

## WORKING WITH A CO-FACILITATOR

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Conducting a hepatitis C training with another facilitator has both benefits and challenges. Some of the benefits of working with a co-facilitator include offering different perspectives and teaching styles to participants, getting support and not having to do the entire training alone, which can be exhausting. Having another person in the room to catch missing or forgotten information, share additional information or experiences and observe group process is helpful. Some potential challenges include

ing honest, open communication with your co-facilitator and making agreements about what happens before, during and after the training.

Before the training, facilitators should meet at least once and ideally several times to ensure effective facilitation during the training. Facilitators may want to discuss their training styles and get to know each other to identify how to complement each other during the training. This discussion may include sharing your strengths and weaknesses so you

front of participants. For example, facilitators will want to determine how to manage time and how to communicate when it is time to move on to the next section. Agreements need to be made about how the other facilitator should (or should not) add comments during another's section and how and when to correct misinformation, since most facilitators don't appreciate being corrected in front of participants. For example, many facilitators end their section by asking the other "Is there anything you'd like to add?" Agreements may also include whether to debrief during or after the training, how decisions will be made to change the agenda if needed, and whether you will be spending breaks and lunch together. While some of these agreements may seem basic or unnecessary, they ensure that facilitators are on the same page. Prior to the training is also the

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conflict among facilitators which disrupts the training, partnering with facilitators who are less experienced and skilled and potentially having less control over the training and content. Most of these challenges can be addressed by hav-

and your co-facilitator know what to expect and can strive to achieve a balance. Prior to the training is the time to make certain agreements about how and when to communicate during the training to avoid awkward moments in

continued on page 5



### IN THIS ISSUE:

Working with a Co-facilitator.....1

News Roundup.....2

## HEPSQUADS

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# HEPSQUADS NEWS ROUNDUP

Liz Highleyman

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## HIGHER ESTIMATED U.S. HEPATITIS C RATE

The most common estimate of the number of hepatitis C cases in the U.S. is 3.9 million, based on data from the 1988-1994 National Health and Nutrition Examination Survey (NHANES). But according to a recent report in the May 16, 2006 *Annals of Internal Medicine*, 4.1 million may be a more accurate estimate. The 1999-2002 NHANES found that the HCV prevalence rate had declined slightly, to 1.6%, but since the total population size had increased, the new estimate was 4.1 million infected, 3.2 million of whom have chronic infection. In the 40-49 age group, the estimated prevalence was 4.3%; among blacks, the prevalence was 9.4%, compared with 3.8% among whites. The latest NHANES estimate may still be too low since it excludes groups at higher risk for HCV, including the homeless, incarcerated individuals, and hospital and nursing home patients. A recent analysis by Brian Edlin, which took these groups into account, suggested that a more accurate estimate may be 5 million, including 3.4 million with chronic infection.

## AMERICAN LIVER FOUNDATION URGES HEPATITIS C TESTING

Many people with hepatitis C do not know they are infected, and therefore do not receive timely treatment. To address this problem, the American Liver Foundation (ALF) declared May to be Hepatitis Awareness Month. "It's important for patients who even think they might be infected to speak to their doctors about being tested and treated as soon as possible for hepatitis C in order to preserve liver health," said Douglas Dieterich, MD. "Many people are walking around with the disease, some for 10 or 20 years, without even knowing they have it and losing time when they could be treated successfully," said ALF president Frederick Thompson.

## ACETAMINOPHEN LIVER TOXICITY

Acetaminophen, found in Tylenol and hundreds of other products, is known to cause liver toxicity – the leading cause of acute liver failure in the U.S. – but many assume this mostly occurs in people with pre-

existing liver disease or when healthy people take an overdose or use the drug with alcohol. A new study in the July 2006 *Journal of the American Medical Association* showed that 4 grams of acetaminophen – the maximum recommended dose of Extra-Strength Tylenol – can cause liver enzyme elevations even in healthy people who use the drug as directed. The study found that about 40% of healthy volunteers who took 4 grams of acetaminophen every twenty-four hours, either alone or in combination with opiates such as oxycodone or morphine, developed maximum ALT levels greater than 3 times the upper limit of normal. After acetaminophen was discontinued, ALT continued to increase for up to four days, but eventually returned to normal. Although acetaminophen is generally regarded as safe, it is important to read medication labels and avoid taking the drug at higher than recommended doses or for longer than the recommended length of time.

