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HAV Vaccination: *Real World Practices*

■■■
Alan Franciscus, Editor-in-Chief

People living with hepatitis C (HCV) are at risk for severe complications if they contract another liver disease such as hepatitis A (HAV). Infection with more than one hepatitis virus is called superinfection and could potentially lead to liver failure and death. For this reason, the HAV vaccine is recommended for people with chronic hepatitis C who have not been previously infected with HAV. Agencies that endorse HAV vaccination in HCV positive individuals include the World Health Organization (WHO), the National Institutes of Health (NIH), the United States Veterans Health Administration, the American Association for the Study of Liver Disease (AASLD), and others. However, despite these recommendations, little is known about real world HAV vaccination practices in HCV positive individuals.

As previously stated, hepatitis A superinfection with hepatitis C can lead to severe health consequences that could lead to death. In one study by Vento et al., conducted in adults with chronic hepatitis C, it was found that 41.2% of patients with acute

HAV superinfection developed acute liver failure, and, tragically, 35.3% died. These deaths could have been avoided by vaccinating hepatitis C positive individuals against HAV.

This article will focus on a recently published article that appeared in the September 2005 issue of *Hepatology* by Shim et al., titled "Susceptibility to Hepatitis A in Patients with Chronic Liver Disease Due to Hepatitis C Virus Infection: Missed Opportunities for Vaccination."

In the study by Shim et al., the records of every patient at 2 main VA medical centers in New York, NY and Brooklyn, NY were reviewed. The people (1,193) who tested positive for the HCV antibody and HCV RNA (viral load) were followed for the period from January through December 2000. Detailed patient characteristics (age, sex, race/ethnicity, active or previous injection drug use, if they were homeless, sex with same sex partners, history of sexually transmitted diseases (STD), presence of cirrhosis and active psychiatric disease) were collected. The follow-up data through June



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30, 2002 was collected and compared to electronic medical records for each person to establish who actually received the HAV vaccination. The findings were validated by a review of the computerized pharmacy database. HAV vaccination was defined such that patients who received at least one HAV vaccine dose out of the series of two doses required for full protection were also considered to have been vaccinated.

It was found in this large retrospective study that 640 (53.6%) individuals were tested for HAV antibody of whom 317 (49.5%) were HAV antibody negative or susceptible to infection with HAV.

Only 94 or 7.9% of the 1,193 patients received one or more doses of the HAV vaccine including 85 or 26.8% of the 317 patients who were susceptible to infection with HAV.

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HAV

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Of the 94 patients who were vaccinated, 45 received only one dose of the HAV vaccine; 41 received two doses and 8 received three doses or more (of the two doses required for protection). Three individuals in the unvaccinated group, but who had been tested and were found to be HAV antibody negative, later acquired HAV infection and one person died of liver failure.

Since the study was only performed in a VA Center setting among mostly male patients, the authors noted that lessons learned from their study may not be able to be duplicated in other clinical settings or in women. However, it was also pointed out that the strength of the study was the large number of HCV infected patients, the availability of long term follow-up data, and the use of various databases such as the computerized patient record system and pharmacy database to verify information.

The authors concluded that “despite published recommendation to vaccinate against HAV in patients with chronic HCV infection, we found that HAV testing and vaccination rates were low in clinical practice.” The authors also noted that clinician and patient barriers to vaccination need to be addressed given the high risk of acute liver failure from infection with acute HAV infection in persons with a chronic liver disease such as HCV.

It is apparent from this study that more education and awareness of the risks of superinfection with acute HAV infection in persons with chronic hepatitis C needs to be addressed. Further-

more, the possibility of severe complications of HAV superinfection is yet another good reason why it is so important to increase public awareness and testing of hepatitis C so that people who are at risk for superinfection with HAV can be identified and receive appropriate medical care.

HEPATITIS A - AT A GLANCE

Hepatitis A (HAV) is spread through contact with food and water contaminated by the feces of an HAV infected person. The hepatitis A virus is spread when the feces (stool) of an infected person are ingested. It can also be spread by sexual contact (anal/oral), changing diapers and, although uncommon, can be spread by injection drug use.

