

# Reality Check!



Alan Franciscus, Editor-in-Chief

One of the most frequent questions we receive is about making a decision regarding starting HCV drug treatment. The new drugs in clinical development have caused many to question whether it is better to be treated now or to wait until the newer treatments are available. This article will touch on the process of HCV drug development, some of the questions that need to be answered about the new therapies, as well as questions to ponder about starting treatment now versus waiting for the new therapies to be approved. It is important to remember that the decision to treat should always be made in consultation with a medical provider.

## NEW MEDICATIONS

First let's take a practical look at the new medications in development. There has been a lot of news about investigational HCV drugs in clinical development within the last year.

We are entering an exciting period of HCV drug discovery that not only offers hope for medications with improved treatment outcomes, but also newer drugs that will have a potential for less side effects than the current HCV medications. However, new antiviral drugs that are farthest along in clinical development are only in phase II studies.

Phase II clinical trials are conducted to obtain preliminary data on the effectiveness of the drug and collect information about the side effects and the risks associated with taking the drug. The number of participants in a phase II study is relatively small (a few hundred to over 500 hundred). At the completion of a phase II study the data is collected and analyzed and a much larger (up to several thousand patients) phase III study is initiated. A larger population of HCV patients treated with a new drug will give us a better picture of the effectiveness of the drug, side effect profile and other important information. Once the phase III study is completed and the data is collected, the pharmaceutical company applies to the Food and Drug Administration (FDA) for marketing approval to treat the general HCV population. The FDA will review the application and data from the clinical trials and will either approve the drug for marketing, request additional studies or more information, or deny approval. It is really difficult to gauge how long it will be before new drugs are available to the general population, but it is estimated that approval of the first new antiviral drug to treat hepatitis C is 3 to 5 years from now. One certainty is that the new drug(s) approved to treat HCV will be used in combina-



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tion with pegylated interferon or pegylated interferon plus ribavirin – at least for many years to come.

## THE MEDIA HYPE

The media has done a great job of making us believe that new and better drugs are going to be available soon. Almost every day we hear of a new drug that is sure to 'cure' hepatitis C and we are led to believe that the 'cure' is right around the corner. Another reason why we all want new medications is the hope that we will discover new medications that will effectively treat everyone with hepatitis C. If you have already been treated and did not respond, the new drugs offer much needed hope for the future. Due in part to the media hype and our own hopes for more effective treatment, many people believe that the newer drugs will be available in the very near future. Unfortunately, treating a disease such as HCV is a complex issue

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## REALITY CHECK

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and while it is a certainty that new and improved drugs will be developed, the development process will be slower than many of us want or have been led to believe.

## UNRESOLVED QUESTIONS

There are many issues that need to be resolved that will be answered during and after the development process. The potential of drug resistance will be at the forefront of research since we are entering an era of medications to treat hepatitis C that directly attack the virus and interfere with the HCV viral replication process. Adherence to the current *indirect* HCV medications (pegylated interferon plus ribavirin) is important because 100% adherence increases the chances for a successful sustained virological response by increasing the drug concentrations in the blood. Adherence to the new *direct* antivirals will also be critical for making sure there is the highest possible drug concentration in the blood; but adherence will become even more critical for preventing drug resistance that could render the drug ineffective. The new drugs will also have to be taken three or four times a day (at the same time every day). Most people think this is a simple matter, but it has been shown that adherence is one of the most difficult issues facing successful management and treatment of any disease.

There are many additional questions that need to be resolved including:

- What is the most effective dose and how often will it have to be taken (once every 6 hours, 8 hours, etc.)?

- What is the optimal duration of treatment?
- Will a sustained virological response translate into a durable or long-lasting response?
- If someone develops drug resistance to a new medication, will it mean that they will not be able to be treated with the same drug or class of drugs?
- Will treatment for some people consist of the long-term use of a certain drug if viral eradication can not be achieved?
- What are the drug interactions between the new medications and any medications people are currently taking for other conditions?
- Will the drugs create any short- or long-term health consequences?

Hopefully, these questions and more will be answered as the new drugs advance through clinical trials.

## SHOULD I BE TREATED?

Most experts would agree that a person with moderate to severe liver fibrosis should be treated now rather than waiting until the newer medications are approved for treatment. Of course there are other considerations for seeking treatment, including quality of life issues (such as severe fatigue), personal issues (starting a family, career goals), insurance issues (comprehensive insurance coverage, part time disability insurance), and other personal issues.

