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BC CHAPTERS NEWS BULLETIN

HEPATITIS C SOCIETY OF CANADA APRIL 1998

Issue No. 11

PCR Undetectable -Testing for HCV

by Darlene Morrow, BSc

Step One: The initial test for HCV is called an antibody test. When your body gets an infection, it produces antibodies (anti-HCV) to help destroy the foreign invader. By testing for anti-HCV, the physician knows that you have been exposed to HCV. Eighty percent of all people infected with HCV go on to develop chronic liver disease. A positive test result, coupled with an elevation in liver enzymes (ALT and AST) showing active liver tissue degradation, more than likely means that the HCV is still present, but the test is not conclusive.

Step Two: To confirm the diagnosis of HCV a PCR (polymerase chain reaction) test is done. This test looks for the genetic material of the virus in your blood. The Hepatitis C virus uses RNA instead of DNA to replicate itself. The HCV RNA PCR can be qualitative (meaning only that it is looking for a positive or negative sign of the HCV RNA) or quantitative (counting the actual number of copies of the virus present in a milliliter of blood).

Limits of the PCR: Here in British Columbia the upper limit of the viral load test is over 750,000 copies, and the lower limit is 200 copies. What does this mean? It means that the test cannot measure a number below 200 copies of HCV RNA. Anything below that number will be classed as undetectable. If you have 199 copies of HCV RNA in your blood, the result could be "undetectable."

Variability in the PCR: There are further complications and uncertainties with the PCR. We can look at three main areas:

1. How the sample is collected and stored.
2. When the sample is collected (time of day)
3. Where the sample is collected from.

How the sample is collected and stored: After the initial blood is drawn, it is centrifuged to separate the white (plasma) and red cells. The PCR test must now be performed within two hours, or else the plasma sample must be frozen at -70C. Any deviation from these steps results in a PCR of questionable value.

When the sample is collected: A study presently underway is looking at the PCR results from samples taken at various times of the day.

(Continued on page 6)

URSOFALK* and the Treatment of Chronic Hepatitis C

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Hospital.

UrsOfalk* is the pharmaceutical name for ursodeoxycholic acid or UDCA. UDCA is a bile salt found in many animals, particularly the bear (hence the name Urso, which means bear). This bile salt is not toxic in humans and has been found to have therapeutic value in certain types of liver diseases. Humans secrete a number of bile salts, classified as primary, secondary or tertiary bile salts, and there is a specific ratio of the different types of bile salts. Bile salts are the major constituent of bile. Bile is a yellow fluid produced by the liver and stored and concentrated in the gall bladder. After eating a meal, food stimulates a hormone in the bowel that causes the gall bladder to contract releasing the bile into the duodenum. A healthy liver produces bile according to the body's needs and does not require stimulation by drugs. Bile salts are required to dissolve cholesterol in the bile and dissolve fat in the intestine. The concentration and ratio of bile salts is very important, and certain bile salts can actually damage the liver if their concentration becomes too high.

UDCA has some beneficial effects in humans. It increases bile flow and stimulates secretion of water in the bile and thus prevents the build up of some other bile salts that may be toxic to the liver. UDCA has been shown to be very beneficial in certain liver conditions, such as Primary Biliary Cirrhosis and Sclerosing Cholangitis because of this action. UDCA also has an immune regulating effect on the liver. It has been suggested that UDCA might counteract the effect of other bile acids on an enzyme that inhibits interferon and on the inhibitory effect of bile acids on the natural killer activity of lymphocytes which attack viruses. In this way, UDCA might make the effect of interferon on hepatitis C greater or more effective.

There have been a number of studies using UDCA alone in patients with chronic hepatitis C and it has no beneficial effect. There have been at least 10 studies in the last three years using UDCA in combination with interferon. Some

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COMING UP:

Victoria Chapter Meetings: Last Wednesday of each month, 1-3 PM, and again at 7-9 PM, St. John the Divine Church Lounge, 1611 Quadra St. (Entrance through the rear, marked Annex) NEXT MEETING: Apr. 29th.

Penticton Chapter Meetings: Third Thursday of every month, 7-9 PM, Penticton Health Unit - Board rooms. NEXT MEETING: Apr. 16th.

Kelowna Chapter Meetings: Last Saturday of every month, 1-3 PM, Rose Avenue Education Room in Kelowna General Hospital. NEXT MEETING: Apr. 25th.

Nanaimo Chapter Meetings: Second Thursday of every month, 7 PM, Health Unit-Central Vancouver Island, 1665 Grant St. NEXT MEETING: Apr. 9th.

Vancouver CLF Support Group Meetings: Second Thursday of every month, 7:30 PM, Nurses' Residence of VGH (12th and Heather). There should be signs directing you to the right room. NEXT MEETING: April 9th. Contact the CLF for more info at 681-4588 or Herb at 241-7766.

Sunshine Coast Support Group Meetings: First Thursday of each month, 7:30 PM, Coast Garibaldi Health Unit in Gibsons. NEXT MEETING: Apr. 2nd. Contact Carol for more information: 886-4298 or email her at <ryker@cheerful.com>

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(A limited number of newsletters will be available free of charge at the meetings, as well.)

