

March 2000's Advocate:

[HCV Consortium Formed in San Francisco](#)

Modeled after an HIV community group, the Consortium aims to bring together service providers, activists and researchers to find solutions to common problems

[Healthwise: Helping Ourselves By Helping Others](#)

Volunteering, attending support groups and other social events is actually good for our health. A reader shares how she stays positive despite treatment.

[Treatment Advocate: Don't Forget: Your Doctor Works for You!](#)

Doctors seem to be too busy to listen these days. Get the most from your doctor's visit by being prepared.

[Understanding Clinical Trials](#)

How clinical trials work and some of the advantages to participating in them. Also a list of some current Hep C trials.

HCV Consortium Formed in San Francisco

A dozen people including activists, service providers, researchers and drug company representatives attended the first meeting of the HCV Consortium in San Francisco on January 25th.

The meeting was an effort to bring together all parties involved in hepatitis C work to exchange views, examine problems and issues and join forces in finding solutions.

Early on, discussion focused on the role of industry representatives at the meeting and in the consortium. All present agreed that it was helpful for everyone that industry reps attend so that they could learn about community needs and so that the community could find out what is happening with treatments.

But the consensus was that the meetings should be a neutral space in which materials from drug companies would not be allowed and that industry reps should not have a vote in decisions taken by the consortium.

Brian Klein suggested that the consortium take a look at Project Inform's proposed guidelines for working with industry and adopt them.

The discussion then moved on to the city's poor record in dealing with HCV. Participants noted that little had been done except for a couple of small studies, and that services were virtually nonexistent.

Alan Franciscus said that the health department was starting to explore how to integrate HCV into its other programs, but that it was necessary to pressure the city to do more and to help the department find funding sources.

The participants next addressed the role of the consortium itself, and the need to attract more people to the group. Alan said some of those invited were not able to make it, and he asked all those present to e-mail him the names of others who should be invited to the next meeting.

There was general agreement that the group should look toward the HIV Community Consortium as a model and make an effort to attract community physicians, researchers, political leaders and others involved in the issue.

Near the end of the meeting, Alan was appointed as chair of the group and Billy Pick as co-chair. The next meeting was called for Wednesday, February 23, 2000.

The level of commitment has been encouraging, says Alan. I believe we have a real opportunity to bring people and organizations together to make a positive change for people with HCV.

Understanding Clinical Trials

Ever wonder how prescription drugs come into existence? The process of inventing, testing, and then getting a drug to your neighborhood pharmacy is a monumental task. In most cases, the timeline from test tube to medicine cabinet takes a decade or more. Unfortunately, many patients need drugs before they become commercially available. There are ways to access experimental drugs while they are still in testing.

The first step in navigating through the complicated world of experimental drugs is learning about "clinical trials." The following is a quick primer on clinical trials. First, you need to understand that all pharmaceutical companies must follow strict rules mandated by the US Food and Drug Administration (FDA) prior to marketing approval. All new drugs must go through several phases of testing before being approved by the FDA as prescription drugs. Even after approval, there's an additional phase of testing (Phase IV).

After a chemical compound is identified and believed to have some benefit for the treatment of a medical condition, a pharmaceutical company must determine how the drug works in humans. When drugs are tested in humans, it's called a "clinical trial." There are four "phases" of clinical trials. Phase I is when a drug is examined for safety in a small number of volunteers. Many drugs never move beyond this phase because, while they may work, they may also cause serious toxicities.

A drug that passes a phase I clinical trial will progress to phase II in order to determine the correct dosage and potential side effects. Drugs in phase III are being studied in larger numbers of people to see if they actually work against a medical condition. Finally, if a drug is approved by the FDA, phase IV studies ensure that there are no bad long-term adverse side effects.

Many people choose to enroll in a clinical trial because they need certain drugs that are not yet available. Some join clinical trials to help scientists make progress against a particular disease. Still others enter because they don't have health insurance and a clinical trial is one way to get free medical care.

Whatever the reason for joining a clinical trial, it's important that patients understand the possible consequences, as well as the benefits. A drug being tested in a clinical trial may not work, it may produce bad side effects, and it's possible that it may permanently damage your body. However, there is also the possibility that the drug will work well.

The following is a list of clinical trials for drugs intended to treat hepatitis C. To find out if you qualify for a particular trial, you'll need to call the company for the specific trial entry criteria. Keep in mind that a clinical trial may not be conducted near you. Unless you can travel to where the trial is being held, it may not be right for you.

Finally, clinical trials are constantly changing. Trials often "close" because they quickly become filled with the maximum number of patients allowed (or other reasons). Others trials "open" as pharmaceutical companies "recruit" patients to study new drugs. Some of the trials listed here may be closed.

