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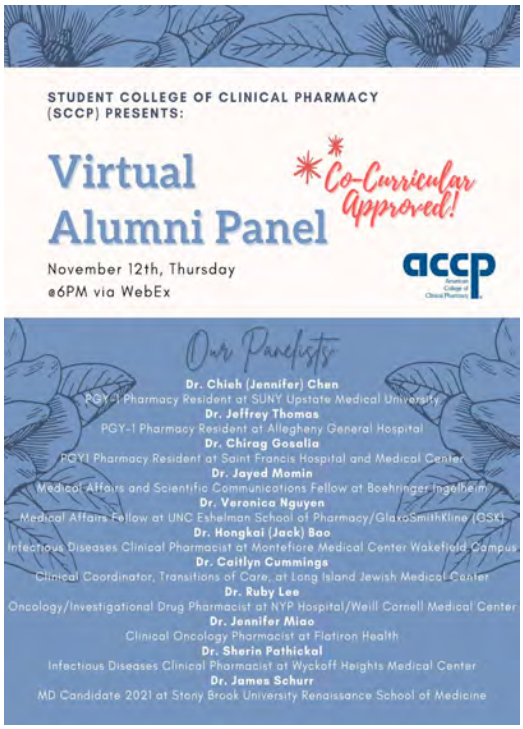
SJU-ACCP Student Chapter Highlights

In this Issue:

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 2020-2021 year!



Virtual Alumni Panel

Our annual Alumni Dinner was revamped into our Alumni Panel this year! This 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. Our alumni were gracious enough to join us for a virtual panel, where they broke out into small groups to answer questions and share the path to their current careers. We invited a total of eleven SCCP alumni who played a crucial role in our student chapter:

Dr. Jennifer Chen - PGY-1 Pharmacy Resident at SUNY Upstate Medical University
Dr. Jeffrey Thomas - PGY-1 Pharmacy Resident at Allegheny General Hospital
Dr. Chirag Gosalia - PGY-1 Pharmacy Resident at Saint Francis Hospital and Medical Center
Dr. Caitlyn Cummings - Clinical Coordinator, Transitions of Care, at Long Island Jewish Medical Center
Dr. Jack Bao - Infectious Diseases Clinical Pharmacist at Montefiore Medical Center Wakefield Campus
Dr. Jayed Momin - Medical Affairs and Scientific Communications Fellow at Boehringer Ingelheim
Dr. Veronica Nguyen - Medical Affairs Fellow at UNC Eshelman School of Pharmacy/GlaxoSmithKline (GSK)
Dr. Ruby Lee - Oncology/Investigational Drug Pharmacist at NewYork-Presbyterian/Weill Cornell Medical Center
Dr. Jennifer Miao - Clinical Oncology Pharmacist at Flatiron Health
Dr. Sherin Pathickal - Infectious Diseases Clinical Pharmacist at Wyckoff Heights Medical Center
Dr. James Schurr - MD Candidate 2021 at Stony Brook University Renaissance School of Medicine

Thank you to our alumni for their past involvement in shaping our organization and for continuously providing advice to guide us down our own career paths!

Pharmacy Based Immunization Webinar

This event featured Dr. Emily Ambizas along with her APPE students, Noah Samuel, PharmD Candidate of 2021, and Brooke Broczkowsi, PharmD Candidate of 2021. They presented NYS recommendations on pharmacist-administered immunizations and shared their thoughts on COVID's impact on immunization practice. Our featured speakers also shared a brief review of the current status of the COVID-19 vaccine, before news of a vaccine became available to the public.

Thank you to our Sim Man Chairs for hosting our very first virtual webinar!

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:

Carina Acosta who presented Paroxysmal Supraventricular Tachycardia
Adrian Wong who presented Congenital Heart Defects
Shivani Shah who presented Kidney Transplant 101
Angel Liu who presented Opioid Use Disorder

Our amazing speakers discussed each topic in depth, allowing students to go beyond the brief overview in class. These short lectures were great opportunities for students to gain more clinical knowledge outside the scope of the classroom.

Ambulatory Care Panel

This was our first-ever Ambulatory Care Panel! The panel featured four ambulatory care specialty pharmacists. The panelists shared information regarding their experiences in a variety of practice sites, ranging from internal medicine, geriatrics, hepatology, and HIV. Our members gained a lot of insight into the field of ambulatory care and what it entails.
We would like to give a special thank you to our panelists:

Dr. Celia Lu, PharmD, BCACP
Dr. Susan Lee, PharmD, BCPS, CDE
Dr. Megan Lam, PharmD, AAHIVP
Dr. Josh Rickard, PharmD, BCPS, BCACP, CDE

Thank you for making our very first Ambulatory Care Panel a success!

