KY Hepatitis Connections

On behalf of the KY Adult Viral Hepatitis Prevention and Control Program, please see our February 2015 edition of the KY Hepatitis Connections. You will find current information about viral hepatitis, opportunities for viral hepatitis continuing professional education, and information about educational materials available. See all the exciting things happening here in Kentucky!

Please feel free to forward, copy and/ or 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. We hope you enjoy our newsletter.

Kathy Sanders, RN MSN

"We strongly urge governments, the pharmaceutical industry, clinicians, community organization’s and non-governmental organizations to work together to make global elimination of HCV a realistic target within our lifetimes."

Dr Ranjababu Kulasegaram-Chair of the British HIV Association Hepatitis Society Subcommittee
HCV: IN THE NEWS:

Ky. heroin bills raise hope, face skepticism

As the Kentucky General Assembly gears up for a shortened session and to tackle heroin legislation, many anti-heroin activists say proposed bills don't go far enough.

"We all know heroin use is an epidemic in our area. But what are our local leaders and institutions doing - or not doing - to fight it? This year the Enquirer will be focusing on solutions to the region's heroin problems."

One of the leading bills proposed to combat Kentucky's heroin epidemic gives an addict a better chance at receiving treatment if he is arrested than if he tries to check into a rehab clinic. Another of the multiple proposals is expected to include a provision that would allow needle exchanges, an approach favored by public health officials trying to ward off the spread of hepatitis or HIV, but abhorred by conservatives not willing to appear soft on crime.

A third ups the criminal penalties for dealing heroin and other opiates without increasing any funding for treatment for addicts.

All of the competing and complementary proposals come about 12 months after the General Assembly failed to do anything about the spread of the drug, even as overdoses continued to skyrocket. There were 72 heroin-related overdose deaths in Boone, Campbell and Kenton counties in 2013 alone – accounting for 31 percent of all such deaths in the state.


Liver cirrhosis more prevalent than previously thought, finds new study

In the US, liver cirrhosis is the twelfth leading cause of death overall and the fifth leading cause of death for people aged between 45 and 54. Symptoms include jaundice, fatigue, bleeding, bruising easily, swelling, confusion and nausea. Many people do not have symptoms of liver cirrhosis; in the early stages, it is often first detected through a routine blood test or checkup.

Led by the Loyola University Chicago Stritch School of Medicine, the study uses data from the National Health and Nutrition Examination Survey (NHANES) for the first time to estimate the prevalence of liver cirrhosis in the general US population. NHANES is an annual US population representative survey carried out by the Centers for Disease Control and Prevention (CDC).

More Evidence That HIV-Negative Gays Contract Hep C Via Sex

Increasing evidence suggests that hepatitis C virus (HCV) transmits sexually among HIV-negative men who have sex with men, and not just among HIV-positive MSM. Publishing their findings in the Journal of Viral Hepatitis, researchers conducted a retrospective study in which they identified 44 HIV-negative MSM with acute hep C at a large, urban British sexual health clinic between January 2010 and May 2014.

The participants’ reports about their sexual or drug-using behaviors typically covered the previous three to six months.

Forty-one (93 percent) of the men reported recent condom-less anal intercourse, with 36 of them (88 percent) reporting both insertive and receptive intercourse, 4 (10 percent) reporting only receptive intercourse, and 1 (2.4 percent) only insertive intercourse. The men reported an average of 7.3 partners, with a range of one to 100 and a median of two. Twelve (27 percent) of the men said they had had group sex, and 11 (25 percent) reported engaging in fisting.

Eleven participants (25 percent) said they had used drugs during sex, with 16 (36 percent) reporting snorting drugs and 9 (21 percent) saying they had injected drugs. It is noteworthy that only about one in five of the men said they had injected drugs, because that is the main alternative way they might have contracted hep C.

Twenty-nine (66 percent) of the men said they were aware of a sexual partner’s HIV or hep C status, with two (4.5 percent) saying they’d had sex with someone they knew had HCV, 13 (30 percent) reporting sex with an HIV-positive partner, six (14 percent) reporting sex with one or more men co-infected with HIV and HCV, and nine (21 percent) saying they had had sex with a partner or partners who they believed were not infected with either virus. Fifteen (34 percent) of the men’s hep C spontaneously cleared.

Read More:  http://www.hepmag.com/articles/sexual_transmission_HCV_2502_25673.shtml

http://www.hepmag.com/articles/sexual_transmission_MSM_2501_26626.shtml

Patient Advocate Foundation Offers New CareLine for Hepatitis C Patients

Patient Advocate Foundation (PAF) – a national, non-profit organization providing professional case management services to patients facing healthcare access issues, is pleased to announce the launch of a new Hepatitis C CareLine, providing individualized, sustained assistance to patients diagnosed with Hepatitis C. The CareLine will provide help to patients across the country to resolve healthcare access and insurance issues, at no charge to the patient.

This new program joins Patient Advocate Foundation’s existing suite of CareLine programs, furthering PAF’s commitment to helping patients with chronic, debilitating, or life-threatening illness navigate the healthcare industry. In 2013, Hepatitis diagnoses ranked in PAF’s top ten list of diseases reported by patients seeking help through the case management team. Through the Hepatitis C CareLine, dedicated
case managers will serve as a direct resource for Hepatitis C patients assisting them with benefit coordination, educational and financial resources, help accessing the latest available treatment, navigation through the appeals and reimbursement processes, as well as other patient services. This new program joins Patient Advocate Foundation's existing copayment support for Hepatitis B and Hepatitis C patients offered through its Co-Pay Relief program.

"Patient Advocate Foundation is committed to helping Hepatitis C patients maintain financial stability while consistently accessing needed treatments and prescribed medical care," says PAF CEO, Alan Balch, Ph.D. "By directly connecting Hepatitis C patients with the correct resources and negotiating on their behalf, we believe PAF can make a difference for patients in the Hepatitis C community."

Any patient or medical provider interested in learning more about Patient Advocate Foundation's Hepatitis C CareLine should call 800-532-5274 or visit hepatitisc.pafcareline.org/. The CareLine will offer live service to patients Monday through Thursday from 8:30 AM – 8:00 PM ET and Friday from 8:30 AM – 7:00 PM ET. Bi-lingual case managers are available to assist Spanish speaking callers.

For more information about Patient Advocate Foundation and their mission to improve healthcare access to all patients, please visit www.patientadvocate.org. See more at: http://globenewswire.com/news-release/2015/01/05/695010/10114015/en/Patient-Advocate-Foundation-Offers-New-CareLine-for-Hepatitis-C-Patients.html#sthash.S6g6gcov.dpuf

Hep C Doesn’t Apparently Lead to Cognitive Decline in People With HIV

Advances in treatment for human immunodeficiency virus (HIV) have made it possible for people with HIV to survive much longer. As they age, however, many experience impaired thinking, memory loss, mood swings, and other evidence of impaired mental function.

To stop these changes, scientists have to learn what is causing them. One possibility researchers are considering is that long-term infections with other pathogens, common in HIV-positive patients, are affecting the brain. But a new study has eliminated one of their prime suspects: the hepatitis C virus, which infects about one in every three HIV-positive patients in the United States.

The research, conducted by a team that includes scientists at Washington University School of Medicine in St. Louis, appeared Dec. 10 in Neurology.

Hepatitis C infection has serious long-term side effects, such as damage to the liver, but our research indicates that it does not affect the brain,” said lead author David Clifford, MD, of Washington University.

The research was conducted as part of the CNS HIV Anti-retroviral Therapy Effects (CHARTER) study, a multicenter collaborative that is examining the long-term neurological effects of HIV infection.

Read More: https://news.wustl.edu/news/Pages/27788.aspx
Cigna Tracks Outcomes for Hep C Patients to Get Real-World View

A top Cigna Corp. pharmacy management executive tells HPW the insurer’s “real-world” monitoring of its members with hepatitis C who have been treated with a prescription combination including the drug Sovaldi had a 91.1% cure rate, or sustained virologic response (SVR), when measured after a 12-week treatment regime.

