Drugs in Development: Genotype 2 and 3

—Alan Franciscus, Editor-in-Chief

Standard of Care: The current standard of care for treating HCV genotypes 2 and 3 is the combination of pegylated interferon (Pegasys or Peg-Intron) plus a fixed dose (800 mg) of ribavirin. The treatment duration is generally 24 weeks. The Food and Drug Administration (FDA) approval was based on phase III trials that found up to 82% viral cure. Previously, the clinical trial data found that the viral cure rates were similar between HCV genotype 2 and 3. This now is changing with the new direct acting antivirals—for some of the drugs in development there is a significant difference in viral cure rates between genotype 2 and 3. Now, it seems like genotype 3 has replaced genotype 1 as the most difficult genotype to treat.

Drug development for treating HCV genotype 2 and 3 has been slow (especially compared to studies for treating HCV genotype 1), but this should change since genotype 1 viral cure rates are reaching 90%+ with shorter treatment durations and fewer side effects. This should ‘free-up’ research to increase development of drugs to treat HCV genotype 2 and especially genotype 3, which is sorely needed.

SOFOSBUVIR/RIBAVIRIN: NEXT STANDARD OF CARE

The next treatment for genotype 2 and 3 will be the combination of Gilead’s sofosbuvir (HCV polymerase inhibitor) and ribavirin. Sofosbuvir is dosed once a day. Ribavirin is dosed twice daily. The application with the clinical trial data has been submitted to the FDA. It is estimated that the two-drug combination will be approved by the FDA by the end of 2013 or early 2014. However, there is some controversy regarding the use of sofosbuvir/ribavirin for the treatment of HCV genotype 3 since the viral cure rates were generally less than optimal. But there are positive trade-offs in using the all-oral combination.

It is important to note that the currently approved HCV protease inhibitors (boceprevir or telaprevir) have not been extensively studied and are not approved to treat genotypes 2 or 3.

Phase 3 study results

There were two clinical trials:

- **POSITRON:** included patients who were interferon intolerant—a contraindication to interferon treatment, an unacceptable side effect profile for interferon, or a patient’s decision not to be treated with interferon. There was a placebo (comparator) that received no treatment (sugar pills).
**Snapshots**

—Lucinda K. Porter, RN

**Article:** Hepatitis C-Associated B-Cell Non-Hodgkin Lymphomas: Epidemiology, Molecular Signature and Clinical Management – J. Peveling-Oberhag, et al.

**Source:** Journal of Hepatology July 2013

Clinical evidence shows an association between chronic hepatitis C virus (HCV) infection and B-cell non-Hodgkin lymphoma (B-NHL). Data suggests a causal relationship between the two, notably because B-NHL occurrence is reduced in those who have a sustained response (SVR) to HCV treatment. This article was a review of the data on the epidemiology, interventional studies, and molecular mechanisms of HCV-associated B-NHL.

**The Bottom Line:** HCV patients have a moderately increased risk of B-cell non-Hodgkin lymphoma. Patients who are in remission from B-NHL, should be considered for HCV treatment in order to prevent B-NHL recurrence. The authors of this article encourage the inclusion of patients with B-NHL in HCV studies.

**Editorial Comment:** I chose this paper because it is a sharp reminder that HCV patients are at increased risk of other comorbidities, and these risks are yet another reason to consider HCV treatment.

**Article:** Sofosbuvir and Ribavirin for Hepatitis C Genotype 1 in Patients with Unfavorable Treatment Characteristics: A Randomized Clinical Trial – Anuoluwapo Osinusi, et al.

**Source:** Journal of the American Medical Association August 28, 2013

This phase 2 study, which was conducted at a single center of the National Institutes of Health, enrolled 60 treatment-naive hepatitis C (HCV) genotype 1 patients with treatment-resistant characteristics. Ten participated in the first proof of concept group, and 50 participants in the randomized group. They received daily sofosbuvir in combination with either weight-based ribavirin or low-dose (600 mg) ribavirin daily for 24 weeks.

