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Combo Treatment With Pegylated Interferon & Ribivirin: How to Get Started

By **Lucinda K. Porter, RN**

An HCV Advocate reader recently wrote suggesting an article directed to patients with chronic hepatitis C virus infection (HCV) who might be considering treatment with pegylated interferon plus ribavirin. She specifically asked for information regarding baseline diagnostic tests for newly diagnosed patients.

Schering Plough's pegylated interferon (Peg-Intron) was approved by the Food and Drug Administration (FDA) in late January. Roche hopes to have its pegylated interferon (Pegasys) approved by the FDA and on the market later this year. Many of you will be considering treatment with one of these two products.

The use of ribivirin with pegylated interferon is still being analyzed from recent clinical trials. Although there is more to be learned about the combination of these two drugs, there is a general assumption that the addition of ribivirin to pegylated interferon will increase the overall efficacy of pegylated interferon alone in the same way that adding ribavirin improved the results of regular interferon.

Currently ribavirin is marketed with interferon alfa-2b under the trade name of Rebetron. At this point, the only way to obtain ribavirin legally in the United States, without also purchasing regular interferon at the same time, is through a compounding pharmacy. However, Schering Plough has applied for approval to sell ribivirin separately. That approval is expected to be granted, sometime in the spring of this year.

What are the recommended laboratory tests one should have before starting treatment with pegylated

interferon plus ribivirin? At this point, I can only offer an educated guess based on the tests that are required for patients who are entering clinical trials using this combination of drugs. In truth, each

company may make their own recommendations and at the time this article went to press, I still had not seen the recommendations. For the most current information, I suggest you ask

the manufacturer to send you information or go to their website. (www.PegIntron.com) The phone number for Schering's patient support line is 1-888-437-2608. Since Roche does not have FDA approval for Pegasys, I have even less access to information. Roche does maintain a web site www.Roche-HepC.com that probably will have current information when Pegasys is marketed in the United States. Their customer service number is 1-800-526-0625.

Before starting treatment with pegylated interferon plus ribavirin, it needs to be established that the patient actually has chronic HCV infection. This is done with an antibody test (anti-HCV) and a viral load (HCV RNA). The antibody test is the indicator of exposure to hepatitis C, and the viral load confirms the presence of the virus in blood. The viral load refers to the HCV RNA by PCR, and it can be

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HealthWise

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Treating HCV in Methadone Maintenance Patients

By **Diana Sylvestre, M.D.**
President, O.A.S.I.S.

O.A.S.I.S. (Organization to Achieve Solutions in Substance-Abuse) has a research program that seeks to determine whether interferon/ribavirin combination therapy is safe, tolerable, and efficacious in methadone maintenance patients with active hepatitis C and liver fibrosis. The program began in late 1999, and 60 methadone patients have been treated to date. A unique group treatment model is used, which combines education, peer support, and concurrent medical monitoring.

When compared with the larger, pivotal treatment studies, the O.A.S.I.S. patients show significant demographic differences, some of which would predict a lower response rate or a higher rate of complications. Although the percentage of males being treated (61%) and genotype distribution is similar to that of other studies, the average age of the patients is nearly a decade older at 50. In addition, the treated patients are more diverse: 74% Caucasian, 16% African American, and 10% Latino. The estimated duration of infection is 28 years, over a decade longer than the pivotal studies, which would predict more advanced disease.

Because psychiatric disease is common in injection drug users, frequently excluding them from treatment, the O.A.S.I.S. cohort includes a substantial percentage of patients who had previously received a psychiatric diagnosis. Specifically, 54% of treated patients have been diagnosed with depression, anxiety, or mixed depression/anxiety. Only 42% of patients exhibit no psychiatric diagnosis.

The patients who were biopsied show substantially more inflammation (METAVIR score (2.4 vs 2.01) and fibrosis (METAVIR 2.5 vs 1.32) than the pivotal studies. Moreover, 29% of patients in the O.A.S.I.S. cohort exhibited cirrhosis as determined by either liver biopsy or by a platelet count of <100,000. This compares with 4-5% in the pivotal studies. Because treatment is less efficacious with higher degrees of fibrosis, this would predict a lower overall response rate.

