

The Future Burden of HCV: Part 2



Alan Franciscus, Editor-in-Chief

In last month's *HCV Advocate* (volume 9, issue 2) I wrote about the first large scale study estimating the future disease burden of hepatitis C, by J. B. Wong and colleagues, published in 2000. In the above referenced article the future disease burden of hepatitis C from 2010 to 2019 was estimated at 208,500 HCV related deaths, 10.7 billion dollars in direct medical costs, 54.2 billion in indirect costs and 21.3 billion in disability costs. In part two of this series on HCV disease burden I will summarize a study by G.L. Davis and colleagues that projected the number of cases of HCV infections, cirrhosis, and liver failure from hepatitis C from 2020 through 2040¹.

The number of people infected with hepatitis C used in this model was based on the Third National Health and Nutrition Examination Survey (NHANES III) study. In this study, the authors used a tested mathematical model (Markov Model) and modified it to include acute HCV infections. Since a portion of people spontaneously clear HCV on their own, the authors assumed that 79% of people initially infected with hepatitis C progress on to chronic infection. The progression from one disease state to

another per year was then calculated. The normal, age-adjusted, all-cause death rates or death by other causes not related to HCV were also factored into the computer model.

The authors concentrated on the small subset of people who developed cirrhosis and complications of liver failure since these are the patients more likely to use medical resources. A sub-analysis was performed to project the impact of treatment on their model. An assumption was made that only people who achieve a sustained virological response (SVR) would have improved liver histology. The authors assumed a SVR rate of 50% based on the clinical trials of pegylated interferon plus ribavirin. The authors admitted that the study was intentionally biased in order to underestimate the projections of the future disease burden.

RESULTS

The computer model calculated that the cases of all HCV-related cirrhosis would increase by 25% in 2010, 32% in 2020, 36% in 2030 and 38% in 2040. HCV-related liver decompensation would increase considerably over the next 30 years – 58% by 2010, 106% by 2020, and 124%



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by 2030 and then stabilize over time. The estimated number of deaths would also increase reaching about 40,000 per year by 2040.

The impact of treatment on disease progression was calculated based on treating 10%, 50% or 70% of all HCV patients with compensated cirrhosis. It was found that successful treatment would decrease disease progression from compensated cirrhosis to decompensated cirrhosis by 5%, 24%, and 34% respectively after 20 years. The authors calculated that treatment of people with mild chronic hepatitis C would not have much of an impact over the next 10 years, but after 20 years there would be a substantially lower future disease burden (11.0% after 10 years, 31.9% after 20 years, and 58.5% after 40 years). It was calculated

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that treatment of patients with normal ALT levels would have little impact (2.0% after 10 years; 6.7% after 40 years).

The authors recommended that “[i]dentification and treatment of a larger proportion of infected patients, education about the importance of abstinence from alcohol (the most important risk factor for disease

progression), and development of better tolerated therapies may help to achieve a more meaningful impact on the morbidity and mortality of this disease.” Furthermore, the authors pointed out that the initial costs of screening and treating patients would more than offset future costs of managing the complications of decompensated cirrhosis which are estimated to be more than 1 billion dollars per year.

The authors concluded that “the message is clear that an

aggressive, proactive approach is needed to first identify, educate, and treat patients with HCV infection and, second, to increase transplant resources.”

¹Gary L. Davis, James E. Albright, Suzanne F. Cook, and Daniel M. Rosenberg. “Projecting Future Complications of Chronic Hepatitis C in the United States” *Liver Transplantation*, Vol 9, No 4 (April), 2003, pp 331-338

Table 1. Prevalence of Chronic Hepatitis C Infection, Cirrhosis, and Complications over Four 1-Decade Intervals.

