American College of Clinical Pharmacy

NYS-ACCP Insider

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SJU-ACCP Student Chapter Highlights

As an ACCP student chapter with Vincentian values at St. John's University, we commit ourselves to the value of service to our community while orienting our students to the practice of clinical pharmacy. Our goal is to provide information regarding career opportunities, to promote excellence in patient care, research and education, and to develop the skills necessary to work on a multidisciplinary team. Take a look at our events that shaped our amazing 2019-2020 year!

In this Issue:

Annual Alumni Dinner

This keynote event invites our alumni back to speak about their experiences and diverse career paths, giving our members the chance to explore a variety of post-graduation opportunities. We invited a total of eight SCCP alumni who played a crucial role in our student chapter:

Dr. Sebastian Choi - Clinical Pharmacy Coordinator at North Shore University Hospital
Dr. James Schurr - Pharmacist and MD Candidate at Stony Brook University
Dr. Jennifer Miao - Clinical Content Team at Flatiron Health
Dr. Caitlyn Cummings - Transitions of Care Clinical Pharmacist at Long Island Jewish Medical Center
Dr. Jack Bao - PGY2 Pharmacy Resident at NYU Langone Health
Dr. Gina Daniel - Pediatric Pharmacist at The Mount Sinai Hospital
Dr. Alex Tai - Clinical Pharmacy Informatics Specialist at Northwell, Enterprise Management
Dr. Ruby Lee - Oncology/Investigational Drug Pharmacist at NewYork-Presbyterian/Weill Cornell Medical Center

We would like to thank our alumni for their past involvement in shaping our organization and for continuously giving us advice after graduating.

Sim Man Collaboration with Physician Assistant Students

Sim Man is a semiannual interprofessional experience held in collaboration between the Pharm.D. program and the physician assistant (PA) program. During this event, pharmacy students work alongside PA students to solve a case using a human patient simulation mannequin. This year, students evaluated a patient who was hospitalized due to community-acquired pneumonia. The PA students diagnosed the patient and ordered the appropriate labs while pharmacy students recommended empiric antibiotic treatment and counseled the patient on a recommended vaccination. Pharmacy professors, Dr. Sharon See, Dr. Bill Maidhof and PA professor Pam Fernandez also worked alongside the students, providing thorough counseling points and clinical pearls to the participants.

Clinical Pearl Series

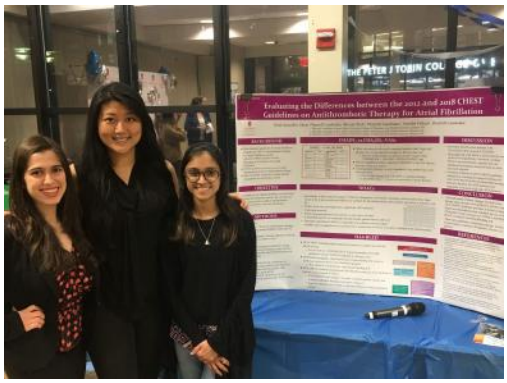
Every month, SJU SCCP invites a P4 PharmD student who is completing their APPE rotations or a pharmacist to share a clinical pearl with the student chapter. Guest speakers included:

Katie Lee who presented Alcohol Withdrawal Syndrome
Samantha Cham who presented Status Epilepticus
Emily Miao who presented Introduction to Lung Cancer
Dr. Ruby Lee who presented Investigational Drug Service
Dr. Joseph Eskandrous who presented Update to Asthma Guidelines
Jennifer Chen who presented Osteoporosis
Kathleen Horan who presented Latent Autoimmune Diabetes

These topics were only briefly touched upon in class, so these short lectures were great opportunities for students to gain more clinical knowledge outside the scope of the classroom.

Mock Competency Exam

St. John's University College of Pharmacy and Health Sciences administers a Competency Exam to all P3 students to evaluate whether or not students are ready to provide an appropriate level of care during their APPE rotations. The College of Pharmacy provided a brief orientation, but our student chapter recognized the anxiousness among students and the need for a structured simulation of the exam. Our P4 PharmD students designed a case study that followed the same structure as our school-administered Competency Exam and provided tips to help students study for and navigate the exam the following week. The event was held in January 2020 and involved over 80 student participants! We would like to thank all of our P4 PharmD volunteers who helped spearhead the program.



Peer Mentoring Showcase

Our Annual Peer Mentoring Showcase is a culmination of a year's worth of work by our peer mentoring groups. Groups were paired according to their interests at the beginning of the year and were encouraged to pick a topic to research and conduct a poster or PowerPoint presentation at the end of the year. Topics included, but were not limited to, new hypertension guidelines, effects of statin use in geriatrics, and antibiotic resistance. We invited all members and groups to come together for our annual night of research and present these projects to fellow students and faculty. This showcase exhibits the innovative mindset of our members and allows them to present new, growing trends in the world of pharmacy.

Volunteering at GallopNYC

GallopNYC is a local organization that utilizes therapeutic horsemanship to help both children and adults with disabilities and special needs build developmental, emotional, social, and physical skills. As volunteers, we are responsible for assisting the guides who lead the horses while spending time with the children and adults who are riding them. Although the time we spend with each person is brief, there is a lasting satisfaction from acting as motivators and cheering for the riders. GallopNYC is a heartwarming experience to take part in, and it is a beautiful sight to see a strong community working together for the well-being of those with disabilities and special needs.

