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Nicole Yioupis
nicole.yioupis15@stjohns.edu

Sophia Villa
vendettaquila1605@gmail.com

Noelle J. Ryan-Bloom
noellerx@icloud.com

Carmela Avena-Woods
avenac@stjohns.edu

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PROVIDING IMMUNIZATIONS IN THE EARLY STAGES OF THE COVID-19 PANDEMIC; A COMMUNITY PHARMACIST AND STUDENT PHARMACIST'S VIEW

Nicole Yioupis, PharmD, RPh

Sophia Villa, PharmD

Noelle J Ryan-Bloom, RPh.

Carmela Avena-Woods, BS Pharm, Pharm D, BCGP

INTRODUCTION & BACKGROUND

St. John's University is a 6-year entry-level Doctor of Pharmacy Degree Program (Pharm D).

After the third-year, students enter what is their first professional year of study. After successful completion of their third-year, students apply for their pharmacy intern permit with the state. Under the direct supervision of a pharmacist, pharmacy interns in New York State may perform all the functions of a registered pharmacist. However, until recently, this excluded administering immunizations. In 2018, administering vaccinations was added to the role of pharmacy interns. In the following year, the college required all students to be certified and registered immunizers prior to starting their Advanced Pharmacy Practice Experiences (APPEs).

In their last professional year of the pharmacy program (year six), students must successfully meet the criteria and complete nine, four-week APPEs. APPEs take place in various pharmacy practice settings such as community, hospital, outpatient, and specialty practice settings. Students are required to be certified and registered immunizers prior to starting their first APPE. Students are currently offered the immunization certificate program at the university outside of the curriculum and the university offers the opportunity for certification for students registered in one elective course.

In New York, all pharmacy immunizers are required to complete a certificate program or its

equivalent, be registered with the state, certified in Cardiopulmonary resuscitation (CPR) and be up to date with all Occupational Safety and Health Administration and bloodborne pathogen training. In addition to administering the vaccine, like pharmacists, interns monitor vaccine storage, reconstitution, and preparation. They also screen patients for eligibility and assist with documentation and recommendations as per the Advisory Committee on Immunization Practice (ACIP). Under the supervision of the pharmacist, interns also counsel, monitor, and answer questions or concerns regarding immunizations as well as medications from patients and other providers.

The Role of the Pharmacist as an Immunizer

In 2008, certified and registered New York State pharmacists were granted the authority to immunize against influenza and pneumococcal disease. Since then, the legislation has been expanded to include up to eight different types of immunizations in New York for preventable diseases such as influenza, pneumococcal, meningococcal, shingles, tetanus, diphtheria, pertussis and COVID-19 (NYSED, n.d.). In November 2021, Governor Hochul signed legislation that expanded the immunizations which can be administered by New York State pharmacists. Pharmacists are now able to administer vaccinations against hepatitis A and

B, human papillomavirus (HPV), measles mumps and rubella (MMR), and varicella to those 18 years of age and older (New York State, n.d.). Since national training programs began in 1996, immunizing pharmacists have directly impacted immunization rates (Hogue et al., 2006).

A meta-analysis looking at immunization rates showed an increase in vaccination rates and vaccine coverage when pharmacists were involved in the immunization process. All 36 studies included in the review showed an improvement in vaccination rates. This occurred regardless of the role of the pharmacist or vaccine administered.

The primary vaccinations in these studies were against influenza and pneumococcal disease. Among the 36 studies evaluated, six were randomized controlled trials that showed a statistically significant increase in immunization rates (RR, 2.74; 95% CI, 1.58-4.74) (Isenor et al., 2016). There are different levels at which a community pharmacist can be involved in immunizations including as educators, facilitators, and in the administration of vaccines (American Pharmacists Association, n.d.).

As one of the most accessible healthcare providers, community pharmacists, have a pivotal role in educating and assisting patients with their vaccination questions in addition to their role in managing their medication and other health needs. As certified immunizers, pharmacists have the resources and experience needed to educate patients on the risks and health benefits associated with getting vaccinated.

Coronavirus 2019

On January 15th, 2020, the first case of Novel Coronavirus in the US was recorded in the state of Washington. The highly infectious coronavirus, also referred to as severe acute respiratory syndrome coronavirus (SARS-

CoV-2) or COVID-19 was first identified in December of 2019 in Wuhan, China. It caused serious respiratory illness and even death among those infected (Centers for Disease Control and Prevention, 2021). By March 13th, 2020, a national emergency was declared in the United States due to an increased number of cases and deaths from the infection. Shortly after, quarantine recommendations were put into place and a complete shutdown of New York City began. Non-essential businesses were forced to shut down to minimize exposure to the virus. Schools and other institutions had to quickly identify other ways to serve their communities and students as they limited or stopped all in-person interactions.