	2000	2010	2020	2030	2040
HCV Infection	2,940,678	2,870,391	2,681,556	2,433,709	2,177,089
Cirrhosis	472,1033	720,807	858,788	879,747	828,134
Decompensated Cirrhosis	65,294	103,117	134,743	146,408	142,732
Hepatocellular Carcinoma	7,271	11,185	13,183	13,390	12,528
Liver-Related Death	13,000	27,732	36,483	39,875	39,064

Table 2. Proportion of Treatment-Related Reduction in Hepatic Decompensation Accounted for by Different Subgroups of Patients

Treated Group	2010	2020	2030	2040
Cirrhosis (excluding cases with complications)	54.5%	26.8%	14.9%	9.1%
Moderate Chronic Hepatitis C	33.5%	37.7%	32.1%	25.7%
Minimal-to-Mild Chronic Hepatitis C	11.0%	31.9%	48.0%	58.5%
Persistently Normal Serum ALT Levels	2.0%	3.5%	5.0%	6.7%



HealthWise:

Stigma: Living with the Labels of Others



Lucinda K. Porter, RN, CCRC

In the latest issue *Hepatitis* magazine, the staff conducted an informal web poll about stigma and viral hepatitis. (January 2006, Vol. 8, No. 1, p. 53) The article reported both good and bad news. First the good news: 42% of the participants felt they had not faced any stigma due to living with hepatitis B (HBV) or hepatitis C (HCV). Now the bad news: 20% felt they had experienced job discrimination due to HBV or HCV; 13% reported hepatitis-related social stigma; 13% had been alienated from family and friends because of viral hepatitis. The most remarkable report was that 8% of those in this informal survey felt that medical professionals had denied service to them because of HBV or HCV.

According to the Oxford Dictionary, the definition of stigma is, “a mark of disgrace associated with a particular circumstance, quality or person.” The Greek and Latin roots of stigma mean “to mark, brand or tattoo.” The dictionary Encarta defines stigma as “a sign of social unacceptability: the shame or disgrace attached to something regarded as socially unacceptable.” Merriam-Webster’s descriptions of stigma include “a mark of shame or discredit; an identifying mark or characteristic; a specific diagnostic sign of a disease.”

Sadly, hepatitis C does carry a stigma. I believe this is for three reasons. First, HCV is potentially infectious. Although not easily transmitted, people are nevertheless fearful and shun those who have the disease. My neighbor would not let her teenager visit my family after she learned I had HCV. Fear and ignorance have cost patients their jobs, friendships and marriages. Hugs and kisses cease. Sexual relationships stop or are never initiated. In the extreme, even marriages have been challenged.

Another stigma associated with HCV is connect-

ed in a more general way. Some people do not like to be around people who are “sick.” The disease itself does not seem to matter. It does not have to be an infectious disease, nor one with obvious symptoms. I speculate that this is a fear-based response. Some people are afraid of illness and death and they shun others who have a disease or illness. They may also be afraid that someone they care for will die, so they reject that person rather than risk the loss.

A third stigma connected to hepatitis C is from

its association with injection drug use. Misinformed people sometimes assume that all hepatitis C patients have a history of injection drug use in spite of the many ways hepatitis C can be acquired. Our society lacks compassion and understanding about injection drug use. Those who never

used injection drugs do not want to carry that label. Former injection drug users feel haunted by their past. Active injection drug users carry the burden of having two stigmatized diseases – addiction and hepatitis C¹.

It is tragic to witness this unnecessary and avoidable ostracism. Those struggling to live with a chronic disease need more support, not less. To some, the isolation is worse than the virus. It is heartbreaking to witness, especially when patients are newly diagnosed and need the most support.

On TV, commercials freely discuss erectile dysfunction, but hepatitis C remains in the closet. This despite an HCV mortality rate that is projected to triple in the next 10 years. It is a sad commentary about our priorities.

My feelings are this: **how** those acquired HCV is nobody’s business; **that** they acquired HCV is everybody’s business. HCV is a community problem

“It is time to look at solutions rather than problems. Dropping the stigma is a good place to start”

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that needs a community response. It is time to look at solutions rather than problems. Dropping the stigma is a good place to start.

What can we do about this? First, start with yourself. Do you label yourself? Do you expect to be shunned? Do you fear that others will reject you in some way? Do you have your own fears about having HCV? If so, talk about this. The best place to discuss these feelings is at an HCV support group. Learn how others live with HCV.