O.A.S.I.S. treatment discontinuation rates were 18%, 8% due to exacerbation of psychiatric disease,

8% due to side effects, and 2% due to exacerbation of medical conditions. This compares favorably with the discontinuation rates seen in the pivotal studies, which were 18% and 21%.

Although sustained response data are not yet available, early end-of-treatment response data are encouraging. Compared with response rates of 50% and 52% in the NEJM and Lancet studies, respectively, the preliminary O.A.S.I.S. end of treatment response rate on approximately half of the treated patients is 55%. It is important to mention, however that this number will likely decline as increasing numbers of genotype 1 patients complete treatment. In addition, the true test of treatment efficacy is the sustained response rate, which is not yet available.

Overall, despite numerous negative prognostic factors, including older age, greater length of infection, psychiatric illness, and more advanced liver disease, recovering injection drug users on methadone are showing that hepatitis C combination therapy is safe, tolerable, and efficacious.

Discarded Leukocytes are Potential Source for Treating Hep C

Pall and Viragen Sign Agreement to Recover White Blood Cells From Blood Filters

Pall Corp., a leader in the blood filtration industry, has granted Viragen, Inc. an exclusive worldwide license to their proprietary technology for the purpose of efficiently removing and recovering leukocytes from used leukoreduction filters.

Leukoreduction filters are used to separate white blood cells from other blood components before the blood is used for transfusions. Leukocytes or white blood cells fight disease and are essential to the functioning of our immune systems, but they can cause adverse reactions when a donor's blood is transfused into a recipient.

Blood centers usually discard the filters after each use, but the harvested leukocytes they contain are valuable for other pharmaceutical purposes. Viragen uses them for the production of its lead product, Omniferon (tm), a multi-subtype alpha-interferon

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Life Insurance and Hep C - A Personal Story

Life insurance coverage can be difficult to obtain when you have a chronic illness, such as Hep C. Most life insurance carriers require a blood test to rule out potential disease before they will cover you. Unfortunately, some people may find out they have Hep C as a result of the blood test. This is difficult, because not only do people have to deal with a new diagnosis and all of its ramifications, but also with being denied life insurance coverage. To complicate matters further, insurance carriers now share information on records— so if one carrier turns you down for having Hep C, others are likely to have access to this information. This can make it almost impossible to get insurance coverage. You may still be able to get coverage, but you have to be careful. Some insurance companies have high-risk policies that will give you coverage at a very expensive rate.

Disclosing that you have a chronic illness can have other pitfalls, as well. You may be turned down for medical insurance, private disability insurance, and, in addition, it can greatly impact your employment. We do have laws that protect us from discrimination based on disabilities, but they do not generally apply to insurance coverage. Discrimination can certainly be subtle or disguised when it comes to your job. Therefore, discretion should be observed regarding whether or not to disclose one's Hep C status. It's not pleasant to hide Hep C and it certainly shouldn't be held against us, but in the real world, this is what may happen.

Recently, a woman contacted us and requested information on life insurance and Hep C. Though we were not able to help her, she proved to be tenacious and resourceful. She wanted to share her story in the hopes that it would help others in their efforts to secure insurance. For obvious reasons, the author is anonymous. – Alan Franciscus, Editor

While my husband and I were stunned to learn that he had tested positive for Hepatitis C, it was nowhere near the emotional response we experienced in trying to obtain a term-life insurance policy for a business we were buying. Allow me to explain...

A little over a year ago, we moved to a more relaxed and remote area of the state. During the relocation process, we set ourselves up with new doctors and my husband underwent his first physical in over 10 years. You can imagine our surprise when the doctor, whom we had just met, delivered the news that my husband tested positive for hepatitis C. Our new doctor, who was not familiar with the virus, wisely recommended we seek the guidance of a hepatologist and helped pave the way to do so. Two doctor appointments later, we learned that the biopsy revealed very little liver damage and the fact that, basically, my husband is quite healthy. The doctor recommended a few minor lifestyle adjustments (which were very easy to accomplish) and we thought, "Hey, this isn't so bad." "We can handle this, no problem." But wait, there is more...