The insurer said it would use the cure-rate information to help manage the cost of current and future hepatitis C drugs. But for now, the new information will help stakeholders manage Sovaldi, Gilead Sciences, Inc.’s “wonder drug” that has flummoxed the industry because of its excellent clinical results, but also very high cost at $1,000 per patient per day, with most regimes lasting 12 weeks (HPW 3/17/14, p. 1).

According to Christopher Bradbury, vice president, integrated clinical and specialty drug solutions for Cigna Pharmacy Management, the carrier is extremely focused on the care and cost aspects of treating hepatitis C.

“We did it [the tracking] for a few reasons. One is that prior reports on earlier generation hepatitis C drugs suggested the real-world results may not be as consistent as what was seen in the controlled clinical studies for a variety of factors,” he tells HPW. “So given the extremely high costs of these therapies, particularly Sovaldi and Harvoni [another hepatitis C drug from Gilead that costs $1,125 per patient per day for regimens of eight, 12 and 24 weeks], plus the large number of individuals with hepatitis C and the overall cost pressures, we thought it was critical to take a real-world assessment on these drugs.”

The FDA approved Sovaldi in late 2013 and Harvoni in October 2014. Harvoni is a once-daily combination pill featuring Sovaldi and ledipasvir. As part of its assessment, Cigna looked at SVR results of members taking the following combinations of drugs: Sovaldi and Olysio; Sovaldi, pegylated interferon and ribavirin; or Sovaldi and ribavirin.

Read More: [http://aishealth.com/archive/nhpw122214-03](http://aishealth.com/archive/nhpw122214-03)
Merck to Seek Approval of New Hepatitis C Drug by Midyear

If all goes as planned, Merck will soon take a major step forward in the hot pursuit among pharmaceutical companies to produce a newer, better, faster-working drug to treat the millions of people who have chronic hepatitis C infection.

By midyear the company expects to submit a New Drug Application to the Food and Drug Administration for approval of grazoprevir/elbasvir, a combination regimen investigational drug designed to be taken once daily as treatment of chronic hepatitis C virus infection. Grazoprevir is an NS3/4A second-generation protease inhibitor and elbasvir is an NS5A inhibitor.

If approved, the drug faces a highly competitive landscape of newly developed medicines for hepatitis C treatment. Gilead Sciences with Harvoni and AbbVie with Viekira Pak are two drug makers already gaining ground with new hepatitis C drugs approved by the FDA in 2014.

Companies that manage drug benefits for millions of patients have recently announced exclusive agreements with either Gilead or AbbVie for use of their hepatitis C treatments. Health officials estimate that at least 3 million people in the United States are infected with the hepatitis C virus, which can severely damage the liver over time. - See more at: http://www.hcplive.com/articles/Merck-to-Seek-Approval-of-New-Hepatitis-C-Drug-by-Midyear#sthash.maxgPR9Q.QCckvBBS.dpuf

Key Hepatitis C Patent Rejected In India For Lack Of Novelty, Inventive Step

On January 13th, 2015, the announcement of a rejection by the Patent Office Controller of India of a patent application by Gilead company for a key drug against hepatitis C is being hailed by advocates as a path to dramatically lower costs of treatment for the disease. Hepatitis C has made news for the emergence of exorbitantly priced medicines over the past year. A look at the decision shows that a provision in India’s law continues to stop patent applications if they fail to show sufficient novelty and inventive step – and are subject to opposition. The patent office decision dated 13 January is available for review at the end of this newsletter.

According to the decision, hepatitis C (HCV) is at epidemic levels, affecting some 170 million people worldwide, and 18 million in India. Others have put the global figure even higher. The decision states that oppositions to several patent applications on sofosbuvir were filed by the Initiative for Medicines, Access & Knowledge (I-MAK), and the Delhi Network of Positive People (DNP+), in November 2013 and March 2014, arguing that they were not sufficiently novel and inventive as required for a patent. Gilead then made arguments explaining why these oppositions were not valid.

In its ruling, the Patent Office did not accept the company’s arguments, and suggested ways in which its arguments could have been more convincing, in particular to show “therapeutic efficacy” so as to satisfy Indian Patent Act Section 3(d). Read More: http://www.ip-watch.org/2015/01/14/key-hepatitis-c-patent-rejected-in-india-for-lack-of-novelty-inventive-step/
FDA Clears Hepatiq Software for Quantifying Liver Disease

The US Food and Drug Administration (FDA) has approved software designed to help determine the severity of liver disease by quantitative analysis of nuclear medicine liver-spleen images. The Hepatiq software, from Hepatiq LLC, calculates perfused hepatic mass, a measure of liver function. The software automates the quantitative liver spleen scan shown to be an accurate predictor of clinical outcomes in the Hepatitis C Antiviral Long-term Treatment Against Cirrhosis trial.

John Hoefs, MD, cofounder and chief operating officer of the company, developed the quantitative liver spleen scan methods to measure hepatic function, fibrosis, hepatic, and spleen volume, and cirrhosis, whereas Dipu Ghosh, the company's chief executive officer, created the algorithms for automating the quantitative liver spleen scan techniques.

"As hepatologists," Dr Hoefs commented in the release, "we have needed and searched for a reliable, precise method of measuring liver function that can be used in the clinical setting. Hepatic function is more important than hepatic fibrosis as hepatic function determines both the likelihood of clinical problems and patient survival. We are very excited that this method will now be available to physicians and patients."

About 15% of adults globally have chronic liver disease. In the United States, about 32,000 people die each year from liver disease, the company notes. Read More: http://www.medscape.com/viewarticle/838013

U.S. Congress Meets Again to Discuss Hepatitis C Drug Pricing

The U.S. Senate recently held another special meeting to look into the high costs of hepatitis C virus (HCV) treatment, the Fiscal Times reports. The question at hand this time was how far the government should go to try to influence pharmaceutical costs, without discouraging drug research and development.

Gilead Sciences currently sells Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir) — two new and highly effective 12-week cures for hep C — at $84,000 and $94,500, respectively. That works out to about $1,000 per pill for Sovaldi and $1,125 per pill for Harvoni — a price many consumers, insurers, and governments around the world claim is too high.

Gilead claims that their pricing is fair, considering how much money they spent developing the pill. The company also argues that government pricing plans could inhibit future research and development of drugs. Even at their current price, the company argues the drugs will help save money in the long run by preventing complications from HCV, such as transplants and cancer treatments. Advocacy groups are proposing that the U.S. government offer a licensing agreement for generic producers to manufacture and sell Sovaldi at a lower cost. Another approach would be to force Gilead to let others use their drug patents under a “non-voluntary acquisition.”

Federal law does give the government the right to appropriate inventions while providing reasonable compensation to the patent holder. So far, that law has never been extended to the pharmaceutical industry. Read More: http://www.hepmag.com/articles/senate_hepatitis_pricing_2831_26619.shtml
What Can Be Done to Prevent Hepatitis C Patients from Being Lost in the Healthcare System?

A new study shows that many patients infected with the hepatitis C virus (HCV) are lost during different stages of health care to manage the disease. This real-life’ view of the HCV patient care continuum in a major U.S. urban area is published in *Hepatology*, a journal of the American Association for the Study of Liver Diseases, and highlights the importance of generating awareness among clinicians and at-risk groups about appropriate HCV testing, referral, support and care.

Despite efforts to manage HCV, it is one of the most prevalent diseases with up to 150 million individuals worldwide living with chronic infection according to the World Health Organization (WHO). In the U.S. about 3.2 million people are infected with HCV, making it the main cause of chronic hepatitis disease. Up to 70% of those with acute infection have no symptoms and are typically unaware they have HCV until years later after the disease has progressed to cirrhosis, liver cancer (hepatocellular carcinoma [HCC]), or liver failure.

Medical evidence emphasizes HCV screening of at-risk individuals such as injection drug users, blood transfusion recipients, children born to mothers with chronic infection, or adults born between 1945 and 1965 in order to improve diagnosis of the disease. Yet some programs are not comprehensive and one prior study estimates that 50% to 75% of chronic HCV patients remain unaware of their infection.