DISCLAIMER: HeCSS cannot endorse any physician, product or treatment. Any guests invited to our group to speak, do so to add to our information only. What they say should not necessarily be considered medical advice, unless they are medical doctors. The information you receive may help you make an informed decision. Please consult with your health practitioner before considering any therapy or therapy protocol. The opinions expressed in this newsletter are not necessarily those of the organization.

THANK YOU!

Victoria Chapter HeCSC acknowledges the personal donations, donations in kind and memorial donations received to date, and the following for discounts, donations of services, or equipment: Monk Office Supply. CFAX 1070 Radio, Apple Canada, and Pacific Coast Net.

The deadline for any contributions of hepc.bull is the 22nd of each month. Please contact: Joan Diemecke at Tel (250) 388-4311, Darlene Morrow at 1203 Plateau Drive, N. Vancouver, BC, V7P 2J3

email: <pdiemecke@compuserve.com>, <hepcbc@sprint.ca> or C.D. Mazoff at <squeeky@pacificcoast.net>

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Interferon and Ribavirin Trials--An Unexpected Surprise

by Darlene Morrow, BSc

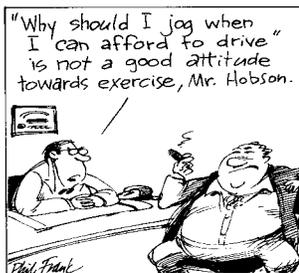
It seems that the more we learn, the more we realize how little we know. Let's look at the "facts" of advancing HCV damage to the liver.

Liver tissue has the ability to regenerate itself. What happens with HCV is that the healthy tissue is replaced with scar tissue. The scar tissue is nonfunctional and therefore incapable of regeneration. The more scar tissue there is (e.g., cirrhosis), the less functional tissue there is. The inability of the liver to reverse the scarring process was widely believed and accepted. The hope for treatment was that the progression of this scarring could be slowed down or stopped. Inflammation would decrease and therefore normalization of liver enzymes would be seen. The possibility of developing liver cancer would also decrease.

Preliminary results from the combo trials have challenged the accepted! The things that we expected to see were there. But the majority of patients also showed a decrease in scarring!!!! How can it be? Right now there are no answers to this question. Somehow the liver is managing to get rid of some of the existing scar and then regenerate healthy tissue in its place. Wow!! Even a patient with early cirrhosis (stage 4) became a stage 2. This is phenomenal.

On the side of caution: these are only preliminary results and we are not yet looking at a large number of people. But we can hope that other researchers will find the same thing. The trials looking at the combination therapy are multicenter and involve a large number of participants. We are encouraged by these early results and dare to HOPE. We should all say a little prayer.

Personal Note: I have been on the combination therapy since August 97. My initial PCR was >750,000. But my 6 month PCR came back UNDETECTABLE!



Reminder: Any change of address, phone number or postal code, please let your phone contact (in Victoria) or your chapter secretary know ASAP
HeCSC Victoria Tel. (250) 388-4311
hepcvic@pacificcoast.net

CANADIAN LIVER FOUNDATION: Update

1-(604) 681-4588 or 1-(800)-856-7266.

The Hepatitis B Awareness Campaign was launched during "Help Fight Liver Disease Month." This campaign will take CLF volunteers and the BC Lions into the schools and other venues to talk to youth about Hepatitis B immunization and Hep B prevention.

Volunteers are needed in Victoria to assist organizing the Living With Liver Disease program and other education events for summer/fall 1998.

The CLF Charity Golf Classic will be held at the Westwood Plateau Golf and Country Club in Vancouver on June 2, 1998. Registration is by phone or fax to 1-(604) 681-4588 or 1-(800)-856-7266.

Hep A Vaccines May Now Be Covered in Your Area

As of April 1, 1998 the BC Provincial government will pay for the Hep A vaccine. The vaccine consists of an initial shot followed by a booster later on. Both will be covered in areas where there have been Hep A outbreaks (from seafood restaurants), e.g., the Lower Mainland. This is a bit of grey area and I encourage everyone to call Public Health, who will be giving the vaccine.

The reason for the coverage is due to the fact that someone with Hep C contracted Hep A and died. What is called "a superinfection" occurred (both viruses together are much more deadly than either one on its own). The resulting fulminant hepatitis was fatal.

The bad news is that there will be no reimbursement to anyone who had his Hep A vaccine prior to April 1, 1998.

Darlene Morrow

Listserve Is Up

We are pleased to announce that the Hepcsc—Canadian Hepatitis Support and Information Mailing List is now in operation. This automatic mailing list is a great place to meet other Canadians with Hepatitis C and to get quick local support and useful information on just about anything you need to know about living with this disease.

To subscribe to the Hepcsc Hepatitis Support and Information email list, just address a message to:

Majordomo@Island.net
 and in the body of the message, type:
 SUBSCRIBE hepcsc
 <yourhandle@yourprovider>

If this is too complicated just send a note to squeeky@pacificcoast.net and I'll log you on.

Squeeky



SQUEEKY'S CORNER

To INF or Not to INF: Is There a Question?

