Spring time… after this long winter, spring will soon be here! We are pleased to share with you the March 2014 issue of KY Hepatitis Connections. The KY Hepatitis Connections provides current information about viral hepatitis, 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.

Please follow us on Facebook at KY Viral Hepatitis.

Kathy Sanders, RN MSN
REMINDER:

**Hepatitis C: Perinatal and Children Aged Five Years or Less**

The Kentucky Department for Public Health sent letter in December 2013 requesting the assistance of Kentucky Healthcare Providers with an active surveillance project to help us estimate the number of pregnant women and children aged five years and less who are infected with hepatitis C virus (HCV), and seen in birthing hospitals, medical practices, and clinics throughout the Commonwealth.

In Kentucky, only acute hepatitis C cases are normally required to be reported. Starting January 1, 2014 through March 31, 2014, we are asking for healthcare providers to voluntarily report: 1) all HCV-positive pregnant women; 2) all infants born to HCV-positive women; and 3) all HCV-positive infants and children aged five years or less seen in birthing hospitals, medical practices, and clinics, in addition to the current hepatitis B infection reporting requirements in these populations. To report any HCV-positive individuals in the above categories during this time period, please complete the reporting form at the end of this newsletter and fax to the Kentucky Department for Public Health at: 502-564-4760. This letter and reporting form were distributed to KY healthcare providers in December 2013.

We deeply appreciate your time and effort in assisting us with this active surveillance project for perinatal HCV infections. If you have additional questions or concerns, please call Kathy Sanders, RN, MSN at 502-564-3261, ext. 4236 or Julie Miracle, RN, BSN at 502-564-4478, ext. 4260.

Hospital Infection Preventionists: Please distribute to medical providers, nursing staff, and other health-care personnel in Emergence Medicine, Critical Care, Laboratory Medicine, Infectious Diseases, Obstetrics, Newborn Nursery, NICU, Pediatrics, Internal Medicine, Family Medicine, and Primary Care or Ambulatory Care.

LHD staff: Please distribute to community healthcare providers in Infectious Diseases, Obstetrics, Pediatrics, Internal Medicine, Family Medicine, and Primary Care or Ambulatory Care and to FQHCs and RHCs.
Patient Advocate Foundation Announces Co-Pay Relief (CPR) Support for Patients Living with Hepatitis C

Patient Advocate Foundation (PAF) announced in February the expansion of its Co-Pay Relief (CPR) program with the opening of the Hepatitis C disease silo. The program is supported through a generous donation of 5 million dollars, this CPR program silo provider’s financial support for pharmaceutical co-payments for insured patients who are facing financial distress and are unable to afford their costs associated with treatment for the virus. "Management of Hepatitis C is extremely challenging for patients as most need ongoing medication to reduce their chance of liver damage or liver cancer. It is in these cases that a patient’s survival and overall health can be jeopardized if he or she is unable to access pharmaceutical treatment and therapies required to control the virus," said Alan Balch, PhD, CEO of PAF. "We are grateful for the significant support we have received for the Hepatitis C silo which allows us to expand our Co-Pay Relief Program in such a meaningful way." The donation allows PAF to provide financial support to Hepatitis C patients ensuring their access to the treatments that can restore balance to their health and markedly improve their quality of life. Qualified patients, whose applications are approved, are eligible for up to $3,000 per year in copayment assistance through the program.

Read more here: http://www.sacbee.com/2014/02/05/6130152/patient-advocate-foundation-announces.html#storylink=cpy

AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C

New direct-acting oral agents capable of curing hepatitis C virus (HCV) infection have been approved for use in the United States. The initial direct-acting agents were approved in 2011, and many more oral drugs are expected to be approved in the next few years. As new information is presented at scientific conferences and published in peer-reviewed journals, health care practitioners have expressed a need for a credible source of unbiased guidance on how best to treat their patients with HCV infection. To provide healthcare professionals with timely guidance, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in collaboration with the International Antiviral Society-USA (IAS-USA) have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management.

