STUDENT CLINICAL DIGEST

Presented by the Student College of Clinical Pharmacy, the University of Georgia College of Pharmacy student chapter of the American College of Clinical Pharmacy

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Clinical Pharmacist Spotlight: Clinical Assistant Professor and Critical Care Pharmacist

By: Madeline Burke, Pharm.D. Candidate

Trisha N. Branan, Pharm.D., BCCCP

What steps did you take to become a clinical assistant professor at UGA?

After completing my residencies, I worked in the Medical ICU in Augusta for 6 years and was a preceptor for many students and residents there. I also helped to develop the Critical Care PGY2 in Augusta before I left and took the position with UGA.

How did your residency training help prepare you for your career?

My residency really gave me a foundation of knowledge and skills within critical care. I feel my residency gave me great skills that can be carried into any clinical position.

How was the transition from student to resident to pharmacist to faculty?

Working for 6 years before entering academia allowed me to build a practice site and get real world clinical experience. This is helpful for bringing more context into the classroom and for me to identify what is most relevant.

What are your current academic and research interests?

I am currently interested in sepsis, infectious complications in critically ill patients, innovative teaching methods, scholarship of teaching and learning, and how critical care education is delivered throughout the country.

What is your current practice site and what is your role there?

I work at Athens Regional Medical Center in the medical and surgical ICUs. I take APPE students and do multidisciplinary rounds daily for about 12 patients. I am responsible for all pharmacotherapy related needs, monitoring, and adjusting medications as needed.

What is your favorite thing about your job here at UGA?

I love getting to interact with students all throughout the program, not just APPE students. I really enjoy watching them grow, change, and learn all throughout their time in pharmacy school.

Which professional organizations are you involved in and how have they helped you grow as a pharmacist?

I held a couple of leadership roles within Georgia Society of Health-System Pharmacists (GSHP), which gave me a sense of ownership and leadership in pharmacy. GSHP helped me understand different aspects of health-system pharmacy, legislative efforts, and the differences between health-system and community and outpatient pharmacy.

I am also a member of the Society of Critical Care Medicine, American Academy of Colleges of Pharmacy, and American College of Clinical Pharmacy, especially the Critical Care PRN.

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How do you maintain a good work/life balance?

It is hard, but I try to structure my week with a balance of work things and what's going on with my family. I make life outside of work a priority and take advantage of the time I spend on campus since time at the hospital is less predictable.

Do you have any advice you would like to add for our members interested in residency training or any advice in general?

Be really flexible and open to any opportunity that comes your way. Find the thing you are passionate about and makes you excited to come to work. Explore different possibilities to see if your intended path will make you happy for the rest of your career.

Find a mentor! They can be anyone you connect with: an upperclassman, professor, coworker. They can have a shared professional interest or personal interest. Make connections and find out how they got where they are. Your mentor should be someone to go to that can encourage you and give you advice.

Technology Update: *The Orange Book* Goes Mobile
Written by: Alyssa K. Elrod, Pharm.D. Candidate

Interested in determining if that bottle of diltiazem is equivalent to another manufacturer's product? Since October 1980, the Food and Drug Administration has published the *Approved Drug Products with Therapeutic Equivalence Evaluations* book, better known as *The Orange Book*.[1] This reference serves as a valuable tool for healthcare professionals when deciding if a drug product is equivalent to another based on therapeutic equivalence, bioequivalence, and other criteria. The FDA added an online search feature for *The Orange Book* to its website in 1997, and PDF versions were made available starting in 2005.

Those who are curious about drug equivalency can now search the even more convenient mobile app known as "The Orange Book Express." The app is available free for download from the Apple App Store and the Google Play Store. Within the app, users can search, see newly added patents, or access the website version of the book. There are multiple ways to search for information, including by active ingredient or proprietary name, applicant holder, application number, or patent number. The information within the app is updated regularly, with the specific month and date of the last update noted. So, when comparing the equivalency of two drug products, you can now reach for your smartphone and "The Orange Book Express" app to answer your question in a quick and convenient manner.

1. "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)." (2016). Food and Drug Administration. Retrieved from www.fda.gov on April 10, 2016.