## SHOULD I WAIT?

Since hepatitis C is a slowly progressive disease (for most people), most experts would recommend that someone with mild liver damage could safely wait until

the newer medications are approved. Unfortunately, there is no “one size fits all” for hepatitis C. For instance, minimal liver damage is a predictor of successful treatment outcome. This means that a person with minimal liver damage who has that opportunity to wait for new medications should weigh the predictive factor against the possibility of waiting for the new drugs to be approved. Another issue for consideration is genotype – since the chances of achieving an SVR in people with genotype 2 and 3 are so high, many experts recommend that these individuals should be treated now.

Living with hepatitis C forces us to make many health-related decisions every day. In order to make the best possible decision it is important to educate ourselves with the facts as much as possible and carefully weigh the pros and cons before we decide on a certain course of action. This course of action should always include a discussion with a medical provider, but it is important to remember that the final decision is yours.

## PREDICTORS OF TREATMENT RESPONSE:

- Genotype 2 or 3
- HCV RNA or Viral Load under 800,000 IU/mL
- Age: Under 40 years old
- Gender: Females respond better than males
- Minimal liver disease
- Little or no steatosis
- Healthy weight or non-obese
- Asian or Caucasian race



# HealthWise:

## *Separating Fact from Fiction*



Lucinda K. Porter, RN

According to the Oxford dictionary, *fact is a thing that is indisputably the case; information that is used as evidence; the truth about events as opposed to interpretation.* Facts should be true, indisputable and durable.

Medical science relies on facts. Facts influence treatment decisions. For instance, in a landmark study, Michael Fried et al. (*New England Journal of Medicine* 2002; 347: 975-982) reported that patients with chronic hepatitis C virus infection (HCV) who do not have at least a 2- $\log_{10}$  drop in viral load in the first 12 weeks of treatment have only about a 3% likelihood of a sustained viral response (SVR) to treatment. This *fact* set the standard of care that has been in existence for years, and generally, patients who do not have at least a 2  $\log_{10}$  viral load drop in the first 12 weeks discontinue treatment, unless there are compelling reasons to continue.

Not all facts are necessarily true, which means they are not facts. In a confidential postal survey published in the journal *Nature* (2005;435: 718-9), Brian Martinson of the Health-Partners Research Foundation in Minneapolis, reported that at least one-third of US scientists violated research standards in the past three years. A few of these transgressions included: tossing out data because it contradicted their previous research, changed or ignored study data to satisfy a sponsor, and overlooked colleagues' flawed data.

Less than 1% admitted to blatant falsification of data, but more than 12% turned a blind eye to their colleagues misuse of data.

Although this behavior is inexcusable, there are explanations for it. Money for research and medicine comes largely from corporate sponsors. Funding from the National Institutes of Health is scant and competition for this is high. Corporate America, such as pharmaceutical companies and medical insurance companies, has a huge influence on research funding.

The good news is that the vast majority of researchers state they do not violate research standards. I do not know that this is true because there is no objective way of proving this. The majority of medical researchers that I have worked with are decent, committed physicians, so I believe they act above reproach.

Unfortunately, it is very difficult to discern the difference between facts and fiction if we have not been given accurate information. However, there are subtler ways that data can be manipulated. This occurs at the statistical level.

A good way to use statistics to mislead people is to choose a small sample size. For instance, if I ask two people their opinion about U.S. involvement in Iraq and their opinions happen to be the same, then I can say that 100% of the people surveyed said they were in favor of (or against) US involvement in Iraq. If I survey two more people and their opinion differs from the first two, then that number drops to 50%.

Another way to manipulate statistics is with the composition of the sample. If I survey people in Norfolk, Virginia, I will likely get a different response than the same survey conducted in Berkeley, California. If I want to prove that U.S. citizens are against current involvement in Iraq, I will conduct the survey in Berkeley.

Watch those surveys. How a question is asked may influence the outcome. For example, Alice takes a poll that asks, "Should we invest more money into access to better healthcare?" Most people will probably favor this. Alice's opponent Betty asks, "Should we raise taxes to fund big government by passing a healthcare funding bill?" Now people are likely to oppose this. However, both Alice and Betty will use the statistics to support their positions.

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## FACTS

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Perseverance is a good way to maneuver statistics. If I want to claim that four out of five nurses recommend my product, I will ask the opinion of five nurses. If only one recommends my product, I will ask five more nurses. If only three of them recommend my product, I will keep asking until I get four out of five. I am under no obligation to tell you that I had to ask 100 nurses before I found the response I wanted.

Even honest researchers are vulnerable to misrepresentation of facts. If a scientist is not thrilled with the outcome of a study, the experiment may be repeated. However, when the study supports the scientist's theory, the study is less likely to be repeated. This is why the best research is that which has been peer-reviewed, scrutinized and independently validated by other scientists.