Do you feel like you deserve HCV as a consequence for current or past behavior? If so, there is something you need to know – no one deserves HCV. It does

not matter how you acquired HCV. This virus is not a punishment or natural consequence – it is an unfortunate but unintended outcome. Guilt and remorse will not improve your health and may have a negative effect. If you struggle with negative emotions, talk to your medical provider. You may need some counseling. **Important Note: If you have thoughts of suicide or hurting yourself or others, seek immediate professional help.**

One final thought to reflect on – there is another definition of stigma. In botany, the stigma is the part of a plant where bees deposit pollen. The stigma bears the fragrant sweet solution that attracts bees. It is a place of fertilization. For those with HCV, it may be the place where shame blossoms into hope. It is time to

bring hepatitis C out of the closet and into the sunshine.

¹For more information about the double stigma associated with injection drug use and HCV, see “Stigma: Hepatitis C and Drug Abuse,” by Janetta Astone-Twerell, Ph. D. Shiela M. Strauss, Ph.D. and Corrine Munoz-Plaza, M.PH. This article can be found under “Medical Writers’ Circle” at www.hcvadvocate.org.

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HCV News Reports from the 2006 Retrovirus Conference



Liz Highleyman

Although this year's Conference on Retroviruses and Opportunistic Infections, held February 6-9 in Denver, did not feature any groundbreaking news on hepatitis or coinfection, some 70 presentations dealt with various aspects of this topic. For conference abstracts and webcasts of oral presentations, visit the website at www.retroconference.org/2006.

Kicking off the conference, Takaji Wakita from Japan (abstract 15) reviewed a new method of cultivating HCV in the laboratory. This method offers "a powerful tool with which to study the viral life cycle," he concluded, compared with existing replicon models that produce non-infectious virus-like particles. At a Wednesday symposium, T. Jake Liang of the National Institutes of Health (abstract 170) presented an overview of HCV, its impact on the liver, and the body's immune response. Stuart Ray of Johns Hopkins (abstract 171) looked at current challenges in the management of HIV/HCV coinfection. Also, Ann Kwong from Vertex Pharmaceuticals (abstract 172) reviewed the development of novel therapies targeting HCV, including the protease inhibitors VX-950 and SCH 5030304, while Daria Hazuda from Merck (abstract 173) followed with a discussion of HCV polymerase inhibitors.

HCV TREATMENT

Manel Crespo and colleagues from Barcelona (abstract 81) reported on treatment of genotype 2/3 HCV in HIV positive patients. In this retrospective review, they looked at data from 42 subjects (41 with genotype 3; 1 with genotype 2) treated with either conventional or pegylated interferon (Peg-Intron) plus ribavirin for 24 weeks. Sustained virological response (SVR) rates were 43% using conventional interferon and 71% using Peg-Intron. End-of-treatment (EOT) and SVR rates were higher among patients who achieved undetectable HCV viral load by four weeks, and relapse rates were lower (46% vs 5%). These results suggest that 24 weeks of pegylated interferon/ribavirin is sufficient for a majority of HIV positive people with genotype 2 or 3 HCV, and that rapid virological response (RVR) at week 4 could be used to predict the eventual outcome. This contradicts some previous research and recent guidelines suggesting coinfecting patients may benefit from longer treatment.

Based on data from the APRI-COT study, Douglas Dieterich and colleagues (abstract 856) reported that rapid virological response at four weeks also predicted SVR in coinfecting patients with genotype 1. Among 176 genotype 1 patients treated with pegylated interferon (Pegasys) plus ribavirin, 75-83% of those with RVR went on to achieve SVR, regardless of whether

they started with high or low HCV viral load. Previous research has shown that lack of early virological response (EVR) at 12 weeks could be used as a cut-off for stopping therapy; these two studies suggest this cut-off may be pushed back even earlier, sparing patients the side effects and cost of additional therapy that is unlikely to produce a sustained response.

In a study by Alison Uriel and colleagues (abstract 854), again, prolonged therapy was not associated with a higher SVR rate. In this multicenter trial, 177 coinfecting participants (80% genotype 1) initially received Peg-Intron/ribavirin for 24 weeks. The 61 patients with undetectable HCV RNA at week 24 were then randomly assigned to receive treatment for 24 (standard course) or 48 (prolonged course) additional weeks; SVR rates were 50% and 54%, respectively. However, more than half of the 61 patients did not complete treatment due to side effects or refusal to consent to further therapy after 24 weeks, leading the researchers to conclude that "longer...therapy may not be feasible for many HIV-infected patients."

