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The Long Island University (LIU) American College of Clinical Pharmacy (ACCP) student chapter was founded in 2002. The mission of the LIU-ACCP chapter is to help pharmacy students develop clinical skills that will be assets for their future careers. Dr. Roda Plakogiannis has been the chapter's primary advisor since the chapter's inception and we are pleased to welcome Dr. Briann Fischetti as co-advisor. The LIU-ACCP student chapter aims to provide guidance regarding clinical practice rotations, job interviews, and research opportunities. Past initiatives include community outreach, journal/guideline clubs, and professional development programs (PDPs) offering insight about residency programs and how to become a competitive applicant. In addition, the LIU-ACCP student chapter encourages its members to be actively involved in extracurricular activities and in the pharmacy community.

October 2019 Halloween Fundraiser

During the 2018-2019 academic year, LIU-ACCP strived to promote initiatives that focused on career preparation and professional training. These included many professional development programs (PDP) with the first being a residency interview presentation by Dr. Justin Lau, a PGY-2 Emergency Medicine pharmacy resident and LIU alumni. We hosted several journal/guidelines club discussions in small groups and had our first mock interviews in collaboration with National Community Pharmacists Association (NCPA) and Lambda Kappa Sigma (LKS). The mock interviews were largely successful due to the involvement of clinical faculty interviewers Dr. Yoonsun Mo, Ms. Tina Verveniotis and Mr. Peter Goldstein who allowed students to practice interview skills. Feedback from faculty was essential for learning about strengths and areas for improvement in preparation for future interviews. The Midyear PDP in collaboration with the American Society of Health-System Pharmacists (ASHP) was useful for students who were interested to hear about what

to expect at the ASHP Midyear Clinical Meeting and how to best prepare for it. Furthermore, Dean John Pezzuto discussed his research involving resveratrol found in grapes. The LIU-ACCP student chapter ended the year by hosting our first panel discussion with Residency Program Directors from several different institutions such as the Brooklyn Hospital Center, LIU at NYU Langone Health, Kings Pharmacy, and Lenox Hill Hospital - Northwell Health. This event was largely successful and had the largest number of attendees.

March 2019 Residency Panel Discussion

Community outreach and direct patient care were also integral aspects of LIU-ACCP's service. Two of our most successful holiday fundraisers were "Toys for Tots" for the holiday season and Spreading Hugs, Not Drugs" for Valentine's Day. The proceeds from both fundraisers were donated to non-profit organizations that aid families in need, namely Toys for Tots and Ameresa respectively. Toys for Tots is a program run by the United States Marine Corps Reserve which distributes toys to children who would otherwise not receive gifts for Christmas. Ameresa assists families who have been affected by emergencies and other natural disasters. In addition, our chapter teamed up with the Student National Pharmaceutical Association (SNPhA) and collectively participated in the Juvenile Diabetes Research Foundation (JDRF) walk to support finding a cure for Type I diabetes. The LIU-ACCP student chapter also hosted a blood pressure screening event at Duane Reade, which was a great opportunity for students to practice measuring blood pressure, as well as educating the community using direct communication and brochures. Overall the chapter did its best to include a variety of events to suit the interests of all members.

October 2019 HIV Guideline Club

2019 Club Fair E-Board

For this upcoming academic year of 2019-2020, ACCP is looking forward to continue organizing events that will continue to be beneficial and informative. We will be hosting several journal clubs and guideline clubs, which will allow students to better understand how to critically assess primary literature and remain up to date with guidelines. Furthermore, LIU-ACCP student chapter is planning to organize PDPs focused on research and post-graduate residency opportunities. Speakers will have specific expertise and share their personal experiences. Lastly, due to overwhelming positive feedback received last year, our chapter will be once again be hosting a panel discussion with Residency Directors from various programs. Students will have the opportunity to ask questions and network with the Directors on an individual basis.

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New Drug Review: Romosozumab (Evenity®)

Evenity (romosozumab) is a sclerostin inhibitor that was approved by the Food and Drug Administration on April 9, 2019 for the treatment of osteoporosis in postmenopausal women at high-risk for fracture.[1] Romosozumab works by inhibiting the action of