Recently two of our mutual friends received very exciting and encouraging results after treatment with combination therapy with Interferon and Ribavirin. For both Joan and Darlene, the treatment was not easy (see "PCR Undetectable" on page 1); but despite very strong side effects, both these gals persisted and feel not only that it was worth it but that they would do it again. In both cases, PCR was undetectable; in one case, at 6 months, in the other, at the end of treatment. In Joan's case, this was temporary; however, a subsequent biopsy revealed that her liver damage had been substantially reversed. (See "PCR Undetectable on page 1 for discussion of PCR).

On the other hand, many people in the Hep C community have taken the decision to seek alternative forms of treatment and to eschew traditional approaches for a variety of reasons ranging from the X-files conspiracy theory of modern medicine to personal choices based simply on unmanageable side effects, or prohibitive costs. Some of these people have had varying success with Western herbal treatment (milk thistle, dandelion, artichoke, etc.) and others with Eastern approaches (Ayurvedic and Chinese medicine). As the discussion between Perry and Tim shows (Name of article page ?) Chinese medicine can greatly improve "quality of life," and is often used as an adjunct to Interferon therapy to help manage side-effects. But as Tim cautions, because there is no necessary relation between symptomatology and progression of disease, and because there are little or no controls on alternative medicine, there is always the risk of doing more damage to oneself in an attempt to avoid the obvious damage that drugs such as Interferon can induce.

What then is one to do?

It is often when one is confused by such complicated choices that one can fall prey to the unscrupulous and even dangerous practices that continue to dupe many of the chronically ill. Warnings about quackery abound on the internet (and can now be found posted on our very own listserve), but even these are sometimes questionable and seem to belie hidden agendas of their own. For example, at the American Council on Science and Health site one can find postings about Chinese Medicine, Therapeutic Touch, and the like, which are clearly intended to discredit. No pretence of rapprochement is evident, and the language is clearly pejorative and patronising.

If I were to read only the articles published in the ACSH journal, I might think that Therapeutic Touch and Chinese Medicine were

pure bunk! After all, the journal is official and its contributors often prestigious. But then, both you and I know from personal experience that many of these "unapproved" modalities have provided relief from pain and improved quality of life for both our friends and ourselves.

Like many with hepatitis C, I continue to take herbs and to investigate alternative approaches. But I am also scheduled to begin combination treatment with Interferon and Ribavirin shortly, in the hope that my liver damage can be reversed. Like Perry, I too feel that my "quality" of life has been greatly ameliorated through herbal and other non-standard treatments. But now I must seriously consider the "quantity" of life that lies before me. *C.D. Mazoff, Ph.D., Dip Th.*

To INF or not to INF: Part One.

(The following interchange between Perry the Winkle and Tim Halloran was posted to the HEPV-L list and is part of a broader discussion)

On Friday, 13 March, 1998, Perry the Winkle posted: "My quality of life is a lot better than many of the reports I've read here [on the list], and I've never taken Interferon."

Tim: "This is to be expected in a lot of cases. Remember, Hep-C is 'The Silent Epidemic.' The reason a lot of people don't know they have it is that they don't have symptoms so they don't get tested for the disease."

Perry: "Still, I function at a fairly high level. The normal brain fog, depression, aches, pains, and fatigue and so on commonly associated with this bug (on or off Interferon and other drugs) has been very much reduced."

Tim: "Here too, taking care of yourself, eating a low-fat diet, doing moderate exercise, getting plenty of rest, and taking herbal supplements can greatly reduce symptoms. But symptoms can come and go with no apparent connection to how well you are taking care of yourself."

Perry: "I may eventually develop (or even be developing) cirrhosis, or cancer."

Tim: "Maybe yes, maybe no. I felt 'just fine' for years - never having any real symptoms except a little fatigue now and then when I pushed myself too hard. My liver enzymes were 'slightly elevated.' I took care of myself, got a flu shot every year, ate a low-fat diet, etc., etc.—but still my liver deteriorated. A few years ago I found myself gaining weight, having a lot edema, getting muscle cramps, needing more sleep. During a laparoscopic gall bladder removal in 1996, surgeons took photos of my liver and suggested that I start thinking about a liver transplant as my liver was close to 90% cirrhotic. Later that year I was hospitalised for endocarditis, at which time my liver doc visited me in the hospital and said that it was time to get screened for a transplant. The infection that

caused the endocarditis and the heavy-duty antibiotics were taking their toll and I should now consider myself to suffer from 'end-stage' liver disease. I was transplanted on June 6, 1997. The post surgical analysis of my diseased liver showed two tiny hepatocellular carcinomas. I had been transplanted just in the nick of time."

Perry: "To get that result, I take herbs....My liver enzymes went down, but not the PCR..... The herbs are based on a traditional Chinese liver formulas."

Tim: "Here is where I must take issue with you. There are no controls over the growing, drying and packaging of Chinese herbs. Particularly in the drying process there is ample cause for concern. The herbs are dried in the open air, and it is not unusual for the herbs to be rained upon then allowed to re-dry in the sun. The problem is that moulds can develop on the plants. Also, livestock can contaminate adjacent soil by eliminating waste. Then too, there is no standardisation by which anyone can determine to any degree of accuracy how much of the active ingredient of the herb one is getting. Those herbs may actually be doing something good for you until the day you take some that are contaminated. Then your already-compromised liver is really in trouble. Then there is the problem that there has been no scientifically-sound research (i.e. - double blind and/or linear studies) to prove the efficacy of these herbs. The Milk Thistle and St. John's Wort you take may actually be doing more for you than your Chinese herbs. There are a number of European studies that link Milk Thistle to reduced liver enzymes and link St. John's Wort to alleviating depression. Common sense mineral supplements may also play a major role in alleviating the symptoms of Hep-C. I took Milk Thistle for years. Although it did help to keep my enzymes only 'slightly-elevated,' it didn't stop the progression of the disease. Elevated enzymes are an indication of ongoing insult to the liver. I wouldn't pass on interferon or interferon/ribavirin just because it has a mediocre success rate. It might work for you. You COULD become PCR negative and have your liver enzymes return to normal, MAYBE. I would think it was worth the try. The alternative is to do nothing and definitely progress to cirrhosis, liver cancer, and end-stage liver disease."