Pediatric Pharmacy Panel

The Student College of Clinical Pharmacy collaborated with the Student Society of Pediatric Pharmacy to host the very first Pediatric Pharmacy Panel, virtually! This event featured a number of amazing panelists that shared their daily responsibilities and their path to becoming the pediatric pharmacists they are today. Our panelists also shared what they love most about pediatrics and shed light on why it is so important to advocate for this patient population. We invited five pediatric pharmacists that truly shape this field of practice:

Dr. Gladys El-Chaar - NYU Winthrop Hospital Children's Medical Center
Dr. Sarah Smith - New York - Presbyterian Hospital/Weill Cornell Medical Center
Dr. Dimitri Savva - New York - Presbyterian Morgan Stanley Children's Hospital
Dr. Jacqueline Chirico - Children's Hospital at Montefiore
Dr. Gina Daniel - Northwell Health/Cohen Children's Medical Center

Thank you to our amazing panelists for sharing your insight on pediatric pharmacy!

Hospital Intern Panel

The Hospital Intern Panel is an annual event in which P3/P4 PharmD students share their experience and insights on the hospitals they work in, the application process, and interview tips. Our members have the opportunity to interact with panelists and get insight on what it is like to work as an intern. Panelists represented various hospitals such as New York Presbyterian, Mount Sinai, Memorial Sloan Kettering, Calvary Hospital, and NYU Winthrop!

-Erica Tonti, PharmD Candidate 2022

NYS-ACCP Newsletter e-Corner

Dear NYS-ACCP Members,

Although 2021 certainly did not go the way we expected it to, and despite the tremendous loss, uncertainty, and change the year entailed, those in the pharmacy profession truly rose to the occasion. We did this by continuing to take care of patients and colleagues, teach learners, carry on with research, leadership, and advocacy efforts, and dedicate tremendous effort to a massive vaccination program, all while doing our best to care for ourselves and loved ones. In the midst of the tragedy and suffering the pandemic has wrought, there have been silver linings, positive reflections and growth, and new connections, perspectives, and resolutions; for that I am grateful. Thank-you to everyone in the pharmacy profession for your admirable and invaluable daily efforts as we look to brighter days ahead, and please continue to take appropriate precautions to protect your own health and that of those around you.

In 2021, NYS-ACCP will continue with the Executive Team Vision of *connectedness* to frame our year. This remains a very appropriate and meaningful theme, amid an ongoing pandemic and other challenges in our society. NYS-ACCP will focus its efforts on connection, collaboration, and inclusion amongst our membership, national ACCP, and other NYS pharmacy organizations. I would like to thank our immediate past-president, Amanda Engle, for all of her efforts this past year, including the development of this Executive Team Vision.

I would also like to thank Dr. Steve Rappaport as Chair of the Research/Travel Ad-Hoc Committee and its members for helping us to support more NYS-ACCP members' research projects. The 2021 NYS-ACCP Research Grant was awarded to Dr. Calvin Meaney. Dr. Meaney is a Clinical Associate Professor and Vice Chair for Research in the Department of Pharmacy Practice at the School of Pharmacy and Pharmaceutical Sciences, University at Buffalo (UB). His proposal was entitled *Optimizing Vancomycin Use and Clinical Outcomes in Hemodialysis Patients*.

We are also excited to be able to support three other proposals with partial funding: Dr. Wesley Kufel (Binghamton University) – *Impact of vancomycin plus ceftaroline combination therapy for persistent methicillin-resistant Staphylococcus aureus bacteremia,* Dr. Chi-Hua Lu (UB) – *Chronic Disease Medication Utilization and the Novel Coronavirus Disease 2019 (COVID-19) Infection*, and Dr. Amanda Mogul (Binghamton University) – *Evaluating the impact of an at home medication disposal system on safe medication disposal*.

Congratulations to all of our awardees, and we look forward to reviewing the results of your projects. All four awardees will present at the next NYS-ACCP Annual Meeting.

Thank-you also to the Student College of Clinical Pharmacy chapter at St. John's University for your time and effort in preparing our NYS-ACCP February newsletter.

As a reminder, we always welcome your thoughts, ideas, and questions; please do not hesitate to reach out to myself or the other Executive Officers.

Best wishes,
Kathryn Connor
NYS-ACCP President
kaconnor@sjfc.edu

Dr. Calvin Meaney

Dr. Meaney is a clinical pharmacist-scientist in the field of nephrology. He is currently a Clinical Associate Professor and Vice Chair for Research in the Department of Pharmacy Practice at the University at Buffalo School of Pharmacy and Pharmaceutical Sciences. His clinical practice is at the Erie County Medical Center, the Regional Center of Excellence in Transplantation in Kidney Care. He serves on two acute care medical teams: (1) Nephrology Consultation Service and (2) Internal Medicine where he precepts pharmacy students and residents.

