



Caring Ambassadors Hepatitis C Program Newsletter May 2008

IN THE NEWS

Hepatitis C clinics needed in state

Never in the history of medicine has a curable chronic infectious disease causing so many deaths been so ignored by government.

<http://newsok.com/hepatitis-c-clinics-needed-in-state/article/3235142/>

“Hepatitis C infects more than 80,000 Oklahomans and often leads to end-stage liver disease requiring liver transplantation or to liver cancer. Deaths due to hepatitis C are underreported and it is likely at least one Oklahoman is dying every day from the consequences of this infection. The majority of those infected are not in the drug culture, but rather everyday citizens. The most famous Oklahoman to die from hepatitis C was Mickey Mantle.” [truncated]

Hepatitis crisis not on Congress' radar

Little interest shown despite CDC warnings of broad implications

<http://www.lvrj.com/news/17255594.html>

“The health crisis created by unsafe practices documented at the Endoscopy Clinic of Southern Nevada has commanded public attention in Las Vegas. But as far as grabbing the lapels of Congress, that is quite another thing. More than a month after warnings went out to 40,000 patients to be tested for HIV and hepatitis strains, Nevada lawmakers are trying to persuade colleagues to take note of the largest notification of its kind in U.S. history. But efforts to interest House and Senate committees to sponsor hearings on the episode in the context of others where questionable activities by doctors led to disease outbreaks have yielded no fruit so far.” [truncated]

New program looks for hepatitis B, C patients for research

<http://www.khnl.com/Global/story.asp?S=8132244>

“HONOLULU -- Hepatitis Support Network of Hawaii and Infections Limited Hawaii created a new program for people with hepatitis B or C who would like to be informed of openings for hepatitis research studies in Hawaii. HOPE Registry Program will help attract clinical trials to Hawaii through rapid enrollment, offer economic advantages to the community and provide new treatments years before they are available for general use. HSNH is offering free testing for hepatitis B and C at a number of locations around the state. For information about testing sites, free hepatitis B vaccinations or to sign up for the HOPE Registry program, call (808) 373-3488 or (808) 221-6204.”

A drug's ability to achieve sustained viral response in genotype 1-infected patients is the most important driver of prescribing decisions for hepatitis C virus treatment

<http://www.pharmalive.com/News/index.cfm?articleid=529360&categoryid=10>

“Decision Resources, one of the world's leading research and advisory firms focusing on pharmaceutical and healthcare issues, finds that a therapy's effect on sustained virologic response in patients infected with genotype 1 hepatitis C virus—for both treatment-naïve and treatment nonresponder patients—is the attribute that most influences gastroenterologists' prescribing decisions in treating the disease. Clinical data and expert opinion shows that Vertex/Johnson & Johnson's telaprevir and Schering-Plough's boceprevir, used in combination with a long-acting interferon-alpha plus ribavirin (Roche's Copegus, Schering-Plough's Rebetol, generics), have advantages in this

attribute over Roche's Pegasys plus ribavirin, the sales leader and current gold standard treatment for the disease.” [truncated]

Government of Canada funds peer support network for people living with hepatitis C virus

<http://www.marketwire.com/mw/release.do?id=841971>

“FORT MCMURRAY, ALBERTA- Brian Jean, Member of Parliament for Fort McMurray - Athabasca, and Parliamentary Secretary to the Minister of Transport, Infrastructure and Communities, today announced, on behalf of Minister of Health Tony Clement, \$13,500 for the Wood Buffalo HIV/AIDS Society to fund a project addressing the hepatitis C virus (HCV) epidemic, including HCV-HIV co-infections. With this funding, the Society will develop a peer-support network to provide a supportive environment for those infected with or affected by HCV in the region.” [truncated]

Slightly abnormal blood test may point to a 'silent' form of hepatitis B

<http://www.physorg.com/news127138588.html>

“Silence isn’t always golden. In the case of hepatitis B, people with a past — and seemingly resolved — infection often don’t know that they still have a silent form of the disorder. Now, new research suggests that slightly abnormal results from a blood test, once thought to be a fleeting curiosity, can tip off doctors to the presence of this potentially infectious and lethal viral renegade.” [truncated]