Watch for bias. Even well-meaning researchers are biased. If I am funded to prove my belief that HCV patients who are optimists fare better during treatment than pessimists, then I have already prejudiced the outcome. I believe I know the answer before I start and I am looking for proof of what I believe. I am likely to prove my theory because of the subtle ways my prejudice will influence the study design, conduct, and interpretation of data. The best way to conduct a study is with no preconceived notion of the outcome.

Most of us rely on numbers. Numbers seem black and white. After all, two plus two equals four. However, the reliability of

numbers is only as good as the humans interpreting them.

So, how do we know what to trust? How can we separate fact from fiction? Here are some suggestions:

- Look at the source. If the statistics are used for political purposes, assume the numbers have been spun. If the numbers come from a reliable medical journal, such as *Hepatology*, *New England Journal of Medicine*, or *Lancet*, it is likely that these have stood up to scrutiny.
- Compare apples to apples. If the subjects in a study were all Caucasian males over the age of 40, then the information may not apply to a 20-year-old African-American female.
- Use critical thinking. Ask questions. Assume nothing. Challenge what you read.
- Check the source of funding for the research. It is not objective research if the data for the product comes solely from the manufacturer. Data needs to be independently verified by more than one source before it can be considered to be reliable.
- Do not let emotions get in the way of facts. It is disturbing to read about HCV, but the vast majority of us will die *with* HCV and *not of* HCV.
- Seek opinions from others who look at the same data. I trust my physician's opinion about what he reads. This means I do not need to slog through the same journal article that he read unless I am interested in it.
- Keep an open mind. Do not form an opinion and look for the facts to conform to your

opinion. This means you are biased too.

Finally, never let research tell you how you feel. If half of surveyed HCV patients report feeling fatigued, that does not mean you should or will feel fatigue. No lab test or research should ever tell you how you feel. Data may be reassuring, but it is not a substitute for your opinion about your body. Four out of five nurses agree with me about this.



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**Raymond M. Johnson,  
M.D., Ph.D.**

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# Treatment for Hepatocellular Carcinoma



Liz Highleyman

**H**epatocellular carcinoma (HCC) is a form of primary liver cancer that can affect individuals with chronic liver disease, including hepatitis B and C. It is estimated that about 5% of people with liver cirrhosis will develop HCC, typically after 25 or more years. HCC accounts for about 1% of all cancers in the United States, but is much more common in parts of the world (such as Asia) with a high prevalence of HBV infection. The incidence of HCC has increased in recent decades, and is expected to continue to rise as people who contracted HCV years ago begin to experience advanced disease progression.

## HCC PREVENTION

HCC is among the most difficult cancers to treat. But studies have shown that successful treatment using interferon-based therapy for hepatitis C or antiviral agents for hepatitis B can reduce the risk of developing liver cancer. One recent study, for example, showed that chronic hepatitis C patients who achieved a sustained virological response with interferon plus ribavirin were about half as likely to develop HCC over three years compared with non-responders. Similarly, another trial showed that chronic hepatitis B patients treated with lamivudine developed HCC at about half the rate as untreated individuals. Some studies suggest that even treatment that does not completely suppress HBV or HCV replication can still slow the develop-

ment of liver cirrhosis and HCC. Management of obesity, diabetes, liver steatosis (fat accumulation), hemochromatosis (iron overload), recovery from alcoholism, and HBV vaccination also reduce the risk of developing liver cancer.

## SCREENING, DIAGNOSIS, AND STAGING

HCC is difficult to detect during its early stages, and by the time most patients develop clinical symptoms, they have advanced cancer that is hard to treat. It is difficult to predict in advance who will develop HCC, though the risk increases with age and it occurs 2-4 times more often in men than women. (See “Hepatocellular Carcinoma: Risk Factors and Prediction” in the February 2005 *HCV Advocate*).

There is no completely accurate screening test for liver cancer. A blood test for alpha-fetoprotein (AFP) is often used, though other diseases and pregnancy can cause elevated AFP levels, and some people with small HCC tumors have normal levels. Imaging tests using abdominal ultrasound, computed tomography (CT) scans, magnetic resonance imaging (MRI), and hepatic arteriography (visualization of the liver’s blood vessels) can sometimes detect developing liver tumors. If a suspicious lesion is detected, a liver biopsy can then be performed to show whether it is cancerous. Many experts recommend that at-risk individuals – especially those with cirrhosis – should be tested

for HCC every 6-12 months, but studies have not yet clarified an optimal screening interval.