The randomized group had all stages of fibrosis, including compensated cirrhosis. The general characteristics: 83% were black; 66% male; 48% body mass index greater than 30; 81% had unfavorable IL28 genotype (CT or TT); 70% genotype 1a; 23% had advanced liver disease; and 62%, baseline HCV RNA levels greater than 800,000.

**The Bottom Line:** Using an all-oral, 24-week HCV treatment regimen of sofosbuvir and weight-based or low-dose ribavirin, results were 68% and 48% respectively, despite the high prevalence of unfavorable predictors of treatment response.

**Editorial Comment:** Although these results aren’t perfect, they are cause for celebration. It is a giant leap forward to say we may be able to cure hepatitis C in more than half of treatment-resistant patients with an all-oral, 24-week treatment. For perspective, these results are better than 48 weeks of peginterferon plus ribavirin. Incidentally, noted hepatologist Gregory Everson recently said, “Interferon-free therapy is evolving rapidly, and I hope that it will be in primary care physicians’ backyards in the near future.” Putting HCV treatment into the hands of primary care providers will create access to treatment for more people.

**Article:** Metabolic Factors and Chronic Hepatitis C: A Complex Interplay – Fabio Salvatore Macaluso, et al.

**Source:** BioMed Research International Volume 2013

This review article discusses the correlation between chronic hepatitis C and various metabolic disorders. The authors focus on insulin resistance/type 2 diabetes, steatosis (fatty liver), visceral obesity (stomach fat), atherosclerosis (hardening of the arteries), vitamin D, menopause, fructose and coffee intake, lipoproteins (cholesterol, etc.), methylenetetrahydrofolate reductase status (an enzyme associated with various diseases), and hyperuricaemia (excess uric acid in blood that is associated with gout and kidney stones).

**The Bottom Line:** Chronic hepatitis C is a systemic disease, leading to metabolic consequences. This paper discusses the
October is National Liver Awareness Month, and frankly, the liver could use all the awareness it can get. This silent, non-complaining organ doesn’t send out distress calls like the heart and lungs do. The liver can be damaged and you might not know it until the damage is quite extensive.

One of the most common liver diseases in the U.S. is chronic hepatitis C viral infection (HCV). Since there are other liver diseases, and because people with HCV may have more than one liver disease, this month’s Healthwise is devoted to raising liver disease awareness. I didn’t include most childhood liver diseases, such as biliary atresia and galactosemia. I also left out gall bladder conditions, saving that in case there is ever a National Gall Bladder Awareness Month (sponsored by the Friends of Foie Gras Society).

Having more than one liver disease usually means a poorer prognosis. Having more than one liver disease is often a case of bad luck, leaving the patient to manage as best as one can, given the circumstances. However, some liver diseases are preventable, and although everyone should try to prevent these, this advice is particularly true for those with hepatitis C.

The symptoms for liver disease are pretty much the same regardless of the cause, with few exceptions. What varies is the severity and speed of which the liver deteriorates. Cirrhosis (severe scarring of the liver) may be caused by any liver disease. In extreme life-threatening circumstances, liver transplantation is an option for most liver diseases.

**Alagille Syndrome** – In this rare inherited disorder, patients have fewer bile ducts, so the liver is unable to adequately perform its many functions. This is usually diagnosed in infancy or early childhood, and it can affect other organs, such as the heart and kidneys. Alagille syndrome is managed in a variety of ways and liver damage, leading to liver transplantation, is common. About one in 70,000 infants are born with alagille syndrome.

**Alcohol-related Liver Disease** – Over-consumption of alcohol can cause liver disease. The type and severity varies, ranging from steatosis (accumulation of fat in the liver cells), hepatitis (inflammation of the liver), fibrosis (damage to liver cells), and cirrhosis. Women are twice as susceptible to alcohol-related liver disease. Alcohol will significantly accelerate the progression of HCV. Even after considerable liver damage, abstaining from alcohol can lead to significant improvement.

**Alpha-1 Antitrypsin (AAT) Deficiency** – This genetic disorder is defined by an inability of the liver to make sufficient AAT protein. In time, the liver and lungs may become damaged. Treatment involves taking AAT, but AAT deficiency does not always progress to severe degrees.