Dr. Meaney's research is focused on the optimization of drug therapy through the application of quantitative clinical pharmacology. He leads a multidisciplinary group of researchers to improve anemia management in hemodialysis patients. Other work has focused on drug-induced nephrotoxicity where he was one of the first researchers to identify vancomycin and piperacillin/tazobactam as a nephrotoxic combination.

In the classroom, Dr. Meaney strives to excite and engage students through real-world application of pharmacotherapy using active learning techniques. He finds the personal interaction with students through advising and mentoring to be the most rewarding part of being a faculty member.

Clinical Spotlight: Elaine Hassan, PharmD

Assistant Director of Pharmacy at NYC Health + Hospitals/Jacobi Medical Center

1. What are your current responsibilities at the NYC Health + Hospitals/Jacobi Medical Center?

"In my current role in the Antimicrobial Stewardship Program (ASP), I advise staff members in different clinical departments on the appropriate use of antimicrobial agents. I also provide hospital-wide ongoing education to physicians and other disciplines by developing educational materials and competencies and providing in-services with close monitoring of complex antimicrobial cases as needed in collaboration with infectious disease (ID) physicians. In ASP, I helped develop strategies to maximize appropriate antibiotic utilization and improve patient outcomes. These include guidelines and prior authorization criteria based on local antibiotic susceptibility data. I also enjoy mentoring pharmacy students in ID externships through St. John's University."

2. When the COVID-19 pandemic first occurred, how did your responsibilities shift and what new roles were you responsible for taking on?

"During the first round of the COVID-19 pandemic, I collaborated with a working group including ID, Medical Critical Care, Surgical Trauma Team, HIV, Research and Pharmacy to consistently revise guidelines on the management of COVID-19. These guidelines were circulated to all hospital clinical staff. I also helped the ID physicians in evaluating patients for criteria to start specific treatments such as dexamethasone and remdesivir."

3. What are some of the research projects that you are involved in?

"Currently, ASP and ID physicians are evaluating and approving antiviral treatment with remdesivir for patients with COVID-19. We will be analyzing the effects of remdesivir on these patients. I am also working closely with the research department to ensure our COVID-19 guidelines include all the current treatment trials that are available to patients. This helps physicians offer the best possible treatment options."

4. What is one challenge you have faced in your career as a pharmacist and how have you been able to overcome that challenge?

"My current role is unique as it is a management position with clinical responsibility. Being able to balance both operations and clinical duties has been challenging at times. To help me overcome this obstacle, I enrolled in courses offered through the corporation to help develop skills in management. These courses taught me how to achieve team goals through negotiation and conflict resolution techniques, to evaluate my staff properly, and to offer constructive feedback for improvement. I was able to learn the importance of hospital performance improvement projects and participate in patient safety executive rounds. All of this including the support of my colleagues in management helped me fulfill my obligations as a pharmacy manager."

5. What advice can you give to students who may want to pursue this role as well?

"My advice for students, especially those considering a specialty in ID, is to try to keep up with the literature. With the COVID-19 pandemic as an example, treatments and recommendations are always changing. It is important to realize as pharmacists, we are the ones being looked at for information about treatment and the most current practice. Also, join professional organizations as these would offer networking possibilities that will help your career."

-Ada Zheng, PharmD Candidate 2021

Updates on Montelukast Boxed Warning and Mental Health/COVID-19 Implications: Do Benefits Outweigh Risks?

In March 2020, the FDA added a Boxed Warning for montelukast (brand name Singulair) due to associated neuropsychiatric side effects, including suicidal thoughts, depression, and aggressive behaviors.[1,2] Montelukast is used to treat chronic asthma in adult and pediatric patients, exercise-induced bronchoconstriction, and allergic rhinitis.[2] Postmarketing data analysis from 2000 to 2015 highlighted the possible connection between mental health concerns and montelukast use. This fifteen year data analysis, reported in 2019 from Sentinel, indicated that suicide incidence rate was slightly higher in patients taking montelukast than in those using inhaled corticosteroids, with incidence rate difference per 1000 person-years being 0.20 in 1:1 Matched Conditional Predefined Analysis; Caliper= 0.05 and 0.19 in 1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05.[3] The Kaplan Meier Survival Curves of Events and Follow-up Time for Suicide, Unconditional Matched Cohort also indicated that survival probability for patients taking montelukast was slightly lower at 0.998, as compared to 1.000 for inhaled corticosteroids.[3] Despite these minimal clinical findings, 2011 and 2016 animal studies identified montelukast in cerebrospinal fluid and brain tissue, suggesting montelukast can cross the blood-brain barrier.[4] Pediatric providers, alarmed by these findings, presented their concerns to the FDA in September 2019.[4] Providers reported two cases of positive dechallenge of neuropsychiatric effects with montelukast, and reemergence of the symptoms after re-challenge occurred.[4] After thorough review, the FDA added the warning label and suggested alternative treatment options be used in patients with mild conditions, or when other medication therapies work sufficiently.[1] Specifically, multiple forums suggested that montelukast use in patients with allergic rhinitis be limited to patients where other treatments proved ineffective, as topical nasal steroids or oral antihistamines may be more

