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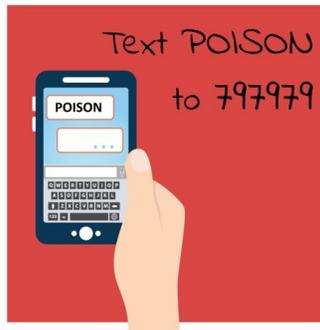
Drug & Poison Center Information Center's Newsletter

Summer 2017



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STEP 1



STEP 2



STEP 3



BE PREPARED ANYTIME & ANYWHERE WITH #POISONHELP



Cincinnati Community Oriented Trauma System (C-COTS) Year One Evaluation Results

Marsha A. Polk, Manager, Education and Outreach
Alysia Longmire, Prevention Education Specialist

The Cincinnati Children's Hospital Medical Center – Drug and Poison Information Center is one of only seven institutions recognized 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. Marsha A. Polk, Manager of Education and Outreach at the Drug and Poison Information Center and Principal Investigator of the DHHS – OMH funded Cincinnati Community Oriented Trauma System (C-COTS) has concluded the first year of the project. Baseline data has been obtained and the Adverse Childhood Experience (ACE) assessment reveals that among the kindergarten to second grade participants assessed, almost half have ACE scores of 3 or higher. ACE scores of 3 or higher indicate increased likelihood of adverse health outcomes. Family member incarceration is the most frequently reported traumatic event, followed by bullying and a family member's unexpected death. In addition, a significant number of the 5 to 7 year olds assessed reported living in a household where someone abuses alcohol and other drugs in their presence; where someone in their home is physically violent; and/or has witnessed someone in the neighborhood being shot or killed. As the project moves into the coming year several items will be addressed. The primary focus will be the implementation of the C-COTS trauma informed intervention model that focuses on educational, social, and emotional supports. This model is intended to provide minority children, adolescents and their families with access to the programming that equips them to remediate unhealthy behaviors. Feel free to contact Marsha Polk, C-COTS Principal Investigator at marsha.polk@cchmc.org or Alysia Longmire at alysia.longmire@cchmc.org.

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Preventing Occupational Fentanyl and Fentanyl Analog Exposures in Emergency Responders

American College of Medical Toxicology (ACMT) & American Academy of Clinical Toxicology
(AACT) Position Statement Excerpts, July 12, 2017



Fentanyl and fentanyl analogs are potent opioid receptor agonists. Fentanyl and its analogs are increasingly implicated in overdose and death in North America among illicit opioid users. To date, there has been limited guidance for emergency responders. We aim to address the risks of occupational exposures to ultra-potent opioids and the role of various types of personal protective equipment to reduce those risks.

The position of ACMT and AACT, is as follows:

General Precautions and Management of Exposure

- Workers who may encounter fentanyl or fentanyl analogs should be trained to recognize the symptoms and objective signs of opioid intoxication, have naloxone readily available, and be trained to administer naloxone.
- For opioid toxicity to occur the drug must enter the blood and brain from the environment. Toxicity cannot occur from simply being in proximity to the drug.
- Toxicity may occur in canines utilized to detect drug. The risks are not equivalent to those in humans given the distinct contact that dogs, and not humans, have with the local environment.

Dermal precautions

- For routine handling of these drugs, nitrile gloves provide sufficient protection.
- In situations where an enclosed space is heavily contaminated with a potential highly potent opioid, water resistant coveralls should be worn.
- Incidental dermal exposures should immediately be washed with copious amounts of water. Alcohol based hand sanitizers should not be used for decontamination as they do not wash opioids off the skin and may increase dermal drug absorption.

Respiratory precautions

- In the unusual circumstance of significant airborne suspension of powdered opioids, a properly fitted N95 respirator or P100 mask is likely to provide reasonable respiratory protection.

Mucous Membrane/Splash Exposure

- OSHA-approved protection for eyes and face should be used during tasks where there exists possibility of splash to the face.

Naloxone Administration and Airway Management

- Naloxone should be administered to those with objective signs of hypoventilation from opioid intoxication.
- If hypoventilation persists following initial naloxone dose and personnel with advanced airway training are not available, repeat naloxone until reversal is seen or 10 mg is administered.
- Personnel with advanced airway training should provide airway support for patients who are in extremis or those who do not improve with naloxone.

Long-term Sequelae of Exposure

- In the absence of prolonged hypoxia, no persistent effects are expected following fentanyl or fentanyl analog exposures.
- Those with small subclinical exposures and those who awaken normally following naloxone administration will not experience long-term effects.

* The American College of Medical Toxicology and American Academy of Clinical Toxicology recognize the challenges in issuing recommendations where available data are incomplete. We believe that recommendations should be protective of emergency responders, but not result in unnecessary delays in care to patients with time-sensitive conditions. We also recognize that PPE can interfere with task performance by emergency responders and law enforcement officials. Due to the limited available data, the following recommendations primarily represent consensus expert opinion.

For more information please visit http://www.acmt.net/resources_position.html

Reference: The American College of Medical Toxicology & The American Academy of Clinical Toxicology. *ACMT and AACT position statement: Preventing occupational fentanyl analog exposure to emergency responders*. Retrieved 8.25.17 from: http://www.acmt.net/Library/Fentanyl_Position/Fentanyl_PPE_Emergency_Responders.pdf

Water Awareness and Algal Blooms

Lisa Geis, EMT



Water based advisories are often seen in the summer. Some of the factors that contribute to Harmful algal blooms (HAB) include sunlight, low-water or low-flow conditions, calm water, warmer temperatures, and excess nutrients (phosphorus or nitrogen). The primary sources of nutrient pollution are runoff of fertilizers, animal manure, sewage treatment plant discharges, storm water runoff, car and power plant emissions and failing septic tanks.

A HAB is a large growth of bacteria that can produce toxins. These toxins may affect the liver, nervous system and/or skin.

Although most blooms are green algae and not harmful, there are some that are actually a type of **cyanobacteria** that have the ability to produce toxins.