People or groups at risk for getting and spreading HAV include workers and people in day care centers and long-term care facilities, such as nursing homes. International travelers are also at risk for HAV if they travel to countries that do not have good sanitation or water processing facilities. HAV outbreaks are also seen in restaurants when food handlers do not follow proper hygiene practices (washing hands thoroughly) and contaminate food and water.

To prevent transmission of HAV, adults and children must wash hands thoroughly, especially after using the toilet or changing diapers. People actively infected with HAV should avoid preparing food for others. Clean up spilled blood or body fluids with a 10:1 bleach solution (10 parts water to 1 part bleach). Wear gloves when touching blood, body secretions, or any cuts or sores. Do not share razors, toothbrushes, or needles. Practice safer sex including latex condoms and latex or plastic barriers for anal/oral sex.

Symptoms of HAV include mild flu-like symptoms (fever, fatigue, nausea, vomiting, loss of appetite, and general malaise), jaundice (yellowing of skin and whites of the eyes), pale colored stools and dark urine. Many people have no symptoms, especially children.

When a person is infected with HAV the body's immune system will clear the virus on its own and the person will then be immune to catching HAV again. People who have been previously infected with HAV do not need to be vaccinated since their bodies have developed HAV antibodies to protect them. Generally, most people do not have any serious complications from HAV except people with pre-existing liver diseases such as hepatitis B or hepatitis C who may develop severe complications such as acute liver failure and possibly death.

The HAV vaccine is considered safe and effective. The two-dose vaccine is administered by injection, with the second dose given 6-12 months after the first. Most experts believe that the HAV vaccine will provide protection from HAV for at least 10 years and longer. HAV vaccines are manufactured by Glaxo-SmithKline (Havrix) and Merck & Co. (Vaqta). There is also a combination HAV and HBV vaccine available called Twinrix made by Glaxo-SmithKline.

For more information about HAV see HCSP's Fact Sheet - *Hepatitis A: What You Need to Know*.

Reference:

Michael Shim, Inessa Khaykis, James Park, and Edmund J. Bini. Susceptibility to Hepatitis A in Patients With Chronic Liver Disease Due to Hepatitis C Virus Infection: Missed Opportunities for Vaccination. *Hepatology*, September, 2005.



HealthWise:

Influenza



Lucinda K. Porter, RN, CCRC

One of the worst disasters in history was not a war, hurricane, earthquake, or tsunami. It was the influenza pandemic in 1918-19. It is called a pandemic because it affected the entire world - 20 to 25% of the world, in fact. Sometimes called the Spanish flu, it caused the death of 20 to 50 million people worldwide. More people died in a single year from this than from 4 years during the 14th century's bubonic plague. In the United States, 675 thousand Americans died. This is 10 times the number of Americans who had just been killed in World War I.

Public health officials warn us that the world is at risk for another pandemic. Immunizations are one of the best defenses against diseases and epidemics. Contrary to popular myths, vaccination does not give us the disease. It protects us.

Influenza, also known as the "flu" affects an average of 5% to 20% of the United States' population. According to the Centers for Disease Control (CDC), every year more than 200,000 people are hospitalized and about 36,000 people die from flu-related complications. Infants, young children, elderly and people with certain health conditions are at the greatest risk for serious complications.

The best way to prevent passing on the flu is by not getting it. The best way to avoid the flu is through vaccination. Unfortunately, this year we may have another vaccine shortage. The impact of Hurricane

Katrina on vaccine supplies is not known yet. We can do our part by learning if we should or should not get a flu shot and acting on that information.

Flu shots are available in October. The CDC advises that those at high risk get the first round of flu shots. If there is no vaccine shortage, flu shots will be available

for everyone beginning October 24, 2005. Those given first priority are:

- People aged 65 years and older
- Residents of long-term care facilities
- Children aged 6–23 months
- Children from 6 months to 18 years of age who are receiving long-term aspirin therapy
- Pregnant women
- Health-care personnel who provide direct patient care
- People living with or caring for children less than 6 months of age
- People aged 2–64 years with chronic health conditions. These include asthma or other chronic lung problems, heart or kidney disease, cancer, diabetes, sickle-cell disease, HIV or other immune compromised conditions such as those requiring the use of corticosteroids, and neuro-muscular conditions (such as multiple sclerosis, Alzheimer's and spinal cord injuries)

"Know your flu risk. If you are advised to, get a flu shot. If you are not at risk, wait until those who need it are vaccinated first."