“The inadequacy of screening programs has made it difficult for state health departments to accurately determine the extent of HCV and the rate of transmission within the community,” explains Kendra Viner, Ph.D., MPH, from the Philadelphia Department of Public Health. “Our study examines the management of HCV care at a population level to determine which patients tend to fall out of the medical system and why this might occur.”


**Hep C-Related Liver Disease Differs by Race** by Benjamin Ryan

If you have hep C virus (HCV), your likelihood of developing cirrhosis or liver cancer may be linked to your race. To determine this connection, researchers examined Veterans Administration records of those confirmed to have hep C between 2000 and 2009; they also looked at cases of liver cancer and cirrhosis among the HCV-positive population through early 2010.

During an average 5.2 years of follow-up care, 13,000 out of 150,000 people with hep C developed cirrhosis and 3,500 of the total were diagnosed with liver cancer. The respective rates of cirrhosis and liver cancer per 100 person-years among the three racial groups were as follows: Latinos, 28.8 and 7.8; whites, 21.6 and 4.7; and African Americans, 13.3 and 3.9.

After adjusting for various factors, researchers found that Latinos had a 28 percent greater risk of cirrhosis and a 61 percent greater risk of liver cancer when compared with whites. Meanwhile, African Americans had a 42 percent reduced risk of cirrhosis and a 23 percent reduced risk of liver cancer compared with whites.
Hashem B. El-Serag, MD, MPH, the chief of gastroenterology and hepatology at both Baylor College of Medicine and the VA Medical Center in Houston, says that genetic differences as well as differences in obesity and insulin resistance may help explain the varying levels of risk according to race. “Studies have shown a much higher incidence of obesity, particularly abdominal obesity, among [Latinos],” he says.

Read More: http://www.hepmag.com/articles/liver_disease_and_race_2897_26554.shtml

**Estimated U.S. Cirrhosis Rates Are 58% Higher Than Once Believed**

New research suggests that the prevalence of cirrhosis among the U.S. population is actually 58 percent higher than the previously thought, Medical News Today reports. Publishing their findings in the Journal of Clinical Gastroenterology, researchers culled data from the National Health and Nutrition Examination Survey (NHANES) to estimate the prevalence of liver cirrhosis.

The investigators estimated that 0.27 percent of Americans have cirrhosis, which translates to 633,000 adults. The previous estimate was just 400,000 cases. Roughly 69 percent of Americans with cirrhosis are unaware of their condition.

Cirrhosis is more prevalent among African Americans and Mexican Americans, people living in poverty, and those without a high school diploma. Diabetes, alcohol abuse, hepatitis C and hepatitis B virus (HCV and HBV), being male, and being older are all independently linked to having cirrhosis. Cumulatively, 53.5 percent of cirrhosis cases have viral hepatitis (mostly hep C), diabetes and alcohol abuse as the primary contributing factors.

People with cirrhosis have a two-year mortality rate of 26.4 percent, compared with 8.4 percent among matched controls without the disease.

About one in four people with cirrhosis reported drinking alcohol excessively during the year before they were surveyed. Almost half reported being HCV positive. Read More: http://www.medicalnewstoday.com/articles/287565.php

**SAVE THE DATE: HCV Advocate Training Coming to KY**

June 11th: Northern Kentucky

June 12th: Eastern Kentucky

Additional information will follow at a later date
**HCV DRUG UPDATES:**

**Hepatitis C Treatments in Current Clinical Development**

As of the last week in December 2014, the following interferon-free, direct-acting antiviral combinations in Phase 3 include:

1. Daklinza (daclatasvir) – By Bristol-Myers Squibb, this NS5A inhibitor has been approved in Europe to be used in combination with Sovaldi. Daklinza is also being studied in combination with two other Bristol-Myers Squibb contenders, Sunpreva (Asunaprevir) and BMS-791325.

2. Grazoprevir (MK-5172) – By Merck, this protease inhibitor is being studied along with Merck’s Elbasvir (MK-8742).

3. Sovaldi (sofosbuvir) – Gilead’s NS5B polymerase inhibitor, Sovaldi is already FDA approved in combination with ribavirin, with the possible addition of pegylated interferon. However, Gilead Sciences is studying Sovaldi along with GS-5816 (their NS5A inhibitor) and ribavirin in an effort to compare the results from treatment with just Sovaldi and ribavirin.

The following drugs are in Phase 2, not far behind the drug combination contenders in Phase 3:

ACH-3102 – Achillion’s NS5A inhibitor, this investigational compound is being evaluated in combination with Sovaldi.

Sovaprevir (ACH-1625) – Previously referred to as ACH-1625, sovaprevir is Achillion’s NS3/4A protease inhibitor. Sovaprevir is being evaluated in combination with Achillion’s ACH-3102 and their NS5B polymerase inhibitor ACH-3422.

Daklinza – This Bristol-Myers Squibb NS5A inhibitor is also in Phase 2 trials with Janssen’s Olysio (simeprevir) and with Vertex’s VX-135.

Olysio – Janssen’s NS3/4A protease inhibitor is currently approved for use with interferon and ribavirin, but is currently in Phase 2 trials to evaluate it with Daklinza, Merck’s Samatasvir (IDS719), and Janssen’s TMC647055 with Ritonavir.

There are a handful of pharmaceutical companies that have taken the lead on Hepatitis C medications. Although Gilead, AbbVie, Merck, Janssen, Bristol-Myers Squibb, and Achillion are not the only drug manufacturers working to stamp out Hepatitis C, they are currently the frontrunners. We will be closely watching what comes of these Phase 2 and Phase 3 trials in anticipation of improved Hepatitis C treatment being safer, more effective, and more affordable.
Updated Hepatitis C Treatment Guidelines Add New Therapies, Hard-to-Treat Patients

The American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA), and International Antiviral Society-USA (IAS-USA) recently updated their hepatitis C treatment guidelines to add newly approved interferon-free direct-acting antiviral regimens and to provide more information about treating patients with HIV/HCV co-infection and decompensated liver disease. The evolving guidelines are available online at http://hcvguidelines.org/.

On December 19 several sections of the guidelines were updated. The most notable change was the addition of Gilead Science’s sofosbuvir/ledipasvir coformulation (Harvoni) and AbbVie’s paritaprevir/ritonavir/ombitasvir plus dasabuvir regimen (Viekira Pak), which received U.S. Food and Drug Administration approval in October and December, respectively.

**Initial Hepatitis C Genotype 1 Treatment**

The guidelines now state that "3 options with similar efficacy in general" are recommended for previously untreated patients with HCV genotype 1a:

- Sofosbuvir/ledipasvir coformulation without ribavirin for 12 weeks, regardless of liver cirrhosis status;
- Paritaprevir regimen plus weight-based ribavirin for 12 weeks for people without cirrhosis or 24 weeks for those with cirrhosis;
- Sofosbuvir (Gilead’s Sovaldi) plus simeprevir (Janssen’s Olysio) with or without weight-based ribavirin for 12 weeks for non-cirrhotic or 24 weeks for cirrhotic patients.

**References**

For people with easier-to-treat HCV subtype 1b, there are also 3 options with similar efficacy:

- Sofosbuvir/ledipasvir coformulation without ribavirin for 12 weeks;
- Paritaprevir regimen without ribavirin for 12 weeks for people without cirrhosis or with ribavirin for those with cirrhosis;
- Sofosbuvir plus simeprevir without ribavirin for 12 for non-cirrhotic or 24 weeks for cirrhotic patients.

The prescribing information for Harvoni notes that a treatment duration of 8 weeks may be considered for previously untreated patients without cirrhosis who have a low pre-treatment HCV viral load (<6 million IU/mL). The ION-3 trial showed that sofosbuvir/ledipasvir for 8 weeks worked as well as 12 weeks for easier-to-treat patients. The revised guidelines, however, do not recommend the shorter duration.

These treatment options all have cure rates above 90% -- substantially higher than the previous interferon-based therapy standard of care, even with the addition of the first generation HCV protease inhibitors telaprevir (Vertex's now discontinued Incivek) or boceprevir (Merck's Victrelis).