Once HCC is detected, the next step is staging to determine the extent of disease. This involves assessing tumor size, number, location, encapsulation, invasion of blood vessels, and whether it has metastasized, or spread to other parts of the body. Several different staging systems are used (e.g., Okuda, TNM, CLIP, BCLC, MELD, Child-Pugh), but studies disagree about which works best. For more on screening and treatment decision-making, see the *Medical Writers’ Circle* articles *Screening for Hepatocellular Carcinoma*, by Morris Sherman, and *Hepatocellular Carcinoma*, by Isabelita Cordoba-Rellosa, on the HCV Advocate web site.

## TREATMENT FOR HCC

Depending on the extent of liver cancer, HCC treatment may aim for a complete cure or palliation (relief of symptoms and prolongation of life). The major approaches include surgical removal (resection), destruction of tumors (ablation), systemic chemotherapy, and liver transplantation. Complete tumor removal and liver transplantation offer the potential for a cure, but many patients with HCC are not good candidates for these methods.

## HEPATIC RESECTION

Hepatic resection involves

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cutting out cancerous tumors. This procedure is most likely to be successful when tumors are small (less than 5 cm), confined to one lobe of the liver, and do not invade the hepatic blood vessels, and when the patient has relatively well-preserved liver function without cirrhosis. In the United States, only a minority of patients (estimates range from 5% to 20%) are considered suitable candidates for resection. Good five-year survival rates (exceeding 50%) have been reported after removal of resectable tumors in patients with early-stage HCC, although the rate is lower in individuals with more extensive cancer and/or advanced cirrhosis. In some cases, use of radiation or chemotherapy can shrink tumors enough to allow for successful removal. However, HCC often comes back after resection, with some studies finding recurrence rates exceeding 75%.

### TUMOR ABLATION

Ablation refers to destruction of tumors using a variety of techniques, including poisoning, radiation, heat, and freezing. An older method involves injection of toxic substances directly into the tumor, including percutaneous acetic acid or ethanol injection (PAI or PEI). Transarterial chemoembolization (TACE) involves the use of embolizing agents to block the hepatic artery and the injection of chemotherapeutic drugs (e.g., doxorubicin, cisplatin) directly into the tumor's blood supply. A newer agent used for this purpose is lipiodol, which concentrates in tumor cells but is cleared by normal cells (a form of

therapy referred to as transcatheter oily chemoembolization, or TOCE). In a 2004 study, 40% of patients who achieved complete tumor necrosis using PAI, with or without TACE, had reduced HCC metastasis within the liver and prolonged survival compared with untreated individuals. Another method involves injection of bead-like microspheres that emit radioactive material (e.g., TheraSphere); however, external radiation therapy is rarely used for liver cancer.

Radiofrequency ablation (RFA) is a method of destroying tumors by heat using a high frequency current delivered via a needle electrode. Several studies have shown that RFA is associated with reduced HCC recurrence and longer survival compared with PAI/PEI, and in recent years, RFA has largely replaced these older techniques. A study presented at the 2006 Digestive Disease Week meeting found that outcomes using RFA were comparable to those of surgical resection. Newer thermal methods using microwaves and lasers may produce superior outcomes. An Italian study found that complete tumor ablation using a percutaneous laser led to improved survival in cirrhotic HCC patients. Another technique, cryoablation, involves freezing a tumor with liquid nitrogen; early outcomes in appropriate patients with unresectable tumors are equivalent to those of resection. Experimental ablation therapies include high-intensity focused ultrasound and the CyberKnife, which delivers concentrated beams of radiation.

All methods of ablation work best on small, localized tumors. Although response rates may approach 80% and long-term remission is sometimes observed,

ablation is considered a palliative rather than curative therapy, and HCC recurrence develops in a majority of cases. Various ablation methods may also be used as adjuvant therapies to improve the outcome of potentially curative treatments such as resection, or as a "bridge" therapy while patients await liver transplantation.

### SYSTEMIC CHEMOTHERAPY

In more advanced cases of HCC, where cancer has spread beyond the liver, systemic chemotherapy may be used. Some of the anti-cancer agents used for this purpose – alone or in various combinations – include adriamycin, cisplatin, doxorubicin, epirubicin, gemcitabine, mitomycin, oxaliplatin, vincristine, and 5-fluorouracil. Unfortunately, HCC is more resistant to chemotherapy than many other types of cancer, and chemotherapeutic agents are associated with side effects ranging from gastrointestinal symptoms to bone marrow suppression. On the whole, research has not shown that systemic chemotherapy for HCC improves survival. Combination therapy using anti-cancer and immunomodulatory agents (such as cisplatin, interferon, doxorubicin, and fluorouracil, known as PIAF) appears to produce somewhat superior outcomes compared with chemotherapy alone, but with the trade-off of worse toxicity.

