# NYS-ACCP INSIDER CCCD

Albany College of Pharmacy and Health Sciences

### **ACPHS-SCCP Student Chapter Update**

#### Written by Sadie Lozier, PharmD Candidate, ACPHS Class of 2024

The Albany College of Pharmacy and Health Sciences (ACPHS) SCCP chapter is well-established on campus and is dedicated to expanding ACCP's core values. The chapter currently has 92 members, ranging from freshman to 4th year PharmD candidates. On campus, we strive to aid student growth as future healthcare professionals and provide networking opportunities with pharmacists practicing in a variety of settings. With the help of our two faculty advisors, Dr. Kate Cabral and Dr. Michael Kane, our organization has been able to provide exceptional networking, professional development, and valuable clinical experiences to our members.

With the health restrictions loosening, our chapter is eager to start holding events out in the community and start providing direct patient care this upcoming year. We offer a variety of opportunities for student involvement in our direct and clinically focused patient care projects. These include our Cardiovascular and Renal (CaRE) screenings, Script Your Future (SYF) project, CaRE for KIDneys project, and Epilepsy project. These patient care projects allow students ample opportunities to interact with patients from a variety of cultural, socioeconomic, and academic backgrounds and allow our members to develop as leaders and promote clinical pharmacy within our school.

Our chapter's CaRE screenings are a great way for our members to gain clinical experience and offers members opportunities for direct patient care. Our CaRE coordinators offer multiple trainings for our members to learn how to measure blood pressure, blood glucose, calculate BMI, and counsel patients on interpretation of their results, as well as their current pharmacologic and non-pharmacologic treatments. So far this year we have held a blood pressure training session to prepare our members to screen the community at the local Health Expo. In the past, this event provided our members with ample opportunities to practice their skills, counsel to a variety of individuals, and increase their confidence in the field. As a chapter we look forward to offering more opportunities within the community because of the mutual benefit it provides us and the public.

# American College of Clinical Pharmacy

#### **Special Points of Interest:**

Tirzepatide Once Weekly for the Treatment of Obesity -The SURMOUNT-1 Trial

Clinical Spotlight: Dr. David Butler, PharmD., BCPS, AAHIVP: Infectious Disease Pharmacist at Albany Medical Center and Assistant Professor at ACPHS

Vonoprazan: A Novel Treatment for Helicobacter pylori Infection

Pharmacogenomics - One Size Does Not Fit All

Our SYF coordinators focus on educating community members on medication adherence and the importance of managing disease states. They offer both on and off campus events to increase awareness and outreach. For example, last year we had a presentation regarding Emocha, an online medication adherence program and the first comprehensive digital medication adherence program for chronic and infectious diseases. This year, our SYF Coordinators are planning to attend the Health Expo and counsel patients on medication adherence. Specifically, they are handing out pill organizers and wallet medication cards to the public.

CaRE for KIDneys visits elementary schools in the Albany area to teach elementary-aged children about diabetes and CV disease while promoting aerobic exercise and healthy diets. Last year, our coordinators held virtual Zoom events with the 15Love organization, a non-profit organization that provides college prep programs, leadership training programs, and SAT prep classes. Additionally, last year with the covid restrictions still present, our members made cards for sick children at a nearby hospital with the hope to brighten their day. This year, we are planning to get back to working with elementary and middle school children in person!

Our Epilepsy project had several pharmacist guest speakers over Zoom last year speak to our members about seizures and their experience with it in practice. This year, so far, our coordinators are participating in the Purple Pumpkin Project in October where we will paint pumpkins purple to raise awareness for Epilepsy and to raise money for the Northeastern New York Epilepsy Foundation.

Our student chapter also hosts Clinical Pharmacy Challenges which are great ways for our members and for ACPHS students to review what they have learned in their didactic courses. We host six challenges each year and each focus on a different clinical topic such as nephrology, neurology, cardiology, and respiratory. Participants of all grades come to gain, refresh, or clarify information pertaining to that topic! To increase attendance, we offer the challenges both via Zoom and in person!