Liver disease: Partnership would teach, treat Medical centers look into hepatology program

<http://www.lvrj.com/news/17591069.html>

“Three prestigious California medical centers are in serious discussions with the University of Nevada School of Medicine to provide sophisticated treatment of liver disease in Las Vegas. The timing of conversations with Loma Linda University, UCLA and California Pacific Medical Center, which already has a part-time presence in Southern Nevada, isn't coincidental.” [truncated]

Number of hand-outs drops in AIDS needle exchange program

http://www.marini.com/ci_8927531?source=most_email

“Marin health aides last year handed out nearly 80,000 clean syringes, a decline in the number of needles in the free needle-exchange program that targets the spread of AIDS and hepatitis C among local drug users. The fiscal year total reflected the third consecutive annual drop since 2003-04, when the program swapped 95,477 used syringes for clean ones. Officials say the decline may be due in part to a pilot pharmacy program called Syringe Access, in which needles are sold without prescriptions at local pharmacies.” [truncated]

ViroPharma ends development of hepatitis C drug

<http://www.reuters.com/article/marketsNews/idUSBNG8187320080416>

“ViroPharma Inc said it discontinued the development of its experimental hepatitis C drug due to safety concerns. ViroPharma, which was developing the drug, HCV-796, with Wyeth, said it does not expect to continue to collaborate with Wyeth on future development of hepatitis C treatment candidates. The company said the risk associated with potential liver toxicity posed too high a hurdle to merit further development of the drug. ViroPharma halted the mid-stage trial of HCV-796 in August 2007 after some patients developed elevated liver enzymes, a warning signal for liver damage. “

Reid seeks \$26 million for hepatitis scare

Emergency request, a boost in war spending bill, likely to face stiff GOP opposition

<http://www.lasvegassun.com/news/2008/apr/18/reid-seeks-26-million-hepatitis-scare/>

“Senate Majority Leader Harry Reid is seeking \$26 million in emergency funds from Congress to help deal with the hepatitis C crisis in Southern Nevada, but the request will likely run into political resistance from President Bush and congressional Republicans who oppose tacking any extra spending onto a bill for the Iraq war. Even Nevada’s other senator, Republican John Ensign, is against it.” [truncated]

Romark Laboratories initiates phase ii study of nitazoxanide in treatment-naive patients with chronic hepatitis C genotype 1

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/04-18-2008/0004795521&EDATE=>

“Romark Laboratories, a privately held biopharmaceutical company, today announced that it has begun enrolling patients in a U.S. clinical trial to evaluate nitazoxanide for the treatment of chronic hepatitis C. Preliminary data from the study is expected in the second half of 2008.

The study, STEALTH C-3 (Studies to Evaluate Alinia for Treatment of Hepatitis C), is a Phase II randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of nitazoxanide in combination with peginterferon alpha-2a (Pegasys(R), Roche) and ribavirin (Copegus(R), Roche) in treatment naive patients with chronic hepatitis C infected with genotype 1.” [truncated]

Hepatitis C listed as 'deportable' (United Arab Emirates)

<http://www.ameinfo.com/153981.html>

“For everyone in the UAE, new and those that will renew visas, who is tested positive for hepatitis C virus [HCV] will be deported, according to a recent Cabinet approval, cited Gulf News. The new rule takes effect by July 1. The disease is added to the list of other 'deportable' diseases such as HIV, tuberculosis and hepatitis B.”