2. OB Express. (2015). Food and Drug Administration (Version 1). [Mobile application software]. Retrieved

Zika Outbreak: What do you need to know
By: Lindsey Sellers, Pharm.D. Candidate

In the past few months, information about the Zika virus has frequently been in the news, and the topic is likely to have reached your pharmacy as well. As a pharmacist, it is important to be able to discuss what the patient knows about the Zika virus, clarify common misconceptions, and be able to counsel patients on the proper precautions they should take when planning to travel outside of the country.

Although Zika virus has received a lot of media attention recently, it is not a new virus. The Zika virus was first discovered in 1947, when it was isolated from a Rhesus monkey in the Zika forest of Uganda. The first human case of Zika was not reported until 1952, and there were few human cases reported until the first human outbreak in 2007 in Yap Island of Micronesia. [1] Between 2013 and 2014 over 28,000 cases were reported in French Polynesia. [1] Early in 2015, the first confirmed case in Brazil was reported; by January 2016 over 20 countries and territories in the Americas reported infection. [1] In February, the World Health Organization (WHO) declared the Zika Virus a public health emergency of international concern. [2]

The Zika virus itself is a single-stranded RNA virus transmitted by the *Aedes* species mosquito. The Zika virus may also spread without the mosquito vector, either by sexual contact or maternal-fetal transmission. The presentation of Zika virus—fever, rash, joint pain and conjunctivitis—is fairly nonspecific and symptoms are usually mild and can last from several days up to a few weeks.[2] It is difficult to differentiate Zika virus from other tropical viruses such as dengue and chikungunya, which all present in a similar manner. Of the three tropical mosquito related diseases, Zika most commonly presents asymptomatically.

Currently, the best means to prevent transmission is through patient education, an area which pharmacists have a direct role. Travelers visiting an area with Zika should be advised to stay in places with air conditioning, window and door screens, and sleep under mosquito nets. When outside, travelers should use repellents such as DEET or picardin. Patients should be counseled to apply these products to both exposed skin and clothing. If also applying sunscreen, the sunscreen should be applied prior to repellent application. Permethrin, an insecticide, is tested and effective against the *Aedes aegypti* mosquito. Permethrin can be used in both pregnant women and children. [4] Due to the potential for sexual transmission, safe sex practices should be used while traveling to Zika infected areas. Because the Zika virus commonly presents asymptomatically and the exact duration of viremia is unknown, patients should continue to follow safe sex practices even after their return. [4]

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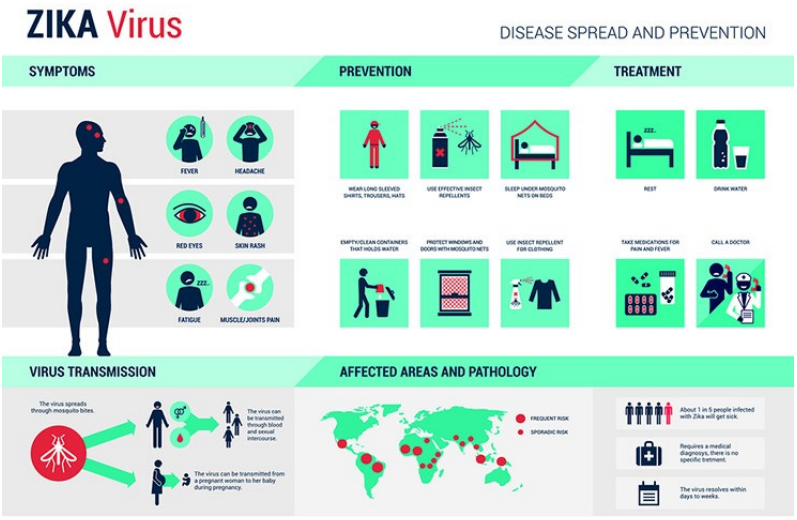


If a patient is infected with the Zika virus, treatment should include supportive care. The patient should receive adequate fluids to prevent dehydration, as well as fever and pain management. Aspirin and NSAIDs should be avoided until dengue is ruled out, as aspirin and other NSAIDs can increase the risk of hemorrhage in patients with dengue. [4]