Hospital Intern Panel

The Hospital Intern Panel is an annual event in which P3/P4 PharmD students share their experience and insights on the hospital they work in, the application process, and interview tips. Panelists represented various hospitals in the New York City and New Jersey area, such as New York Presbyterian, Mount Sinai, Memorial Sloan Kettering, Montefiore, Cohen Children's Medical Center, and Jersey Shore University Medical Center. Over 90 students attended!

ACCP Presidential Visit

Dr. Nesbit, national president of American College of Clinical Pharmacy, visited the St. John's University campus and spoke to students about her pharmacy journey and the benefits of being ACCP members. Dr. Nesbit also gave advice on how students can gain the most benefit from attending the ACCP Annual Meeting. She encouraged students to attend the various educational sessions catered for students and to network with other students and professionals.

ACCP Annual Meeting

The 2019 ACCP Annual Meeting was held on October 26-29, 2019 in New York Hilton Midtown. Over 40 members attended the meeting. The highlight event was Emerge from the Crowd: How to Become a Standout Residency Candidate. The event had various sessions on professional networking, determining "fit" for a residency program, and writing a letter of intent. Students also participated in roundtable sessions, where students networked with residents and pharmacists from different specialties, such as cardiology, endocrinology, infectious diseases, and critical care. Many of the pharmacists present served as chairs of their respective ACCP Practice and Research Network (PRN). This was a unique opportunity to connect with leading professionals from all across the country.

Bee Happy Foundation Service Event

Bee Happy Foundation is a 501c(3) non-profit organization centered on supporting children in hospitals receiving long term treatment for chronic, life-threatening illnesses. As volunteers, we packed and delivered Happy Boxes filled with carefully chosen crafts, games, and toys that help ease the discomfort that comes with staying in a hospital over a long period of time. Each child gets their very own Happy Box!

Rho Chi Post Newsletter Collaboration

This year, we collaborated with the Rho Chi Post for our student chapter's second NYS ACCP newsletter. The Rho Chi Post is an award-wining, monthly, electronic, student-operated newsletter founded and developed by our school's Rho Chi Beta Delta Chapter back in 2011. Alongside our current SCCP executive board and senior members, editors from the Rho Chi Post team graciously volunteered their expert eyes to review our articles. Check out their website and newsletter here!

- WingSze (Angel) Liu, PharmD Candidate 2021
- Carina Acosta, PharmD Candidate 2021

Meet our NYS – ACCP Officers

President: Amanda Engle, PharmD, BCPS

Dr. Amanda Engle received a Bachelor of Science in Biochemistry from Syracuse University followed by a Doctor of Pharmacy degree from the University of Maryland, Baltimore with concurrent completion of the Johns Hopkins Clinical Pharmacy Practice Development Program. She then completed residency training at St. Peter's Hospital in Albany, New York and achieved Board Certification as a Pharmacotherapy Specialist. Dr. Engle practiced as a Clinical Pharmacy Specialist at Bassett Medical Center in Cooperstown, New York where she specialized in Pain and Palliative Care. While there, Dr. Engle helped lead the development of numerous quality improvement and research initiatives including several aimed at reducing risk with opioid use. Dr. Engle is currently an Assistant Professor at Albany College of Pharmacy and Health Sciences with a shared role at Albany Medical College to develop interprofessional education opportunities between pharmacy and medical students. There she teaches internal medicine and interprofessional education experientially, and pain management and various internal medicine topics didactically. Her research interests continue to include opioid use risk reduction as well as educational and patient outcomes of interprofessional student teams. Dr. Engle enjoys spending time with family and friends cooking, hiking, playing board games, and hanging out with her 9 month old bernese mountain dog-poodle mix (Bernedoodle) puppy.

President-Elect: Kathryn A. Connor, Pharm.D., BCCCP

Dr. Kathryn Connor is an Associate Professor of Pharmacy Practice at the Wegmans School of Pharmacy (WSoP) at St. John Fisher College and a Critical Care Clinical Specialist in the Surgical ICU at the University of Rochester Medical Center in Rochester, NY. She earned her Pharm.D. at Wayne State University in Detroit, MI. She completed her PGY-1 residency at the Johns Hopkins Hospital in Baltimore, MD and her PGY-2 Critical Care residency in Memphis, TN. Dr. Connor teaches didactically and precepts students and residents at her practice site in the ICU. She is also the Faculty Liaison for the WSoP student ACCP chapter, and is passionate about involving students in clinical pharmacy and encouraging early participation in professional organizations. Dr. Connor's research interests focus on infectious diseases, nephrology, and acid-base physiology. When she is not working, Dr. Connor enjoys animals and nature, traveling, eating vegan food, various intellectual and cultural pursuits, and spending time with her husband and three young children.