About one in 2500 people in the world have this disorder, mostly of white European ancestry.

**Autoimmune Hepatitis** – In this disease, the body’s immune system goes haywire and mistakenly attacks liver cells. Steroids may be used to treat autoimmune hepatitis, which like many autoimmune disorders, can be very difficult to treat. Prognosis varies, but in severe cases, liver transplantation may be advised. About 70% of those with autoimmune hepatitis are women, predominantly between 15 and 40 years old.

**Gilbert Syndrome** – This inherited disorder is caused by a decrease in bilirubin-processing enzymes in the liver. This leads to excess bilirubin accumulation in the blood. It is a mild disease, sometimes completely asymptomatic. Gilbert’s hardly ever causes serious problems. The primary symptom is jaundice. Estimates of prevalence range from 5 to 7% of the population.
Healthwise

has Gilbert’s and it is more common in men than women.

**Hemochromatosis** – This disease is a condition where too much iron is absorbed via the digestive tract; the excess is stored mainly in the liver. There are two kinds of hemochromatosis. The primary type is hereditary. Secondary hemochromatosis is caused by anemia, alcoholism, and other disorders. Hereditary hemochromatosis is common; approximately 10% of those or Northern European descent carry the gene; roughly 1% have the condition. The prognosis of hemochromatosis is good when it is managed, primarily with regular removal of blood, such as what is done when donating blood.

**Liver Cancer** – There are two categories of liver cancer—primary and secondary. Secondary liver cancer is more common in the U.S. Also known as metastatic cancer, it starts in another part of the body and spreads to the liver. Primary refers to cancer that starts in the liver. Cancerous tumors may be called malignant hepatomas, the most common of which are hepatocellular carcinoma (HCC) and cholangiocarcinoma. There are other forms of primary liver cancer, all originating in the liver. More than 90% of HCC occurs in people with risk factors. Those with chronic hepatitis B or C virus are at risk for HCC. Cirrhosis (from all causes) is linked to more than 80% of all HCC. Men have about a 1 in 100 chance of developing liver or bile duct cancer; women are 1 in 250.

Noncancerous, or benign, growths can form in the liver. These may be tumors, lesions, or cysts. They often have alarming names, such as hemangioma or adenoma. These are rarely life threatening, usually fixable and don’t spread to other parts of the body.

**Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic steatohepatitis (NASH)** – These are best described as “fatty liver disease.” NAFLD is less severe and may go on for many years without any indication. NASH may also remain asymptomatic, but can progress to cirrhosis. Fatty liver disease is caused by excess body weight, diet, certain medications, and other medical conditions, such as metabolic syndrome. Fatty liver diseases are often treatable, with weight loss and dietary changes. It is currently estimated that 25-37% of the U.S. population has NAFLD; 2-5% have NASH. Fatty liver disease is on its way to “beating out” HCV for the top reason for liver transplantation.

**Primary Biliary Cirrhosis (PBC)** – The liver’s bile ducts become inflamed and damaged; bile builds up in the liver, which destroys its cells and may cause cirrhosis. If the disease progresses to end-stage liver disease, organ transplantation is prescribed. The cause of this chronic disease is unclear, but it may be an autoimmune condition. PBC usually occurs between the ages of 40 and 60 and affects women more often than men.

**Primary Sclerosing Cholangitis (PSC)** – This is a chronic, slowly progressive disease that damages and blocks bile ducts inside and outside the liver. Tissue damage occurs which may eventually cause cirrhosis, liver failure, or the need for liver transplantation. The cause is unknown but it may be an autoimmune condition. More men than women have PSC.

**Vibrio Vulnificus** – This bacteria-induced infection is not a liver disease. However, V. vulnificus is a huge threat to those with HCV or other liver diseases and since the incidence of this bacteria is on the rise, this is a good time to mention this. Vibrio vulnificus is found in raw or undercooked shellfish.

**Viral Hepatitis** – These include hepatitis A, B, C, D, and E. They are all completely different from one another. What these viruses have in common is that they primarily affect the liver. Like HCV, hepatitis B is blood borne, but it is much more infectious than C. Hepatitis B may be transmitted sexually via body secretions. You can’t get hepatitis D unless you have hepatitis B. Hepatitis A and E are spread through food or water contaminated by feces from an infected person; E is uncommon in the U.S.