Higher-dose therapy has also been suggested for coinfecting patients. However, T. Ruys and colleagues (abstract 852) reported that high-dose induction therapy with Peg-Intron (3 mcg/kg/week for four weeks, 2 mcg/kg/week for four

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weeks, then 1.5 mcg/kg/week for 40 weeks) plus ribavirin did not appear more effective than standard-dose Peg-Intron (1.5 mcg/kg/week for 48 weeks) plus ribavirin. In this pilot study of 23 coinfecting participants (10 genotype 1; 10 genotype 3; 3 genotype 4), 38% of patients in the induction arm achieved SVR, compared with 35% in the standard-dose arm. Nearly one-third of subjects in the high-dose induction arm required dose reduction or treatment discontinuation due to neuropsychiatric side effects, versus none in the standard-dose arm.

The reason for poorer response to interferon in HIV/HCV coinfecting compared with HCV mono-infected individuals remains unclear. Some researchers have hypothesized that the difference is related to immune status. However, in a study by Susan Hopkins and colleagues (abstract 860), nadir (lowest ever) CD4 count did not predict response to pegylated interferon plus ribavirin. This retrospective analysis included 124 coinfecting patients (about half with genotype 1) in London and Dublin. Median baseline and median nadir CD4 counts were 440 and 208 cells, respectively; about 60% were on HAART. SVR was achieved by 25% of genotype 1 and 75% of genotype non-1 patients. In a multivariate analysis, genotype was the only statistically significant predictor of sustained response – nadir CD4 count had no significant effect.

PROGRESSION AND FIBROSIS

Offering some promising news, Pablo Barreiro and colleagues from Madrid (abstract 859) reported that successful hepatitis C treatment can

reverse liver damage in HIV/HCV coinfecting individuals. In this study of 112 patients (70% genotype 1; 44 with SVR; 68 nonresponders or relapsers), moderate to severe fibrosis (stage F3-F4) was less common in sustained responders. Further, fibrosis scores decreased as elapsed time since completion of hepatitis C treatment increased. Several past studies have shown that patients with HCV mono-infection who achieve SVR experience regression of liver fibrosis, and it is reassuring to learn that this can also occur in coinfecting individuals – although the researchers noted that “long periods of time seem to be required to show this benefit.”

Barreiro’s study offered evidence that the noninvasive FibroScan elastometry test is useful for coinfecting individuals as well as those with HCV alone. Mark Sulkowski and colleagues (abstract 867) also reported on a noninvasive metric – the Johns Hopkins Fibrosis Index – comprised of laboratory measures (albumin, AST, and platelet count) and history of alcohol use that accurately predicted fibrosis in coinfecting patients. In addition, Huda Al-Morhi and colleagues from Montreal (abstract 869) used the noninvasive APRI index to assess fibrosis in 162 coinfecting patients. In a multivariate analysis, any amount of past alcohol use was linked to more severe fibrosis, but not history of injection drug use or tobacco or marijuana smoking. Higher CD4 cell count was associated with less severe fibrosis, but current HAART use had no significant effect.

HIV TREATMENT

Research continues to provide conflicting data on treatment of HIV in coinfecting individuals. Renato Maserati and colleagues

(abstract 846) analyzed 201 coinfecting and 684 HIV mono-infected subjects in the Italian MASTER Cohort who were on HAART with undetectable HIV viral load for at least 12 months. In contrast to some past studies, the researchers found that having HCV did not appear to reduce CD4 cell recovery. However, presence of genotype 2 or 3 HCV was significantly associated to worse CD4 recovery compared with genotypes 1 or 4. Marina Nuñez and colleagues from Madrid (abstract 847) presented data showing that HIV/HCV coinfection is associated with increased T-cell apoptosis (programmed cell death), which may help explain impaired CD4 cell recovery following HAART initiation.