Since we both had fallen in love with the area to which we had moved, it was not curious that my husband, whose work took him away from home for up to nine months a year, wanted to be at home on a more regular basis. As I loathed the absences, and the fact that his job was considered to be one of the most dangerous and stressful possible, I completely supported his desire to make the change. This led us to find and buy a business. In order to finance the business, it was necessary for my husband to obtain a term-life insurance policy, which required a blood test.

As we knew life insurance would be an issue, we

approached the insurance agent we had previously worked with at our former location. We were very up front about not only the health issue, but the timeframe, as well. While we deferred to his expertise, we posed the question: would it be worth exploring a "high risk" carrier? We thought a regular carrier would decline the application. Unfortunately for us, words fell upon deaf ears - the agent sent our applications to the regular three insurance companies he usually used and, consequently, our applications were declined.

After I was thoughtlessly and doggedly questioned by the agent as to "how on earth did HE get this nasty bug?," the same agent suggested we work with a broker whom he had "worked with before," and whom he thought would be helpful. Since we needed the coverage, we patiently waited while nothing happened. No applications arrived, phone calls were returned very slowly, and e-mails went unanswered for days at a time. As time – and with it, our opportunity to buy the business – slipped by, we confessed our situation to our business agent who referred us to a local insurance agent/broker. As luck would have it, (this time - seemingly in our favor), the agent had done a fair amount of research for a family member who was Hep C positive and who also needed life insurance. EUREKA! We felt relieved. We felt elated. We felt "ahhhh," but my intuition told me that it was not a done deal. And it was not. We were up front with the second insurance person and he reviewed the companies that had declined the applications. His concern was that we were already on record as having

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either a qualitative or quantitative test. The qualitative is slightly more sensitive analysis and is usually done to confirm HCV infection, i.e., to exclude a false positive HCV antibody result. The quantitative test is an actual measurement of the number of viral particles in circulation and is frequently done just prior to treatment and at various intervals throughout the course of therapy. A genotype test is also performed to establish the specific type of HCV infection that is present. Genotype influences the length of treatment with Rebetron, and possibly pegylated interferon plus ribivirin, and predicts the likelihood of a sustained response to treatment.

In addition to establishing the diagnosis of chronic HCV, the following baseline tests are usually performed to gather more information:

Complete Blood Count

Liver Panel or Chemistry Panel

Thyroid function tests (TSH, T4)

Pregnancy test

The liver panel can provide information about the condition of the liver. Your physician will be able to give you an opinion about whether proceeding with treatment is appropriate. In addition to the lab tests, this opinion will be based on a medical history and physical examination. It is important to rule out certain chronic diseases, including some heart, lung, and eye conditions. Uncontrolled thyroid disease, diabetes, and seizure disorders are contraindications for treatment. Other conditions that may interfere with the suitability of treatment include psychiatric

illnesses, autoimmune diseases, and certain blood disorders. Naturally, all chronic or serious health problems will be considered when considering proceeding with treatment for chronic HCV.

The factors that are considered before undergoing a course of treatment may seem complicated, but to an experienced physician these issues are usually straightforward. Your doctor may want to include tests that are not mentioned in this article e.g., liver biopsy, ultrasound, or other blood tests, or may have a reason to not do one of the suggested tests. However, the key tests before treatment will likely be a complete blood count, hepatic panel, viral load, HCV genotype, thyroid tests, and pregnancy test. If you have any questions about your physician's recommendations, share your concerns. Most likely your doctor will offer explanations for his or her recommendations. Asking questions is an important part of building a relationship with your care provider as well as expanding one's base of knowledge. Whether or not you proceed with treatment, being informed and able to communicate well with your physician or nurse practitioner will support your health.

Note: The author would like to express her gratitude to Emmet Keefe, M.D. for his support and feedback in the writing of this article.

Lucinda K. Porter, RN

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The HCV Advocate 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.

