

# NYS-ACCP INSIDER

St. John Fisher College Wegmans School of Pharmacy



## Special Points of Interest:

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Advancements in Lipid  
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Cipriano

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WsoP Chapter Summary

Dear Colleagues,

I am very pleased to present to you the first NYS-ACCP quarterly newsletter of 2021! The Wegmans School of Pharmacy (WsoP) student chapter of ACCP aims to educate students about the vast fields of pharmacy practice and increase awareness of the current events related to pharmacy. This newsletter will be heavily focused on the current COVID pandemic that has become a worldwide crisis. It is important for us to understand what the pandemic is, what the new treatment guidelines are, and what pharmacists can do to help improve management of COVID patients to optimize outcomes. Discussing this pandemic and its relevance to pharmacy will provide new insights to those reading and may even spark new ideas on how to manage this matter in your practice setting. Please feel free to reach out to me with any questions or comments regarding this newsletter at [gks09117@sjfc.edu](mailto:gks09117@sjfc.edu).

Respectfully,

Grace Shashaty, WsoP ACCP President

**COVID-19 Clinical Update:**

The situation surrounding coronavirus (COVID-19), a contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is constantly evolving and new drug therapies are being approved by the FDA for emergency use authorization (EUA) frequently. Below is a current overview of drug therapies the National Institute of Health recommends based on clinical trial data that has been completed since the start of the pandemic. These guidelines encompass the majority of the population. However, more recommendations exist for special populations and disease states.

**Current Treatment Guidelines for Outpatient:****Bamlanivimab and Casirivimab plus Imdevimab:**

- **Use** - EUA by the FDA to treat mild to moderate COVID-19 primarily in the outpatient setting.<sup>1</sup>
- **MOA** - monoclonal antibodies that are thought to prevent SARS-CoV-2 from entering the host cells by binding to the spike protein.<sup>2</sup>
- **Prophylaxis** - no drugs have been approved for prophylaxis
- **Vaccine** - Two mRNA vaccines (Pfizer and Moderna) have been approved by the FDA for administration to help prevent patients from contracting COVID-19.<sup>3</sup>

**Current Treatment Guidelines for Hospitalized Patients:**

**Remdesivir** - currently the only antiviral drug approved by the FDA for the treatment of COVID-19.<sup>1</sup>

- recommended for hospitalized patients who require supplemental oxygen and is typically seen in combination with dexamethasone.<sup>1</sup>

**Dexamethasone** - shown to increase survival rates in patients on mechanical ventilation (remdesivir is not currently approved for patients on this type of ventilation as it has not shown mortality benefit in patients with more severe disease.<sup>1</sup>)

**Baricitinib** - patients who are unable to use corticosteroids like dexamethasone alternative therapy recently approved for emergency use authorization by the FDA.<sup>4</sup>

- oral Janus kinase inhibitor approved for the treatment of severe rheumatoid arthritis, but has shown benefit in COVID-19 patients due to its ability to suppress inflammation and immune response similar to dexamethasone.<sup>4</sup>
- Unlike dexamethasone, baricitinib is not recommended for monotherapy, but to be used in combination with remdesivir for patients requiring supplemental oxygen or mechanical ventilation.<sup>4</sup>

Hypercoagulability is a complication of COVID-19 that has become an increasing concern.

- Current treatment guidelines recommend anticoagulation prophylaxis for patients during their hospitalization and then discontinuation upon discharge.<sup>5</sup>