New sections will be added, and the recommendations will be updated on a regular basis as new information becomes available. An ongoing summary of "recent changes" will also be available for readers who want to be directed to updates and changes.

Read More: http://www.hcvguidelines.org/
Treatment of Patients With Dual Hepatitis C Virus and Hepatitis B Virus Infection

Abstract

Dual hepatitis C virus (HCV)/hepatitis B virus (HBV) infection is not uncommon in HCV or HBV endemic areas and among subjects at risk of parenteral transmission. In patients dually infected with hepatitis C and B, the disease manifestations are usually more severe than those with either virus infection. In the past decade, the following issues have been resolved. In dually infected patients with active hepatitis C, combined pegylated interferon alfa plus ribavirin was effective, the treatment outcomes being similar to patients with HCV monoinfection. During long-term follow-up, the HCV response was sustained in around 97% of patients; and the long-term outcomes including the development of hepatocellular carcinoma and liver-related mortality were improved. However, several clinical issues remain to be resolved. First, host and viral factors influencing the long-term outcomes and treatment options in patients with dual HCV/HBV infection await further studies. Second, about 60% of dually infected patients with baseline undetectable serum HBV DNA levels develop HBV reactivation after the start of treatment. How to prevent and treat HBV reactivation should be clarified. Third, about 30% of dually infected patients lose hepatitis B surface antigen at 5 years after the end of combination therapy; the mechanisms need further investigations. Fourth, the optimal treatment strategies for dually infected patients with active hepatitis B or established cirrhosis should be explored in future clinical trials. Finally, the role of new direct-acting antiviral-based therapy for the treatment of patients with dual HCV/HBV infection also remains to be evaluated.


Killing Pain: Fewer Opioid Scripts

Doctors and other health providers wrote about 11 million fewer prescriptions for narcotic painkillers in 2013 than in 2012, but some experts expected a bigger drop-off given the brighter spotlight on the nation’s opioid epidemic.

In 2013, there were 230 million prescriptions for opioids such as Vicodin, OxyContin and Percocet, according to data from IMS Health, a drug market research firm. That represents about a 5% drop from a year earlier when 241 million were written. Opioid prescriptions had grown substantially since the 1990s. Read More: http://www.medpagetoday.com/PainManagement/PainManagement/44499?isalert=1&uun=g418265d818R5517831u&utm_source=breaking-news&utm_medium=email&utm_campaign=breaking-news&xid=NL_breakingnews_2014-02-27
Decoding cell death signals in liver inflammation

Inflammation can be either beneficial or detrimental to the liver, depending on multiple factors. Mild (i.e., limited in intensity and destined to resolve) inflammatory responses have indeed been shown to exert consistent hepatoprotective effects, contributing to tissue repair and promoting the re-establishment of homeostasis. Conversely, excessive (i.e., disproportionate in intensity and permanent) inflammation may induce a massive loss of hepatocytes and hence exacerbate the severity of various hepatic conditions, including ischemia-reperfusion injury, systemic metabolic alterations (e.g., obesity, diabetes, non-alcoholic fatty liver disorders), alcoholic hepatitis, intoxication by xenobiotics and infection, de facto being associated with irreversible liver damage, fibrosis, and carcinogenesis. Both liver-resident cells (e.g., Kupffer cells, hepatic stellate cells, sinusoidal endothelial cells) and cells that are recruited in response to injury (e.g., monocytes, macrophages, dendritic cells, natural killer cells) emit pro-inflammatory signals including – but not limited to – cytokines, chemokines, lipid messengers, and reactive oxygen species that contribute to the apoptotic or necrotic demise of hepatocytes. In turn, dying hepatocytes release damage-associated molecular patterns that upon binding to evolutionary conserved pattern recognition receptors-activate cells of the innate immune system to further stimulate inflammatory responses, hence establishing a highly hepatotoxic feedforward cycle of inflammation and cell death. In this review, we discuss the cellular and molecular mechanisms that account for the most deleterious effect of hepatic inflammation at the cellular level, that is, the initiation of a massive cell death response among hepatocytes.