## OBESITY AND HEPATITIS C

It is increasingly clear that obesity and associated metabolic conditions, including insulin resistance and type 2 diabetes, play a role in liver disease progression and poor response to hepatitis C treatment. In particular, metabolic syndrome and obesity are associated with steatosis (fatty liver), which is linked with worse fibrosis progression and a greater risk of cirrhosis and liver cancer. In the June 2006 issue of *Hepatology*, Michael Charlton, MD, and colleagues reported that patients are likely to respond better to hepatitis C treatment if they first lose excess body weight and treat metabolic abnormalities. The first-line approach involves lifestyle modification, including healthy diet and exercise. If this is not adequate, anti-diabetes drugs such as metformin (Glucophage) and pioglitazone (Actos) may play a role. Treatment strategies that focus on improving underlying metabolic factors associated with poor response to hepatitis C therapy may help "overcome the low sustained viral response rates observed in

*continued on page 3*

## NEWS ROUNDUP

*continued from page 2*

obese patients infected with HCV,” the researchers concluded.

### **SMOKING MAY WORSEN LIVER FIBROSIS, COFFEE APPEARS PROTECTIVE**

Tobacco smoking may increase the risk of liver fibrosis progression in people with chronic hepatitis C, according to a study in the June 2006 issue of *Clinical Gastroenterology & Hepatology*. In a study of 170 participants with chronic hepatitis C, 21% of smokers had fibrosis scores of 3 or 4 (advanced fibrosis or cirrhosis), compared with 14% of nonsmokers. The researchers hypothesized that low oxygen levels due to smoking might lead to increased levels of cytokines involved in fibrosis and tumor formation. Coffee, on the other hand, may help prevent fibrosis. As reported in the June 12, 2006 *Archives of Internal Medicine*, a study of more than 125,000 health plan members without known liver disease at baseline found that 330 subjects developed liver cirrhosis during the follow-up period. Participants who drank coffee regularly had a lower risk of developing alcoholic cirrhosis, and the risk appeared to go down the more coffee they drank. Drinking tea was not linked with reduced cirrhosis risk, suggesting that the protective effect may be attributable to another ingredient in coffee besides caffeine.

### **STATINS ACTIVE AGAINST HCV IN LABORATORY STUDIES**

Statin drugs are active against HCV in laboratory cell cultures, according to a study in the July 2006 issue of *Hepatology*. Also known as HMG-CoA reductase inhibitors, statins are widely prescribed to manage high blood cholesterol. Fluvastatin (Lescol) demonstrated the strongest anti-HCV activity when added to HCV in laboratory cell cultures. Atorvastatin (Lipitor) and simvastatin (Zocor) showed moderate activity, lovastatin (Mevacor) had weak activity, and pravastatin (Pravachol) showed no activity against HCV. When added to cultures along with pegylated interferon, all the statins except pravastatin exhibited a stronger inhibitory effect on HCV replication. While this research is still in the preclinical stage, the researchers concluded that statins could potentially be used as new anti-HCV agents in combination therapy.

### **HIGHLIGHTS FROM RECENT CONFERENCES**

Two major conferences on liver disease took place recently, the European Association for the Study of the Liver (EASL) annual meeting, held in Vienna in April, and the Digestive Disease Week conference, which took place in Los Angeles in May. Highlights from EASL are covered in the June issue of *HCV Advocate*, and DDW is covered in the July and August issues.

In some reassuring news, data reported at EASL showed that patients who achieve sustained virological response (SVR) six months after the end of treatment are very unlikely to relapse in the future; after five years of follow-up, 98% of nearly 500 patients in six clinical trials who achieved SVR still had undetectable HCV viral load.