- (1) Therapeutic Management [Internet]. National Institutes of Health. U.S. Department of Health and Human Services; 2020 [cited 2020Dec23]. Available from: <https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/>
- (2) Statement on Bamlanivimab EUA [Internet]. National Institutes of Health. U.S. Department of Health and Human Services; 2020 [cited 2020Dec23]. Available from: <https://www.covid19treatmentguidelines.nih.gov/statement-on-bamlanivimab-eua/>
- (3) Different COVID-19 Vaccines [Internet]. Centers for Disease Control and Prevention. Centers for Disease Control and Prevention; 2020 [cited 2020Dec23]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>
- (4) Statement on Baricitinib EUA [Internet]. National Institutes of Health. U.S. Department of Health and Human Services; 2020 [cited 2020Dec23]. Available from: <https://www.covid19treatmentguidelines.nih.gov/statement-on-baricitinib-eua/>
- (5) Antithrombotic Therapy [Internet]. National Institutes of Health. U.S. Department of Health and Human Services; 2020 [cited 2020Dec23]. Available from: <https://www.covid19treatmentguidelines.nih.gov/adjunctive-therapy/antithrombotic-therapy/>

- **Brittany Post, PharmD Candidate: WSoP Class of 2023, WSoP ACCP President-elect**

## The Race for a COVID-19 Vaccine in the U.S.

At the beginning of 2020, the world was hit by a pandemic unlike any other – COVID-19. Since March of 2020, the virus has taken many lives and made thousands more ill, leaving the American people wondering – how will we get ahead of this? The next logical step in prevention of a virus such as this is a vaccine – and the process of developing, testing, and approving a vaccine can take years, years that we do not have. This has caused the federal government and pharmaceutical companies to put this vaccine on a “fast-track” – something that does not sit right with many.



Photo: [https://www.europeanpharmaceuticalreview.com/disease\\_conditions/covi](https://www.europeanpharmaceuticalreview.com/disease_conditions/covi)

In mid-March 2020, different pharmaceutical companies, the most prominent being Pfizer, started developing and testing the COVID-19 vaccine. Pfizer and BioNTech teamed up to create the revolutionary vaccine – the only hurdle being the FDA approving it with enough time for it to be distributed before the death tolls rose again. The United-Kingdom and Canada authorized the wide-spread distribution – on December 3<sup>rd</sup> and December 9<sup>th</sup> 2020, respectively. The United States followed suit not long after and authorized the vaccine for distribution on December 11<sup>th</sup>, 2020 – making this vaccine a landmark in FDA history, taking only 9 months to go through clinical trials and get approved for distribution<sup>5</sup>.

The biggest question on everyone’s mind is: who gets the vaccine first? The answer to that question largely depends on your state. The consensus is that those that are highest risk will be given the vaccine first – front-line healthcare workers and residents and workers in long term care facilities. Dr. Fauci, the director of the National Institute of Allergy and Infectious Disease, is projecting that “the groups receiving the vaccine in December, January, February, and March will include those in high priority groups, including health care workers, those over 75 years of age, and first responders.” (CNN, 12.11.2020). After March, the vaccine would then be distributed to the general public.

The Pfizer vaccine is given in two doses, where the second dose is given three weeks after the first dose. In comparison, the Moderna vaccine, the 2<sup>nd</sup> COVID-19 vaccine to be approved, is given in two doses, 4 weeks apart. In clinical trials the Pfizer vaccine has been shown to be 95% effective, while Moderna has been shown to be 94% effective. There were not any major, uncommon side effects<sup>5</sup>. The only barrier to the Pfizer vaccine being widely distributed is the fact that it needs to be stored in ultra-cold freezers, something most retail or community pharmacies do not have. The vaccine must be stored at -94° F for it to remain effective, but it can be stored in a refrigerator between 2° to 8°C (36° to 46°F) for up to 5 days before it is ineffective<sup>5</sup>. Moderna’s vaccine is more stable at higher temperatures and can be stored in a refrigerator between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours<sup>5</sup>. This is something that many small and chain pharmacies will need to consider before purchasing batches of the vaccine once it becomes widely available.

(5) Sharma O, Sultan AA, Ding H, Triggle CR. A Review of the Progress and Challenges of Developing Vaccine for COVID-19. *Front Immunol.* 2020 Oct 14;11:585354. doi: 10.3389/fimmu.2020.585354. PMID: 33163000; PMCID: PMC7591699.