Missing from this list is specific mention of those with chronic hepatitis C infection (HCV), cirrhosis, and those undergoing HCV treatment. Having HCV is not an automatic qualification. If you have complications from HCV, or you are waiting for a liver transplant, your medical provider may recommend that you have an

early flu shot.

Receiving HCV treatment is not an automatic qualification for a flu shot. Some experts believe that patients have a lower flu risk during treatment

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Flu

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because interferon stimulates the immune system. Others feel that since interferon lowers the white blood cell count, infection risk may increase. Patients can be vaccinated during treatment, it is just not known if they should be given priority. Treatment may provide an excellent time to get a flu shot since interferon stimulates the immune response.

Those who should not get a flu shot are:

- People who have a severe allergy to chicken eggs
- People who have had a severe reaction to a flu shot in the past

- People who developed Guillain-Barré syndrome (GBS) within 6 weeks of getting a flu shot in the past

- Children under 6 months old

- People with a moderate or severe illness with a fever. These people can be vaccinated once their symptoms lessen.

There are two types of vaccines. The standard flu shot contains “killed” virus. The only “side effect” is a sore, possibly red injection site. There is a nasal-spray vaccine that contains live, weakened virus. This nasal spray form is not subjected to prioritization and can be given to healthy people between 5 and 49 years old and by those who are

not pregnant. Unlike the flu shot, the spray can cause mild flu-like symptoms. Both types provide flu protection approximately 2 weeks after being administered.

Sometimes people have a cold and they use the expression, “I have the flu.” This is a common mistake. Although both are caused by viruses, the flu is more severe than a cold. The CDC lists the following symptoms of the flu:

- Fever (usually high)
- Headache
- Extreme fatigue
- Dry Cough
- Sore throat
- Runny or stuffy nose
- Muscle aches

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Mother-to-Child HCV Transmission

■■■
Liz Highleyman

Hepatitis C specialists usually reassure HCV-positive women that the risk of mother-to-child HCV transmission during pregnancy or birth is quite low. Most research indicates that perinatal or vertical transmission occurs about 5% of the time. As is true for sexual transmission, however, high HCV viral load and coinfection with HIV appear to increase the chances of mother-to-child HCV transmission. For both types of transmission, recent data are conflicting, and the issue continues to generate controversy.

Numerous researchers have observed mother-to-child HCV transmission rates ranging from 0% to 10%. S.L. Thomas and colleagues conducted a systematic review of published and unpublished HCV vertical transmission studies. Analyzing data from 976 infants in 28 studies, they found that overall transmission rates were less than 10% in eight out of 12 studies of HIV-negative mothers with HCV. Rates were higher, however, in most of the seven studies in which at least half the mothers were HIV/HCV coinfecting.

A recent report from the European Paediatric Hepatitis C Virus Network, however, suggests that vertical HCV transmission may be more common than previously believed. J. Mok and colleagues conducted a prospective study of 54 HCV-infected children who were first given PCR tests for HCV RNA within three days of birth. Seventeen children (31%) were found to have detectable HCV RNA on the first test. Among the 37 children who had negative PCR tests at three

days, 27 had detectable HCV RNA when tested again at three months, and nine more received their first positive HCV PCR result after three months. These data, the authors concluded, “suggest that at least one-third and up to half of [HCV-] infected children acquired infection in utero.” However, this study was small, and further research is needed to verify its results.

As noted above, two key factors appear to substantially increase the risk of HCV transmission from mothers to babies: high HCV viral load and coinfection with HIV. Research indicates that HCV transmission is most likely to occur when mothers have HCV viral loads above 1,000,000 copies, and very uncommon when they have undetectable HCV RNA. In the studies reviewed by Thomas, just eight instances of HCV transmission were observed from mothers who had undetectable HCV RNA.

Among HIV/HCV coinfecting women, some studies have detected vertical transmission rates in the range of 15-40%. A meta-analysis by B.L. Pappalardo and colleagues of 1,010 infants in nine studies revealed that the overall risk of vertical HCV transmission was 3.5-fold higher among infants born to coinfecting mothers compared to those born to mothers with HCV alone. When considering only women with detectable HCV, coinfecting mothers were still 2.2 times more likely to transmit HCV. However, not all data support this finding. In Mok’s study, a higher proportion of infants who tested positive for HCV RNA within three days were born to coinfecting

mothers, but this association did not reach statistical significance. D. Conte and colleagues, too, reported that HIV coinfection was not associated with a higher HCV transmission rate.

