ACCP STUNEWS

ACCP Clinical Research Challenge 2017

Do you think you have what it takes to develop a research protocol? Then participate in the ACCP Clinical Research Challenge 2017!

The ability to critically analyze the primary literature is a key skill for clinical pharmacists and leads to improved health outcomes for patients through evidence-based medicine. The ACCP Clinical Research Challenge (CRC) is a novel competition that allows teams of three pharmacy students from colleges of pharmacy nationwide to participate in an online journal club, submit a letter of intent, and design a research protocol. This competition is targeted toward pharmacy students pursing their first professional pharmacy degree in their first 2 professional years.

Only one team per institution may enter the competition. Institutions with branch campuses, distance satellites, or more than one interested team are encouraged

Continued on page 3

Issue 30, November 2016

2017 ACCP Student Clinical Research Challenge 1

Student Chapter Spotlight: QTc prolongation 1

Clinical Spotlight 2

Student Chapter Challenge 4

Clinical Case 6

Student Chapter Spotlight:

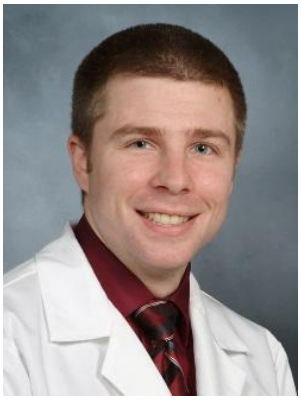
A Clinical Pearl: QTc Prolongation for the Student Pharmacist

Andrea LeVoir and Cassandra Skoog, PharmD Candidates 2017
University of Minnesota College of Pharmacy

Clinical Pearls are a cornerstone of pharmacy education. Learning to present clinical information and apply clinical knowledge can be difficult for students. For these reasons, we decided to initiate a Clinical Pearl session for our student chapter. This session focused on how to identify and treat QTc prolongation. We chose this topic because QTc prolongation is a common potential adverse effect associated with many medications that can be difficult to evaluate and act on. The Clinical Pearl was led by a local clinical pharmacist specializing in psychiatry who presented a real patient case to students and guided them through the clinical assessment. During the event, students were able to participate in a small-group conversation, which allowed them to critically evaluate QTc prolongation risk.

Continued on Page 4

Clinical Spotlight:
David M. Salerno, PharmD



PGY2 Pharmacy Resident – Solid Organ Transplantation
New York – Presbyterian Hospital

Interviewed by Thu Nguyen, PharmD Candidate 2018, Touro College of Pharmacy

1. **What made you interested in clinical pharmacy?**

I became interested in clinical pharmacy during my advanced practice experience rotations in my final year of pharmacy school. I was fascinated by the complexity of patients and how their specific clinical situations never seemed to fit the guideline recommendations learned during pharmacy school. It was very apparent to me that I would require advanced training under the guidance of clinical experts in order to provide optimal patient care. My interest in transplantation started in pharmacy school during the one lecture provided about immunosuppressive medications.

2. **What made you pursue postgraduate residency training?**

I decided to pursue postgraduate training in order to learn how to become a well-rounded, independent practitioner and leader within the pharmacy profession. Providing evidence-based pharmacotherapeutic recommendations is only one piece of a clinical practitioner's responsibilities. Advanced training, including residency, instills a teaching, practice, and service model that provides a comprehensive provision to the pharmacy profession.

3. **What is your current practice and/or role?**

I am currently a postgraduate year two (PGY2) pharmacy resident in solid organ transplantation at New York-Presbyterian Hospital in New York, New York. I rotate through all of the respective transplant disciplines between Columbia University Medical Center and Weill Cornell Medical Center in New York City, providing advanced pharmacotherapeutic recommendations to the multidisciplinary transplant teams. Transplant pharmacy is unique in that a pharmacist is required to be part of the transplant multidisciplinary team and participate in all phases of patient care, including the pre-, peri-, and postoperative phases.

4. **What type of person do you think would best be suited for practicing in your specialty?**

The type of pharmacist who would be most successful in my particular specialty is a person who is interested in immunology and providing care for a diverse group of patients in various care settings (from ambulatory care clinics to medical and surgical intensive care units). In addition, a successful transplant pharmacist may be required to have organ-specific knowledge to provide care to kidney, pancreas, liver, small bowel, heart, and lung transplant recipients. Finally, a transplant pharmacist needs to enjoy patient interaction and teaching patients about their medications.

5. **With your specialty practice, where do you see your specialty going in the future?**

Transplant pharmacy is a growing specialty that is rapidly advancing. More than 100,000 patients are waiting for organs within the United States, with a relatively stagnant donor pool. Clinical research and drug development will be key to optimizing the outcomes of patients successfully transplanted. Pharmacists will play an integral part in managing a transplant recipient's immunosuppression, concomitant medications, and various primary disease states that burden all patients, irrespective of the transplant. In addition, there is a tremendous opportunity for pharmacist-led research to advance practice.