Read More: http://www.journal-of-hepatology.eu/article/S0168-8278(13)00213-4/fulltext

Interferon-stimulated genes and their role in controlling hepatitis C virus

Infections with the hepatitis C virus (HCV) are a major cause of chronic liver disease. While the acute phase of infection is mostly asymptomatic, this virus has the high propensity to establish persistence and in the course of one to several decades liver disease can develop. HCV is a paradigm for the complex interplay between the interferon (IFN) system and viral countermeasures. The virus induces an IFN response within the infected cell and is rather sensitive against the antiviral state triggered by IFNs, yet in most cases HCV persists. Numerous IFN-stimulated genes (ISGs) have been reported to suppress HCV replication, but in only a few cases we begin to understand the molecular mechanisms underlying antiviral activity. It is becoming increasingly clear that blockage of viral replication is mediated by the concerted action of multiple ISGs that target different steps of the HCV replication cycle. This review briefly summarizes the activation of the IFN system by HCV and then focuses on ISGs targeting the HCV replication cycle and their possible mode of action.

Read More: http://www.journal-of-hepatology.eu/article/S0168-8278(13)00548-5/fulltext
Does occult HBV infection have an impact on the evolution of chronic hepatitis C?

Viral co-infections with HBV or HIV are well known to aggravate the evolution of chronic hepatitis C (CHC). With respect to HBV, although the impact of overt infection has been well characterized, the role of occult HBV infection (OBI) on the outcome of CHC remains elusive [1], [2]. OBI are mainly defined by the persistence of HBV genome in the liver of individuals testing negative for HbsAg [1]. The mechanisms by which the persistence of the viral genome is not associated with a full expression of viral antigens and viral replication are still partially known [3]. The pathobiological and clinical consequences of HBV genome persistence as an OBI, whether as a mono-infection or as a co-infection with HCV, include an increased severity of liver disease and an increased risk of HCC [4]. However, most of the published studies were cross-sectional and were therefore subjected to potential bias in patient selection.

OBI is highly prevalent in patients with CHC, at least in areas of high HBV prevalence. Whether OBI might negatively influence CHC clinical outcome, favoring its progression toward cirrhosis, has been largely debated for many years. Controversies remains on the possible prooncogenic role exerted by OBI, particularly in CHC patients [5]. A recent meta-analysis suggested that OBI increases the risk of hepatocellular carcinoma (HCC) development in both HCV and non-HCV infected patients [6], but other studies performed in North America did not find such an association [7].

One main reason for the discussion of the possible contribution of OBI to a more severe evolution of CHC is the lack of longitudinal studies evaluating the clinical outcome of HCV patients according to the status of OBI during a sufficient period of observation to allow clinical events to occur. Read More: http://www.journal-of-hepatology.eu/article/S0168-8278(13)00455-8/fulltext

Alliance pushes Congress on payment for telemedicine

WASHINGTON – Medicare should cover telemedicine services regardless of geography, and physicians who use the technologies should be paid appropriately by all health insurers.

Those are among the goals of the Alliance for Connected Care, led by three formers leaders of the U.S. Senate. Read More: http://www.internalmedicineonews.com/specialty-focus/practice-trends/single-article-page/alliance-pushes-congress-on-payment-for-telemedicine/010b407e91b89fbcfa8b3e7ca30ae09.html

Cincinnati Needle Exchange Program Launches In RV

The first syringe exchange program in Hamilton County launched Feb. 10 in a Springdale shopping center, and the medical RV being used to combat the spread of HIV and hepatitis by heroin addicts could travel to other communities. Called the Cincinnati Exchange Project, the public health initiative also is intended to encourage addicts to enter drug rehab programs, according to Dr. Judith Feinberg, a professor of internal medicine at the University of Cincinnati who is medical director of the project.

