, Mitchell Shiffman and colleagues reported the first results from the ongoing HALT-C trial. The study evaluated 604 patients with chronic hepatitis C who did not respond to previous treatment with standard interferon (with or without ribavirin). Patients had bridging fibrosis or cirrhosis; the main goal of the ongoing study is to see if treatment can delay or stop fibrosis progression. Participants were retreated with Pegasys plus ribavirin. Those who showed an early response at 20 weeks continued treatment for 48 weeks. At the end of treatment, the response rate was 32%; and at the end of follow-up (72

continued on page 2



IN THIS ISSUE:

News Roundup ----- 1

Let's Keep Counseling
in the HIV and HCV
Testing Process ----- 4

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NEWS ROUNDUP

continued from page 1

weeks), the SVR rate was 18%. The SVR rate was 14% for patients with genotype 1, 65% for genotype 2, and 54% for genotype 3. Individuals who were previously treated with standard interferon monotherapy were most likely to respond to the new regimen.

Another therapy being studied for nonresponders is consensus interferon-alpha, or Infergen. Steve Kaiser reported at DDW on a study of 50 patients (about half with genotype 1) who did not respond to pegylated interferon plus ribavirin. Subjects received either low-dose or high-dose daily Infergen induction therapy, followed by daily Infergen plus ribavirin for 34-56 additional weeks. SVR rates were 24% for the low-dose induction arm and 30% for the high-dose arm. Also at DDW, Carroll Leevy reported that after 24 weeks, 47% of 32 previous Peg-Intron/ribavirin nonresponders achieved an undetectable HCV viral load when retreated with a combination of daily Infergen plus twice-weekly Actimmune (interferon gamma-1b) plus ribavirin; SVR results are not yet available. Treatment of nonresponders remains an important area of research. A new study called REPEAT (for REtreatment with PEGasys in PATients Not Responding to Peg-Intron Therapy) is now underway at more than 30 U.S. medical centers. See the June *HCV Advocate* for more on nonresponders, and look for HCSP's new booklet, "The Next Steps," coming soon.

■ HCV AND RACE/ETHNICITY

Another topic that has received much attention recently is racial/ethnic differences related to hepatitis C. Past retrospective studies in which African Americans were underrepresented suggested that blacks respond less well than whites to interferon-based therapy. Two recent prospective studies confirmed this finding. In the June 2004 issue of *Hepatology*, Lennox Jeffers and colleagues reported on a study of 78 blacks and 28 whites (all with genotype 1) receiving HCV treatment for the first time. After 48 weeks of therapy with Pegasys plus ribavirin, 26% of blacks achieved SVR, compared with 39% of whites. This was the highest response rate yet observed in a black population. In a second study reported in the May 27, 2004 issue of the *New England Journal of Medicine*, Andrew Muir and colleagues treated 100 black and 100 white subjects (98% in both groups with genotype 1) with Peg-Intron plus ribavirin for 48 weeks. SVR rates in this study were much lower for blacks than whites: 19% vs 52%, respectively. A retrospective analysis by Richard Sterling and colleagues reported in the May issue of the *American Journal of Gastroenterology*, however,

found that among 59 inmates treated with standard interferon plus ribavirin in Virginia prisons, SVR rates were similar—33% and 29%, respectively—for whites and blacks with genotype 1 HCV.

Although blacks seem to respond less well to interferon, it also appears they may not suffer as much HCV-related liver damage compared with whites or Hispanics/Latinos. For example, in the June 2004 issue of *Clinical Gastroenterology and Hepatology*, Anne Celona and colleagues reported on an analysis of data from more than 1,000 HCV positive patients in Los Angeles. Latino patients had significantly higher ALT and bilirubin levels and lower serum albumin levels than all other ethnic groups. In the same issue, Kester Crosse and colleagues reported that in a retrospective comparison, black patients had lower average ALT levels and lower histological activity scores, indicating less liver fibrosis, and inflammation. The authors concluded that black patients with chronic HCV "have milder liver necroinflammation and fibrosis than white patients with similar HCV duration."

The reason for differences in treatment response and liver damage are unclear. Blacks are more likely than whites to have hard-to-treat genotype 1 HCV, but the Lennox and Muir studies included only or mostly genotype 1 patients. It may be that different racial/ethnic groups process interferon differently in their bodies, or that there are genetic differences in immune response. A large National Institutes of Health study called VIRAHEP-C is currently looking at treatment response in African-Americans. For more on racial/ethnic differences and hepatitis C, see the July *HCV Advocate*.

■ GENERIC RIBAVIRIN

In early April, the Food and Drug Administration (FDA) approved two generic versions of ribavirin. The generic drugs will be marketed by Sandoz (a subsidiary of Novartis) and Three Rivers Pharmaceuticals in partnership with Pharmaceutical Resources, Inc. Patient advocates have long called



Generic drugs are typically priced much lower than their brand-name equivalents. But both Sandoz and Three Rivers set prices for their generic ribavirin at about \$10 per capsule, in between the average wholesale prices for Schering-Plough's Rebetol (about \$11) and Roche's Copegus (about \$6).



continued on page 3

NEWS ROUNDUP

continued from page 2

for the approval of generic ribavirin, which has been held up for years by patent disputes. But many were disappointed at the cost of the new versions. Generic drugs are typically priced much lower than their brand-name equivalents. But both Sandoz and Three Rivers set prices for their generic ribavirin at about \$10 per capsule, in between the average wholesale prices for Schering-Plough's Rebetol (about \$11) and Roche's Copegus (about \$6). Soon thereafter, Schering announced its own generic version of ribavirin, priced to undercut the newcomers. The first manufacturers of a new generic drug receive exclusive marketing rights for six months. But more companies will likely enter the generic ribavirin market by the end of the year, hopefully driving down prices.