Clinical Research Challenge 2017 (cont.)

encouraged to conduct a local competition. ACCP provides a written examination that institutions may use as a basis for their local competition, if they desire. This examination is already available and may be requested by the ACCP faculty liaison or registering faculty member via e-mail. Please address your e-mail request to Michelle Kucera, Pharm.D., BCPS, at mkucera@accp.com. The deadline to complete team registration and confirm eligibility is February 1, 2017

Round 1: Online Journal Club – The article title will be released on February 3, 2017, and the exam portal will be open on February 6, 2017, from 7 a.m. to midnight (EST). This round consists of a multiple-choice exam based on the selected primary literature.

Round 2: Letter of Intent (LOI) – The LOI round is a new addition to the competition this year with the goal of helping students refine future full-proposal submissions. The top 40 teams will advance to round 2 and will have until February 24 to submit an LOI based on a clinically focused question. After the proposals are evaluated by a three-member review panel, the top 20 teams will be invited to submit a full research proposal.

Round 3: Research Proposal – Teams qualifying for round 3 will develop their full research proposals over a 4-week period and submit them by the deadline of April 14, 2017. The CRC proposals will be reviewed by the Research Protocol Review Committee and Competition Oversight Panel, and winners will be announced on June 5.

Teams with the top three research proposal submissions will be asked to present their research design during a poster session at the 2017 ACCP Annual Meeting in Phoenix, Arizona. In addition, each member of said teams will receive a complimentary Annual Meeting registration and a cash prize.

For more information, please visit www.accp.com/stunet/crc/index.aspx.

New Drug Update: Isavuconazonium Sulfate (CRESEMBA)

Eugene Kwachuh, PharmD Candidate 2017
University of Maryland Eastern Shore School of Pharmacy and Health Professions
Reviewed by: Yen Dang, PharmD, CTTS-M and Curtis Smith, PharmD, BCPS

Introduction: The mortality rate for invasive fungal infections (IFIs) ranges from 30% to 90%, with invasive aspergillosis as the most prevalent.[1] IFIs are the most important life-threatening infection in immunocompromised patients. The choice of agents to use in these settings is limited by the availability of data. On March 6, 2015, the FDA approved isavuconazonium sulfate (Cresemba) for the treatment of invasive aspergillosis and invasive mucormycosis in adults 18 years and older.[2] Isavuconazonium sulfate becomes the sixth antimicrobial or antifungal designated as a Qualified Infectious Disease Product (QIDP).[2] Available in both oral and intravenous formulations, isavuconazonium sulfate is the water-soluble prodrug of isavuconazole, an azole antifungal that inhibits fungal cell membrane synthesis.[3] Isavuconazole's spectrum of activity allows for its potential utility in many IFIs; however, practitioners will have to balance its effects on CYP450 inhibition and high potential for cross-resistance with usage.

Continued on Page 5

Student Chapter Challenge

If you could go back in time and give yourself one piece of advice before starting pharmacy school, what would it be and why?

Barkha Jain, PharmD Candidate 2019
Rutgers University – Ernest Mario School of Pharmacy

If I could go back in time and give myself one piece of advice before starting pharmacy school, I would tell myself to foster grit. I was a shy and studious student back in high school. I often didn't pursue some student activities and advanced-level classes out of fear of rejection and/or failure. However, in hindsight, I wish I had. The earlier I had persistently pursued activities that interested me, the sooner I would have learned how to handle both success and failure. Now in college, I have experienced my fair share of successes as well as failures and rejections. I will admit, however, that failure and rejection still sting. This is why I believe that cultivating grit is important. Grit is a unique blend of passion, perseverance, resilience, purpose, and focus. Although often not as glamorous as it sounds, grit allows an individual to persist with his or her goals even in the face of setbacks.

There is no doubt about the intensity of the pharmacy curriculum. Performing poorly on tests, not landing a coveted internship position, losing professional organization elections, and experiencing other forms of rejections/failures have often led to second thoughts and feelings of self-doubt. However, after such disappointments, I have realized that it is best to learn from those mistakes and find my grit to do better the next time.

Student Chapter Spotlight – QTc Prolongation (cont.)

For this pilot Clinical Pearl, we wanted to have a smaller group to ensure an engaged and thorough discussion. After the event, students gave positive feedback about the individualized session and indicated that they enjoyed working closely with the preceptor. In the future, we will pursue other areas of clinical interest such as oncology/hematology and cardiology. To expand the event in the future while maintaining the small-group dynamic, we plan to have several small groups and preceptors discuss a single case. At upcoming events, we plan to focus on other areas of clinical pharmacy, such as oncology, cardiology, and toxicology, according to student interest.