Antiangiogenesis agents (e.g., bevacizumab) work by inhibiting blood vessel formation, thus cutting off a tumor's blood supply. Since hormones are believed to promote HCC progression, researchers have explored therapy using androgen-inhibiting (e.g., flutamide) and estrogen-inhibiting

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agents (e.g., tamoxifen). Though results have been mixed, studies overall do not show that these treatments improve survival. Various newer agents are under study, including sorafenib, a kinase inhibitor that targets both tumor cells and tumor blood vessels.

### TRANSPLANTATION

Liver transplantation remains the best hope for curing HCC. Various criteria (e.g., Milan, UCSF) are used to determine which patients are appropriate candidates for transplantation, based on the number and size of tumors. In the case of small, localized tumors, some studies indicate that outcomes are better with surgical resection. Transplantation is considered the best option for cirrhotic patients with small tumors, who tend to have poor outcomes with

resection. Recent studies have produced five-year post-transplant survival rates of around 60%-70% – up from historical rates of 20%-40% – largely due to improvements in staging to select appropriate candidates. Yet even transplantation is not considered a highly promising treatment for HCC, since the disease can recur in the new liver (in about 20% of cases), and this option is severely limited by the shortage of available donor organs.

### CONCLUSION

Several recent analyses have shown that improvements in detection, staging, and treatment have led to progressively increased survival rates in patients with HCC over the past two decades. Despite these advances, however, HCC remains one of the most difficult cancers to treat. Because most patients are diagnosed only after HCC has progressed to advanced stages, survival is often measured in months rather than years.

A variety of treatment options is available, but with all forms of therapy, results are uniformly better when liver cancer is treated at the earliest possible stages when tumors are small, localized, few in number, and have not invaded the liver's blood supply, and when patients have well-preserved liver function. Outcomes may also be improved by combining different types of treatment, for example resection followed by chemotherapy.

While HCC treatment will no doubt continue to evolve in the coming years – possibly using immunotherapy or gene therapy – the best hope is prevention of liver cancer through wider HBV vaccination and improved therapies for chronic hepatitis B and C.

## EXCITING NEW PUBLICATIONS FROM HCSP

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- *Hepatitis B: What You Need to Know*
- *What Are Antivirals?*
- *HBV: Drugs in Current Clinical Development*
- *What's New in Hepatitis B Treatment*
- *Which Antiviral to Use First*

### HCC CLINICAL TRIALS

- GV1001 (Heptovax) from Pharmexa is a therapeutic vaccine for advanced liver cancer that is now in Phase II clinical trials in France, Spain and Germany.
- PI-88, an anti-tumor drug from Progen Industries, is also in Phase II trials. PI-88 is a treatment for primary liver cancer following surgical resection of a liver tumour. Preliminary results from the Phase II study of patients treated with 160 mg showed a substantial delay in tumour recurrence compared to the patients who did not receive PI-88. The final data is expected to be released by the second quarter of 2007.

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## Extrahepatic Manifestations: *Prurigo Nodularis*



Alan Franciscus, Editor-in-Chief

*Prurigo nodularis* (PN) is a condition that is characterized by itchy, crusty and firm bumps that are usually found on the lower arms and legs, but can also be found on the face, trunk and palms. PN may start out as smaller red itchy bumps but as the bumps mature they will turn dry and rough. PN bumps are extremely itchy and, as a result of intense scratching, skin infection and scarring can occur.

The exact cause of PN is unknown, but it has been associated with hepatitis C, HIV infection, mycobacteria infection, *Helicobacter pylori*, hepatic or kidney dysfunction, anemia, and other skin diseases.

As mentioned above PN is extremely itchy, but the scratching actually causes the bumps. The skin bumps are the result of the nerve endings in the skin being stimulated (by scratching the skin) which sends a signal that causes the itching signal from the skin nerve to become stronger.

There is no cure for PN. By the time someone goes to their doctor for this condition they have usually tried over-the-counter topical skin creams that usually provide little or no relief. Prescription steroid creams, antihistamine creams or pills, anti-depressants, or in severe cases freezing the bumps with liquid nitrogen spray are used to manage the condition.

Most extrahepatic manifestations can be treated by treating the underlying cause (hepatitis C), but there is no literature to support this theory with *Prurigo Nodularis*.



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