Past- President: Amanda RM Winans, PharmD, BCPS, CACP

Amanda McFee Winans earned her PharmD in 2007, graduating from Albany College of Pharmacy. She completed a postgraduate Pharmacy Practice Residency with an emphasis in Pain and Palliative Care at Bassett Medical Center in Cooperstown, New York. Dr. Winans currently serves as the primary pharmacist clinician of the outreach Anticoagulation Management Service at Bassett Healthcare, caring for cardiology and cancer patients alike. She continues to support the pain and palliative care practice at Bassett Medical Center through the Pain Management Committee and related quality improvement initiatives. Dr. Winans holds adjunct faculty appointments with multiple Colleges of Pharmacy and holds Clinical Faculty appointment in Pharmacology at Columbia University College of Physicians and Surgeons. She has authored and contributed to numerous peer-reviewed manuscripts related to anticoagulation, and pain and symptom management

Secretary/Treasurer: Bennett Doughty, PharmD, BCPS, BCPP

Dr. Bennett Doughty earned his Doctor of Pharmacy degree from the University of Connecticut School of Pharmacy in 2016. Following graduation, Doughty completed two years of residency training at the VA Connecticut Healthcare System in West Haven, Conn., specializing in psychiatric pharmacy. Doughty joined the Binghamton School of Pharmacy and Pharmaceutical Sciences in 2018 as a clinical assistant professor in psychiatry/neurology within the Department of Pharmacy Practice. He also serves as a clinical psychiatric pharmacy specialist at the Guthrie Robert Packer Hospital in Sayre, Pa., where he works in an integrated psychiatric clinic within internal medicine. Doughty's research interests primarily focus on the engagement of patients in substance use disorder treatment, particularly within the opioid epidemic. In his spare time, Bennett enjoys running, hiking, skiing, playing piano, and re-watching episodes of "The Office."

Clinical Spotlight: Dr. Caitlyn Cummings

Clinical Pharmacist in Transitions of Care at Long Island Jewish Medical Center

1. Can you explain your role at Long Island Jewish Medical Center hospital and how it may differ from any other Transitions of Care roles?

"My role at Long Island Jewish Medical Center is as one of the transitions of care clinical pharmacists." Caitlyn gets a unique position where she can work with the endocrine service helping with transitioning high risk patients with comorbid diabetes. The patient population is predominantly non-insured or Medicaid and she gets the opportunity to spend time educating patients throughout their hospital stay on their diabetes and comorbidities, how to use insulin and/or other devices, their medications, as well as non-medication therapies for their diseases. She also helps with assisting in discharge by scheduling follow-up appointments at the clinic and making sure the patients' medications are sent appropriately and are affordable. After the patients are discharged, she will follow up over the phone with the patient and pharmacy to troubleshoot any problems once the patient is home. Lastly, if the patient chooses to follow-up in our medicine and/or endocrine clinic, she has the ability to follow-up with the patient in the ambulatory care setting for about 3 months. "There are so many transitions of care opportunities for pharmacists to play a role in and they are all extremely important to assist patients during critical transition periods. My role is unique with the patient population I serve, as well as with the opportunity I have to follow patients throughout both their inpatient stay and outpatient follow-ups. It allows me to build relationships and trust with my patients. Typically, TOC pharmacists would work on initiatives to prevent hospital readmission, educate patients, reconcile medications between settings, disease-specific initiatives, and follow-up over the phone. I am able to do all of that and follow-up with patients in the ambulatory care setting."

2. What drew you towards pursuing this role? Did you always know you wanted to be a Transitions of Care Coordinator?

"Working in community pharmacy throughout pharmacy school, I saw many issues that occurred when patients were discharged from the hospital - lack of education on new therapies, duplicate medications, and more importantly, confusion and frustration after their hospital stays. I also knew that I loved both internal medicine and ambulatory care throughout my APPE rotations and PGY-1. This opportunity arose at the right place at the right time (towards the end of my PGY-1 training) and it combined everything I was passionate about! I feel very fortunate to be in this position for the last 3 years."

3. What advice do you have for students that may want to pursue this role as well?

"I would say that all students will play a role in TOC in some way, shape, or form during their pharmacy careers! For those who are really interested in pursuing a TOC position, there is no one size fits all approach and being flexible and open to opportunities is key. Everyone's path is different and different opportunities may lead you down different paths. A pharmacy residency helped me build a strong clinical foundation first

but it may not be the path for everyone. It is good to have a plan about long-term goals but the path to get there may be different for everyone! If you ultimately desire a clinical role, doing a general PGY-1 residency should prepare you and enhance your clinical skills. Remember, TOC can take on many forms in all sorts of positions not just in a dedicated TOC position." "Pharmacists in the community do TOC work when reconciling medications after a patient is discharged or when patients see multiple providers and interactions occur. Additionally, in the hospital or community, you can play a role during care transitions and help prevent readmissions through patient/family education, phone call follow-ups, or by finding therapeutic alternatives to help with cost or medication adherence."

4. What is one challenge you have faced in your career and how have you tried to overcome that challenge?

"There are always going to be challenges in your career that are out of your hands but the most important thing you have control over is your own perspective – so I try to see challenges as opportunities. One "opportunity" I came across when I first started was the inappropriate prescribing of diabetes supplies upon discharge (for example, prescribing pen needles when insulin vials were prescribed). I spent many extra hours fixing discharge issues, educating individual providers, and tracking this data. Because diabetes supplies are a free text prescription, there was a large variety of errors. So together with the endocrine team, we collaborated with IT to create a pre-populated diabetes supplies favorites list which has tremendously cut down on errors upon discharge. We have also provided a lot of educational opportunities for providers at the hospital and created a Diabetes Scholars program which has empowered providers to better care for patients with diabetes."