effective.[1,5,6] If patients begin experiencing neuropsychiatric symptoms, they are advised to immediately discontinue the medication.

In May 2020 and September 2020, articles from Turkey and France discussed montelukast as a possible treatment option for COVID-19, due to its mechanisms as a cysteinyl leukotriene (cysLT) receptor antagonist.[9-11] This decreases cytokine production and inflammation, which helps limit a cytokine storm. The virus creates a cytokine storm through a positive feedback mechanism caused by an increased release of cytokines from leukotrienes.[9] Interestingly, previous studies depicted montelukast's ability to reduce neuroinflammation.[9,12] This is important, as 36.4% of COVID-19 patients in China suffered neurological symptoms.[9,13] The possibility of montelukast ceasing the progression of illness is also being investigated; retrospective studies at Robert Wood Johnson University Hospital/Rutgers University are comparing COVID-19 patients who received montelukast with COVID-19 patients who did not.[7,10] Further peer review needs to be completed on their findings, but the National Institute of Health is currently conducting clinical trials regarding montelukast and COVID-19.[7,8]

The boxed warning comes at a relevant time, as COVID-19 apprehension and mental health concerns regarding pandemic-induced emotional stress increase, especially for patients with pre-existing mental health conditions. As pharmacists and interns, we need to be cognizant of patients taking montelukast. This includes assessing the patient's mental health, notifying patients of these side effects, and monitoring patients accordingly. We should also be aware of alternatives for medication therapy interventions in all settings, understand appropriate uses for montelukast, and weigh risks versus benefits for patients.

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Immunizer: A Pharmacist's Many Hats and Now an Intern's… and a Technician?

The ongoing COVID-19 pandemic has single-handedly redefined life as we know it. Nearly a year since the first confirmed case of COVID-19, it is more clear than ever that the novel virus is here to stay. While pharmaceutical companies raced to be the first to develop a safe and effective vaccine, pharmacists continued to justify the value of their services. Provider status for pharmacists has long been debated, and to this day, varies between states. Pharmacists did not earn the authority to immunize in the state of New York until 2008.[1]

To contain the spread of this unprecedented virus, legislation has been enacted in favor of pharmacist provider status. Moreover, conversations about whether or not certified pharmacy technicians (CPhTs) should be granted the privilege to administer the COVID-19 vaccine, or any vaccine for that matter, have been ongoing.[2] Initially, it was only the flu vaccine which could be administered at local pharmacies in NYS by pharmacists.[1] Today, in addition to the influenza vaccine, pharmacists are authorized to administer 4 other vaccines, including pneumococcal, meningococcal, tdap, acute herpes zoster (shingles). [3] However, due to the pandemic, pharmacists have been pre-authorized to administer the COVID-19 vaccine once available, as well as expand access to childhood vaccines.[4]

Notably, on December 7, 2018, New York joined 48 other states in "authorizing a vital service to the public, " when on this day, a bill was signed into law by Governor Andrew Cuomo, allowing for the following: Under pharmacist supervision, pharmacy interns would be permitted to immunize patients.[3] It is not only pharmacists who are equipped to arm the frontlines in the battle against this historic happening, since intern pharmacists are newly capable of expanding access to the long-awaited vaccine. So where do technicians fit into the picture?

Three years ago, Idaho emerged as the first state to add pharmacy technicians to the list of healthcare workers eligible for immunizing duties.[2] To be clear, patient counseling is not ever to be designated to pharmacy technicians by pharmacists. This includes pharmacy technicians who are registered immunizers. Simply put, technicians are not a source of vaccine information. These individuals are only authorized to perform physical administration of a vaccine, which begs the question: how does allowing technicians to immunize improve immunization rates? Let us say a patient who urgently needs to be immunized turns to the pharmacy, except the pharmacist is stuck in a conference call in the middle of the day, and cannot vaccinate. Sure, you can have an intern do it, but the intern is in class and does not work that day of the week. Having a technician who is qualified to safely administer the vaccine to the patient is valuable to the team. Under these circumstances, the patient does not have to be kept waiting, or reschedule the service. It was only a year later that Rhode Island would follow suit and allow their technicians to adopt immunizer duties. [2] In Arizona, pharmacy technicians are even administering immunizations to pediatric patients. [2] Such is the fuel for growing frustration among the aspiring pharmacists of NYS, for a while NYS-registered interns were just awarded the right to immunize, Connecticut's interns have long indulged in this benefit.

