KY Hepatitis Connections

We are pleased to share with you the June issue of *KY Hepatitis Connections*. The *KY Hepatitis Connections* provides current information, opportunities for viral Hepatitis continuing professional education and information about educational materials available.

Please feel free to forward and/or copy and distribute to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral Hepatitis and its impact on our families throughout the Commonwealth.

Kathy Sanders, RN MSN

The Dark Side of Telaprevir By Nicole Cutler L.Ac.

In the spring of 2011, the arrival of telaprevir (INCIVEK) on the market seemed to be a big win for the Hepatitis C community. Approved by the FDA to treat Hepatitis C in unison with interferon and ribavirin, telaprevir appeared to improve treatment success rates in a shorter period of time without adding any substantial safety concerns. However, it was just a matter of time before the safety profile of telaprevir showed its true colors.

Developing new drugs for a hard-to-treat illness like chronic Hepatitis C is far from a simple process:

1. Experiments and analysis suggest potential new drugs.
2. An educated hypothesis is made.
3. Millions of dollars in research and development back the hypothesis.
4. Data is collected and analyzed.
5. If proven safe and effective, the task of getting the drug approved and available to the public begins.

Read More at: http://www.hepatitis-central.com/mt/archives/2013/04/the-dark-side-of-telaprevir.html?eml=hepcen183&utm_source=iContact&utm_medium=email&utm_campaign=Hepatitis%20Cenral&utm_content=HepCen+%23183+A

New Hepatitis C Drug Continues Curing In Clinical Trials

As clinical trials continue to show positive results, sofosbuvir seems to be poised to gain FDA approval. BY JONATHAN WEISS | APR 24, 2013 01:19 PM EDT

Coming on the heels of a recent report indicating that the Hepatitis C drug sofosbuvir surpassed expectations, a Phase III clinical trial out of Weil Cornell Medical Center in New York City has shown that the result of using the drug cures most patients with two subtypes of the virus.

A new drug awaiting FDA approval seems to have high cure rates in clinical trials.

"The new sofosbuvir therapy offers a much-needed alternative to standard therapy with interferon, which can cause significant side effects for hepatitis C patients," says the study's lead investigator, Dr. Ira Jacobson, chief of the Division of Gastroenterology and Hepatology and Vincent Astor Distinguished Professor of Medicine at Weill Cornell Medical College.

Read more at: http://www.medicaldaily.com/articles/14872/20130424/new-hepatitis-c-drug-continues-cure-clinical-sofosbuvir.htm

CDC Urges Second Test to Catch Hepatitis C Infection.

UNITED STATES :: Viral Hepatitis Medscape Medical News (05.07.2013) :: By Robert Lowes

Following an eight-site study, CDC recommends that all people who test positive for hepatitis C virus (HCV) also should have an HCV RNA test to find out whether they have cleared the virus or they still have it. Approximately 20 percent of HCV-infected people get well without treatment. Since HCV has few symptoms, infected people may not realize they are sick for many years. Untreated HCV, which causes 15,000 deaths each year, can lead to liver damage and liver cancer, the "fastest-growing cause of cancer-related deaths" in the United States.

CDC also recommends that all American baby boomers, people born between the years 1945 to 1965, have an HCV test. CDC Director Thomas Frieden, MD, MPH reported that most of the HCV-infected people identified in the eight-site study (67.2 percent) were baby boomers. This cohort also comprised the majority (72 percent) of HCV-related deaths. Approximately 3 million American adults have HCV, according to CDC, although up to 75 percent of this number do not realize they have the virus. Frieden advised that new HCV treatments are more effective in curing the infection and preventing transmission of the virus.

The full report, "Vital Signs: Evaluation of Hepatitis C Virus Infection Testing and Reporting—Eight U.S. Sites, 2005–2011," was published online in the Morbidity and Mortality Weekly Report at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm62e0507a1.htm.