Since having two liver diseases is worse than having one, it is recommended that those with HCV be immunized against hepatitis A and B. There are no vaccines for hepatitis C, D and E.
Enrollment starts October 1, 2013 in the new health insurance plans created by the Affordable Care Act. Coverage under the plans will be effective January 1, 2014. Several recent columns have explored this major change in health insurance. Persons without coverage or who need to consider changing coverage should start the process at www.healthcare.gov.

With the prospect of obtaining health insurance becoming available to persons who had been unable to purchase it due to their medical history, now would be a good time to review just what health insurance is, the types of coverage available, and some of the terms people getting health insurance should know.

Health insurance from its origins was designed to help pay the medical bills associated with an unexpected and unforeseen medical condition that requires medical treatment. As the healthcare field has become more complex and medical costs much more expensive, health insurance has evolved as well into a product that can be complicated to understand and often difficult to deal with.

In an effort to simplify comparison of various health insurance plans, the health exchanges through which the plans will be purchased have standardized plans as much as possible. Under the Affordable Care Act (ACA) health exchanges there are only three types of plans, all of which are considered “Managed Care Plans”:

HEALTH MAINTENANCE ORGANIZATIONS (HMO)

Under an HMO plan, all medical services are provided by medical providers, doctors, hospitals, laboratories, etc., who are part of the HMO network. By joining the Network, the providers have agreed to limit their medical costs and follow the medical protocols of the HMO.

Once enrolled, the insured member chooses a Primary Care Physician (PCP) and that physician coordinates all of the care of the member, determining what tests and procedures are necessary and deciding when the member needs to be referred to a specialist. Under an HMO, the PCP must authorize all care; the member cannot see a specialist without a referral from the PCP.

The only exception to this type of HMO is called a staff model, where all providers are employees or contract directly with the HMO. Kaiser Permanente is the best example of a staff model HMO.

The main features to remember about HMOs are:

- The member must use a provider within his or her network in order to have the medical charges covered; and,
- All care must be provided, authorized, or referred by the Primary Care Physician, frequently called The Gatekeeper for obvious reasons.
EXCLUSIVE PROVIDER ORGANIZATION (EPO)

An EPO is very similar to an HMO with one major exception. Although the member must use network providers, an EPO does not require all care to go through a Primary Care Physician. A member can determine when a specialist is needed and make the appointment directly as long as the specialist is also in the network. Again, the choice is limited to those providers within the medical organization the member has chosen when enrolling.

However, like an HMO, no benefits are paid if the member uses a provider outside the plan’s network.

PREFERRED PROVIDER ORGANIZATION (PPO)

A PPO will also have a network of providers like an HMO or an EPO. Like an EPO, it will not require using a Primary Care Physician as gatekeeper.

However, unlike both an HMO and EPO, some coverage will be provided if the member uses a provider that is totally outside the plan’s network. Benefits paid by the plan will be much higher if provided by network providers, with out-of-network providers paid at a much lower rate. This encourages using providers in the network.

Because some coverage is provided outside the network to providers who do not contract with the plan, PPOs tend to have more expensive premiums than HMOs or EPOs.

INSURANCE TERMS

There are certain terms used in all of the health plans noted above that members should be aware of and understand:

- **Emergency Medical Services** – Despite the requirement to use network providers in the above plans, all plans will cover charges for emergency care whether performed in or out of the plan’s network, the goal being to get the member to care as soon as possible. Coverage outside the network, however, is normally only for “life-threatening emergencies,” so not all ER visits are covered, just the true emergencies. However, courts have generally agreed that life-threatening means “to the average layperson, the medical condition is reasonably perceived to be life-threatening.” This means that a trip to the non-network ER could still be covered even if the perceived heart attack turned out to be just a bad case of indigestion.