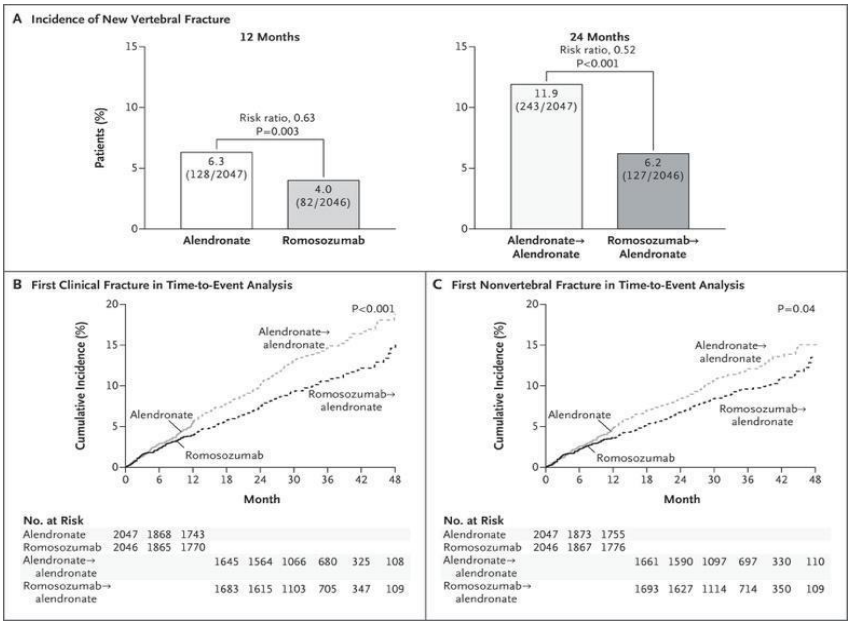
sclerostin, which is a regulatory factor in bone metabolism. Romosozumab increases bone formation and to a lesser extent decreases bone resorption. Romosozumab is only available as an injectable form in a single-use prefilled syringe-containing 105 mg per 1.17 mL.[4] Syringes should be stored in the refrigerator between 2-8 degrees C in the original carton to protect from light (4). The dose for romosozumab is 210 mg administered subcutaneously with 2 separate syringes (each containing 105 mg) in the abdomen, thigh, or upper arm monthly.[1] The limited duration of use is 12 months or 12 cycles, as the effectiveness of romosozumab weakens overtime.[1] Lastly, there is no dosage adjustments in patients who have renal or hepatic impairment, however patients that are on dialysis, or have with severe renal impairment are at a greater risk of developing hypocalcemia.[1]

The approval of romosozumab was based on the publication of two phase III clinical trials funded by Amgen and UCB Pharma. The most recent trial published in September 2017 was a multicenter, international, randomized, double-blinded trial that explored the superiority of romosozumab to alendronate.[2] A total of 4,093 patients were included to compare monthly subcutaneous romosozumab (210 mg) or weekly oral alendronate (70 mg). Patients were monitored for a period of 12 months in blinded fashion followed by an additional 24 months of open label alendronate therapy. All patients received daily calcium (500-1000 mg) and vitamin D (600-800 IU) supplementation throughout the study.

The primary endpoints associated with this study included the cumulative incidence of new vertebral fractures at months 12 and 24 and the cumulative incidence of clinical fractures at the time of the primary analysis. Secondary endpoints included the incidence of nonvertebral fractures, adverse events and formation of anti-romosozumab antibodies. Bone mineral density (BMD) at the total hip, femoral neck and lumbar spine and serum concentrations of bone turnover markers β-CTX and P1NP were evaluated in a subgroup. A total of 3,654 patients (89.3%) completed the initial 12 months of the trial and 3,150 (77.0%) completed the primary analysis period. Reasons for discontinuation were similar in both treatment groups.

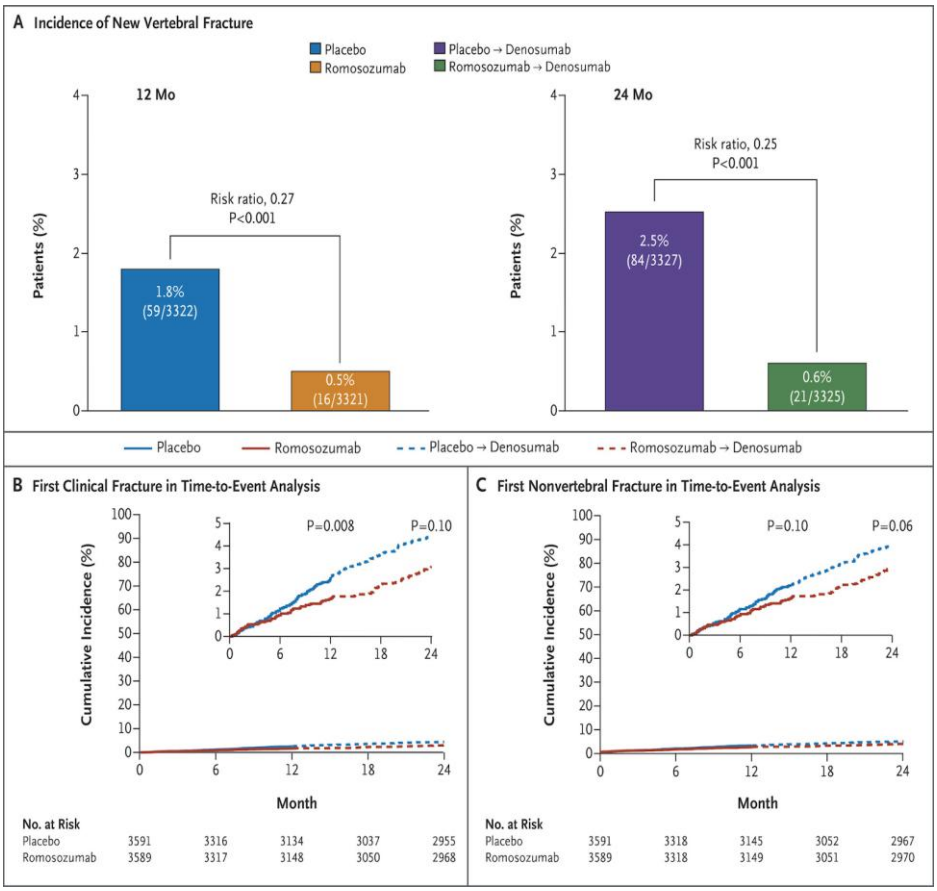
Study 1 results found that romosozumab resulted in a 48% lower risk of new vertebral fractures than the alendronate group at 24 months, (6.2% [127 of 2,046 patients] vs. 11.9% [243 of 2,047 patients]; RR, 0.52; 95% CI, 0.40-0.66; P<0.001) (Figure 1A). At the time of primary analysis, the romosozumab group displayed a 27% lower risk of clinical fractures compared to alendronate alone, (HR, 0.73; 95% CI, 0.61-0.88; P<0.001) (Figure 1B). Incidence of clinical fracture was 9.7% (198 of 2,046) in the romosozumab group compared to 13% (266 of 2,047) in the alendronate group. In addition, at the time of primary analysis, the romosozumab group showed a 19% lower risk of nonvertebral fractures compared to alendronate alone, (8.7% [178 of 2,046 patients] vs. [217 of 2,047 patients]; HR, 0.81; 95% CI 0.66-0.99; P=0.04) (Figure 1C). The romosozumab group also displayed a 38% lower risk of hip fracture compared to alendronate alone (HR, 0.62; 95% CI, 0.42-0.92; P=0.02). Within the initial 12-month period, romosozumab displayed expeditious effects on bone mineral density vs. alendronate. Favorable effects on bone turnover markers were seen with romosozumab, increasing P1NP and decreasing β-CTX. Alendronate decreased both markers below baseline. Anti-romosozumab antibodies were experienced in 15.3% (310 of 2,028 patients) with no observable effects on efficacy or safety. Adverse events were similar in both treatment groups.