**Genotype 1 Re-treatment**

For genotype 1a and 1b patients without cirrhosis who were previously treated with pegylated interferon plus ribavirin, the guidelines recommend the same options as for treatment-naive patients.

Treatment-experienced genotype 1a and 1b patients with compensated cirrhosis, can either take sofosbuvir/ledipasvir alone for 24 weeks or with ribavirin for 12 weeks, the paritaprevir regimen with ribavirin for 12 (genotype 1a) or 24 (genotype 1b) weeks, or sofosbuvir plus simeprevir for 24 weeks.

For treatment-experienced people without advanced fibrosis who were not cured using a prior sofosbuvir-containing regimen, the guidelines suggest that patients "defer antiviral therapy pending additional data or consider treatment within clinical trial settings."

For those with advanced fibrosis who cannot wait, the recommendation is sofosbuvir/ledipasvir with or without ribavirin for 24 weeks. Further recommendations are provided for people who previously failed interferon-based triple therapy including telaprevir or boceprevir.

**Not Recommended**

The revised guidelines state that regimens not recommended for treatment-naive or treatment-experienced genotype 1 patients include sofosbuvir plus ribavirin alone (previously an alternative for genotype 1 patients who could not take interferon) and regimens containing pegylated interferon plus ribavirin, either alone or with sofosbuvir, simeprevir, telaprevir, or boceprevir.

Treatment-experienced people who previous tried interferon-based therapy with an HCV protease inhibitor also should not use interferon-free regimens containing the newer HCV protease inhibitors.
simeprevir or paritaprevir.

Many patients and providers will be glad to see the elimination of interferon-based therapy, which lasts up to 48 weeks, can cause difficult side effects, and does not cure as many people as the new interferon-free regimens.

**Other Genotypes**

Recommendations for people with HCV genotype 4 are generally similar to those for people with genotype 1. Sofosbuvir/ledipasvir for 12 weeks is recommended for people with genotype 6.

Guidelines for people with HCV genotypes 2 or 3 have not changed substantially from the initial version -- sofosbuvir plus ribavirin for 12 to 24 weeks -- as ledipasvir and the paritaprevir regimen are not effective against these genotypes.

**HIV/HCV Coinfection**

Recommendations for initial hepatitis C treatment and re-treatment are the same for HIV/HCV co-infected patients as for HIV negative people with HCV alone, although drug-drug interactions with antiretrovirals need to be taken into account.

Ledipasvir is known to increase levels of tenofovir (Viread, also in the Truvada, Atripla, Complera, and Stribild coformulations), so kidney function should be monitored and it should not be used by people with creatinine clearance below 60 mL/min.

The paritaprevir regimen should be used with antiretroviral drugs known not to interact, including raltegravir (Isentress), probably dolutegravir (Tivicay), enfuvirtide (Fuzeon), tenofovir, emtricitabine (Emtriva), lamivudine (Epivir), and atazanavir (Reyataz). The dose of ritonavir used to boost HIV protease inhibitors may need to be adjusted or dropped since the paritaprevir coformulation already contains ritonavir.

Several contraindications are listed for using specific HIV and HCV drugs together. The guidelines emphasize that antiretroviral therapy should not be interrupted in order to use a non-recommended or interacting HCV drug.

** Decompensated Cirrhosis and Post-Transplant**

On December 29 the guidelines were updated again to include information for treatment of people with decompensated cirrhosis -- moderate or severe liver impairment with Child-Turcotte-Pugh class B or C.

People with HCV genotypes 1 or 4 and decompensated cirrhosis may be treated with sofosbuvir/ledipasvir plus ribavirin for 12 weeks. Ribavirin should be started at a low dose of 600 mg and increased as tolerated. Patients with anemia or ribavirin intolerance can drop ribavirin and extend treatment duration to 24 weeks. This regimen "should be used only by highly experienced HCV practitioners," the guidelines emphasize.

Treatment-naive or -experienced liver transplant recipients with HCV genotypes 1, 3, or 4 -- including
those with compensated cirrhosis -- can be treated with sofosbuvir/ledipasvir plus weight-based ribavirin for 12 weeks, or without ribavirin for 24 weeks if unable to take it. The paritaprevir regimen plus ribavirin for 24 weeks, or sofosbuvir plus simeprevir for 12 weeks, are additional alternatives for transplant recipients with genotype 1.

For transplant recipients with decompensated cirrhosis, sofosbuvir/ledipasvir with a low escalating dose of ribavirin for 12 weeks is recommended for those with genotypes 1, 3, or 4, while sofosbuvir plus ribavirin for 24 weeks is recommended for those with genotype 2. Regimens containing pegylated interferon, simeprevir, the paritaprevir regimen, telaprevir, or boceprevir are not recommended for transplant recipients with decompensated liver disease.


PERINATAL HCV

Vertical Transmission of HCV: The Next Big Treatment Frontier

Novel antiviral therapies with overwhelmingly positive sustained virologic response rates have dominated headlines in hepatitis C virus for the past few years, but many experts said eradication efforts may never completely succeed until the clinical community deals with vertical transmission of the disease.

A recent study conducted by Lenka Benova, MSc, a research fellow at the London School of Hygiene and Tropical Medicine in London, along with Laith Abu-Raddad, PhD, associate professor of public health at Weill Cornell Medical College in Qatar, and colleagues highlighted some of the key issues in the discussion. They systematically reviewed 109 papers on vertical transmission risk of hepatitis C virus and found that more than one in 20 infants delivered by women with chronic HCV becomes infected, making vertical transmission the primary transmission route among children. The overall risk for vertical transmission of HCV antibody-positive and RNA-positive women was 5.8% (95% CI, 4.2-7.8) for children of HIV-negative women and 10.8% (95% CI, 7.6-15.2) among those born to women with HIV, according to the study findings.

Beyond the HIV association, some data show stark disparities between infection rates in the developed world compared with those in the developing world, a problem that continues to confound both the research and clinical communities. There are gaps in knowledge surrounding pregnancy and breastfeeding as they pertain to vertical transmission, and there is currently insufficient information available about the role of revolutionary direct-acting antiviral therapies as a solution to this problem. Read More: http://www.healio.com/infectious-disease/hepatitis-c/news/print/hcv-next/%7B2cadb674-f088-41ec-ac98-4fe364a45421%7D/vertical-transmission-of-hcv-the-next-big-treatment-frontier
REMINDER: HEPATITIS C Voluntary Reporting:

Hepatitis C: Perinatal and Children Aged Five Years or Less. Update on the Project for Voluntary Reporting in Kentucky.

Health care providers are asked to report voluntarily:

- all HCV-positive pregnant women;
- all infants born to HCV-positive women; and
- all HCV-positive infants and children 5 years old and younger seen in birthing hospitals, medical practices and clinics

Routine testing for HCV is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Data from the CDC states that approximately 6 out of every 100 infants born to HCV infected woman become infected. The risk is greater, 2 to 3 times, if the woman is co-infected with HIV. There is currently no HCV treatment approved for pregnant women, [http://www.cdc.gov/std/treatment/2010/hepc.htm](http://www.cdc.gov/std/treatment/2010/hepc.htm)

**Infant born to mothers with HCV**

Infants born to HCV-positive mothers should be tested for HCV infection. Children born to HCV-positive mothers can be tested with the HCV RNA tests at 2 months of age or older (at a routine well-child visit) or HCV antibody testing can be done at 18 months of age (wait until 18 months of age to avoid detecting maternal antibody).


There are no FDA approved HCV treatments for young children. In October, a clinical trial announcement was made to study these young children/adolescents and the treatment of HCV:


Thank you for your continued support of this project and your ongoing assistance to report 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 your communities.

Please continue to report any HCV-positive individuals in the above categories. Complete and fax the reporting form at the end of this newsletter. **Please note the new fax number:**

Please fax forms to 502-696-3803
Viral Hepatitis Prevention Program Staff:

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Adult Viral Hepatitis Prevention Program Coordinator  
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KathyJ.Sanders@ky.gov
Drug Overdose Deaths, Hospitalizations, and Emergency Department Visits in Kentucky, 2000 - 2012
Drug Overdose Deaths, Hospitalizations, and Emergency Department Visits in Kentucky, 2000-2012

January, 2014

Prepared by
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Joshua W. Lambert, MS

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About this report ....................................................................... 42
1. The total number of Kentucky resident drug overdose deaths leveled off from 2011 to 2012 (1,022 deaths in 2011 and 1,031 deaths in 2012).