SCCP-ACPHS Advocacy chair was created as a new position in our executive board last year. Our school hosted an Advocacy Alliance month last Spring which involved several professional organizations at ACPHS including SCCP. In the Spring, we had Mr. Mokhiber, a former Executive Secretary of the New York State Board of Pharmacy, who discussed legislature in the executive budget, explained provider status, and compared NYS pharmacy law to more progressive states. This upcoming week, our advocacy chair is holding an information session for members on the meaning of advocacy in the pharmacy profession, its importance, and what is currently being advocated within New York State.

We are excited to provide our members with clinical knowledge, skills, and patient care opportunities for the coming year. Our chapter received lots of interest from many students at our first membership drive this Fall and we look forward to having them join us at our events this year to increase community outreach.



#### VONOPRAZAN: A NOVEL TREATMENT FOR HELICOBACTER PYLORI INFECTION

#### <u>By Elizabeth Lambert, PharmD Candidate,</u> <u>ACPHS Class of 2025</u>

Helicobacter pylori is a bacterium that infects and damages stomach tissue, resulting in inflammation of the stomach and duodenum. Urease, an enzyme produced by this bacterium, reduces the acidity of the stomach. This leads to a weakened stomach lining which allows for peptic ulcers to develop. (1)



If an individual is infected with H. pylori, eradication is the goal. Due to increasing resistance to antibiotics, however, eradication has become more difficult to achieve. Triple therapy of a proton pump inhibitor (PPI) with clarithromycin and amoxicillin or metronidazole is the standard treatment protocol due to high eradication rates of more than 90%. As the bacterium has become increasingly resistant to antibiotics, eradication rates have fallen to below 70%. (2)

H. pylori replication and survival are influenced by gastric pH. Vonoprazan is a potassium-competitive acid blocker that increases gastric pH rapidly. This compound is able to maintain high pH levels more effectively than PPIs indicating it could be utilized in H. pylori eradication. This article will review the first phase three clinical trial conducted in the United States and Europe which compared vonoprazan triple and dual therapy to PPI-based triple therapy for H. pylori eradication. (3) (continued on page 3)

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#### <u> Our Student Chapter 2022 - 2023 E-Board</u>

(from back to front, left to right):

Nathalie Soriano Pereira (Publicity Chair), Haley Frechette (Secretary), Nicole Suker (Clinical Pharmacy Challenge Coordinator), Edward Chu (Care for KIDneys Coordinator), Austin Lewerk (CaRE Coordinator), Lydia Hylaab (Care for KIDneys Coordinator), Natalie Hart (Script Your Future Coordinator), Jessica Pinkerton (Clinical Pharmacy Challenge Coordinator), Julia Sexton (Advocacy Chair), Alexis Mierek (Script Your Future Coordinator), Sadie Lozier (President), Elizabeth Lambert (President-Elect), Jilu Jacob (Care for KIDneys Coordinator)

#### TIRZEPATIDE ONCE WEEKLY FOR THE TREATMENT OF OBESITY – THE SURMOUNT-1 TRIAL

#### By Lara Tran, PharmD Candidate, ACPHS Class of 2023

Glucagon-like peptide-1 (GLP-1) receptor agonists work by mimicking the effects of the incretin hormone GLP-1 and help increase insulin secretion, decrease glucagon release, increase satiety, and slow gastric emptying (1). Unlike GLP-1, glucose-dependent insulinotropic polypeptide (GIP) has minor effects on insulin secretion but regulates energy balance through cell-surface receptor signaling in the brain (2,3). Tirzepatide, a novel GIP/GLP-1 receptor agonist, was developed and was originally indicated for treatment of type 2 diabetes mellitus. However, its use has now



expanded. Recent studies have demonstrated the benefit of GIP/GLP-1 agonists in weight loss beyond glycemic control. The exact mechanism is unknown, but it is hypothesized that it targets the pathways of endogenous nutrient-stimulated hormones (3). The SURMOUNT-1 trial investigated the safety and efficacy of tirzepatide in overweight and obese adults who did not have diabetes (3).