Condition: hepatitis C
Product: pegylated interferon alfa 2a (Pegasys)
Product status: Phase III
Company: Hoffmann-La Roche
Contact: (973) 235-5000

Condition: hepatitis C
Product: pegylated interferon (Peg-Intron)
Product Status: Phase III
Company: Schering Plough
Contact: (714) 545-0100

Condition: hepatitis B or C
Product: recombinant beta interferon
Product status: Phase I/II
Company: Serono Laboratories
Contact: (781) 982-9000

Condition: hepatitis B or C
Product: recombinant beta interferon 1a
Product status: Phase II
Company: Biogen
Contact: (617) 679-2000

Condition: hepatitis C, interferon non responders
Product: interferon/iron reduction
Product status: Phase IV
Company: Schering Laboratories
Contact: (908) 298-4000

Condition: hep C, relapsed after alpha interferon
Product: beta interferon
Product status: phase II
Company: Chiron
Contact: (510) 655-8730

Condition: hepatitis C
Product: lymphoblastoid
Product status: phase III
Company: Glaxo Wellcome
Contact: (919) 248-2100

Condition: hepatitis C
Product: thymosin/interferon alpha
Product status: phase III
Company: SciClone/Schering
Contact: (650) 358-3456

Condition: hepatitis C
Product: granulocyte macrophage colony stimulating factor
Product status: phase II
Company: Immunex
Contact: (206) 587-0430

Condition: hepatitis C
Product: ursodeoxycholic acid
Product status: phase II
Company: Axcan Pharma/Mayo Clinic
Contact: (514) 467-5138

Healthwise: Helping Ourselves By Helping Others

Recently I attended a workshop led by Rick Griggs of "Griggs Achievement". The focus was on achieving balance in one's life. Griggs performed an in-depth analysis of successful people who lead balanced lives. He noticed that people who maintain balanced lifestyles have several characteristics in common. These include regular social engagements with friends, taking vacations, and regular involvement in annual activities, such as fishing trips, sporting events, conferences, and retreats. Also on the list is participation in volunteer or committee activities.

This last activity shows up on number of lists of recommendations to promote a balanced life-style. Picking up a health magazine or "volunteering" are suggestions for psychological well being.

Recent articles tout the benefits of volunteer work, reporting that the simple act of giving of one's self can boost longevity as well as overall health. The reasons for this are not known. There is some speculation that the act of doing for others serves to distract us from our own worries and concerns. This may positively impact our immune system. There is also a social aspect to involvement in community activities, which provides support, stimulation, and good feelings about one's self.

There are no shortages of volunteer opportunities. For those with chronic hepatitis C, consider participating in an area that focuses on an issue related to HCV infection. What are your strengths and interests? Do you have a passion for the political arena or the health field? Do you prefer the tasks of envelope stuffing or office duties? Do you like to chat on the phone? Are you a public speaker? A fund-raiser? Do you write? Do you like the camaraderie that support groups provide?

Consider contributing your time and talents, whether it is an hour a month or an hour a week. No martyrs are needed. Consider starting out with short-term, realistic goals. The rewards will be far greater than you can imagine.

Motivation

The following was sent to me by Marnie Fehrer in response to my request for readers to share their strengths and hope. In spite of being in treatment, Marnie sent me the following:

"Over time, I've learned to look at what psychospiritual lessons I can learn from having hepatitis C. For me, that involves viewing it as an opportunity to slow down and be more present, learning to accept and love myself just as I am, remembering to nurture myself and also allowing myself to ask for and accept support.

To help me during the year's treatment with Rebetrone, I do a lot of reframing. When the part of me that dreads taking the interferon comes up, often I am able to reframe it so the fatigue is my body's way of allowing my energy to be put into healing. I am then able to thank the medicine for its powerful healing. Noticing that I feel better when I haven't had interferon for three days reminds me that this is all temporary and I feel very thankful for that.

Starting each day by writing out five things that I'm grateful for helps me to focus on the positive.

To help keep me positive and also to help pull me out of a negative mood, I have an affirmation tape that I made. It is custom-made with uplifting reminders and easy to just pop into the tape deck in the car or at home. I also have one that has positive statements about my health: "There is no more hepatitis C in my body. My liver is strong, the virus is gone." Saying it in sync with the rhythm of my breath helps to keep the message alive (anchor it) with each breath.

Sharing with close friends has helped me develop a support system that is invaluable. I have people I can socialize with who understand if I just want to be quiet and rest. At times when I'm moving too far into negativity to pull myself out, they are there with a positive comment and support. I've also reached out to

various prayer groups as a way to feel support that is both universal and spiritual."

Thank you Marnie, for taking the time to contribute to Healthwise. You are an inspiration.

Treatment Advocate: Don't Forget: Your Doctor Works for You!

Of course, no one likes to go to the doctor. But I have to tell you after the last 2 years since my HCV diagnosis, I really hate going to the doctor. One of the worst parts about going to see your physician is that most just don't seem to listen. More than once, I've had a doctor say, "Why didn't you tell me about that before?" Well, if she'd bothered to look at the chart, she would have seen it right away.

Studies have shown that doctors typically listen to a patient's initial "statement" for only 23 seconds before changing the subject or moving the conversation into another area of concern.

Now, anyone who has been to the doctor's office also knows they are extremely busy and seeing umpteen patients at a time, and the truth is with their patient load, they really don't have that much time to see you.