Data from the large WIN-R trial confirmed that a 24-week course of pegylated interferon/ribavirin is adequate for people with genotype 2 or 3 HCV, but the ACCELERATE trial suggested that further shortening treatment to 16 weeks is not advisable, since this leads to a higher rate of relapse. For “super-responders” who achieve undetectable HCV viral load by week 4, a shorter course of therapy appears to be effective, even for those with harder-to-treat genotypes 1 or 4. In the REPEAT trial, which included 950 participants who did not respond to prior treatment with Peg-Intron plus ribavirin, 62% of patients who received a high induction dose (360 mcg) of Pegasys plus weight-based ribavirin achieved early virological response at week 12. For patients who do not achieve full HCV suppression, another study added to the evidence that long-term maintenance therapy with low-dose pegylated interferon can reduce liver inflammation and fibrosis. Other data from WIN-R showed that among genotype 1 patients, weight-based ribavirin dosing was more likely to produce SVR compared with a flat dose (34% vs 29%). Tobacco smoking (in genotype 2 or 3 patients) and cirrhosis were associated with poorer response to therapy, while lower pre-treatment HCV viral load (less than 2 million copies) predicted a better response.

The Virahep-C study, an ongoing National Institutes of Health trial looking at racial differences in hepatitis C treatment response, found that during the first four weeks of therapy with pegylated interferon/ribavirin, blacks had a lower rapid

*continued on page 4*

## NEWS ROUNDUP

*continued from page 3*

virological response rate than whites, although there were no major differences in interferon concentrations or kinetics. Other analyses indicated that genetic variations in the interferon-signaling pathway and in the major histocompatibility complex (a group of genes involved in immune activation) appear to contribute to racial differences in treatment response. Another study found that Hispanics with genotype 2 or 3 (but not 1) had a significantly lower sustained response rate to pegylated interferon/ribavirin compared with whites (43% vs 71%), despite similar treatment discontinuation rates.

### PROMISING DATA ON EXPERIMENTAL AGENTS

While new data were presented at EASL and DDW on novel types of interferon and modifications of standard therapy, the most excitement revolved around “STAT-C,” or Specifically Targeted Antiviral Therapy for HCV (a term referring to agents that have direct activity against the virus). Researchers at DDW reported that all 12 treatment-naïve genotype 1 patients receiving the Vertex HCV protease inhibitor VX-950 plus Pegasys and ribavirin achieved undetectable viral load after 28 days; all but one maintained HCV suppression after stopping VX-950 and continuing on Pegasys/ribavirin. VX-950 was well-tolerated, with no serious adverse events or treatment discontinuations. In late June, Vertex announced that it would collaborate with Janssen Pharmaceutica and Tibotec (divisions of Johnson & Johnson) to further develop and commercialize VX-950; studies of 12- and 24-week combination therapy are underway.

The HCV polymerase inhibitor valopicitabine (NM283) plus ribavirin produced significantly greater HCV suppression at 24 weeks compared with pegylated interferon/ribavirin retreatment in previous nonresponders; Phase III trials are underway, though Idenix recently reduced the doses under study to prevent gastrointestinal side effects. Another HCV polymerase inhibitor, ViroPharma/Wyeth’s HCV-796, demonstrated favorable pharmacokinetic parameters and produced viral load reductions of 0.3 to 1.4 logs, depending on dose, in a Phase 1B trial. There were three presentations on InterMune’s NS3/4A protease inhibitor, ITMN191, which demonstrated potent anti-HCV activity in laboratory studies, good oral bioavailability in animals, and appears to have a favorable resistance profile. Another antiviral agent,

Migenix’s celgosivir (MX-3253) was well tolerated, though it demonstrated minimal anti-HCV activity as monotherapy; the agent will now be tested as part of combination regimens. Finally, the toll-like receptor-9 agonist CPG 10101 (Actilon), used in combination with pegylated interferon/ribavirin, was well-tolerated and produced superior HCV suppression compared with standard therapy; in mid-June, the Food and Drug Administration granted CPG 10101 “fast track” status. In more disappointing news, Anadys Pharmaceuticals announced in June that it was suspending a study of its toll-like receptor-7 agonist, ANA975, pending further assessment of toxicity data from preclinical studies.