Figure 1. Incidence Rates of Fracture Types in Trial 1



The second phase III clinical trial was called the FRAME study, which was an international, randomized, double blinded, placebo-controlled, parallel group study. FRAME was published in September 2016 and explored the efficacy of romosozumab compared to placebo followed by denosumab therapy.[3] A total of 7,180 patients met the study criteria and were randomized in 1:1 fashion to receive either monthly subcutaneous romosozumab (210 mg) or matching placebo for a double-blinded period of 12 months. After completion, all patients received open

Figure 2. FRAME Trial Incidence Rates of Fracture Types



label subcutaneous denosumab (60 mg) administered every 6 months for an additional 12 months. All patients received daily calcium and vitamin D supplementation throughout the study. The primary endpoint was the cumulative incidences of new vertebral fractures through month 12 and 24. Secondary endpoints included the cumulative incidence of clinical fractures (composite of nonvertebral fracture and symptomatic vertebral fracture), nonvertebral fractures, major nonvertebral fractures, new or worsening vertebral fractures, hip fracture and osteoporotic fractures. Adverse events and romosozumab antibodies were assessed monitored throughout the study. A subpopulation was used to evaluate serum concentrations of P1NP and β-CTX and bone mineral density at the lumbar spine, total hip and femoral neck. Eighty-nine percent (6,390 patients) completed the initial 12 months of the trial and (83.9%) completed the additional 24 months. Similar reasons for discontinuation were seen in both treatment groups.

After the initial 12 month period, romosozumab demonstrated a 73% lower risk of new vertebral fractures compared to placebo (0.5% [16 of 3,321 patients] vs. 1.8% [59 of 3,322 patients]; RR, 0.27; 95% CI, 0.16-0.47; P<0.001) and after 24-months, there was a 75% lower risk of new vertebral fractures seen in the romosozumab group compared to placebo (0.6% [21 of 3,325 patients] vs. 2.5% [84 of 3,327]; RR, 0.25; 95% CI, 0.16-0.40; P<0.001) (Figure 2A). In addition, at month 12, romosozumab showed a 36% lower risk of clinical fractures compared to placebo (1.6% [58 of 3,589 patients] vs. 2.5% [90 of 3,591]; HR, 0.64; 95% CI, 0.46-0.89; P=0.008), however there was no statistically significant difference at 24 months (Figure 2B). At 12 and 24 months, there were fewer nonvertebral fractures observed in the romosozumab group compared to placebo, however the difference was not statistically significant (Figure 2C). Romosozumab also displayed robust efficacy in rapidly increasing bone mineral density at all fracture sites (P<0.001 for all sites). Rapid increases in P1NP and decreases in β-CTX were witnessed in the romosozumab group, where as both markers decreased in the placebo group. Transition to denosumab resulted in an increase in bone mineral density and a decline in bone turnover markers in both treatment groups. Adverse events were similar in both treatment groups. Neutralizing antibodies were witnessed in 25 patients in the romosozumab group (0.7%) with no detectable impact on efficacy or safety.

The most common side effects associated with romosozumab are arthralgia (>10%), headaches (5%-7%), and hypersensitivity response (7%).[4] Five percent of those who have used this drug also reported local injection site reaction.[4] Risk of heart attack, stroke and cardiac events are also higher in patients receiving romosozumab.[1] The side effects, such as hypersensitivity reactions and increase risk of cardiac events, are commonly seen with drugs that are monoclonal antibodies. These side effects should be monitored thoroughly. Patients should let their doctors know of any unusual feelings they have while taking romosozumab. The main contraindications for romosozumab are hypersensitivity reactions, such as angioedema and urticaria to the active ingredient or any fillers that are in the drug's formulation, and uncorrected hypocalcemia.