■ PATIENT-PHYSICIAN COMMUNICATION

Most people with hepatitis C understand the importance of a good doctor-patient relationship. Good communication with health-care providers can be a key to managing side effects, maintaining adherence, and achieving the best possible treatment outcomes. Unfortunately, a study in the April 2004 issue of *Hepatology* found that hepatitis C patients often report conflicts or problems communicating with their doctors. Many patients believed their doctors had poor communication skills or were incompetent in diagnosing or treating hepatitis C, and many felt they were not listened to, were misunderstood, or were stigmatized. Psychosocial problems

Psychosocial problems such as depression, poor coping skills, and family difficulties were the best predictors of communication difficulties with doctors, but individuals with diagnosed psychiatric illness or current or past substance use were not more likely to report patient-physician conflict.

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continued on page 5



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Let's Keep the Counseling in the HIV and HCV Testing Process

Melissa Pierce, MA
Health Education Specialist, Butte County Public Health

I work in HIV and HCV prevention. Sometimes this work brings me to the county jail where I test and counsel inmates regarding HIV and HCV. On one such recent occasion I was accused by a guard of socializing with an inmate and for taking too long. Apparently my expressing interest in this person's piercing and tattooing history and experience was not deemed essential to the testing service they allow us to provide there.

My training as an HIV and HCV counselor taught me to utilize several basics of any successful counseling endeavor, namely to be open, respectful and genuinely interested in clients and the risks they discuss in session. This process is more of an art than a science and can look very different according to the uniqueness of each and every encounter. In all cases, unless a client gets a sense

that I care, there is little hope of inspiring any positive movement towards increased self-care or risk reduction of any type. With rapport and relationship building, a process that may take a series of meetings over an extended period of time and circumstances, there is the possibility of positive change. If I did not believe this I could not continue this work. The only hope I have of beginning this process is to successfully convey to a person that I care. Obtaining risk information, education and fluid sample collection are of course a part of all HIV and HCV test sessions, but the counseling part of this process is also an integral, state-mandated component. I'm glad it is. This keeps the human element in the fore where it needs to be with this intensely serious threat to human health.

HIV and HCV are, after all, infections shared among

humans. If we were not able to include counseling as part of the testing process, how helpful would our efforts be? Isn't it through the very human process of conversation and empathic listening that

healthy "mirrors" to see ourselves accurately and to recognize the good within us craving expression? Might not HIV and HCV testing be an ideal time to provide that mirror, that "other" that can per-



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strides toward healthier relationships find their beginnings? Isn't addiction in its various forms responsible for the choices that put people at risk for HIV (not to mention incarceration)? And doesn't addiction stem from people feeling a need to escape some feeling rather than being present for every moment, including the difficult ones in life? Don't we all need

perhaps spark in those being tested some remembrance of their own divinity and soul-right to a life of happiness free of infection and addiction and perchance incarceration?

Perhaps this is too grand a hope but it is a good prayer and a worthy effort, one I am pleased and proud to be engaged in wherever I test and counsel individuals for HIV and HCV. □

hepatitis C
BASICS

• *hcsPFACT* sheets •

easy **C** facts

are publications of the Hepatitis C Support Project. They are a series of fact sheets written by experts in the field of liver disease. They are available for printing in English and Spanish at

www.hcvadvocate.org

NEWS ROUNDUP

continued from page 3

report patient-physician conflict. In an accompanying editorial, Robert Fontana and Ziad Kronfol noted that both patients and physicians may experience "frustration with the lack of safe and effective treatment options" for hepatitis C. But, they emphasized, "Patients who feel their needs and concerns are being addressed are more likely to comply with prescribed treatments and experience improved health outcomes." They suggested that physicians should provide more time for questions, include patients in decision-making, and encourage patients to participate in support groups.

SEXUAL TRANSMISSION

Most current hepatitis C prevention guidelines say that monogamous, heterosexual couples do not need to use condoms or other barrier methods to prevent HCV transmission. A study published in the May 2004 issue of the *American Journal of Gastroenterology* confirms that sexual transmission of HCV among monogamous, heterosexual couples is very rare. In this long-term prospective study, the researchers followed 895 HCV-uninfected individuals who had monogamous sexual relationships with HCV-infected partners. Just three new HCV infections in the uninfected partners were seen during 10 years of follow-up (an incidence rate of only 0.37 per 1,000 person-years). However, the newly infected partners had different HCV genotypes or viral isolates than their spouses, indicating that even these cases were not due to sexual transmission. "Our data indicate that the risk of sexual transmission of HCV within heterosexual monogamous couples is extremely low or even null," the researchers concluded. The study supports the current prevention recommendations for monogamous heterosexual couples. However, other research suggests sexual transmission rates are higher among men who have sex with men and people with multiple sexual partners, so individuals in these groups should consider safer sex precautions. □



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.

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train the trainer workshops

Lincoln, NE

July 19th and 20th, 2004

Philadelphia, PA

August 4th and 5th, 2004

Newark, NJ

August 9th and 10th, 2004

Phoenix, AZ

September 9th and 10th, 2004

Chico, CA

October 21st and 22nd, 2004

Coming Soon:

Ann Arbor, MI

Omaha, NE

recertification workshops

Sacramento, CA

July 12th, 2004

Fresno, CA

September 22nd, 2004

Tucson, AZ

October 1st, 2004

Prescott, AZ

October 4th, 2004

Phoenix, AZ

October 6th, 2004

October 8th, 2004

community forums

Fresno, CA

September 22nd, 2004

Visalia

September 23rd, 2004

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