"Any day above ground is a good one"
Tim Halloran, The Bear.



(Continued from page 1)

studies have treated with interferon first and then added UDCA; some used both drugs from the start. Most of the studies used UDCA for a period of six months. Almost all the studies agree that UDCA given in addition to interferon has no greater effect in inducing a sustained remission at the end of therapy. Only one study suggested that the serum enzyme levels might fall to a greater degree with UDCA. All studies agreed that the long term result was no different with UDCA; in other words, the number of responders, the number of relapsers, and the number of non-responders was the same for interferon alone and for interferon plus UDCA. The only difference seemed to be that the time from response to relapse in the patients who eventually did relapse was longer in those patients given UDCA with interferon. One study suggested that the initial response rate was better with UDCA but in the end the number who achieved a sustained response was no different.

Thus, it seems that UDCA has no significant lasting beneficial effect in chronic hepatitis C, given either as a single agent or given in combination with interferon. Whether it will have any role in other combination therapies has yet to be determined.

ACSH Volume 8 Number 3 1996

Therapeutic Touch: Reach Out and Dupe Someone?

by Linda Rosa

Nurses do some strange things for their patients. They hang crystals on IV poles, necklace their patients with herbs and channel astral entities. But the strangest nursing practice of all — and the most widespread — may be Therapeutic Touch (TT). Every day nurses enter hospital rooms across the U.S. to perform this ritual, which they claim heals their patients. TT is often performed without the knowledge of the physician in charge and usually without the patient's informed consent.

TT was developed at New York University's school of nursing by Dolores Krieger, Ph.D., R.N., who first described it in a 1975 American Journal of Nursing article claiming that TT could increase blood levels of the oxygen-carrying molecule hemoglobin. Krieger says that TT is the healing transfer of prana, an ayurvedic or Hindu concept of "life force." Others say it resembles qi, the mystical root of Chinese folk medicine. You'd assume from its name that TT relies on the palliative effects of human contact. But actually, it doesn't involve any touching at all. In TT, a nurse, sometimes called a healer, waves her hands two to six inches over the patient's body, working from head to toe. Her hands interact with a supposed "human energy field" that surrounds the body. After she detects "differences" in the field indicating disease or trauma, her waving hands then smooth or "unruffle" the patient's energy aura, relieving discomfort and allowing the

body to heal itself.

TT is premised on the notion that there really are human energy fields that TT can modify. But when the University of Colorado, a major center of TT activism, empanelled a blue-ribbon jury to review the science behind TT, the jury could find no evidence for such fields:

Although TT practitioners [admit] that the existence and nature of the energy field is a hypothesis which has not been confirmed in over 20 years, in practice they behave as if the energy field were a perceptible reality. There is virtually no acceptable scientific evidence concerning the existence or nature of these energy fields. There is no ongoing research on this concept . . . nor are there any plans for such research, nor even any ideas about how such research might be conducted.

TT's proponents dismiss such criticisms as scientific nitpicking. "[Having] a Ph.D. in physics is not necessary to understand new theories and the meaning they may have for nursing practice," says nursing professor Therese C. Meehan. For her and others, it's enough that they have seen TT work; whether it has a scientific basis is irrelevant.

TT researchers have made numerous claims for what the technique can do. Among the supposed benefits:

- TT accelerates the healing process in 99.5 percent of cases. The rate at which new bone forms during the healing of fractures, for example, is more than doubled when TT is used.
- TT strengthens the immune systems of both practitioners and recipients.
- TT stimulates the circulatory and lymphatic systems.
- TT relieves the side effects of AIDS, Alzheimer's disease and thyroid imbalances.
- TT can improve the prognosis for many different types of cancer.

The studies claiming therapeutic benefits from TT have serious flaws, however:

- All of them lack a suitable placebo group.
- The numbers of patients in the studies are too small for the findings to be statistically valid.
- Hardly any of the studies that show benefits from TT have been conducted "double blind." (In double-blind studies, neither the patients nor those judging the outcome know who receives treatment and who doesn't).
- When well-done studies involving TT-treated patients and a placebo group have been conducted, they have failed to find any therapeutic benefit from TT.
- Studies showing that TT helps patients have not been replicated.

Quoting again from the Colorado panel's report: "To date [1994] there is not a sufficient body of data, both in quality and quantity, to establish TT as a unique and efficacious healing modality. There are major gaps in the literature regarding the actual efficacy of the practice of non-contact TT as a unique healing modality."