In conclusion, in two clinical trials romosozumab was effective at reducing fractures compared to current available treatments. However, due to it being a monoclonal antibody, side effects are more common and more severe. In addition, the cost of

romosozumab may hinder its use. With more data and experience, romosozumab may become the first line treatment option for osteoporosis.

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Highlights from the 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

Atrial fibrillation, also referred to as AFib or AF, is the most common type of heart arrhythmia or abnormal heart rhythm that can increase your risk to have a stroke, heart failure or other heart-related complications. Atrial Fibrillation affects more than 2.7 million people in the United States alone, and that number is expected to double over the next 25 years.[1] During AF, the normal beating in the upper chambers (the atria) of the heart is irregular and is out of coordination with the two lower chambers (the ventricles) of the heart.[2] While AF itself is not life threatening, a major concern with AF is the potential to develop blood clots within the atria of the heart. These blood clots may travel to other organs and block the blood flow, such as the brain, which may result to a stroke. Atrial fibrillation symptoms often include heart palpitations, weakness, fatigue, shortness of breath and chest pain. Some people who have AF are not aware that they have it and do not experience any symptoms. Fortunately, diagnostic tests are readily available to detect AF and treating it early on can improve the quality of life and prolong life.

Up until recently, clinicians relied on the "2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation" to assist them in clinical decision making for the management of patients with AF.[1] Since then, new data from clinical trials had emerged that warrants an update to the practice guidelines for the management of patients with AF. In January 2019, the American Heart Association (AHA), American College of Cardiology (ACC), and the Heart Rhythm Society (HRS) released a focused update to the 2014 practice guideline.[3]

Areas of Consideration

Highlights of new 2019 AF practice guideline recommendations and modified recommendations from the 2014 AF practice guideline are grouped into seven main categories. These recommendations of AF guidelines are closely related to and dependent on the CHA2DS2 -VASc score. This score would evaluate the risk of developing an ischemic stroke in an AF patient. This score takes in consideration any patient history of congestive heart failure, hypertension, stroke, diabetes, vascular disease and the patient's age and sex.

Area 1: Selecting an Anticoagulant Regimen – Balancing Risks and Benefits

a) In the new 2019-focused update of AF guideline, direct oral anticoagulants (DOAC's) are recommended over warfarin as first-line therapy for eligible patients except in patients with AF who have mechanical heart valves or patients with moderate-to-severe mitral stenosis. The updated list of DOACs that are recommended over warfarin in DOAC-eligible patients with AF include factor Xa inhibitors, edoxaban, rivaroxaban, and apixaban, and direct thrombin inhibitor, dabigatran. Randomized controlled trials comparing DOACS with warfarin have shown consistent evidence of noninferiority and, in some trials, superiority for the combined endpoint of

stroke or systemic embolism. DOACs are also associated with significantly lower rates or similar serious bleeding compared to warfarin.

b) DOACs are not recommended for use in patients with severe hepatic dysfunction.[3] A modification to the 2014 guideline was made by adding the evaluation of hepatic function in addition to renal function before initiation of a DOAC and should be reevaluated at least annually thereafter.

c) In the 2014 AF guideline, warfarin was the choice of oral anticoagulant for AF patients with a CHA_2DS_2-VASc score ≥ 2 in men or ≥ 3 in women and have end-stage chronic kidney disease (creatinine clearance <15 ml/min) or who are on dialysis. New evidence has been added that suggested that it might be reasonable to prescribe apixaban as an alternative to warfarin for the aforementioned AF patients.

Area 2: FDA-Approved Reversal Agents

a) Idarucizumab, a monoclonal antibody fragment, received full FDA approval and is recommended for the reversal of dabigatran in the event of life-threatening bleeding or an urgent procedure.[3] Idarucizumab was found to bind to dabigatran, which rapidly normalizes hemostasis and decreases levels of circulating dabigatran in subjects who are taking dabigatran and experiencing severe bleeding.

b) Under the FDA's accelerated-approval pathway, andexanet alfa, a recombinant factor Xa, was approved to be used as an antidote against direct factor Xa inhibitors. It was reported to be useful for the reversal of rivaroxaban and apixaban in the event of life-threatening or uncontrolled bleeding.[3]

Area 3: Nonpharmacological Stroke Prevention

Percutaneous left atrial appendage occlusion with a new device called the Watchman device was approved by the FDA and has been compared with warfarin in patients with AF at increased risk of stroke. Two randomized controlled trials have shown that patients receiving the Watchman device [Figure 1] had significantly fewer hemorrhagic strokes than did patients receiving warfarin.[3] While oral anticoagulation remains the preferred therapy for stroke prevention for most patients with AF and heightened stroke risk, the Watchman device provides an alternative to patients with AF at increased risk of stroke who have contraindications to long-term oral anticoagulation.