In the end, whether you disagree or agree that technicians should be granted access to vaccinate, you cannot deny that for strength in numbers, they need to. Granting permission should not be a battle of the ego, but a battle of patient protection and succeeding in personalized patient care, putting people on the path to better health.

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Management of Adrenal Insufficiency During Ramadan (Muslim Fasting)

Fasting is a sacred act embedded in many religions. It holds spiritual value that makes it difficult for many muslims to give up. One type of fast, usually observed by muslims during Ramadan, is abstaining from food/drink from dawn to sunset. Clinical guidelines on fasting with certain comorbidities, including adrenal insufficiency, are lacking. Patients with adrenal insufficiency must take multiple doses of glucocorticoid replacement a day. Lack of patient adherence could be fatal.

Adrenal insufficiency occurs when the adrenal glands don't make enough cortisol. There are three types of adrenal insufficiencies: Primary, Secondary, and Tertiary. Despite the different pathological causes for each type, they all require glucocorticoid replacement. The choice of medication for each patient depends on its biological half-life.[1] Dosing should be adjusted in such a manner that the interval between the two doses matches the cortisol day curve as much as possible. The most common medication regimen is twice daily oral hydrocortisone (10 mg + 5 mg) which works for a fasting patient if taken at dawn and sunset (the beginning and end of a fast).[1] However, if the fasts are during longer days, then there is a risk of cortisol levels dropping low before sunset, and patients need to be advised to break the fast early if feeling ill. Another alternative is switching the patient to once daily oral prednisolone 5 mg tablet as the patient can take it either at dawn or sunset.[1] Physicians should be wary of the dose conversions from hydrocortisone to prednisolone. Modified-release preparations of hydrocortisone may sound ideal, but the formulation is more expensive, limited worldwide, and some preparations are still in clinical trials.[1]

According to the most recent guideline published in the Clinical Journal of The Society For Endocrinology And the Endocrine Society of Australia, healthcare providers should begin by assessing patient risk stratification, including, stability of disease, additional comorbidities (especially diabetes), time of diagnosis and if pregnant.[1] Patients would be categorized into low/moderate, high, or very high risk. Low/moderate risk patients could still fast without major issues. High risk patients should not fast and very high risk patients must not fast. If however, the high risk and very high risk patients still decide to fast, practitioners should explore alternative options with their patient. If no alternatives are pursued and the patient is adamant on fasting, then education and emergency plans must be in place well before the start of Ramadan.

Patient education plays a vital role in the safe management of adrenal insufficiency during fasting. Patients and caregivers should be clear about warning symptoms of adrenal insufficiency, such as fatigue, nausea and vomiting. As a safety measure, patients should always carry a syringe and a vial of hydrocortisone or dexamethasone with them, and be able to administer it to themselves if acute symptoms are present.[1] Patients with primary adrenal insufficiency should be advised to avoid exertional activity and hot climates to minimize loss of sodium.[1] Dietary planning for the dawn and sunset meals should also be discussed to avoid any food that might exacerbate the condition during fasting.

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The Impact of the COVID-19 Pandemic on Psychiatric Care

The COVID-19 pandemic has changed the ways in which psychiatric healthcare can be safely and effectively delivered. Outpatient visits have become less frequent, making it difficult to monitor patients, promote adherence, and optimize patient care.

Effect in the Outpatient Setting

To follow social distancing guidelines, many mental health services have transitioned to telemedicine, or the long-distance delivery of healthcare via telecommunications such as telephone, video, or text[1]. Telemedicine is possible in the psychiatric field since many services can be delivered remotely with few exceptions, such as long acting injection (LAI) administration or certain types of intensive therapies. Early analyses show that there is better attendance for telemedicine than for in-person appointments[1]. However, telemedicine may exacerbate disparities among patients without internet or computer access, with insurances that do not yet cover these services, or the elderly or computer illiterate.

Practicing social distancing, maintaining proper hygiene, and wearing personal protective equipment (PPE) can be challenging for psychiatric patients with cognitive impairment or difficulty following guidelines[2]. Patients with psychiatric disorders exhibit a higher rate of risk factors for comorbidities, such as obesity or tobacco smoking, making them more susceptible to the negative effects of COVID-19.[2]

Effect in the Inpatient Setting

Inpatient facilities pose a risk to the spread of the virus as they tend to be environments where patients receive care in close proximity. New guidelines and protocols are constantly being updated in order to keep up with the rise in cases. In order to prevent the spread of the virus, COVID-19 positive patients were separated from all other patients.The implementation of stricter policies, such as not allowing visitors or any group activities, has contributed to increased social isolation for patients in psychiatric inpatient settings[2].