-Ruchira Kasbekar, PharmD Candidate 2020

Switch from Vancomycin Trough to AUC Monitoring

Vancomycin remains as one of the mainstay therapies against MRSA infections in hospitals today. However, effective monitoring continues to be a problem in many hospitals, leading to decreased efficacy and increased renal side effects in many patients. According to the IDSA 2009 guidelines, vancomycin is most accurately monitored using serum trough concentrations. For severe infections where the minimum inhibitory concentration (MIC) is <1 mg/L, the trough levels should fall between 15-20 mg/L to achieve an area under the curve/minimum inhibitory concentration (AUC/MIC) > 400.[1] Conversely, many studies now suggest that a goal of AUC/MIC > 400 could be attained at a much lower trough concentration without incurring the nephrotoxicity associated with high trough concentrations, leading to a paradigm shift from trough-based to AUC/MIC monitoring in the upcoming IDSA guideline update.

Trough levels often misrepresent the AUC/MIC concentration and higher trough levels of 15-20 mg/L incur higher risks of nephrotoxicity, which was shown in a retrospective analysis that included 100 adult patients who were treated with vancomycin for positive MRSA infections. The patients were then stratified into four main groups based on their trough levels: <10, 10 to 14.9, 15 to 20, and >20 mg/L.[2] Surprisingly, there were no significant differences in the attainment of AUC/MIC >400 mg/L between the 15 to 20, 10 to 14.9, and >20 mg/L groups.[2] In fact, the 10 to 4.9 mg/L group had a higher percentage of patients reaching the AUC/MIC goal than the 15 to 20 mg/L (51.6% vs 45.7%).[2] Hale then averaged the trough levels over a 10-day course of

treatment and found that patients who developed acute kidney injury (AKI) had significantly higher vancomycin trough levels than those who did not develop AKI (19.5 ± 3.6 vs 14.5 ± 4.2 mg/L, P < .001).[2] With greater nephrotoxicity risks and lower achievement of AUC/MIC goal, a trough level of 15-20 mg/L no longer seems to be the most accurate and safe marker for vancomycin monitoring.

Three methods of AUC monitoring have been established including Rodvold Method, Trapezoidal Method, and the Bayesian Method. Rodvold Method, the simplest method, relates vancomycin clearance to the patient-specific creatinine clearance. It does not require specific software or dosing calculator and uses a readily available lab value, serum creatinine, instead of multiple serum levels to estimate an AUC.[3] However, creatinine clearance estimations can be uncertain especially in the elderly and the obese. For this reason, the Rodvold Method has the potential to underestimate the AUC. An alternative method, the Trapezoidal Method, relies on serum levels of vancomycin rather than serum creatinine. Although this method can provide a more accurate estimation of the AUC when compared with the Rodvold Method, it requires the collection of two serum levels, cumbersome manual calculations, and education in obtaining and interpreting levels,[4] Finally, the Bayesian Method, can calculate the AUC and dose adjustments based on a single serum concentration, predict future drug concentrations, and store patient data, which can be used for subsequent calculations.[5] However, Bayesian software programs require training to use and can be potentially expensive. DoseMeRx, one of many Bayesian software programs that exist, has a platform access fee of ($25/bed) in addition to a premium drug model fee of $7,000.[6]

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-Chieh (Jennifer) Chen, PharmD Candidate 2020
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An Update on Community-acquired Pneumonia Guidelines

Community-acquired pneumonia (CAP) is one of the most common infectious diseases and a leading cause of morbidity and mortality worldwide. Health care professionals have been following the standards of therapy listed in the 2007 American Thoracic Society/Infectious Diseases Society of America (ATS/IDSA) guidelines for the last twelve years. In October of 2019, a joint update of ATS/IDSA's CAP guidelines was published.[1]

Typically, samples of sputum and blood are not collected from patients with CAP due to the lack of evidence demonstrating better patient outcomes.[1] In prior guidelines, routine sputum and blood samples were only recommended in patients with severe CAP because delaying the initiation of therapy against uncommon pathogens led to higher mortality rates and an increased risk of antibiotic failure.[2] Current guidelines follow this

standard, but also incorporate this recommendation in patients suspected of having methicillin-resistant S. aureus (MRSA) or P. aeruginosa.[1] Obtaining routine sputum and blood cultures in patients with these risk factors allow healthcare professionals to effectively de-escalate or adjust therapy.[1]

The 2019 guidelines made a few changes on clinical recommendations regarding empirical antimicrobial therapy. In prior guidelines, macrolide monotherapy was listed as first-line for outpatient treatment of patients who were previously healthy and had no risk factors for drug-resistant S.pneumoniae.[2] However, due to increasing counts of macrolide failure and resistance, the first-line recommendation has been reduced to a conditional recommendation; macrolides are only recommended if local pneumococcal resistance is less than 25 percent.[1, 3] Amoxicillin, although not considered in previous guidelines, is currently first-line of treatment with support from several studies that demonstrate its efficacy and safety.[1]

The 2007 guidelines gave equal weight in recommending β-Lactam/macrolide and β-lactam/fluoroquinolone empiric therapy for inpatient adults with severe CAP.[2] However, with evidence from seventeen observational studies, the 2019 guidelines favor β-Lactam/macrolide treatment due to lower mortality rates.[1] Nonetheless, the lack of randomized controlled trials hinders a definitive recommendation between the two treatments.[1]

In previous guidelines, any patient who acquired pneumonia in a nursing home or health-care facility was categorized as having healthcare associated pneumonia (HCAP), and consequently was treated empirically.[2,4] The current guidelines recommend abandoning HCAP categorization because many studies have found that the factors previously used to categorize HCAP did not predict a predominance of antibiotic-resistant pathogens, leading to an unnecessary use of broad-spectrum antibiotics.[1] These patients should only be treated empirically if they are diagnosed with severe CAP or demonstrate risk factors for MRSA or P. aeruginosa.[1]

The update on CAP guidelines led to improvements in antibiotic stewardship and empiric therapies. Although this article highlights the notable changes between the prior and current guidelines, it is surprising that many of the recommendations made in 2007 remained the same. It is apparent that more research and studies are needed to improve our understanding of the treatment of CAP.