### CLINICAL TRIALS

With the hepatitis C treatment pipeline as full as it’s ever been, numerous clinical trials are enrolling to test new experimental agents and new treatment strategies. A few open studies are listed below; for more, visit the federal government’s clinical trials web site at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for “hepatitis C” and “HCV.”

- Two Phase II studies (PROVE 1 in the U.S. and PROVE 2 in Europe) of VX-950 plus pegylated interferon/ribavirin in treatment-naïve patients; a Phase IIb study of VX-950 in prior nonresponders is expected to begin later this year.
- A 48-week Phase II trial evaluating the safety and activity of CPG 10101 in combination with pegylated interferon/ribavirin in prior nonresponders.
- A study of pegylated interferon maintenance therapy for HIV/HCV coinfecting patients.
- A study of individually adapted duration of pegylated interferon/ribavirin therapy in genotype 1 patients.
- A trial of pioglitazone for the management of insulin resistance and steatosis in people with hepatitis C.

### COINFECTION NEWS

In the May 12, 2006 issue of *AIDS*, researchers reported on a study of 10,500 HIV positive patients at 100 U.S. medical centers, 19% of whom were coinfecting with HCV. Coinfection was not associated with progression to AIDS-defining opportunistic illnesses or death, adding to the evidence that while HIV clearly seems to accelerate HCV-related liver disease progression, HCV does not appear to worsen

*continued on page 6*

# CO-FACILITATOR

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time to identify any potential disagreements about training content. For example, there may be differing opinions about hepatitis C and sexual transmission or about hepatitis C treatment. Negotiations prior to the training regarding language and content are much easier than dealing with it when it occurs during the training. Finally, facilitators will need to decide who will take the lead on each section of the training and which sections, if any, will have both facilitators involved. It is important to have one facilitator be the lead so only one person is calling on participants, but otherwise some activities or portions of the training will benefit from multiple trainers being involved. For example, during a brainstorm, one facilitator can encourage responses and call on participants while the other one writes down the comments on an easel. Spending this time before the training together will help the training run more smoothly for you and the participants.

During the training, facilitators should be in constant verbal and non-verbal communication and support each other based upon agreements made prior to the training. This may include eye contact, hand gestures and verbal check-ins. When one facilitator is taking the lead, the other can observe the group to gauge their understanding of the material and their need for clarification, the need for a change in activity or a break. Some training books refer to this as the “vibe watcher” – someone who is able to focus on the participants and their needs since the lead facilitator is focusing on content. Depending on prior agreements, facilitators may check in at breaks and during lunch to give feedback, adjust the agenda or discuss group process challenges. The other important aspect of working with a co-facilitator is to make sure the training is balanced and that neither trainer has more power. For example, if one trainer interrupts or challenges another trainer in front of the group, this can undermine the facilitator’s connection with the group. Sometimes, if a facilitator has a particularly strong personality or has extensive expertise, s/he may need to “step back” and allow room for the other facilitator to lead the group to create balance. Any major changes in the agenda such as shortening or extending a section, taking a break or lunch earlier or later or dropping activities should be discussed and agreed upon by both facilitators. This unified approach supports participants in experiencing the facilitators as a team, which enhances their training

experience.

After the training, it is important to debrief with your co-facilitator and note any changes or feedback that should be incorporated into future trainings. This may include reviewing the participant evaluations together or simply sharing your experience of the training. Some facilitators like to give each other specific feedback, especially if they have worked together in the past. While participant feedback is important, facilitators are in a wonderful position to give each other meaningful and constructive feedback on specific facilitation skills. If there are next steps identified, this is the time to determine which facilitator will follow-up. This may also be the time to discuss any awkward moments during the training and to strategize about how to deal with them again in the future if you will be working together.

