



2011 Year in Review

—Alan Franciscus, Editor-in-Chief

It's that time of year again when the HCSP/HCV Advocate staff review and pick the top stories of 2011. I think you will agree that this year has been an amazing year for HCV. We all agreed that the biggest, baddest, and best news of the year was the approval of the HCV protease inhibitor com-

ination therapy in May. The other stories listed below are more difficult to rate, but are important and noteworthy because they are major advances in the development of HCV therapies (including the interferon-free therapies), approval of new diagnostic tests, and increased awareness of viral hepatitis.

FDA APPROVAL

The most important news story of 2011 was the approval of the first HCV protease inhibitors (PI) used in combination with pegylated interferon plus ribavirin (PEG/RBV) to treat chronic HCV genotype 1. On May 13, 2011 the Food and Drug Administration (FDA) approved the triple combo of **boceprevir** (brand name Victrelis) plus PEG/RBV to treat chronic hepatitis C genotype 1 patients. Later in the year, boceprevir with PEG/RBV was also approved in Canada and Europe. The second HCV protease inhibitor, **telaprevir** (brand name Incivek with PEG/RBV) was approved on May 23,

2011. Telaprevir has also been approved in Canada and Europe under the name Incivo.

The FDA approval of boceprevir and telaprevir is a milestone in advancement of HCV treatment for people with HCV genotype 1 because of the dramatic increase in cure rates—up to ~79%. In addition, HCV populations such as African Americans, Hispanics and people with cirrhosis who did not respond well to the old standard of care—PEG/RBV—also saw major advances.

Another milestone was the approval of the **HCV OraQuick HCV Antibody Tests**—whole blood and finger prick was FDA

approved in February 2011 and the CLIA waiver received FDA approval at the end of November 2011. In case you are interested, CLIA is an acronym for Clinical Laboratory Improvement Amendments. The OraQuick HCV antibody test using the oral swab technology is currently under review by the FDA and this along with the CLIA waiver is expected to be approved in 2012. A game changer!

In related news, the CDC has been piloting “Aged-Based Testing” of HCV that would test everyone at a certain age and thereby diagnose the majority of

CONTINUED ON PAGE 2

IN THIS ISSUE

HEALTHWISE: <i>Telling Our Stories</i>	3
HCV SNAPSHOTS	4
BRAIN FOG: IT REALLY IS ALL IN YOUR HEAD	6

2011 Review

FROM PAGE 2

the 75% of people who are infected with hepatitis C but don't know it. The year or range of birth years for one-time testing will be between 1946 and 1965—the years considered to be the baby boomer generation.

This year a study was published that looked at an outbreak of acute HCV in Massachusetts between 2007 and 2009. **1,925 new cases** of HCV infection (1026 confirmed; 899 probable) were reported among people aged 15-24 years. Similar outbreaks have been seen in other states across the country so it's very likely that there are many more new and chronic infections of HCV in the U.S. than currently reported.

CLINICAL TRIALS

2011 will go down as a ground-breaking year for the development of medications to treat chronic hepatitis C. Direct acting antiviral (DAA) medications in combination with and without interferon and/or ribavirin entered into phase 1, 2, and 3 studies. Early data are very encouraging.

At year end there are **six phase 3 studies** that are either on-going or that will begin shortly with various HCV inhibitors including BI 201335 (HCV protease inhibitor), BMS-79005-daclatasivir (HCV NS5A inhibitor), and TMC435 (HCV protease inhibitor). PSI-7977 (HCV polymerase inhibitor)

will be the first DAA to enter into Phase III studies that will contain interferon-free arms. Additionally, a cyclophilin inhibitor, alisporivir, and a new long-acting formulation of interferon called Lambda entered into phase III studies.

Acquisitions and collaborations of pharmaceutical companies were plentiful in 2012, and were viewed as helping companies with existing HCV medications strengthen their drug portfolio. The mega deal of the year (or decade) was the acquisition of Pharmasset by Gilead Sciences for **11 billion dollars** (yes that's \$11,000,000,000). Pharmasset has many HCV drugs in development including the potential blockbuster HCV polymerase inhibitor PSI-7977 mentioned above.