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-Darien Lee, PharmD Candidate 2021
-Amy Liu, Pharm D Candidate 2022

The Marik Protocol

The combination of ascorbic acid (vitamin C), corticosteroids, and thiamine (vitamin B1) seems like an unusual medication regimen to encounter in an intensive care unit. However, this regimen has been shown to reduce organ failure, mortality, medication use, and shock-free days in patients experiencing septic shock.

Septic shock is defined as a series of diagnoses that includes sepsis, hypotension requiring vasopressor therapy, and serum lactate greater than 2 mmol/L after adequate fluid resuscitation.[1] The Marik protocol includes the administration of 1500 mg ascorbic acid, 100 mg thiamine, and 50 mg hydrocortisone parenterally every 6 hours for 4 days, and has been shown to decrease organ dysfunction, kidney damage and mortality in patients with septic shock. This regimen works in adjunct to standard therapies used to treat septic shock, such as intravenous broad-spectrum antibiotics, vasopressors, and activated protein C, which acts as an anticoagulant, cytoprotective and anti-inflammatory agent. In current practice, however, there is no therapy proven to attenuate organ injury in septic shock. Therefore, the implementation of this protocol would drastically change the management of septic shock.

A retrospective study conducted by Paul E. Marik compared this new regimen with a placebo group and found statistically significant improvement in hospital mortality percentage, odds of mortality, the sepsis-related organ failure assessment score, and mean duration of vasopressors.[2] These results favor the use of ascorbic acid, thiamine, and hydrocortisone in combination with traditional septic shock regimens. Further randomized clinical trials have been conducted to analyze the impact of this regimen on patients, such as the ACTS trial and VICTAS trial.[3]

Although the mortality of septic shock varies between institutions, severe septic shock is generally associated with a high degree of mortality as compared to other diagnoses, ranging anywhere from 40% or higher.[4] Dr. Marik's study determined that his protocol reduced mortality to 8.5%, reduced odds of mortality, prevented progressive organ failure, and minimized the duration of vasopressor treatment by 66%.

The results of Dr. Marik's study validated the use of inexpensive medications already available at all hospitals as a new way to reduce the severity of septic shock symptoms. While septic shock is still considered a medical emergency, the management of this severe condition has evolved and developed in a way that allows medical professionals to minimize patient harm with the use of vitamins and other commonly used medications with fewer side effects or adverse effects.

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-Chirag Gosalia, PharmD Candidate 2020
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-Ivonna Reda, PharmD Candidate 2022

Optimal Management of Infections with ESBL-producing bacteria

Antimicrobial resistance is garnering more attention as the issue is becoming larger daily. Extended-Spectrum β-Lactamase (ESBL) infections are caused by the ESBL enzyme located in strains of gram-negative bacteria; they are commonly associated with Escherichia coli (E. coli), Salmonella enterica, and Klebsiella pneumoniae. Carbapenems are the most commonly used antibiotics to treat these infections. However, the overuse of carbapenems creates an increase in antimicrobial resistance. This rising resistance level and the rapidly increasing number of ESBL infections are causes of concern within the healthcare community. Recently, there have been studies on using non-carbapenem β-lactams for the treatment of ESBL infections in an effort to lower these resistance levels. This would provide an alternative route that may cure these infections without the use of broad spectrum antibiotics such as carbapenems.

Antibiotics such as cephamycins and cefepime were studied to determine if they could provide a less antibiotic-resistant treatment for ESBL infections. Cephamycins such as cefoxitin and cefotetan were shown to work against ESBL Enterobacteriaceae in vitro, but also had reports of outer membrane protein (OMP) mutations and plasmids.[1] It is important to note that the use of cephamycin against ESBL producing bacteria in vitro is limited due to the scarcity of clinical data.[1] One of these studies showed an advantage of carbapenems over cephamycins while the rest of the studies showed no difference.[1] Therefore, until more data is available on the use of cephamycins on non-urinary sources and severe infections, cephamycins are limited to treat ESBL infections in the urinary tract due to the fact that gram-negative bacilli E.coli is the most common causative pathogen.[1-3]

Another type of antibiotic that was tested on ESBL producing bacteria was cefepime. This antibiotic led to concerns after the Clinical and Laboratory Standards Institute (CLSI) cefepime breakpoint left some ESBL enzymes that would do a “hidden” antibiotic resistance.[1] Cefepime demonstrated the “inoculum effect,” where its minimum inhibitory concentration heavily increased as the bacterial load increased, although there was an initial susceptibility.[1] For example, at high inoculums, cefepime was not effective in sustaining the bactericidal activity against ESBL producing bacteria.[1] In addition, poor dosing and/or interval schedules led to poor results.[1] An observational study comparing carbapenems over cefepime for the treatment of ESBL infections showed that carbapenems were superior in the treatment of those infections than cefepime.[1]

Given all of the information above, the use of non carbapenem B-lactams for the treatment of ESBL-producing organisms can be a possible solution in decreasing carbapenem use. This reduction can aid in decreasing the upward antimicrobial resistance trend. Additionally, cephamycins and cefepime can be alternatives to mild to moderate “low-inoculum” ESBL infection. However, as this is still a topic that is being researched, it is important to note that for critically ill patients with a high bacterial load or elevated B-lactate MIC, carbapenem should be utilized initially.