But, its proponents ask, "Even if scientific support is lacking, what's the harm in doing TT?" The answer, of course, is that harm can occur in many ways: when patients neglect effective treatments in favor of ineffective ones; when false hopes and expectations are raised; and when insurance, hospital, and out-of-pocket costs are incurred and no benefit results.

Despite the lack of evidence that TT works, use of the technique is increasing. TT has now become entrenched in the nursing profession and is actually accepted as a standard treatment.

According to its advocates, TT is taught in at least 80 nursing schools, with some schools even giving graduate credit for it. The National League for Nursing, the accrediting agency for curricula in nursing schools, has long promoted TT through books and tapes. Most states allow nurses to maintain their licenses by taking continuing-education courses in TT. Staff nurses from Michigan to Hawaii have been called on the carpet in their hospitals for refusing to practice TT.

Why has nursing embraced TT?

It helps raise the stature of the profession in the eyes of patients and nurses as well. A nurse administering TT becomes a healer on a par with a doctor. In addition, TT helps augment nurses' incomes. Nurses opening private practices commonly charge \$35 for a 20-minute TT session.

Unfortunately, nursing has no equivalent to medicine's or dentistry's Councils of Scientific Affairs, which assess the safety, efficacy and appropriateness of unregulated procedures. So there is no way for the profession to formulate a policy against the practice of TT.

Can the government do anything about an unproven practice that has gained legitimacy?

If TT's practitioners waved a wand instead of their hands—particularly a wand connected to a box with some knobs and dials—then the Food and Drug Administration (FDA) could regulate TT as a medical device, and the burden would be on its advocates to prove that it works. But TT involves no devices and, in any event, federal authorities have no direct control over professional practice.

The federal government has actually been supporting TT rather than deterring it. Recently, Congress mandated that the National Institutes of Health set up an "Office of Alternative Medicine" (OAM), which has given for researching the usefulness of TT in treating stress. The Department of Defense, meanwhile, has given \$355,000 to an University of Alabama team looking at TT's ability to reduce pain and infection in burn patients.

Most nurses who practice TT genuinely believe that it helps patients. But patients should not infer from a nurse's sincerity or professional credentials that TT is a valid treatment. In fact, despite TT's widespread use, there is no evidence that it provides any benefit whatever.

Linda Rosa, R.N., is a writer in Loveland, CO, and chair of the Questionable Nurse Practices Task Force of The National Council Against Health Fraud.
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Adverse Events Associated with Interferon Alfa Therapy in Patients with Chronic Viral Hepatitis

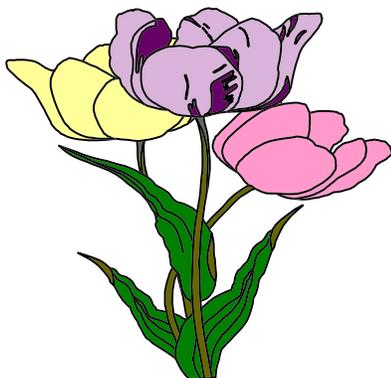
Rakesh Vinayek, A. Obaid Shakil

Interferons are proteins with antiviral, antiproliferative and immunomodulatory activities. Interferon alfa has been used extensively for the treatment of patients with chronic viral hepatitis. Virtually all patients treated with interferon alfa develop adverse effects, most of which are transient and subside spontaneously. Among the more serious side-effects, neuropsychiatric are the commonest, and include marked somnolence, depression, psychosis, suicidal ideation and seizures. Ocular disorders such as retinal hemorrhages and exudates occur frequently, particularly in patients with diabetes mellitus and hypertension. Autoimmune disorders, such as thyroiditis, develop in a significant proportion of patients treated. Interferon alfa can also exacerbate pre-existent autoimmune diseases, such as rheumatoid arthritis and diabetes mellitus. It often causes mild myelosuppression which may result in leukopenia, thrombocytopenia or anemia. Other disorders reported to occur include, severe hepatic dysfunction, gastrointestinal disturbance, interstitial pneumonitis and various skin conditions. Patients on interferon alfa, especially those with decompensated cirrhosis, are more prone to develop serious, often life-threatening infections. Thus, adverse events in most patients treated with interferon alfa are mild and reversible; however, serious problems can develop. Patients and their families should therefore be fully informed, regarding the risks involved, prior to institution of interferon alfa therapy.

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Keywords *interferon alfa; adverse events; chronic hepatitis*

source: <http://www.hbuk.co.uk/hb/journals/vh/vh97/vh003.003/vh970034.art/0034h.htm>

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Early results suggest that the HCV RNA level may well vary during the day. Therefore it could be important to collect samples at the same time for the duration of the study.

Where the sample is collected from: At present the test is performed using your plasma. Recent studies suggest that whole blood may be a better place to look.¹ In addition HCV resides in your liver cells where it disguises itself using your own cell membrane as its outer layer (it is now no longer recognizable as a foreign product). Once in the liver, replication of the virus occurs. More recent studies have shown that as many as 60 percent of those patients that tested PCR (HCV RNA) undetectable in plasma showed HCV RNA positive when the test was performed in liver tissue.² But not all studies have confirmed these results and more research is necessary before a more definitive answer is possible.