The Ohio Department of Health posts different advisories based on the risk for humans to these algal blooms. The first is just the advisory which generally looks like this:

Advisory

Have fun on the water, but know that blue-green algae are in many Ohio lakes. Their toxins may be, too.

Be Alert! Avoid water that:

- looks like spilled paint
- has surface scums, mats or films
- is discolored or has colored streaks
- has green globs floating below the surface



Avoid swallowing lake water.

For more information, visit ohioalgaefinfo.com or call 1-800-OHBEACH.



Warning

WARNING

AN ALGAL BLOOM IS PRESENT AND/OR ALGAL TOXINS HAVE BEEN DETECTED. SWIMMING AND WADING ARE NOT RECOMMENDED FOR:

CHILDREN, PREGNANT OR NURSING WOMEN, THOSE WITH CERTAIN MEDICAL CONDITIONS AND PETS.

FOR MORE INFORMATION GO TO:
WWW.OHIOALGAEINFO.COM
OR CALL 1-866-644-6224

Danger

DANGER

AVOID ALL CONTACT WITH THE WATER

ALGAL TOXINS AT UNSAFE LEVELS HAVE BEEN DETECTED

FOR MORE INFORMATION GO TO:
WWW.OHIOALGAEINFO.COM
OR CALL 1-866-644-6224

An **orange** Recreational Public Health Advisory will be added to the white sign when a HAB is visually confirmed and/or when cyanotoxin levels are equal to or exceed Recreational Public Health Advisory threshold. It indicates that an algal bloom has been detected, and that swimming and wading are not recommended for children, pregnant or nursing women, those with certain medical conditions, and pets.

A **red** sign will be added to the white sign when HAB toxin levels are equal to or exceed the Elevated Recreational Public Health Advisory threshold. It advises that algal toxins at unsafe levels have been detected and to avoid all contact with the water.

If you come into contact with HABs, swallow water with HAB toxins or breathe in water droplets, you could get a rash, have an allergic reaction, get a stomachache, or feel dizzy or light-headed. HABs also are toxic to pets. Also do the following after contact:

1. If you come in contact with HAB toxins you should rinse off with fresh water as soon as possible.
2. See a doctor if you or your children might be ill from HAB toxins. If your pet appears ill, contact your veterinarian.
3. Report the bloom to Ohio EPA by completing the report form and emailing it to HABmailbox@epa.ohio.gov.

HABs have different colors and looks. Some colors are green, blue-green, brown, black, white, purple, red and black. They can look like film, crust or puff balls at the surface. They also may look like grass clippings or dots in the water. Some HABs look like spilled paint, pea soup, foam, wool, streaks or green cottage cheese curd.

You can find public beaches and water advisories listed on the following website. This is the most up to date information posted by the Ohio Department of Health <http://publicapps.odh.ohio.gov/beachguardpublic/>

For more information about harmful algal blooms, contact: [Public Interest Center](#), Ohio EPA (614) 644-2160

References:

- Ohio Environmental Protection Agency. *Ohio Algae Information for Recreational Waters: Advisories*. Retrieved 8.25.17 from: <http://epa.ohio.gov/habalgae.aspx#147744473-advisories>
- Ohio Environmental Protection Agency. *HAB General Handout*. Retrieved 8.25.17 from: <http://epa.ohio.gov/Portals/0/general%20pdfs/HABGeneral.pdf>
- Ohio Environmental Protection Agency. *HAB Warning Sign*. Retrieved 8.25.17 from: <http://epa.ohio.gov/Portals/0/general%20pdfs/OrangeRecreationalPublicHealthAdvisory.pdf>
- Ohio Environmental Protection Agency. *Ohio Algae Information for Recreational Waters: Basics*. Retrieved 8.25.17 from: <http://epa.ohio.gov/habalgae.aspx#147744472-basics>

Fake Oxycontin Tablets : Cuyahoga County

Tisha Carson RPh, CSPI

In July, the Cuyahoga County Medical Examiner sent a strong warning to the public regarding counterfeit pills made to look like OxyContin. He released this statement:

"Today the Cuyahoga County Drug Chemistry Laboratory identified carfentanil in pills that were made to look like OxyContin tablets. This situation is alarming, as the potency of carfentanil is substantially greater than the oxycodone found in OxyContin, and there is a serious risk of unintentional overdose in their use," said Dr. Thomas Gilson. "People who recreationally use OxyContin purchased from street sources should be aware of this very dangerous development that may result in rapid death. These fake tablets are illegally manufactured to resemble OxyContin. The supply of tablets dispensed legally from a pharmacy will not be affected by this."

The round, light blue pills with an imprint code of M surrounded by a square were submitted to the laboratory by the Cleveland Police Department. OxyContin is prescribed to treat severe pain. Carfentanil is meant to be used in large animals and is not safe in humans. Carfentanil is 5000 times more potent than OxyContin.



(Photo Courtesy of Cuyahoga County Medical Examiner's Office)

If you or anyone that you know is actively using or recovering from opioid addiction, contact Project DAWN for information at 216-778-5677. Eligible program participants, are given FREE Naloxone kits – the opioid reversing antidote.

The [Alcohol, Drug Addiction and Mental Health Services](#) (ADAMHS) Board of Cuyahoga County provides a 24-hour crisis hotline at 216-623-6888. Additionally, the Cincinnati Drug and Poison Information Center (DPIC) is open 24-hours a day at 800-222-1222.

