DPICtions

Drug & Poison Center Information Center's Newsletter

Fall 2018

In this issue

Cincinnati Children's Hospital – Drug and Poison Information Center Receives Funding from the Ohio Department of Mental Health and Addiction Services Bureau of Prevention

The **Cincinnati Children's Hospital – Drug and Poison Information Center (DPIC)** has received funding from the Ohio Department of Mental Health and Addiction Services (OMHAS) to implement a community based comprehensive approach designed to address unresolved trauma and the connection between that trauma and substance abuse. This project does not replicate existing services but expands the scope of other trauma initiatives currently conducted by DPIC. DPIC will partner with the People Color Wellness Alliance (POCWA) to implement community-based Trauma Informed Care in the urban core of Cincinnati. To assure that the challenges of inclusivity, cultural relevance, cultural sensitivity, interdependence, and trust are maintained, DPIC will utilize a grassroots community coalition approach and replicate a model approved by the U.S. Department of Health and Human Services/Office of Minority Health/Addressing Childhood Trauma. Project partners will work as a team united in the Collective Impact process to strategize methods involving youth in school and/or community settings who are at high risk of, or display behaviors consistent with toxic stress, exposure to trauma, and/or diagnosed with PTSD. The youth participants and their families reside in the economically deprived and socially ignored section(s) of the Urban Core of Cincinnati. Program participants include children of incarcerated parents. Most live at or below poverty level and are at high risk for negative social, emotional and personal development that increase their risk of involvement in the drug culture. The Collective Impact process will engage DPIC and POCWA to format strategies that address the problem(s) of exposure to trauma and its relationship to involvement in the drug culture.

New Safety Warnings for Fluoroquinolone Antibiotics

Sheila Goertemoeller PharmD, DABAT, ICPS

The fluroquinolones are a class of broad spectrum antibiotics used widely to treat a range of infections from pneumonia to pyelonephritis. They work by inhibiting an enzyme essential for the replication of certain bacteria. The first fluroquinolone Ciprofloxacin hit the US market in 1987, followed in succession by Norfloxacin, Ofloxacin, Levofloxacin, Moxifloxacin and Gemifloxacin. As a class, fluroquinolones are generally well tolerated and serious side effects are uncommon. The most common side effects are gastrointestinal in nature. Other noted side effects for some fluroquinolones include changes in blood sugar, peripheral neuropathy or mood alteration. In 2008, a boxed warning was added to all fluroquinolones regarding its potential to cause tendinitis or tendon rupture across all ages in patients, with or without risk factors.

In July 2018, the FDA strengthened existing warnings regarding blood sugar and central nervous system side effects to include updates on the prescribing information across all fluoroquinolones. The warnings on the prescribing label now state that **fluoroquinolones can cause hypoglycemia leading to coma, and serious changes in mood or behavior.** The warnings are particularly concerning for those with diabetes, the elderly or mental health patients. What this translates to in terms of what patients and prescribers should do is to continue communication regarding side effects or changes in medical history with each other. For example: if a patient goes in to an emergency clinic for a suspected infection, they should let the health care team know if they have been recently diagnosed with diabetes. Patients prescribed fluoroquinolones should vigilantly watch for hypoglycemic side effects (dizziness, excessive sweating, or tiredness) or changes in behavior or memory.

These warnings and label changes came upon after review of submitted adverse effect to the FDA. The FDA continues to monitor post marketing safety of medications. Health care professionals are encouraged to report serious side effect to fluroquinolones or any other medications to Medwatch by calling 1-800-332-1088 or by following the FDA online link https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home As a result of vigilant post marketing safety surveillance the FDA has withdrawn from the US market the following fluoroquinolones: Gatifloxacin (hypo and hyperglycemia), Grepafloxacin (hepatotoxicity), and Temafloxacin, Lomefloxacin, Sparfloxacin and Enoxacin because of multiple serious side effects.

