

Student Clinical Digest

Clinical Pharmacist

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College of Pharmacy student chapter of the American College of Clinical Pharmacy

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Spotlight: Ambulatory Care

Anh Nguyen,
Marisa Fortunato,
Pharm.D. Candidates
University of Georgia



**PGY2 Residency Director
Beth Bryles Phillips,
Pharm.D., BCPS**

SCCP: Why did you choose a career in academic and clinical pharmacy with a specialty in ambulatory care?

BP: I decided that I wanted to pursue a specialized training in ambulatory care when I was in my PGY-1 residency year. I was very excited about all areas of pharmacy such as critical care, cardiology, etc. But I found that I loved ambulatory care the most because I really enjoyed interacting and developing close relationships with my patients as well as being able to evaluate the long-term impacts of their drug therapies.

I am very interested in academia because I really enjoy teaching and sharing my knowledge with students and residents. In addition, the publication requirement that comes with being a faculty member also helps me stay on top of the game in terms of clinical knowledge.

SCCP: How would you describe your typical workday at your practice site?

BP: At my practice site, I often have my residents and APPE/IPPE students with me. When I get there in the morning, I discuss with my

students and residents the patients who we are going to see that day. Students then present patient cases and we talk about important things; after our discussion, we go see our patients. Then we spend our afternoon documenting our recommendations in patient charts as well as discussing relevant clinical topics. After that, we go back to patients' room where students get to counsel on drug therapies.

SCCP: What educational steps did you take to get where you are today?

BP: After finishing my Pharm.D. education, I completed two years of residency trainings : PGY-1 pharmacy practice residency at an academic teaching hospital and PGY-2 in Ambulatory Care at a VA hospital. In addition, when I was a resident, I was able to gain opportunities in publication, scholarship, research, and teaching.

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New Drug Digest: Canagliflozin (Invokana)

Jennifer Dean,
Pharm.D. Candidate



Canagliflozin is a new oral anti-diabetic agent used concurrently with diet and exercise to treat type II diabetes. Being the first sodium-glucose co-transporter 2 (SGLT2) inhibitor, canagliflozin decreases blood glucose by causing an increase in the amount of sugar excreted through the urine. Urinary tract infections are the most common side effect. Important to note is that Canagliflozin is contraindicated in patients with severe renal impairment (GFR < 30ml/min) or end stage renal disease.

Reference: Canagliflozin. Lexi-Drugs Online [Internet]. Hudson (OH) : Lexi-Comp, Inc. 1978-2013 [cited 2013 Nov 21]. Available from: http://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/4230722.

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Janssen Pharmaceuticals

Proposed Changes to Hydrocodone Scheduling

Huldah Abaidoo, Pharm.D.
Candidate

Prescription drug abuse and misuse, especially in the case of prescription painkillers, has become a growing problem in America. It is said that 80% of the world's pain pills are consumed in the United States and "almost twice as many people abuse prescription drugs as the number of people abusing cocaine, heroin, hallucinogens and inhalants combined" ("FDA Aims to Tighten", 2013). Food and Drug Administration (FDA) has been looking at various ways to respond to this looming crisis.

One such effort is a proposal to change the scheduling of hydrocodone combination pill, which combine hydrocodone with less potent painkillers like acetaminophen (e.g. Lortab or Vicodin). Accessibility and over prescribing by doctors, who perceive them to be less addictive than Schedule II medications like Percocet, have been the main

source of problems. ("FDA Aims to Tighten", 2013). The FDA has thus developed a proposal to make scheduling of these painkillers more restrictive by changing the hydrocodone combination products from a Schedule III to Schedule II classification. Dispensing of Schedule II drugs are especially stringent because no refills of the prescriptions are allowed. Additionally, the prescription would be required as a hard-copy and verbal order prescriptions would not be allowed.

This change has its supporters, including the National Institute on Drug Abuse, but it also has its critics. It may surprise some that many pharmacists, including the American Pharmacists Association, are opposed to the reschedule. This they argue is "because there is clear evidence that this change will reduce patient access to medications and cause harm – largely to patients living with chronic pain" ("FDA Recommends Rescheduling", 2013). The proposal, which is still being developed, is to be submitted to the Department of Health and Human Services by early December. The Drug Enforcement Administration (DEA) will ultimately make the

decision about this change (*Statement of Proposed Hydrocodone Reclassification*, 2013). With this potential change affecting not only the patients and doctors but also the pharmacy, it will be interesting to see the outcome, and more important what else can be done to reduce the growing epidemic of prescription drug abuse.

References:

"FDA Recommends Rescheduling Hydrocodone to Schedule II." *American Pharmacists Association*. N.p., 25 Oct.2013. <<http://www.pharmacist.com/fda-recommends-rescheduling-hydrocodone-schedule-ii>>.

Staff, CNN, Leslie Bentz, Jacque Wilson, Nadia Kounang, and Stephanie Smith. "FDA Aims to Tighten Control of Hydrocodone." *CNN*. Cable News Network, 25Oct.2013. <<http://www.cnn.com/2013/10/25/us/fda-painkiller-controls/>>.