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-Yuri Kim, PharmD Candidate 2021
-Erica Kohen, Pharm D Candidate 2024

The Pharmacist's Role in PTSD in the VA Setting

Post Traumatic Stress Disorder (PTSD) can be a disabling condition that occurs not only in war veterans, but also in survivors of child abuse, violence, motor vehicle accidents, and national disasters amongst other causes.[1] While most cases are currently treated within the Veterans Affairs (VA) hospitals or on an outpatient basis, PTSD is becoming more commonplace in the community setting. Treating PTSD patients is multifactorial and involves psychotherapy and pharmacotherapy. Pharmacists play a critical role in the collaborative treatment of PTSD within the VA system.

The United States Department of Veterans Affairs (VA) and the Department of Defense (DOD) have set forth guidelines to provide healthcare professionals with the basis on which to evaluate, treat, and manage individuals presenting with PTSD and acute stress symptoms. The guidelines for treatment in clinical practice outside the VA are the guidelines set forth by the VA for diagnosis and treatment.[2]

A collaborative practice is an agreement between one or more practitioners and clinical pharmacists. This agreement allows pharmacists to assume responsibility for performing physical assessments, ordering drug therapies and related laboratory tests, administering medications, and managing drug regimens. A referral in conjunction with a collaborating provider is needed when the patient presents with concerns outside of the scope of practice for the pharmacist. A scope of practice is a legal document outlining the pharmacists duties for patient care relevant to a particular area of practice and setting. Veterans Health Administration (VHA) requires this for all clinical pharmacists with direct patient care responsibility for collaborative medication management, which is giving them the authority to initiate, modify, renew, or discontinue medications.[3,4]

Within the VA Health System, pharmacists are utilized in a variety of ways, including as clinical pharmacists who work under a scope of practice in a mental health outpatient care setting. Clinical pharmacists are defined by the American College of Clinical Pharmacy as "practitioners who provide comprehensive medication management and related care for patients in all health care settings. They are licensed pharmacists with specialized advanced education and training who possess the clinical competencies necessary to practice in team-based, direct patient care environments".[3] The VA Office of Inspector General (OIG) highlights clinical pharmacists as having specialized advanced education and training (ie. residency training at minimum) that allow them to provide comprehensive medication management. Under scopes of practice, pharmacists are able to manage numerous disease states (i.e. hypertension, diabetes, psychiatry, etc.), provide direct patient care, and function at the highest level of clinical practice with autonomy within the parameters of their scopes of practice. Clinical pharmacists are not authorized to diagnose. If a diagnosis is necessary, pharmacists would refer patients to appropriate providers.[4]

Pharmacists are given an expanded scope of practice within the VA setting that highlights their extensive training in school and post-graduation. With increased autonomy, clinical pharmacists have a more hands on approach with patients and follow them closer than often seen in the community setting.

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Cognitive Enhancing Dietary Supplements: the Effects of Omega-3 Fatty Acids and Ginkgo Biloba

With an ever-growing aging society, cognitive impairment and dementia are becoming significant social issues. As there are currently no treatments that have been proven to prevent or cure cognitive dysfunction, many Americans with this condition are turning to alternative medicine to preserve their cognition. Dietary supplements are commonly used by patients who are losing their cognitive function despite the insufficient evidence for their safety and efficacy. The absence of FDA regulation and the spread of misinformation about the effectiveness of dietary supplements place a huge burden on pharmacists from whom patients seek guidance. Omega-3 and ginkgo biloba are two examples of commonly used dietary supplements which are thought to enhance cognitive function.[1]

Omega-3 is a fatty acid that has been linked to a possible reduction in cognitive decline. Docosahexaenoic acid (DHA), one of two types of omega-3, is primarily found in membranes that surround nerve cells and has been thought to cause anti-inflammatory, and thereby protective effects on these nerve cell membranes.[2] Although a plethora of clinical trials have been conducted to test this theory, there remains insufficient evidence to conclude that the use of omega-3 provides any protective effect on cognition. In addition, a prospective cohort study approved by the Institutional Review Boards of both the Boston Veterans Affairs Medical Center and Tufts New England Medical Center, was conducted in elderly men within the Department of Veterans Affair over a period of six years which examined the correlation between omega-3 administration and preservation of cognitive function.[3] Patients were administered an average of 0.26g of omega-3 per day and results indicated no correlation between omega-3 administration and preservation of cognitive function.[1] Even though omega-3 is well tolerated, studies have shown that there may be an interaction between warfarin and DHA containing supplements. Supplementation with omega-3 may also be associated with a reduced risk of cardiovascular events. Whether this reduced risk may lead to improved outcomes in cognition warrants further investigation.[1]

Ginkgo Biloba is a plant extract presumed to have antioxidant and anti-inflammatory properties similar to omega-3. It is believed to regulate neurotransmitter function and protect cell membranes within the brain. A phase 3 clinical trial identified as Ginkgo Evaluation and Memory (GEM)[2] enrolled 3,000 individuals ages 75 and older who received either placebo or 120mg of Ginkgo Biloba extract.[2] Enrolled patients were examined every six months for six years with the ultimate goal of assessing whether there is a correlation between ginkgo biloba administration and preservation of cognitive function.[1] Between the use of ginkgo biloba and placebo, there was no statistical difference with respect to the rates of cognitive decline or disease occurrence. Although the evidence of adverse events after administration of ginkgo biloba is limited, the supplement may interact with antiplatelet or anticoagulant medications which may lead to bleeding. In the GEM study, although not statistically significant, twice as many hemorrhagic strokes occurred in patients who were administered Ginkgo Biloba compared with placebo.

