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as voters head to the polls this November, it is important to keep in mind that this election is like no other in recent history. We are witnessing an unprecedented voting process, with early voting, mail-in ballots, and in-person options to ensure that everyone has a chance to vote in whatever way they feel safest. As we went to press, new warnings about another wave of the coronavirus disease 2019 (COVID-19) pandemic were being reported, just as our medical experts had predicted, as hospitalizations and infection rates ticked upward.

With the “twindemic” of the COVID-19 and influenza season underway, the pharmacy workforce, more than ever, are positioned to support vaccination efforts. Over the next few months, educating the public about flu vaccination and promoting uptake will be key to mitigating burden on the health care system as flu and COVID converge. On page 22 in this issue, we bring you coverage from the National Community Pharmacists Association 2020 Annual Convention, which was held virtually October 18-29, on how pharmacists can truly make a difference this season, from increasing vaccination rates to advising about best treatments for respiratory infections.

By the end of this month, we will be celebrating the Thanksgiving holiday. This year in particular, the media (including webinars, podcasts and content from MJH Life Sciences™) has done an exceptional job of educating the public on the importance of getting vaccinated and being careful at family gatherings. Continue to remind those who pass through the pharmacy, so that however they are celebrating the holiday this year, it’s a happy and safe one for them and their loved ones.

In other news, within this issue you’ll also find our cannabidiol (CBD) guide, which offers a wide breadth of information and education on the landscape of CBD in pharmacy. How can you use CBD products to boost your business? How should you counsel patients on CBD use? What legal considerations should you know about? Our CBD guide for pharmacists starts on page 34.

As we continue to navigate these unprecedented times, visit drugtopics.com for up-to-date information and timely pharmacy news.

Thank you for reading.

Mike Hennessy Sr
Chairman and Founder of MJH Life Sciences™
CANCER CARE IN TRANSITION

How community pharmacists can advance care as patients come home

SPECIAL REPORT

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Modernera’s COVID-19 Vaccine Elicits Immune Response in Older Adults

By Jennifer Barrett

Moderna’s coronavirus disease 2019 (COVID-19) vaccine candidate mRNA-1273 induced immune responses in older adults, according to a second interim analysis of a phase 1 study evaluating safety and immunogenicity.

This open-label phase 1 trial is evaluating the safety and immunogenicity of the vaccine in older adults; the interim analysis evaluated a 2-dose vaccination schedule of mRNA-1273 given 28 days apart in 40 healthy adult participants across 2 dose levels (25 µg and 100 µg) in 2 age cohorts (56 to 70 years old and 71 and older). Results were reported through day 57, or 1 month after the second dose.

Overall, the data showed that the binding- and neutralizing-antibody responses appeared to be similar to those previously reported among vaccine recipients between the ages of 18 and 55, the investigators reported. The US government recently entered an agreement with Moderna for the purchase of 100 million doses of mRNA-1273 for $1.5 billion, with the option for the US to buy up to an additional 400 million doses.

Long-Acting Antibody Combination Heads to Phase 3 Trials for COVID-19

By Jennifer Barrett

AstraZeneca’s investigational long-acting antibody (LAAB) combination will advance into phase 3 clinical trials for coronavirus disease 2019 (COVID-19).

AZD7442, a combination of 2 LAABS derived from convalescent patients after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was discovered by Vanderbilt University Medical Center (VUMC) and licensed to AstraZeneca in June 2020.

AstraZeneca will conduct 2 phase 3 studies of AZD7442. One trial will enroll approximately 5000 participants to examine the safety and efficacy of AZD7442 to prevention COVID-19 infection for up to 12 months. The second trial will evaluate postexposure prophylaxis and preemptive treatment in approximately 1100 participants. Additional trials will evaluate the treatment in approximately 4000 patients for the treatment of COVID-19.

AstraZeneca plans to supply up to 100,000 doses starting toward the end of 2020. The US government can acquire up to an additional 1 million doses in 2021 under a separate agreement, the company said.
NIH Study Aims to Identify Most Promising COVID-19 Treatments

A new National Health of Institutes (NIH) study aims to determine which investigational coronavirus disease 2019 (COVID-19) treatments have the most potential to warrant advancement into larger clinical trials.

The ACTIV-5 Big Effect Trial (BET) launched by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, will enroll adult volunteers hospitalized with COVID-19 at as many as 40 US sites.

According to NIAID Director Anthony S. Fauci, MD, the goal of the study is to identify as quickly as possible the experimental therapies that demonstrate the most clinical promise and move them into larger-scale testing for COVID-19. ACTIV-5/BET is a phase 2 adaptive, randomized, double-blind, placebo-controlled trial. The study will compare different investigational therapies with a common control arm to determine which treatments have relatively large effects.