Reference: Cleveland Channel 19 News. (July 26, 2017). *Warning: Fake OxyContin pills putting people in danger*. Retrieved from: <http://www.cleveland19.com/story/35976874/warning-fake-oxycontin-pills-putting-people-in-danger>

Emerging Threat Report

Second Quarter 2017

Drug Enforcement Administration (DEA)

The Emerging Trends Program compiled a quarterly snapshot for the second quarter of 2017 with data from a query of seizure and analysis information from the DEA's lab. In the Opioid/ Analgesics category there were 269 identification of fentanyl and related substances. 69% of the identifications were fentanyl, followed by furanyl fentanyl (9%). Of the 187 fentanyl identifications, fentanyl was found as the only controlled substance in 46% of the identifications, and **fentanyl was found in combination with heroin in 43% of the identifications.**



Reference: NDEWS National Drug Early Warning System. *Emerging threat reports: Second quarter 2017*. Retrieved 8.25.17 from: <https://ndews.umd.edu/sites/ndews.umd.edu/files/emerging-threat-report-2017-quarter-2.pdf>

National Institute for Occupational Health and Safety (NIOSH) Plans New Location

Frank Quattrone RN, BSN, CSPI
Earl Siegel PharmD



NIOSH is a federal agency responsible for conducting research and making recommendations for the prevention of work related injuries and illness. It is part of the Centers for Disease Control and Prevention within the U.S. Department of Health and Human services. NIOSH has more than 1300 employees from a diverse set of fields including epidemiology, medicine, nursing, industrial hygiene, safety, psychology, chemistry, statistics, economics and many branches of engineering. They are combining 3 locations in a planned new building at a site at the northwest corner of Reading Road and Martin Luther King.

In 2004, it was proposed to build a new building in Cincinnati area to consolidate the aging Robert A Taft Laboratory and Alice Hamilton Laboratory that were built in the 1950s. In 2007, a location in Clermont County was being considered for the building but the recession put this on hold. Senator Sherrod Brown helped obtain funding for the new federal building from the U.S. Department of Health and Human Services 2015 annual budget in the amount of \$110 million.

One month ago, the Centers for Disease Control and Prevention announced it planned to purchase and build the new facility. The location will be near the University of Cincinnati, many local hospitals and the new Martin Luther King Jr Drive interchange with Interstate 71. Planning is to begin next summer with projected completion in the early part of 2021.

DPIC has worked with NIOSH in the past and is looking forward to enhanced collaboration.

Reference: Cincinnati Business Courier. \$100M federal research lab to be built in Cincinnati. Retrieved 8.25.17 from: <https://www.bizjournals.com/cincinnati/news/2015/02/23/uptown-pushing-to-land-110-federal-research-lab.html>



Marijuana Slang: Terms You May or May Not Know

Frank Quattrone RN, BSN, CSPI

Marijuana, aka weed, pot, dope, grass, herb, reefer, BC bud or ganja to name a few has its own culture. Legalization of Marijuana for medical purposes in many states and recreational use in some states has sparked a surge in the growing vernacular associated with the plant, how it is used and the form it comes in.

The traditional way of smoking marijuana required a bong, pipe or joint/blunt. Common slang for smoking marijuana include toking, poking, burning one, mowing the grass, hitting the hay to name a few. More recently, concentrated extracts are created by using butane lighter fluid to create a variety of marijuana products all of which include much higher levels of THC than traditional marijuana. Butane hash oil (BHO) comes in various forms and names. The term Budder is used to describe a form of hash oil that is soft at room temperature; it actually resembles real butter. Shatter or Ice are names used to describe a form of hash oil that is hard and is broken into pieces. Wax or Ear Wax is a name used to describe hash oil that is opaque and crumbly. Very common currently are vaping and dabbing. Vaping is taking concentrated cannabis and putting it into a vape pen. Dabbing is dropping marijuana concentrate on a hot surface and inhaling the vapor often through a glass 'rig' which is a glass pipe that filters the vapor through water.



Historically, most readers may be familiar individual marijuana users baking dried marijuana into a variety of foods, most commonly brownies. More recently, commercially available marijuana food products have become available. These are named edibles. They are often marked as special or medicated. In addition to commercial packaged brownies, candies and suckers are now available. These products may be put in packaging that resembles common foods with a play on words. An example is 'Keef Kat' in a package that looks like a real 'Kit Kat' candy bar. The concentration of marijuana in these edibles is often higher than in traditional homemade marijuana brownies.

These are only a few examples of marijuana terms. New names, formulations and ways of using marijuana will continue to evolve as it becomes more widely available.

References: Prevention Wellness Plus. *Essential marijuana terms*. Retrieved 8.25.17 from: http://preventionpluswellness.com/marijuana-terminology/?utm_source=BPH+Contacts%2C+SA+Coalitions%2C+SA+State+Agencies%2C+DFC+Fundees%2C+Schools+Feb+%2713&utm_campaign=9db0e3b2c7-EMAIL_CAMPAIGN_2017_02_11&utm_medium=email&utm_term=0_44c09e0059-9db0e3b2c7-68128417

Safe Medicine Storage

Regina Tarantino BSN, RN, CSPI



Today society takes more medications than in the past. Paralleled by this increase, accidental medicine poisoning in children is on the rise. The only safe storage for medications is “up, and away, and out of sight and reach every time” (MacKay, Murphy, & Steel, 2017, p. 13). Parents have indicated they understand, but is this rule followed 100% of the time? Often, our knowledge of safe medicine storage and our actions (possibly for the sake of convenience) do not coordinate.

A disconnection between what we know and how we handle medications is evident by research that estimated approximately “60,000 young children –or four busloads per day in the U.S.—are seen at emergency departments (EDs) because they got into medicine” (MacKay et al., 2017, p. 2). An additional surveillance study indicates the majority of hospitalizations for accidental prescription drug ingestion involved one to two-year-old children. Some of these drug ingestions involved two or more prescription drugs (Lovegrove et al., 2014).

Lovegrove et al. (2014) found twelve active ingredients in the United States marketed medications implicated in most of these hospitalizations. In descending order, these medications are opioids, benzodiazepines, sulfonyleureas, beta blockers, centrally acting alpha-adrenergics, calcium channel blockers, atypical antipsychotics, SSRIs, anticonvulsants, ace inhibitors, skeletal muscle relaxants, and amphetamine-related stimulants. Two active ingredients, buprenorphine and clonidine, lead the way in hospitalizations. Many of these active ingredients can be found in the one pill can kill list (<https://www.cincinnatichildrens.org/service/d/dpic/community/prevention>).