WHD AT THE WHITE HOUSE

This year's World Hepatitis Day (WHD) included the first ever White House event that brought policy makers, government officials, researchers, health care providers and patient advocates together to discuss the global impact of hepatitis B and C. This year WHD was changed to July 28 in honor of Dr. Blumberg (1925 – 2011) who along with his research team discovered the hepatitis B virus.

Along with the festivities at the White House, Merck launched their **Tune In to Hep C** campaign with **Greg All-**

man and Natalie Cole as their spokespeople. A benefit concert held in New York City on the eve of WHD Performances included the Allman Brothers Band with special guests Natalie Cole, David Crosby, Graham Nash, Phil Lesh, and Billy Gibbons as well as guest instrumentalists. Of note, Greg Allman received a Grammy nomination for Best Blues Album for *Low Country Blues*. If you haven't picked up the album, do yourself a favor and give it a listen. It's a real gem.

I was in attendance at both events and it was very gratifying and exciting to finally see hepatitis B and C get the much needed attention from the government and the entertainment industry.

HARM REDUCTION

At year end, New Jersey's assembly had approved needle exchange. Providing that Governor Christie signs the bill into law, New Jersey will be the **49th state to have syringe access** without a prescription for adults. This leaves Delaware as the only state in the country that doesn't! Our Canadian friends to the north have been hard at work with implementing far-reaching harm reduction models that include safe-injection sites, and crack pipe exchange sites that are a blueprint that many in the U.S. would like to emulate.

CONTINUED ON PAGE 5

HEALTHWISE

Telling Our Stories

—Lucinda K. Porter, RN

When I tell my story about having chronic hepatitis C virus (HCV) infection, it usually begins with the moment I got the virus. Recently I realized that this is not the real beginning. My story starts at the point I decided to make a difference. This was when I volunteered at a needle-exchange site because I wanted to help stop the spread of HCV and HIV. That experience opened my eyes, but more importantly, it connected me to like-minded people. This small act led me to Alan Franciscus, Executive Director of the *Hepatitis C Support Project* and Editor-in-Chief of this newsletter. My association with him changed my life in so many ways, all of them good.

This work brings me into contact with people from all over the world—many of whom have told me their stories. Their accounts of trials and tribulations crack my heart wide open, inspiring me to do more. I wish I could scoop up these stories and share them with you. Some are so amazing, especially ones about people who go through HCV treatment and lose spouses or have other serious health or family problems. When I hear these, I think that if they can get through HCV treatment, anyone can!

In my story, I have lived with this virus since 1988. I am a

nurse because of having HCV. This virus pulled me towards others who have it, eventually taking me to work with liver disease patients at Stanford University Medical Center. I went through treatment twice, one of which was 48 weeks of peginterferon and ribavirin, working the entire time at Stanford. I responded to treatment but relapsed. I plan to do treatment again, perhaps this year.

Someone who understands the value of our stories is Nirah Johnson, LMSW. She collects stories through her work as a Community Project Specialist in the NYC Department of Health & Mental Hygiene, where she organizes four community Hepatitis C Task Forces in areas of NYC most affected by Hepatitis C. “I heard many life stories that were truly mind blowing, that should be a full length movie, and I wished everyone could hear, be inspired and learn from these stories.” However, Nirah noticed that HCV patients were reluctant to share their stories, much less speak publicly about them. This is likely because an HCV diagnosis comes attached with complications, not just physical ones, but emotional, spiritual, and social issues. The effects of HCV include confusion, social marginalization, and fear of stigmatization.

Nirah wanted to help people develop their stories in a safe space, and thus the NYC Hepatitis B & C Personal Stories Workshop was born in November 2010. “The workshop helps members become clear and comfortable with their own stories, and then prepares the stories to travel out to the world as teachers,” said Nirah. In short, by giving a voice to the pain, the stories have the potential to teach and to heal.

In my story, HCV is a gift rather than a burden (although it is a gift I will gladly give up the next time I undergo treatment). Sharing my body with this virus reminds me to take better care of myself. Without it, I might have waited until I had one of those life-threatening “wake-up” calls that shake many of us out of complacency, a call that sometimes comes too late. Having HCV is like having a small voice in my head—it reminds me to exercise, eat a healthy diet, and to abstain from alcohol.