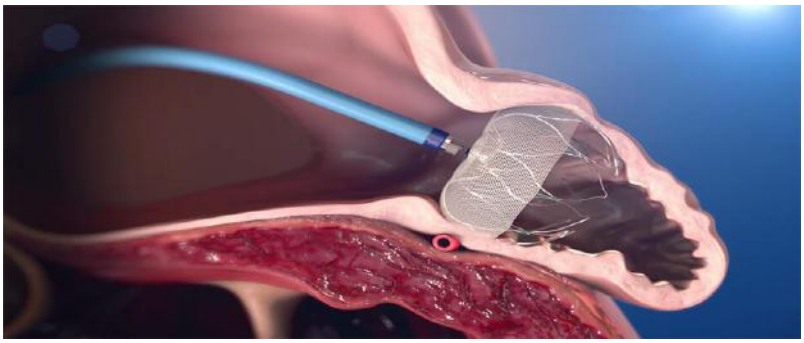

Figure 1. a Watchman device; Reprinted from watchman.com 2019

Area 4: Catheter Ablation in HF

New evidence suggests that AF catheter ablation may be reasonable in select patients with symptomatic AF, HF and some non-HF patients with a reduced ejection fraction (HFrEF) to lower mortality rate and decrease HF hospitalizations. A published study has shown that when comparing to a group of HF patients with medical therapy, patients in the AF catheter ablation group had significantly reduced overall mortality rate, reduced rate of hospitalization for worsening HF, and improved LV ejection fraction and

more patients in the AF catheter ablation group were in sinus rhythm.[3] A separate relatively small randomized controlled trial (RCT) demonstrated that in patients with persistent AF, HFrEF, and an implanted cardioverter-defibrillator, patients who had AF catheter ablation yielded better results in the maintenance of sinus rhythm than in patients taking amiodarone therapy.

Area 5: AF Complicating Acute Coronary Syndrome

Based on new published data, the focus update clarifies the use of anticoagulants in AF patients undergoing percutaneous coronary intervention (PCI) with stenting:

a) If triple therapy (oral anticoagulant, aspirin, and $P2Y_{12}$ inhibitor) is prescribed, it is reasonable to choose clopidogrel over prasugrel for the $P2Y_{12}$ inhibitor.
b) If triple therapy is prescribed, a transition to dual therapy (oral anticoagulant and $P2Y_{12}$ inhibitor) at 4 to 6 weeks may be considered.[3]
c) Double therapy with a $P2Y_{12}$ (clopidogrel or ticagrelor) and dose-adjusted vitamin K antagonist or double therapy with a $P2Y_{12}$ (clopidogrel) and low-dose rivaroxaban 15 mg daily or dual therapy with $P2Y_{12}$ (clopidogrel) and dabigatran 150 mg twice daily is reasonable to reduce the risk of bleeding as compared with triple therapy.[3]

Area 6: Device Detection of AF

Conventional external monitoring for detecting silent AF in patients with cryptogenic stroke or stroke of unknown cause quite frequently yield inconclusive results. Due to new findings from a recent RCT, the focus update recommends the use of an implantable cardiac monitor (loop recorder) in patients with cryptogenic stroke to increase the chances of detecting silent AF through prolong electrocardiogram monitoring that would otherwise, be undetectable with external ambulatory monitoring.

Area 7: Weight Loss in Patients with AF

In the new focused update, patients who are overweight or obese with AF are recommended to be on a weight loss program combined with risk factor modification. New data have shown that putting these patients on a structured weight management program helped with reducing symptom burden, the number of AF episodes, the severity, and their cumulative duration as opposed to risk factor modification alone.[3] Additionally, these patients who are on a weight loss program saw improved outcomes of AF catheter ablation. Studies have demonstrated that the degree of improvement in the AF type and symptoms is correlated to the degree of weight loss.

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Clinical Spotlight: Dr. Rebecca Cope, PharmD., BCACP

Dr. Rebecca Cope is an Assistant Professor of Pharmacy Practice at Long Island University Pharmacy in Brooklyn, New York. She graduated with her PharmD degree from Albany College of Pharmacy and Health Sciences in 2013. She then went on to complete her PGY-1 Pharmacy Practice residency at The Brooklyn Hospital Center, followed by a PGY-2 residency in Global Health and Underserved Care at UPMC in Pittsburgh, PA. After completion of residency training, Dr. Cope obtained her first academic position as Assistant Professor of Pharmacy Practice at Touro College of Pharmacy and then began teaching at Long Island University in 2016. She is board certificated in ambulatory care (BCACP) and has been practicing as an ambulatory care pharmacotherapy specialist at The Brooklyn Hospital Center for the past five years.

Q: What made you want to become a clinical pharmacist?

A: I think part of what draws people to clinical pharmacy is finding a specialty that they really love. So for me, that was ambulatory care because as an ambulatory care pharmacist you're working very collaboratively with patients in an effort to help them be able to manage their health and different disease states; such as diabetes and hypertension. Especially as an ambulatory care pharmacist, it's not about just talking over their disease state and educating them on certain topics, but it's about optimizing their medication therapy. I think that's really what clinical pharmacy is. You really focus on optimizing a patient's drug therapy, regardless of what setting you're working in. So to be able to see patients, for example, for their diabetes and tell them to stop drugs that they've been on, start new drugs, or consolidate their medications, (maybe they're on a couple different pills and I can reduce that pill burden); all these things even though they might seem like small changes, make a huge impact on a patient's quality of life.

Q: What does a typical shift consist of for a clinical pharmacist?