## Advancement in Lipid Management: Nexletol (bempedoic acid):

February 21<sup>st</sup> 2020 marked the official FDA approval for a new agent that works upstream from and is complementary to statins, Nexletol (bempedoic acid). Nexletol works through Adenosine triphosphate-citrate lyase (ACL) inhibition, the first agent of its class to do so. With no contraindications identified in clinical trials, Nexletol provides a further tool in the efforts of providers to lower lipid levels in high risk patients. As the prevalence of cardiovascular disease increases, the use of concomitant blood pressure control and lipid lowering therapy becomes more vital. The approval of this new class of drugs, paves the way for future agents and a further understanding of lipid management.



Photo: [www.thecardiologysadviser.com/home/topics/metabolic/dyslipidemia/nexletol-a-first-in-class-ldl-c-lowering-oral-therapy-now-available/](http://www.thecardiologysadviser.com/home/topics/metabolic/dyslipidemia/nexletol-a-first-in-class-ldl-c-lowering-oral-therapy-now-available/)

Nexletol has a unique mechanism of action, and is the first FDA approved agent to target the inhibition of ACL. After activation in the liver by acetyl-CoA synthetase (ACSVL1), Nexletol becomes active and inhibits ACL, upstream of statins, which then further upregulates LDL receptors, leading to a further decrease of LDL-C in the bloodstream. This new drug is indicated for patients, in adjunct to diet and a maximally tolerated statin, for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional LDL-C lowering<sup>6</sup>.

Clinical trials were conducted to not only establish safety but determine efficacy, defined as the lipid lowering abilities of this new agent. The CLEAR Harmony study was a 52 week, randomized, double blind, phase 3 trial that tested the effects of Nexletol in 2,230 patients with a fasting LDL-C  $\geq 70$  mg/dL, and high risk patients with ASCVD and/or HeFH. The effect of Nexletol and Nexlizet on cardiovascular morbidity and mortality have not yet been determined due to its recent approval. However, this clinical trial showed a significant decrease in LDL-C, a mean of 18%, in patients using Nexletol versus placebo. In addition to a low to moderate intensity statin, a subgroup of patients taking Nexletol experienced a 20% mean reduction in LDL-C compared to placebo at 12 weeks. A second subgroup of patients, taking a high intensity statin, experienced a mean reduction of 17% in LDL-C compared to placebo at 12 weeks<sup>6</sup>. Both values were found to be statistically significant in clinical trials. Clinical significance has not yet been determined due to the lack of time on the market.

As with any drug, Nexletol and Nexlizet carry their own inherent risks. The most notable in the CLEAR Harmony study were back pain, hyperuricemia, abdominal pain or discomfort, muscle spasms, increased risk for tendon rupture, and pain in the extremities. Nexletol and Nexlizet are recommended to be discontinued if a patient becomes pregnant and are not recommended during breast feeding<sup>6</sup>.

(6) Nexletol[package insert]. Ann Arbor, MI: Experion; 2020

## Clinical Spotlight: Gabriela Cipriano, Pharm. D

Ambulatory Care Pharmacist at the Anthony Jordan Health Center (AJHC)

### **What made you interested in clinical pharmacy?**

Growing up Dr. Cipriano was always interested in going into medicine of some form. It started when she noticed that her grandmother was on all different kinds of medications and she noticed that she was on multiple duplicate therapy, possibly because the patient or patient to provider information was not always translated well. While deciding on whether to pursue a career as an MD or a pharmacist, she was able to attend different medical conferences that broadened her view of what a pharmacist could do and how this fit in with how she wanted to treat patients and bridge the gap between patients and providers.

### **How did you get to be where you are now?**

While Dr. Cipriano grew up in California, she ultimately decided to do her Pharm. D training at Washington State University. While on her 4<sup>th</sup> year rotations she was able to spend some time out in Rochester, NY and discovered that the patient populations that she wanted to help the most were also out here. After researching residency programs, a clinical pharmacy residency and position seemed to be the best type of pharmacy job that would feel her desire to work directly with patients and help them overcome any medical literacy and language barriers that may occur. She applied for a community pharmacy residency program at the U of R, where she was the first community pharmacy resident through that program. After that she joined the Wegmans School of Pharmacy and joined the Anthony Jordan Health Center where she currently works.