The gifts from HCV are not limited to my health. I have an incredibly rich life because of the people I meet. I am surrounded by compassionate and generous people who give and give and give. My world is so different from the world portrayed by the news media. I navigate a

HCV Snapshots

—Lucinda K. Porter, RN

Article: Vitamin D: An Innate Antiviral Agent Suppressing Hepatitis C Virus in Human Hepatocyte – Gal-Tanamy M, Bachmetov L, Ravid A, Koren R, Erman A, Tur-Kaspa IR, Zemel R.

Source: *Hepatology*; Volume 54, Issue 5, pages 1570–1579, November 2011.

This study looked at the connection between vitamin D₃ supplementation and improved response rates to treatment for chronic hepatitis C virus (HCV) infection. The research showed the various pathways that vitamin D₃ uses, showing the antiviral properties of vitamin D₃ particularly during interferon treatment. Researchers noted that vitamin D₃ combined with interferon alfa has a synergistic relationship (the drug interactions are magnified, in this case in a beneficial way). Also noted was that vitamin D₃ combined with interferon alfa decreases viral production more than interferon alfa without vitamin D₃.

The Bottom Line: Vitamin D₃ may have a significant impact on HCV and treatment for it.

Editorial Comment: Vitamin D is in the headlines quite a bit these days. To find current guidelines on dosing and other pertinent information, visit www.mayoclinic.com/health/vitamin-d/NS_patient-vitamind

Article: HIV and HCV Health Beliefs in an Inner-city Community – Krauskopf K, McGinn TG, Federman AD, Halm EA, Leventhal H, McGinn LK, Gardener D, Oster A, Kronish IM.

Source: *Journal of Viral Hepatitis*; Volume 18, Issue 11, pages 785–791, November 2011.

This team of researchers surveyed a random sample of New York City patients about their knowledge of HIV and HCV. Since our beliefs about diseases influence our health-related behaviors, the survey focused on beliefs.

When questioned about the causes of HIV and HCV, nearly 25% believed that HCV could be caused by eating contaminated food, whereas only 8% believed that HIV could be acquired via food. More than 90% stated correctly that HIV could be transmitted via sharing needles, but less than 60% knew that sharing needles could spread HCV.

When asked if the illness could cause problems that may last for many years, nearly 84% knew that HIV would, but only 58% knew that HCV could. Roughly, 42% correctly identified that HCV may remain in the body for life; with only 6% stating that HCV may cause problems.

When asked if there were medications that might cure

HIV, 8% incorrectly answered. Less than 25% knew that HCV was curable. The majority of those surveyed did not know that HCV may cause cancer and that there were measures they could take to avoid the complications of HCV.

The Bottom Line: Those surveyed knew significantly more about HIV than HCV despite the fact that more people in the U.S. are infected with HCV and that more die from HCV than HIV.

Editorial Comment: This journal article appeared online in 2010 and was published in November 2011. I was glad to see it reprinted, as it is quite interesting, particularly because it shows what people think they know about HCV, rather than knowing the facts. Looks like activists, advocates, and healthcare workers have a big job ahead. The researchers in this paper noted that compared to HIV, HCV is under-publicized.

Article: Level of α -Fetoprotein Predicts Mortality Among Patients With Hepatitis C-Related Hepatocellular Carcinoma – Tyson GL, Duan Z, Kramer JR, Davila JA, Richardson PA, El-Serag HB.

Source: *Clinical Gastroenterology and Hepatology*; Volume 9, Issue 11, Pages 989–994, November 2011.

CONTINUED ON PAGE 5

Snapshots FROM PAGE 4

Hepatocellular carcinoma (HCC) is one of the potential consequences of HCV, a cancer that is rapidly increasing in numbers in the U.S. One of the lab tests used to monitor HCV patients for HCC is α -fetoprotein (AFP). This study collected data from 1998 to 2007, looking at AFP levels of 1064 subjects, one to 2 months prior to HCC diagnosis.

AFP results were sorted by:

- less than 10 ng/mL (18%)
- 10 to less than 100 ng/mL (30%)
- 100 to less than 1000 ng/mL (22%)
- 1000 ng/mL or more (29%).