A: For me as an ambulatory care pharmacist, my schedule is set up by clinics. For example, on Wednesdays I spend my mornings at an off-site family medicine clinic in Bushwick. How that clinic works is that patients meet with their primary care provider and if they have a chronic disease state that the primary care provider requires assistance with managing, they refer them to come see me. I have my own schedule and my own exam room, so after a patient makes an appointment and they arrive during that visit, we go through their medication history. Some of these patients I have seen frequently for years now and that's when I usually follow up with them on everything from their last visit and see what other medication tweaks we can make, talk about their lifestyle changes, and how it's going for them overall. Then at the end of each visit, I will make whatever changes need to be made, send over prescriptions for those medications, order any labs that need to be drawn, give them any referrals that they need, etc. Typically, in the morning I might see around 5 to 6 patients, then I come back to the main campus of The Brooklyn Hospital Center. On Wednesday afternoons I work in an anticoagulation clinic with a very similar schedule, but in that clinic all the patients are on warfarin and they're all coming in for INR monitoring. Therefore, in this clinic we're more focused on one specific medication and managing that one medication. It generally follows the same system of patients being referred by their primary care providers, they come in, get registered, we meet with them for approximately 15-20 minutes, we review everything pertinent to warfarin management, check their INR, and based on what their INR is make any modifications to their warfarin. We then counsel the patient, send their prescription to the pharmacy, and schedule a follow-up appointment. However, my schedule tends to vary week per week, as one half day per week I work in an HIV clinic, other mornings I do more anticoagulation clinics, or I might go participate in the pharmacotherapy clinics. It depends and fluctuates based on the other ambulatory clinical pharmacist as well.

Q: What would you say was the hardest part of your journey to becoming a clinical pharmacist?

A: I definitely think residency was the hardest part of my journey to becoming a clinical pharmacist. For students who are considering postgraduate clinical training, your heart really has to be in it as it is going to be a very challenging couple of years. You can expect to be working 80 hours a week with a very heavy workload as the goal is that you become an expert in two years in what would probably take you at least five years to get in practice. So you are going to be really busy and really tired; especially if you want to get as much out of it as you can. It's a big workload. Its long hours. You might be living in a place that's new to you so you might not have your usual support system. You constantly have to move from place to place. You're not getting paid very much; so you have to really want to do it. However, at the same time, I look back on residency and I loved both of my residency years. I got to meet so many amazing people, I had so many amazing opportunities, and if I had to go do a residency again, I would choose the same programs I was a part of.

Q: What was the most fulfilling?

A: The most fulfilling part is that I'm at a place where I have been seeing patients for so long that I know not just their medications, but I know about their families, their interests and hobbies, their struggles and they know about mine too. It is always really rewarding to see someone's A1c come down from 14% to 7% after working with them for some time. Even though most of the credit belongs to the patient as they are the ones making those changes; to have a hand in optimizing their medications and knowing the patient sees the benefit of that, is always very fulfilling.

Q: What advice would you give to students who are interested in applying to residencies and how can they make themselves stand out?

A: The more, the better. However, you want to make sure to get involved in things that you love doing. I do think student-run pharmacy organizations; such as ACCP have a lot of awesome opportunities for students. You can learn a lot from these professional organizations. If you can get involved in a research project, I always think that's really beneficial as well. Something else I do is take students who are interested in global health international experiences and medical mission trips. Your final P6 year you can go on an international APPE to all sorts of different locations. Whatever it is, as long as it's something you enjoy, I feel like you would be able to really focus on it. I think it's better to be heavily involved and hold leadership positions then just try to be minimally involved in many organizations.

Q: Is there a project you worked on that you are most proud of?

A: I published a paper in collaboration with Dr. Agnes Cha looking at the effect that pharmacists have in an interdisciplinary HIV clinic model. In this model patients don't come in to see the pharmacists separately, however when they come to see their primary care doctor for a visit, the pharmacist is in the room as well. This model has been going on for several years, thanks to Dr. Cha, and we were able to study what impact this model had on patient care and outcomes. Patients with chronic disease, like diabetes, high blood pressure, etc., who were seen with the pharmacist had better outcomes than patients who were being managed without a pharmacist involved. I think projects like this really show the impact of clinical pharmacists.

Q: Can you describe a time when you made a substantial impact on a patient's care?

A: One patient in particular comes to mind that I have on my Wednesday morning clinic. When he first started coming to see me he didn't quite understand too much about his type 2 diabetes. His biggest concern at that time was just wanting to get off the medications that he was on and he just kept saying, "If

I can get my blood sugar down, I can stop these medications." Through a number of visits, using motivational interviewing techniques and different analogues with him, he finally understood that these medications needed to be life-long medications for him. Once he accepted that, he really started focusing on his diabetes management by taking his medications, monitoring his blood sugar, and lowering his A1c. His A1c had been very high when I first met him, somewhere between 12-14%, and now we have it constantly at somewhere between 7.5-8%.

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Reviewed by Briann Fischetti, PharmD., AAHIVP, BCACP

Clinical Spotlight: Dr. Kyle Hampson, PharmD., BCPPS, BCNSP

Dr. Kyle Hampson earned his Pharm.D. at Duquesne University in Pittsburgh, Pennsylvania. He then completed a PGY1 Pharmacy Practice Residency and a PGY2 pharmacy residency in nutritional support at Emory University Hospital in Atlanta, Georgia. Before becoming a professor at Long Island University, he was a clinical pharmacy specialist at Children's Mercy Hospital in Kansas City, Missouri. Currently, as the Pharmacotherapy Specialist in Pediatrics and Nutrition Support at The Brooklyn Hospital Center, he provides inpatient pharmacotherapy services for the pediatric intensive care unit, neonatal intensive care unit, general pediatrics, and nutrition support services.