Statement on Proposed Hydrocodone Reclassification from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research. U.S. Food and Drug Administration, 24Oct.2013. <<http://www.fda.gov/drugs/drugsafety/ucm372089.htm>>

Antibiotic Misuse: The Terrible Creation of Superbugs

Brittany Thompson, Pharm.D. Candidate

The advances made in antibiotic treatments made since the introduction of penicillin in the 1940s have been vastly beneficial for patients. However, taking antibiotics when unwarranted (such as in viral infections) or not taking the entire course of the antibiotic contributes to the formation of multidrug-resistant superbugs. Additionally, the failure of first-line antibiotics means that patients must resort to less conventional medications, many of which are more costly and associated with more-serious side effects.

Take this short quiz to see what you know about antibiotic use.

What health issue does the bacteria *Clostridium difficile* cause?

- a. syphilis
- b. throat inflammation
- c. bacterial vaginosis
- d. painful diarrhea

Answer: d. painful diarrhea. This bacterial infection occurs mostly in nursing home patients and recently hospitalized individuals. Between 2000 and 2007, the number of deaths related to *C. difficile* increased 400% because a stronger strain of the bacteria emerged in 2000. 90% of these deaths occur in people aged 65 and older. *C. difficile* is in the highest category of the CDC's bacterial threats list.

True or False? Most of the antibiotics sold in the United States are used in children's hospitals.

Answer: False. There is evidence that more antibiotics are used in food production than in humans. Antibiotics are commonly used in livestock to prevent, control, and treat disease and to promote growth, a practice that the CDC is taking measures to halt. This is an issue because people consuming said contaminated animal products can develop antibiotic-resistant infections.

Which class of drugs are used as a "last resort" treatment for gram-negative bacterial infections due to concerns of nephrotoxicity and neurotoxicity?

- a. Fluoroquinolones
- b. β -lactams
- c. Polymyxins
- d. Aminoglycosides

Answer: c. Polymyxins. The toxicity of polymyxins may be partly due to their D-amino acid and fatty acid content.

Polymixin B causes nephrotoxicity by increasing membrane permeability, leading to an increased influx of cations, anions, and water, causing cells to swell and lyse. However, it should be noted that the dosages of polymyxins used in former studies were considerably higher compared to the recommended dosages administered nowadays.

Although bacterial drug resistance is a natural event, it is accelerated by overuse or underuse of antibiotics. In fact, according to a recent CDC report, 2 million people in the U.S. get infections that are resistant to antibiotics and 23,000 die as a result every year. In order to raise awareness and combat this issue, the CDC promotes its annual 'Get Smart About Antibiotics Week' in November to raise awareness about the threat of antibiotic resistance with hopes of decreasing inappropriate antibiotic use. Doctors, pharmacists and other healthcare professionals are being called to practice "antibiotic stewardship" by providing antibiotics only when absolutely necessary.

References: <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>,
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550802/>

Clinical Pharmacy Across the Seas

Payal Kakadiya, Pharm.D. Candidate

The American College of Clinical Pharmacy is working with pharmacists around the globe in implementing and advancing clinical pharmacy. "Being a Clinical Pharmacist" was first offered at the 13th Asian Conference on Clinical Pharmacy in Haiphong, Vietnam in September 2013. The goal of the program was to introduce the attendees to advanced clinically pharmacy practice and develop specific skills that pharmacists can use in their daily practice to optimize patient care. During the three-day conference, participants discussed current issues facing the profession, research findings, and how to advance the education of clinical pharmacy. The sessions provided an overview of the different patient-care services and described the roles and responsibilities of clinical pharmacists in different healthcare settings. Other sessions also provided illustrative patient cases to apply clinical knowledge and skills in real-life settings.

In June 2013, the Board of Directors of the Accreditation Council for Pharmacy Education approved the first international pharmacy degree program certification. This certification attests that the program meets the requirements set by the International Quality Criteria for Certification of Professional Degree Programs in Pharmacy. The first certification was given to King Saud University College of Pharmacy in Saudi Arabia.

Drug Shortages: History, Statistics, and Pharmacists

Aros Mahmud, Pharm.D. Candidate

The FDA on October 31, 2013 released the Drug Shortage Strategic Plan, outlining further strategies the agency will implement to enhance an effort they began in 2011 – trying to prevent drug shortages as much as possible. Their first efforts may have begun in 2011, but the problem was underway for much of the years preceding 2011. Beginning in 2006, drug shortages started on a mission.¹ Whereas previously the frequency was consistent from year to year, each year after 2006 the number of new drugs added to the shortage list was greater than the number added to the list during the previous year.

President Obama finally broke the silence in 2011 and issued an executive order, calling the FDA to action. Ever since, manufacturers are required to warn the FDA ahead of time when they have reason to suspect that their product may experience shortage in the coming days or months.² This allows the FDA time to work with the manufacturer and steer away the potential shortage. In addition to the advance notice system, other steps were also taken. As a result, in 2012, drug shortages became half as frequent as during 2011 and the upward trend was finally broken.³ The strategic plan of 2013 now hopes to take that outcome and begin with it a trend in the opposite direction.