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2018-2019 Update for Influenza Prevention and Treatment

Regina Tarantino, RN, BSN, CSPI

There are four primary updates from the Advisory Committee on Immunization Practices (ACIP) for this flu season. Vaccine viruses included in the 2018-19 U.S. trivalent influenza vaccines will be an A/Michigan/45/2015 (H1N1) pdm09-like virus, an A/Singapore/INFIMH-16-0019/2016 (H3N2)–like virus, and a B/Colorado/06/2017- like virus of Victoria lineage. Quadrivalent influenza vaccines will include the strains in the trivalent vaccine plus the influenza B vaccine virus, a B/Phuket//3073/2013 of Yamagata lineage.

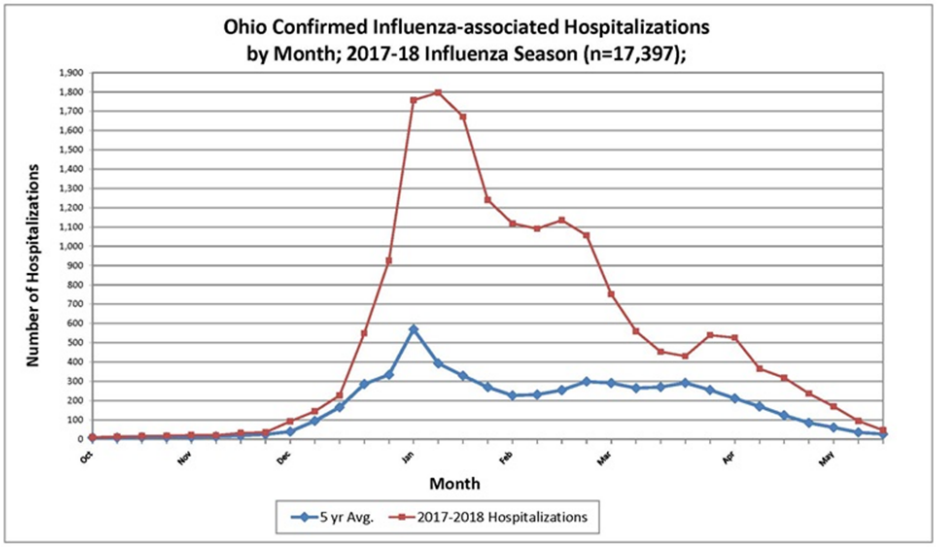
Vaccines that are expected to be available include Inactivated influenza vaccines (IIVs), recombinant influenza vaccine (RIV), and the live attenuated influenza vaccine (LAIV). In addition, standard-dose, unadjuvanted, inactivated influenza vaccines will be available in quadrivalent (IIV4) and trivalent (IIV3) formulations. High-dose inactivated influenza vaccine (HD-IIV3) and adjuvant inactivated influenza vaccine (aIIV3) will be available in trivalent formulations.

After two seasons of non-use, the LAIV4 (FluMist Quadrivalent) is now recommended for whom it is appropriate. IIV, RIV4, or LAIV4 are recommended for individuals with egg allergies. Egg allergies that caused only hives after egg exposure should receive the vaccine. Patients who report egg allergies and state they have experienced angioedema, respiratory distress, dizziness, or recurring vomiting and treated with epinephrine or other emergency interventions, may also receive recommended, and age and health status appropriate vaccine (IIV, RIV4, or LAIV4). The vaccine administration in the latter group should be monitored by a health-care professional in a medical setting who is familiar, can recognize, and manage severe allergic reactions. The ACIP recommends that all patients be observed for 15 minutes after vaccine administration in the event the patient experiences syncope. Any prior severe allergic reaction to influenza vaccine regardless of the suspected allergen is a contraindication to future use.

ACIP will continue to monitor pertinent data in regards to anaphylaxis cases which developed after Influenza vaccine administration.

There is also an expansion of age requirements for Afluria Quadrivalent (IIV4) from ≥ 18 years to ≥ 5 years. The age expansion also includes Fluarix Quadrivalent (IIV4) from ≥ 3 years to ≥ 6 months. For more information and updates, health care providers can access https://www.cdc.gov/flu periodically. Also, https://www.cdc.gov/flu/professionals/acip/2018-2019/2018-19summary.htm is a great reference.