So, how does a toddler get into medication, when parents have the highest intentions in keeping their children safe? The answer is pretty simple. Parents are human and make mistakes, especially when they are worn out and in the wee hours of the morning! However, putting all medications, supplements, and vitamins “up, and away, and out of sight and reach every time” (MacKay et al., 2017, p. 13) is the simple solution. The key phrase is “every time” after every use. The key word here is “all” medication, supplements, and vitamins.

MacKay et al. (2017) point out what research provides as common errors parents make. Parents assume that their child can differentiate medicine from candy. However, many medications look and taste like candy. Parents think a safe place to keep medication is on a counter in which the child cannot reach. Parents do not realize the hidden climbing skills, determination, and imagination of their child. Approximately half of the over-the-counter medication poisoning cases are due to the ingenuity and climbing skills of the future rock climbers of America! Just telling your child to stay away from medication is not sufficient. Would you instruct your child to stay away from the pool, but leave them near the pool?

A parent will leave out a medication as a visual reminder to take or give at the right time. However, if the parent can see the medication, so can their child. Safe storage is not in a purse or diaper bag. Parents will let their toddler pull things out of the diaper bag/purse to keep them occupied, forgetting about slipping the baggie of Tylenol or their pill organizer into the bag days earlier. Parents leave the cold medication on the child’s bedroom dresser when illness occurs because it is a convenient place at 2:00 a.m. Guess who decides to self-medicate when the parent leaves the room. Medication kept out of sight but in a cabinet or drawer within the child’s reach is still dangerous. Toddlers continuously go on explorations, and nothing is left unturned. “An analysis of emergency department visits in 2011 indicated 20 percent of children got into medicine that was on a counter, dresser, table or nightstand” (MacKay et al., 2017, p. 9). Supervision alone will not keep children out of medications due to the parent being distracted. Parents cannot have eyes on their child 100% of the time. MacKay et al. (2014) note that a typical statement in an ED is, “I only turned my back for a minute.”



Importantly, child-resistant caps are not child proof. These caps merely slow the toddler down a bit. “Research suggests 45-55% of accidental poisonings involved child-resistant packaging (MacKay et al., 2017, p. 2). Lastly, children love to imitate. Parents should try to avoid taking medications in front of their child.

Let’s look at the pros and cons of pill organizers:

- For those individuals with one or more chronic diseases, the pill organizer is used to help them remain compliant and hopefully avoid taking a double dose the their daily medications. Many medications taken on a daily basis have a very small safety window, meaning an extra dose could cause a dangerous reaction. However, what is beneficial to one group may cause harm to another.
- Wang, Hoppe, Brou, and Heard (2017) cite “one remarkable example is the first generation of airbags. While these airbags decrease injuries for adults and teenagers, they increased the risk of injury to smaller children” (p. 897). Pill organizers are especially dangerous because they open the opportunity for the child to ingest more than one type of dangerous medication. Although further studies are needed, Wang et al. (2017) found in their research that pill organizers “were strongly associated with [pediatric] ED visits” (p. 900). This association strongly suggests that pill organizers are not very safe, nor are they kept in a child-safe place.
- Remember, nothing is child resistant! The only safe storage for medications is “up, and away, and out of sight and reach every time” (MacKay, Murphy, & Steel, 2017, p. 13). Safe storage of medication/supplements, whether prescribed or over-the-counter, is as simple as that!

For a detailed and helpful checklist regarding Safety with Medication and Storage, go to <https://www.safekids.org/tip/medication-safety-tips> or the Cincinnati Drug and Poison Information’s website <https://www.cincinnatichildrens.org/service/d/dpic/community/prevention> .

References

Drug and Poison Information Center. *The toxic toddler: One pill can kill*. Retrieved 8.25.17 from: <https://www.cincinnatichildrens.org/service/d/dpic/community/prevention>

Lovegrove, M. C., Mathew, J., Hamp, C., Governale, L., Wysowski, D. K., & Budnitz, D. S. (2014, October). Emergency hospitalizations for unsupervised prescription medication ingestions by young children. *PEDIATRICS*, 134 (4).

MacKay, J. M., Murphy, K., & Steel, A. (2017). Safe medicine storage: A look at the disconnect between parent knowledge and behavior. Retrieved from: <https://www.safekids.org/blog/simple-steps-safe-medicine-storage>

Wang, G. S., Hoppe, J. A., Brou, L., & Heard, K. J. (2017). Medication organizers (pill minders) increase the risk for unintentional pediatric ingestions. *Clinical Toxicology*, 55(8), 897-901. <http://dx.doi.org/10.1080/15563650.2017.132117>

Charcoal– Not Just for the Barbeque Grill A New Mechanism for Safe Disposal of Medications

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The Drug and Poison Information Center receives calls weekly from concerned individuals who have cleaned their medicine cabinet, or have concerns about the safe disposal of medications. Between 1997 and 2012, over 13,000 children required hospitalization due to exposure to prescription opioids and over 55,000 opioid exposures were reported to Poison Control Centers between January and October of 2016 (1).

Findings published online June 13, 2016, in the Journal of the American Medical Association (JAMA) Internal Medicine Journal, revealed that 6 out of 10 adults who use opioids had or expected to have left over medications. According to the 2013, Substance Abuse and Mental Health Services Administration (SAMHSA) National Survey on Drug Use and Health almost 70% of those who used prescription pain relievers non-medically got them from friends or relatives.

The safe disposal of medications is a growing health concern, with some communities even hosting regular prescription drug take back events.

A new product, DETERRA- drug deactivation system, provides a simple and convenient way of disposing of unwanted medications, while reducing both the effect on the environment and safety risks associated with normal trash disposal of medications. DETERRA contains a proprietary form of activated carbon which renders drugs inactive by adsorption in the presence of water. Mallinckrodt Pharmaceuticals has developed this product and they market it as a safe method of inactivating and disposing of medications including opioids.