I Was A Home HCV Test Guinea Pig

Service, Cost Show Value of Home HCV Testing Kit

By Alan Franciscus
Editor

In 1996, I was diagnosed as HCV-positive by my doctor and I went through some very difficult emotional ups and downs. At that time, support groups for people with HCV were nonexistent in the San Francisco Bay Area. In addition, I could find very little information on Hep C and what I did find was contradictory and scary. It was a struggle, but with time, I learned to cope and accept the fact that I had a chronic illness that could be potentially fatal. Unfortunately, anonymous or confidential testing was not available then, and once my positive HCV status became part of my medical records, I was not eligible for private disability or life insurance, at least not at a reasonable cost.

Five years later, public anonymous or confidential testing is still not available. However, people now have access to private anonymous testing with a kit called Home Access Hepatitis C Check. The Home Hepatitis C Check is completely anonymous. A personal pin number is included with the kit and this

is the only means by which you can be identified. I have to admit that I have some reservations about HCV home-testing and with results given over the phone. In a perfect world, access to free public anonymous or confidential testing would be available to everyone. This would consist of pre and post-test counseling that would include education on prevention, as well as emotional support and disease management advice for those who test HCV-positive. But given the fact that anonymous or confidential testing through your local health department is still not available and is not likely to be in the foreseeable future, the only alternative is home testing.

Before recommending this type of test, I wanted to try it personally. This had obvious limitations, since I already knew that I had Hep C, but it also had an advantage, because I would have less of an emotional reaction dealing with the test results. Each person's experience in this regard will be slightly different, so keep in mind that the following was my individual experience.

Day One

I opened the box and found some pretty good information on hepatitis C in both English and

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been declined by three carriers. And, while the second insurance person understandably did not promise us coverage, he also was headed out of town on vacation, which made both my husband and I nervous, since we were so close to escrow. However, since we needed the coverage and were satisfied that the agent knew the territory, we took our only choice - we waited.

We were clear with our first agent that while we were waiting for applications from his suggested broker, we were also pursuing another angle with a local insurance agent. Our original agent was trying very hard to be helpful. Unbeknownst to us, none of the phone calls he placed to the insurance broker he had worked with before were returned, so he took matters into his own hands by informally applying and blindly forwarding information to carriers on our behalf. Unfortunately, much misinformation was over-shared and we quickly racked up companies who declined us, even informally. The majority of the carriers who declined us did not deal with the Hepatitis C community, but boy, they sure knew about my husband! We learned of our first agent's activities when the second local agent returned from vacation and applied to a company he used and learned that someone had already had a conversation with the company about coverage for my husband. After running into this situation the third time, our second agent withdrew from trying to obtain coverage for my husband.

Being completely frustrated, afraid, and also worried that we would lose the business opportunity, I turned to the Internet. Much surfing led me to The National Hepatitis C Coalition in Tennessee, which is run completely by volunteers at <http://www.nationalhepatitis-c.org>. They returned my phone call in less than 12 hours and advised me of another insurance group. At this time, less than four weeks remained until we were to close escrow on what would hopefully be our business. It was pointed out to me repeatedly that this was not enough time to complete the task at hand. I explained to the insurance group that we did NOT want to divulge to the lender that we needed more time to obtain life insurance, nor the reason for the delay. I told them that we needed help and fast. A customer service

representative referred me to one of their agents who knew exactly what to do and got it done quickly. And by the skin of our teeth, we acquired the life insurance to finance the business.

I am sure that not all such stories have a happy ending, but I wanted to share our experience. I also wanted to share the insight that one must be very cautious in revealing health-status information. In our case, judgments were made, damage was done, and it's something we can't retract. The information is out there, (over 20 companies declined us), and whoever has access to it knows why we were declined. My husband and I are not ashamed that he has hepatitis C. However, there are those who do not understand the virus and would hold him at arms length, and possibly refuse to do business with him. We were so very lucky to get help from The National Hepatitis C Coalition, the insurance group to whom they referred us, and the insurance agent who acted successfully on our behalf. If it weren't for these people and the front offices of our regular doctor and hepatologist who responded so quickly and pleasantly to our requests for help, frankly, we would not have met with success.