As of July 2021, there were over 33,000,000 reported cases of the disease and close to 600,000 deaths nationally due to COVID-19. Over 2,000,000 of those cases and 53,100 deaths were in New York City (USAFacts, 2021). This respiratory infection affected every aspect of daily life, but those most affected were older adults, who were the most susceptible to COVID-19 infection and severe complications from

it. Further, the pandemic decreased older adults' access to care, family and friends (United Nations, 2020, May).

On December 11th, 2020, the first sign of real hope came with the emergency use of a vaccine against COVID-19. This vaccine was approved under an emergency use authorization (EUA). EUA is a process to increase the availability of medically approved or unapproved products during public health emergencies. Treatments under EUA undergo vigorous safety and efficacy testing before being approved. The first COVID-19 vaccine approved by the Food and Drug Administration under EUA in the US was from Pfizer-BioNTech (Centers for Disease Control and Prevention, 2021c). A second vaccine approved by the manufacturer Moderna quickly followed

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with approval for EUA on December 18th. Both vaccines use mRNA technology. This teaches our body to effectively recognize and fight against the protein found in this new virus. Both vaccines are given in a 2-dose series for maximal protection. Following the two-dose series, both vaccines were found to effective against preventing death and serious infection (Centers for Disease Control and Prevention, 2021c).

A third single dose vaccine by Johnson and Johnson's Janssen, often referred to as the "J&J vaccine", was given EUA approval in the US on February 27, 2021 (U.S. Food & Drug Administration, 2022). This vaccine uses an inactivated virus (adenovirus) to elicit an immune response against COVID-19. While initially criticized for only having a decreased efficacy, this vaccine was also found to effective in the prevention of severe infection (hospitalization and death) in those who contract COVID-19, just as the first two vaccines (Centers for Disease Control and Prevention, 2021c; Centers for Disease Control and Prevention, 2021d). All vaccines are highly effective against severe infection. However, access to vaccines became the greater concern.

Despite a great sense of hope from the vaccines, new concerns arose as availability of the vaccines was scarce and access to the vaccine posed some challenges. As a result, each state implemented their own plan on how to vaccinate individuals based on their risk of infection. This was guided by the Centers for Disease Control and recommendations from experts in medical and public health (Centers for Disease Control and Prevention, 2021b). The vaccines would be available to patient populations in phases. Healthcare personnel and residents of long-term care facilities were identified as the first group of individuals to be vaccinated. The next prioritized group included other essential workers and those over the age of 75 (Centers for Disease Control and Prevention, 2021b). Other groups that followed were those over the age of 65 and those with certain disease states, before including the general adult population.

From the time the first vaccine was approved for use, the demand for immunizers increased as did concerns about the vaccine and access to the vaccine. Staff and members of community pharmacies, and other health facilities were particularly overcome with questions and concerns. As the vaccine became available to patients outside of long-term care facilities, patients were directed to state and pharmacy websites to schedule appointments which were often inundated with many users. In the early stages, this was the only way to obtain an appointment for a vaccination. This posed challenges to those who did not have access to the internet or were not skilled in using this technology.

During the COVID-19 pandemic, community pharmacists were once again recognized as vaccine advocates by adopting various roles to help overcome many of the challenges that the community was facing during the pandemic. Particularly as immunizers, pharmacists were well trained in screening patients and identifying those at risk of vaccine-preventable diseases, such as COVID-19 (Bach & Goad, 2015). During the COVID-19 pandemic especially, community pharmacists had a key role in ensuring proper storage, preparation and administration of doses in various vaccination sites across the state and nation (Strand et al., 2020). The initial vaccines had very specific storage requirements. For some doses, the vaccine had to be reconstituted (mixed) prior to vaccination. Community pharmacists stepped up first as vaccine distributors and facilitators for Long Term Care (LTC) facilities to help improve accessibility and vaccinate high-risk populations. By partnering with various nursing homes and assisted living facilities, approximately 8 million doses of the COVID-19 vaccine were administered to LTCF staff and residents by May 2021 (Centers for Disease Control and Prevention, 2021b). In addition to immunizations, community pharmacists have been called on to coordinate the administration of COVID-19 testing. With the authority to order and administer COVID-19 tests, community pharmacists have helped increase

access to testing and reduce hospital burden and community exposure (Strand et al., 2020).