How the PCR is used: Initially it was thought that the PCR could be used to help guide the selection of people infected with HCV who would most likely respond to interferon. Could we tie PCR levels to successful treatments—e.g., would a low PCR mean a better response? Does an early response mean a better chance of success? Data from subsequent studies have not fully supported these hypotheses. And in fact, it has been difficult to find a correlation to relate to the PCR. And we must be VERY, VERY careful about the significance we place on these numbers. It is a double-edged sword. These numbers can be used by the government to deny equal access to the drugs and Pharmacare coverage. And for most people the cost of interferon is prohibitive enough without Pharmacare. At the very best, all we can say is that the PCR test is a research tool. The proper use of that tool will be determined through future research.

For the present: the PCR is used to determine response to treatments such as interferon and ribavirin. The PCR is performed at the beginning to give a baseline. It is repeated in 6 months. The hope is that the PCR will be undetectable at this time. If it is undetectable, the individual is classed as an initial responder to the therapy. But the really hard part is remaining PCR undetectable. The full treatment course for the combo is 12 months. Six months after completion the PCR is repeated. If the individual is still PCR undetectable, they are classed as a sustained responder. And it looks like there is a really good chance of remaining PCR undetectable IF you make it past this point.

References

1. Schmidt, W.N.; Wu, P.; Han, J.Q.; Perino, M.J.; Labrecque, D.R.; Stapleton, J.T. "Distribution of Hepatitis C Virus (HCV) RNA in Whole Blood and Blood Cell Fractions: Plasma HCV RNA Analysis Underestimates Circulating Virus Load." *Journal of Infectious Diseases*, July 1997;176(1):20-26.
2. Detection of Hepatitis C Virus (HCV) in Liver Tissue of HCV RNA Seronegative Patients By Means of anti-HCV-Antibodies and RT-PCR. V Dries; I von Both; M Müller; G Gerken; P Schirmacher; M Odenthal; KH Meyer zum Büschenfelde; HP Dienes. AASLD Annual Meeting 97.

From the WellnessWeb The Patient's Network

Bunko Squad—Quack, Quack??

Quackery

Quacks are people who sell unproven remedies, once known as "snake oil" salesman who traveled from town to town making amazing claims about "fabulous" products. Sometimes only the wallet is at stake, but quackery can also interfere with proven remedies.

A Government study found that 60 percent of victims of health-care fraud are older people with chronic illnesses and pain, who are often desperate for anything that can offer hope.

Anti-aging potions are a favorite quack products. Think twice about claims about ways to reverse aging, wrinkles, and prevent or cure baldness. Arthritis remedies are especially easy to fall for because symptoms tend to come and go making it seem like the product is working. There are few enough effective treatments for cancer, but treatments that have no proven value, or body of evidence to support them can cause patients to lose time and miss opportunities to use effective therapies.

Don't believe ads or other information in newspapers, magazines, radio, TV, or the Internet without questioning the source and double checking with a second opinion or testimonial from someone you trust. Be especially skeptical of claims of quick or painless cures, "secret" formulas, and claims made without supporting evidence or that sound to too good to be true.

Quackery...The Billion Dollar Miracle Business

Courtesy of the U.S. Department of Health and Human Services.

Americans spend billions of dollars on products that do nothing for us - and may even harm us. And we'll do it for the same reason people have done it since ancient times ... we want to believe in miracles. We want to find simple solutions and shortcuts to better health.

It's hard to resist. All of us, at one time or another, have seen or heard about a product - a new and exotic pill, a device, or potion - that we're told can easily solve our most vexing problem. We can eat all we want and still lose weight, grow taller, or build a bigger bustline. We can overcome baldness, stop aging, cure arthritis, and even cancer.

It sounds too good to be true - and it is. But we're tempted to try the product in spite of all we know about modern medical science - or perhaps because of it. After all, many treatments we take for granted today were once considered miracles.

How can we tell the difference?

SEPARATING FACTS FROM FANTASY

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Just what is quackery? Simply put, quackery is the promotion of a medical remedy that doesn't work or hasn't been proven to work. In modern times, quackery is known as health fraud. But call it quackery or call it health fraud, the result is the same - unfulfilled wishes, wasted dollars, and endangered health.

Often quack products are fairly easy to spot, like the magic pills that keep you young forever. But sometimes the products are vaguely based on some medical report that you may even have heard about in the news.

In general, when looking over ads for medicines and medical devices, watch out for those that seem to promise too much too easily. And investigate, before you participate.

THE HIGH PRICE OF HEALTH FRAUD

Quack cures rob us of more than money. They can steal health away or even take lives. Quacks may lure the seriously and often desperately ill, such as people suffering from arthritis and cancer, into buying a bogus cure. When people try quack remedies instead of getting effective medical help, their illnesses progress, sometimes beyond the treatable stage.

TODAY'S TARGETS FOR QUACK ATTACKS

Quacks have always been quick to exploit current thinking. The snake-oil salesmen a few generations back carried an array of "natural" remedies. And today, quacks take advantage of the back-to-nature movement, capitalizing on the notion that there ought to be simple, natural solutions to almost any problem. Some current target areas for such promotions include:

ARTHRITIS—Over 30 million Americans suffer from arthritis, and the nature of the disease makes it fertile ground for fraud. And because symptoms may come and go, or the disease may be in remission for several years, arthritis sufferers may actually believe at least temporarily, that they've been cured by a quack remedy.