This phase 3 double-blind, randomized, controlled trial included 2539 participants from nine countries, who were randomized in a 1:1:11 ratio to receive a once-weekly subcutaneous tirzepatide (5 mg, 10 mg, or 15 mg) or placebo for 72 weeks (3). As an adjunct, participants engaged in at least 150 minutes of weekly physical activity and had a reduced-calorie diet (3). The mean change in weight at 72 weeks with tirzepatide 5 mg was -16% (95% CI, -16.8 to -15.2), or a mean weight reduction of 16.1 kg; -21.4% (95% CI, -22.2 to -20.6), or an average reduction of 22 kg with the 10 mg dose; and -22.5% (95% CI, -23.3 to -21.7), or a mean reduction of 23.6 kg with the 15 mg dose. In addition, 50% (95% CI, 46 to 54) and 57% (95% CI, 53 to 61) of participants in the 10 mg and 15 mg groups reached a weight reduction of 20% or more, as compared to 3% (95% CI, 1 to 5) with placebo (3). The most frequently reported adverse events were nausea, diarrhea, and constipation3. Treatment discontinuations due to adverse events were 4.3%, 7.1%, and 6.2% in the 5 mg, 10 mg, and 15 mg of tirzepatide groups, compared to 2.6% in the placebo group (3).

In conclusion, the SURMOUNT-1 trial is the first clinical trial to evaluate the use of tirzepatide in overweight or obese patients without diabetes. The study's global nature, large sample size, and overall high completion rate make its results relatively generalizable (3). On October 6th, 2022, the FDA announced it has granted fast-track designation to tirzepatide regarding an obesity indication and is awaiting results from SURMOUNT-2 study (4). Tirzepatide should be considered as a new standard of care for weight loss management in patients with obesity, in addition to physical activity and a healthy diet. With its convenient weekly dosing schedule, tirzepatide may eventually become the cornerstone for weight loss management, minimizing the need for the use of older and less effective weight loss medications, and serving as an alternative to bariatric surgery.

#### References

1. Prasad-Reddy L, Isaacs D. A clinical review of GLP-1 receptor agonists: efficacy and safety in diabetes and beyond. Drugs Context. 2015; 4:212283.

2. Pelle MC, Provenzano M, Zaffina I, Pujia R, Giofrè F, Lucà S, et al. Role of a Dual Glucose-Dependent Insulinotropic Peptide (GIP)/Glucagon-like Peptide-1 Receptor Agonist (Twincretin) in Glycemic Control: From Pathophysiology to Treatment. Life. 2022, 12, 29.

3. Jastreboff AM, Aronne LJ, Ahmad NN, Wharton S, Connery L, Alves B, et al. Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med. 2022; 387:205-16.

4. Kansteiner F. Lilly's tirzepatide slides into FDA fast lane for obesity, turning up heat on Novo Nordisk's Wegovy. Fierce Pharma. 2022 Oct.

(continued from page 2)

This multicentered, randomized, clinical trial analyzed patients aged eighteen and older with at least one of the following conditions: dyspepsia, nonbleeding peptic ulcers, or a history of peptic ulcers not previously treated for H. pylori infection. Patients were treatment-naïve and confirmed to be infected with H. pylori via a C-urea breath test (C-UBT) and endoscopic gastric mucosal biopsy. Exclusion criteria included patients with gastric cancer, gastric or duodenal ulcer with current or recent bleeding, or clinically significant gastrointestinal bleeding within four weeks of randomization. 1046 participants were randomized to a 14-day course of one of three treatment groups: vonoprazan 20 mg dual therapy with amoxicillin 1 g three times per day (n=349), vonoprazan 20 mg triple therapy with amoxicillin 1 g and clarithromycin 500 mg twice daily (n=349), or lansoprazole 30 mg triple therapy with amoxicillin 1 g and clarithromycin 500 mg twice daily (n=348). Four weeks following the conclusion of the therapy course, C-UBTs were obtained to assess H. pylori status. (3) The study was completed by 94.8% of participants, including 96.8% in the vonoprazan triple therapy group, 92.8% in the vonoprazan dual therapy group, and 94.8% in the lansoprazole triple therapy group. Eradication rates, for patients without clarithromycinresistant or amoxicillin-resistant strains of H. pylori in the full analysis set, were 84.7% among the vonoprazan triple therapy group compared to 78.8% among the lansoprazole triple therapy group (difference 5.9%; 95% CI, -0.8 to 12.6; noninferiority P < 0.001). Eradication rates 78.5% among the vonoprazan dual therapy group compared to lansoprazole triple therapy group (difference -0.3%; 95% CI, -7.4 to 6.8; noninferiority P= 0.007). Eradication rates among participants with clarithromycin-resistant strains of H. pylori were 65.8% in the vonoprazan triple therapy group compared to 31.9% in the lansoprazole dual therapy group (different 33.9%; 95% Cl, 17.7-48.1; P < 0.001). Eradication rates were found to be 69.6% in the vonoprazan dual therapy group compared to the lansoprazole triple therapy group (difference 37.7%; 95% Cl, 20.5-52.6; P < 0.001). In summary, vonoprazan-based treatment regimens were found to be non-inferior to lansoprazole-based triple therapy in eradicating H. pylori infection. Such regimens were also found to have higher eradication rates in patients with clarithromycin-resistant strains of H. pylori.3 Voquenza Triple Pak (vonoprazan fumarate 20 mg, amoxicillin 500 mg, clarithromycin 500 mg) and Voguenza Dual Pak (vonoprazan 20mg, amoxicillin 500 mg) received FDA approval for the treatment of Helicobacter pylori on May 3, 2022. (4)