Providing vaccines in the early stages of the pandemic; A pharmacist's role and perspective

As a pharmacist during the COVID-19 pandemic, my practice has changed immensely. In addition to my daily duties in the community pharmacy during the pandemic, I was asked to immunize up to three Long Term Care facilities (LTCF) weekly in addition to providing vaccination clinics for schools and corporations. The LTCF had anywhere from 18 immunizations to 600 immunizations scheduled in a single day. That would mean I was either alone or leading a team of 12 pharmacists and interns to facilitate and provide those immunizations. Through all of this, I had so many experiences. One that really stands out in my mind is when I was in one LTCF where I noticed that every patient had their own room. I had told the nurse how great it was for these patients to all have a private room. Quickly, she responded that they were all only private because their roommates had all passed from COVID. She had tears in her eyes, as did I. I never realized how appreciated I was until that day. Every facility I visited, I was thanked by the staff and administrators. They were thankful not only for their residents, but for their staff that had suffered so much and would now have some reassurance that they'd make it through this because they were immunized. So many residents were lost. All I could think was that if even one person was saved because of this endeavor, it was all worth it.

In another instance, we gave a gentleman a vaccine and returned 3 weeks later for his second dose only to find out that COVID took him just days after his first vaccination. It was heartbreaking as this man was full of life and personality the last time I had seen him. The vaccine hadn't come soon enough for him. In one of the facilities, I immunized an Auschwitz survivor. She told me the story of how she had escaped alive and that I was again helping her stay alive with this vaccine. Many patients explained how they hadn't seen their families in over a

year and because of the vaccine, that would soon change.

Being an immunizer also came with some challenges in the LTCFs. In many facilities, I was tasked with servicing the dementia unit. This was hard. In some cases, I had to talk to patients to put them at ease before I immunized them. Not knowing if I had a troublesome patient, I just had to be aware and do my best with each vaccination administered. I also had some nurses worried I wouldn't be able to give a patient a vaccine because the patient may be agitated. They cared for their residents as did I. I didn't let any patient's situation or barrier stop me because the opportunity for them to be immunized was too important to pass up. Regardless of the situation, I did my best to ensure they got the vaccine. My experiences really made me proud to be a pharmacist and to be able to help so many. Between my pharmacy and the vaccination clinics I ran, I have immunized several thousand people.

The in-school clinics and the corporate clinics were a different dynamic than the LTCFs. These clinics had anywhere from 30 to 300 vaccinations scheduled in a day. These were operated by teams of one to six pharmacy personnel, which would include pharmacists, interns and/or technicians. The way they differed was that the patients were all coherent and able to converse with us. Also, the patients all traveled to us as opposed to us traveling to them and going from room to room. Some of them would cry as they got the vaccine because they were so elated to finally receive it. Some were terrified because they weren't positive the vaccine was safe to take. Educating them and comforting them was so important. One useful tool, in addition to sharing my knowledge, that I found to comfort patients was laughter. I would keep talking and make them laugh, and before they knew it, the vaccine was done. As a pharmacist, I am accustomed to preparing and dispensing prescriptions and counseling the patients on the safe and effective use of medications. However, this was a different level of counseling. It was like I was touching their hearts. I was giving them something that could potentially

be saving their life and the lives of their loved ones. Pharmacy became so much more for me. I never expected to feel this way, but now I do.

The COVID-19 pandemic has made the role of the pharmacy intern more important to a pharmacist. I had the honor of bringing interns along with me to the LTCF clinics. Their assistance was invaluable. At the LTCFs, interns helped by preparing doses of the vaccine, taking patient's temperatures, educating patients on the vaccine, immunizing, and then entering data for record keeping. I couldn't have done it without them. We never had enough pharmacists for clinics, so interns were a godsend. I also had similar assistance from pharmacy interns at the school clinics where we immunized the teachers and school staff. In the community pharmacy, pharmacy interns help manage the COVID immunizations, allowing me to also focus on preparing and dispensing prescription orders and other community needs. Without my interns, I would have been struggling to keep up with all of the prescriptions as we do upwards of 30 immunizations daily. I'm so proud of my interns. I listen to them as they put patient's minds at ease before and after giving immunizations. They counsel patients and the patients leave with a smile and sense of comfort and care. I've been fortunate to be able to work with so many promising future pharmacists. It's amazing to be able to share once-in-a-lifetime experiences like these with students, so that they learn from them as I have.

Providing vaccines in the early stages of a pandemic; A pharmacy interns' role and perspective

While vaccine administration and distribution began in December 2020, the 2021 PharmD Candidates were returning to face to face learning at their prospective clinical APPE site. Providing direct patient care and applying the knowledge they learned in a classroom can be exciting but also bring on a fair share of anxiety for many students starting APPEs. Starting clinical rotations during a pandemic added a different layer to those feelings. For this rotation we were given the unique experience and opportunity to assist in ending this pandemic firsthand alongside pharmacists in several vaccination clinics. In the spring semester of 2021, vaccines were not yet being administered to the general public. New York was still in the early phases of administering the vaccines. During our Community Pharmacy APPE, we were asked to join other pharmacists in providing vaccines to those residing or working in Long Term Care facilities, in addition to our experience in a community pharmacy. Not only was this an opportunity to continue to learn and apply our knowledge, but it was also an opportunity to be a part of ending a pandemic.

