

Facilitating Hepatitis C Trainings

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The difference between hepatitis C presentations and facilitating workshops or trainings on hepatitis C is the ability of the facilitator to effectively involve participants in the learning process. Facilitators manage group dynamics and balance process and content to create a two-way sharing of information that meets the objectives of the training while supporting active participation in the process. Content is the hepatitis C information that is being

be conveyed in a short amount of time, and large audiences prevent much interaction. Most adults learn best when involved in the learning process, and effective facilitation skills create safety, promote interaction and encourage input from participants to enhance the effectiveness of the training experience for all.

Most facilitation skills mirror effective client-centered counseling skills. Verbal and non-verbal active listening

dating their contribution allows participants to feel heard. All participant comments should be acknowledged in some way, otherwise participants may feel shut down, or feel their input isn't valued as much as another participant. Other counseling skills also translate to facilitation skills: being neutral and non-judgmental (and honest when you are not), asking open-ended questions, using curiosity, meeting participants where they are, and utilizing participants' own experiences. While these may seem basic, they can make a huge difference in participant experience and involvement. For example, asking "What questions do you have?" or "Who has thoughts on this?" instead of typical closed-ended questions will increase the likelihood of input. Utilizing these and other basic facilitations skills will vary depending on group dynamics and the natural

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Identifying a trainer's natural style is the first step in recognizing which facilitation skills they may need to enhance, and which come naturally

taught and process is the delivery of that content or the way the content is being taught. Presentations on hepatitis C content are important, especially at conferences and other settings where a lot of information must

skills are the cornerstone of skills used by facilitators to demonstrate that the trainer is listening and responding to the comments of the group. Repeating participants' comments, paraphrasing their statements, or vali-

HEPSQUADS NEWS ROUNDUP

Liz Highleyman

NEW ESTIMATE OF HEPATITIS C PREVALENCE

It is typically said that about 3.9 million people in the U.S. have contracted hepatitis C and that 2.7 million are living with chronic infection. But Brian Edlin from Cornell presented evidence at the American Association for the Study of Liver Diseases (AASLD) meeting, held November 11-15 in San Francisco, that this figure is probably an underestimate since it is based on household data (*abstract 67707*). The National Health and Nutrition Examination Survey (NHANES) fails to account for populations not represented in households, some of which have higher HCV rates than the general population:

- Incarcerated people (nearly two million, with an estimated HCV rate of 32%)
- Homeless people (more than 800,000; estimated HCV rate 35%)
- Patients in hospitals (approximately 650,00; estimated HCV rate 17%)
- Nursing home residents (more than 1,600,000; estimated HCV rate 5%)
- Active-duty military personnel (about 1,400,000; estimated HCV rate 0.5%)

Altogether, Edlin calculated that 800,000 to 1.2 million more people have contracted HCV than usually reported, for a total of about 5 million. Assuming a spontaneous viral clearance rate of 25%, about 3.4 million currently have chronic hepatitis C. National HCV prevalence may be even higher because the number of unstably and sporadically housed people may greatly outnumber those who are homeless.

AASLD: NEW ORAL HEPATITIS C THERAPIES

The AASLD meeting also featured presentations on three experimental oral therapies for hepatitis C. Christopher O'Brien presented the first data from a Phase IIb trial of valopicitabine (NM283), an HCV polymerase inhibitor being developed by Idenix Pharmaceuticals (*abstract 63186*). In this study of

190 previous nonresponders with genotype 1 HCV, subjects receiving 800 mg valopicitabine once daily plus Pegasys for 12 weeks saw their HCV viral loads decrease by an average of 2.5-2.7 logs; 63%-71% achieved an early virological response, and 21% experienced at least a 4 log decrease in HCV RNA. Valopicitabine appeared safe and was generally well-tolerated. In December, Idenix announced that it was finalizing the design of a Phase III trial of valopicitabine plus pegylated interferon in treatment-refractory patients, which is expected to begin enrolling soon. On January 9, the company released preliminary data from an ongoing study showing that valopicitabine plus Pegasys produced at least a 4 log reduction in HCV RNA in treatment-naive individuals after four weeks, with half achieving undetectable viral loads.

Stefan Zeuzem from Homburg, Germany, reported on a Phase Ib trial of Schering-Plough's NS3 serine protease inhibitor, SCH503034 (*abstract 67484*). In this international study of 61 prior nonresponders with genotype 1 HCV, 60% of patients taking 400 mg SCH503034 three times daily for 14 days achieved a maximum HCV RNA reduction of more than 2 logs (100-fold); none had less than a 1 log decrease. Zeuzem also presented data from a small study showing that SCH503034 plus Peg-Intron produced at least an additive decline in HCV viral load (*abstract 67627*). No serious adverse events were observed - including the type of cardiac toxicity that doomed Boehringer Ingelheim's earlier HCV protease inhibitor, BILN-2061.

