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The Initiative to Increase Access to Naloxone

By Nathan Holcomb, PharmD

Data from a recent study found that 110 Americans on average die daily from drug overdoses. In 2013, more than 44,000 people lost their lives due to a drug overdose, making it the leading cause of death from injury in the United States. Over half of these drug overdose deaths involve the use of opioids, including heroin; prescription medications such as morphine, hydrocodone, or oxycodone; and others. It is common knowledge that the use and abuse of opioids has been on the rise for many years now, and the increasing rate of overdose deaths has been parallel. The deaths from overdose coming from heroin and prescription opioid medications are due to the severe respiratory depression that opioid overdoses produce. During this time of respiratory depression, it often takes several hours before the overdose results in death.

Commonly, people who overdose on opioids are with or around other people. The time it takes between the onset of respiratory depression and death is extremely crucial because of what can be done in that time to save the person. Unfortunately, in many cases it is too late or nothing is done at all to attempt to prevent these deaths.

Because of the increasing incidence of deaths as a result of opioid overdoses, many states have been passing legislation that will allow for increased access to naloxone (Narcan®). A 2006 Massachusetts study from a public health regulation authorizing an opioid prevention program showed positive results. The program involved intranasal naloxone education and distribution of the medication to potential bystanders such as family members and drug-using partners. By the end of the study, it was found that educated non-medical persons are able to successfully recognize an opioid overdose and administer intranasal naloxone in order to reverse fatal overdoses. Since then, many states have implemented similar programs and have found similar positive results.

Centers for Disease Control and Prevention has reported that naloxone programs for drug users, their caregivers, and potential bystanders have reversed over 10,000 opiate overdoses from 1996 to 2010. Results such as this have sparked a flame in many states, resulting in varying new forms of legislation and increasing the access to and availability of naloxone. The 90th session of the South Dakota Legislature recently passed legislation to allow trained first responders to carry and administer naloxone to anyone experiencing symptoms of an opioid overdose. First responders in this case were defined as law enforcement officers, emergency medical technicians (EMTs), and firefighters. From now on in South Dakota, first responders will be able to quickly identify and reverse opioid overdoses, providing valuable time to get overdose cases to the emergency room for continued treatment.

Recently, during the 2014 annual conference for the American College of Emergency Physicians (ACEP), two resolutions were adopted in relation to improving access to naloxone. The first resolution, Resolution 39, calls for ACEP to work to develop a policy on clinical situations in which it becomes appropriate for emergency physicians to prescribe naloxone. The second resolution, Resolution 42, states two different things. The first is that ACEP advocates and supports the training and supplying of first responders such as police, firefighters, and EMTs to administer both injectable and intranasal forms of naloxone. The second part states that the organization advocates and supports that pharmacists dispense naloxone over the counter and provide opioid overdose education.

The Rx Abuse Stakeholders (RAS) group in Wyoming has been working with the Wyoming Legislature's Interim Joint Judiciary Committee on this matter. Legislation is being prepared for the 2017 session that will increase access to naloxone by first responders. The proposed statute change would also allow pharmacists to prescribe naloxone. Food and Drug Administration (FDA) is also considering labeling naloxone as an over-the-counter drug. With so many state legislatures and health care organizations working to improve access to naloxone, the future looks brighter in regard to decreasing opioid overdose deaths nationwide.

David Wills, MBA, Receives Award

The Cardinal Health Generation Rx Champions Award was presented to David Wills, MBA, coordinator of the Wyoming Prescription Drug Monitoring Program (WORx), at the annual Wyoming Pharmacy Association Awards banquet in June 2016. The Cardinal Health Generation Rx Champions Award recognizes outstanding efforts for community-based prescription drug abuse prevention. David has been the WORx manager since 2008. He has worked with the legislature to enhance the program, and he provides informational presentations around the state. David is a member of the RAS and attends the National Association of State Controlled Substances Authorities annual meetings. David's individual attention to pharmacists and practitioners in Wyoming has made the use of the WORx program grow from around 800 searches per month to over 12,000. This has had a significant impact on the incidence of medication seeking through "doctor shopping." David encourages pharmacists to register to use this important tool at *www.WORxPDMP.com.*

Website to Verify DEA Registrants

A pharmacist checking for an active Drug Enforcement Administration (DEA) registration can visit *https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp.* If you need to verify a prescriber's DEA license number, it can be verified by using this link. However, you must first log in with your pharmacy's DEA and federal tax identification numbers/employer identification numbers.