No Link Found Between Hepatitis B and Multiple Sclerosis

It has been speculated that there may be an association between hepatitis B vaccination and multiple sclerosis. Now, a new study published in a recent New England Journal of Medicine article reports the findings by researchers who assessed the risk of developing multiple sclerosis after hepatitis B vaccination.

In a longitudinal study of 238,000 female US nurses with data from as early as 1976, the researchers found no association between hepatitis B vaccination and multiple sclerosis. Furthermore, there was no association between the number of doses of vaccine received and the risk of multiple sclerosis.

In an accompanying editorial, Bruce G. Gellin writes, "The results of this study should provide reassurance to recipients of the vaccine, to patients with multiple sclerosis, and to their physicians."

It is highly recommended that people with HCV be vaccinated against hepatitis A and hepatitis B unless previously exposed.

Source: N Engl J Med 2001; 344:327-32, 01 Feb 2001

Home Testing

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Spanish. The “Frequently Asked Questions” produced by the American Liver Foundation in association with Home Access Health were easy to understand and satisfactorily answered basic questions about HCV. I was a little bothered by the broad inclusion of sexual transmission without any specific detail. I would have preferred a statement such as, “Sexual transmission appears to be very low - anywhere from one to five per cent.” But the overall information was very thorough and comprehensive. The information on the accuracy of the test was very good and included a warning that the results could be positive, negative, indeterminate, or “result not available.” The necessity of following the instructions carefully was clearly indicated.

The instructions on how to fill out the forms, draw a blood sample, ship the sample, and get your results were very simple and easy to understand. The hardest part for me was how to draw a blood sample and the kit also gave a number to call for help.

The next step was actually drawing a blood sample. For some reason, I had a problem with the thought of sticking myself with a needle. I’ve been through treatment twice and self-injected myself hundreds of times, but I still felt somewhat queasy about sticking myself with a needle. However, once I followed the instructions for the spring action device (lancet), it was very easy and painless. Next, you have to “milk” your blood and blot the circle on the card provided in the kit. You have to be careful to really cover the entire circle to make sure there is enough blood for the lab to test for the HCV antibody. You then take the card and insert it into the prepaid mailing package and send it off to Home Access.

I mailed it and called Home Access to register my pin number. They ask you to take a fairly long survey, but this should be considered, because it could help in efforts to gather more data on HCV.

Now came the waiting...the results for my test would be ready within 10 business days.

Day 10

I called on the morning of the tenth business day. After going through a couple of different phone menus, I was connected to the person who would give me my results.

Of course, I tested HCV-antibody positive. The person who gave me the results was very calm and reassuring and told me that I needed to see a doctor for further evaluation. She also explained that I would need to have more blood tests and talk with a doctor about treatment options, if appropriate. I was also counseled on prevention measures. Some of the measures included:

- * Practicing safer sex, but it was explained that sexual transmission is very low, even for your partner.
- * Covering all wounds.
- * Making sure that you don’t share any items such as razors where blood may be present.

The person I spoke to asked for my phone number so that someone could call me to follow up. I told her that I had a roommate and was uncomfortable with receiving phone calls regarding this issue. She explained that they would only ask for me personally and not offer any information to anyone else, but she was sensitive to my reluctance and did not push it. She also asked if she could send a packet of information that would include physician referrals, which would be completely confidential. She also offered to send a test kit for my partner at no cost. I could sign up for it now or call at a later date.

All in all, I was very impressed and have to say that it is a good product with good services. It’s relatively inexpensive, \$59.99, compared to a blood draw, lab work, and a doctor’s visit. Of course, I really believe that a test with pre and post-test counseling is optimal, but given the current state of public testing, this is a very good alternative for confidential testing.

I would encourage people who test HCV-positive to consider the impact of disclosure on their lives. Issues of medical insurance, life insurance, and disability insurance should be explored carefully before seeking further testing by your doctor. Educate yourself as much as possible. HCV is a slowly progressive disease for most people. Talk to your doctor “off the record” before you decide to take any tests that would alert insurance companies. There are certain blood tests, such as a CBC, that can indicate how much HCV has impacted your health and your liver and you should consider these before you take tests that might prevent you from getting the benefits that you will need to live with HCV.