Olysio, New Hepatitis C Therapy, Approved by FDA

The FDA has approved a new protease inhibitor to treat adult patients with chronic hepatitis C virus (HCV) genotype 1 infection. Janssen Therapeutics’ Olysio (simeprevir) is approved for use in combination with pegylated interferon (PEG-IFN)-alfa and ribavirin for treatment-naive patients as well as patients for whom previous HCV antiviral therapies were ineffective.

“Olysio is the third FDA-approved protease inhibitor to treat chronic HCV infection,” said Edward Cox, MD, director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research, in an FDA statement. “[It] provides health professionals and patients with a new, effective treatment for this serious disease.”

In its approval, the FDA cited safety and efficacy data from more than 2,000 patients in several placebo-controlled clinical trials: QUEST-1 and QUEST-2, which included treatment-naive patients with compensated liver disease, and PROMISE, which included patients who relapsed or for whom earlier treatment with PEG-IFN had failed. All patients in these studies received PEG-IFN and ribavirin in combination with simeprevir or a placebo. In the QUEST trials, 80% of patients who were treated with simeprevir achieved sustained virologic response (SVR) compared with 50% of patients in the placebo group. Similarly, in the PROMISE study, 79% of patients in the treatment group achieved SVR compared with 37% of patients in the control group.


Gilead Files for U.S. Approval of Ledipasvir/Sofosbuvir Fixed-Dose Combination Tablet for Genotype 1 Hepatitis C

If Approved, Fixed-Dose Combination Would be First Oral Treatment Regimen for Patients with Genotype 1 HCV Infection, Eliminating Need for Both Interferon and Ribavirin --

On February 10, 2014 announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for a once-daily fixed-dose combination of the NS5A inhibitor ledipasvir (LDV) 90 mg and the nucleotide analog polymerase inhibitor sofosbuvir (SOF) 400 mg for the treatment of chronic hepatitis C genotype 1 infection in adults. The data submitted in the NDA support the use of LDV/SOF in patients with genotype 1 hepatitis C virus (HCV) infection, with a treatment duration of eight or 12 weeks depending on prior treatment history and whether they have cirrhosis. Approximately 75 percent of people infected with HCV in the United States have the genotype 1 strain of the virus.

Newly found tactics in offense-defense struggle with hepatitis C virus

The hepatitis C virus (HCV) has a previously unrecognized tactic to outwit antiviral responses and sustain a long-term infection. It also turns out that some people are genetically equipped with a strong countermeasure to the virus' attempt to weaken the attack on it.

The details of these findings suggest potential targets for treating HCV, according to a research team led by Dr. Ram Savan, assistant professor of immunology at the University of Washington. The study was published in *Nature Immunology*.

Read More: http://www.sciencecodex.com/newly_found_tactics_in_offense-defense_struggle_with_hepatitis_c_virus-127583

FDA Gives Bristol-Myers' Hepatitis Drug 'Breakthrough' Designation

Bristol-Myers Squibb’s (BMY) investigational treatment for hepatitis C infection was awarded “breakthrough therapy designation” on Monday by U.S. drug regulators.

The U.S. Food and Drug Administration has only approved four breakthrough therapies since the FDA’s Safety and Innovation Act was signed into law in July 2012.

The rare designation is intended to expedite the development and review process of drugs for serious or life-threatening conditions. These drugs are put on a fast-track approval program and given intensive guidance from the FDA.

The approval of Bristol-Myers’ combination therapy for the treatment of genotype 1b chronic hepatitis C infection follows preliminary data from an ongoing late-stage trial.

Study Sheds Light on How Hepatitis C Virus Evades Immune System

Hepatitis C virus (HCV) appears to disable a specific variant of the IFNL3 gene, which plays a role in the immune system's response against viral infection, explaining how people with a favourable gene pattern are more likely to clear the virus naturally or with interferon-based treatment, researchers reported in the January 2014 issue of Nature Immunology.