ACIP recommends that the influenza vaccine is offered to patients by the end of October. However, the vaccine should continue to be offered for as long as vaccinations are available. Children greater than 6 months up to 8 years require 2 doses. These patients should receive the initial dose as soon as possible and the second dose before the end of October. The 2nd dose should be held until at least 4 weeks from the initial dose (Grohskopf et al., 2018).



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Dragon's Breath

Sara K. Pinkston, RN, MSN, CSPI

A new trend in frozen desserts is called Dragon's Breath, Heaven's Breath, and/or nitro puff. It consists of colorful cereal made into balls and covered with liquid nitrogen right before serving. When ingested the resulting vapor comes out of the nose & mouth and resembles smoke as seen in pictures of mythical dragons. Although colorful and possibly entertaining, these frozen desserts may cause burns of the mouth and skin as well as breathing difficulties.

The FDA distributed a safety alert August 30, 2018, regarding the frozen treats. It warns the liquid nitrogen, which is sprayed on the balls of cereal right before consumption, can cause severe damage to skin and internal organs if mishandled or ingested. This is due to extremely low temperatures caused by the liquid nitrogen. Breathing difficulties have been reported as well, especially in those with asthma.

The safety alert warns "consumers to avoid eating, drinking, or handling foods prepared using liquid nitrogen at point of sale and immediately before consumption, due to risk of injury" (US FDA, 2018). These products have been sold in malls, state and local fairs, and food courts. Even after the liquid nitrogen has evaporated the foods' temperatures can remain extremely low and have caused injury.

The FDA advises consumers who have experienced injury by handling or eating products sprayed with liquid nitrogen to immediately contact their health care provider. They should also consider reporting their injury via MedWatch at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

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Cincinnati Community Oriented Trauma System (C-COTS)

Year Two Evaluation Results

Alysia Longmire, Prevention Education Specialist

Miyohnna Terry, Prevention Education Specialist

The Drug and Poison Information Center just completed Year 2 of the Cincinnati Community Oriented Trauma System (C-COTS) Project. This project is funded by the U.S. Department of the Health and Human Services (DHHS)- Office of Minority Health (OMH) to implement strategies that address childhood exposure to trauma. Strategies take place over a five-year period and include Trauma Informed Care training for school staff, parents, service providers, and community residences; annual assessment of Kindergarten – Second Grade students in school settings; interventions tailored to assessment results; parent engagement/parenting skills training; health promotion; mental health services, and substance abuse prevention. According to research conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) and others, exposure to traumatic experiences (including adverse childhood experiences) has been linked to substance abuse disorders. These disorders, including abuse and dependence, often coexist with Post Traumatic Stress Disorder (PTSD) and other behavioral conditions. The C-COTS Project obtained baseline data during the first year of the project. The baseline data revealed that among the kindergarten to second grade participants assessed, almost half had Adverse Childhood Experiences (ACEs) scores of 3 or higher, indicating increased likelihood of adverse health outcomes.

During Year 2, the implementation of the C-COTS trauma informed intervention model that focuses on educational, social, and emotional supports began. This model has provided participants with access to programming that equips them to remediate unhealthy behaviors. Six community service providers initiated Trauma Informed Care; conflict resolution; healthy lifestyles; safe and drug free lifestyles; violence prevention; and other interventions. In subsequent years, we will measure the impact of C-COTS interventions on behavioral outcomes displayed by participants.

Feel free to contact Marsha Polk, C-COTS Principal Investigator at marsha.polk@cchmc.org, Alysia Longmire at alysia.longmire@cchmc.org, or Miyohnna Terry at miyohnna.terry@cchmc.org.