- **Deductibles** – This is a dollar amount that must be paid by the member for medical services before any benefits become payable by the plan. The deductible is normally calendar year and, once satisfied, there is no deductible for the remainder of that year. A deductible may apply before any benefits are paid by the plan or it may just apply to certain charges such as a Prescription Drug Deductible or in-patient hospitalization. Deductibles are more common in PPO plans, but also appear in other types as well.

- **Co-Pays** – A co-pay is the dollar amount that is paid by the member directly to a medical provider at the time of service. Very common with HMOs and EPOs, this is the $5 or $10 a member pays when he or she sees the doctor or the $2 or $25 he or she pays to pick up a prescription. Co-Pays tend to be in plans that do not use a deductible or are used in lieu of a deductible for certain types of charges.

- **Co-Insurance** – Co-insurance is the percentage of an eligible medical charge that a member is expected to pay. For example, the plan may pay 80% of a charge, leaving the member to pay a co-insurance percentage limit on payments described below.
of 20% or 70% - 30%. The use of Co-Insurance is more common with PPOs, and tends to be used most often with Deductibles as well.

- **Out-of-pocket Limits** – All plans under the new healthcare law must have a maximum amount of money that the member will spend in a calendar year. Once that limit has been reached, the insurance plan pays 100% of the eligible charges for the remainder of that calendar year. The out-of-pocket limit only counts amounts paid for the member’s portion of medical bills and does not include premium payments.

- **Allowable Amount (or Eligible Charges)** – No insurance plan promises to pay 70%, 80%, or 100% of ALL medical bills. Historically, they only agree to pay the “usual, reasonable and customary charges” for a treatment or procedure. Today, this is no longer a major issue as the contracts between medical providers and the insurance plans restrict the amount that providers can charge contractually. Under these managed care plans, as long as the treatment was in-network, the member is not obligated to pay more than the Co-Pay or Co-Insurance percentage of the contracted amount, regardless of what the provider tries to charge. The member is not liable for any charges in excess of the contracted benefit.

- **Appeal/Grievance** – If a member disagrees with the decision of the insurance company, the plan must provide a method in which members can question the decision and appeal to have the decision reversed. The Appeal or Grievance procedure will be spelled out in the insurance booklet.

- **Exclusions and Limitations** – All plans will have a list of procedures and conditions for which they will provide no coverage. While the list may vary from plan to plan, they typically exclude things such as voluntary cosmetic surgery, medical condition incurred while committing a felony, or while serving in the armed forces. In addition, plans may cover some items but strictly limit the number of procedures or the amount they will pay. Examples would be limiting the number of days in a convalescent care facility or the number of acupuncture visits they will cover.

There are, of course, other terms used in health insurance; however, plans may use them in slightly different ways. The insurance booklet/certificate will have a section that defines the terms used, and they typically capitalize or place in bold all words that are defined within the plan document.
Genotypes 2, 3

- **FUSION:** included patients who were previously treated but did not achieve a viral cure. There was not a placebo arm in the FUSION study.

Genotype 2

- **POSITRON:** A total of 109 patients were treated with sofosbuvir plus ribavirin for 12 weeks. Thirty-four patients received placebo. In the group which received sofosbuvir/ribavirin the viral cure rate was 93%. In those who did not have cirrhosis, 92% achieved a viral cure compared to 94% in those who had cirrhosis.

- **FUSION:** A total of 36 prior non-responders received sofosbuvir plus ribavirin for 12 weeks. Thirty-two prior non-responders received sofosbuvir plus ribavirin for 16 weeks. In the 12 week treatment group 86% achieved a viral cure and 94% in the 16 week group achieved a viral cure. In participants who did not have cirrhosis the viral cure rate was 68%. In those with cirrhosis the viral cure rate was 21%.

More information about treatment response in hard-to-treat HCV genotype 1 can be found in this month’s Snapshots column.

Genotype 3

- **POSITRON:** A total of 98 patients were treated for 12 weeks with sofosbuvir plus ribavirin and 37 people were included in the placebo arm. Approximately 20% of the patients had compensated cirrhosis. Sixty-one percent achieved a viral cure. In the participants who did not have cirrhosis the viral cure rate was 68%. In those with cirrhosis the viral cure rate was 21%.