2. The Kentucky resident age-adjusted drug overdose mortality rate decreased from 24.2 in 2011 to 23.9 in 2012 (1.2% decrease).

3. Pharmaceutical opioids remained the primary cause of Kentucky resident drug overdose deaths in 2012; pharmaceutical opioids accounted for 471 drug overdose deaths.

4. Heroin contributed to 129 Kentucky resident drug overdose deaths in 2012, a 207% increase from the 42 heroin-involved deaths recorded in 2011.

5. Benzodiazepines contributed to 362 Kentucky resident overdose deaths in 2012, decreasing 16% from 2011.

6. Kentucky age-adjusted drug overdose hospitalization rates decreased 2.4% from 2011 to 2012, from 146.6 hospitalizations/100,000 population in 2011 to 143.1 in 2012.

7. Intent to self-harm was the primary reason for 2012 Kentucky resident inpatient hospitalizations, similar to years 2000-2011.

8. Benzodiazepines were the primary drugs involved in Kentucky resident inpatient hospitalizations in 2012 decreasing 11% to 1,686 hospitalizations in 2012.

9. Pharmaceutical opioids were the second leading drug type involved in drug overdose related hospitalizations in 2012, decreasing 8% from 1,610 hospitalizations in 2011 to 1,483 in 2012.

10. Total charges for drug overdose hospitalizations rose 7% from $121.1 million in 2011 to $129.3 million in 2012.

11. The primary expected payer source for Kentucky resident drug overdose inpatient hospitalizations was Medicare followed by Medicaid for 2011 and 2012; Medicare was billed $41.3 million and Medicaid was billed $34.1 million in 2012.

12. Casey, Carroll, Nicholas, Powell, and Johnson counties had the highest Kentucky resident drug overdose emergency department (ED) visit rates, 2008-2012.
Executive Summary (cont’d)

13. Kentucky resident drug overdose ED visit numbers and rates leveled off in 2012 from 6,496 visits and an age-adjusted rate of 153.1 visits/100,000 population in 2011 to 6,492 visits and an age-adjusted rate of 153.0 in 2012.

14. Kentucky resident drug overdose ED visit charges increased 5% from $14.6 million in 2011 to $15.3 million in 2012.

15. Self-pays were the primary payer billed for drug overdose ED admissions in 2012 at $5 million; Medicaid was billed $4.2 million and commercial insurance was billed $3.6 million.

16. Benzodiazepines were the primary drugs involved in Kentucky drug overdose ED visits in 2012 with 856 visits; pharmaceutical opioid involvement decreased 6% to 721 visits in 2012.

17. Heroin involvement in drug overdose related ED visits increased 197% from 266 ED visits in 2011 to 789 visits in 2012.

18. Medicaid recipient total drug overdose ED charges totaled $740,000 in 2012, a 27% increase from a total of $584,000 charged in 2011.

19. Medicaid recipient total drug overdose inpatient hospitalization charges totaled $11 million in 2012, approximately the same as in 2011.

20. Kentucky resident opioid-related disease condition hospitalization charges totaled $167 million in 2012; Medicaid was billed for $55 million.

21. There were 824 Kentucky resident neonatal abstinence syndrome hospitalizations. Associated charges amounted to $40 million; Medicaid was charged $35 million.

22. Of the 9,713 pharmaceutical opioid or heroin related hospitalizations in 2012, viral hepatitis was co-diagnosed for 1,653 (17%) of them with associated charges of $37 million.

23. There were 1,192 hospitalizations involving opioid drug dependence and viral hepatitis in 2012, a 22% increase over the 976 hospitalizations in 2011.
Drug Overdose
Deaths
2000-2012
Kentucky Resident Drug Overdose Deaths, 2000-2012


Kentucky Resident Age-Adjusted Drug Overdose Mortality Rates, 2000-2012

Kentucky Resident Drug Overdose Deaths by Gender, 2000-2012


Kentucky Resident Age-Adjusted Drug Overdose Mortality Rates by Gender, 2000-2012

Kentucky Resident Drug Overdose Deaths by Intent, 2000-2012


Kentucky Resident Crude Drug Overdose Mortality Rates by Intent, 2000-2012

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonopioid analgesics</td>
<td>T39</td>
<td>16</td>
<td>25</td>
<td>23</td>
<td>28</td>
<td>33</td>
<td>27</td>
<td>36</td>
<td>9</td>
<td>7</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Antiepileptic, sedative-hypnotic, anti-Parkinsonism, antidepressant, and other psychotropic drugs, not elsewhere classified</td>
<td>T42, T43</td>
<td>87</td>
<td>87</td>
<td>78</td>
<td>84</td>
<td>51</td>
<td>64</td>
<td>93</td>
<td>98</td>
<td>307</td>
<td>467</td>
<td>405</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>T42.4</td>
<td>45</td>
<td>29</td>
<td>31</td>
<td>41</td>
<td>23</td>
<td>33</td>
<td>54</td>
<td>84</td>
<td>279</td>
<td>430</td>
<td>362</td>
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<tr>
<td>Narcotics and psychodysleptics not elsewhere classified</td>
<td>T36-T38.9, T40(.0-.9), T41, T44, T45(.0-.4), T45(.6-.9), T46-T50.8</td>
<td>188</td>
<td>229</td>
<td>231</td>
<td>300</td>
<td>296</td>
<td>282</td>
<td>299</td>
<td>312</td>
<td>522</td>
<td>656</td>
<td>677</td>
</tr>
<tr>
<td>Opiates/opioids</td>
<td>T40(.0-.4)</td>
<td>149</td>
<td>193</td>
<td>190</td>
<td>239</td>
<td>248</td>
<td>243</td>
<td>265</td>
<td>285</td>
<td>480</td>
<td>568</td>
<td>569</td>
</tr>
<tr>
<td>Heroin</td>
<td>T40.1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>14</td>
<td>34</td>
<td>42</td>
<td>129</td>
</tr>
<tr>
<td>Pharmaceutical Opioids</td>
<td>T40.0, T40(.2-.4)</td>
<td>149</td>
<td>192</td>
<td>190</td>
<td>239</td>
<td>247</td>
<td>243</td>
<td>262</td>
<td>271</td>
<td>449</td>
<td>538</td>
<td>471</td>
</tr>
<tr>
<td>Methadone</td>
<td>T40.3</td>
<td>73</td>
<td>116</td>
<td>118</td>
<td>136</td>
<td>126</td>
<td>106</td>
<td>89</td>
<td>53</td>
<td>96</td>
<td>95</td>
<td>76</td>
</tr>
<tr>
<td>Cocaine</td>
<td>T40.5</td>
<td>30</td>
<td>27</td>
<td>32</td>
<td>53</td>
<td>48</td>
<td>36</td>
<td>36</td>
<td>15</td>
<td>31</td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td>Other and unspecified narcotics</td>
<td>T40.6</td>
<td>22</td>
<td>23</td>
<td>26</td>
<td>28</td>
<td>15</td>
<td>14</td>
<td>17</td>
<td>22</td>
<td>30</td>
<td>79</td>
<td>89</td>
</tr>
<tr>
<td>Drugs not elsewhere classified or unspecified</td>
<td>T50.9</td>
<td>222</td>
<td>284</td>
<td>284</td>
<td>327</td>
<td>274</td>
<td>281</td>
<td>279</td>
<td>273</td>
<td>606</td>
<td>793</td>
<td>796</td>
</tr>
<tr>
<td>T50.9 Only</td>
<td>173</td>
<td>218</td>
<td>205</td>
<td>233</td>
<td>222</td>
<td>221</td>
<td>232</td>
<td>215</td>
<td>289</td>
<td>307</td>
<td>299</td>
<td></td>
</tr>
</tbody>
</table>
Kentucky Resident Drug Overdose Deaths by Contributing Drugs, 2000-2012