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NAYZILAM® (midazolam) Nasal Spray CIV, the First and Only Nasal Rescue Treatment for Seizure Clusters in the U.S.

Seizure clusters, also termed acute repetitive seizures, are characterized by shorter than usual interseizure intervals.[1] When seizure activity increases in frequency and is recurrent, it can lead to a further decline in patients' quality of life and increased morbidity, hospitalization, and risk of mortality.[2] Among the one-third of patients living with uncontrolled epilepsy, it is estimated that more than 150,000 of these patients experience seizure clusters.[5]

Approved by the Food and Drug Administration (FDA) in May 2019, NAYZILAM® (midazolam) nasal spray is the first FDA-approved nasal option for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy aged 12 years and older.[3] NAYZILAM comes as a single-dose nasal spray unit and can be administered by a non-healthcare professional at home or a non-hospital setting. If the seizure cluster continues for 10 minutes after the first dose, a second dose of NAYZILAM may be administered if instructed by the healthcare provider.[23]

NAYZILAM, classified as a benzodiazepine, is a federal controlled substance (C-IV) due to its potential for abuse and dependence. As with all benzodiazepines, including NAYZILAM, its concomitant use with opioids, alcohol, or other central nervous system depressants may result in profound sedation, breathing problems (respiratory depression), coma, and death.[3] Both patients and their caregivers should be informed about these risks during patient counseling. Caregivers should know how to identify seizure clusters and how to administer this rescue treatment appropriately, as well as be instructed to follow patients closely for the signs and symptoms of respiratory depression.[3]

Early intervention may help avoid emergency department visits and provide patients and their caregivers a greater sense of control.[2] The development of less invasive, non-intravenous routes can positively impact a patient's quality of life. Compared to other formulations, intranasal midazolam is less intrusive, allows greater privacy, and is more suitable for use in the community setting.[4] With these advanced formulation designs, patients and their caregivers must be well-educated about how to use this rescue medication appropriately to improve outcomes in this group of epilepsy patients. Regarding cost, it is anticipated that NAYZILAM prescriptions will cost commercial patients $40 per box.[5] With the NAYZILAM Savings Card, eligible patients could pay $20 per box.[5] The NAYZILAM nasal spray has been made available in retail pharmacies since December 2, 2019.[5]

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Asenapine Transdermal Patch Approved for Schizophrenia Treatment

Grappling with the symptoms of schizophrenia can be a treacherous and harrowing experience. For millions of people in the United States alone, coping with the symptoms of schizophrenia is an arduous reality of everyday life. While there is a spectrum of severity, the more severe cases can leave a person wholly detached from the world around them. From general anxiety to irrational hallucinations, it is difficult to imagine the struggles one faces when having to live with such a mental illness. With any debilitating disorder, even the simple act of taking medication can become a daily hurdle.

On October 15, 2019, the Food and Drug Administration (FDA) approved Noven Pharmaceuticals' asenapine (Secuado) transdermal patch for the treatment of adults with schizophrenia.[4] This is the first transdermal patch approved to treat this condition. The patch can be applied to the hip, abdomen, upper arm, or upper back area.[3] Secuado is available in three dosage strengths - 3.8mg/day, 5.7mg/day, 7.6mg/day.[3] In contrast, the current dosing of sublingual asenapine tablets for patients with schizophrenia is initially 5 mg twice daily, which may be increased to 10 mg twice daily after one week based on tolerability.[2] Given the difficulties of traditional dosing, the transdermal patch offers an opportunity to ease the adherence issues and potentially lead to better health outcomes.

Regarding adverse effects, Secuado was evaluated for safety in 315 adult patients with schizophrenia for up to six weeks in a placebo-controlled trial (NCT02876900)[1]. Common adverse effects experienced included extrapyramidal disorder, application site reaction, and weight gain.[3] Akathisia, a disorder marked by feelings of restlessness and an inability to sit still, led to 4.9 percent of patients discontinuing treatment.[3]

Secuado is not approved to treat patients with dementia-related psychosis.[3] Secuado has a black box warning for an increased risk of mortality in elderly patients with dementia-related psychosis.[3] Contraindications to Secuado include severe hepatic impairment (Child-Pugh C) and a history of hypersensitivity reactions to asenapine or any components of the transdermal system.[3]

With this breakthrough transdermal patch, once daily dosing will help patients overcome medication adherence challenges they may face when managing their mental disorder. In addition, the transdermal patch allows caretakers and doctors to have visible evidence that patients are being adherent to their medication regimens.

