

HCV ADVOCATE

Volume 2 Issue 1

Hepatitis C Support Project

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HAPPY NEW YEAR

NEW FORMAT !!

In an effort to make the HCV Advocate more 'user friendly' for our subscribers outside of the San Francisco Bay Area, we are taking all local information out of the body of the newsletter. Instead we will attach a flyer listing local support groups and events for SF Bay Area subscribers only. As always we encourage individuals from around the country to copy our newsletter and give it to anyone interested and write us with suggestions on how we can better serve you.

HealthWise

Lucinda Porter, RN
Lin Maslow, RN

The Basics of Clinical Trials

What images and feelings come to mind when you hear the words "clinical trial" or "investigational drug"? Does guinea pig come to mind or does access to a promising new drug create hope? Are you cautious or opposed to being in a study; or are you the type of person that is eager to try anything and feel good about contributing to science? Clinical trials can be a mixture of all these feelings. Here is a brief explanation of some aspects of clinical research.

There are many kinds of studies. This article focuses on drug studies. The process of testing a new drug involves many checks and balances. When the way is cleared for a drug to be tested on humans, the process begins with a Phase I trial, which is usually conducted on a small number of healthy volunteers. (Can you imagine healthy people taking interferon?) The goal of a Phase I trial is to establish safety and tolerability, as well as dosage ranges and side effects. Whether or not the drug is an effective treatment is the focus of Phase II studies. The number of participants is usually low in Phase I and II trials. The largest enrollment opportunity occurs with the Phase III stage. Trials can be designed in a variety of ways, but usually the goal is to compare results between people taking the new drug regimen versus the standard treatment, a placebo or to no treatment

continued on page 3

INSIDE THIS ISSUE

- 1 HealthWise - Basics of Clinical Trials
- 2 How to Prepare for Your Doctor's Visit
- 4 Qi-Gong Retreat
- 5 A Year Of Pegylated Interferon
- 7 INFO Updates - The B Vitamins
- 6 Highlights from Liver Disease Conference

HCV ADVOCATE

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After Diagnosis: How to Become Your Own Best Advocate

Alan Franciscus

Part Two - How to Prepare for Your Doctor's Visit

In December's issue we discussed how to become an educated patient. Now that you have started the education process, it is time to put some of this new information to use in making health-related decisions with your physician.

First, establish a relationship based on mutual respect. This is absolutely essential for a working partnership with your physician. Next, decide how much you want to become involved in your health care decisions. Do you want to be actively involved in your treatment plan? Do you want your physician to make all the decisions? Do you want a little of both? Generally, healthcare decisions are a collaborative effort by patient and doctor. Most physicians will be eager to have a patient take charge and become actively involved their health care decisions.

Planning your visit:

Sit down a couple days in advance and write out any questions. Try to anticipate answers so that you will be prepared for further questions. All of us experience anxiety during physician's visits. So much information is given that it is impossible to remember every thing you and your doctor talk about. If this is a real concern, you may want to have a family member or friend sit in on the appointment as a patient advocate. This practice is becoming more common and I encourage anyone to try it at least once. Give a copy of the questions to your advocate and they will make sure that all your questions will be asked. The advocate can also take notes and ask questions that may not occur to you at that moment.

Some basic hints:

1. Take a list of all your medications.
2. Ask your doctor to explain any language that is not clear to you. Many physicians forget that lay people do not understand or may misinterpret scientific jargon.
3. Ask your doctor to explain any laboratory tests that are unclear to you and what may be the implications.
4. Ask your doctor to explain the possible side effects from procedures or medications
5. Ask for copies of any and all laboratory tests that are performed.
6. Ask you doctor to write down a plan of action.
7. Do not rush into making decisions. If you are uncomfortable with making an immediate treatment decision, tell your doctor you need time to think it over.

After your appointment, take notes and talk with family and friends about your visit - they may have additional questions for your doctor. If you do have additional questions call your doctor or schedule another visit.

Suggested reading: Rx For Patient Power: The Patient's Handbook by Jane M. Orient, M.D. and Kathryn Serkes. **FREE - Call 800-635-1196**

Next month we will discuss the emotional aspects of your visit and your on-going advocacy.

The Hepatitis C Support Project offers information about various forms of intervention in order to serve our membership at large. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one. Additionally, views express in the HCV Advocate do not necessarily reflect the views of the HCV Advocate or the Hepatitis C Support Project.