Total Number


Total number of drug overdose deaths
Prescription opioids (T40.0, T40.2, T40.4)
Heroin (T40.1)
Deaths with at least one code for drug contributing to the deaths (T36-T50.8)
Benzodiazepine
Cocaine (T40.5)

Occurrences of Specific Drugs among the Contributing Causes for Kentucky Resident Drug Overdose Deaths, 2011-2012

Drug Overdose Hospitalizations
2000-2012
Kentucky Resident Drug Overdose Hospitalizations, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Age-Adjusted Drug Overdose Hospitalization Rates, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Drug Overdose Hospitalizations by Gender, 2000-2012

Total Number

Kentucky Resident Age-Adjusted Drug Overdose Hospitalization Rates by Gender, 2000-2012

Hospitalization Rate (#hospitalizations/100,000 population)
Kentucky Resident Drug Overdose Hospitalizations by Intent, 2000-2012

Kentucky Resident Drug Overdose Hospitalization Rates by Intent, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
<table>
<thead>
<tr>
<th>Kentucky Resident Drug Overdose Related Hospitalizations</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-9-CM Codes</td>
<td></td>
</tr>
<tr>
<td>DRUG</td>
<td>3,372</td>
</tr>
<tr>
<td>Nonopioid analgesics</td>
<td>590</td>
</tr>
<tr>
<td>4-Aminophenol</td>
<td>351</td>
</tr>
<tr>
<td>Opiates/opioids</td>
<td>339</td>
</tr>
<tr>
<td>Heroin</td>
<td>8</td>
</tr>
<tr>
<td>Pharmaceutical Opioids</td>
<td>332</td>
</tr>
<tr>
<td>Methadone</td>
<td>31</td>
</tr>
<tr>
<td>Cocaine</td>
<td>90</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>1,781</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>793</td>
</tr>
<tr>
<td>Psychostimulants</td>
<td>63</td>
</tr>
<tr>
<td>Anticoagulants</td>
<td>87</td>
</tr>
<tr>
<td>Other Unspecified</td>
<td>1,755</td>
</tr>
</tbody>
</table>
Drug Overdose Hospitalizations by Total Length of Stay, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Total Charges for Drug Overdose Hospitalizations, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Drug Overdose Hospitalizations by Expected Payer, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Total Drug Overdose Hospitalization Charges by Expected Payer, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Drug Overdose
Emergency Department Visits
2008-2012
Kentucky Resident Drug Overdose Emergency Department Visits, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Age-Adjusted Drug Overdose Emergency Department Visit Rates, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Drug Overdose Emergency Department Visits by Gender, 2008-2012

Kentucky Resident Age-Adjusted Drug Overdose Emergency Department Visit Rates by Gender, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Drug Overdose Emergency Department Visits by Intent, 2008-2012

 Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Crude Drug Overdose Emergency Department Visit Rates by Intent, 2008-2012

 Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
### Kentucky Resident Drug Overdose Related ED Visits

<table>
<thead>
<tr>
<th>DRUG Involved</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2008</td>
</tr>
<tr>
<td><strong>Nonopioid analgesics, Antipyretics, and Antirheumatics</strong></td>
<td></td>
</tr>
<tr>
<td>4-Aminophenol derivatives</td>
<td>805</td>
</tr>
<tr>
<td></td>
<td>428</td>
</tr>
<tr>
<td><strong>Opiates/opioids</strong></td>
<td>590</td>
</tr>
<tr>
<td>Heroin</td>
<td>73</td>
</tr>
<tr>
<td>Pharmaceutical Opioids</td>
<td>518</td>
</tr>
<tr>
<td>Methadone</td>
<td>54</td>
</tr>
<tr>
<td><strong>Cocaine</strong></td>
<td>42</td>
</tr>
<tr>
<td><strong>Antidepressants, barbiturates and other antiepileptics, sedative- hypnotics, and psychotropic drugs not elsewhere classified</strong></td>
<td>2,033</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>804</td>
</tr>
<tr>
<td>Psychostimulants with abuse potential including methamphetamine, MDMA (Ecstasy)</td>
<td>133</td>
</tr>
<tr>
<td><strong>Anticoagulants</strong></td>
<td>65</td>
</tr>
<tr>
<td><strong>Other specified and unspecified drugs</strong></td>
<td>3,195</td>
</tr>
</tbody>
</table>

For ICD-9-CM codes see Appendix A

Kentucky Resident Drug Overdose Emergency Department Visits by Drugs Involved, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Medicaid Recipient
Opiate Overdose
Hospitalizations and
Emergency Department Visits
Medicaid Recipient Opiate Overdose Hospitalizations by Gender, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Medicaid Recipient Opiate Overdose Hospitalizations by Intent, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Medicaid Recipient Total Opiate Overdose Inpatient Hospitalization Charges, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Medicaid Recipient Opiate Overdose Emergency Department Visits by Gender, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Medicaid Recipient Opiate Overdose Emergency Department Visits by Intent, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Medicaid Recipient Opiate Overdose Total Emergency Department Charges, 2008-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Opioid-Related Disease Condition Hospitalizations 2000-2012
Note: 6.7% of all opioid-related disease condition hospitalizations listed also an ICD-9-CM code for drug overdose.

Note: 0.3% of all opioid-related disease condition hospitalizations listed both condition types.
Kentucky Resident Opioid-Related Disease Condition Hospitalizations by Gender, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Opioid-Related Disease Condition Hospitalization Charges, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Opioid-Related Disease Condition Hospitalization Charges by Expected Payer, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Kentucky Resident Hospitalizations Involving Opioid Drug Overdose or an Opioid-Related Disease Condition AND Viral Hepatitis, 2000-2012

Year | Opioid type drug dependence & Viral hepatitis | Nondependent opioid abuse & Viral hepatitis | Drug overdoses due to the effect of opiates and related narcotics & Viral hepatitis
--- | --- | --- | ---
2012 | 378 | 144 | 0
2011 | 293 | 114 | 0
2010 | 208 | 85 | 0
2009 | 157 | 85 | 0
2008 | 135 | 53 | 0
2007 | 108 | 45 | 0
2006 | 113 | 56 | 0
2005 | 89 | 33 | 0
2004 | 210 | 65 | 43
2003 | 203 | 59 | 34
2002 | 138 | 35 | 20
2001 | 118 | 29 | 20
2000 | 72 | 24 | 8

Total Number

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky Outpatient Services Database, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
Neonatal Abstinence Syndrome
Hospitalizations
2000-2012
Kentucky Resident Neonatal Abstinence Syndrome Hospitalizations, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.

Kentucky Resident Neonatal Abstinence Syndrome Hospitalization Charges, 2000-2012

Produced by the Kentucky Injury Prevention and Research Center, January 2014. Data source: Kentucky inpatient hospitalization discharge data, Office of Health Policy. Data for 2010-2012 are provisional and subject to change.
### Kentucky Resident Neonatal Abstinence Syndrome Hospitalizations by Expected Payer, 2000-2012

<table>
<thead>
<tr>
<th>Year</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Self-Pay or Charity</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>5</td>
<td>20</td>
<td>&lt;5</td>
<td>&lt;5</td>
<td>$235,423</td>
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<tr>
<td>2001</td>
<td>16</td>
<td>41</td>
<td>&lt;5</td>
<td>&lt;5</td>
<td>$1,465,498</td>
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<tr>
<td>2002</td>
<td>11</td>
<td>67</td>
<td>8</td>
<td>7</td>
<td>$1,138,068</td>
</tr>
<tr>
<td>2003</td>
<td>21</td>
<td>99</td>
<td>&lt;5</td>
<td>&lt;5</td>
<td>$2,291,710</td>
</tr>
<tr>
<td>2004</td>
<td>14</td>
<td>139</td>
<td>&lt;5</td>
<td>9</td>
<td>$3,044,646</td>
</tr>
<tr>
<td>2005</td>
<td>12</td>
<td>147</td>
<td>7</td>
<td>9</td>
<td>$3,044,646</td>
</tr>
<tr>
<td>2006</td>
<td>11</td>
<td>202</td>
<td>9</td>
<td>5</td>
<td>$5,103,135</td>
</tr>
<tr>
<td>2007</td>
<td>37</td>
<td>270</td>
<td>18</td>
<td>&lt;5</td>
<td>$3,718,883</td>
</tr>
<tr>
<td>2008</td>
<td>38</td>
<td>355</td>
<td>40</td>
<td>&lt;5</td>
<td>$2,291,710</td>
</tr>
<tr>
<td>2009</td>
<td>42</td>
<td>402</td>
<td>35</td>
<td>6</td>
<td>$3,044,646</td>
</tr>
<tr>
<td>2010</td>
<td>90</td>
<td>526</td>
<td>55</td>
<td>7</td>
<td>$3,718,883</td>
</tr>
<tr>
<td>2011</td>
<td>59</td>
<td>694</td>
<td>54</td>
<td>17</td>
<td>$39,770,716</td>
</tr>
</tbody>
</table>

Note: Counts less than 5 were suppressed by state data management policy.