Many hospitals have chosen to provide psychiatric consultations through telephone or video cameras where possible, similar to the adaptations made in outpatient settings. However, treatment for some patients is more difficult to manage as some medications for this patient population require blood work, monitoring, or in-person administration. Patients may be more hesitant to obtain necessary laboratory work in person for fear of increasing their chances of contracting COVID-19. A rebound in hospitalization rates is expected once the number of COVID-19 cases decline and patients feel more comfortable seeking care.[2]

Effect on Healthcare Professionals

Healthcare workers, especially in the inpatient setting, have had to step in to help treat COVID-19 patients, making it difficult for hospitals to allocate as much time and resources towards psychiatric care. Residents and other healthcare professionals-in-training have shifted their attention to COVID-positive patients, and less towards subspecialties such as behavioral health.[1] The effects of the pandemic on healthcare workers also includes a rise in mental health issues, including depression, anxiety and trauma-related concerns.[2]

Mental Health Consequences of COVID-19

A recent cohort study assessed whether COVID-19 was associated with increased rates of subsequent psychiatric diagnoses, or whether patients who already have a history of psychiatric illness are at a greater risk of contracting COVID-19. In the study, a total of 54 health care organizations in the U.S. were taken into consideration. Patients with no previous psychiatric history showed an increased incidence of psychiatric diagnosis, with the highest numbers in anxiety, insomnia, and dementia specifically in patients over 65 years old. It was also found that a history of psychiatric diagnosis was a risk factor for COVID-19. However, it remains to be seen whether this is due to behavioral factors such as social distancing adherence and smoking, or if it is due to the psychological impacts of certain psychiatric disorders or medications.[3]

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Nurtec™ ODT (rimegepant) for the Acute Treatment of Migraine in Adults

Migraine, a neurological disease, is characterized by debilitating attacks that last anywhere from 4 to 72 hours. Varying symptoms including pulsating or throbbing headaches ranging between moderate and severe pain intensity, nausea, and/or sensitivity to sound or light. Aura is a sensory disturbance, most commonly visual in nature, associated with seeing various shapes, bright spots, or flashes of light. Nearly 40 million people in the United States suffer from migraine and more than 90% of migraine sufferers are unable to function normally during an attack. [1] In need of an efficient acute treatment for migraine, the approval of NURTEC™ ODT (rimegepant) is a targeted and effective new treatment option.

Approved by the Food and Drug Administration (FDA) in February 2020, NURTEC™ ODT (rimegepant) is the first and only calcitonin gene-related peptide (CGRP) receptor antagonist available in a fast acting orally disintegrating tablet (ODT) that is indicated for the acute treatment of migraine with or without aura in adults. [2] NURTEC is unique in that it serves as a "one and done" treatment with a dose of one 75 mg tablet daily. UBRELVY, a previous contender for the treatment of migraines, differs from NURTEC in the frequency and effectiveness of one single dose. For patients taking NURTEC, one 75mg dose is sufficient whereas with UBRELVY, a second dose can be repeated two hours after the initial dose of 100mg. [7] Ordinary tablets such as UBRELVY can take up to two hours for their onset of action. NURTEC™ ODT is not indicated

for the prevention of migraines, though it allows for rapid onset of action as it dissolves in seconds when placed on or under the tongue.

Calcitonin Gene Related Peptide (CGRP) is the most potent endogenous vasodilator found in the brain and it's release results in the initiation of neurogenic inflammation. [3] CGRP antagonists such as NURTEC act on the CGRP pathway by blocking the CGRP receptors by suppressing the transmission of pain, thereby inhibiting the relay of pain signals. [3]

Compared to traditional acute migraine treatments, NURTEC has relatively few and mild side effects. The most common side effect found was nausea in 2% of people who participated in clinical studies. [5] NURTEC can be used in patients with a stable history of heart attack, stroke , or controlled risk factors such as high blood pressure however cannot be used in patients with severe hepatic impairment, or end stage renal disease. [5] Being a substrate for CYP3A4 and CYP2C9, NURTEC will have drug interactions with medications that affect these enzymes. Therefore a CYP3A4 inhibitor such as ketoconazole or grapefruit juice will increase the concentration of NURTEC, as well as P-glycoprotein inhibitors such as verapamil. [4] NURTEC ODT requires a prescription and comes in a dose pack containing 8 tablets. 86 percent of patients treated with NURTEC ODT did not use a migraine rescue medication within 24 hours. [6] The approval of NURTEC ODT is exciting for people with migraine as it provides a new treatment option to help regain control of their attacks and their lives.