Before you add to the \$2 billion spent annually on quack arthritis cures, remember that although medical science offers effective treatments, it has found no cure for arthritis. The list of fraudulent "miracle cures" for the disease ranges from snake venom to lemon juice, from the harmless milk of vaccinated cows to the dangerous use of steroids. More dangerous and costly arthritis treatments are offered by legitimate-looking clinics, often located outside the United States. While some clinics may offer effective treatment, many prescribe untested diets or drugs that either offer no cure or cause additional health problems. Beware of arthritis clinics that offer cures. It is important to remember that pain relief and inflammation treatments are not the same. A product that advertises relief for the minor pains of arthritis does not necessarily treat inflammation.

FITNESS—Quacks know that people would like to have the benefits of exercise without actually exercising. So recent years have brought all sorts of "body toning" devices, such

as electrical muscle stimulators. Such devices are, of course, worthless for "body toning" and can even be dangerous, but they're advertised and sold as substitutes for exercising.

WEIGHT LOSS—These schemes are probably the most popular form of quackery. Millions seek a painless way to win the battle of the bulge. Since proper diet and exercise take constant discipline and work, quack claims are especially appealing and, to some, worth a try. Since overweight can lead to number of health problems, including high blood pressure, heart attack, stroke, and kidney disease, quick weight-loss products that don't work aren't worth a try when they can harm you if only by not helping you.

The fact is that you cannot lose weight if you do not cut down on the amount of food you eat or exercise more to burn up calories. Products that trim you and tone you effortlessly haven't been invented yet.

CANCER—Here quack cures are probably the cruelest and most expensive. Seriously ill people may spend thousands of dollars on phony treatments. Often, quack cancer treatment clinics are set up just outside the United States, so that they're beyond the jurisdiction of U.S. authorities. Before you request admission to any cancer clinic, talk to your doctor about it, and check out the credentials and reputation of the practitioners.

QUACK ADVERTISING—THE NEED FOR HEALTHY SKEPTICISM

Many people believe that advertising is screened by a government agency and that, therefore, all claims about health products in advertising must be truthful. This is not the case, except for drugs and medical devices that require pre-market approval by FDA. There is no federal, state, or local government agency that approves or verifies claims in advertisements before they are printed. Law enforcement authorities can take action only after the advertisements have appeared.

This holds for claims of a "money-back guarantee." Many quacks are fly-by-night operators who do not respond to refund demands.

BEWARE OF TESTIMONIALS THAT SOUND TOO FANTASTIC TO BE TRUE

Health fraud promoters are fond of using testimonials from "satisfied users". Legitimate testimonials may be useful, but beware of testimonials reporting incredible results, especially when no medical support for the claim is offered. This is particularly important since "satisfied users" may, in some cases, have experienced the sugar pill, or "placebo" effect. The placebo effect occurs when people, believing they have been given a real medicine, experience a benefit from it. It is the power of suggestion at work, which is helpful to the person who experiences it, but doesn't mean that other people will have the same belief in the product.

YOU CAN PROTECT YOURSELF

Apply the "it-sounds-too-good-to-be-true" test

to ads for health products by watching for these common characteristics of quackery:

- o A quick and painless cure.
- o A "special," "secret," "ancient," or "foreign" formula, available only through the mail and only from one supplier.
- o Testimonials or case histories from satisfied users as the only proof that the product works.
- o A single product effective for a wide variety of ailments.
- o A scientific "breakthrough" or "miracle cure" that has been held back or overlooked by the medical community.

INVEST YOUR TIME BEFORE YOU INVEST YOUR MONEY

Before buying a suspect product or treatment, check with one or more of the following:

- Your doctor, pharmacist, or other health professional.
- The Better Business Bureau
- Government agencies such as state's Attorney General, Federal Trade Commission, Food and Drug Administration, or Postmaster.



LIST OF HAZARDOUS HERBS

Here is a list of nine herbs that the FDA says are related to serious adverse reactions or possible dangers:

—Chaparral. Can cause liver inflammation. Has been promoted as a "blood purifier," cancer cure and acne treatment..

—Comfrey. At least seven cases of liver complications have been reported in users. Comfrey stimulates cell growth and is used for wound healing when taken externally. Toxic to the liver when taken internally.

—Yohimbe. Produces adverse reactions when consumed with certain foods -- liver, cheese and red wine. Is valued as an aphrodisiac.

—Lobelia. High doses can suppress breathing, cause sweating, speed the heart, lower blood pressure and even lead to coma or death. The source of lobeline, an ingredient in some over-the-counter smoking deterrents

—Germander. Linked to liver inflammation, including one death. Used as a weight-loss aid. —Willow bark. Contains salicylates, like aspirin, which could cause stomach irritation or Reye syndrome. Is promoted as an "aspirin-free" pain reliever, but no adverse effects have been reported.

—Jin Bu Huan. An overdose can result in severe sedation requiring medical treatment, and liver inflammation. Is marketed as a sedative and pain reliever.

—Stephania and Magnolia. Have been implicated in severe kidney injury to at least 48 women. .

—Ma huang. Associated with high blood pressure, rapid heart rate, nerve damage, muscle injury, psychosis, stroke and memory loss; Used for weight control and enhanced energy and to treat asthma and hay fever. Contains pseudoephedrine, the active ingredient in decongestants such as Sudafed.