1. Chen LH et al. Zika virus: rapid spread in the western hemisphere. Ann Int Med. E Pub first 2 Feb 2016.
2. "About Zika Virus Disease." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 22 Feb. 2016. Web. 07 Apr. 2016.
3. Zika Virus – What Clinicians Need to Know. CDC. Jan 26, 2016. http://emergency.cdc.gov/coca/ppt/2016/01_26_16_zika.pdf
4. Gauthier, Timothy, PharmD, BCPS-AQ ID, and Meghan Jeffres, PharmD, BCPS, CDE, CPP. "Zika Outbreak: What Pharmacists Need to Know." Expanding Opportunities through Patient Care: APhA 2016 Annual Meeting & Exposition. Maryland, Baltimore. 5 Mar. 2016. Lecture.
5. Am J Trop Med Hyg. 2015;93(4):869–874.
6.http://www.caribbean360.com/news/zika-virus-what-you-need-to-know

Checking the Box: FDA mandates Black Box Warning for immediate-release opioid pain medications related to increased misuse and deaths

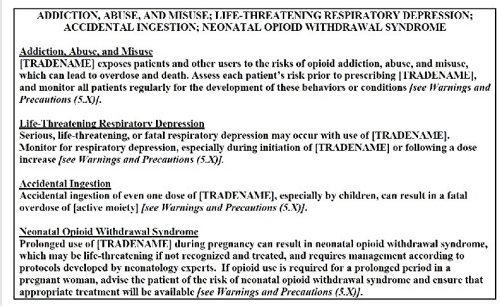
By Justin Moore, Pharm.D. Candidtae

In recent years, opioid abuse and related deaths have grown to become one of the leading causes of mortality in the United States. Prescription drug abuse, now an epidemic facing our country, has resulted in increased drug overdose death rate of 137% since 2000. When focusing on overdose death rates associated with opioid use, the death rate increases to 200%.[2] Government agencies and health professionals are creating new initiatives and safeguards to curtail the rate of opioid abuse in hopes to prevent more drug-related adverse events and deaths.

In an effort to place more accountability on prescribers and patients, the Food and Drug Administration announced new class-wide label changes for immediate-release opioid pain medications. The label changes includes "a new boxed warning about the serious risks of misuse, abuse, addiction, overdose and death".[3] This change should encourage prescribers to contrast the serious risks and benefits of opioid use for their patients. The hope being that immediate-release opioids will be used only in cases of severe pain that cannot be alleviated by alternative therapy.

From a patient perspective, "clearer instructions regarding monitoring and drug administration, including initial dosage, dosage changes during therapy, and a warning not to abruptly stop treatment in a physically dependent patient" have all been included to increase patient safety and discourage ease of abuse.[3] Other labeling changes will include an increased risk of neonatal opioid withdrawal syndrome, drug-drug interactions resulting in serotonin syndrome, and undesired endocrine system effects. Efforts such as those taken by the FDA contribute to the collective outcry for a decline in opioid abuse. Other governmental agencies including the U.S. Department of Health and Human Services have made reducing the misuse and abuse of opioids a top priority. Their plan includes "providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions and address the over-prescribing of opioids, increasing use of naloxone to help reduce the number of deaths associated with prescription opioid and heroin overdose, and expanding the use of Medication-Assisted Treatment (MAT), a comprehensive way to address the needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders."[1]

As student pharmacists and practicing pharmacists, it is our responsibility to take an active role in the clinical decision-making of patients in our communities, which can be done through increased patient counseling and education, advising physicians about the risks of inappropriate opioid use, and collaborating with government initiatives to reduce the prevalence of opioid related abuse and decrease the amount of preventable prescription drug-related deaths in today's society.



ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse
[TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [TRADENAME], and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.X)]*.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME]. Monitor for respiratory depression, especially during initiation of [TRADENAME] or following a dose increase *[see Warnings and Precautions (5.X)]*.

Accidental Ingestion
Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] *[see Warnings and Precautions (5.X)]*.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.X)]*.

1. "HHS Takes Strong Steps to Address Opioid-drug Related Overdose, Death and Dependence." *U.S Department of Health and Human Services*. N.p., 26 Mar. 2015. Web. 24 Mar. 2016.
2. "Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 01 Jan. 2016. Web. 26 Mar. 2016.
3. "U.S. Food and Drug Administration." *FDA Announces Enhanced Warnings for Immediate-release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*. U.S. Food and Drug Administration, n.d. Web. 24 May 2016.