Henk Reesink from Amsterdam reported on a Phase Ib dose-ranging trial of another HCV protease inhibitor, Vertex Pharmaceuticals' VX-950 (*abstract 62580*). In this study of 36 subjects with genotype 1 HCV (mostly nonresponders but a few treatment-naive), patients receiving any dose of VX-950 monotherapy (450 or 750 mg three times daily or 1,250 mg twice daily) for 14 days achieved at least a 2 log reduction in HCV RNA; in the 750

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mg arm, viral load decreased by an average of 4.4 logs, or about 25,000-fold. There were no severe adverse events, dose reductions, or treatment discontinuations. Reesink said VX-950 produced “the most rapid and dramatic response” seen to date with a single anti-HCV agent. Vertex filed an Investigational New Drug application for with the FDA in November, and the agency granted VX-950 “fast track” status (expedited review) in December. On January 9, the company released new data from a 20-person randomized Phase Ib trial showing that genotype 1 patients who received 750 mg VX-950 three times daily plus Pegasys achieved a median 5.5 log (300,000-fold) decrease in HCV RNA after 14 days; half (4 out of 8) achieved undetectable HCV viral loads. Vertex will soon begin a 200-person Phase II trial of VX-950 plus pegylated interferon with or without ribavirin.

While larger and longer studies are needed to verify these promising results, they suggest that antiviral drugs – perhaps combined in fully oral regimens – may be the wave of the future in hepatitis C therapy. For the latest status of these and other experimental agents, see the chart on the HCV Advocate web site at www.hcvadvocate.org/hepatitis/hepC/HCVDrugs.html. For currently enrolling studies, check out <http://www.hcvadvocate.org/community/trials.asp> where there is also a link to the U.S. government’s web site www.ClinicalTrials.gov. Once there you can search for “HCV” or the name of a specific investigational drug.

VALEANT TO ACQUIRE INFERGEN

On November 29, Valeant Pharmaceuticals announced that it would acquire U.S. and Canadian rights to consensus interferon (Infergen) from InterMune for an initial payment of \$113.5 million. InterMune had been developing consensus interferon and interferon-gamma (Actimmune) for the treatment of hepatitis C in previous nonresponders and relapsers. Valeant hired some 50 members of InterMune’s sales and marketing staff, giving the company a presence in the hepatitis C market prior to its launch of viremagine (a prodrug of ribavirin that is less likely to cause anemia), which is now in Phase III trials.

MILK THISTLE MAY NOT HELP LIVER DISEASE

Milk thistle (*Silybum marianum*) – and its active ingredient Silymarin – is among the most commonly used herbs for liver problems. But two recent medical literature reviews suggest it may not actually be effective. Andrea Rambaldi and colleagues with the Cochrane Hepato-Biliary Group conducted a review and meta-analysis of trials studying milk thistle for viral hepatitis B or C or alcoholic hepatitis; results were published in the November 2005 *American Journal of Gastroenterology*. The authors reviewed 13 randomized clinical trials with a total of 915 participants conducted through December 2003. On the whole, milk thistle or its components had no significant effect on all-cause mortality, liver disease complications, or liver tissue health, compared with placebo or no intervention, but was associated with significantly reduced liver-related mortality in all trials. In the second review, published in the November 2005 *Journal of Viral Hepatitis*, K.E. Mayer and colleagues analyzed data from 148 articles discussing studies of silymarin and chronic viral hepatitis. Silymarin use was associated with decreased liver enzyme levels in four studies and performed better than placebo in one study. The authors concluded, however, that, “[t]here is no evidence that silymarin affects viral load or improves liver histology in hepatitis B or C.” While a majority of evidence appears to suggest that milk thistle has little or no effect on chronic liver disease, there have been enough promising findings to warrant further controlled studies.

SALIVA-BASED HCV TEST APPEARS PROMISING

A simpler and less painful HCV antibody test may be available in the near future. In a study of 37 kidney dialysis patients by Arie Yaari and colleagues from Israel, the novel test, which looks for HCV antibodies in saliva samples, was at least as accurate as a standard serum test (results were published in the online edition of the *Journal of Virological Methods* on December 19). The new ImmunoComb II test detected HCV in 100% of patients who had symptomatic hepatitis and 94% of asymptomatic patients. If larger studies confirm these results, this could be a milestone because saliva tests would be easier to perform and thus less expensive than blood tests, and would

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encourage testing among individuals who fear needle sticks. The new test could allow for mass HCV screening in both developing and wealthy countries – an important advance since many people with hepatitis C do not know they are infected.