### **What is your current practice role and what is your patient population like?**

Currently Dr. Cipriano sees mostly Hispanic and Spanish-speaking patients that need help and adjustment with their medications. Most can be of lower socioeconomic status and may not be the most versed in healthcare and their own disease states. She has a Collaborative Drug Therapy Management (CDTM) agreement with providers at her health system that allows her to directly interact with their medications without constantly needing to refer to the physician, which is a huge boon for her practice.

### **Would you say you have a unique role that you play at your site?**

Dr. Cipriano believes that her cultural background plays a huge part in her role at AJHC. By being able to communicate to her patients on their level and in a language they are comfortable with there is a trust that is built up very quickly. She is able to help patients navigate their new diagnosis around their own culture and how they can best manage everything that has been thrown at them recently.

### **What advice would you give to a pharmacy student looking to go into your role?**

The best thing to do is to invest the time and energy into making yourself the candidate that is set apart from the crowd. Clinical pharmacy roles are becoming more and more competitive and where maybe one residency used to be enough to be competitive, two years of advanced learning may be considered even more competitive now. Doing anything now that can set you apart from the crowd in the future will be incredibly beneficial to a student looking to get into a clinical pharmacy role, so investing that time in yourself now can pay off in a great way in the future.

-Greyson Ankenman, PharmD. Candidate WSoP Class of 2022, WSoP ACCP Student Liaison



“There is an added value to the patient when a provider looks and talks like you.”

## 2020-NYS ACCP Annual Meeting

The 2020 NYS-ACCP annual meeting was held virtually November 5<sup>th</sup>-November 6<sup>th</sup>. Pharmacy students, residents, fellows, practitioners, and educators representing different NYS regions were in attendance. First, we recognize Wegmans School of Pharmacy's own Dr. Kathryn Connor of the NYS-Planning Committee for taking on the substantial task of converting the in-person meeting into a successful virtual meeting. The evening of the 5<sup>th</sup> was started off with a virtual happy hour in which the attendees were able to socialize and network with each other. The next event was the Quiz Bowl in which WsoP's Allison LeFever, Morgan Marriott, Ashley Hannigan, and Michael Sellars won against St. John's University! Following this was the Buddy Program; this event allowed students and other attendees to buddy-up with experienced attendees and ask them any questions they had on their clinical field, advocacy, or other topics of interest.

The second day set a platform for presentations provided by pharmacists on several topics including immunotherapy, pharmacogenomics, medication safety, and marijuana/CBD. Pharmacy residents gave enthusiastic presentations on the use of clonidine in dexmedetomidine withdrawal, pharmacists billing for services, and venous thromboembolism prophylaxis for discharged patients. This year's keynote speaker, Dr. Amy Dzierba, from New York-Presbyterian Hospital discussed the impact that the COVID-19 surge had on hospital pharmacy practice in New York City. The global pandemic has obviously induced major changes to the pharmacy practice and Dr. Dzierba spoke about specific areas in clinical pharmacy practice and the changes in COVID-19 treatment recommendations.

Pharmacy students were able to join a Residency Panel between presentations to ask more questions and learn about the varying clinical residencies. Finally, ACCP welcomed the new president-elect of 2021, Dr. Calvin Meaney, the 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. Though virtual this year, the meeting was still a successful networking event as well as a significant platform for clinical pearls and continuing education. As successful as the virtual event was this year, we hope to see everyone in person for next year's meeting.