New Drug Highlight: Entresto®
By Rachel Stephens, Pharm.D. Candidate

Entresto® (sacubitril and valsartan), manufactured by Novartis, was approved in July 2015 for the treatment of heart failure with a reduced ejection fraction (HFrEF). It is a combination of a neprilysin inhibitor (sacubitril) and an angiotensin II receptor blocker (valsartan).[1] On May 11, 2016, the ACC/AHA/HFSA published an update to the 2014 ACCF/AHA Guidelines for the Management of Heart Failure to include Entresto® as an alternate first line agent to an ACEI or an ARB for the treatment of HFrEF.[2] The drug approval and inclusion in the heart failure guidelines is based on the results from the PARADIGM-HF trial. This trial showed Entresto® to be superior to enalapril in reducing the risk of cardiovascular death or hospitalization ($p<0.0001$).[3]

Other Information[1]

Do not use concomitantly with an ACEI or within 36 hours of last ACEI dose

Dosing: Start 49/51 mg BID then double dose after 2-4 weeks to a target dose of 97/103 mg BID as tolerated

Dose reduce if: not previously taking a low dose of an ACEI or ARB, severe renal impairment, moderate hepatic impairment

Contraindicated: History of angioedema

Side Effects: hypotension, hyperkalemia, cough, dizziness, renal failure

1. http://www.centerwatch.com/drug-information/fda-approved-drugs/drug/100083/entresto-sacubitril-and-valsartan
2. J Am Coll Cardiol. 2016; ():. Doi:10.1016/j.jacc.2016.05.011
3. J Am Coll Cardiol. 2015 Nov 10;66(19):2059-71. doi: 10.1016/j.jacc.2015.08.878.
4. https://www.entrestohcp.com/dosing

Patient oriented evidence that matters (POEMs) vs. Disease oriented medicine (DOEs)
By Khushbu Tejani, Pharm.D. Candidate

Evidence based medicine is a systematic process in which clinical research is reviewed, analyzed, and applied to ensure patients receive optimal care. As research and technology advance, more and more clinical data comes to light. While there are numerous groundbreaking studies changing the way medicine is practiced, there are also many studies only used for reporting purposes. To help differentiate which ones are worth a reader's time, drug information specialists have come up with two categories into which clinical evidence can be sorted: Patient Oriented Evidence that Matters (POEM) and Disease Oriented Medicine (DOE).

Both POEMs and DOEs are types of evidence-based medicine but they differ in the outcomes they measure. POEMs focus specifically on outcomes significant to the patient. Such outcomes would include: an increase in survival, an improvement in quality of life, or a decrease in drug-related events. These outcomes are what patients are most concerned about due to the information being readily understandable and applicable to their lives. This is one step further than just patient-oriented evidence because we are now focusing on the outcomes that matter to patients. Most healthcare professional prefer POEMs because they are what patients want to see and can change how medicine is practiced.

DOEs, on the other hand, stand for disease-oriented evidence. Disease-oriented outcomes refer to intermediate endpoints that are more concrete such as blood pressure and A_1c goals. These types of outcomes can be further extrapolated to patient-oriented outcomes. For example, concluding a decrease in blood pressure to a specific goal can result in a decrease in mortality. This is an instance where data can become misleading and difficult for patients to understand because not all extrapolations or generalizations of data may apply to them.

Determining whether evidence is a POEM or a DOE is critical in how the outcomes are applied. One method is to analyze whether the outcome evidence is assumed or known from clinical findings. Assuming overall survival will increase due to earlier diagnosis is a logical conclusion that we can make. However, it is considered a DOE rather than POEM until it is verified by conclusive evidence.[1]

Healthcare professionals must embrace change and adapt new methods into their practice. Being able to identify which research is noteworthy and has the most beneficial impact on their patients is critical in the progress of healthcare. Distinguishing between a POEM and a DOE is crucial to the application of clinical research in regards to patient care. Identifying POEMs from DOEs can save critical time and provide the most appropriate care for each specific patient.

1. Slawson DC, Shaughnessy AF, Bennett JH. Becoming a medical information master: feeling good about not knowing everything. J Fam Pract 1994;38:505-13.