Telaprevir-based prove studies show significantly higher SVR rates in treatment-naive genotype 1 hepatitis C patients in half the time of current treatments

<http://www.medadnews.com/News/Index.cfm?articleid=533562>

“Vertex Pharmaceuticals Incorporated today announced data from two large Phase 2b clinical trials evaluating the investigational hepatitis C virus (HCV) protease inhibitor telaprevir (VX-950), dosed in combination with pegylated interferon (peg-IFN) and ribavirin (RBV) in treatment-naive, genotype 1-infected HCV patients. Final results from PROVE 1 and further interim analysis from PROVE 2 showed consistently higher SVR rates and antiviral response in the 24-week telaprevir arms -- 61% of patients in PROVE 1 and 68% of patients in PROVE 2 achieving SVR, compared with 41% of patients in the PROVE 1 control arm achieving SVR and 48% of patients in the PROVE 2 control arm having undetectable HCV RNA at 12 weeks post-treatment. These data will be presented at the 43rd Annual Meeting of the European Association for the Study of the Liver in Milan, Italy from April 23-27, 2008.” [truncated]

OctoPlus presents positive Locteron phase IIa study results at EASL conference

<http://www.abnnewswire.net/press/en/50800/OctoPlus.html>

“OctoPlus N.V., the drug delivery and development company, announces that extended results from its successful SELECT-1 Phase IIa clinical trial of Locteron® for the treatment of chronic hepatitis C (HCV) will be presented today at the 43rd Annual Meeting of the European Association for the Study of Liver Diseases (EASL). The poster presentation titled "Viral Kinetics during Treatment

with a Controlled-Release Recombinant Interferon Alfa-2b in Genotype 1 Chronic Hepatitis C Patients" is presented in Category 5h. The study results presented at EASL show a strong and statistically significant effect of Locteron on the amount of HCV virus particles, and this effect increased with higher doses. Patients receiving Locteron experienced side effects that were less frequent and less severe than those previously reported in clinical trials for other interferons. Biomarker results demonstrate Locteron's biological activity with sustained presence of interferon alfa in the body, and showed improvement of liver function in terms of liver enzyme test results." [truncated]

Study shows positive findings in treating patients with advanced hepatitis C

http://www.eurekalert.org/pub_releases/2008-04/bidm-ssp042408.php

“The hepatitis C therapy peginterferon alfa-2b, when given as low-dose maintenance therapy, can prevent disease progression in certain patients who failed previous interferon-based hepatitis C therapies and have advanced liver disease, according to findings from a large, four-year study presented today at the 43rd annual meeting of the European Association for the Study of the Liver (EASL).” [truncated]

Pharmasset adds two cohorts to R7128 hepatitis C study

<http://www.earthtimes.org/articles/show/pharmasset-adds-two-cohorts-to-r7128-hepatitis-c-study,365537.shtml>

“Pharmasset, Inc. will enroll two additional cohorts in the on-going Phase 1 study protocol to evaluate 4 weeks of combination therapy with R7128. R7128, a prodrug of PSI-6130, is a nucleoside analogue polymerase inhibitor of hepatitis c virus (HCV) that is being developed through Pharmasset's collaboration with Roche.” [truncated]

Why the world should ask 'Am I Number 12?'

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/04-24-2008/0004799404&EDATE=>

“Am I Number 12 Viral Campaign for World Hepatitis Day - May 19th 2008. More Than 200 Patient Groups Launch Global Viral Campaign
The World Hepatitis Alliance and over 200 patient groups around the world are asking 'Am I Number 12?' (<http://www.aminumber12.org>) to increase awareness of the shocking statistic that one in 12 people on the planet are living with hepatitis B or hepatitis C and yet the majority of those infected are unaware.” [truncated]

Important progress toward control of hepatitis B and C

<http://www.foxbusiness.com/story/important-progress-control-hepatitis-b-c/>

“Scientists presenting at today's sessions of the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL) reported encouraging findings regarding the potential efficacy of treatment strategies using new drugs designed to combat hepatitis B and C.” [truncated]

Roche's investigational hepatitis C polymerase inhibitor, R1626, demonstrated significant end-of-treatment response in phase IIa study

<http://www.earthtimes.org/articles/show/roches-investigational-hepatitis-c-polymerase,368050.shtml>

“Roche's investigational therapy for chronic hepatitis C virus (HCV) infection, R1626, has shown a significant end-of-treatment response rate when given in combination with PEGASYS(R)

(peginterferon alfa-2a) and COPEGUS(R) (ribavirin). R1626 also shows a high barrier to the development of resistance.” [truncated]