Certain antiretroviral medications used to treat HIV, in particular protease inhibitors, have been linked to increased blood cholesterol and triglyceride levels. Jack Stapleton and colleagues (abstract 878) analyzed 1440 HIV positive participants (161, or 11% with HCV) starting HAART for the first time in the ACTG 5001 (ALLRT) study. Blood fat levels rose over time in both HIV mono-infected and HIV/HCV coinfecting subjects. In contrast to some past studies, fasting cholesterol levels were similar in the two groups after 48 weeks. However, more HIV mono-infected than coinfecting subjects required lipid-lowering medications (4% vs none). In a study of 415 HIV mono-infected and 307 HIV/HCV coinfecting subjects (13% with genotype 3), G. Lapadula and colleagues (abstract 877) found that coinfecting patients were less likely to develop high cholesterol and triglyceride levels while on HAART, but that this effect was driven by

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Patient Assistance Programs



Alan Franciscus, Editor-in-Chief

Many Americans do not have insurance for healthcare services and/or prescription coverage. In order to provide free or low cost medicines to those who qualify, patient assistance programs were created by the pharmaceutical industry. In addition to these services some pharmaceutical companies will work with patients to see if the prescription for their drug is covered by the patient's insurance company or other drug plans.

Partnership for Prescription Assistance was launched in 2005 as a centralized site for help with patient assistance prescription coverage. Pharmaceutical, and local and national organizations participate to bring more than 475 public and private patient assistance programs together in one place.

The Partnership for Prescription Assistance was formed because many Americans do not know that they may qualify for free or low cost medication. A centralized location will make it easier for patients to locate assistance programs. The goal or mission of the Partnership for Prescription Assistance is to bring about more awareness of the patient assistance programs and to help put people in touch with these programs.

To find out if you qualify for an assistance program go to the Partnership for Prescription Assistance Web Site <https://www.pparx.org> or call 1-888-477-2669 (toll free) for more information.

To speed up the process, have the following information available:

- Age
- State of residence and zip code
- Estimated gross annual household income
- Number of people living in the household
- Brand name of the prescription medicines that you are currently taking or have been prescribed (Pegasys/Copegus – Roche; PegIntron/Rebetol – Schering)
- Type of health insurance and/or prescription coverage (if any)
- Name and contact information of physician who prescribed or will prescribe the medication.

The people who assist you are specially trained to be courteous and sensitive to the special issues of information related to money and issues surrounding illness. All of the information is strictly confidential.

If it is determined that you may be eligible for a particular program you will be asked to fill out an application. For most people this process is stressful for a variety of reasons so it is highly recommended that you involve a caregiver, social worker, benefits counselor, healthcare professional, or friend to help with the initial process and fill out the application. After you fill out the patient information, the application will have to be sent to your medical provider to complete.

The pharmaceutical companies that provide patient assistance programs can also be contacted directly:

- Roche – Pegasys plus Copegus (ribavirin): Pegassist Patient Assistance Foundation – 1-877-734-2797
- Schering – PegIntron plus Rebetol (ribavirin): Commitment to Care – 1-800-521-7157

HCSP GUIDES

The Hepatitis C Support Project has published various publications in our "Guide" series. The Guides are available on our Web site www.hcvadvocate.org

A Guide to Understanding and Managing Fatigue – this Guide provides a comprehensive overview of the causes of fatigue as well as simple tips to help manage this often debilitating symptom of HCV.

Management of Hepatitis C by the Primary Care Provider: Monitoring Guidelines. This Guide gives the medical provider with the necessary information to help identify and manage hepatitis C positive individuals. (Available in English and Spanish.)

A Guide to Hepatitis and Disability is one of the most comprehensive documents available on how to prepare and file for social security disability. There is additional information on commercial disability insurance, and health insurance.

First Steps for the Newly Diagnosed is an HCSP guide designed to help the person who is newly diagnosed with the medical aspects of HCV including a lab tracker, questions to ask your medical provider and more.

Women and Hepatitis C: An HCSP Guide, by Lucinda Porter, RN, discusses the issues around hepatitis C and how they differ in women.

The Guides are downloadable in copy-ready format. Permission to reprint is granted and encouraged with credit to the hepatitis C Support Project.



Extrahepatic Manifestations: *Non-Hodgkin's Lymphoma (NHL)*



Alan Franciscus, Editor-in-Chief

First of all, NHL in people with hepatitis C is uncommon. In addition, most studies show that the incidence of NHL in people with hepatitis C usually occurs after many years of infection with hepatitis C.