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National Pharmacy

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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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Service Animals in Pharmacies

By Lisa Hunt, RPh, Compliance Officer

Attendees at the 50-state FDA pharmacy compounding meeting in 2016 learned that a pharmacy in another state was cited for a dog hair in a vacuum cleaner bag by an FDA inspector. Even though most of the discussion was on sterile compounding, recent FDA guidance suggests hairs can make any product "adulterated." See the August 2016 FDA draft guidance document regarding "insanitary conditions." This brings up concerns for service dogs in product preparation areas because of possible allergen and hair transmission. If your pharmacy is frequented by service animals or if staff require assistance from a service animal, please familiarize yourself with Wyoming Pharmacy Act Rules Chapter 13, Section 5(d), which states, "The area(s) used for compounding shall be maintained in a clean and sanitary condition," and also familiarize yourself with FDA's current position by visiting *www.fda.gov/drugs/drugsafety/ucm514486.htm.*

Thank You to Sigsbee Duck, MD, RPh

Sigsbee Duck, MD, RPh, a member of the Wyoming State Board of Pharmacy since 2013, recently resigned his appointment. The Board appreciates his service and commitment. He is a valuable resource for the practices of medicine and pharmacy and recently served as president of the Wyoming Medical Society. Dr Duck is also licensed as a pharmacist and graduated from the Mercer University School of Pharmacy where he was a member of the Rho Chi Pharmacy Honor Society.

Wyoming RAS Website and Toolkit

By Alec Richards, 2017 PharmD Candidate

Prescription drug abuse has been a huge concern throughout the US. As this problem continues to grow, it is very important to have organizations take a stand and fight for the appropriate use of prescription medications. The Wyoming RAS is doing just that. Established in 2008, the RAS is a nonprofit organization funded through grants and donations. In such a short time, the RAS has been making a huge impact with not only education but also with Wyoming laws and policies. Their mission statement is as follows:

> The Wyoming Rx Abuse Stakeholders (RAS) advocates for the appropriate use of prescription medication by increasing awareness, providing education, and impacting policy amongst the public, health care professionals, and law enforcement in order to prevent the misuse, abuse, and diversion of prescription medications in Wyoming.

The RAS has many member organizations, including state boards of pharmacy, medicine, dentistry, and nursing; the Wyoming Department of Health; the Wyoming Division of Criminal Investigation; Recover Wyoming; and many others. The RAS primary mission is to generate awareness and education about the growing prescription drug abuse epidemic. The RAS website provides facts and statistics regarding prescription drug abuse as well as many great links to resources. These resources include educational materials about drug abuse, current news, and information about recovery and treatment. The RAS has also approved a collaborative pain management toolkit, posted on its website at *www.wyrxabusestakeholders.com.*

The toolkit provides comprehensive information regarding opioid medications for health care providers in pain management. RAS members actively promote programs such as the medication donation and take-back programs in Wyoming and are involved in so many other ways.

Organizations such as the RAS are important when trying to combat prescription drug abuse. Awareness is one of the most important tools we can utilize in order to try to curb the epidemic. I would encourage everyone to visit the RAS website in order to learn more about the organization and to get involved in order to help prevent prescription drug abuse. As pharmacists and technicians, we can serve a critical role in patient safety in regard to opioid abuse. We are accessible and knowledgeable. We have access to patient records and have the last chance to talk to patients before they take their medication. This is a huge responsibility – but we have the resources available to us to make a difference. If you are interested in more information or would like to get involved with the organization, contact wyrxabusestakeholders@gmail.com.

Recent Disciplinary Actions

B.W., Pharmacist License #3666: Conditional license due to conviction of driving under the influence.

K.R., Pharmacy Technician License #TT2598: Voluntary surrender of permit due to conviction of controlled substance prescription fraud.

M.W., Pharmacy Technician License #2211T: Administrative penalty of $200 for failing to obtain six hours of continuing education (CE) in 2015. Additional CE is required in 2016, including three hours on pharmacy law.

Pharmacy License #R10130: Administrative penalty of $2,000 for failure to ensure that pharmacists prescribing and administering immunizations were properly registered to do so.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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