Interim results from boceprevir phase II study in genotype 1 treatment-naive hepatitis C patients presented at EASL

<http://www.foxbusiness.com/story/markets/industries/health-care/interim-results-boceprevir-phase-ii-study-genotype--treatment-naive-hepatitis-c/>

“Schering-Plough Corporation today reported that results from a planned interim analysis of an ongoing Phase II study of boceprevir, its investigational oral hepatitis C protease inhibitor, in 595 treatment-naive patients with chronic hepatitis C virus (HCV) genotype 1 were presented at the 43rd Annual Meeting of the European Association for the Study of the Liver (EASL). The ongoing study evaluates boceprevir in 28-week and 48-week treatment regimens.” [truncated]

BHIVA: No evidence of a hepatitis C epidemic in HIV negative gay men

<http://www.aidsmap.com/en/news/F9C11A12-FB93-487C-AEFB-110C5EC85DF1.asp>

“Data from attendees at a London GUM clinic presented at the 14th BHIVA Conference on Friday suggest that there is no increase in hepatitis C infections amongst HIV negative gay men. The study found that the likelihood of being newly diagnosed with hepatitis C was not significantly greater in gay men than it was in heterosexual men, and hepatitis C infection was much more strongly associated with having HIV than it was with sexual orientation.” [truncated]

Debio 025 in hepatitis C

<http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/04-28-2008/0004800968&EDATE=>

“Debiopharm Group a global independent biopharmaceutical development specialist focusing on serious medical conditions, particularly oncology, presented positive efficacy results of a phase IIa study with Debio 025, a selective cyclophilin (Cyp) inhibitor with a potent in-vitro and in-vivo anti-hepatitis C (HCV) effect. Data indicates that Debio 025 shows an important additive anti-HCV effect when co-administered with pegylated Interferon (Peg-IFN) alpha-2a to treatment-naive HCV patients.” [truncated]

Roche presents favorable data on hepatitis drug Pegasys

http://www.marketwatch.com/news/story/roche-presents-favorable-data-hepatitis/story.aspx?guid=%7B51838D9C-BDAF-499D-BBE2-7DF529D27D1A%7D&dist=msr_2

“Swiss drug company Roche Holding AG said Monday studies of its hepatitis treatment Pegasys shows it to be more effective than a rival, combination therapy. Roche announced that compelling new data from three studies indicate that chronic hepatitis C patients who received PEGASYS plus COPEGUS had a greater chance of being cured of their disease than those who received combination therapy with another pegylated interferon and ribavirin. Results from the studies were presented this week at the 43rd Annual Meeting of the European Association for the Study of the Liver in Milan, Italy. “[truncated]

Hepatitis B an issue 'too hot to handle' (Australia)

<http://www.theaustralian.news.com.au/story/0,25197,23607861-23289,00.html>

“People with the incurable viral illness hepatitis B are missing out on vital services because the disease is seen as a racial hot potato, according to a top Australian virologist who criticised the Government for failing to tackle the problem. Stephen Locarnini, director of the World Health Organisation's Collaborating Centre for Virus Reference and Research in Melbourne, said at an

international meeting of liver specialists in Italy that while HIV and hepatitis C benefited from having patient advocacy groups lobbying, hepatitis B was largely ignored despite affecting almost 200,000 Australians - more than 10 times as many as HIV, and comparable to hepatitis C.”
[truncated]

CLINICAL TRIALS, COHORT STUDIES, PILOT STUDIES

Pegylated alpha-interferon-2a plus ribavirin compared with pegylated alpha-interferon-2b plus ribavirin for initial treatment of chronic hepatitis C virus: Prospective, non-randomized study. Escudero A, et al. J Gastroenterol Hepatol. 2008 Apr 19

http://www.ncbi.nlm.nih.gov/pubmed/18422960?ordinalpos=19&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

Racial differences in the evaluation and treatment of hepatitis c among veterans: A retrospective cohort study.