An explanation of how the product works as explained by the manufacture is:

1. Sealable pouch contains active carbon
2. Patient adds any remaining medication and water to the pouch
3. Carbon binds to the active ingredients and breaks the medication down
4. Sealed pouch can then be safely disposed of in household garbage

Mallinckrodt also states that the DETERRA drug deactivation system works for pills, liquids, and patches. They tout a 99% success rate in deactivating drugs (2,3). They also state that the product is environmentally friendly rendering the compound safe for land fields.

While this technology, may solve the problem of the safe disposal of medications, we might ask if there are public health concerns that may be created by using this product. DPIC is following the trend, and will assess its impact on the incidence of poisoning; toxicology of exposure to the contents of the DETERRA product; and the effects that the use of DETERRA may have on public health.

References

1. DPICtions, Drug and Poison Information Center's Newsletter, Spring 2017
2. National Institute on Drug Abuse (NIDA) Efficacy Report Reference number N44DA-14-220
3. American Association of Pharmaceutical Sciences, Presented 2012. Mercer University College of Pharmacy and Health Sciences)



Opana ER Withdrawn from the Market

Shannon Staton-Growcock MSN, RN, CSPI



Opana ER was an opioid approved by the Food and Drug Administration (FDA) for pain management in 2006 as an extended-release opioid. Each pill is designed by the manufacturer to be swallowed whole and to slowly release the medicine into the bloodstream over a number of hours. But if crushed and snorted or injected, the opioid can deliver a potent high.

As public health authorities and the FDA became increasingly concerned about the nation's epidemic of opioid abuse and overdoses, the company reformulated Opana ER in 2012, by adding a coating that was intended to make it harder to snort or inject the medicine. However, review of all available post-marketing data, demonstrated a significant shift in the route of abuse of Opana ER.

An FDA advisory committee voted in March that Opana ER's benefits no longer outweighed its risks. On June 8th, 2017 the FDA requested the drug maker, Endo Pharmaceuticals, stop selling Opana ER. The FDA says the move marks the first time the agency has taken steps to remove an opioid from the market because of "public health consequences of abuse." The FDA's decision is based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation.

On July 7, 2017 Endo Pharmaceuticals agreed to the voluntary withdrawal of Opana ER from the market. The company states: "as a pharmaceutical company with a demonstrated commitment to the improvement of pain management, Endo feels a strong sense of responsibility to improve the care of pain for patients, while at the same time taking comprehensive steps to minimize the potential misuse of its products," according to the firm's statement.

Please be aware that the generic versions of Opana ER (oxymorphone ER) will still be available on the market. President and Chief Executive Officer of Impax Labs noted from an 07-Aug-2017 press release that they were pleased to have reached an agreement to settle this outstanding contractual litigation, between Endo Pharmaceuticals and IMPAX Labs. Due to this agreement brand name Opana ER is being removed from the market but generic oxymorphone hydrochloride extended release tablets will be available from IMPAX labs with the original non-reformulated coating. As they will continue to make available IMPAX's generic version of original Opana ER (oxymorphone hydrochloride) CII ER tablets for prescribing physicians that prefer this product to treat patients.

Caution will need to be taken for health care professionals, law enforcement providers and patients to be aware that some extended release oxymorphone tablets will remain in the marketplace. It is important to properly identify these products and differentiate them from Opana ER as exposures to this product begin to decline.

Impax Generics to remain on market:

Opana ER Tablets to be withdrawn:



References:

Endo Pharmaceuticals. *Opana ER*. Retrieved 8.25.17 from: <http://www.opana.com>

Global Pharmaceuticals. *Oxymorphone hydrochloride ER*. Retrieved 8.25.17 from: http://www.globalphar.com/products/oxymorphone_hydrochloride_er_ci

Markets Insider. (Aug 7, 2017). *Impax announces settle of contract litigation on Opana ER (PR Newswire)*. Retrieved from: <http://markets.businessinsider.com/news/stocks/Impax-Announces-Settlement-of-Contract-Litigation-on-Opana-ER-Oxymorphone-Hydrochloride-CII-Extended-Release-Tablets-1002236836>

NPR Global Health Now. (June 8, 2017). *FDA calls on drugmaker to pull powerful opioid off the market*. Retrieved from: <http://www.npr.org/sections/health-shots/2017/06/08/532126206/fda-calls-on-drugmaker-to-pull-a-powerful-opioid-off-the-market>

Pharmacy Times. (July 06, 2017). *Endo to pull Opana from the market following FDA request*. Retrieved from: <http://www.pharmacytimes.com/product-news/endo-to-pull-opana-from-the-market-following-fda-request>

US Food and Drug Administration. (June 08, 2017). *FDA requests removal of Opana ER for risks related to abuse*. Retrieved from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Dangerous Curiosity

Robyn Davis MSN, RN, CNL, CSPI



Have you watched or read the news lately? Just a quick glance through a local and national news source today yielded at least 2 headlines where 'drugs' was included in the headline. Substance abuse has become a monumental concern and is earning more and more attention from community, state, and national leaders. If there is any truth in the saying history always repeats itself then wouldn't knowing historical substance abuse trends provide guidance for our current leaders trying to manage the substance abuse epidemic?

The National Institute on Drug Abuse has been funding the Monitoring the Future (MTF) program since 1975. The focus of the survey is to report and interpret trends in adolescent use of illicit and licit substances and plot those trends over a continuum. So the good news is we don't need a crystal ball or time machine because we already have years of data!

MTF annually surveys a nationally representative sample (approximately 50,000) of American Secondary School students in grades 8, 10, and 12 (12th graders since 1975, and 8th and 10th graders since 1991). Further follow up is done yearly with graduated students to follow them into adulthood until the age of 55 years.

The 2016 results are in! *Volume 1* presents the data from the 42nd survey of drug use and related attitudes and beliefs among 12th graders and 26th survey of 8th and 10th grade students. Remember 8th and 10th graders weren't included until 1991. *Volume II* presents data from the 1977 through 2016 follow-up surveys of the graduating high school classes of 1976 through 2015. This article will only focus on *Volume 1* results. So, how do things look?