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Rukobia (fostemsavir): A Novel Agent for HIV Treatment

HIV drug resistance has been increasing steadily. The mutations in genetic structure occur because the reverse transcriptase enzyme that copies viral RNA to DNA is prone to error and the virus replicates rapidly.[1] Additionally, poor adherence, subtherapeutic blood levels of antiretroviral agents, and inappropriate choice of an antiretroviral agent lead to HIV drug resistance. According to the World Health Organization, acquired HIV drug resistance ranges from 50% to 97% among patients failing NNRTIs-based antiretroviral therapy and from 21% to 91% among patients failing NRTIs.[2] This alarming statistic highlights the importance of new advances in drug development to combat HIV resistance.

On July 2nd 2020, the United States Food and Drug Administration approved ViiV Healthcare's Rukobia (fostemsavir), indicated for HIV treatment in heavily treatment-experienced adults with multidrug-resistant infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[3,4] Rukobia is a novel agent in HIV treatment as it is the first medication developed in the gp120 attachment inhibitor class. Rukobia is a prodrug that is metabolized to temsavir, the active component that binds to the gp120 subunit of the virus and prevents the conformational change needed for it to interact with the $CD4^+$ T-cell. As a result, the virus is prevented from entering the cell.

Rukobia is available in a 600 mg extended-release oral tablet and is dosed as one tablet taken twice daily with or without food. Nausea is the most common side effect, as seen in 10% of the study population, followed by diarrhea and headache, with each side effect seen in 4% of the study population. Severe adverse reactions include immune reconstitution syndrome, QTc prolongation at higher than recommended dosages, and elevations in hepatic transaminases in patients with hepatitis B or C virus coinfection. Rukobia is contraindicated with strong cytochrome P450 CYP3A inducers, such as carbamazepine, phenytoin, and St. John's wort. The inducers would decrease temsavir plasma concentrations and virologic response.

Approval for Rukobia was based on a phase 3 multinational trial (BRIGHTE), which evaluated the drug's efficacy and safety in 371 patients.[5] All of the patients enrolled were failing their current regimen and exhausted at least four of the six antiretroviral classes. For the first eight days of the study, Rukobia was added to the failing HIV regimen. The Rukobia group showed a significant decrease in the HIV-1 RNA level compared to the placebo group. For the remainder of the study, patients took Rukobia in addition to optimized background therapy. In the Rukobia group, the rate of virologic response, defined as an HIV-1 RNA level < 40 copies per milliliter, was 57% at week 48, which indicates continued efficacy. Rukobia proves to be a promising agent for patients with a history of multidrug resistant HIV infections and limited treatment options.

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CABENUVA: HIV Treatments From Oral to Injection

When the United States was first introduced to AIDS (Acquired Immune Deficiency Syndrome) in 1981, little was known about the disease and its virus, HIV (Human Immunodeficiency Virus). It was not until 1987, six years after the onset of the first identified case of AIDS, when the first antiretroviral therapy Zidovudine (AZT) was approved by the FDA (Food and Drug Administration).[1] Now, approximately 40 years later, research for AIDS and HIV has advanced significantly, with over 30 FDA approved antiretroviral agents available on the market today and more in research and development. In August 2020, ViiV Healthcare announced their resubmission for FDA approval of CABENUVA, the first once-monthly, long acting, injectable combination regimen for the treatment of HIV-1 infection, after its initial rejection in December of 2019.[2] Despite its rejection, it was soon approved in Canada in March of 2020, marking it as the first global regulatory approval for this therapy.[3] The CABENUVA regimen has just been approved by the FDA on January 21, 2021 as a treatment for patients with HIV.[9]

CABENUVA is a combination regimen consisting of integrase strand transfer inhibitor (INSTI) cabotegravir, and non-nucleoside reverse transcriptase inhibitor (NNRTI), rilpivirine.[4] The first month consists of an oral lead-in of 30 mg cabotegravir tablet once daily and 25 mg rilpivirine tablet once daily. During the second month, intramuscular (IM) injection is initiated at a dose of 600 mg cabotegravir and 900 mg rilpivirine. The IM continuation injections of 400 mg cabotegravir once monthly and 600 mg rilpivirine once monthly start after the third month and continue onwards.[5] This injection will be utilized to replace daily oral therapy as a means to increase adherence among HIV positive populations since administration only takes place once a month.