In 2009 researchers discovered that individuals with certain variants of a gene dubbed IFNL3 or IL28B -- located near an area that encodes interferon lambda, one of the body's natural interferons -- were more likely to spontaneously clear HCV and responded better to interferon-based therapy. This genetic variance largely explains the well-known difference in treatment response rates between black and white or Asian hepatitis C patients.


Hepatitis: Websites & Resources

Treating HCV in the Community GI Setting – How to Make it Work

Gastroenterologists recognize treating HCV is the right thing to do but may face clinical challenges managing HCV patients. That’s why the ACG is offering a new resource for the busy GI practice. Developed by an Expert Task Force on Hepatitis C, chaired by Dr. Mitchell Shiffman, the College is proud to introduce these materials which feature:

ACG Hepatitis C Resource Kit

The ACG Hepatitis C Treatment Resource Kit covers clinical management issues such as:

- Pre-Treatment Assessment
- Initial Work-up
- Patient Counseling and Education
- Documenting Response to Treatment
- Monitoring Parameters for HCV RNA During Treatment
- Laboratory Studies During Therapy
- Use of Growth Factors
- Managing Depression
- Managing Cytopenias

Revisions, deletions and additions to CPT codes affecting gastroenterology.


Best Practices in the Management of HCV/HIV Co-infection: Optimizing Treatment Success

Jürgen K. Rockstroh, MD, provides a concise update on screening strategies and emerging treatment options for patients with HIV/HCV co-infection.

HCV Advocate

If you need quality information about hepatitis C, the best source for basic fact sheets and unbiased information is the HCV Advocate, a Website founded by Alan Franciscus. Alan has been conducting hepatitis C training sessions for healthcare professionals across the United States since the 1990s. His groundbreaking work to reduce the stigma of the disease and to focus on the treatment has helped shift the national conversation. Although the HCV Advocate can be a bit overwhelming in terms of the amount of information provided—over 200 fact sheets about every aspect of hepatitis C—just use the search engine on the site to ask a specific question.

HCV Lessons Launched by HCV Advocate

The Hepatitis C Support Project (HCSP) is a registered non-profit organization founded in 1997 by Alan Franciscus and other HCV positive individuals to address the lack of education, support, and services available at that time for the HCV population. HCSP’s mission is to provide unbiased information, support, and advocacy to all communities affected by HCV and HIV/HCV co-infection, including medical providers.

The HCV Advocate has announced the launch of new updated and revised HCV lessons that have been developed in collaboration with Vertex Pharmaceuticals. They are great tools for educating yourself, your peers, support group members, clients or anyone interested in understanding the entire spectrum of hepatitis C. Each lesson contains important facts, discussion topics, self-help strategies, and resources for additional information and support.
Hepatitis C Support Group Lessons

- **Lesson 1: What Is Hepatitis C, How Does It Spread and What Are the Symptoms?**—Provides basic information on how hepatitis C is transmitted and how to prevent transmission.

- **Lesson 2: Monitoring and Watching Hepatitis C**—Information about what damages the liver, HCV disease progression, and staying healthy.

- **Lesson 3: The Stigma of Hepatitis C: Bias and Prejudice**—Hepatitis C is a highly stigmatized condition. This section gives people information and tools to deal with stigma and how to move beyond it for improving their emotional and physical health.

- **Lesson 4: Telling Others You Have Hepatitis C**—This is one of the most difficult issues people with hepatitis C face almost every day, but especially after being diagnosed. This lesson gives suggestions on dealing with telling others.


New HCV Interim Treatment Recommendations Available

The latest treatment recommendations for hepatitis C virus (HCV) infection are now available on HCVguidelines.org, the result of a collaboration between the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA.

The evidence-based consensus recommendations for the screening, treatment, and management of patients with HCV were developed by a panel of 27 liver disease and infectious disease specialists and a patient advocate.

Between 3 and 4 million Americans have HCV that may progress to advanced liver disease and/or hepatocellular cancer, according to information on the Website.