HealthWise – continued from page 1 -

at all. In the case of hepatitis C, interferon might have been compared with a placebo since there was no other approved treatment. The combination therapy for chronic hepatitis C (ribavirin/interferon) was compared to monotherapy (interferon), the standard treatment, in recent trials. Finally, there are Phase IV trials. These are conducted after the FDA has granted approval and the drug is licensed. The focus is on refining the treatment to maximize effectiveness, to collect data on a large number of subjects and to manage treatment issues such as side effects.

The pros of being in a study may include:

- Free medication
- Possible free care (this is not always offered)
- The potential for early treatment (this is not a guarantee)
- More time spent with healthcare team and close monitoring
- Self-satisfaction derived from being a research subject

The cons are:

- The potential of not receiving the study drug
- The risks of unforeseen adverse reactions
- The extra time involved in appointments and record-keeping

An example of a person who might seek out a hepatitis C study is an HMO patient who did not respond to interferon monotherapy. Since the FDA has not granted approval for the use of the combination interferon/ribavirin therapy for non-responders, some HMOs are refusing to pay for this treatment. A person with this profile might choose to look for a trial to get this treatment.

The rules and regulations for clinical trials are elaborate and well designed. Safety and patients' rights are highly protected. Before a trial can begin, it has to meet a strict set of standards. Every trial must be approved by an Institutional Review Board (IRB) before subjects can be enrolled. An IRB is a multidisciplinary group that includes doctors, pharmacists, and community representatives and also may have nurses or other health professionals. Trials are reviewed throughout the process and all people associated with it are mandated to keep very careful records long after the study has terminated. It is a requirement for patients to be given their rights, including the right to drop out of a study for any reason. Because of the many concerns surrounding a study, eligibility requirements are sometimes very restrictive. It can be disappointing to be turned down for a study. If this happens, either look for another study or wait until a study opens up for patients with your profile.

Finding a study may take a little effort. In the San Francisco bay area, there are many research sites. Currently there is research going on at Stanford, UCSF, the San Francisco and Palo Alto VA hospitals, and California Pacific Medical Center. The Internet is another source of information about trials. There are AIDS/HIV and cancer sites along with a variety of general resources. This newsletter also lists contacts for clinical trials. Networking through support groups as well as the Internet can also provide some valuable leads.

Clinical trials are not for everyone. It takes a certain amount of commitment as well as motivation. However, the rewards can be great. The next time you take an antibiotic or a pain reliever, think about the people who agreed to be research subjects. Before you swallow that pill, consider saying thank you.

Internet resources:

Stanford Medical Center http://www.med.stanford.edu/shs/clinical_trials (650) 723-4000

FDA (Food and Drug Administration <http://www.fda.gov/cder> 1-800-532-4440

NIH (National Institute of Health) <http://www.nih.gov> (301) 496-4000

ACTIS (AIDS Clinical Trials) <http://www.actis.org> 1-800-TRIALS-A

Qi-Gong Retreat

Joe Shaw

On the shores of Zaca Lake, in the mountains above Santa Barbara, 12 people, most of whom have Hepatitis C, gathered for a weekend of "Qi-Gong." Pronounced "chi-gong," it's an ancient Chinese science used to promote health and longevity.

This picturesque lake, with flocks of ducks, geese and herons, surrounded on all sides by mountains, and the site of old Chumash healing sites, was a perfect setting for a restful weekend. Qi-gong teacher Lawrence Wong, from the Bay Area, led us over the weekend in exercises designed to teach us to focus on our internal energy, or "qi," and to redirect it for maximum healing effects. This ancient Chinese practice utilizes breathing, motion and massage. We learned a soothing chant-like sound for healing the liver, as well as learning part of the "Wild Goose" exercise. We learned about zen walking and about many other healing and pain relief techniques.

A natural cynic when it comes to alternative medicine, I found myself won over by the peaceful, calm feelings that washed over me as I practiced some of the techniques we learned that weekend. I found Qi-gong to be excellent at reducing the stress and side effects I felt that weekend from my combo therapy.

The weekend was made complete by the fellowship of others with Hepatitis C, and by delicious vegetarian food supplied by a superb local chef, (please see the recipe on this page) by bonfires at night by the lake, and by clear skies full of stars.