Phase III trials FLAIR and ATLAS have been completed to compare the long acting CABENUVA therapy with oral triple therapy. FLAIR studied participants that were antiretroviral therapy naive and were given a fixed-dose combination of abacavir, lamivudine, and dolutegravir orally. After 20 weeks, the participants were randomized to either continue their oral therapy or to begin the one month oral CABENUVA lead-in before the long acting injection. In the ATLAS study, the patients were randomized to either continue their oral antiretroviral therapy or switch to the one month oral CABENUVA regimen before the long acting injection from their previous antiretroviral therapy. These two studies demonstrated that the CABENUVA regimen is non-inferior to the oral antiretroviral regimens currently available. Adherence to an oral antiretroviral regimen has barriers including pill burden, stigma, and access to a support system of loved ones. In comparison, the CABENUVA regimen tackles the hurdles brought forward by the oral antiretroviral regimens.[6]

Healthcare staff gave their perspective on whether this regimen was a viable intervention, barriers to implement, and who were the best candidates for this regimen. CUSTOMIZE was a novel, hybrid trial designed to test the practicality of using CABENUVA in the healthcare setting over a 12 month period. The intervention of CABENUVA sparked interest and had the approval of 84% of the healthcare staff. Initially, the staff were concerned about implementation based on a patient's ability to keep up with their appointments and accessibility to the clinic. However, by month four concerns over these barriers decreased due to resources for

both staff and patients. These toolkits provided assistance in training for staff along with more information on the regimen to help answer any questions. They found this regimen a promising alternative for patients on an oral antiretroviral regimen and those having trouble with adherance.[7]

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Bamlanivimab: A SARS-CoV-2 Neutralizing Antibody Given EUA by the FDA

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), a novel coronavirus causing Coronavirus disease 2019 (COVID-19), emerged in late December 2019, with the World Health Organization declaring the virus to be a global emergency on January 30, 2020[1]. With over 19 million confirmed COVID-19 related deaths in the United States alone[2], there is currently a need for effective treatments against COVID-19. As such, an intrigue into the use of monoclonal antibodies have been developed as a potential treatment against this novel coronavirus. Monoclonal antibodies are synthetic proteins that mimic the endogenous antibodies found in our immune system & are designed to target specific antigens[3]. LY-CoV555 (bamlanivimab) is a monoclonal antibody developed by Eli Lilly that specifically targets the spike protein on SARS-CoV-2[4]. By inhibiting this protein, bamlanivimab prevents viral attachment & entry into human cells.

A phase 2, placebo-controlled, double-blinded, multi-site randomized control study funded by Eli Lilly titled "SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with COVID-19" has published its results in the New England Journal of Medicine analyzing the safety & efficacy of this monoclonal antibody. The interim review consisted of 452 outpatients recently diagnosed with mild-moderate COVID-19 who would receive placebo or one of three doses of bamlanivimab (700mg, 2800mg, 7000mg) as a 1 hour infusion[4]. The primary outcome of the trial was a change from baseline in SARS-CoV-2 viral load at day 11 after positive results on testing. Secondary outcomes included safety assessment, symptom improvement, & hospitalization rate. Regarding the primary outcome, the results showed the 2800 mg group achieving a statistically significant change from baseline in viral load (95% CI, -0.53 [-0.98 to -0.08]) while the 700 mg & 7000 mg groups were

deemed to be statistically insignificant as their confidence intervals crossed 1 (95% CI, -0.20 [-0.66 to 0.25] & 95% CI, 0.09 [-0.37 to 0.55]) respectively[4].

Despite an underwhelming primary outcome, the secondary outcomes were more substantial. Regarding symptom burden, patients who received any dose of bamlanivimab showed a reduction of symptom severity, with more prominent improvement exhibited if given earlier. For hospitalization rates, 1.6% of patients were hospitalized in the bamlanivimab group compared to 6.3% who received placebo. Finally, bamlanivimab had a safety profile comparable to placebo. 22.3% of patients receiving bamlanivimab reported any adverse event compared to 24.5% who received placebo (majority of cases were mild in nature with nausea & diarrhea being the most prominent)[4].

Overall, the researchers of this trial concluded that bamlanvimab has a safety profile similar to that of placebo, & patients diagnosed with mild to moderate COVID-19 who received bamlanivimab had fewer hospitalizations & a lower symptom burden when compared to those who received placebo. Results from this study prompted the FDA to quickly grant emergency use authorization for bamlanivimab for the treatment of mild-moderate COVID-19 in adult & pediatric patients. This EUA allows patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age & older weighing at least 40 kilograms, & who are at high risk for progressing to severe COVID-19 or hospitalization to receive 700 mg IV bamlanivmab[5]. Currently, with no FDA approved drugs indicated for the treatment of COVID-19, this EUA for bamlanivimab will potentially minimize the healthcare burden associated with COVID-19 hospitalizations until a more effective treatment is established.

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