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Rybelsus® (Semaglutide): The First Oral GLP-1 Receptor Agonist

Injectable Glucagon-like-peptide (GLP-1) Receptor Agonists have served as a viable second-line treatment option for patients in the treatment of Type II Diabetes Mellitus, but their use has been limited due to patient aversion to self-injection. GLP-1 Receptor Agonists have a multi-fold mechanism of action: they enhance the release of insulin from beta cells, decrease the release of glucagon from alpha cells, and slow the emptying of the stomach. This delayed gastric emptying prolongs the feeling of satiety after the consumption of a meal, and decreases subsequent food intake. Together, these mechanisms reduce blood glucose levels. Due to the peptide-structure of the GLP-1 agents, subcutaneous injection has been the only available method of administration of these agents. Poor absorption in the gastric mucosa along with rapid degradation in the stomach has prevented oral use in the past. Rybelsus® (Semaglutide) is the first orally administered GLP-1 agonist, and it is formulated with sodium N-(8-[2-hydroxybenzoyl] amino) caprylate, which functions as an absorption enhancer in the gastric mucosa. FDA approval of Rybelsus® was granted to Novo Nordisk on September 20, 2019 based on the data and results from the 10 PIONEER clinical trials.[1]

Rybelsus® is approved for the adjunctive treatment of Type II Diabetes Mellitus in conjunction with exercise and diet modification. It is not recommended as a first line therapy option, and should be reserved for patients who failed other treatment regimens. Two doses are approved for once-daily use: 7mg and 14mg. Therapy should be initiated at 3mg daily for 30 days, and then increased to 7mg daily; the 3mg dosing does not effectively decrease glycemic levels, but is necessary to minimize side effects and other possible reasons for premature discontinuation of therapy.[3] Rybelsus® should be taken on an empty stomach 30-60 minutes prior to the first meal of the day, with a sip of water not exceeding 4 ounces.[2]

The black box warning associated with Rybelsus® is for the risk of thyroid C-cell tumors due to the prevalence in rodents in trials. Although this correlation is not known in human beings, Rybelsus® should be avoided in individuals with a history of medullary thyroid carcinoma or a history of Multiple Endocrine Neoplasia syndrome type 2 due to the potential risk.[3] Common adverse effects of Rybelsus® include gastrointestinal discomfort (nausea, vomiting, diarrhea, stomach pain, constipation). Nausea, vomiting, and diarrhea, typically are most common during initiation of therapy, and tend to subside with continued use.[2]

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Food and Drug Administration Approves Elexacaftor/Ivacaftor/Tezacaftor (Trikafta™): New Medication for Cystic Fibrosis

On October 21, 2019, the Food and Drug Administration approved elexacaftor/ivacaftor/ tezacaftor (Trikafta™), the first triple combination therapy to treat cystic fibrosis (CF). Trikafta™ is approved for treatment of CF in patients 12 years and older who have at least one F508del mutation in the CFTR gene, which affects up to 90% of CF patients.[1]

CF is a progressive, genetic disease that causes chronic lung infections, diabetes, and limits one's ability to breathe. In healthy individuals, the CFTR protein is created, moves to the cell surface, and allows the transfer of chloride in water. In individuals with CF, mutations in the CFTR gene cause the CFTR protein to become dysfunctional and chloride transfer does not occur. Without the chloride to attract water to the cell surface, mucus in various organs becomes thick and sticky. This mucus clogs airways, trapping germs leading to infections, inflammation, respiratory failure, among other complications.[2]

With Trikafta™ being a combination drug, all active ingredients have different roles. Elexacaftor and Tezacaftor act as protein correctors in CF patients who have the f508del mutation and mimic the action of f508. After the CFTR protein reaches the cell surface, to facilitate the action of protein, ivacaftor becomes the potentiator to fully control the flow of salt and water, which helps the cilia sweep watery mucus from the lung lining and keeps the surface clean.[1]

Trikafta™ is supplied as two separate products packaged together: elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg are formulated together as a fixed dose combination in orange shaped tablets and ivacaftor 150mg is formulated in blue capsule shaped tablets. Oral dosing in individuals twelve years of age and older is as follows: 2 tablets of elexacaftor100/tezacaftor50/ivacaftor75mg in the morning and 1 tablet of ivacaftor 150mg at bedtime. There are no contraindications listed in the manufacturer's labeling.[1]

Trikafta™ has become the first line therapy in patients with two F508del variants who are 12 years and older and has replaced tezacaftor-ivacaftor and lumacaftor-ivacaftor in clinical practice guidelines. Both triple and dual therapies demonstrate efficacy in this patient population, however, in a four week trial, triple therapy achieved much greater improvements in FEV_1 and symptom related quality of life compared with tezacaftor- ivacaftor.[2]

More than 10% of patients see adverse reactions within the central nervous system, gastrointestinal tract, liver, and respiratory system. Headache is the most frequently reported side effect (17%), followed by upper respiratory tract infection (16%), abdominal pain (14%), diarrhea (13%), and increased indirect serum bilirubin (11%).

The efficacy of Trikafta™ in eligible patients with CF was demonstrated in two clinical trials. The first trial was a 24-week, randomized, double-blind, placebo-controlled trial which assessed 403 patients who had an F508del mutation and a mutation on the second allele that results in either no CFTR protein or a CFTR protein that is not responsive to ivacaftor or tezacaftor/ ivacaftor alone.[3] The second trial was a four-week, randomized, double-blind, active-controlled trial where 107 patients who had two identical F508del mutations.[4]

Both trials assessed increases in the FEV_1 as the primary outcome and found that Trikafta™ increased the FEV_1 by 13.8% from baseline compared to placebo and increased the mean FEV_1 by 10% from baseline compared to

tezacaftor/ivacaftor. Results from the first trial also showed improvements in absolute change in sweat chloride levels, secondary outcome, number of pulmonary exacerbations, and body mass index with treatment of Trikafta™.[4]

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