The Bottom Line: The lower the AFP levels, the longer the average survival times for HCC patients:

- 709 days for patients with less than 10 ng/mL
- 422 days for patients with 10 to less than 100 ng/mL
- 208 days for patients with 100 to less than 1000 ng/mL
- 68 days for patients with 1000 ng/mL or more.

Editorial Comment: AFP levels are usually done for HCV patients with stage 3 or higher liver disease, and usually accompany an ultrasound or other imaging study. This study sheds more light on the AFP test.

Article: Changes in Hepatitis A and B Vaccination Rates in Adult Patients with Chronic Liver Diseases and Diabetes in The U.S. Population – Younossi Z, Stepanova M.

Source: *Hepatology*; Volume 54, Issue 4, pages 1167–1178, October 2011.

Hepatitis A and B immunization is recommended for people with chronic liver disease (CLD), including HCV. This study obtained data in the National Health and Nutrition Examination Surveys (NHANES) performed from 1999 through 2008. There were 24,871 participants; 14% had CLD.

The Bottom Line: Researchers noted that hepatitis A and B vaccination rates are increasing but still remain low. Among those with CLD, approximately 20% have had hepatitis A immunizations; 32% have had hepatitis B immunizations.

Editorial Comment: If you have HCV, fatty liver disease, or other chronic liver disease, protect your liver by reducing your risk of acquiring another liver disease. Be sure your hepatitis A and B immunizations are up-to-date.

For more information about vaccines, read HCSP's *HCV Wellness: Immunizations for Adults* www.hcvadvocate.org/hepatitis/factsheets_pdf/immunization.pdf or visit the Centers for Disease Control and Prevention website www.cdc.gov/vaccines/default.htm

2011 Review

FROM PAGE 2

HCSP

2011 was a very important year for the Hepatitis C Support Project / HCV Advocate: We have updated all of our fact sheets and guides with the latest information, including the newly approved drugs, and conducted 50 HCV and HBV trainings throughout the U.S. In fact, this year was the year that we have completed **at least one training in every U.S. state** since the launch of our workshops in 2002. We distributed over a staggering **600,000 pieces of educational literature** and our Web site www.hcvadvocate.org continues to grow with 27 million hits in 2011—providing one-stop shopping for the HCV community. We also launched our tattoo safety website www.hepatitistattoos.org and our [HBV Advocate Web site](http://www.HBVAdvocateWebSite.com) continues to grow and expand.

A special mention: Lucinda Porter, RN our colleague and friend published her book *Free From Hepatitis C: Your Complete Guide to Healing Hepatitis C*. Way to go Lucinda!

On a final note we would like to honor our friend Dr. Emmet Keefe (1942 - 2011) who provided HCSP/HCV Advocate and the HCV community with encouragement and advice. Emmet, we miss you.

Brain Fog: It Really Is All in Your Head

—C.D. Mazoff, PhD

Like many people with hepatitis C, I am symptomatic—more at some times than others, and always unpredictably so, which is of course a royal pain! The hardest part for me has always been the brain fog. That's what first got me. I used to teach before I got ill and when my hep hit, that part of my life went out the window because I became so fogged out that I couldn't read, and kept getting lost on the public transport and was too out of it to drive.

But it did get better—with treatment and rest. Although my 3 bouts with interferon treatment didn't cure me, they did vastly improve my ability to function. However my brain has been getting foggy again and it really scares me, so finding any encouraging news about what the heck "brain fog" is and etc. really helps.

We do have some great articles up on the site about cognitive impairment, in particular Lucinda K. Porter's "[Hepatitis C and Brain Fog](#)" and references in the May 2010 HCV Advocate newsletter; but since then more evidence has been found which further explains the 2-fold mechanism of brain fog in patients with hepatitis C and *without* hepatic encephalopathy.

Cerebral microglial activation in patients with hepatitis

c: in vivo evidence of neuroinflammation, by V. P. B. Grover et al.,¹ clearly shows that brain fog is caused by a) the direct action of the virus on brain cells, and b) by an immune type response against viral activity.