At the first vaccination clinic, we were surprised by the limited number of pharmacists and the large population of residents and employees that wanted to be vaccinated. Although this was both a surprise and challenge, we felt motivated and wanted to put our clinical skills to use in a way we had never done before. As interns, we reconstituted over 70 vaccines providing stability to the pharmacists who were immunizing residents on each floor of the LTCF. With the preparation of each dose, we were able to sharpen our sterile compounding technique and gained immense experience in preparing vaccines. At the second clinic, we had the opportunity to personally vaccinate over 50 employees of the facility. Responsibilities included reviewing patient's screening forms to ensure eligibility and counseling them on potential side effects of the vaccination. This experience has impacted us in a way that will stick with us throughout our careers as pharmacists.

As COVID-19 vaccinations continue to become readily available to the general public, our experience has given us the confidence to continue to positively impact the community. It felt amazing to put our communication and clinical skills to use in a practical environment, especially during a critical time when our skills were needed most. We are proud to be a part of a community of pharmacists who put themselves on the frontlines to ensure those at the highest risk remained safe. We are grateful for the opportunity St. John's and community pharmacists have given us to learn while making a difference in the world.

One overall lasting impression was the overwhelming gratitude that patients had after receiving the vaccination or answering their questions. They were beyond elated to finally have hope and security that came in the form of a vaccine, and they were extremely grateful to us for taking the time to make sure that they were safe and taken care of. At times, it was overwhelming with the sheer quantity of vaccines that had to be reconstituted within a short period of time, and the number of questions to answer and manage, but the result was worth it.

CONCLUSION

Since the opening of the first vaccination clinics described in this article, the recommendations and use of COVID-19 vaccinations has expanded and continues to change. All COVID-19 vaccinations were initially available to individuals based on an Emergency Use Authorization (EUA). Since then, both mRNA vaccines have received full Federal Drug Association (FDA) approval. At this time, the Pfizer vaccine has been extended to those 12 years of age and older and for patients 5 years of age and older under the EUA. Additionally, the CDC and various other medical associations have identified the need for and recommend booster doses using all three vaccines for those who already completed their series and an additional dose for those who are immunocompromised to maintain adequate protections against the virus. This is regardless of the vaccine they initially received. As a result, pharmacists, pharmacy interns and certified pharmacy technicians in NYS continue to serve their communities by keeping up to date with recommendations to combat the various strains of COVID-19. Pharmacists help to identify when a vaccine is needed and what the current recommendations are for various patient populations as more medical treatments are developed to combat the virus. This is while still serving their communities in the safe and efficacious use of all medications.

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ABOUT THE AUTHORS

Nicole Yioupis is a Doctor of Pharmacy graduate from St. John's University, College of Pharmacy and Health Sciences with over 5 years of experience in community pharmacy. Nicole's areas of interest include becoming a preceptor, immunizations and further serving the geriatric community. Nicole is a licensed immunizer and currently practices as a pharmacist at a Long-Term Care pharmacy in Woodbury, NY.

Sophia Villa is a recent graduate of St. John's University, College of Pharmacy and Health Sciences. Sophia's areas of interest include pediatrics, HIV, and oncology. She is a certified immunizer who enjoys educating patients about vaccines. Her ultimate career goal is to obtain specialized residency training in order to practice as a board-certified pediatric pharmacist.

Noelle Ryan-Bloom has been practicing in community pharmacy for over 25 years. In that time she has been a preceptor to countless pharmacy students from the St. John's University College of Pharmacy and Health Sciences and externs from multiple technician training programs such as NY Medical Training Center, Molloy College and Hofstra University. She was responsible to facilitate many Long Term Care Facility Covid-19 clinics across Long Island because of her extensive flu clinic background. Her areas of interest are diabetes and immunizations. She is a Pharmacy Immunizer that leads the region in immunizations in her locations and is one of her company's immunizations leads.

Carmela Avena-Woods has been practicing as a community pharmacist for over 20 years, with over 10 years of teaching experience as an Associate Clinical Professor at St. John's University, College of Pharmacy and Health Sciences. In affiliation with her academic position, she serves as a preceptor and pharmacist at Walgreens in Garden City, NY. Carmela's areas of interest are immunizations, Medication Therapy Management (MTM) and Chronic Obstructive Pulmonary Disease. Carmela is a Board-Certified Geriatric Specialist and a Pharmacy Immunizer, who has also trained countless students and pharmacists to become immunizers and conduct MTM consults.