#### References

1. Helicobacter Pylori [Internet]. Baltimore, MD: Johns Hopkins Medicine; 2022 [cited 2022Oct10] Available from:

https://www.hopkinsmedicine.org/health/conditionsand-diseases/helicobacter-pylori

2. Goderska K., Agudo Pena S., Alarcon T. Helicobacter pylori treatment: antibiotics or probiotics. Appl Microbiol Biotechnol. 2017 Oct 26; 102(1): 1-7

3. Chey W., Mégraud F., Laine L., Lopez L., Hunt B., Howden C. Vonoprazan Triple and Dual Therapy for Helicobacter pylori Infection in the United States and Europe: Randomized Clinical Trial. Gastroenterology, 2022 Sep; 163(3): 608-619

4. Drugs@FDA: FDA-Approved Drugs. Federal Drug Administration; 2022 [cited 2022Oct10]. Available from

https://www.accessdata.fda.gov/scripts/cder/daf/inde x.cfm?event=overview.process&ApplNo=215152 CLINICAL SPOTLIGHT: DR. DAVID BUTLER, PHARM.D., BCPS, AAHIVP: INFECTIOUS DISEASE PHARMACIST AT ALBANY MEDICAL CENTER AND ASSISTANT PROFESSOR AT ACPHS

#### By Alexis Mierek, PharmD Candidate, ACPHS Class of 2024

1. You have a B.S. in biology, graduated magna cum laude from Washington State University and then went on to do complete a residency and a 2-year fellowship. How were you able to accomplish all of this? Specifically, what did you do throughout school that allowed you to accomplish this and how did that prepare you for where you are currently in academic position?

I did not finish pharmacy school until I was 32. After graduating with a bachelors, I did not know what I wanted to do next – medical or pharmacy school. It took me a few years after graduation until I realized I wanted to do pharmacy. Because I had already completed a degree and had a rigorous under-grad, it was not a huge



transition to pharmacy school because I knew what to expect regarding workload. I also was fortunate enough to not have to work to make ends meet, so I was able to have all my focus on pharmacy school.

#### 2. How did you decide you wanted to complete fellowship in addition to residency?

I did not realize there was even an infectious disease fellowship until my PGY-1. During that year, I had made a connection with the CDC antimicrobial stewardship pharmacist who really pushed me in that direction. Infectious disease was very intriguing to me because it is always evolving and there is something new that is being discovered.

## <u>3. Which one (residency or fellowship) had a greater impact on your current scope of practice of infectious diseases?</u>

For infectious disease, a fellowship, by far, had a greater impact. A PGY-1 is more generalized. I completed my PGY-1 at the Mann-Grandstaff VA Medical Center in Spokane, Washington. Because I completed it here, the only infectious diseases I saw and dealt with, were osteomyelitis and pneumoniae, which are not as interesting and fun as other infections. Whereas during my fellowship, I was able to see all the "fun" parts of infectious disease and learned a lot more with the fellowship being more research focused.

# 4. Do you wish there was anything else you could have done throughout schooling that would have helped you post-graduation?

