

# HEPSQUADS

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a quarterly  
training  
newsletter from  
the Hepatitis C  
Support Project

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## HEPSQUADS NEWS ROUNDUP

Liz Highleyman

### ■ HIGH HEPATITIS C RATES IN U.S. VETS

U.S. veterans have a hepatitis C infection rate more than twice as high as that of the general population, according to a report in the January 2005 issue of *Hepatology*. In a study of nearly 1,300 patients at Department of Veterans Affairs medical centers, the rate of hepatitis C virus (HCV) infection was estimated to be about 5%. Nearly one-third of responding participants reported at least one traditional risk factor. Among those who tested HCV antibody positive, 78% had either received a blood transfusion or injected drugs. Tattoos and incarceration—but not direct military-related exposures—were also linked to higher HCV rates.

### ■ HEPATITIS C SUPERINFECTION

HCV superinfection may occur almost as often as first-time infections, according to a study in the October 15, 2004 *Journal of Infectious Diseases*. In a study of 25 young, recently infected

injection drug users in San Francisco, researchers identified five individuals (20%) infected with a second strain of HCV after initial seroconversion. The incidence of new first HCV infections in this population was 25%—only slightly higher than the superinfection rate. The occurrence of superinfection suggests that the body does not develop cross-protective immunity against different HCV strains, which could be a roadblock to developing an effective vaccine.

### ■ SHORTER TREATMENT FOR GENOTYPES 2 AND 3?

Because patients with HCV genotypes 2 or 3 typically respond well to interferon-based therapy, they may benefit from a shorter course of treatment, Norwegian researchers reported in the December 2004 issue of *Hepatology*. In this study, 122 genotype 2 or 3 patients were treated with Peg-Intron plus ribavirin for either 14 weeks if they experienced an early virological response at

weeks 4 and 8, or else for the standard 24 weeks. Six months after the end of treatment, 90% of those in the 14-week arm and 56% in the 24-week arm achieved sustained virological response (SVR). If larger, randomized trials confirm these results, a shorter course of therapy could become standard for early responders with genotypes 2 or 3, thus shortening the duration of side effects and reducing treatment costs.

### ■ TREATMENT FOR NORMAL ALT

Experts disagreed about the benefits of treating hepatitis C patients with persistently normal ALT (liver enzyme) levels, in part due to the belief that such individuals are unlikely to progress to severe liver disease. However, research shows that some—if not most—patients with normal ALT experience some degree of fibrosis progression, and recent studies indicate that this group can benefit as much from treatment as patients

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# NEWS ROUNDUP

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with elevated ALT. According to a study in the December 2004 *Gastroenterology*, 30% of 212 normal ALT patients receiving Pegasys plus ribavirin for 24 weeks and 52% of 210 patients treated for 48 weeks achieved SVR, compared with none of 69 untreated patients (corresponding SVR rates were 13% and 40% for genotype 1, and 72% and 78% for genotypes 2 and 3). Roche announced in early November that the European Medicines Agency had approved Pegasys plus ribavirin to treat HCV positive people with persistently normal ALT, who account for about one-third of all chronic hepatitis C patients.

## ■ AASLD HIGHLIGHTS

### Treatment Duration

The American Association for the Study of Liver Diseases (AASLD) annual meeting—the most important yearly meeting for hepatitis researchers—took place in October 29–November 2 in Boston. One presentation suggested that longer duration of hepatitis C treatment may lead to better sustained response rates. In a German study of 456 genotype 1 patients treated with Pegasys plus ribavirin, a lower relapse rate was seen in patients treated for 72 weeks (19%) compared with the standard 48 weeks (26%). The difference was more pronounced among patients with a late virological response (HCV viral loads above 1,000 IU/L at week 4 or 12). The researchers concluded that a small but significant proportion of genotype 1 patients could benefit from longer treatment; a larger prospective study is underway to confirm these findings.

### Durability of Response

Another study found that among a group of 845 patients who achieved SVR (174 on Pegasys monotherapy, 671 on Pegasys plus ribavirin), about 99% still had undetectable HCV RNA after as many as five years of follow-up. In related news, Japanese researchers reported in the November 2004 *Journal of Medical Virology* that sustained response to hepatitis C treatment can last as long as 12 years—though few patients to date have received interferon-based therapy for such long periods. Research is underway to determine the reason(s) for HCV reemergence in a small number of patients.