Besides HCV viral load and HIV/HCV coinfection, other risk factors have not been consistently linked to perinatal HCV transmission. For example, Mok’s team found that women with genotype 1 HCV were more likely to pass on the virus, but Conte’s team did not see the same association.

The method and timing of HCV transmission during gestation or during delivery remain uncertain. J. Rakela and colleagues found that HCV may be passed from mothers to infants by means of HCV-infected peripheral blood mononuclear cells (PBMCs; a type of white blood cell), although this does not appear to be the sole means of transmission. Mok’s team suggested that more than one mechanism may be involved. They hypothesized that the infants in their study who had detectable HCV RNA at three days were probably infected in the womb, while those who tested PCR negative at birth but PCR positive more than three months later were likely infected during the birth process.

Some studies suggest that elective (planned) Cesarean section (C-section) may reduce the risk of perinatal HCV transmission. For example, in a study by D.M. Gibb and colleagues, none of the 31 infants of HCV-positive mothers delivered by elective C-section contracted HCV, compared with 5.9% of the 54

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VERTICAL TRANSMISSION

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babies born by emergency C-section and 7.7% of the 339 infants delivered vaginally. In the studies by Mok and Conte, however, C-section did not appear to protect infants from contracting HCV. Since the risk-to-benefit ratio remains unclear, most experts (including the U.S. Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists) do not recommend routine C-section for HCV-positive women.

Research on perinatal HCV transmission must be interpreted with caution. In particular, studies that test infants for HCV antibodies cannot easily be compared with studies that use PCR technology to measure HCV RNA. For one thing, newborn infants still carry their mothers' antibodies, and may not truly be infected themselves; the usual recommendation is that babies should be tested for HCV antibodies after 12-18 months. On the other hand, in Rakela's study, only about half (seven out of 13) of babies with detectable HCV RNA developed HCV antibodies by one year of age. Thus, perinatal transmission studies that look only at early HCV antibody positivity may either be overestimating or underestimating true infection rates.

In addition, it is not known what having detectable HCV RNA means for babies. Compared to adults, infants are more likely to spontaneously clear HCV, but the likelihood of this occurring remains uncertain; spontaneous clearance rates ranging from 20% to 75% have been reported in various studies. In a study of 28 babies born to HCV-infected mothers, S. Della Bella and colleagues found that 20 (71%) showed evidence of HCV-specific CD4 cell

activity, which the researchers suggested might help explain the low vertical HCV transmission rates typically observed.

To date, there has been little research on the natural history of hepatitis C in individuals with vertical infection. In one such study, the European Paediatric Hepatitis C Virus Network team prospectively followed 266 children with vertically acquired HCV (10% of whom also had HIV) from birth for up to 16 years (average follow-up about four years). About one-quarter appeared to have cleared HCV (indicated by two negative HCV PCR tests, normal ALT, and no clinical signs), at a median age of 15 months. One-half had chronic asymptomatic infection and about one-third had chronic active infection (detectable HCV RNA). The only clinical sign of liver disease was hepatomegaly (enlarged liver), observed in 10% of the children. Although this study "confirm[ed] the low prevalence of HCV-related clinical signs and symptoms among vertically infected children in the first 10-15 years of life," the longer-term consequences of chronic HCV infection remain a concern, especially in the light of a recent study by R. D'Souza and colleagues showing that 71% of Asian patients infected with HCV for more than 60 years developed cirrhosis.

Lowering HCV viral load clearly reduces the risk of mother-to-child HCV transmission, but standard treatment with pegylated interferon plus ribavirin is contraindicated in pregnant women because ribavirin has been linked to birth defects. In the future, new anti-HCV medications may prove safe for pregnant women and their developing babies, and may be used as is the case with anti-HIV therapy to reduce the risk of perinatal transmission. Until that time, HCV-positive women should discuss their individual risk factors

with their healthcare providers if they learn they are pregnant or are thinking about becoming pregnant.