I, one hundred percent, wish I did more. I did as much as I could tolerate throughout pharmacy school. The one thing I wish I had done differently was gone back to complete a master's degree. My fellow colleagues here at the college all have either a PhD, MPH, or other master's degree, where they have a formal degree saying that have certain skills in a particular area. I, on the other hand, do not have this formal degree. This does not mean I do not have the same skills as my fellow colleagues but there's nothing set in stone acknowledging these skills.

#### 5. What advice would you give someone who wants to get into this area?

Some advice I would give would be that infectious disease is not just one specialty. It involves every organ system that you learn about through school – cardiology, nephrology, respiratory and much more. Infectious bugs affect every one of those systems. Before you are to consider going into this field, you should be comfortable with everything else you have learned throughout pharmacy school. In addition to the bugs, the drugs we use to treat them can also have negative effects on each of these systems. Another piece of advice I would give is to not stretch yourself too thin. As an advisor, when I see students struggling, I ask them about their daily living; what they do on a day-to-day basis. Most of the time, the students that are struggling are the ones who are trying to do so much and work many hours throughout the week, on top of schooling. The problem with stretching yourself thin is that after a hard day's working, you need a break and the last thing you want to do is start studying lectures. So, try not to do too many things because your education is very important and the real reason you are here. *6. What are your main roles and daily responsibilities as a clinical pharmacist and preceptor at* 

#### <u>Albany Medical Center?</u>

My roles at Albany Medical Center change. Another professor at the college and I switch off at Albany Med with the APPE students. I am usually there in the mornings with them where we workup patient cases for antimicrobial stewardship rounds. Our main purpose is to optimize a patient's therapy and focus on deescalation of medications. We see if the correct drugs are being utilized for the correct bugs, as well as seeing if the durations of therapies are accurate.

# 7. Can you provide some insight as to the current research you are conducting and what are the overreaching goals you are hoping to achieve?

My current research focuses on very resistant, gram-negative bacteria. I am currently working with Acinetobacter baumannii. Carbapenem-resistant Acinetobacter like this one, are currently on the CDC's urgent threat list from 2019. In short, A. baumannii is a nastier cousin of Pseudomonas. It is less infectious, however, it infects those who are more immunocompromised and sicker. My goal is to either find new ways for old antibiotics to be effective against this bacterium or to find new drugs. Since it is resistant to carbapenems, we are also seeing if we can utilize carbapenems in a different manner; possibly at a higher dose or a new combination that has not been used before.

#### 8. Where do you think the role of an infectious disease pharmacist is going in the future?

The answer I can give you now is similar to the answer I would have said ten years ago which is antimicrobial stewardship. It really is our responsibility as pharmacists to optimize a patient's outcome on antibiotics. We really strive and want our patients to recover faster with very little side effects. Long term speaking, I believe that pharmacists will play a very pivotal role as more bugs become more resistant to even more drugs. It will be very crucial for us to know all the options available and when they are appropriate. By that, I mean, it is important as pharmacists to utilize and understand guidelines, but it is just as important to know when they do not apply to an individual patient and when exceptions to those guidelines exist.

#### PHARMACOGENOMICS - ONE SIZE DOES NOT FIT ALL

#### By Brittney M. Singramdoo, PharmD Candidate, ACPHS Class of 2023

The didactic curricula instituted at most pharmacy schools across the nation underscore the importance of offering patient-centered care. Factors such as the patient's lifestyle, socioeconomic status, access to treatment, and personal preference are often considered when selecting medication regimens. What is seldom considered, however, is how a patient's genes can affect their response to medications. So what does that mean for our patients? For many patients, that could translate to the delivery of suboptimal care (1). For example, a recent report released by the Personalized Medicine Coalition revealed that antidepressants were found to be ineffective in 38% of patients receiving them (2). This is consistent with the finding that a 42% variance in antidepressant response can be attributed to genetic polymorphisms in patients with major depressive disorder (3). Similar trends can be seen with drugs used in the management of asthma, diabetes, arthritis, Alzheimer's, and cancer, where 40%, 43%, 50%, 70%, and 75% of their respective patient populations were found to have been ineffectively treated (2). Not only does the current paradigm hinder the efficacy of prescribed therapies, but the overall safety of our patients is also at risk (4).