Working Human Liver Tissue Created with 3D-Bioprinting. By Mark Hoffman

3D bioprinted human liver tissue was successfully created by the company Organovo, revealed at the annual Experimental Biology conference this week in Boston. The in-vitro mini-livers are just half a millimetre deep and 4 millimetres across but can perform most functions of the real thing. To create them, a printer builds up about 20 layers of hepatocytes and stellate cells – two major types of liver cell. Crucially, it also adds cells from the lining of blood vessels. These form a delicate mesh of channels that supply the liver cells with nutrients and oxygen, allowing the tissue to live for five days or longer. The cells come from spare tissue removed in operations and biopsies. Continue reading this entire article: http://www.scienceworldreport.com/articles/6477/20130425/3d-bioprinted-human-liver-tissue-functional-replacement-organs-goal.htm

Hep C Triple Drug Combo Effective Without Interferon or Ribavirin

Daclatasvir/asunaprevir/NS5B inhibitor effective in treatment-naive HCV patients April 30, 2013

Treatment-naive patients with chronic hepatitis C experienced high rates of sustained virologic response from a combination of three direct-acting antivirals in a study presented at the International Liver Congress in Amsterdam.

In an open-label phase 2 study, researchers randomly assigned 32 treatment-naive patients with chronic HCV genotype 1 to 60 mg NS5A inhibitor daclatasvir (DCV) once daily, 200 mg protease inhibitor asunaprevir (ASV) twice daily and 75 mg non-nucleoside NS5B inhibitor BMS-791325 twice a day for 24 or 12 weeks (n=16 each). A second cohort was later assigned DCV, ASV and 150 mg BMS-791325 (Bristol-Myers Squibb) for 24 (n=16) or 12 weeks (n=18).Continue reading this entire article: http://www.healio.com/hepatology/chronic-hepatitis/news/online/%7B9073D629-ADD8-412C-A8A6-EA7A3A55FC6E%7D/DaclatasvirasunaprevirNS5B-inhibitor-effective-in-treatment-naive-HCV-patients

Study Shows Simeprevir Improves Hep C Therapy.

Addition of simeprevir to peginterferon/ribavirin improves SVR rate among HCV patients May 1, 2013

Simeprevir improves rates of sustained virologic response and may allow for a 24-week treatment duration when added to interferon-based therapy for chronic hepatitis C, according to data presented at the International Liver Congress in Amsterdam.

In the double blind, phase 3 QUEST-1 study, researchers randomly assigned 394 treatment-naive patients with HCV genotype 1 to either 150 mg oral HCV NS3/4A protease inhibitor simeprevir or placebo, for 12 weeks, plus 48 weeks of pegylated interferon alfa-2a with ribavirin (PR). Patients with HCV RNA below 25 IU/mL after 4 weeks of treatment and undetectable RNA at 12 weeks stopped treatment at 24 weeks. All placebo recipients received 48 weeks of PR therapy. Continue reading this entire article: http://www.healio.com/hepatology/chronic-hepatitis/news/online/%7B0BDBD39D-184B-496C-AFA97338569379F3%7D/Addition-of-simeprevir-to-peginterferonribavirin-improves-SVR-rate-among-HCVpatients

New: Free Online Tool & Training available to Hepatitis C health care providers of all levels

Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C)

The PREP-C provides Hepatitis C health care providers of all levels a standardized method for assessing a patient's readiness to begin HCV treatment. By identifying psychosocial factors that can potentially interfere with treatment adherence prior to treatment initiation, health care providers have the opportunity to provide support and interventions in order to improve psychosocial stability so that treatment is most tolerable and successful.

How to use the PREP-C

- The PREP-C interactive assessment tool is now available online free of charge for health care providers to use with their patients. Learn more: www.PREPC.org
- The PREP-C can also be used as a training for health care providers of all levels who seek to understand the ideal elements involved in a comprehensive HCV pre-treatment psychosocial evaluation.