Rousseau CM, et al. Am J Public Health. 2008 Apr 1

http://www.ncbi.nlm.nih.gov/pubmed/18382007?ordinalpos=104&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

Evaluation of oral cannabinoid-containing medications for the management of interferon and ribavirin-induced anorexia, nausea and weight loss in patients treated for chronic hepatitis C virus. Costiniuk CT, Mills E, Cooper CL. Can J Gastroenterol. 2008 Apr;22(4):376-80.

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Fluvastatin inhibits hepatitis c replication in humans. Bader T, et al. Am J Gastroenterol. 2008 Apr 9

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Peginterferon pharmacokinetics in African American and Caucasian American patients with hepatitis c virus genotype 1 infection. Howell CD, et al. Clin Gastroenterol Hepatol. 2008 Apr 11

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Sustained virological response based on rapid virological response in genotype-3 chronic hepatitis C treated with standard interferon in the Pakistani population. Zuberi BF, et al.

World J Gastroenterol. 2008 Apr 14;14(14):2218-21.

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Risk factors for hepatocellular carcinoma in a Japanese population: a nested case-control study. Ohishi W, et al. Cancer Epidemiol Biomarkers Prev. 2008 Apr;17(4):846-54.

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Obesity is an independent risk factor for hepatocellular carcinoma development in chronic hepatitis C patients. Ohki T, et al. Clin Gastroenterol Hepatol. 2008 Apr;6(4):459-64.

http://www.ncbi.nlm.nih.gov/pubmed/18387499?ordinalpos=89&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

Prospective study of short-term peginterferon-alpha-2a monotherapy in patients who had a virological response at 2 weeks after initiation of interferon therapy. Jeong S, et al. J

Gastroenterol Hepatol. 2008 Apr;23(4):541-5.

http://www.ncbi.nlm.nih.gov/pubmed/18397484?ordinalpos=58&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

Clinical trial: exposure to ribavirin predicts EVR and SVR in patients with HCV genotype 1 infection treated with peginterferon alfa-2a plus ribavirin. Bain VG, et al. Aliment Pharmacol Ther. 2008 Apr 7

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Predictors of a sustained virological response in patients with genotype 4 chronic hepatitis C. Gad RR, et al. Liver Int. 2008 Apr 5

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Eight-week regimen of antiviral combination therapy with peginterferon and ribavirin for patients with chronic hepatitis C with hepatitis C virus genotype 2 and a rapid virological response. Toyoda H, et al. Liver Int. 2008 Apr 1

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A randomized intervention trial to reduce the lending of used injection equipment among injection drug users infected with hepatitis c. Latka MH, et al. Am J Public Health. 2008 Apr 1

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The impact of chronic hepatitis C and co-morbid illnesses on health-related quality of life.

Kwan JW, et al. Qual Life Res. 2008 Apr 22

http://www.ncbi.nlm.nih.gov/pubmed/18427949?ordinalpos=12&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

Hepatitis C patients' self-reported adherence to pegylated interferon and ribavirin. Weiss JJ, et al. Aliment Pharmacol Ther. 2008 Apr 16

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BASIC AND APPLIED SCIENCE, PRE-CLINICAL STUDIES

Selection of Replicon Variants Resistant to ACH-806, a Novel Hepatitis C Virus Inhibitor with No Cross-Resistance to NS3 Protease and NS5B Polymerase Inhibitors. Yang W, et al. Antimicrob Agents Chemother. 2008 Apr 14

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Mitochondrial electron transport inhibition in full genomic hepatitis C virus replicon cells is restored by reducing viral replication. Ando M, et al. *Liver Int.* 2008 Apr 10

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Evaluation of the Versant HCV genotype assay (LIPA) 2.0. Verbeeck J, et al. *J Clin Microbiol.* 2008 Apr 9

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Insulin resistance and lichen planus in patients with HCV-infectious liver diseases. Nagao Y, Kawasaki K, Sata M. *J Gastroenterol Hepatol.* 2008 Apr;23(4):580-5.

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Insulin resistance and hepatitis C virus: a case-control study of non-obese, non-alcoholic and non-steatotic hepatitis virus carriers with persistently normal serum aminotransferase.