Precision medicine seeks to enhance clinical decisions regarding a patient's treatment by utilizing all available data, including the results obtained from genomic testing (5). This approach recognizes that a patient's environment, lifestyle, and genome can influence treatment safety and efficacy. Within the last decade, there has been a significant increase in the discovery of pharmacogenes, or genetic variants, linked to altered medication response. The Clinical Pharmacogenetics Implementation Consortium (CPIC) has identified more than 167 pharmacogenes to which they recommend appropriate prescribing action be taken (6). Currently, the U.S. Food and Drug Administration has incorporated pharmacogenomic information in the drug labels of over 340 medications, including tramadol, nitrofurantoin, ondansetron, amitriptyline, mercaptopurine, rosuvastatin, clopidogrel, and omeprazole. A complete list can be found in their "Table of Pharmacogenomic Biomarkers in Drug Labeling" (7).

Despite the relatively recent identification of genetic polymorphisms associated with variable therapeutic response, clinical implementation of this research into routine practice continues to be lacking. Current barriers include a lack of clinician familiarity with pharmacogenomics, resulting in an unwillingness to deviate from the traditional "trial and error" method of prescribing, as well as concerns over the cost-effectiveness of such an initiative. Nonetheless, several health systems across the country, including Mount Sinai Hospital in New York, have begun to offer point-of-care clinical decision support to their prescribers through preemptive or required genotyping in select patient populations. When a clinician attempts to prescribe a medication to a patient with a known pharmacogenomic variant that may affect their therapeutic response, the electronic health record will display an automated alert (which has been previously transcribed and integrated into the system by pharmacists and informatics specialists), notifying the clinician of the appropriate action to take—whether it be a change in dose or medication—as determined by relevant CPIC guidelines (5,8). Recent evidence suggests that clinical implementation of pharmacogenomics has led to increased efficiency in workflow, an average of \$218.34 per member per month savings, and a 1.9%, 6.8%, and 14.9% reduction in outpatient, emergency department, and inpatient visits, respectively (1). Moreover, UnitedHealthcare, the nation's largest insurer, has started to cover pharmacogenetic multi-gene panel testing, noting that it is "proven and medically necessary" to "guide therapy decisions" (9).

While clinical adoption of translational genomics has proven to be an uphill battle, pharmacogenomicists remain committed to bridging the gap between the scientific discovery of pharmacogenes and its implementation in routine practice. It is through their valiant efforts that we can finally work towards achieving health equity in all patients.

#### References:

- 1) Jarvis JP, Peter AP, Keogh M, et al. Real-World Impact of a Pharmacogenomics-Enriched Comprehensive Medication Management Program. J. Pers. Med. 2022; 12(3):421.
- 2) The Personalized Medicine Report 2020 [Internet]. Personalized Medicine Coalition. 2021 [cited 2022 Oct 12]. Available from: https://www.personalizedmedicinecoalition.org/index.cfm
- 3) Tansey KE, Guipponi M, Hu X, et al. Contribution of common genetic variants to antidepressant response. Biol Psychiatry. 2013;73(7):679-682.
- 4) Ito, S. Opioids in Breast Milk: Pharmacokinetic Principles and Clinical Implications. J Clin Pharmacol. 2018; 58 Suppl 10:S151-S163.
- 5) Gottesman O, Scott SA, Ellis SB, et al. The CLIPMERGE PGx Program: clinical implementation of personalized medicine through electronic health records and genomics-pharmacogenomics. Clin Pharmacol Ther. 2013; 94(2):214-217.
- 6) Genes-drugs [Internet]. CPIC; 2022 [cited 2022 Oct 12]. Available from: https://cpicpgx.org/genes-drugs/.
- 7) Table of Pharmacogenomic Biomarkers [Internet]. U.S. Food and Drug Administration. FDA; 2022 [cited 2022 Oct 12]. Available from:
- https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling.
- 8) Duarte JD, Dalton R, Elchynski AL, et al. Multisite investigation of strategies for the clinical implementation of pre-emptive pharmacogenetic testing. Genet Med. 2021;23(12):2335-2341.
- 9) Pharmacogenetic testing Commercial Medical Policy [Internet]. UnitedHealthcare; 2022 [cited 2022 Oct 23]. Available from: https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/pharmacogenetic-testing.pdf.