Monthly PREP-C Training & Discussion Tele-conference calls are conducted free of charge. Learn more and register at www.PREPC.org

The PREP-C was developed by Jeffrey J. Weiss, PhD, MS, Mount Sinai School of Medicine, New York, New York; Carolyn A. Licht, PhD, SUNY Downstate Research Foundation, Brooklyn, New York; Nirah Johnson, LMSW, NYC Department of Health & Mental Hygiene, Office of Viral Hepatitis Coordination, Long Island City, New York.

NEW CME CREDITS AVAILABLE

HCV Diagnosis and Evaluation

Click the buttons below to view the presentation.

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HIV/HCV Coinfection

HIV/HCV Coinfection

To obtain the available twelve (12) CME credit hours, you must review the entire conference proceedings and complete the CME test and evaluation.

You can also visit our website at www.PracticePointHIV.com to access this video update as well as other certified CME/CE opportunities.

Now compatible with mobile devices including smartphones, tablets and pads.

https://www.practicepointhiv.com/Login/tabid/160/Default.aspx?returnurl=%2fArticleView%2ftabid%2f69%2fArticleId%2f123%2f2013-Optimal-Management-of-HIV-and-Hepatitis-Clinical-Conference-XXI.aspx

Ryan White Program Addressing Co-infection with Viral Hepatitis

May 2, 2013
By Rupali K. Doshi, MD, MS, Medical Officer, HIV/AIDS Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services and Laura W. Cheever, MD, ScM, Acting Associate Administrator, HIV/AIDS Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services

For many years the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) has worked to increase access to hepatitis C treatment for HIV-infected patients in Ryan White-funded programs.

This attention is warranted given that, according to the *Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, an estimated 33% of persons living with HIV are coinfected with the hepatitis B virus (HBV) or hepatitis C virus (HCV). Further, the progression of viral hepatitis is accelerated among persons with HIV; therefore, persons who are coinfected with HIV and HCV experience greater liver-related health problems than non-HIV infected persons. The CDC also notes that while "antiretroviral therapy has extended the life expectancy of people living with HIV (PLWH), liver disease—much of which is related to hepatitis B and C infection—has become the leading cause of non-AIDS-related deaths among this population."

Hepatitis C Treatment Expansion Initiative

One important initiative is the Hepatitis C Treatment Expansion Initiative. Funded by HRSA/HAB as a Special Project of National Significance (SPNS), this initiative supports two groups of Ryan White program grantees that have received $80,000 per year for two years to test a new model of integrating hepatitis C treatment into their clinical practice. The overall goal of the initiative is to enable sites to increase the number of co-infected patients treated for hepatitis C.

http://blog.aids.gov/2013/05/ryan-white-program-addressing-coinfection-with-viral-hepatitis.html

American Liver Foundation: Launch of Web-Based National Healthcare Provider Resource Locator

The American Liver Foundation's National Office is pleased to announce the launch of a Web-based national healthcare provider resource locator. The healthcare provider resource locator is a major component of the HepC123 Program, a comprehensive patient and caregiver education and support service for those affected by Hepatitis C.

The healthcare provider resource locator can be found here http://hepc.liverfoundation.org/find-a-healthcare-provider/. The locator is intended to assist patients and their families affected by liver disease, to find a local liver specialist.

Data sources that were used to populate the existing database include the American College of Gastroenterology, Centers for Medicare and Medicaid and the Health and Human Services. Healthcare provider information found in the healthcare provider resource locator is limited to individual physicians and/or practices that treat those affected by liver disease, including viral hepatitis. In an effort to be as comprehensive as possible, we want to ensure that ALF's premier volunteers, or medical advisory committee members, are included in this invaluable patient resource.

New Antiviral Treatment Could Significantly Reduce Global Burden of Hepatitis C

Scientists show potential impact of therapy in reducing transmission in UK, Canada and Australia May 6, 2013

Around 150 million people globally are chronically infected with the hepatitis C virus (HCV) -- a major cause of liver disease and the fastest growing cause of liver transplantation and liver cancer. New prevention strategies are urgently required as people are continuing to be infected with HCV. Findings, published in Hepatology, reveal the impact of a new antiviral treatment that could potentially reduce HCV rates in some cities affected by chronic HCV prevalence by half over 15 years.