I-STOP Patient Care?

By: Abigail Shell Pharm.D Candidate

"I will embrace and advocate changes that improve patient care."[1] Thus concludes the seventh of the eight lines that compose the oath of a pharmacist pledged by all new graduates of colleges of pharmacy across America. With the continual progression of technology inherent in the Information Age, the question arises: what are the actual effects on patients with advances like electronic prescribing? Programs, like New York's newly completed I-STOP, aim to curtail overprescribing and remove illegibility from the pharmacist's concerns but are not without their price. Are these benefits worth the cost of half the community pharmacist's face-to-face patient interactions? The practice of pharmacy is evolving, but even evolution must be directed, in this case, ever toward improving patient care.

"I will embrace and advocate changes that improve patient care.[1]"

What is I-STOP? New York state's pioneer attempt to address opioid overprescribing and overdose-related deaths, the Internet System for Over-Prescribing Act, or I-STOP, regulates narcotic access from the physicians' side.[2] Beginning in 2013, the act required physicians to reference the Prescription Monitoring Program (PMP) before writing a prescription for a Schedule II, III, or IV controlled substance and alluded to future legislation requiring the shift to electronic prescribing. Two years later, the New York State Department of Health was successful in supporting legislation to mandate electronic prescribing for all controlled and non-controlled medications in the state, but due to the logistical considerations in both physicians' offices and pharmacies regarding the secure computer system requirements necessary to prevent unauthorized access, the deadline for these upgrades was extended for one year. As of March 27, 2016, however, electronic prescribing of all prescriptions is mandatory across the state of New York.[3]

What does this mean for pharmacists and patients? Logistically, the process of filling prescriptions remains the same, but a drop-off window is now unnecessary as handwritten prescriptions are illegal and even oral prescriptions are allowed only in pre-specified emergency situations with appropriate documentation[4]; faxed prescriptions, however, are still allowed. Patients can specify their pharmacy of choice, but no provisions for "price shopping" have yet been made. A non-issue for patients with regular pharmacies, this specificity may be an unintended benefit for the pharmacist-patient relationship as patients will now be forced to take a more active role in their prescription healthcare both by calling individual pharmacies for prices if cost is of major concern and by having to find one pharmacy to call home, if for no other reason than convenience.

With regard to the pharmacist, the benefits are more mixed. Removing handwritten prescriptions from the equation streamlines the data entry portion of the pharmacy technician's job, but this increase in efficiency comes at the cost of personal patient interaction. Moving forward, many New York pharmacists will now see the majority of their patients only at the point of dispensing, preventing them from performing initial triage or catching patient-specific issues not detailed in the patient's profile before dispensing occurs. Pharmacists are the most accessible healthcare providers, and as such, should take care to constantly prioritize the patient, even as they incorporate efficient new technology.

New York is not Georgia, and the I-STOP legislation is not a federal mandate, so the impact of mandatory electronic prescribing has yet to be felt in Georgia. Since 2010, however, electronic prescribing of Schedule II-V controlled substances has been legal via DEA-authorized secure computer systems between registered prescribers and pharmacies, and an ever-increasing number of physicians are making this transition.[5] As the effects of New York's new mandate accumulate, Georgia may follow suit, but the voices of its community-based pharmacists must be heard advocating whether or not this new step in electronic efficiency is the most effective step in improving patient care.

1. American Pharmacists Association (2016). Oath of a Pharmacist. Retrieved from https://www.pharmacist.com/oath-pharmacist.
2. PracticeFusion (2016). Learn about I-STOP. Retrieved from http://www.practicefusion.com/new-york-istop-epcs-requirements/.
3. New York State Department of Health. (April 2016). Electronic Prescribing. Retrieved from http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/.
4.New York State Ophthalmological Society (n.d.) FAQs on NYS Mandatory E-Prescribing. Retrieved from http://www.nysos.com/library/nyserx.pdf.
5.Georgia Drugs and Narcotics Agency (July 2014). EPCS (Electronic Prescriptions for Controlled Substances) Updated 9-26-2014. Retrieved from https://gdna.georgia.gov/press-releases/2014-09-26/epcs-electronic-prescriptions-controlled-substances-updated-9-26-2014.

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