- Anastasia Soroka, PharmD Candidate: WsoP Class of 2023, WsoP ACCP Membership Chair

## ACCP WSoP Student Chapter Summary

Since the creation of the ACCP student chapter at the Wegmans School of Pharmacy in January of 2014, many students have joined with a collective interest in clinical pharmacy. This year has brought on many challenges with the global pandemic, and the student chapter needed to adapt quickly to the changes. All meetings were held over Zoom, including elections, journal clubs, and guest speakers. We started the semester off with our September Journal Club led by Dr. Fang Zhao on the activities of drug excipients in biologic targets. Also in September, we had three students win the 2020 ACCP Clinical Pharmacy Challenge WSoP local competition, Melissa Kabb, Shanaya Bulmer, and Amber Skinzera, and many more participate. The winners of the local competition were entered into the national competition held by the national ACCP organization.

We celebrated National Pharmacy Week in October by cohosting a guest speaker with ASHP. Dr. Casey Wilbert, Director of Pharmacy at Rochester General Hospital spoke to the pharmacy students over a zoom call. The ACCP student chapter also co-hosted a talk with ASHP and PPA. Dr. Justin Jopson from Rochester General Hospital spoke about his role as a pediatric pharmacist. In November, we had the pleasure of congratulating four of our very own WSoP students for winning the NYS-ACCP Quiz Bowl, Allison LeFever, Morgan Marriott, Ashley Hannigan, and Micheal Sellars. They even received a congratulatory plaque to hang at the school! Overall, this past year has been an interesting one to say the least, and we are proud to have our ACCP student chapter continue to participate, excel, and continue learning about clinical pharmacy. We are determined to keep offering opportunities and events for our members in the future.

**-Anastasia Soroka, PharmD Candidate: WSoP Class of 2023, WSoP ACCP Membership Chair**



## **New Service, New Challenges: How Do Young Pharmacists Adapt and Thrive**

Starting a job in a new setting comes with its set of challenges that may vary per one's professional background, level of experience, and other factors. The elation to have matched to a PGY-2 program and the opportunity to continue to apply and hone the clinical skills amassed over our previous year helped balance the angst of it all. Coming into this residency was exciting for both my colleague and I as we were getting closer to achieving our goals of becoming pharmacotherapy expert practitioners in the field of ambulatory care pharmacy. The Rheumatology/Nephrology/Public Health residency program at Albany College of Pharmacy and Health Sciences (ACPHS) was the ideal placement for furthering this ambition of ours with the plethora of unique rotations offered. Like most institutions and programs across the country, we had to learn to adapt and think creatively amid the challenges and not-so-apparent opportunities the COVID-19 pandemic brought on. Some of the hurdles that arose early on were getting up to speed on specialized pharmacotherapy, acclimating to new services, and taking on a preceptor role.

Following our first year of residency, we were looking to practice as independent practitioners in a specialized clinic where pharmacy services are leveraged to enhance patient care. It should be noted that, although we were very experienced in caring for patients in the ambulatory care setting, both my colleague and I had very limited knowledge and experience in rheumatology. A lot of the skills in our arsenal were transferable; however, there was a sizable knowledge gap to be closed quickly. The orientation and first month in a clinic served as an opportunity to familiarize ourselves with the different disease states and patient management. It was overwhelming to say the least, yet through in-depth review of rheumatology practice guidelines, topic discussions on emerging literature, and participation and attendance at lecture series held by expert practitioners, we were able to achieve the solid foundation necessary to uphold the level of care required for this unique patient population. Looking back, it is astounding at all the learning that took place over the past 6 months and the growth we both gleaned working directly with our preceptor, providers, and the rest of the team at the clinic.

In addition to the hands-on clinical experience, we were involved in academia and scholarship which enhanced our communication, precepting, and teaching skills. Precepting is an essential and ever-evolving aspect of pharmacy that ensures the continuum of learning, the preparation of stellar practitioners, and the delivery of outstanding service to our community. Precepting can be daunting, especially while transitioning from student to resident to seasoned pharmacist. We looked forward to becoming more involved in the process, for we knew all too well the clumsiness and lack of confidence that comes with inexperience, yet we have a great appreciation of all the learning to be had and the potential that can be achieved in such a short amount of time. It was somewhat easier for us to connect with the students and get past the wall of communication. We took great pleasure in getting to know the students, their aspirations, and answering the questions they had regarding post-graduate life.