- **Fusion:** Sixty-four patients were treated with sofosbuvir plus ribavirin for 12 weeks and 63 patients were treated for 16 weeks. In the 12 week treatment group 86% achieved a viral cure and 94% in the 16 week group achieved a viral cure. In patients with cirrhosis the viral cure rate was 30% and 62% for those who were treated for 16 weeks. In patients with cirrhosis the viral cure rate was 19% in the 12 week group compared to a viral cure rate of 37% in the group which was treated for 16 weeks.

“Hopefully, the reason genotype 3 treatment results were much lower will be elucidated to help maximize treatment results.”

Because the response rates for HCV genotype 2 were impressive and produced fewer side effects (mainly from ribavirin) it will be most likely the next standard of care. However, the genotype 3 results were lackluster which may hamper the uptake of the therapy as a standard of care. Nevertheless, since the treatment duration was reduced and the side effect profile was lower (compared to PEG/RBV therapy) it will be an option for some people. Hopefully, the reason genotype 3 treatment results were much lower will be elucidated to help maximize treatment results.

There are other drugs under study to treat HCV genotypes 2 and 3 in development. Below is a sample of clinical studies that have either reported results or are currently enrolling patients. As you can see, the drug development pipeline for the treatment of HCV genotypes 2 and 3 is robust and hopefully better cure rates will be forthcoming especially for those with genotype 3.

Listed below are some of the clinical trials underway for the treatment of HCV genotype 2 and 3:

- **ABT-450/ritonavir, ABT-267, RBV:** A phase 2 study
Genotypes 2, 3 **FROM PAGE 8**

of the three combination drugs to treat HCV genotype 2 (and 1b) is currently being conducted in Japan.

**ALISPORIVIR (DEB 025)**

alisporivir is a host-targeting antiviral that in clinical studies was combined with ribavirin or PEG/RBV. A phase 2 study of 385 treatment naïve genotype 2 and 3 patients (more than twice as many patients were genotype 3) produced viral cure rates from 80% to 85% compared to 58% in the group that received PEG/RBV without alisporivir. The amount and severity of the side effects were less in the groups that received alisporivir without PEG. Alisporivir, however, is currently on hold due to 3 cases of pancreatitis (one person died) so the future of alisporivir for the treatment of hepatitis C is uncertain.

**MK-5172, PEG/RBV**: A phase 2 study in people with HCV genotype 2 or 3. The patients will receive the combination of MK-5172 and PEG/RBV for 12 weeks. Some patients will continue PEG/RBV for an additional 12 weeks.

**MK-5172, MK-8742, RBV**: A phase 2 study is underway to treat HCV genotype 2.

**PEGYLATED INTERFERON LAMBD (PEG-LAMBD), DACLATASVIR, RIBAVIRIN**: A small phase 2 study using peg-lambda plus ribavirin to treat HCV genotypes 2 and 3 resulted in viral cure rates up to 71% for genotype 2 and up to 88% for genotype 3. The side effects from PEG-lambda are reported to be fewer than those of pegylated interferon. The combination of PEG-Lambda and daclatasvir plus ribavirin to treat HCV genotypes 2 and 3 for 12 or 24 weeks is currently in a phase 3 clinical study.

**PEGYLATED INTERFERON ALPHA 2A (PEG), DACLATASVIR, ASUNAPREVIR, RIBAVIRIN**: A phase 2 study is underway for HCV genotype 2, 3 and 4 in prior non-responders and treatment naïve genotype 1 to PEG/RBV therapy.

**SOFOSBUVIR/GS-5885** (fixed dose combination): A phase 2 study started in the second quarter of 2013 to treat genotype 3 treatment naïve patients.

**SOFOSBUVIR/LEDIPASVIR** (fixed dose combination): An arm of a larger study is underway to treat HCV genotype 2 or 3 treatment naïve and treatment experienced patients. Treatment duration is 12 weeks.

“Patrick Daniel presents hepatitis C information in a straight-forward, funny, and insightful manner. He draws on his own and others’ experiences, showing patients a clear path through hepatitis C and its treatment. Patrick’s book is like having a companion, reassuring readers that they are not alone, and helping to make the path to health a little easier.”