Although that's no excuse, it is the reality and we, as informed patients sometimes have to take matters into our own hands.

Unfortunately, that means we have to talk fast, convincingly and intelligently to get the physician's attention and keep it.

That means being prepared for our doctor's visit. Being prepared means we need to be ready to make the most out of the time we do have with our physician. How can we do that? It's not difficult, it just takes a little time. Before you make your sojourn to his office there are several things you can plan ahead of time in order to get your doctor to listen so that he knows exactly what's bothering you.

Making the most of your visit to the doctor:

Get to the point. Plan what you're going to say before you get there. What are you feeling? What do you expect from this visit?

Know what you're talking about. Educate yourself about your health problem. Buy a book, go to the library or search the internet about your condition.

Write it down. Do you have questions for your physician? Make a list and prioritize it before your visit. Don't be intimidated or afraid to ask your questions.

Make a list of your medications. Sometimes you may have two versions of the same drug or the directions on your medication are incorrect. Go over them with the doctor.

Keep a treatment diary. Write down what your doctor says so you won't forget. Ask her to help you write down diagnoses, medication and side effects. Make sure you understand your diagnosis and the risks or problems associated with your treatments.

Take someone with you. If you have a friend in your support group who is knowledgeable about HCV, take them with you. They can act as an advocate for you. They won't be as stressed as you are and they can help you to remember what the doctor said or help you to remember the questions you want to ask.

Fire your doctor. Sometimes that's the only way you can get a doctor that listens. Your relationship with your doctor is too important to be one-sided. You need one that will listen to your concerns.

For Your Eyes Only

Let me tell you about my recent trip to the optometrist to renew my eyeglass and contact prescriptions. On my previous trip in June, the optometrist had said I would be needing bifocals. Well I thought that this time I would get them because I had noticed that reading was harder with my glasses. Turns out the optometrist

said that I had two hemorrhages inside my eye. That combined with the vision change prompted her to tell me to go to the doctor and get tested for diabetes.

As you can imagine, that alarmed me somewhat. The doctor found that I didn't have diabetes and the ophthalmologist told me my eyes were normal. So what happened? Did interferon treatment or HCV affect my vision? There was definitely a small amount of vision loss, but it could be age-related. So I went on a little search and found some studies on vision problems and interferon. Don't be unnecessarily alarmed. But do remember HCV and interferon can affect you in a number of ways and it always is a good idea to make sure you're taking care of your entire body.

Neurovisual impairment: a frequent complication of alpha-interferon treatment in chronic viral hepatitis.

Following our earlier observation of clinically evident optic tract neuropathy in patients receiving low-dose interferon (IFN) therapy, we prospectively evaluated 53 consecutive patients treated for chronic hepatitis B or C with a median dose of 3 MU of IFN-a2b thrice weekly.

Measurements included routine ophthalmologic evaluation and recordings of visual evoked responses (VER), electroretinograms (ERG), visual acuity, and visual fields, before, at the end of IFN treatment, and at follow-up visits.

Baseline P100 latencies of VERs were abnormally prolonged in 24 patients; age was the only significant covariate associated with increased risk for an abnormal base-VER by multiple logistic regression. In 45 patients with normal baseline P100 latencies, the end-of-treatment VERs were significantly prolonged compared with baseline, becoming abnormal in 11. This subgroup had older age and reduced visual sensitivity compared with their own pretreatment measurements and had a sigmoid distribution with a steep increase of values beyond the 5th decade.

In a logistic regression model, significant predictors of abnormal end-VERs were patients' age, presence of hepatitis B virus infection and serum cholesterol levels above 240 mg. Subconjunctival hemorrhages were seen in 2 cases and funduscopic examination revealed cotton wool spots in one other.

After stopping IFN, the treatment-associated neurovisual abnormalities reversed to normal in 7 patients and persisted in 5 for up to 37 months observation, all patients remaining clinically asymptomatic.

In conclusion, subclinical neurovisual impairment is a frequent, largely unrecognized complication of low-dose IFN therapy, and patients with chronic hepatitis B and older age appear to be most susceptible. This apparently innocuous complication is long lasting, possibly irreversible in some patients, with yet undetermined consequences on visual function.

-Hepatology 1998 May

Ocular complications with high-dose interferon alpha in chronic active hepatitis.

PURPOSE: Interferon alpha, which is used to treat various systemic disorders, has many reversible side-effects involving various organ systems.

In this study, chronic active hepatitis patients undergoing interferon alpha therapy were followed with regard to the ocular side-effects.

METHODS: Thirty-six patients with chronic active hepatitis undergoing subcutaneous interferon alpha therapy for 1 year were enrolled. Complete ocular examination and photographic documentation were performed at baseline of the therapy and monthly thereafter.

RESULTS: Trichomegaly was noted in 2 (6%) patients. Fifteen patients (42%) were found to have retinopathy with cotton wool spot formation and splinter hemorrhages.

CONCLUSIONS: These findings emphasize the need to monitor these retinal complications, which may result in loss of vision in patients receiving interferon alpha therapy.

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-Eye 1999 April