### Kentucky Resident Neonatal Abstinence Syndrome Hospitalization Charges by Expected Payer, 2000-2012

<table>
<thead>
<tr>
<th>Year</th>
<th>Commercial</th>
<th>Medicaid</th>
<th>Self-Pay or Charity</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>$75,463</td>
<td>$155,642</td>
<td>$4,318</td>
<td>$1,074</td>
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<tr>
<td>2001</td>
<td>$989,491</td>
<td>$464,827</td>
<td>$11,180</td>
<td>$20,927</td>
<td>$1,465,498</td>
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<tr>
<td>2002</td>
<td>$181,443</td>
<td>$932,251</td>
<td>$24,374</td>
<td>$113,947</td>
<td>$1,138,068</td>
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<tr>
<td>2003</td>
<td>$685,212</td>
<td>$1,597,333</td>
<td>$9,166</td>
<td>$145,842</td>
<td>$2,291,710</td>
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<td>$2,731,983</td>
<td>$50,125</td>
<td>$189,625</td>
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<td>2005</td>
<td>$471,640</td>
<td>$3,201,153</td>
<td>$46,089</td>
<td>$276,770</td>
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<td>2006</td>
<td>$161,693</td>
<td>$4,802,755</td>
<td>$138,686</td>
<td>$134,258</td>
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<td>$6,001,220</td>
<td>$414,598</td>
<td>$355,295</td>
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<td>$2,700,471</td>
<td>$11,503,166</td>
<td>$685,389</td>
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<td>$3,142,217</td>
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<td>$1,198,435</td>
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<td>$1,231,209</td>
<td>$580,403</td>
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<td>$28,130,564</td>
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<td>$1,606,756</td>
<td>$476,472</td>
<td>$39,770,716</td>
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**APPENDIX A**

ICD-9-CM codes for acute poisonings due to the effects of drugs (drug overdoses)

<table>
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<tr>
<th>Type of Poison</th>
<th>ICD-9-CM codes</th>
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<tr>
<td>DRUG</td>
<td>E850-E585, E950(.0-.5), E962.0, E980(.0-.5), 960-979</td>
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<tr>
<td>- Nonopioid analgesics, Antipyretics, and Antirheumatics</td>
<td>E850(.3-.8), 965(.1-.8)</td>
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<tr>
<td></td>
<td>-- 4-Aminophenol derivatives</td>
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<tr>
<td>- Opiates/opioids</td>
<td>E850(.0-.2), 965.0</td>
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<tr>
<td></td>
<td>-- Heroin</td>
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<tr>
<td></td>
<td>-- Pharmaceutical Opioids</td>
</tr>
<tr>
<td></td>
<td>--- Methadone</td>
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<tr>
<td>- Cocaine</td>
<td>E854.3, E855.2, 968.5, 970.81</td>
</tr>
<tr>
<td>- Antidepressants, barbiturates and other antiepileptics, sedative-hypnotics, and psychotropic drugs not elsewhere classified</td>
<td>E851-E853, E854(.0-.2,.8), E855.0, E950(.1-.3), E980(.1-.3), 966, 967, 969, 970(.0,.1,.89)</td>
</tr>
<tr>
<td></td>
<td>-- Benzodiazepines</td>
</tr>
<tr>
<td></td>
<td>-- Psychostimulants with abuse potential including methamphetamine, MDMA (Ecstasy)</td>
</tr>
<tr>
<td>- Anticoagulants</td>
<td>964.2</td>
</tr>
<tr>
<td>- Other specified and unspecified drugs</td>
<td>E850(.9), E855(.1,.3-.9), E856-E858, E950(.0,.4,.5), E962.0, E980(.0,.4,.5), 960-963, 964(.0,.1,.3-.9), 965.9, 968(.0-.4,.6-.9), 970(9), 971-979,</td>
</tr>
</tbody>
</table>

For more information, please refer to:

Consensus Recommendations for National and State Poisoning Surveillance, Safe States, April 2012.
Conclusions

The combination of multiple prevention approaches such as mandatory enrollment and use of the Kentucky All Schedule Prescription Electronic Reporting system by prescribers and dispensers, physician ownership of pain clinics, prescriber guidelines for pain treatment, and increased law enforcement resulted in substantial decreases in Kentucky resident prescription drug overdose deaths, inpatient hospitalizations, and ED admissions from 2011 to 2012.

With that said, pharmaceutical opioids remained the primary drugs involved in drug overdose deaths; benzodiazepines were the primary drugs involved in drug overdose-related inpatient hospitalizations and ED visits. Pharmaceutical opioid involvement decreased 12% for drug overdose deaths, 8% for inpatient hospitalizations, and 6% for ED visits from 2011-2012. Correspondingly, benzodiazepine involvement decreased 16% for drug overdose deaths, 11% for inpatient hospitalizations, and 9% for ED visits from 2011-2012. Raising awareness of the dangers of mixing benzodiazepines with opioids should be an emphasis of physician continuing education for relaying to opioid patients during medical consultations.

While the contribution of prescription opioids and benzodiazepines to drug overdoses decreased from 2011 to 2012, there was a precipitous increase in heroin involvement in drug overdose deaths, inpatient hospitalizations, and ED visits over the same time period. Heroin involvement increased 207% for drug overdose deaths, 174% for inpatient hospitalizations, and 197% for ED visits. Opioid-related hospitalizations and ED visits are costly in more than only financial terms. Disease conditions already present or those caused by opiate addiction such as viral hepatitis also exert an enormous societal as well as financial toll on the commonwealth’s population. Increased law enforcement, adjudication, legislation, and heroin abuse treatment should be a major priority for Kentucky to reduce heroin-related deaths, and hospitalizations.

Total inpatient hospitalization charges for drug overdoses rose 7% in 2012 to $129.3 million. Likewise, drug overdose ED charges rose 5% to $15.3 million in 2012. The primary expected payers for drug overdose related inpatient hospitalizations were Medicare ($41.3 million) and Medicaid ($34.1 million). Self-pays were the largest expected payer for drug overdose ED visits ($5 million) followed by Medicaid ($4.2 million).

Medicaid recipient opiate overdose ED charges increased 27% in 2012 to $740,000. Inpatient hospitalizations of Medicaid recipients for opiate overdoses leveled off in 2012 at $11 million. Elevated Medicaid charges illustrate the need for naloxone (an opiate antidote) reimbursement by Medicaid so that Medicaid recipients are not charged for its purchase. Intranasal administration of naloxone during an opiate overdose has been credited with saving countless lives.