*Available from Amazon*

—Lucinda K. Porter, RN, Author of *Free from Hepatitis C: Your Complete Guide to Healing Hepatitis C* and *Hepatitis C One Step at a Time* (September 2013)
Snapshots  

FROM PAGE 2

The relationship between chronic hepatitis C and each of the above disorders. Because of risks of liver and cardiometabolic disease, the researchers recommend discussion of lifestyle issues such as physical activity and healthy diet.

**Editorial Comment:** This was a fascinating article, packed with more information than can be summarized in a Snapshot. I recommend reading this entire article. The discussions of vitamin D, menopause, fructose, and caffeine were particularly interesting.

_www.hindawi.com/journals/bmri/2013/564645/

**Article:** Administration of Low Dose Epoetin Alfa Facilitates Adherence to Ribavirin in Triple Therapy with Peg-IFN-Alfa2b and Telaprevir – Hasashi Ishida, et al.

**Source:** Hepatology Research  
August 19, 2013

This study investigated whether erythropoietin (EPO) could reduce ribavirin-induced anemia to help maintain the ribavirin (RBV) dose during the first 12 weeks of triple therapy using peginterferon, ribavirin, and telaprevir. Twenty-two HCV patients with genotype 1 were enrolled. Hemoglobin concentrations were measured weekly and EPO was applied per protocol.

**The Bottom Line:** Hemoglobin decline was well-controlled by EPO administration. The average adherence to RBV during the triple therapy phase was 97.5% with a 77% sustained virological response (SVR).

**Editorial Comment:** Although new treatments are on the horizon, the reality is that those seeking treatment now need ways of maximizing their chances of having a favorable treatment outcome. Also, ribavirin may be in use for quite some time, so anemia will continue to be an issue. I hope to see this study replicated in interferon-free studies.


**Source:** Centers for Disease Control and Prevention’s (CDC) Morbidity and Mortality Weekly Report (MMWR); August 16, 2013 / 62(32); 645-648

CONTINUED ON PAGE 11
Liver ABC’s

**Wilson’s Disease** – This genetic disorder causes the accumulation of copper in the body, particularly the liver, brain, eyes, and other organs. If left untreated, high copper levels can cause liver damage. Wilson’s disease affects about one in 100,000, usually showing up in children or young adults.

As we began National Liver Awareness Month, ask yourself this: are you doing everything you can to take care of your liver? If you have HCV, have other liver diseases been ruled out, such as fatty liver disease? Are your vaccines complete and current? Is your weight normal and are you eating well? Do you avoid raw or under cooked shellfish? Do you abstain from drinking alcohol?

The liver is a marvelous, resilient organ—but you still have to take care of it. Awareness is the first step.

Lucinda K. Porter, RN, is a long-time contributor to the HCV Advocate and author of recently released *Free from Hepatitis C* and *Hepatitis C One Step at a Time*. Her blog is <LucindaPorterRN.com>

For more information:
- HCV Advocate’s Factsheets and Guides, particularly *HCV Wellness: Vibrio Vulnificus*
- [American Liver Foundation](http://www.liverfoundation.org)
- [Centers for Disease Control and Prevention](http://www.cdc.gov)
- [National Institute of Diabetes and Digestive and Kidney Diseases](http://www.niddk.nih.gov)

The Bottom Line: The majority (60%) had their initial HCV test in a physician’s office; 45% reported that symptoms, such as jaundice, prompted them to be tested. About 22% sought testing because of risk factors (e.g., injection drug use and hemodialysis). Most (78%) were born during 1945–1965 and had a high school diploma or its equivalent (84%). Nearly all had medical insurance (98%). Less than half were employed (45%) and nearly a quarter received disability payments (23%).

Editorial Comment: Now that the recent U. S. Preventive Services Task Force (USPSTF) strongly endorses the CDC’s recommendations, perhaps we will see more extensive HCV screening, earlier intervention, and reduction of morbidity and mortality. See the August 2013 *HCV Advocate* for more information about the USPSTF recommendation.