All in all, we learned a lot about how to use Qi-gong to heal our livers and to reduce the natural stress in our lives in a beautiful setting. There is another retreat scheduled for the spring. Please check the Hep C Advocate for dates and times to be announced. ♦

Three Sisters Stew

Over 60% of the foods we eat today originated in the Americas. In Native American cosmology, corn, beans, and squash are called "the three sisters". They are often grown together, using agricultural technique in which each crop supports and protects the others. This stew was served at the Qi Gong retreat at Zaca Lake and the women who cooked for us were kind enough to share the recipe. It is easy to make and does not call for precision. It is a delicious and hearty winter stew. Thanks to Abundance Catering, Pam Nance & Simone Tempkin (805)683-4659. They specialize in Vegetarian Organic Retreat Catering and do a wonderful job - Rose Christensen.

| | |
|---|--|
| 1-2 Tbsp. Olive oil | 2 C. coarsely chopped onion |
| 2-4 cloves garlic, minced | 2 tsp. dill weed (or 1 Tbsp. fresh) |
| 1 tsp. thyme (or 2 tsp. fresh) | 1 small or 1/2 large Kambucha Squash (no need to peel) in bite size pieces 2-3 |
| C. sliced mushrooms | 1 Red bell pepper, seeded & chopped |
| 2 C. veggie stock or water | 2 C. fresh or frozen corn kernels |
| 2 Tbsp. cider vinegar | Salt & Pepper to taste |
| 1 Tbsp. cornmeal (to thicken it) | |
| 2 C. cooked kidney beans (canned is OK - if you cook dried beans, use the water for the soup stock) | |

In a large pot, saute onion in oil until translucent. Add garlic, dill, thyme & squash. Continue sauteing for about 15 minutes, stirring often. Add mushrooms & bell pepper, saute until they are soft, about 5 minutes. Add the stock, bring to a boil, then lower heat & simmer for 15-20 minutes. Then add the corn, beans, vinegar, salt & pepper. Bring to a light boil and add the corn meal, stirring frequently

A YEAR OF PEGYLATED INTERFERON

Russell Keimer

At the end of September 1998, I finished a 48-week course of pegylated interferon as a participant in a clinical trial of this formulation by Schering-Plough, administered and monitored at the VA Medical Center at Ft. Miley. As it was a blind study, at this point I do not yet know what dosage of interferon I was receiving. I gave myself one injection, once a week, for 48 weeks. My viral load, which had reached 5 million by the time I started, dropped to 500 thousand in a month. By two months, the tests showed my viral load to be undetectable, which it continued to be for the rest of the treatment. Toward the end of December I will have another blood draw, then wait an anxious two weeks for the results. I seem to have cleared each hurdle along the way to and through this - qualifying for the study, tolerating the medication and not developing any alarming blood or other changes that would have required my withdrawal, and seeing it through to the end. The prompt and continued response to the interferon while I was taking it gives me hope that the response will be sustained now that I have stopped. Has it "worked"? I think the jury's still out on that question.

What was the experience like? Tolerable, but awful. I was interferon naïve when I started, and can make no comparisons to other types of interferon or different dosing regimens. My understanding is that the peg-inf is designed to slowly but steadily be absorbed into the system, thus avoiding the peaks-and-valleys in blood levels that seem to occur with the more common 3x a week injection regimen that's been in use. It calls for fewer injections, though in truth the actual injections were a minor irritant compared to the discomforts provoked by the interferon itself. The first dose took hold about 5 hours after injection, arriving like a freight train with yours truly tied to the tracks. The fevers, sweats, chills, aches and so on were scary, to be sure. These more extreme manifestations abated in the ensuing weeks. For a few months I felt I could count on a rhythmic cycle each week, taking a shot on Friday, having it hit home on Saturday. The weekend was a total loss, but by midweek I was often feeling almost normal. By the third or fourth month this correspondence of days of the week to discomfort level seemed to go out the window. I could never tell from one day to the next how I was going to be feeling. I declined or deferred a lot of social invitations, and found it difficult to plan much with any sense of confidence that I'd be interested in or able to follow through on commitments.

While the grossest flu-like symptoms did lighten up early on, they were replaced by a laundry list of complaints, some of them almost petty, some that stretched me near to my personal limits. I itched. My hair began falling out, not in gobs, but enough to challenge my vanity. My face took on a rosy glow, as if I were freshly sunburned. Digestive distress was episodic. I felt as if I became somewhat of a blockhead, unable to solve simple problems or remember the most basic things. For a time I was very apprehensive that I would absent-mindedly step into traffic, as zombie-like as I was feeling. I grew really, really irritable - I dropped and spilled things, felt abandoned when no one called, then felt bothered when they did call. Housekeeping got really marginal. I learned to make myself eat, though shopping, cooking and washing up were effortful in the extreme. A light, plant-based diet had the most appeal, and even though I did get into a menage-a-trois with Ben & Jerry I still lost 45 pounds!