FDA Approves New Drug Epidiolex®, a Cannabidiol Product

Elizabeth Howell, PharmD Candidate James L. Winkle College of Pharmacy

Cannabidiol (CBD) is a naturally occurring cannabinoid, and the active ingredient in the newly approved drug called Epidiolex®. Epidiolex® is the first drug to be approved for clinical use containing a product derived from marijuana. Epidiolex® does not contain the psychoactive component tetrahydrocannabinol (THC) that is in marijuana. FDA approval was received on June 25th, 2018. Data supports its use in two severe and rare forms of epilepsy. The FDA approved the oral solution for the use in Lennox-Gastaut Syndrome and Dravet Syndrome, with an initial dose of 2.5mg/kg twice daily, and a maintenance of 5mg/kg twice daily. It isn't known exactly how the drug works to reduce the number of seizures in these conditions. Some studies suggest it has low abuse potential but the data is not clear. The DEA just changed the classification of Epidiolex® from a Schedule I to Schedule V on September 28th, 2018 to reflect a lower level of abuse potential.

Epidiolex® is metabolized by the liver, and therefore may have the potential to cause liver injury. Serious signs to look out for include: dark urine, severe fatigue, stomach pain, light-colored stools, throwing up, or yellow skin or eyes. The presence of any of these warrant an immediate call to your doctor. Less serious side effects that can occur include: feeling sleepy, appetite loss, feeling tired or weak, loose stools, or weight loss.

Lennox-Gastaut syndrome is a form of epilepsy that develops most commonly in children 3-5 years of age. Patients experience different types of seizures that may occur throughout the day. In the majority of patients a cause can be identified. As a result of the high frequency of seizures these children commonly experience some loss of cognitive function and behavioral irregularities. Lennox-Gastaut is resistant to many medications and therapies, making it a focus area for research and drug development.

Dravet syndrome is also a form of epilepsy that develops usually during the first year of life. Seizures are frequent and lengthy causing delay in childhood development, in addition to loss of muscle control, speech impairment, and other health problems. The mechanism is more understood and frequently is associated with a mutation in a specific gene. Epidiolex® is the first medication approved for the treatment of Dravet syndrome.

Trials have shown a tremendous impact on the reduction of seizure frequency in these patient populations. Through the FDA's Compassionate Use Access program, more than 1,000 patients with either Lennox-Gastuat or Dravet Syndrome have been treated at no expense with Epidiolex®. Previous to enrollment in the program these patients were out of options to treat the debilitating seizures. The cost is expected to be quite high once it is available, with estimates of $32,500 per patient, per year. The U.S. government is expected to pick up some of that cost since Epidiolex® has an orphan drug status. There are still questions that haven't been answered just yet, such as safety with long term use or potential for drug interactions, but as Epidiolex® is used these will eventually be discovered. Despite some uncertainty, research has shown a glimpse into the possibility for a seizure free life in patients who had little hope before.

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Aiming to Decrease Pediatric Adverse Events:

Responsible Use of Antibiotics

Angela Campos RN, MSN, CNL, CSPI, CPST

The term "super bugs" is nothing new in the US. For years we've been aware that the over prescribing of antibiotics has contributed to antibiotic resistant bacteria. *Be Antibiotics Aware* is a campaign started by the CDC to raise awareness of the side effects of antibiotic overuse. Antibiotics are a lifesaving scientific achievement but they are not without risk, especially to our Pediatric population. A CDC study estimates that from 2011-2015 about 70,000 children visited the ED for a related adverse drug event (Lovegrove et al., 2018). 1 in 400 children under age 2 visit the ED each year for antibiotic reactions (Lovegrove et al., 2018). An analysis spanning 11 years identified children 0-4 years had the highest incidence of antibiotic adverse drug related incidents; the most common symptoms seen were dermatologic and gastrointestinal symptoms (Burgeois, Mandl, Valim, & Shannon, 2009).