### Interferon Maintenance Therapy Improves Fibrosis

Even among patients who do not achieve SVR, long-term interferon maintenance therapy may help delay or reverse liver disease progression. The COPILOT trial is studying maintenance therapy using colchicine (a plant alkaloid used

to treat gout) vs low-dose (0.5 mcg/kg/week) Peg-Intron monotherapy in 550 patients with advanced fibrosis who did not respond to prior therapy. After two years, Peg-Intron worked better than colchicine in reducing the rate of clinical endpoints (bleeding varices, liver failure, liver cancer, liver transplant, or death). In the Peg-Intron group, 20 out of 270 patients reached a clinical endpoint compared with 39 out of 264 in the colchicine arm. The annual clinical event rate was 3.5% for Peg-Intron vs 7% for colchicine. In another study looking at two doses (90 or 180 mcg/week) of Pegasys monotherapy or standard interferon monotherapy in patients with bridging fibrosis or cirrhosis, the greatest improvement in liver histology was seen in patients who achieved SVR, but a considerable number of relapsers and nonresponders also obtained “moderate histologic improvement.”

## ■ NEW HCV TREATMENTS ON THE HORIZON

Several experimental treatments are under study for hepatitis C. In the November 2004 issue of *Gastroenterology*, German researchers reported early results from a series of studies of BILN-2061, an experimental HCV serine protease inhibitor. The studies included 31 patients with genotype 1 HCV and minimal fibrosis, 10 with advanced fibrosis, and 10 with compensated cirrhosis. Most patients in all three studies achieved viral load reductions of 2-3 logs. Good antiviral activity was seen in patients with and without cirrhosis, and the drug was well tolerated. However, further clinical trials have been put on hold due to animal toxicity issues. Although BILN-2061 was well tolerated in preclinical studies and short-term clinical trials, cardiac problems in monkeys given high doses have raised concerns that Boehringer Ingelheim seeks to address before proceeding with human trials.

At AASLD data were presented on viramidine, a prodrug of ribavirin that targets the liver and has less effect on red blood cells. In two studies viramidine appeared similarly

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# NEWS ROUNDUP

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active against HCV, but was significantly less likely to cause hemolytic anemia, a major treatment-limiting side effect of ribavirin. Researchers also presented Phase I/II data on Idenix Pharmaceuticals' polymerase inhibitor, NM283. In a dose-escalating trial involving 95 genotype 1 patients, HCV viral load fell 1.2 logs by day 7 in those taking the highest dose (800 mg). No serious adverse events or treatment-limiting toxicities were seen. In an interim analysis of an ongoing Phase II trial, 9 out of 12 patients (75%) taking NM283 plus pegylated interferon experienced early virological response; over the 28-day treatment period there was a 2.7 log (99.8%) reduction in HCV RNA. Based on these results, the study has been extended to three months.

Several other hepatitis C therapies in the pipeline bear watching. Albuferon is a long-lasting form of interferon bound to the blood protein albumin, allowing it to remain in the body up to four weeks after a single injection. Anadys Pharmaceuticals' isatoribine regulates innate immunity. In a small (32 patient) Phase IB study, the drug was well tolerated and produced a statistically significant reduction in HCV viral load. Vertex recently announced that it would soon begin enrollment for a Phase IB trial of its protease inhibitor VX-950, after no safety concerns or major adverse events were detected in a small study of healthy HCV negative volunteers.

## NEW HEPATITIS C TRIALS

Clinical trials can be a great way to gain early access to promising therapies and to help advance the state of hepatitis C treatment. Schering-Plough is starting two large international clinical trials to study Peg-Intron plus ribavirin in "difficult to treat" patients. The SUCCESS trial will study genotype 1 patients identified as slow responders, looking at whether extending treatment to 72 weeks will improve outcomes. This study aims to enroll 1,200 participants in Canada and Europe. The ESPECIAL study will enroll genotype 1 patients who did not respond to prior treatment with Pegasys (the other approved brand of pegylated interferon) plus ribavirin. The SLAM-C trial will study the use of Pegasys plus ribavirin for maintenance therapy to slow liver disease progression in HCV/HIV coinfecting patients. Finally, Roche will conduct the largest trial to date comparing Pegasys/ribavirin response rates in Latino and white patients. It is known that African-Americans respond less well to interferon-based therapy, but there is not yet enough data to determine how well Latinos respond or whether hepatitis C progresses more rapidly in this group. The study will enroll 540 patients at 45 sites in the U.S. and Puerto Rico. □



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# Working with Challenging Training Participants

Heather Lusk, Hawaii Hepatitis C Coordinator

**GROUP PARTICIPATION IN HEPATITIS C TRAININGS MAKES** trainings unique and separate from presentations where content is given to participants instead of involving them in the learning process. Even with the same content, each hepatitis C training is different because of the contributions from participants: their experiences, insights and knowledge increase the value of the training for all. Most great training experiences aren't so because of the content, they are memorable because of what participants brought to the training. That said, once in a while participants don't enhance the training. In fact, sometimes individuals may disrupt the learning process. It is a trainer's responsibility to address participant challenges in a respectful and timely way for the benefit of the entire group and to maintain the integrity and safety of the learning environment.