Here's a look at the highlights of substance use problems that currently remain among young people in the U.S. reported in 2016 ¹:

- 21% of today's 8th graders and 49% of 12th graders have tried an *illicit drug* (if inhalants are included as an illicit drug).
- By their late 20s, about 61% of today's young adults have tried an *illicit drug*, and more than 36% have tried some *illicit drug other than marijuana*, usually in addition to marijuana (not including inhalants.)
- 6% of 12th graders (1 out of 17) smoked *marijuana daily*. 14% of 12th graders (1 out of 7) has been a daily marijuana smoker at some time in their life for at least a month.
- 16% of 12th graders (1 out of 6) had *five or more drinks in a row* on at least one occasion in just the two weeks prior to the survey. The study also has documented evidence of *extreme binge drinking* in the prior 2 weeks:
 - ⇒ 4.4% of 12th graders indicating having had 10 or more drinks in a row.
 - ⇒ 2.3% of 12th graders indicating 15 or more drinks in a row.
- 9% of 12th graders (1 out of 11) currently smoke *cigarettes*, and 5% of 12th graders (1 out of 5) is already a *daily smoker*. In addition, we know from studying previous cohorts that many young adults increase their levels of smoking within a year or so after they leave high school.

The second part of the study assesses adolescents for their beliefs and perceptions about illicit and licit substances. The survey continues to identify students with a low perceived risk of a substance are more likely to use that substance.

(contd.)

Dangerous Curiosity (contd.)

Robyn Davis MSN, RN, CNL, CSPI



The table below highlights the attitudes and beliefs among 12th Graders that perceive harm with Regular Use and Experimental Use of the following substances ¹:

Perceived harm

Substance	Regular use	Experimental Use
Heroin	85%	65%
Crack	82%	54%
Cocaine	78%	53%
Amphetamines	51%	31%
Sedatives (barbiturates)	47%	27%
Marijuana	31%	13%
Cigarettes (1 or more packs per day)	77 %	***
E-cigarettes	18%	***
Alcohol	41%	10%
Synthetic (bath salts)	64%	54.9
Adderall	41%	32%
Narcotics (excluding heroin)	72%	44%

***data not collected during survey

MTF has identified that for more than a decade – from the late 1970s to the early 1990s – the use of a number of illicit drugs declined appreciably among 12th grade students, and declined even more among college students and young adults in the U.S.² This is encouraging and warrants a closer look at what interventions were utilized in the 1990s to create a change in attitudes and beliefs about drug use, and peer norms against drug use. Awareness and access are necessary components of an epidemic³ and that means that each new generation of adolescents need to understand the reasons they should not use drugs. Otherwise, curiosity will get the best of them and lead them down a dangerous path of experimentation. National, State, and Community groups can join forces and utilize this data to develop and implement strategic interventions to combat substance access while providing substance awareness to deter adolescents from becoming victims of curiosity.

References:

¹ Monitoring the Future. *Key findings on adolescent drug use*. Retrieved 8.25.17 from: <http://www.monitoringthefuture.org/>

² Kraus, L., Guttormsson, U., Leifman, H., Arpa, S. et al. (2016). *The 2015 ESPAD report: Results from the European School Survey Project on Alcohol and Other Drugs*. The European Monitoring Centre for Drugs and Drug Addiction.

³ Johnston, L. D. (1991). Toward a theory of drug epidemics. In L. Donhew, H. E. Sypher, and W. J. Bukiski (Eds.), *Persuasive communication and drug abuse prevention* (pp.93-131). Hillsdale, NJ, Earlbaum

University of Michigan News Service. (September 23, 2016). Compared with Europe, American teens have high rates of illicit drug use. Retrieved 8.25.17 from: <http://ns.umich.edu/new/releases/24210-compared-with-europe-american-teens-have-high-rates-of-illicit-drug-use>

Kentucky Makes Headlines with Gabapentin

Sara King Pinkston, RN, MSN, CSPI



Effective July 1, 2017, Kentucky became the first state to make all **gabapentin products Schedule 5 controlled substances** (<https://www.goodrx.com/blog/gabapentin-now-a-controlled-substance-in-kentucky/>)

What does this mean?

Authorized persons must be properly licensed and registered with the DEA to order the dispensing of a controlled substance. Therefore, in Kentucky only DEA registered practitioners may issue prescriptions for gabapentin or order the direct administration or dispensing of gabapentin to a patient (<http://www.irc.ky.gov/kar/902/055/035reg.htm>).

Other implications:

- In Kentucky physician assistants (PA) no longer have authority to prescribe any controlled substances. If a person's Rx is from a PA, it will no longer be valid
- Existing gabapentin prescriptions will expire after 5 refills, or 6 months, from the date the prescription was issued.
- No one will be able to transfer any gabapentin prescriptions to other pharmacies that were written before January 1, 2017.
- No one will be able to receive gabapentin samples. (<https://www.goodrx.com/blog/gabapentin-now-a-controlled-substance-in-kentucky/>)
- It will need to be reported to the states prescription drug monitoring program.

Have any other states made gabapentin a controlled substance?

As of this writing, no other state has made gabapentin a controlled substance. However, it may be only a matter of time before other states follow Kentucky's lead.