The trial will test:
- **Risankizumab** (Boehringer Ingelheim and AbbVie) in conjunction with remdesivir compared with a placebo plus remdesivir.
- **Lenzilumab** (Humanigen) with remdesivir compared with placebo and remdesivir.
Advancements in pharmacy management systems and increased usage of electronic medical records (EHRs) allow community and independent pharmacists to practice more clinically—beyond just dispensing medications.

Pharmacists already store information such as drug-dispensing histories that may not be available to other health care professionals. By making this information securely available to other health care providers through the EHR, pharmacists can contribute to a comprehensive overview of a patient's medicine use, including medication adherence and persistence inferred from the frequency of dispensing.

Access to dispensing records and other drug-related histories also may facilitate effective and efficient medication reconciliation at transitions of care, such as admission to and discharge from the hospital.

Continuing to Evolve

Early pharmacy management systems essentially were designed for gathering lists of the prescriptions patients received. The systems didn't connect with insurance companies, and there were few drug interaction checks.

“Today, a wide array of features within pharmacy management systems help pharmacists provide advanced clinical care, including diabetes management, weight management, and smoking cessation,” said Heidi Polek, RPh, a pharmacist and strategic program manager for DrFirst, a provider of innovative technology solutions that works with 67,000 pharmacies nationwide. "Pharmacy management systems also help pharmacists create electronic care plans that can be shared with patients and providers."

For instance, a pharmacist looking at a patient's profile will be reminded if they need immunizations. And when patients share important information such as blood pressure or cholesterol levels, pharmacy management systems now provide areas to save this information, allowing pharmacists to more completely assess a patient's medication and health history. Ultimately, this enables more collaborative care between a pharmacist and a provider.

“Although e-prescribing is widely available, pharmacists still contend with the need to manually correct free text found in patient directions [known as sigs] for 84% of new prescriptions, which can lead to errors, take time away from patients, and slow down pharmacy productivity,” Polek said.

DrFirst is bringing technology driven by artificial intelligence to community pharmacies across the nation to help address this issue, which will improve safety and give pharmacists more time for patient counseling. SmartSig, which accurately translates 93% of patient directions, interprets electronic prescriptions as they enter a pharmacy system and fills in the information pharmacists typically type, minimizing the occurrence of misinterpretation or incorrect entry errors.

DrFirst works with multiple pharmacy system providers—including BestRx, Rx30, Computer-Rx, QS/1, and Speed Script—to enhance the clinical information gathered from patients and improve communication with health care teams, bridging gaps to help EHRs and pharmacy management systems “talk” with each other and enhance patient care.

Richard Scholz, RPh, chief strategy officer of ERxDirect, a platform of Health in Motion Network that offers the first fully virtually enabled independent pharmacy group in the United States, noted that community pharmacy has been a leader in adopting electronic pharmacy profiles dating back to the 1980s.

“The pharmacist utilizes the patient’s electronic pharmacy record to manage [adherence], check for drug-drug interactions, prevent duplicate or overlapping drug regimens, and check for drug-disease contraindications,” he said. “This clinical functionality is built into most pharmacy management software solutions to facilitate the pharmacist making clinical decisions.”

Unfortunately, community pharmacy has had limited visibility of
the patient’s clinical EHR originating from the treating practitioners’ EHR system.

“The community pharmacist’s role has evolved through the addition of expanded clinical services, compounding, and specialty pharmacy clinical support,” Scholz said. “Each of these expanded clinical services is supported by the pharmacies’ [EHR]. The new opportunity is for pharmacies to be capable of sharing any of their medical records within their care management team to improve coordination of care and optimize outcomes.”

ERxDirect provides a platform for member practitioners, pharmacists, and patients to securely communicate and seamlessly share medical records through the patient’s utilization of Health in Motion Network’s Total Health Engagement application.

“Physician group practice and health system EHR technology is evolving in a siloed, proprietary manner,” Scholz said. “Empowering patients to have access to those proprietary EHR-generated medical records and be capable of sharing the medical records with other members of the patient’s health care team is a valuable tool to expand patient understanding of their health challenges and treatment opportunities.”

Luis Rodriguez, president of Keycentrix, a pharmacy software and technology company, noted that the pressures of data collection, tracking performance metrics, direct and indirect remuneration, modern systems security, and shifting generational demographics are shaping demand and pushing pharmacies to further infuse technology into their operations.

“Pharmacies are leveraging mobile communications and tools to influence adherence, coordinate delivery, navigate a complex universe of benefits, and tie in the providers.”