Early on I resolved that I would manage to get dressed and go out at least once every day, and I was able to do so, though at times this amounted to no more than a short trudge to the corner market and back. Walking became painful and slow, as my legs ached and cramped a great deal. A low-grade but seemingly permanent headache set in, coupled with an intermittent misery I came to call "neon bones". It felt as if, were I to look at my hands, I would be able to see the bones glowing right through the flesh. I took a lot of pain meds - ibuprofen, tylenol, tylenol with codeine. The pills helped, though ultimately nothing really worked. I just got used to feeling bad. Overall, I would characterize the experience as one of the persistent absence of well-being. I never felt good, but at times I didn't feel too bad.

continued on page 6 -

Highlights from the 49th Annual Meeting of the American Association for the Study of Liver Disease –

The following excerpts were taken from the WellnessWeb. To view the entire text go to the WellnessWeb at <http://www.highlights.wellweb.com/home.html>.

Erythropoietin Useful in Treating Ribavirin/Interferon Induced Anemia in patients with Hepatitis C

Erythropoietin is a useful therapy for the anemia associated with interferon alfa plus ribavirin combination therapy, according to a study conducted at New York University Medical Center and Liberty Medical Associates. In this study involving 47 patients, 17 of them (36%) developed symptomatic, new onset anemia during the first year of treatment. All 17 patients were started on erythropoietin. Three patients dropped out because of the anemia or because treatment had no therapeutic effect. It was found that the shortness of breath and fatigue improved along with their hemoglobin levels for the remaining 14 patients on erythropoietin therapy.

High Dose Consensus Interferon Clears Hepatitis C Virus in Seventy-Three Percent of Previously Untreated Patients

Sixty-two Percent of Genotype-1 Patients Become HCV RNA Negative

In previously untreated HCV patients, high dose consensus interferon (Infergen) given five days a week produced substantially more responses than did the same drug given three times a week. Seventy-three percent of patients randomized to receive 15 micrograms of drug five times per week eliminated the virus from their blood after twelve weeks of therapy, compared to 38% of patients on the three day a week schedule, based on HCV RNA testing.

continued on page 8 -

Pegylated – continued from page 5 -

I slept a great deal, often two naps a day on top of a fitful night's sleep. Chugging tons of water is part of the deal, so sleeping through the night was impossible. Sleep was a real balm and escape, though my dreams at times got very nightmarish.

I'm very grateful to my faithful friends who stuck around to help me through this trial. A few people pretty much bailed on me, but in truth I don't think I was a whole lot of fun to be around. Suffering in silence has never been my thing, but if all you have to share is a litany of discontents it does wear on people. I'm doubly grateful to the members of my support group who listened to me carp and complain for a year.

Do I have any advice for someone contemplating a round of this medication? First off - get your support system in order. Once you're on drug it will be a lot harder to do everything. Also - seriously - get a good bed, a comfortable chair or sofa, a cordless phone. I came to love remote controls. Reading became difficult, I just couldn't concentrate. Too much TV is not a good replacement. Having a computer with internet access was a lifesaver for me. I felt I stayed connected to the world, used email to talk to friends, and broadened my knowledge of HCV by scouring the web for new information.

As yet there seems to be very little in the way of tangible results reported for this drug. An artifact of its being so new, I think. Hopefully I'll be able to report that I'm one of the success stories. Since going off drug I experienced a slow but fairly steady improvement all around, though of late I haven't been feeling good. What, if anything, this augurs for my future is yet to be seen.

INFO UPDATES - A Closer Look At Vitamins: The B Vitamins

By Lynn Shawn, *The Hepatitis Place* - <http://www.hepplace.com>

The B vitamins are a group of water-soluble vitamins that assist in energy production and healthy mental functioning. The B vitamins are intricately involved with one another in the body's metabolic processes. These vitamins are commonly known as thiamin, riboflavin, niacin, B6 (pyridoxine), and B12 (biotin).

Thiamin, or Vitamin B1, is responsible for energy production in the brain. Many Americans do not consume the recommended daily allowance of thiamin. The early symptoms of mild thiamin deficiencies include fatigue, depression, appetite suppression, nausea, or constipation.

Vitamin B2, or riboflavin, is also very important in energy production. Riboflavin deficiencies are somewhat rare in the United States because the vitamin can be obtained in eggs, milk, meat and cereals. Riboflavin deficiency is most often seen in chronic alcoholics due to their poor dietary habits. The deficiencies of riboflavin will result in migraine headaches, anemia, seborrheic dermatitis, and cataracts.