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Flu

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- Intestinal problems such as nausea, vomiting and diarrhea

The flu travels from person to person, usually by coughing and sneezing. A good way to get the flu is by touching your nose, eyes or mouth after touching something contaminated with the virus.

Healthy adults can pass on the flu to others a day before they show any flu symptoms and for up to 5 days after they become ill. This means you can pass on the flu before you even know you have it.

There are steps you can take to protect yourself and others from the flu:

- Keep your distance from people who are sick
- If you have the flu, avoid close contact with people
- If you are sick, stay home from work, school and other public places
- Cover your mouth with tissue when you cough or sneeze
- If you do not have tissue close by, turn your head and cough into your upper sleeve
- Properly dispose of used tissue
- If you have the flu, wash your hands before touching food or objects that other people may use
- If you don't have the flu, wash your hands after touching publicly shared objects
- Clean publicly shared items, such as telephones, keyboards, and faucet handles
- If soap and water are not available, use sanitizing wipes or gels to clean your hands

- Keep yourself healthy by developing good sleeping, eating, and exercise habits

If you do get the flu, be sure to rest and drink plenty of liquids. To reduce fever, stay cool, but not cold. Acetaminophen, removing layers of blankets and clothing, and lukewarm sponge baths can provide relief. Call your medical provider if you cannot get symptoms under control, such as fever, vomiting, or diarrhea. Since you can pass this on to others, call for advice and let your medical provider determine if you need to be seen.

There are antiviral medications that can reduce the severity of the flu. These are effective if taken within the first 48 hours of the flu. Call your medical provider as soon as you show signs of the flu and discuss whether or not antiviral medication is appropriate for you.

Know your flu risk. If you are advised to, get a flu shot. If you are not at risk, wait until those who need it are vaccinated first. If there is leftover vaccine, you may have a chance to get a flu shot later in the winter. Flu shot or no flu shot, remember to take good care of yourself.

For more information: www.cdc.gov/flu



NEW: **A GUIDE TO HEPATITIS AND DISABILITY**

The Hepatitis C Support Project has recently posted A Guide to Hepatitis and Disability on our Web site www.hcvadvocate.org that is one of the most comprehensive documents available on how to prepare and file for social security disability. Included in the Guide is helpful information on how to prepare and file for long and short term disability insurance. There is additional information on commercial disability insurance, and health insurance. There is also information on what to do if your claim is denied and a comprehensive list of web site links to and contact information for various state and federal social security offices.

This document was prepared by Christine Kukka and Jacques Chambers from a compilation of articles by Jacques Chambers found in his monthly Benefits Column, which appear on our web site at :
http://www.hcvadvocate.org/hepatitis/living_w_hepatitis_C.asp

We would be very interested in hearing from our readers about their experiences when filing for social security. If you would like to share your experience, please contact Alan Franciscus at
alanfranciscus@hcvadvocate.org

Extrahepatic Manifestations: *Porphyria Cutanea Tarda (PCT)*

■■■
Alan Franciscus, Editor-in-Chief

Porphyria Cutanea Tarda (PCT) is one of the most common types of a condition called porphyria caused by a deficiency of an enzyme called uroporphyrinogen decarboxylase (UROD). The reduced activity of UROD results in an overproduction and build up of the protein uroporphyrinogen in the blood and urine of patients. This results in the abnormal production of heme, a compound found in all body tissues and especially in the liver and red blood cells.

PCT can be caused or triggered by hemochromatosis (accumulation of iron in the liver), heavy alcohol use, estrogens, hepatitis C and other viral infections. An inherited deficiency of UROD is responsible for about 20% of cases of PCT.

SYMPTOMS

The symptoms of PCT are mostly confined to the skin. Skin lesions

or blisters are most often seen on the hands, forearms, back of the neck and face and areas exposed to the sun. The skin may become red, blister and peel after exposure to the sun or minor trauma. PCT can also cause either darkening or lightening of the skin, increased facial hair, scarring, alopecia (hair loss), thickening of the skin, itching and premature aging of the skin. In severe cases calcium may be deposited in the skin causing non-healing ulcers.

Liver function enzymes can be abnormal although enzymes are usually only mildly elevated. A liver biopsy should be performed to assess iron stores and to check for any damaged caused by PCT.