2016-2017 ACCP NATIONAL STUDENT NETWORK ADVISORY COMMITTEE

LEADERSHIP:

Brian Kurish – Chair
Anesia Reticker – Vice Chair
Rachael Scott – Secretary

MEMBERS-AT-LARGE:

Spencer Blohowiak
Aakash Gandhi
Sarah Lewter
Jordan Perrine
Maggie Ramirez
Amanda Van Matre
Kelsey Williams

ACCP STAFF LIASON:

Michelle Kucera, Pharm.D., BCPS

QUESTIONS/COMMENTS:

Email: stunews@accp.com

CRESEMBA (cont)

Pharmacology: Once administered, isavuconazonium sulfate is hydrolyzed into the active ingredient, isavuconazole, which disrupts ergosterol biosynthesis by inhibiting the action of the CYP450 enzyme 14-α-demethylase. Depletion of ergosterol weakens the cell membrane and impairs its function.[2,3] Accumulation of the toxic methylated sterol precursors leads to inhibition of fungal growth. Isavuconazole's structural formula contains a triazole ring, which makes it more selective for fungal CYP450. Like most azoles, resistance can occur from multiple mechanisms involving target gene *CYP51*.[3]

Dosage Regimen: Isavuconazonium sulfate comes in two formulations: 372-mg vials and 186-mg capsules. Each 372-mg vial and 186-mg capsule is equivalent to 200 mg and 100 mg of isavuconazole, respectively. The loading dose for the intravenous formulation is 372 mg every 8 hours for a total of six doses; that for the oral formulation is two 186-mg capsules every 8 hours for a total of six doses. The maintenance dose is either 372 mg intravenously once daily or two 186-mg capsules orally once daily. There is no dosing adjustment for renal impairment of any stage or Child-Pugh classes A and B. For Child-Pugh class C, isavuconazole should only be used if the benefit outweighs the potential risk. Nursing mothers should not breastfeed while taking isavuconazole. Use in pregnancy is advised only if the potential benefit outweighs the risk.[3]

Clinical Pearls: Current guidelines recommend voriconazole and amphotericin B as first-line therapy options for invasive aspergillosis and invasive mucormycosis, respectively.[7,8] However, isavuconazole's favorable, more predictable pharmacokinetics can make it a good alternative agent for the treatment of both fungal infections. Isavuconazole comes in both intravenous and oral formulations, unlike amphotericin B. Compared with amphotericin B, isavuconazole has more selectivity for fungal CYP450 than for human because of its triazole ring. Moreover, isavuconazole had fewer infusion-related reactions than either voriconazole or amphotericin B during clinical trials. Because of isavuconazole's high oral bioavailability and already established bioequivalence, patients receiving this agent can switch between intravenous and oral formulations without dose adjustments, as opposed to voriconazole, which requires a 300-mg oral dose to achieve an exposure similar to 4 mg/kg intravenously.[9] The intravenous formulation of isavuconazole does not contain cyclodextrin, a substance in voriconazole that causes nephrotoxicity. Isavuconazole also does not require weight-based dosing or dose adjustment in patients with renal impairment, unlike voriconazole. These factors allow isavuconazole to be a safe and effective option for the treatment of invasive aspergillosis and invasive mucormycosis in adults.

References:

1. Petitit N, Carver P. Isavuconazole: a new option for the management of invasive fungal infections. Ann Pharmacother 2015;49:825-42. Available at http://aop.sagepub.com/content/49/7/825.full.pdf+html. Accessed July 23, 2016.
2. FDA News Release, Press Announcement. March 6, 2015. Available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437106.htm. Accessed July 23, 2016.
3. Cresemba (isavuconazonium sulfate) [prescribing information]. Northbrook, IL: Astellas Pharma US, April 2015. Available at https://www.us.astellas.com/docs/cresemba.pdf. Accessed July 23, 2016.
4. FDA Advisory Committee Briefing Materials: Prepared by FDA for Anti-infective Drugs Advisory Committee Meeting. January 22, 2015. Available at www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM430747.pdf. Accessed July 23, 2016

2016 ACCP StuNews November Case

Reviewed by 2016 ACCP Clinical Pharmacy Exam Panel

A 33-year-old woman presents to the indigent county health clinic with a 4-day history of burning on urination and a 2-day history of recurrence of her genital herpes. On physical examination, the medical resident notes occasional coughing with blood-streaked sputum.

Past Medical History: The patient tested HIV positive 3 years ago when she presented with a sore on her labia and was given a diagnosis of (and treated for) primary syphilis. She receives care at this clinic, but she has repeatedly declined treatment for HIV. She has herpes recurrences about every other month.

Social History: The patient admits being a sex worker for the past 10 years and declines any offer for job/skill training programs. She admits that she uses protection during sex only when her clients request it.