Q: What made you want to become a clinical pharmacist?

A: I learned about clinical pharmacy when I volunteered at a hospital pharmacy one summer during pharmacy school. I was excited to see pharmacists working directly with providers and making a difference in patient's lives.

Q: What does a typical shift consist of for a clinical pharmacist?

A: Depending on your role, every day can be very different. For an inpatient clinical pharmacist, the day starts with working patients up and rounding with the team. The afternoons usually involve meetings at the hospital, working on projects for your patients or unit, and conducting patient counseling sessions. Some inpatient clinical pharmacists also have one or two days a week of clinic where they follow up on their patients after hospital discharge.

Q: What would you say was the hardest part of your journey to becoming a clinical pharmacist?

A: I love math, but I am TERRIBLE at physics.

Q: What was the most fulfilling?

A: As a student, I helped to organize grassroots legislative advocacy efforts for pharmacy political issues in Pennsylvania. It was very rewarding to see letter writing campaigns and meetings with legislators translate into new laws that impact the way pharmacists practice in the state.

Q: What advice would you give to students who are interested in applying to residencies and how can they make themselves stand out?

A: My biggest piece of advice would be to get involved! Programs will get many applications with high GPAs (and they are important, too), but that doesn't complete the package. The people interviewing you want to make sure that they can work with you for a year (or two) and will be more interested in hearing about your various experiences and activities. Being involved and active in different organizations will give you more to talk about and provide opportunities to strengthen your time management skills, which are crucial for residency.

Q: What unique skills or abilities do you possess that you believe sets you apart from other candidates?

A: I think that my biggest strength is that I don't give up easily. It is always hard to juggle different things that come up in life: school/work, family, community, etc., but when I am really passionate about a project, I find the time and extra effort to devote to making the project come to fruition.

Q: Is there a project you worked on that you are most proud of?

A: At my previous institution, I helped transition the parenteral nutrition ordering system to a safer process. This was a large undertaking, as there were currently three different ways to order TPN at the hospital and providers were used to ordering TPN 'their way'. I had to work with many different departments, some that understood why a change was needed and others that did not. After a year of planning and working out issues, we finally 'went live' with the new software system which was much safer.

Q: Can you describe a time when you made a substantial impact on a patient's care?

A: I completed my residency at a large medical center in Atlanta that referred patients from all over Georgia. There was one patient that came to us after a really long journey: not only did she live 5 hours away, but multiple providers had refused to treat her because of her complexity. By the time she saw us, she was extremely anxious and did not trust the medical teams. Every day after rounds, I would go back to her room and explain to her and her husband what the team was talking about and reviewed her progress and the changes that we were making to her parenteral nutrition and medications. Three months later, when she was being sent home, she refused to leave her room until I came to see her one last time. This is one of my proudest moments as a pharmacist--we can't forget that our patients are people, and sometimes taking 10 minutes out of your day makes a world of difference.

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Collaborative Drug Therapy Management (CDTM): What is it and How far has it Grown?

As the field of pharmacy grows more diverse, new advancements are constantly being created to upkeep with modern day demands. Demands within healthcare have been steadily increasing and are tied with economic and social factors. Such demands call for a new approach in order to provide the most effective care possible. By lowering healthcare costs and allowing access to healthcare professionals within different fields, a more effective result is met. Hence, collaborative drug therapy management (CDTM) was developed to help improve the healthcare system in the United States.

Collaborative drug therapy management has been gaining popularity over the last decade. According to the CDC, CDTM is defined as a collaborative practice agreement (CPA) between one or more healthcare providers and pharmacists. In addition, New York State Council of Health System Pharmacists defines CDTM as a collaborative protocol in which the pharmacist works with physicians/healthcare providers located in facilities such as diagnostic centers, treatment centers, or hospital based outpatient departments (including outpatient clinics), as regulated by article twenty-eight of the public health law. Using both definitions, we see that CDTM is an ideal method to provide effective and affordable care, while allowing pharmacists to impact patients on a larger scale.

While the concept of CDTM has grown in popularity in recent years, there are restrictions to the settings and pharmacists that are allowed to participate. Under article twenty-eight of public health law, hospital-based outpatient departments, treatment centers, and diagnostic centers are included, which narrows the scope of who is allowed to practice CDTM. The public health law excludes residential health care facilities, rehabilitation centers, and nursing homes except for nursing homes with an on-site pharmacy. Pharmacists who work in these facilities are allowed to participate in CDTM, under several conditions: they must be employed by the facility that practices CDTM, must be registered and possess a pharmacy license in New York, as well have several years of experience depending on the pharmacy degree possessed. Additionally, pharmacists, who wish to practice CDTM, must either complete an accredited pharmacy residency and/or be board certified from an accredited body approved by the NYS Education Department. Lastly, if all requirements are met, pharmacists must complete an application and get approval from the State Education Department (SED).