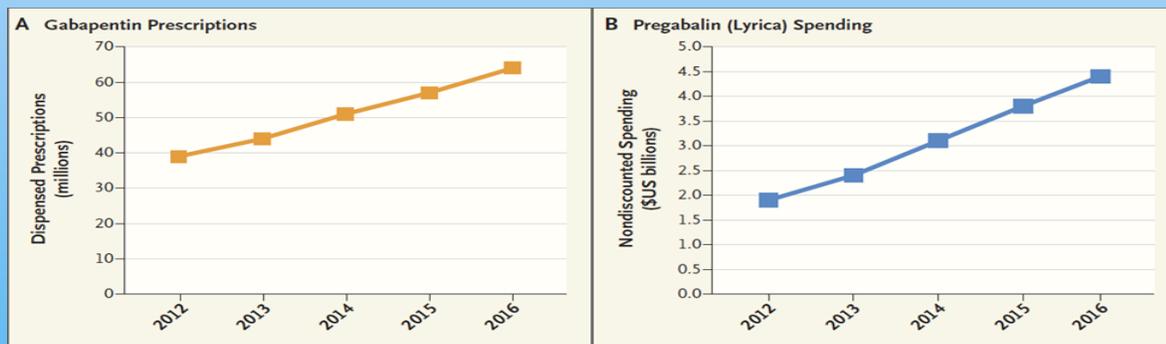
Ohio stopped just short of making gabapentin a Schedule 5 Controlled Substance. As of December 1, 2016, it has required pharmacies, prescribers, and wholesalers to report dispensing, personal furnishing, and wholesale sale of gabapentin to Ohio Automated Rx Reporting System (OARRS) (<http://pharmacy.ohio.gov/Documents/Pubs/Special/OARRS/Reporting%20gabapentin%20products%20to%20OARRS%20>). So, although gabapentin is not a Schedule 5 controlled substance in Ohio, it is being added to the Ohio Board of Pharmacy's list of drugs reportable to OARRS.

Minnesota, Virginia, Illinois, Wyoming, and Massachusetts also have prescription monitoring programs for gabapentin. (<https://www.goodrx.com/blog/gabapentin-now-a-controlled-substance-in-kentucky/>)

Why is this happening?

Gabapentin (a drug used to treat neuropathic pain caused by damage to nerves from diabetes and shingles; seizures, restless leg syndrome, anxiety or insomnia) is not considered an addictive drug. However, it does have characteristics that offer the potential for abuse. According to an article from the British Journal of General Practice, August 2012, gabapentin effects "vary with the user, dosage, past experience, psychiatric history, and expectations."¹ Individuals have described experiences with gabapentin abuse which have included euphoria, improved sociability, a marijuana-like "high", relaxation, and sense of calm, and "zombie-like" effects.¹

The number of prescriptions written for gabapentin is on the rise. According to IMS Health gabapentin was the 10th most prescribed medication in the United States in 2016. 64 million prescriptions were dispensed in 2016 up from 39 million in 2012.² Part of this may be explained by the fact that many physicians shrink from prescribing opioids for chronic pain. In looking for alternatives that are non-opioid, non- NSAID, and non-acetaminophen, gabapentin has been a viable choice.² However, there have been some reports of use and abuse as well. A recent Medscape "Ask the Pharmacist" article describes gabapentin misuse in correctional facilities and non-prescribed gabapentin use by patients in substance abuse clinics. Also reported were several cases where patients developed withdrawal symptoms after abrupt discontinuation of high doses of gabapentin.³



Dispensed Prescriptions for Gabapentin and Nondiscounted Spending for Pregabalin, 2012–2016.

Data are from IMS Health.

All of these factors led to Kentucky's decision to make **gabapentin a Schedule 5 controlled substance** and for other states' decision to report and monitor prescriptions of gabapentin.

REFERENCES

Goodman, C.W. & Brett, A.S. (August 3, 2017). Gabapentin and pregabalin for pain: Is increased prescribing a cause for concern? *The New England Journal of Medicine*, 377, 411-414.

Melton, S.T. (June 17, 2014). *Has Gabapentin Become a Drug of Abuse?* Retrieved 8.25.17 from: <http://www.medscape.com/viewarticle/826680>.

Smith, B.H., Higgins C., Baldacchino A., Kidd B., Bannister J. Substance misuse of gabapentin. *British Journal of General Practice*, 62(601), 406. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3404313/>

Summer Poison Safety– Bites

American Association of Poison Control Centers (AAPCC)



Stinging insects like mosquitoes, bees, wasps, and other critters like ticks and spiders love summer as much as we do! Most insect and spider stings or bites can cause red, itchy, or sometimes painful bumps, but poisonous or venomous species can cause more severe reactions. In addition, allergies to bites and stings can be very dangerous. Finally, there are several infectious diseases that people can get from insects, especially mosquitoes, such as the Zika virus.

How to prevent insect bites and stings: Following all directions on the label, apply insect repellent whenever you this summer. Concentrations of up to 30% DEET have been shown to be safe for use on children older than 2 months, but be sure to follow application instructions carefully. Only use bug spray that is meant to be used on skin; never use household insect or pest killer on the skin. Be sure to follow application instructions carefully, and wash off the product once returning indoors. If anyone ingests, inhales, or sprays insect repellent into the eyes, call your local poison control center at 1 (800) 222-1222 immediately. If you have general questions about selecting, storing, or using insect repellent and other pesticides, call or visit the National Pesticide Information Center's website. Also, consider planting pest-repellant plants to help prevent these bites and stings. Consult a master gardener or the National Pesticide Information Center for advice.



Reference: The American Association of Poison Control Centers. *Summer poison safety: Bites*. Retrieved 8.25.17 from: <http://www.aapcc.org/prevention/summer-poison-safety/>

Summer Poison Safety– Cooking

American Association of Poison Control Centers (AAPCC)

Food poisoning, also called foodborne illness, is illness caused by ingesting contaminated food. Infectious organisms such as bacteria, viruses, parasites, or their toxins are the most common causes of food poisoning. Infectious organisms or their toxins can contaminate food at any point of processing or production. Contamination can also occur at home if food is incorrectly handled or cooked. The most common symptoms of food poisoning include upset stomach, abdominal cramps, nausea and vomiting, diarrhea, fever, and dehydration. Symptoms may range from mild to severe and may differ depending on the causative agent. Severe cases of food poisoning can cause long-term health problems or death. The CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases. AAPCC offers the following simple food safety tips for preparing and enjoying meals:

PREPARE:

Keep meat, poultry, seafood, and eggs separate from all other foods in your grocery bags, in the refrigerator, and while prepping.