RISE IN HCV-RELATED HOSPITALIZATIONS

While the rate of new HCV infections has declined dramatically in recent years, the disease is placing increased demands on the healthcare system as people infected years or decades ago begin to develop progressive liver damage. As reported in the December 2005 issue of *Hepatology*, William Grant and colleagues analyzed inpatient data from the Healthcare Cost and Utilization Project, outpatient data from the National Ambulatory Medical Care Survey, and medication use data from the Verispan Source Prescription Audit. They found that the number of HCV-related hospital admissions, number of days spent in a hospital, hospital charges, and physician visits increased by 25-30% annually from 1994 to 2001. The healthcare burden rose chiefly among patients 40-60 years old, reflecting the aging and associated disease progression of individuals infected in the past. Increased healthcare usage was especially pronounced among patients coinfecting with HCV and HIV. “Our findings highlight the urgency concerning HCV outcomes,” the authors concluded. “Across the United States, health care providers are using tremendous amounts of resources for HCV care.”

DOES HCV VIRAL LOAD PREDICT RISK OF DEATH?

Unlike HIV disease, where higher viral load is clearly linked with worse disease progression, most past research has not found an association between HCV viral load and liver disease severity or mortality. A recent study, however, calls the previous findings into question. Michie Hisada from the National Cancer Institute and colleagues analyzed data from 6,570 HCV positive injection drug users, some of whom were coinfecting with HIV and/or human T-lymphotropic virus type II (HTLV-II); results were published in the December 2005 issue of *Hepatology*. The risk of death due to end-stage liver disease (ESLD) increased as HCV viral load rose, but the likelihood of AIDS-related

death and mortality due to other causes was not associated with HCV RNA level. In addition, ESLD risk did not differ based on HIV status after adjusting for HCV viral load (which also conflicts with past research indicating that coinfecting patients have more rapid liver disease progression than those with hepatitis C alone). Though the authors concluded that “HCV RNA level is a predictor of [ESLD],” further research is needed to explain why these results differ from those seen in other studies. If these findings are confirmed, they suggest that reducing HCV viral load with effective therapy may decrease the risk of death due to ESLD, even if HCV is not completely suppressed or eradicated.

HIV/HCV COINFECTION NEWS

In an editorial accompanying Hisada’s article, Theo Heller and Leonard Seeff from the National Institutes of Health pondered possible reasons for the divergent findings regarding HCV viral load and disease progression. Attempting to tease out cause and effect, they raised the possibility that higher HCV RNA and worse liver disease progression might both be due to compromised immunity, rather than higher HCV viral load itself somehow promoting ESLD.

Two recent studies of HIV/HCV coinfection lend support to this theory. In the January 2006 *Journal of Hepatology*, Norbert Bräu and colleagues reported results of a retrospective analysis of data from 656 HCV patients, 42% of whom were also HIV positive. Among coinfecting patients receiving effective combination anti-HIV therapy (HAART) leading to undetectable HIV viral load, liver fibrosis progression was slower than in coinfecting individuals with detectable HIV RNA. In fact, the fibrosis progression rate in coinfecting patients with fully suppressed HIV was similar to that of HIV negative individuals with hepatitis C. Likewise, Sumita Verma and colleagues reported at AASLD and in the January 15 *Clinical Infectious Diseases* that coinfecting individuals with well-controlled HIV thanks to HAART had a liver disease progression rate similar to that observed in patients with HCV alone; coinfecting patients receiving suboptimal anti-HIV therapy, in contrast, had more advanced liver disease and faster fibrosis progression.

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FACILITATING TRAININGS

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teaching style of the trainer.

Managing group dynamics and supporting group process is a prime responsibility of a hepatitis C trainer. One of the most important skills in managing group process is called “stacking.” Stacking provides an opportunity for those with their hands raised to continue to participate in the conversation, while understanding their turn will come to communicate their perspective or question. When participants have something to add to the dialogue and their hand is raised, they may not be able to focus on the current discussion because they want to ensure they are seen by the facilitator. The stacking technique is the process of calling on each individual, in order, such as “We will hear from Kirk, then Juan then Malia.” Participants are able to put down their hands with the assurance that they will be called upon to share their input. Stacking also allows the rest of the group to support the trainer by remembering who is next in awaiting their turn to comment. Another facilitation skill that supports group process is encouraging quiet participants to talk and helping talkative participants leave room for others to share. Encouraging quiet participants to talk can either be direct, such as asking a specific participant what he or she thinks about a topic, or general by stating “Let’s hear from someone we haven’t heard from yet.” The same techniques work for participants who may overshare. Making a general statement about hearing from different people or viewpoints first, followed by a direct statement such as “We have heard quite a bit from you today – before we hear your perspective, would anyone else like to share?” will help maintain balanced participation. Two other facilitation skills will support group process: linking comments participants made earlier to the current topic, and redirecting comments or questions to the rest of the group. Stating “As Carlos stated earlier...” validates participants’ additions to the training and demonstrates how comments are linked to the overall objectives of the hepatitis C training. Asking for additional thoughts or opinions such as “That is an interesting point. What do others think?” will promote honest discussion that is inclusive of different perspectives and models and demonstrate to the participants that everyone’s beliefs are important and valued in the discussion.