Hospital is the setting most affected by drug shortages because shortages tend to occur to sterile injectable medications, as they do in 74% of incidences.^{1,4} Moreover, classes suffering the most shortages are oncology drugs, antibiotics, and IV nutrients and electrolytes.

To minimize the impact of drug shortages on patients in this setting, the need for interdisciplinary teamwork is heightened. Everyone's communication lines must be connected to everyone else's communication lines. In particular, the value that the pharmacist brings is critical. The pharmacist is able to use his/her skills, resources, and extensive knowledge of drugs to identify the best alternative possible when a drug runs low. When a therapeutically equivalent substitute is not possible, the pharmacist can provide insight on a bioequivalent substitute or on an off-label use. Moreover, these tasks must be performed while balancing cost consciousness. It can be a complex decision process. At the same time, their work allows patients to remain treated on a carefully selected substitute. Hopefully, more patients will avoid complications altogether when the FDA implements its new strategies.

References:

1. Food and Drug Administration. 2011. A review of FDA's approach to medical product shortages. <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm277745.htm>. (accessed November 21, 2013).
2. The White House. 2011. Executive Order 13588. <http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages>. (accessed November 21, 2013).
3. Food and Drug Administration. 2013. FDA takes two important actions on drug shortages. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373044.htm>. (accessed November 21, 2013).
4. Duke, Melissa. 2011. Mitigating the impact of medication shortages on public health. <http://japha.org/article.aspx?articleid=1043982>. (accessed November 21, 2013).

New Drug Digest: Macitentan (Opsumit)

Jennifer Dean, Pharm.D.
Candidate



Macitentan is the first and only treatment for pulmonary arterial hypertension that prevents disease progression. It prevents vasoconstriction in the pulmonary artery by inhibiting the binding of endothelin-1, a potent vasoconstrictor, to endothelin receptors ET_A and ET_B. While the FDA does not require liver enzyme testing, there have been reported cases of increased hepatic enzymes. Since Opsumit is a category X drug, women must enroll in the OPSUMIT REMS program, and they are required to provide a monthly negative pregnancy test.

Reference: Macitentan. Lexi-Drugs Online [Internet]. Hudson (OH) : Lexi-Comp, Inc. 1978-2013 [cited 2013 Nov 21]. Available from: http://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/4779928.

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Actelion Pharmaceuticals

Clinical Pharmacist Spotlight: Ambulatory Care

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SCCP: What types of research projects, educational opportunities, or classes do you typically offer for students? And at what points should they participate in your project?

BP: Every year, I offer an elective course known as “Introduction to Post-graduate Residency Training” to all 3rd year students who are interested in completing residency training upon their graduation. Certainly, this course as well as other courses in our curriculum will help students discover whether residency training is something they really want to pursue. In addition, I provide mentorship for students who want to pursue residency training beyond the completion of the course. I also work with many students for their seminar preparation.

SCCP: As our SCCP faculty advisor, what kinds of educational opportunities can SCCP provide to its members?

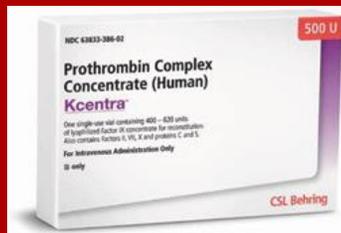
I believe that SCCP is a great avenue for student involvement. Students can learn more about clinical pharmacy, get to know people in our profession, and expand their networking. Taking advantage of those learning opportunities offered by SCCP, such as CV review service and the Clinical Pharmacy Challenge student competition, students can gain unique experiences that help them better prepare for residency training.

SCCP: What are your best pieces of advice for students who are interested in residency and clinical pharmacy?

BP: Start to prepare for residency training as early as you can. Take the residency elective course in third year, work hard in school, and learn as much as you can. Get involved in extracurricular activities and clinical experiences, and importantly, treat each APPE rotation as a real job interview.

New Drug Digest: Prothrombin Complex Concentrate (Kcentra)

Jennifer Dean,
Pharm.D. Candidate



Kcentra is an IV agent used to reverse acute major bleeding in patients with an acquired deficiency in clotting factors due to vitamin K antagonism. As a prothrombin complex concentrate, it contains vitamin K dependent clotting factors: Factor II, Factor VII, Factor IX, Factor X, Protein C, and Protein S. The dosage of Kcentra is determined by the patient's baseline INR and weight. Advantages of Kcentra include not requiring thawing or blood group typing. It is coadministered with IV vitamin K. The most serious adverse reactions to monitor for are stroke, pulmonary embolism, and deep vein thrombosis.

Reference: Kcentra. Lexi-Drugs Online [Internet]. Hudson (OH) : Lexi-Comp, Inc. 1978-2013 [cited 2013 Nov 21]. Available from: http://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/1034779.

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CSL Behring Pharmaceuticals