Wash your hands, kitchen surfaces, utensils, and cutting boards frequently, especially after handling or preparing uncooked food and before touching or eating other foods. Wash produce but not eggs, meat, or poultry, which can spread harmful bacteria.

Use the microwave, cold water, or the refrigerator method to defrost your frozen meat or poultry. Do not thaw or marinate these items on the counter, and be sure to cook them immediately after thawing.

COOK:

The bacteria that cause food poisoning multiply quickest in the 'Danger Zone,' which is between 40° and 140° Fahrenheit. In general, it's best to keep hot food hot, and cold food cold.

Use a food thermometer to check if meat is fully cooked and heated high enough to kill harmful bacteria. Cook turkey until it reaches 165° F.

The safest way to cook stuffing is outside of the turkey in a casserole dish. However, if you choose to cook stuffing inside the turkey, stuff the turkey just before cooking, and use a food thermometer to make sure the center of the stuffing reaches a minimum internal temperature of 165°F. Remove the stuffing immediately after the turkey is finished cooking and place in a separate serving dish.

STORE:

Refrigerate leftovers promptly – within two hours – at 40° F or below to help reduce the risk of bacterial growth.

Prevent cross-contamination by completely and securely covering foods in the refrigerator.

Consume or freeze leftovers within 3-4 days.

Poison centers are available to provide expert, free, and confidential information and treatment advice 24-hours per day, seven days a week, year-round, including holidays. If you have any questions about safe food preparation, or if you or someone you know suspects food poisoning, call your local Poison control Center 1(800) 222-1222. More information visit <https://www.cincinnatichildrens.org/service/d/dpic>.

Reference: The American Association of Poison Control Centers. *Summer poison safety: Cooking*. Retrieved 8.25.17 from: <http://www.aapcc.org/prevention/summer-poison-safety/>

Summer Poison Safety—Pesticides

American Association of Poison Control Centers (AAPCC)



Never use outdoor-use pesticides indoors. Pesticides meant for outdoor use can be more toxic than those designed for indoor use are.

Read and follow all directions on the label, each and every time you use a pesticide. Remember that some products come in a concentrated solution and must be diluted before use.

Only use pesticides in a well-ventilated area and keep kids and pets away during application.

Wear protective clothing like gloves and a mask as directed on the product label, and wash your hands and change your clothes after using pesticides.

Keep pesticides and garden chemicals in their original containers, never in containers that could be mistaken for juice or food. This way there is no question as to what they are, and the instructions are handy. Keep them in a locked cabinet or shed, away from children and pets, and never near food or drinks.

Never use or purchase any pesticide that does not have an EPA registration number, directions for use, or ingredients on the package. Illicitly marketed pesticides are nearly always more toxic than those approved for indoor use.



If someone swallows or inhales a pesticide, or gets a pesticide in the eyes or on the skin, call your local Poison control Center 1 (800) 222-1222. For general questions about the risks of using or how to select, store, or use insect repellents and other pesticides, call the National Pesticide Information Center at 1 (800) 858-7378 or visit NPIC's website.

Reference: The American Association of Poison Control Centers. *Summer poison safety: Pesticides*. Retrieved 8.25.17 from: <http://www.aapcc.org/prevention/summer-poison-safety/>

Summer Poison Safety—Plants

American Association of Poison Control Centers (AAPCC)

The list of plants that may be poisonous or cause severe skin irritation is long, and varies by the region where you live. The warmer temperatures in spring and summer mean that while we spend more time outside, these plants are thriving in backyards and or favorite hiking spots! Teach children not to eat mushrooms or berries growing outside. Edible mushrooms and even berries can look very similar to toxic species, so the experts at poison centers recommend never eating “picked-from-the-wild” produce. (Even if you are visiting a bona-fide edible berry patch or fruit orchard, it's best to first wash any soil contaminants or pesticides off of any type of produce before eating it.)

If you have children, pets, or care for anyone mentally disabled, we recommend doing a garden and houseplant inventory to ensure you are aware of any potentially toxic plants growing in your garden, house, or elsewhere on your property. There are a variety of websites that can help you identify toxic plants. Also, consult a [master gardener](#) for advice.

If a person eats or develops a rash from an outdoor or household plant, call your local Poison control Center 1 (800) 222-1222. Visit <https://www.cincinnatichildrens.org/service/d/dpic/community/prevention> for a handout on poisonous plants.



Reference: The American Association of Poison Control Centers. *Summer poison safety: Plants*. Retrieved 8.25.17 from: <http://www.aapcc.org/prevention/summer-poison-safety/>

Spotlight on a Poison Specialist—Chad Royer RPh, CSPI

How did you come to work here?

During my first semester of pharmacy school in 1993 our Director, Earl Siegel, gave a talk in one of my classes. His material was interesting and since he seemed like a good person to work for I discussed a job opportunity with him. I've been working at DPIC ever since, except for a 4 year break to practice small town retail pharmacy in the upper peninsula of Michigan immediately after graduating from pharmacy school.

What is your favorite thing about your job?

Probably getting to do something that seems useful. However, the people I work with and getting to work a non-traditional schedule are also close.

What do you do for fun?

Mostly outdoor activities, such as boating, riding motorcycles and quads, kayaking, fishing, hunting, and biking.

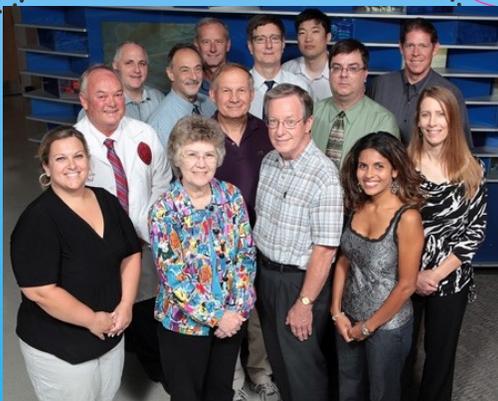


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When you dial 1-800-222-1222, your call is answered by a medical professional with special training in poison management. Help is fast, free, confidential and

available 24 hours a day, every day.