APhA DrugInfoLine®

May 2019

Pharmacogenomics Corner

Advising on this article: Mary W. Roederer

May 7, 2019

Pharmacists need more education on pharmacogenomics

Key Point

In recently conducted interviews, community pharmacists practicing at sites that offer well-established patient-care services cited the need for additional pharmacogenomic training and education. The pharmacists also indicated the need for clinical resources and access to a network of pharmacogenomic experts who can help them implement these services.

Source URL:

http://www.aphadruginfoline.com/pharmacogenomics-corner/pharmacists-need-more-education-pharmacogenomics

Gastroenterology

Advising on this article: C. Wayne Weart

May 7, 2019

Acetaminophen levels may be undetectable in overdoses

Key Point

Plasma levels of acetaminophen were undetectable in blood samples of approximately one-half of adults who presented with acute liver failure due to acetaminophen overdose, according to the results of a retrospective study published in Clinical Gastroenterology and Hepatology.

Source URL:

http://www.aphadruginfoline.com/gastroenterology/acetaminophen-levels-may-be-undetectable-overdoses

Cardiology

Advising on this article: Eric MacLaughlin

May 14, 2019

Accurate measurement of BP is essential to reduce CV risks

Key Point

The American Heart Association (AHA) has released an updated statement on accurate measurement of blood pressure (BP) in adults and children. The statement focuses on office BP assessments, ambulatory blood pressure monitoring (ABPM), and home blood pressure monitoring (HBPM), as the quality of measurement varies widely across settings.

Source URL:

http://www.aphadruginfoline.com/cardiology/accurate-measurement-bp-essential-reduce-cv-risks

Pharmacogenomics Corner

Advising on this article: Mary W. Roederer

May 14, 2019

Use of pharmacogenomic information results in numerous clinical benefits

Key Point

Incorporating pharmacogenomic information into prescribing decisions increases patient–provider communications, patient recall of medication changes, and provider knowledge of pharmacogenomics, according to results of an observational study published in The Pharmacogenomics Journal.

Source URL:

http://www.aphadruginfoline.com/pharmacogenomics-corner/use-pharmacogenomic-information-results-numerous-clinical-benefits

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
May 2, 2019	
Ketorolac tromethamine injection USP 60 mg/2 mL ***(No trade name—Sagent Pharmaceuticals/Zydus (Cadila Healthcare Limited))*** **Microbial growth detected during a routine simulation of manufacturing process**	Sagent Pharmaceuticals announced a voluntary nationwide recall of one lot (#M813513) of ketorolac tromethamine injection USP 60 mg/2 mL (30 mg per mL) because microbial growth was detected during a routine simulation of the manufacturing process. This product was manufactured by Zydus (Cadila Healthcare Limited) and distributed by Sagent. Adult patients administered the product intravenously are at most risk of a serious bloodstream infection of sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. No batches of distributed product have been identified as actually containing microorganisms. To date, Sagent has not received reports of any adverse events associated with this issue. The product is a NSAID indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level. It is supplied in 2-ml glass tubular vials. The lot number being recalled was distributed to hospitals, wholesalers, and distributors nationwide from January to March 2019.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/microbial-growth-detected-during-routine-simulation-manufacturing-process

New Drug Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
May 2, 2019	
Dengue virus vaccine	FDA has approved Dengvaxia, the first vaccine for prevention of dengue disease caused by all dengue virus serotypes (1, 2, 3, and 4) in people aged 9 through 16 years who have laboratory-confirmed previous dengue infection and who live in endemic areas. Dengvaxia is a live, attenuated vaccine that is administered as three separate injections, with the initial dose followed by two additional shots given 6 and 12 months later. Dengue disease is the most common mosquito-borne viral disease in the world and is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands. The first infection with dengue virus typically results in either no symptoms or a mild illness that can be mistaken for the flu or another viral infection. A subsequent infection can lead to severe dengue, including dengue hemorrhagic fever, a more severe form of the disease that can be fatal. Symptoms may include stomach pain, persistent vomiting, bleeding, confusion, and difficulty breathing. Approximately 95% of all severe/hospitalized cases of dengue are associated with second dengue virus infection. Because there are no specific drugs approved for treatment of dengue disease, care is limited to managing the symptoms. Safety and effectiveness of the new vaccine were determined in three randomized, placebo-controlled studies involving approximately 35,000 individuals in dengue-endemic areas, including Puerto Rico, Latin America, and the Asia Pacific region. The vaccine was determined to be approximately 76% effective in preventing symptomatic, laboratory-confirmed dengue disease in individuals aged 9 through 16 years who previously had laboratory-confirmed dengue disease. Dengvaxia has already been approved in 19 countries and the European Union. The most commonly reported adverse effects by those who received Dengvaxia were headache, muscle pain, joint pain, fatigue, injection-site pain, and low-grade fever. The frequency of adverse effects was similar across Dengvaxia and placebo recipients and tended to decrease after each subsequent dose of the

(Dengvaxia—Sanofi Pasteur)

FDA approves first vaccine to prevent dengue disease in endemic regions

vaccine. Dengvaxia is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. This is because in people who have not been infected with dengue virus, Dengvaxia appears to act like a first dengue infection—without actually infecting the person with wild-type dengue virus—such that a subsequent infection can result in severe dengue disease. Health professionals should evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus. This can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.

Source URL:

http://www.aphadruginfoline.com/new-drug-approvals/fda-approves-first-vaccine-prevent-dengue-disease-endemic-regions