News Briefs

Alternate Methods of Administering Interferon

Suppositories

At the 51st annual meeting of the AASLD, Japanese researchers reported that the administration of interferon alpha (INF) suppositories to HCV-infected individuals suppressed HCV replication.

Fourteen patients with chronic HCV were treated with one INF suppository (1000 units of lymphoblastoid INF alpha) a day for 24 weeks. The researchers reported that serum HCV levels were significantly decreased from 4 weeks to 20 weeks compared with before the treatment. The scientists concluded that the rectal administration of the low dose INF suppressed HCV replication and should be considered as a different form of administration from INF injection. This report did not list side effects.

Source: Yoshimichi Haruna and others, AASLD, abstract 844

Nasal

Nastech Pharmaceutical Company, Inc., announced a Phase I clinical trial in the US to evaluate the nasal administration of interferon. The objective of this Phase I clinical trial is to determine nasal absorption, tolerance, and safety of interferon alpha in healthy volunteers.

Source: PRNewswire

Oral

Amarillo Bioscience is currently developing an oral formulation of low-dose interferon alpha (INF) for treating hepatitis C. Amarillo believes that an oral form of INF will not cause the severe side effects associated with interferon by injection, and can be stored at room temperature and would cost less than the current form of interferon.

Source: Company press release

Adverse Effects of Kava

The British Journal of Medicine recently reported the case of a 50-year-old man who went to his doctor with fatigue, "tanned skin" and dark urine. This patient had been taking three to four capsules of kava extracts daily for two months (maximum recommended dose is three capsules). He did not drink

alcohol or consume other drugs. Within 48 hours after admission to a hospital, the patient developed stage IV encephalopathy. The patient received a liver transplant two days later and fully recovered.

Kava is a member of the pepper family and grows as a bush in the South Pacific. Explorer Captain James Cook, who gave this plant the botanical name of "intoxicating pepper," first discovered kava kava. Kava has been used for over 3,000 years for its medicinal effects as a sedative, muscle relaxant, diuretic, and as a remedy for nervousness and insomnia.

This case points to the necessity for cautious use of herbs and over-the-counter medications by people with hepatitis.

Source: BMJ 2001;322:139 (Jan 20, 2001)

Weight Reduction Improves Liver Histology

At the 51st annual meeting of the AASLD, Australian researchers reported that weight reduction improved the fibrosis, ALT, insulin and triglycerides in individuals with HCV.

The researchers studied seven patients (five males and two females, ages 40-45 years) with chronic HCV to determine the effect of weight reduction on hepatic steatosis (fatty degeneration of the liver), necroinflammatory activity (cell death), fibrosis (scarring), and lipid peroxidation (a chemical breakdown of lipid molecules with a high oxygen content). All patients increased their daily exercise and received a calorie-controlled diet for 12 weeks. Liver biopsies were obtained prior to and three to six months following the study. The mean weight loss was 8.8 kg (19.4 lbs). The results were remarkable: the grade of steatosis decreased in all seven patients, fibrosis score was reduced in three of seven patients. Additionally, the mean ALT reduction was from 120 to 85 over the 12-week period. The weight loss was also accompanied by significantly reduced fasting serum insulin and triglycerides.

The authors concluded that these results support the need for larger studies to assess the place of weight loss in the management of chronic hepatitis C.

Source: Andrew D. Clouston and other, AASLD, Abstract 593

Support Groups

Northern California

Half Moon Bay
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Monterey
Cyndra Horton (831) 883-0711

Redwood City
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Ojai

Leukocytes

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currently in Phase II clinical trials in Europe for the treatment of hepatitis C. Viragen, Inc., which is engaged in the research, development, and manufacture of immunomodulatory therapeutic products, has white-blood-cell sourcing agreements with the American Red Cross, America's Blood Centers, and the German Red Cross, among others. The agreement with Pall will give them the means to take advantage of an additional resource for leukocytes, namely the discarded blood filters.

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California Pacific Medical Center

Linda Brooks (415) 202-1504 or (415) 202-1506

San Francisco General Hospital

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Stanford University Hospital

Stanford Liver Research Clinic (650) 724-7057

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