Identifying a trainer’s natural style is the first step in recognizing which facilitation skills they may need

to enhance, and which come naturally. Most facilitators lean towards a certain leadership or trainer style and may need to actively work to reflect a comprehensive and balanced facilitation approach. For example, some hepatitis C trainers are more directing: they tell and give information, solve problems, make decisions for the group and use skills to “push” information to the group. Other trainers are more empowering: they ask for information from the group, ask the group to solve problems, share in decision making and use skills to “pull” information from the group. Overusing push skills without pull skills can create minimal participation and lack of participant ownership of the training. Overusing pull skills without push skills may result in misinformation or ambiguity, as most of the information is coming from participants. Most effective facilitators will have a balance of these styles, just as they will have a balance of content and process.

Webster’s dictionary defines facilitation as “[to] assist the progress of a process or an action; to make easier or less difficult.” The goal of effective facilitation skills for hepatitis C trainings is to assist the process of learning for participants through engaging group members to appropriately participate – which makes learning about hepatitis C more accessible and meaningful to both participants and trainers alike.



Got an Event?

Have your events listed on the HCV Web site. Send the following to cdmazoff@hcvadvocate.org

Event: _____

When: _____

What: _____

Where: _____

Contact information: _____

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A number of other recent journal articles and conference presentations have focused on various aspects of HIV/HCV coinfection, including an overview of hepatitis C treatment and management of adverse events in the December 1 *Journal of Hepatology*; an examination of the link between HIV and liver-related mortality in the December 2 issue of *AIDS*; a review of the clinical presentation and course of acute hepatitis C in HIV positive individuals in the January 1 *Journal of Acquired Immune Deficiency Syndromes*; and a look at sexual transmission of HCV among men who have sex with men in the U.K. presented at AASLD (abstract 67040).

MOTHER-TO-CHILD TRANSMISSION MORE COMMON IN GIRLS THAN BOYS

Infant girls are more than twice as likely as boys to contract HCV from their mothers during pregnancy or birth, according to a study reported in the December 1 *Journal of Infectious Diseases*. Researchers with the European Pediatric Hepatitis C Virus Network studied 1,787 pregnant women with hepatitis C and their infants. The overall mother-to-child HCV transmission rate was 6.2%. The rate was slightly higher – though the difference was not statistically significant – among women coinfecting with HIV than among those with HCV alone (8.7% vs 5.5%). Transmission was more likely from mothers with detectable HCV RNA during pregnancy or delivery, but a few nonviremic women also transmitted the virus. Elective cesarean section did not protect infants against contracting the virus, and breast-feeding did not increase the risk. A related study in the same issue by Eric Mast and colleagues found a perinatal transmission rate of 4.7% from mothers with detectable HCV RNA, while no infants of mothers with undetectable HCV viral load were infected. Here, the HCV transmission rate was significantly higher if the mother also had HIV. Girls in this study were also about twice as likely to be infected than boys, but the difference did not reach statistical significance. In an accompanying editorial entitled “Nature Usually Favors Females,” R. Palmer Beasley suggested that the higher infection rate among girls may be due to excess male mortality in utero.

Alcohol and Drug Addiction Counseling for Hepatitis C Patients

Currently, few communities have experience combining HCV testing, counseling, prevention, and treatment services with HIV/AIDS or any other public health program. Recent demonstration projects have shown that integrating HCV counseling, testing, and education into existing programs is feasible and can enhance identification of persons at risk or needing care for HCV. In order to support this need, the Hepatitis C Support Project, in partnership with Qi/Commonhealth®, is offering this Web-based, self-paced CE accredited program. This program has been made possible by an unrestricted educational grant from Roche Pharmaceuticals.

Once you have completed the tests and the course evaluation and submitted them on-line, we will provide you with a CE certificate for your records. Please make sure to complete the course evaluation, as it will help us better address your needs in future programs.

To find out more, go to www.hcvadvocate.org and click on the CEU button to the right.

Materials Order Form

We are happy to be able to provide HCV support groups and non-profit agencies in the United States with a limited amount (see below) of our educational materials. There is no charge for these materials. Please fill out the form below and fax it to 1-877-203-3580.

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_____ A Guide to Understanding HCV (limit 25 per agency)

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