Working with a co-facilitator during a hepatitis C training can be very fulfilling, fun and alleviate some of the stress of training alone. The success of cofacilitation is based upon the commitment to communicate, respect each other, compromise when necessary and support each other in providing the best training experience possible to the participants. For many facilitators, the benefits of working with a co-facilitator outweigh the challenges, especially when cofacilitators are able to be honest, supportive and open to learning from each other.



## Got an Event?

Have your events listed on the HCV Web site. Send the following to [cdmazoff@hcvadvocate.org](mailto:cdmazoff@hcvadvocate.org)

Event: \_\_\_\_\_

When: \_\_\_\_\_

What: \_\_\_\_\_

Where: \_\_\_\_\_

Contact information: \_\_\_\_\_

## NEWS ROUNDUP

continued from page 4

HIV disease progression.

Other recent research showed that steatosis was significantly more common and more severe in HIV/HCV coinfecting patients than in those with HCV alone. As reported in the June 2006 *Journal of Hepatology*, 72% of coinfecting individuals had some degree of steatosis, compared with 52% of HCV-monoinfecting patients. Another study, published in the August 1, 2006 issue of *Clinical Infectious Diseases*, found that steatosis was associated with genotype 3 HCV and use of two nucleoside reverse transcriptase inhibitors, d4T (stavudine, Zerit) and ddI (didanosine, Videx).

Fortunately, the evolution of anti-HIV therapy makes it easier for coinfecting individuals to avoid the most hepatotoxic drugs. In June, the FDA approved darunavir (Prezista, formerly TMC-114), a new protease inhibitor that works against drug-resistant HIV. July witnessed the approval of Atripla, a combination pill containing tenofovir and emtricitabine (the drugs in Truvada) plus efavirenz (Sustiva) – the first one-pill, once-daily complete antiretroviral regimen.

### ADVOCACY AND ACTIVISM

Nearly 100 patients, advocates, and activists gathered in Sacramento in May to discuss California's hepatitis C epidemic and form a statewide policy coalition; a follow-up meeting was held in late June in Los Angeles. The group discussed HCV-related developments at the state and national levels, and explored policies to prevent HCV transmission and ensure adequate treatment. The newly formed Strategic Statewide Policy Coalition, which includes the California Hepatitis C Alliance and the Drug Policy Alliance, plans to hold a larger public education meeting in the fall. For more information check out the *California Hepatitis C Alliance Newsletter* at [http://www.hcvadvocate.org/community/community\\_pdf/California%20HepC%20Alliance%20Newsletter\\_1.pdf](http://www.hcvadvocate.org/community/community_pdf/California%20HepC%20Alliance%20Newsletter_1.pdf)



## Attention Trainers!

The Hepatitis C Support Project has launched a new program to help trainers with their educational efforts. Included are tools to help you educate others. Listed below are various files to download and use for your training needs.

1. **One Day 2006** is the entire slide presentation that we are currently using for our trainings. Included in the slides are notes – just click on the note function. *Format:* MS PowerPoint
2. **Overview of HCV in English** is a template for general information about hepatitis C in English. Included in the slides are notes – just click on the note function. *Format:* MS PowerPoint
3. **Overview of HCV in Spanish** is a template for the above file in Spanish. *Format:* MS PowerPoint
4. **HCV Myths** is a presentation about various myths about hepatitis C. Included in the slides are notes – just click on the note function. *Format:* MS PowerPoint
5. **Game:** Heparady contains a sample game board, questions/answers. *Format:* MS Word.
6. **Crossword Puzzle:** Puzzle #1 and answers *Format:* Adobe pdf.

To access these files just cut and paste the following into your browser:

<ftp://Trngforms:HCSP123@www.hcvadvocate.org>

### YOUR BROWSER MUST BE ENABLED FOR FTP.

#### To enable ftp in Internet Explorer

1. In internet explorer, click on tools, internet options, advanced
2. Then click on Enable folder view for ftp
3. Scroll down
4. Click on Use passive ftp

Please keep checking back – we will be posting additional files to help educate people about hepatitis C. If you have any suggestions for information that will help you, please email [alanfranciscus@hcvadvocate.org](mailto:alanfranciscus@hcvadvocate.org)

Making a Difference in Your Community.

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