Message from the National Office:

We continue to be incredibly busy in the National Office. Calls are flooding in from people wondering about compensation details. I wish we had more definitive news. Hopefully, by the time you read this there will have been an announcement.

On March 4, our President, Jeremy Beaty wrote letters to each provincial minister of health and to federal ministers Alan Rock, Paul Martin and Anne McLellan.

In his letter, Jeremy states:

"We would emphasise that this man-made tragedy has killed Canadians and ruined families...We are most concerned that the governments of Canada are now planning to only compensate victims who were harmed between 1986 and 1990. We are writing to ask you to re-evaluate your position on this issue. To proceed would be a grave injustice to the other victims and would generate substantial new claims against the Red Cross and the federal and provincial governments. Not only would it do an injustice to Krever's stated position and recommendations, but it would be a government decision made on a narrow legal interpretation that is based on fault but does not admit fault...The 1986 date has been established by class action lawyers who have selected a safe date to win their case on behalf of their clients. There is no other validity to this date...The governments of Canada have a choice to make: to deal with compensation in a cold, litigious manner as an out-of-court settlement, or to heed Justice Krever and act based on compassion and social justice. The history books will describe your actions in resolving this greatest man-made tragedy in Canadian history."

Jeremy also offered, in his letter, to meet with any of the ministers to discuss this concern, but to date has received no response. He and I have also been busy co-ordinating media coverage of the ongoing compensation debate. You probably have seen or heard either one of us or any one of our Board members on local or national media, commenting on the latest government move or delay.

The latest class action was filed on March 10 in Toronto; it is another option for those transfused before 1986 or after 1990 in any province, except BC which has a class action for this time frame. The numbers to call for more information are:

1-800-468-4466 or (604) 874-7171
Transfused in all other provinces:
David Harvey (416) 597-4060

Until next time,
Tim McClelland
Executive Director



CLASS ACTION SUITS:

BRITISH COLUMBIA

Camp Church and Associates
Sharon Matthews / Kim Graham
4th Floor, Randall Building
Vancouver, B.C. V6B 1Z5
1-800-689-2322

Grant Kovacs Norell
Bruce Lemer
Grosvenor Building
930-1040 West Georgia Street
Vancouver, BC, V6E 4H1
Phone: (604) 609-6699 Fax: (604) 609-6688

Before August 1, 1986
Klein Lyons
David A Klein
805 West Broadway, Suite 500
Vancouver, B.C. V5Z 1K1
(604)874-7171
(604)874-7180 (FAX)

also:

Dempster, Dermody, Riley and Buntain
William Dermody
4 Hughson Street South, 2nd Floor
Hamilton, Ontario L8N 3Z1
(905) 572- 6688

The toll free number to get you in touch with the Hepatitis C Counsel is 1-(800)-229-LEAD (5323). It may not be working yet so please be patient.

TRACEBACK PROCEDURES:

This information is for anyone who has received blood transfusions in Canada, if they wish to find out if their donors were Hep C positive.

TRACEBACK INQUIRIES

Contact:
Dr. Lisa Jeppesen, Dr. P Doyle, or Glenda
The Canadian Red Cross Society
4750 Oak Street
Vancouver, BC, V6H 2N9
1-888-332-5663 (local 207)

Class Action/ Compensation

If you would like more information about the class action/compensation, you can contact:

Tricia Plunkett. Tel. (250) 479-5369
e-mail: plunket@islandnet.com

Meetings will be set up so that we can share our experiences dealing with lawyers, the results of our own investigations, and so that we can decide what is in our own best interest as far as legal steps to take.

I'VE BEEN DIAGNOSED. NOW WHAT ?

If you're diagnosed with hepatitis C, get informed. Check with your local support group. (If in doubt, call 1-800- 652-HEPC)

Make sure that you:

- Get re-tested to confirm the diagnosis.
- Get vaccinated against hepatitis A and B.
- Are sent to a specialist.
- Get copies of all tests.

The specialist should:

- Order an ultrasound yearly, if your family doctor didn't.
- Order an alphafetoprotein test yearly.
- Order a liver biopsy. (This is usually done by needle aspiration, but there are other options if there is a bleeding problem, for example.)
- Discuss treatment options with you. (Get a second or even a third opinion if you don't agree.)



Juanita's Burritos

(6 servings)

- 1) 3 onions, minced
- 2) 1 t. oregano
- 3) 1 1/2 t. chili powder
- 4) 3/4 t. paprika
- 5) 1/2 t.+ salsa
- 6) 6 large flour tortillas
- 7) 3 C. cooked split peas
- 8) 1/2 t. ground cumin
- 9) 3 T. crumbled feta cheese
- 10) 6 tomatoes, cut in quarters
- 11) juice from one lime
- 12) 2 minced green onions

Spray a frying pan. Add ingredients 1-6. Fry over low heat 5 or 6 minutes and add peas. Divide the mix amongst the tortillas, add cheese, and roll up. Clean and re-grease frying pan, and fry the burritos, seam down, for 2 minutes. Blend tomatoes and lime juice. Turn burritos over, pour tomato mix over them, and cook covered over low heat for 4 minutes. Top with green onions, and serve hot.