We were fortunate to have APPE students in person at The Center for Rheumatology, which allowed us to provide more guidance and in-person teaching visit opportunities. We had two to three students at a time spread out in a large conference room to follow social distancing guidelines. When it came to the patient teaching visits, initially we had the students on a Zoom call where they could observe and listen in on the visit. As they progressed through the rotation, each student had the opportunity to go in the patient room with one of us or our preceptor and lead the visit while their peers observed on Zoom. Feedback from students included that having the residents as resources were useful, and they enjoyed the impact that their consults had on patient care. My colleague and I were delighted to assist our students in their CVs and letters of intent review well after they completed their rotation with us.

In contrast, precepting during our public health rotation was mostly virtual with the occasional in-person home visit. We had five students during this past module. There were plenty of tasks and projects to go around, however the remote learning environment was not very conducive to students' engagement and prompt achievement of meaningful outcomes. The unpredictable nature of the patient home visit and public health concerns strained our ability to get the students involved as much as we would have liked. To circumvent that, each student was assigned patients and tasked with completing an extensive SOAP of all their disease states which was shared with the preceptors and peers. The students had extensive exposure to disease state management while working in our blood pressure, behavioral health and HIV monitoring programs. The students enjoyed the continuity of care they were able to provide to their assigned patients. The group presentations and discussions helped strengthen their knowledge and created a dynamic learning environment.

Another great aspect of precepting we have come to appreciate while at the clinic has been the layered learning approach between the students, residents, providers, and preceptors. All parties involved bring in different levels of knowledge which can be used to bolster the overall experience. The layered learning model is a teaching strategy designed to train residents to precept students and other residents with the oversight of a seasoned clinical pharmacist.<sup>[1]</sup> Activities done with students, including consults, topic discussions, and journal clubs helped grow not only the students' knowledge, but our own as well. We provided feedback on presentation of the material, and our preceptor would provide additional in-depth information on the subject. This model helped us refine our clinical skills while taking on the role of co-preceptor.

We were also involved in creating and presenting formal presentations for the ACPHS continuing education (CE) series. We have the students attend these sessions, as it is a nice refresher for what they learned in school or on rotations. These sessions are great for us to study for board certification and provide live CE credit at the same time. Overall, we tried to incorporate students into various activities as much as possible and would hold them to the same standard as if they were completely in-person. It is important to set the expectations up front, and to address any issues encountered early on. Our advice to students reading is that although online rotations certainly aren't easy, rotations are a crucial part of your training and preparation for post-graduation professional life. Treat every rotation as if it were an interview, and always put your best foot forward. Do not hesitate to bring up with your preceptor any concern or personal life interference that may impinge on your ability to learn. Our goal is to promote your growth as a future practitioner and catalyze your path to success.

There is so much more that could be said about residency. This is a brief snapshot of the wealth of experience we dove into this year. We are truly humble and grateful to be an integral part of the healthcare system and provide much-needed care to our patients and community. We are cognizant the road ahead will be full of challenges and exciting opportunities and we can't wait to see what the future holds. No matter what setting you work in, we encourage all pharmacists, new and old, to get out of their comfort zone, face the challenges head on, and continue to enhance the quality of care we provide for our patients. Until then, we hope our column finds you, your team, family and loved ones safe and well. Thank you for being heroes to the community during these unprecedented times. It is a great privilege to be part of such a noble profession.

#### References:

1. Loy BM, Yang S, Moss JM, Kemp DW, Brown JN. Application of the Layered Learning Practice Model in an Academic Medical Center. *Hosp Pharm.* 2017;52(4):266-272. doi:10.1310/hpj5204-266

**By: Christ Ange Katche, PharmD, MBA and Kaitlyn McCarthy, PharmD**

## 2020 NYS-ACCP Executive Board

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