The CDC's *Be Antibiotics Aware* campaign (https://www.cdc.gov/antibiotic-use/) aims to raise awareness with prescribing clinicians and caregivers to understand that an antibiotic is not always the right treatment for a child's illness. They have laid out core elements for antibiotic stewardship in outpatient, hospital, and long term care facility settings. Antibiotic stewardship is defined as measuring antibiotic prescribing, improving prescribing by clinicians and use by patients so they are only used when needed, minimizing missed or delayed diagnoses leading to underuse of antibiotics, and ensuring that the right drug, dose, and duration are selected when an antibiotic is truly needed (Sanchez, Fleming-Dutra, Roberts, & Hicks, 2016). The campaign website holds resources for clinicians and patients on identifying proper use of antibiotics and treatment alternatives when antibiotics are not the answer. There are printable resources available. #BeAntibioticsAware

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Unusual Uses of Personal Activity Trackers

Shannon Staton-Growcock, MSN, RN, CSPI

So it's that time of year, the weather has turned cold and the holidays will soon be upon us. One of the hot items that may be on wish lists is the new Apple iWatch or some other brand of activity tracker (FitBits, Garmin, Alta HR, etc). These activity trackers are a wonderful tool to monitor heart rate, help improve exercise training routines, and in some cases have been lauded for more serious benefits as well. There are a number of examples of some trackers warning the user about possible life-threatening health complications. There is even a current commercial depicting how an activity tracker alerted a man to seek medical help and he ended up having a pulmonary embolism.

In light of all these health benefits, these new personal electronic tools have a flip side. Some people are using their heart rate monitors to track an extremely unhealthy pursuit: illegal drug use and an attempt at staying "safe" during drug binges. People on Reddit, Twitter and other social media platforms have been sharing stories about using their wearable devices to track their heart rate when using drugs such as cocaine, ketamine and speed. Klee, 2018 noted a few social media posts that provided examples of the types of information drug users are reporting in conjunction with their activity trackers. One user noted when their device shows their heart rate is 150 beats per minute or more they have determined they need to skip the next bump (or line). Another user noted that his normal resting heart rate runs between 75 to 90 beats per minute, but spikes up to 180 when he's taking 4-MMC, a type of amphetamine. The user commented that's the same level his heart rate reaches while playing sports (Sgobba, 2018).

Cocaine, amphetamines and other stimulants increase your heart rate and blood pressure. They also create a risk for other irregularities to occur in your heart rhythm. That is often why cardiologists caution use of these medications. Medical professionals warn that using heart rate monitors to protect yourself from overdosing may provide a false sense of security (Al-Heeti, 2018). The risks exist, whether you're tracking your heart rate during that drug use time or not. It's important to reiterate heart rate trackers were created to help gauge exertion during biking, running, swimming, or other cardiac workouts, not illegal drug use.

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Valsartan Recall

Ethan Kursim, PharmD candidate, James L Winkle College of Pharmacy

In July, 2018 the FDA issued a voluntary recall of drug products containing the active ingredient valsartan, a drug used to treat high blood pressure. The recall has been expanded to include several manufacturers of valsartan containing drugs, however not all valsartan containing products have been recalled. This recall is due to the presence of the chemical N-nitrosodimethylamine (NDMA), a probable human carcinogen (a substance that could cause cancer) appearing in the drug products. The NDMA impurity is thought to be related to a change in manufacturing process of valsartan. NDMA is a contaminant commonly found in the environment, being found in water and foods, including meats, dairy, and vegetables.

The FDA's review is ongoing at the time of this article and includes investigating NDMA levels in the recalled drug products, assessing NDMA's effects on patients who have received the medications, and developing measures to reduce or eliminate the impurity from future batches.

The FDA recommends that patients currently taking valsartan from a recalled lot should continue taking the medication until their doctor or pharmacist provides a replacement or a different treatment option is offered. Not all valsartan products contain NDMA, so pharmacists may be able to provide a refill of valsartan medication with a lot# not affected by the recall. Various manufacturers of valsartan were included in the recall. The list of affected lots of valsartan can be found on the FDA website: https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615703.pdf

The website also lists a shorter list of valsartan products that were not included in this recall: https://www.fda.gov/downloads/Drugs/DrugSafety/UCM615704.pdf
The recall currently extends to valsartan and valsartan combination products such as valsartan/ hydrochlorothiazide and amlodipine, along with valsartan, and hydrochlorothiazide.