Because of recent changes in HCV testing guidelines, increasing numbers of patients are being diagnosed with HCV who were unaware they have the disease, Adrian Di Bisceglie, MD, president of AASLD, explained in a joint statement from the AASLD and the IDSA. "The guidance provided through HCVguidelines.org comes at a critical time as more and more of these patients seek treatment that has the potential to effectively 'cure' them," Dr. Di Bisceglie said.


CDC Viral Hepatitis Fact Sheets

CDC has numerous fact sheets on hepatitis A, hepatitis B, hepatitis C, and hepatitis in special populations. Many of the fact sheets are available in other languages. There is a complete list of all available fact sheets that is updated whenever new fact sheets or translations are added.

CDC Viral Hepatitis Posters

CDC has multiple hepatitis posters available for ordering at no cost. Some posters are available in other languages.


Hepatitis B Corner

Public Comment on Draft Evidence Report and Draft Recommendation Statement: Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults

On February 10, 2014, the United States Preventive Services Task Force (USPSTF) issued draft recommendations on hepatitis B (HBV) screening for non-pregnant adolescents and adults. Presently, only pregnant women have an HBV screening recommendation from the USPSTF at an “A” grade. The USPSTF issued a draft “B” grade for HBV screening of populations most vulnerable to HBV infection, defined as:

- Foreign-born individuals from countries with a 2% or higher HBV prevalence rate
- Persons living with HIV (PLWH)
- Persons who inject drugs (PWID)
- Gay, bisexual and other men who have sex with men (MSM)
- Household contacts or sexual partners of persons living with HBV.

A “B” grade recommendation can have a substantial impact on identification of people living with HBV who do not know their status, bringing more people into care and treatment and decreasing new HBV infections. It will also have implications on coverage of HBV screening as USPSTF grades guide reimbursement requirements for private insurers, Medicare and Medicaid. This will also allow for HBV screenings to be included in the list of preventive services of the Affordable Care Act.
To read the draft recommendations go to:

Additionally, we encourage you and your local providers to submit comments. Comments must be submitted by March 10, 2014.

Management of chronic hepatitis B in childhood: ESPGHAN clinical practice guidelines:

More than 360 million persons worldwide (6% of the world population) are chronically infected by the hepatitis B virus (HBV). Although the incidence of HBV infection has dramatically declined since the implementation of universal immunization programs in several countries and blood-donor screening, a significant number of children are still infected each year, often developing chronic infection and requiring appropriate follow-up [1]. Despite a rather benign course of chronic hepatitis B (CHB) during childhood and adolescence, 3–5% and 0.01–0.03% of chronic carriers develop cirrhosis or hepatocellular carcinoma (HCC), respectively, before adulthood [2], [3]. Such a risk for HCC rises to 9–24% when considering the whole lifetime, with an incidence of cirrhosis of 2–3% per year [4], [5]. Worldwide universal vaccination remains the goal for eliminating HBV infection and its complications. Treatment of CHB in childhood has been hampered by the chronic delay in licensing new drugs for pediatric use. Safe and effective antiviral therapies are available in adults, but few are labeled for the use in children, and an accurate selection of whom to treat and the identification of the right timing for treatment are needed to optimize response and reduce the risk of antiviral resistance. Although several guidelines on the management of adult patients with CHB have been published by major international societies, the clinical approach to infected children is still evolving, and is mostly based on consensus of expert opinion [1].

Read More: http://www.journal-of-hepatology.eu/article/S0168-8278(13)00346-2/fulltext

REP 9AC Plus Interferon Clears Hepatitis B and Generates Surface Antibodies

REP 9AC is the much-anticipated new hepatitis B drug that within weeks suppresses the hepatitis B virus, enabling patients to lose the hepatitis B surface antigen—something no other drug has been able to do. In this latest study, when interferon was added to REP 9AC, patients even developed surface antibodies—essentially permanently getting rid of the infection.

Read More: http://www.medhelp.org/posts/Hepatitis-B/REP9AC-at-APASL2013---15th-annual-TIDES-meeting/show/1955587
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