As of 2015, 48 states have official regulations for the practice of collaborative drug therapy management. In New York State, the first bill that authorized pharmacists to participate in a collaborative practice agreement with physicians was approved by the Senate and Assembly and was signed into law on May 17, 2011. This law expanded the definition of the profession of pharmacy, provided in the NYS Education Law, to include collaborative drug therapy management. Under this law, which is also known as chapter 21 of the laws of 2011 amending section 6801-a of the Education Law, pharmacists are allowed to modify drug regimens as long as the patient gives consent to the CDTM agreement and both the physician and pharmacist are employed within the same facility. Pharmacists are allowed to modify drug strength, frequency of drug regimen, and route of administration. Also, pharmacists can order and interpret laboratory tests relating to drug therapies. Pharmacists, however, are not allowed to substitute or change the medication initially prescribed by the physician, unless there is a written protocol authorizing pharmacists to substitute medication orders.

While the 2011 law was a progressive step towards the expansion of CDTM, the law still had limitations, as it only allowed CDTM in teaching hospital settings and excluded general hospitals and nursing homes that have on-site pharmacies. In 2015, a new amendment to this CDTM law was introduced. It expanded the scope of CDTM to all hospitals, including general hospitals, as well as pharmacies located in nursing homes. One drawback that remains is that the 2015 law is set to sunset in July 2020, which means that it would expire unless a new CDTM bill is approved before that time. For this reason, it is important for pharmacists to be aware of the legislative process and to advocate for bills that would expand collaborative practice in New York. Currently, a new bill, S4296, which is in the committee stage of approval, aims to end the sunset provision of the CDTM law and to allow nurses, not just pharmacists, to collaborate with physicians under agreement protocols. With the emergence of new laws that protect and expand collaborative practice between health professionals, patients will be able to obtain services that are more timely, affordable, and effective.

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Implications of Pharmacogenomic (PGx) Testing on Clinical Practice

Pharmacogenomics is an emerging field of research that will likely continue to grow. Pharmacogenomic (PGx) testing is a promising diagnostic tool to improve treatment outcomes and reduce healthcare spending. Genetic enzyme variants account for the extent of a drug's activity and metabolism. Personalization of medication ensures the right drug and dose is delivered based on an individual's genetic makeup. Adverse drug reactions (ADRs) are more commonly seen in patients with either poor or ultra-rapid drug metabolism.[1] These patients may experience longer hospital stays and additional health care costs. Differences in drug metabolism can account for why the same medication dose may be therapeutic for one individual, but ineffective or potentially toxic for another.[1] Therefore, PGx testing can be helpful for tailoring treatments to be more effective, increasing patient medication adherence, and decreasing ADRs.[1]

Diagnostic companies have developed software to make PGx testing more accessible to health care providers. For example, Admera Health's PGxOne Plus screens for over fifty genes by using DNA taken from a cheek swab. Prescribing recommendations are then provided for over two hundred twenty commercially available medications in comprehensive reports. Practitioners can easily interpret this information which includes caution and warnings, as well as alternative dose and medication suggestions. The medications span over fourteen therapeutic areas including psychiatry, cardiology, pain management, and oncology. Drug-drug interactions and food-drug interactions are also presented in the PGx reports.[1]

Medicare and certain private insurers reimburse for medically necessary PGx testing. This service is valuable for evaluating the safety and efficacy of drugs with a narrow therapeutic index such as cancer drugs. St. Jude Children's Research Hospital is a pioneer in pediatric oncology and clinical PGx practice. In 2015, close to half of their patients received at least one "high-risk" medication and all had either cancer or another chronic disease.[2] For these patients, determining the most effective treatment as early as possible can be life-saving. St. Jude's implements a PG4KDS pharmacogenetic test and then incorporates the results into the electronic health records (EHR). The successful integration of PGx into clinical software systems is challenging but nevertheless important for its widespread use.

More recently, other hospitals have started including PGx data in EHR such as Mount Sinai Health System's CLIPMERGE PGx.[3] Seattle-based Genelex, which is one of the first clinical laboratories to provide PGx testing, has now integrated with Epic. This is significant because Epic is the EHR system used by many top-ranked hospitals across the country. Genelex is also the creator of YouScript Precision Prescribing software which helps clinicians identify patients that are candidates for PGx testing. Studies have found that the implementation of YouScript reduces hospitalizations by 39% and emergency room visits by 71% in the elderly population taking multiple medications.[4] It is likely that other hospitals will recognize the merit of PGx testing for improving clinical outcomes and decreasing healthcare spending. One study from the American Journal of Managed Care found that patients had a 6.3% increase in therapy adherence after receiving PGx testing, saving $562 in outpatient costs per person in four months.[1] In addition to increased patient adherence, PGx testing is associated with ADR prevention which can optimize treatment regimens and save money. The same study reported that ADRs may lead to longer hospital stay and added costs up to $6,000 per year.[1]

Precision medicine allows for tailored prescribing and can be a useful clinical tool. Fortunately, diagnostic software has made personalized prescribing easier than ever before. The implementation of PGx into EHR should further increase its accessibility to health care providers. As practitioners become accustomed to viewing PGx reports, their comfort level with incorporating this data into practice should increase. Pharmacists, as drug experts, are well suited for identifying patients who would benefit from PGx testing. In September 2018, Long Island University launched a new two year clinical and research Fellowship in Precision Medicine/Pharmacogenomics for PGY-1 residency trained pharmacists. The position works in collaboration with Dr. Jeffrey Idle, a global pioneer in precision medicine, and Director of the Division of Systems Pharmacology and Pharmacogenomics at the Samuel J. and Joan B. Williamson Institute. Furthermore, pharmacy fellows provide patient care in an interdisciplinary medicine clinic.[5]

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