Microglial cells "are a type of glial cell that are the resident macrophages of the brain and spinal cord, and thus act as the first and main form of active immune defense in the central nervous system (CNS)."² Glial cells, themselves are:

supportive cells in the central nervous system—the brain and spinal cord. Glial cells do not conduct electrical impulses (as opposed to neurons, which do). The glial cells surround neurons and provide support for them and insulation between them. Glial cells are capable of extensive signaling in response to a diversity of stimuli. Bidirectional communication exists between glial cells and neurons, and between glial cells and vascular cells."³

And macrophages are a type of white cell that gobbles up the bad guys (see the film *Osmosis Jones* for a great description of how the immune system works).

Grover et al. were able to

set up a very sophisticated research procedure to analyze various types of brain imaging scans from different parts of the brains of live subjects with and without hepatitis C. Previous analyses of brains and brain scans were post mortem; but using live subjects allowed the researchers to administer psychological and motor skill tests to the same subjects whose brains had been scanned, and to correlate the scan results. Brain imaging is very sophisticated and very accurate in determining different types of brain damage caused by different conditions. All brain damage is not the same, and certain conditions are linked to specific damage patterns in various brain locations. For example, Parkinson's and Huntington's both occur in the basal ganglia but Parkinson's involves the SNc region and Parkinson involves damage to the striatum.⁴

Importantly (especially for me—I have genotype 1), Grover et al. conducted further tests on the patients with genotype 1 since there is post-mortem evidence of genotype 1 viral replication in the brain (his note 10).

Results of the PET scans showed that "in genotype 1

CONTINUED ON PAGE 7

Brain Fog FROM PAGE 6

patients, the mean thalamic BP (binding potential=shows cellular change) in genotype 1 patients was significantly higher than controls, (P = 0.005), with 50% of these patients having BP greater than highest control values." This is important to know because the thalamus is the part of the brain that "affects relaying sensation, spatial sense, and motor signals to the cerebral cortex, along with the regulation of consciousness, sleep, and alertness." ⁵

As well, basal ganglia affectivity was significantly elevated for all patients with HCV compared to controls, and was not limited to genotype 1. The basal ganglia (or basal nuclei) situated at the base of the forebrain are strongly connected with the cerebral cortex, thalamus and other brain areas. The basal ganglia are associated with a variety of functions, including voluntary motor control, procedural learning relating to routine behaviors or "habits" such as bruxism [teeth clenching and grinding], eye movements, and cognitive, emotional functions. ⁶

CONCLUSIONS OF THE GROVER ET AL. STUDY

There were several conclusions to this study, but the ones I found most pertinent were:

1. The *in vivo* findings support the hypothesis that cerebral microglial activation occurs in HCV infection and, to [Grover's] knowledge, this is the first study to report this in living patients, in the presence of mild liver disease only.
2. Grover et al. "did not measure cytokine levels in this study and no samples were available for retrospective analysis, [so] the underlying cause for cerebral neuroinflammation in this patient population remains unclear, but [their] findings may be related to either the effects of peripheral circulating cytokines on the brain, given that all the patients had viral hepatitis, or a direct virological effect of HCV within the CNS, or a combination of both factors."

Grover does mention that a number of studies now support the concept of HCV replication in the brain, and below is a short review of other studies that I found on Pubmed which also shed light on the problem.

- *Influence of hepatitis C virus on neurocognitive function in patients free from other risk factors: validation from therapeutic outcomes.* Pattullo V, McAndrews MP, Damyanovich A, Heathcote EJ. *Liver*

Int. 2011 Aug;31(7):1028-38. doi: 10.1111/j.1478-3231.2011.02549.x. Epub 2011 May 25.

In this study the authors wanted to find out if treatment-induced viral clearance abolished mild neurocognitive dysfunction and altered cerebral proton magnetic resonance spectroscopy.

Conclusions: The hepatitis C virus has a measurable effect on CNS integrity in patients screened for other medical and/or psychiatric comorbidities. *Viral clearance has not been demonstrated to abolish these abnormalities.* Yikes!!!!

- *Hepatitis C infection, Cognition, and inflammation in an Egyptian sample.* Farag NH, Rashed HA, Hassan M, Darweesh A, Shehata M, Hassanein T, Mills PJ. *J Med Virol.* 2011 Feb;83(2):261-6.