There are a few things trainers can do at the beginning of a training to make it easier to address challenges later in the day. Establish group agreements (or ground rules) in the beginning by asking participants what they need in order to establish a safe learning environment. This sets clear boundaries about what is and is not acceptable in the training and also gives participants a chance to share what is important to them. While all are important, one of the most helpful is "step up/step back" or "be aware of how much you are talking". These two concepts ask participants to be mindful of how much room they take up and to talk less if they usually talk a lot, and to talk more if they usually don't talk very much. Another technique is for the trainer to clarify how much time is available for group discussion and acknowledge there may be times when the trainer will have to move

the group along in order to accomplish the objectives of the training. Sometimes a discussion is more relevant than the next topic and the agenda should be flexible, and other times it is important to move on. These and other group agreements can be reviewed or referenced later in the day if people are struggling with maintaining the agreements.

Once a trainer becomes aware of a challenge, it is important to ascertain if the participant is aware of his/her behavior. The technique for working with participants who are unaware of the impact they are having on the group is very different from participants who are purposely sabotaging the training. While it may not always be easy to tell the difference, most of the time participants are not aware of their behaviors or, if they are aware, do not realize they are having a negative impact on the group. Being gentle, perhaps even using appropriate humor, and talking to the person in private is important when working with someone who is unintentionally challenging. People who are intentionally challenging (usually forced to come to the training or are very emotionally tied to the subject) often demand a more direct approach.

For participants who talk too much or too little, it may be helpful to remind the entire group of the group agreements. When asking for thoughts from the group, using a caveat such as "let's hear from someone we haven't heard from yet" may remind those who have shared a lot to give some space for others. For a very talkative participant, a trainer may have to have a private discussion with them during a break. It is important to appreciate their contributions

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- Understand the hepatitis C virus (HCV), how HCV is identified, acute vs. chronic infection, and the progression of the disease.
- Identify persons at risk or needing care for HCV.
- Create a counseling plan for prevention and management of HCV in persons at risk, needing treatment, or receiving treatment.

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## CHALLENGING TRAINING PARTICIPANTS

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while emphasizing the importance of hearing from everyone.

Sometimes a participant's sharing is not about the content, but involves personal self-disclosure. Self-disclosure, especially related to living with hepatitis C, adds depth and perspective to the discussion. However, some participants may share too much personal information or push their experience or values on others (experience with HCV treatment is a prime example). It is important to honor the personal sharing of participants as people are taking a risk by being vulnerable and sharing their feelings or experiences. A simple "thank you for sharing" or "that brought up a lot of feelings for me, how about others?" acknowledges a particularly intense or emotional disclosure. If someone is very opinionated, it can again be helpful to ask the group if other people have a different experience or opinion they would like to share. It can be awkward to transition back into content after a heavy personal disclosure, and taking a short break may help shift the energy in the room. Naming the dynamic in the room (since everyone already feels it anyway) can assist in this transition as well. A comment such as "it is hard to get back to data after that, and yet we have much left on the agenda—how does everyone feel about moving on?" allows participants to be involved in the decision to move on.

For a participant who challenges the trainer's facts or ideas, it may be helpful to say to the group "what do others think about this?" or "who else has thoughts on this?" It is important to clarify the difference between scientifically known facts (replicated research) and items people read or heard about recently. Stating "oh, I hadn't heard that. I will follow up and get back with you" or "that is new information to me, where did you hear that?" acknowledges their contribution without getting into an argument about who is correct. If the trainer is sure the participant is incorrect, gently share the correct information and cite the source, acknowledging that it can be challenging to wait for research to give us the answers to what we know from doing this work on the front line.

The most important piece of addressing participant challenges is how a trainer does it, not what is said but how it is said. Handling challenges is an opportunity for trainers to demonstrate their credibility and respect for participants while honoring the principle that the group is more important than any one individual (including the trainer). Being humble, patient, and respectful while maintaining structure and boundaries is a balance all trainers strive for. Group participation in hepatitis C trainings is worth the occasional participant challenge, though how the challenge is facilitated by the trainer will have the biggest impact on the group's experience. □



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