Tanaka N, et al. *Liver Int.* 2008 Apr 5

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Long-term outcome of percutaneous ethanol injection therapy for minimum-sized hepatocellular carcinoma. Taniguchi M, et al. *World J Gastroenterol.* 2008 Apr 7;14(13):1997-2002.

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Retrospective evaluation of serum markers APRI and AST/ALT for assessing liver fibrosis and cirrhosis in chronic hepatitis B and C patients with hepatocellular carcinoma. Lin CS, et al. *Intern Med.* 2008;47(7):569-75.

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Non-invasive prediction of the degree of liver fibrosis in patients with hepatitis C using an ultrasound contrast agent. A pilot study. Searle J, et al. J Med Imaging Radiat Oncol. 2008 Apr;52(2):130-3.

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Des-gamma-carboxyprothrombin, alpha-fetoprotein and AFP-L3 in patients with chronic hepatitis, cirrhosis and hepatocellular carcinoma. Durazo FA, et al. J Gastroenterol Hepatol. 2008 Apr 19

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Key steps in the structure-based optimization of the hepatitis C virus NS3/4A protease inhibitor SCH503034. Madison V, et al. J Synchrotron Radiat. 2008 May;15(Pt 3):204-7. Epub 2008 Apr 18.

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HIV/HCV COINFECTION

Improving HIV screening and receipt of results by nurse-initiated streamlined counseling and rapid testing. Anaya HD, et al. J Gen Intern Med. 2008 Apr 18

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Impact of HIV on host-virus interactions during early hepatitis c virus infection. Danta M, et al. J Infect Dis. 2008 Apr 17

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Prevalence and clinical relevance of occult hepatitis B in the fibrosis progression and antiviral response to INF therapy in HIV-HCV coinfecting patients. Laguno M, et al. AIDS Res Hum Retroviruses. 2008 Apr 8 [Epub ahead of print]

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HCV NS3/4A protein activates HIV-1 transcription from its long terminal repeat.

Wu X, et al. Virus Res. 2008 Apr 21

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Extremely high prevalence and genetic diversity of hepatitis C virus infection among HIV-infected injection drug users in Taiwan.

Liu JY, et al. Clin Infect Dis. 2008 Apr 23

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Similar hepatitis C virus RNA kinetics in HIV/hepatitis C virus monoinfected genotype 2 or 3 matched controls during hepatitis C virus combination therapy. Olle K, Anders S, Ola W.

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Insulin resistance impairs rapid virologic response in HIV/hepatitis C virus coinfecting patients on peginterferon-alfa-2a. Nasta P, et al. AIDS. 2008 Apr 23;22(7):857-61

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Impact of HIV on host-virus interactions during early hepatitis C virus infection. Danta M, et al. J Infect Dis. 2008 Apr 17

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EPIDEMIOLOGY, DIAGNOSTICS, AND MISCELLANEOUS WORKS

Hepatitis C patients' self-reported adherence to pegylated interferon and ribavirin.

Weiss JJ, et al. Aliment Pharmacol Ther. 2008 Apr 16

http://www.ncbi.nlm.nih.gov/pubmed/18419757?ordinalpos=7&itool=Email.EmailReport.Pubmed_ReportSelector.Pubmed_HVDocSum

The burden of hepatitis C virus infection is growing: A Canadian population-based study of hospitalizations from 1994 to 2004. Myers RP, Liu M, Shaheen AA. Can J Gastroenterol. 2008

Apr;22(4):381-7.

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Impact of chewing betel-nut (*Areca catechu*) on liver cirrhosis and hepatocellular carcinoma: a population-based study from an area with a high prevalence of hepatitis B and C infections. Wu GH, et al. Public Health Nutr. 2008 Apr 15;11:1-7

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Prospective evaluation of transient elastography for the diagnosis of hepatic fibrosis in Asians: comparison with liver biopsy and aspartate transaminase platelet ratio index (APRI). Chang JP, et al. Aliment Pharmacol Ther. 2008 Apr 11
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