Results from this pilot study indicate that HCV+ patients have worse cognitive performance and somewhat greater inflammatory activity as compared to controls. The increased inflammation may be associated with the cognitive impairments observed in these HCV+ patients.

Brain Fog

FROM PAGE 9

• *Activation of brain macrophages/microglia cells in hepatitis C infection.* Wilkinson J, Radkowski M, Eschbacher JM, Laskus T. Gut. 2010 Oct;59(10):1394-400. Epub 2010 Jul 30. Evidence was found for activation of brain macrophages/microglia cells in autopsy brain tissue from HCV-positive patients. These findings could relate to the common presence of neurocognitive dysfunction among patients with chronic hepatitis C.

I'm glad I took the time to

look into this more deeply, and that there is current research confirming that HCV does penetrate the brain barrier. There is still a lot of ignorance and stigma associated with hepatitis C, and I can remember back to when I was accused of making it up (when I went to a disability hearing). So this information is one more bit of ammunition you can use if you are arguing a disability case, and need some medical proof, or just if you need to understand why you are so foggy at times. Show this stuff to your doctor!

Honestly though, knowing the above, that it's not all in

my head (or it is all in my head) does make me feel a bit better, I think.

Endnotes

1. Journal of Viral Hepatitis, 2011 doi:10.1111/j.1365-2893.2011.01510.x
2. <http://en.wikipedia.org/wiki/Microglia>
3. www.medterms.com/script/main/art.asp?articlekey=11382
4. http://en.wikipedia.org/wiki/Basal_ganglia
5. Wiki
6. Wiki

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Stories

FROM PAGE 3

planet where people help others. My tribe knows that HCV is an equal opportunity destroyer and doesn't care how someone acquired this virus. I hang out with people who are willing to love the people that others cross the street to avoid.

My HCV story led me to people like Alan Francisus and Nirah Johnson. It led me to my mentor and friend, recently deceased Emmet B. Keeffe, MD, as well as to many others. Collectively, our narratives connect us, so that we are bound not by a virus, but by our stories about it.

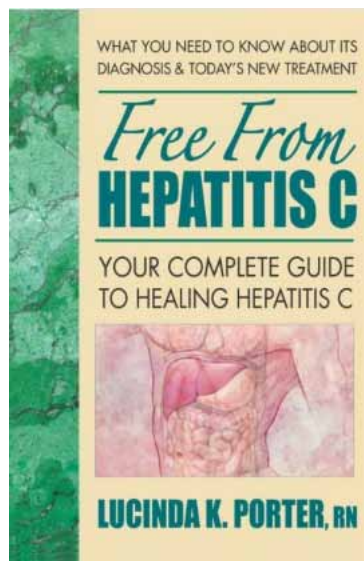
Speaking up about having HCV is a brave and radical act. It takes courage to declare that you have an illness, particularly a potentially transmissible one. Telling your story is like extending a hand in the dark to console another. It reminds us that we aren't alone, which may be especially comforting to those who are newly-diagnosed or struggling with HCV. In the words of Holocaust survivor, Elie Wiesel, "Whoever survives a test, whatever it may be, must tell the story. That is his duty."

LINKS TO MORE INFORMATION

- HCV Advocate www.hcvadvocate.org/community/stories.asp Personal stories can be read as well as written for inclusion.
- Smith Magazine's Six-word Memoir www.smithmag.net/sixwords Can you tell a story in 25 words or fewer? Inspired by

Ernest Hemingway's six-word novel, "For sale: baby shoes, never worn."

- StoryCorps www.storycorps.org Since 2003, over 50,000 people have shared life stories with family and friends through StoryCorps. Each conversation is recorded on a free CD to share, and is preserved at the Library of Congress.
- The Moth <http://themoth.org> This nonprofit organization is dedicated to the art and craft of storytelling. Listen to stories on *The Moth Radio Hour*.
- Viral Hepatitis Action Coalition – Faces of Hepatitis www.viralhepatitisaction.org/faces Watch and submit stories.
- World Hepatitis Alliance's Wall of Stories – "This is hepatitis"... Real Lives Real Stories www.worldhepatitisalliance.org/Community_Map/Real_Lives.aspx Share your story through this website.



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