A multipronged strategy to reduce substance abuse in the Commonwealth of Kentucky involves the basic elements of the public health model that includes comprehensive surveillance and tracking of drug overdoses, identification of the risk factors that result in drug overdoses, development of interventions to prevent drug overdoses, and the widespread adoption of substance abuse prevention interventions. In addition, increased continuing education of physicians on drug abuse and treatment, increased law enforcement, increased adjudication, and increased substance abuse treatment facilities are necessary to decrease the extraordinary toll of substance abuse on Kentucky citizens who are addicted.
About This Report

This report presents drug overdose morbidity and mortality data for Kentucky residents, using multiple data sources:
- Kentucky Inpatient Hospitalization (IH) Discharge Files, Cabinet for Health and Family Services, Office of Health Policy, 2000-2012 (data for 2010-2012 are provisional and subject to change).
- Kentucky Emergency Department (ED) Discharge Files, Cabinet for Health and Family Services, Office of Health Policy, 2008-2012 (data for 2010-2012 are provisional and subject to change).

Drug overdose mortality and morbidity case selection was based on operational definitions of acute drug poisoning (also called “drug overdose”) by the Injury Surveillance Workgroup on Poisoning (ISW7) in their Consensus Recommendations for National and State Poisoning Surveillance, The Safe States Alliance, Atlanta, GA, April 2012.¹

Drug Overdose Deaths:

Each death certificate contains one underlying cause of death and multiple contributing causes of death. The underlying cause of death is defined as the reason that initiated the chain of events leading directly to death. The underlying and contributing causes of death are coded according to the International Classification of Diseases, 10th revision (ICD-10) [www.who.int/classifications/icd10/].

Definition: Drug overdose deaths were identified as deaths with an underlying cause of death in the following range: X40-X44(accidental/unintentional drug poisoning), X60-X64(suicide by drug poisoning), X85 (homicide by drug poisoning), and Y10-Y14 (drug poisoning with undetermined intent).

The types of drugs contributing to drug overdose deaths were identified using ICD-10 codes T36-T50.9 listed in any of the multiple causes of death fields. Contributing drugs were reported in standardized categories, following the ISW7 Poisoning Matrix for ICD-10 Coded Mortality Data.¹

Drug Overdose Hospitalizations and ED Visits:

IH and ED data were coded according to the International Classification of Disease, 9th revision, Clinical Modification (ICD-9-CM, www.icd9cm.chrisendres.com). The ICD-9-CM system describes an injury using diagnosis codes and E-codes. The Kentucky IH and ED data systems include up to 25 diagnosis code fields per case. The first diagnosis code is called the principal diagnosis code. The principal diagnosis for a hospitalized patient is the main reason for the patient’s hospital stay and is based on the clinical findings during the patient’s stay. For ED data, the primary diagnosis code is the diagnosis established to be the main reason for the visit to the emergency department. Other conditions/diagnoses that exist at the time of the IH/ED visit and affect the diagnosis, treatment, or length of stay in the health facility, are also coded in the remaining 24 diagnosis code fields in the IH/ED datasets and are called secondary diagnoses. Injury diagnoses should be supplemented (when circumstances of the injury are known) with additional codes called E-codes. E-codes are separated into three groups: external-cause-of-injury codes, place-of-injury codes, and activity codes.
The external-cause-of-injury code describes the external cause (in this case, poisoning) and the intent of injury. Based on the external-cause-of-injury code, a drug poisoning can be classified by intent as accidental (unintentional, E850-E858), intentional (self-harm, E950.0-E950.5; or assault, E962.0), or undetermined (E980.0-E980.5 when based on insufficient documentation in the medical chart to determine whether the drug overdose was accidental or intentional). Some injury records in the IH or ED datasets, however, are not supplemented with E-codes at all. We treat such records as a separate category and refer to them as “missing intent” or “no E-code”. IH and ED electronic records may contain up to three designated E-code fields. On average, more than 90 percent of the Kentucky HD and ED cases with poisoning diagnoses are supplemented with valid external-cause-of-injury codes.

**Definition:** A hospitalization or emergency department visit was considered a drug overdose if

1) any of the ICD-9-CM codes in the range 960-979 were listed in any diagnosis (principal or secondary) fields; or

2) any of the ICD-9-CM codes in the range E850-E858, E950.0-E950.5, E962.0, or E980.0-E980.5 were listed in the E-code fields.

This Injury Surveillance Workgroup on Poisoning¹ definition is a broader definition than the definition used in the 2012 report² on drug overdose morbidity and mortality in Kentucky. Therefore, if comparing the morbidity sections in the current and in the 2012 report, one will notice about a 30% increase in the reported cases of drug overdose hospitalizations or ED visits. The 2012 report was based on definitions derived from the external-cause-of-injury matrix and didn’t capture encounters of care where the principal diagnosis was not a drug overdose but the secondary diagnosis was drug overdose. A study on drug overdose ED visits in the U.S. suggested that mild or moderate drug overdoses were likely to have the drug poisoning as their primary diagnosis but severe drug poisoning cases were likely to have a critical illness as the primary diagnosis.³ Severe drug overdoses can result in acute respiratory, heart, or renal failure that may be listed as principal diagnoses with a drug overdose listed as the secondary diagnosis. As the state enacts policies and plans for adequate substance abuse treatment resources, the most comprehensive definition to track and enumerate total drug overdose hospitalizations and ED visits was used to provide a more accurate picture of the magnitude of substance abuse and misuse, the specific drugs involved, and the specific populations at higher risk for drug overdoses.

Only records for KY residents treated in Kentucky acute care hospitals or Kentucky emergency departments are included in this report. Data for Kentucky residents treated in neighboring states were not available and not included in this report. Therefore, the presented counts and rates likely underestimate the full extent of drug overdoses in Kentucky. Reported frequencies reflect the number of visits/hospitalizations since follow-up visits and readmissions for one and the same drug overdose could not be identified.

Age-adjusted morbidity and mortality rates were based on 2000 U.S. standard population data. For each of the three data sets, the number of cases classified as assault was low (48 ED visits from 2008–2012, 35 hospitalizations from 2000–2012 and seven fatalities from 2000–2012) and were not included in the figures or discussed in this report.

A section on mental disorder hospitalizations involving opiates/opioids was included in the report in order to describe disease conditions induced by opium, heroin, and/or opioid analgesics. The case selection followed the ISW7¹ framework and included hospitalizations related to opioid type dependence, drug dependence on combinations of opioid type drugs with any other, or nondependent opioid abuse, identified by any of the following ICD-9-CM codes in any of the diagnosis fields: 304 (.00-.02, .70-.72), 305 (.50-.52).
In the hospital discharge dataset, drug overdoses due to the effect of opiates and related narcotics were identified as records with any of the ICD-9-CM code 965(.00-.09) in any of the diagnosis fields.

Viral hepatitis cases were identified by ICD-9-CM code 070 in any of the diagnosis fields.

Neonatal Abstinence Syndrome (NAS) is a drug withdrawal syndrome in a newborn that is caused by the mother’s drug abuse during pregnancy. Hospitalizations involving drug withdrawal syndrome in a newborn are identified by the ICD-9-CM code 779.5 listed in any of the diagnosis fields. A section on NAS hospitalizations was added to this report to describe another aspect and burden of drug abuse and addiction in the Commonwealth.

References:
**Kentucky Reportable Disease Form**

Department for Public Health
Division of Epidemiology and Health Planning
275 East Main St., Mailstop HS2E-A
Frankfort, KY 40621-0001

Hepatitis Infection in Pregnant Women or Child (under the age of five)
Fax Form to 502-696-3803

### DEMOGRAPHIC DATA

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<td>Neg</td>
<td>/ /</td>
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<tr>
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### SERUM AMINOTRANSFERASE LEVELS

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Mother: Hepatitis Risk Factors
- IDU
- Multiple Sexual Partners
- Tattoos
- STD
- HIV
- Foreign Born / Country

Child: Hepatitis Risk Factors
- Mother HBV Pos
- Household member exposure HBV Pos
- Mother HCV Pos
- Household member exposure HCV Pos
- Foreign Born / Country

Mother: Hepatitis A vaccination history: Yes No Refused Dates Given: / / If yes, how many doses: 1 2 3 Year completed: / /

Hepatitis B Vaccination history: Yes No Refused

Child: Hepatitis A vaccination history: Yes No Refused Dates Given: / /

Hepatitis B Vaccination history: Yes No Refused Dates Given: / /

Was PEP Infant of Positive HBV mother given at birth? Yes No