The designation "Non-Hodgkin's Lymphoma" encompasses a variety of cancers of white blood cells that affect lymphoid tissues. The exact cause of these cancers is not fully understood but it is believed to be caused by an altered or depressed immune system. Other conditions and medications that have been linked to NHL include HIV infection, immunosuppressive medications, rheumatic diseases and hepatitis C.

The lymphatic system is a circulatory system that collects

white blood cells which are taken from veins, circulated throughout the body, and returned to the bloodstream. Once the lymphatic fluid is returned to the blood supply, the kidneys are responsible for removing the waste products. Lymphatic organs include the spleen, tonsils, appendix, and thymus. Moreover lymphatic glands are also found in patches located in the intestines. The lymphatic system carries white blood cells that help fight infection.

Typically, lymphoma occurs when white blood cells divide continuously without pause, which prevents them from maturing. This process can cause an

overproduction of the immature cells which can crowd out the mature white blood cells, platelets and red blood cells.

"...people with hepatitis C who are heavy smokers have about a 4-fold increased risk for developing NHL."

It is not fully understood how HCV causes NHL. There are theories that the virus might be the causative agent, or that the constant immune system stimula-

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NEBRASKA DONOR REGISTRY:

The state of Nebraska offers an organ donor registry for its residents. The Nebraska registry's web site reports that the death rate while waiting for an organ averages nearly one per hour and that someone joins the organ transplant list approximately every eleven minutes. Did you know that organ donation does not interfere with funeral arrangements or open casket funerals? Another fact is that nearly all major religions in the U.S. endorse organ donation. Many religions consider this an act of charity and a generous gift.

Residents of Nebraska can register online at www.nedonation.org. The state will uphold any documented decision. Potential donors are encouraged to discuss organ donation with their family or others close to them.

NHL

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tion from hepatitis C causes NHL. However, we do know that the incidence of NHL in people with hepatitis C is higher than in the general population.

One very large study from Sweden of 27,150 HCV infected persons found that the incidence of NHL was nearly double in persons with hepatitis C who had been infected with hepatitis C for longer than 15 years. Other studies have found a similar or even a higher risk for HCV-infected patients developing NHL. Smoking cigarettes also has been found to increase the risk of NHL even without hepatitis C. In 2005 a study from Italy linked smoking to the development of NHL. The same study found that people with hepatitis C who are heavy smokers have about a 4-fold increased risk for developing NHL.

In the general population the treatment of NHL consists of chemotherapy. But, as with many HCV-related extrahepatic manifestations treatment also consists of treating the underlying disease – hepatitis C. In fact, some studies have found that interferon with or without ribavirin leads to a remission of NHL especially in people who achieve an SVR. But remission with treatment of interferon only occurred in the hepatitis C group. This further supports the association between HCV and NHL.




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those with HCV genotype 3.

One of the major stories at this year’s conference was a report by Kenneth Lichtenstein and colleagues suggesting that earlier initiation of HAART in HIV mono-infected individuals is associated with better outcomes and fewer adverse side effects. Laure Valerio and colleagues (abstract 891) presented evidence that starting HAART earlier benefits coinfecting patients as well. Using a mathematical model, Valerio’s team estimated that a cohort of coinfecting individuals with a mean age of 37 starting HAART for the first time with a CD4 cell count of 200-350 had a projected life expectancy of 13.21 years (assuming that antiretroviral therapy would remain effective for 10 years). However, life expectancy increased to 14.48 years when HAART was initiated with 350-500 CD4 cells, leading the researchers to conclude that, “Earlier ART initiation is likely to increase life expectancy of HIV/HCV-co-infected patients by at least 1.27 years.”





Stigma: Hepatitis C and Drug Abuse

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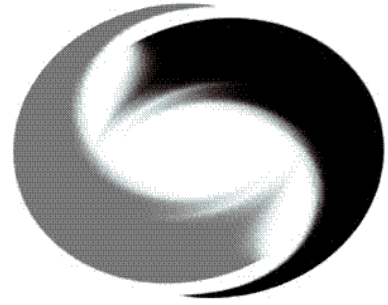
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