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Not Your Grandma's Marijuana
Medical Marijuana in Ohio- Part 1 of 3

Jan Scaglione, B.S., M.T., PharmD, D.ABAT

The law in Ohio that allows citizens to gain access to medical marijuana, HB 523, became effective September 8, 2016 and operational this past September 8th. At the time of this article, there are no dispensaries actually dispensing medical marijuana, but operations are under way to make this happen somewhere between December 2018 to February 2019. This article goes over the law itself, Part 2, in the next edition of DPICtions, will go over authorized forms of medical marijuana we will see in the dispensaries, and Part 3 will examine known pharmacology and reported side effects from concentrated forms of marijuana.

I titled this article specifically to draw your attention to the fact that while we may believe we have an understanding of marijuana in general, we do not know or understand the world of concentrated marijuana very well at all. Marijuana is still a schedule I controlled substance on a federal level in the U.S., and as such, has been deemed to have no medical value. The State of Ohio Board of Pharmacy gave medical marijuana a schedule II designation, indicating there is medical value, but high abuse liability to it. Medical marijuana is concentrated cannabis with a specific percentage of tetrahydrocannabinol (THC), the psychologically active part of the plant. Research involving high concentrations of THC cannabis is just beginning in the U.S., leading to misleading assumptions of safety compared to early forms of marijuana. For now, let's look at the law and what it entails.

There are currently 21 medical conditions that qualify a person for medical marijuana use in Ohio. The list of conditions may be found on the Ohio Medical Marijuana Control Program (OH-MMCP) website at https://www.medicalmarijuana.ohio.gov/. Updates on all the information included in this article will be available there as well. If a person has a medical condition that is not listed as qualifying for medical marijuana, the State Board of Pharmacy is willing to consider adding additional ones to the list. Physicians that would like to help patients obtain medical marijuana will write a "Certificate To Recommend", or CTR, that will enable a patient to go to a dispensary and obtain it. This is different than a prescription that someone brings to a pharmacy, and again has to do with the fact that marijuana is still federally controlled as an illicit substance. There are approximately 300 physicians so far in Ohio that have taken the 2-hour continuing education course that allows them write a CTR for a patient. Many physicians are not expected to train to write CTR's for patients, so a patient will need to understand that not every physician will be able to perform this function for them if desired.

There are 26 companies cultivating medical marijuana with provisional licenses and of these, 10 have obtained operational licenses so far and are actively growing it. Two companies have indicated they will have plant material ready by either the end of 2018 or beginning of 2019 for patients. A total of 13 provisional licenses for processors have been granted, and 5 testing laboratories will analyze the products produced by both the cultivators and processors. The first available form of medical marijuana is expected to be plant material. There will be a maximum of 60 dispensaries within the state of Ohio, split among 4 primary districts; Northwest, Northeast, Southwest, and Southeast. Check the OH-MMCP website for information on a specific county. Look for more to follow in Part 2 on this topic.

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American Association of Poison Control Centers

Cincinnati Children's
changing the outcome together

Visit our website https://www.cincinnatichildrens.org/service/d/dpic

Visit our blog https://www.cincinnatichildrens.org/service/d/dpic/dpic-blog

The Cincinnati Drug and Poison Information Center (DPIC) at Cincinnati Children's Hospital Medical Center is a 24-hour emergency and information telephone service for anyone with concerns about poison or drugs.

The center's specially trained staff of pharmacists, pharmacologists and nurses and drug / poison information assistants answer questions about poisonings, drug abuse, product contents, substance identification, interactions and adverse reactions.

The Drug and Poison Information Center also works to provide you with important prevention information, educational materials, first-aid information, common household hazards and references to national helpline organizations and agencies.

The phone number for the Cincinnati Drug and Poison Information Center is **1-800-222-1222.**

The center also offers contract services to businesses looking for pharmacovigilance and safety surveillance for post-marketing and clinical trials.

POISON Help
1-800-222-1222

Editors: Alysha Behrman RN, MSN, CSPI, ICPS; Sheila Goertemoeller PharmD, D.ABAT, ICPS ; Robert Goetz PharmD, D.ABAT; Marsha A. Polk HPT, OCPS; Jan Scaglione MT, PharmD, D.ABAT; Earl G. Siegel PharmD, OCPS; Shan Yin, MD, MPH.

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