DIAGNOSIS

Diagnosis is made based on the presence of skin lesions on physical examination, as well as by the measurement of UROD in blood, urine

and stool samples.

MANAGEMENT

The signs and symptoms of PCT can be managed, but there is no cure. The management of PCT includes avoiding the sun, alcohol and estrogens, and restriction of iron rich foods. Short term iron depletion by phlebotomy (removal of blood) is usually the first line of treatment and can improve the signs and symptoms of PCT. Phlebotomy is stopped once iron stores and porphyrins in the blood return to normal, but if signs and symptoms return additional phlebotomies may be required. Anti-malarial drugs, such as Chloroquine, are also used to treat PCT.

Treatment of the underlying disease (HCV) with interferon plus ribavirin has also been found to decrease skin lesions as well as UROD's found in urine.



BLOOD, ORGAN AND TISSUE DONOR REGISTRY

Hurricane Katrina has changed our nation. The toll on Louisiana, Alabama, Mississippi and Florida is enormous and continues to grow as these communities cope with Katrina's devastation. Many of us have donated money and time in response to these needs. Now more than ever, please add blood, tissue and organ donation to your giving. You may not give blood if you are HCV-positive, but you can urge others to donate. In addition, there are blood donation restrictions for certain people who are close to HCV-positive individuals. However, all of us, young and old, with or without hepatitis C, can request that our organs and tissue be donated upon death. The use of organs is made on a case-by-case basis at the time of death. Talk to your family and friends your wishes. Find out what the guidelines are in your state. For general information for the entire United States, visit www.organdonor.gov/opo.htm. The Louisiana Organ Procurement Agency had to relocate during the hurricane. For up-to-date information, contact www.lopa.org

HCSP sends condolences and hopes for a swift recovery to friends, colleagues, and residents of the Gulf Coast.

Book Review:

Living with Hepatitis C for Dummies



Lucinda K. Porter, RN, CCRC

There are many fine books about hepatitis C (HCV). Although plentiful, I always thought hepatitis C would make an excellent subject for the “For Dummies” series. Apparently, Wiley Publishing thought so too.

Living with Hepatitis C for Dummies, by Nina L. Paul, PhD, is like others in the “For Dummies” series, complete with its trademark black and yellow cover. The author has a research background and an easy to understand writing style. This book is informative, thorough and upbeat. Dr. Paul covers all aspects of HCV, such as diagnostic tests, treatment and transmission. Her description of the hepatitis C virus and the immune system is well done. *Living with Hepatitis C* has chapters on liver transplantation, building a medical support team as well as complementary and alternative medicine.

The strongest part of the book is “Living a Good Life with Hep C.” Paul offers concrete suggestions about nutrition, sleep, support, exercise, relationships, the workplace as well as other important aspects of wellness. She uses lists, tips, tables, and diagrams throughout the book. Specific groups of people with hepatitis C, such as children, veterans

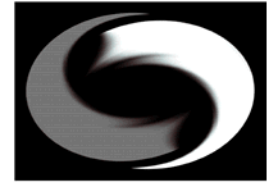
and those in prison are briefly addressed. The chapter for family and friends is packed with wisdom.

The weakest part of *Living with Hepatitis C for Dummies* is management of HCV treatment-related side effects. I would have preferred to see a chapter about side effect management rather than “Ten Tips for Vacationing with Hepatitis C.” Also, if there was a good explanation of portal, periportal and bridging fibrosis, I could not find it. A glossary would have been helpful, but these are not typically included in the “For Dummies” books.

The strengths of this book far outnumber its weaknesses. Although a valuable resource for everyone, *Living with Hepatitis C for Dummies* is a perfect book for people who are new to the subject. I recommend it for anyone needing a general introduction to the world of HCV.

Living with Hepatitis C for Dummies

By Nina L. Paul, PhD
Wiley Publishing, Inc. 2005
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\$16.99 U.S.



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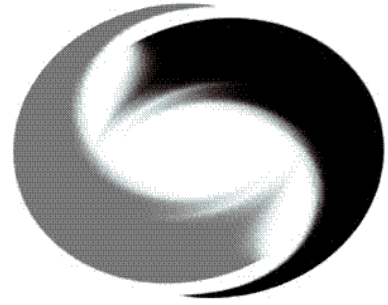
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