Tobacco: 20-year history; alcohol: 4 or 5 strong cocktails 5–7 nights a week; denies using any recreational/illicit drugs for the past 3 years

Current Medications: Acyclovir 800 mg orally twice daily x 5 days during an outbreak (last filled 1 year ago); trimethoprim/sulfamethoxazole 1 tablet orally every other day (not prescribed, sharing a friend's prescription); ibuprofen 200 mg 2 tablets as needed for headache/hangover

Allergies: Cat dander

Vital Signs: Height 168 cm; weight 50 kg; HR 82 beats/minute; BP 124/76 mm Hg; Temp 100.6°F (38.1°C); RR 25 breaths/minute

Laboratory Values: Urine: + *Neisseria gonorrhoeae* (by NAAT [nucleic acid amplification test] assay); sputum: acid-fast bacilli positive, mycobacterial species pending; BUN/SCr ratio: 30 mg/dL/1.5 mg/dL (10.7 mmol/L/132.6 mmol/L); WBC: 16 x 10^3 cells/mm^3 (16 x 10^9/L) with left shift; CD4: 102 cells/mm^3; HIV RNA viral load: 257,250 copies/mL; HIV genotype from 2 years ago: wild-type virus; rapid plasmin reagin (RPR): 1:1 (no change over the past 2 years)

Other Laboratory Results: WNL (within normal limits)

Clinical Case Questions

Question 1: The patient has agreed to start therapy for her HIV infection, but she would prefer to minimize the number of tablets taken per day. Which combination of antiretroviral agents is available as a 1-tablet, once-daily dosing option?

1. Dolutegravir, tenofovir disoproxil fumarate (DF), lamivudine
2. Dolutegravir, abacavir, emtricitabine
3. Elvitegravir, cobicistat, tenofovir alafenamide, emtricitabine
4. Elvitegravir, cobicistat, tenofovir DF, lamivudine

Question 2: Which regimen is recommended as prophylaxis for opportunistic infections in this patient?

1. Trimethoprim/sulfamethoxazole double strength (DS) 1 tablet daily
2. Trimethoprim/sulfamethoxazole DS 1 tablet daily, fluconazole 200 mg orally once daily
3. Trimethoprim/sulfamethoxazole DS 1 tablet daily, azithromycin 1.2 g orally once weekly
4. Trimethoprim/sulfamethoxazole DS 1 tablet daily, fluconazole 200 mg orally daily, azithromycin 1.2 g orally once weekly

Question 3: One month later, results of the TB resistance tests show that this patient's TB is resistant to rifampin and isoniazid. The patient states that her coughing decreased over the first 2 weeks but that it has returned to baseline over the past 2 weeks. Which TB regimen is best to recommend for this patient?

1. Levofloxacin, amikacin, rifapentine, pyrazinamide, isoniazid
2. Levofloxacin, para-aminosalicylic acid, kanamycin, amikacin, ethambutol
3. Pyrazinamide, levofloxacin, amikacin, ethambutol, cycloserine
4. Pyrazinamide, levofloxacin, amikacin, streptomycin, ethambutol

Question 4: The physicians want to initiate treatment for HIV as well as for tuberculosis (TB) using a rifabutin-based regimen. Although the patient prefers a 1-tablet regimen, she is amenable to other options. Which regimen is most appropriate?

1. Dolutegravir/abacavir/lamivudine combination tablet once daily
2. Dolutegravir 50 mg, abacavir 600 mg, and lamivudine 150 mg, each once daily
3. Elvitegravir 150 mg, tenofovir DF 300 mg, and emtricitabine 200 mg, each once daily
4. Elvitegravir/cobicistat/tenofovir alafenamide/emtricitabine combination tablet once daily

Question 5: Which is the best regimen to treat her current non-HIV sexually transmitted infections?

1. Ceftriaxone 250 mg intramuscularly once, azithromycin 1 g orally once, and acyclovir 400 mg orally twice daily
2. Ceftriaxone 250 mg intramuscularly once, azithromycin 1 g orally once, and famciclovir 500 mg orally twice daily
3. Ceftriaxone 250 mg intramuscularly once, penicillin G 2.4 million units intramuscularly, and famciclovir 500 mg orally twice daily
4. Ceftriaxone 250 mg intramuscularly once, penicillin G 2.4 million units intramuscularly, and acyclovir 400 mg orally twice daily

ACCP HEADQUATERS

13000 West 87th Street Parkway
Lenexa, Kansas 66215-4530

Telephone: (913) 492-3311
Fax (913) 492-0088
Email: accp@accp.com

For more information:

Check out our website:
http://www.accp.com/index.aspx

Find us on Facebook
https://www.facebook.com/ClinicalPharm?fref=ts

Follow us on twitter: @ACCP
https://twitter.com/ACCP