In Europe, the US, and other developed countries the majority of HCV infections occur among people who inject drugs (PWID). Although current prevention strategies, which are based on needle and syringe programs and opiate substitution therapy, can avert HCV infections and have reduced its prevalence in some cities from the very high levels that occurred in the 1980s, these interventions are unlikely alone to achieve further substantial reductions.
HCV treatment as prevention has been proposed as a possible solution. However, while current HCV antiviral treatment of pegylated-interferon and ribavirin can cure approximately 60 per cent of people treated, they are poorly tolerated, long in duration (five to 11 months), and have a low take-up among PWID. Continue reading this entire article: http://www.hepctrust.org.uk/News_Resources/news/2013/May/Direct+acting+Antivirals+Could+Dramatically+Reduce+Hepatitis+C+Transmission+among+IDUs

Adverse Events Common With Triple Therapy in HCV Cirrhosis

Reuters May 22, 2013 - By David Douglas

In cirrhotic patients, triple-therapy against hepatitis C virus (HCV) produces a high virological response rate, but at the cost of a high rate of serious adverse events, French researchers say.

In the French CUPIC cohort, four in ten cirrhotic patients on triple therapy with pegylated interferon and ribavirin plus boceprevir or telaprevir suffered a serious complication (death, severe infection, or hepatic decompensation). This cohort, Dr. Christophe Hézode told Reuters Health by email, consisted of "HCV genotype 1 treatment-experienced patients with compensated cirrhosis."

In a May 13th online paper in The Journal of Hepatology, Dr. Hézode of Universite Paris-Est, Creteil and colleagues say phase III trials have yielded similar results in treatment-experienced cirrhotics and non-cirrhotics, but patients were highly selected.

To evaluate the effect in "real-world" patients, the team analyzed 497 patients who reached at least week 16 in a 48-week triple therapy early access program. All had previously received interferon.

Forty percent (199 patients) had serious adverse events, with 58 patients stopping their treatment as a result. Refractory anemia was also common. Six patients died and another 32 (6.4%) had severe infection or hepatic decompensation or another serious event. Continue reading this entire article:
http://www.hepctrust.org.uk/News_Resources/news/2013/May/Adverse+Events+Common+With+Triple+Therapy+in+HCV+Cirrhosis

DDW 2013: Advanced Fibrosis Does Not Affect Response to Faldaprevir All-oral Regimen

5/22/13

An interferon-free combination of faldaprevir, BI 207127, and ribavirin produced high and similar sustained response rates for treatment-naive genotype 1b hepatitis C patients with either absent-to-moderate liver fibrosis or advanced fibrosis/cirrhosis, according to a presentation at the Digestive Disease Week conference (DDW 2013) this week in Orlando.

The introduction of direct-acting antiviral agents (DAAs) has changed the treatment paradigm for chronic hepatitis C, but even with second-generation drugs, treatment can be challenging for difficult-to-treat patients including people with advanced fibrosis or cirrhosis.

The SOUND-C2 study was an open-label Phase 2b trial that evaluated all-oral regimens containing the HCV protease inhibitor faldaprevir (formerly BI 201335) dosed at 120 mg once-daily, plus the polymerase inhibitor BI 207127 at 600 mg twice-daily (BID) or 3-times-daily (TID), with or without ribavirin, taken for 16, 28, or 40 weeks.

As reported at the AASLD Liver Meeting last November, rates of sustained virological response at 12 weeks post-treatment (SVR12) were unimpressive overall compared with some other interferon-free regimens -- 52% to 69% in the ribavirin-containing arms -- but reached 85% for patients with easier-to-treat HCV subtype 1b (the ribavirin-free arm was halted early due to lower efficacy). Patients with cirrhosis generally did well, but represented only about 9% of the study population. Continue reading this entire article:

http://hivandhepatitis.com/hepatitis-c/hepatitis-c-topics/hcv-treatment/4114-ddw-2013-advanced-fibrosis-does-not-affect-response-to-faldaprevir-all-oral-regimen

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