Niacin, also referred to as Vitamin B3, is another B vitamin that is critical in the production of energy. Niacin is also involved in blood sugar regulation and in antioxidant processes. Niacin is not a true vitamin since it can be derived from the amino acid known as *tryptophan*. The synthesis of niacin from tryptophan requires vitamins B1, B2 and B6. Individuals with poor nutritional intake may suffer from niacin deficiency leading to dermatitis, weight loss, diarrhea, depression and dementia. When these niacin-deficient symptoms become severe, a condition known as *pellagra*, occurs.

Pyridoxal, pyridoxamine and pyridoxine are collectively known as vitamin B6. This vitamin is involved in the formation of body proteins, red blood cells, and neural transmission within the nervous system. Vitamin B6 is also responsible for correct immune function and hormonal balance.

The requirement for vitamin B6 in the diet is proportional to the level of protein consumption. Deficiencies of vitamin B6 are rare, but are usually related to an overall deficiency of the entire complex of B vitamins. Characteristics of B6 deficiencies include depression, anemia, impaired nerve function, seborrhea, and eczema.

Vitamin B12, or biotin, helps with the metabolism of fats and amino acids. Biotin promotes strong nails, healthy hair and skin, and aids in the treatment of diabetes. Without biotin, the body's metabolism is critically affected. Deficiencies of biotin are rare because the liver stores large reserves. Biotin deficiencies are usually seen only after long-term antibiotic therapy. When present, biotin deficiency is characterized by dry, scaly skin, anorexia, nausea, and seborrhea.

The B vitamins, like other water-soluble vitamins, require good dietary intake, good digestion and absorption. Hepatitis C patients with advanced liver disease may have vitamin B deficiencies due to poor digestion and absorption processes. Inadequate nutrition or poor dietary selection may also be a factor in a vitamin B deficiency. Typically, a diet that includes a variety of beans and whole grains will offer good nutritional value for the vitamin B complex. Persons requiring additional vitamin B supplementation can consume brewer's yeast, which provides a high vitamin B content.

In general, the B vitamins (thiamin, riboflavin, B6 and B12) are not associated with toxicity. However, supplemental doses of niacin have been associated with abnormal liver enzyme results. Treat vitamin supplements like all medications and consult with a physician before use.

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Highlights – continued from page 6 -

"We have collected a lot of three month HCV RNA data, and even though the study is in its infancy, we're very excited," says Dr. Carl Jones, gastroenterology fellow at Allegheny General Hospital, Pittsburgh, Pennsylvania. Even at this relatively early point in the study, Dr. Jones says he believes the results are clinically important. "Based on statistics, I'm projecting that we should see a 26 to 30% response rate in genotype-1 patients receiving the drug three times a week and 50 to 55% in the five times a week group. That's much better than what we are seeing with combination therapy, and we should have more reliable data in six to eight months," Dr. Jones says.

Daily Lymphoblastoid Interferon Successful in Genotype-1b Patients

Higher Dose Three Times a Week Proves Less Effective

In a study of 80 naïve patients with genotype-1b HCV infection, daily lymphoblastoid interferon gave significantly better early and sustained responses compared to higher doses three times a week. The daily dose was three million units a day, and the thrice-weekly dose was six million units each time.

Dr. Raffaello Bruno of the Division of Infectious and Tropical Diseases at the University of Pavia, Italy treated all patients for one year. "We enrolled only patients with genotype-1b because it is the most difficult type of HCV to eradicate," explains Dr. Bruno. "We found that the daily dose of three million units was more effective for these patients. Seventy-eight percent of the daily dose group had a sustained response and only 23% of the thrice-weekly group had a sustained response."

Side effects were comparable in the two groups and never serious enough to require therapy withdrawal, and no patients were lost to follow-up. Histological response will be evaluated after 12 months of follow-up.

The findings from this study support a daily dosing schedule for the treatment of patients with chronic HCV infection. They provide corroborative evidence that HCV can have a very fast replication cycle, necessitating a dosing schedule that keeps a relatively constant level of interferon in the blood to keep the virus in check. A further study on this point—escalating doses of interferon based on patients' responses—also tried to determine which patients should be continued on the drug and which ones may not respond in the long run. ♦

For more information about hepatitis C, please contact the following organizations:

- American Liver Foundation 800-223-0179 <http://www.liverfoundation.org/>
- Hepatitis Foundation International 800-891-0707 <http://www.hepfi.org/>
- Hep C Connection 800-522-4372 <http://www.hepc-connection.org>

Subscription rates: \$12.00 / year – 12 issues – back issues available at \$1.00 each. Please fill out the form below and send to:
HCV ADVOCATE
P.O Box 427037
San Francisco, CA 94142

Make checks payable to: Hepatitis C Support Project

Name: _____

Address: _____

City: _____ State _____ Zip Code _____

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