Ketan Mehta, CEO of Micro Merchant Systems, said the company has several tools to help a pharmacist provide the best patient care possible.

“We have 2-way texting that gives the pharmacist a way to continue chatting with a patient and let them know when it’s time to take medication, and the system will automatically send a reminder to the patients,” Mehta said. “There will also be reminders for refills and helping them through the automated refill process.”

The company also offers PrimeRxPay, which allows a pharmacy to send a text message to the patient, then the patient pays for his or her copay remotely and in a secure manner, and the funds get deposited by the credit card processor, allowing the pharmacy to collect prescription copays from patients.

Once the credentials are provided to the pharmacy, they will be able to log on and view a patient by name or date of birth, and view the prescription profile. By default, PrimeRx pulls up the prescriptions filled in the last 30 days.

“Some of the newer technologies we are focused on are related to patient engagement,” Mehta said. “We are able to create a clinical assessment or questionnaire for the patient in the pharmacy system and then push it out to the patient. They provide feedback about their health and medications they are taking, allowing the pharmacist to focus on the clinical component and keep helping the patient to have better outcomes.”

EHR Challenges
One of the biggest barriers in adoption of newer EHR technology or any management system in the community pharmacy setting is a resistance to change.

“During the pandemic, however, pharmacists have had to change what has traditionally been a face-to-face model to keep their staff and patients safe,” Polek said.

Other barriers for community pharmacists to fully participate in expanded patient care management may be payer related, such as pharmacists being recognized as a provider by CMS, or financial constraints posed by transitioning resources to pharmacy care management.

According to Mehta, the new-age pharmacies opening up today understand the importance of synergy between these systems. However, many long-time pharmacists remain stuck in their ways.

“That model has to change,” he said. “On top of everything the pharmacists do, the mindset of moving along with technology can be challenging. Slowly, things are changing, but it’s important to utilize these tools for better health outcomes.”
Diversifying the Pharmacy Business

In the face of increasing pressures, independent pharmacies must look to diversify their services to improve the viability of their businesses in today’s challenging environment. By Jennifer Barrett

In the face of increasing industry pressures, independent pharmacies must look to diversify their services to improve the viability of their businesses in today’s challenging environment.

In an interview with Drug Topics®, Jenni Zilka, Group Vice President of Good Neighbor Pharmacy’s (GNP) Field Programs and Services at AmerisourceBergen and Braheim Knight, RPh, Pharmacy Business Coach at AmerisourceBergen, discussed how pharmacies can optimize their business performance and profitability.

The coronavirus disease 2019 (COVID-19) pandemic has undoubtedly emphasized and accelerated the need for certain clinical services within community pharmacies—and GNP has been working with customers to meet that demand through its Business Coaching program.

“The [GNP] Business Coaching program provides pharmacies with personalized support from an expert who understands the unique needs of their business in a very detail-oriented way,” Knight explained. “The program allows pharmacists to focus their attention and energy on the health of their business….As pharmacy business coaches, we evaluate the precise needs of the pharmacy, we identify areas of opportunity to improve operations, and we create an action plan for success.”

Business coaches work 1-on-1 with pharmacies to identify the right mix of tools and services to match their needs. These offerings can range anywhere from adherence tools like medication synchronization to digital platforms.

Knight has been a business coach with AmerisourceBergen since 2016, but his pharmacy career began in 1998 as a technician. He then went on to become a licensed pharmacist in 2000 where he spent 16 years in the chain industry before receiving his Master of Business Administration degree in health care management. On what inspires him in his role, Knight pointed to the passion that independent pharmacies have for their communities and their patients.

“The COVID-19 pandemic emphasized and accelerated the need for certain clinical services within community pharmacies, and we’ve been working closely with our customers to help them manage that demand,” Knight said. “Beyond COVID-19, independent pharmacies are always implementing clinical services that will positively impact the lives of the patients they serve.”

Approximately 90% of Americans live within 5 miles of a community pharmacy, so the broad availability of these services will be essential to reach as many patients as possible, especially during the pandemic. “Independent community pharmacies are invaluable assets to the healthcare system, providing a trusted, accessible and localized health destination to ensure communities can get the holistic care they need,” Zilka said. “That said, broad industry pressures are creating challenges for the long-term viability of community practices.”

Knight and Zilka provided insight into how independents can expand and optimize their services to prepare for the future of the industry.

Opportunities Amid COVID-19

The pandemic has underscored the need for expanded clinical services, especially given the mounting demand for COVID-19 testing and immunizations.

“Community pharmacies have a unique opportunity to play …

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CANCER IN TRANSITION

How community pharmacists can advance care as patients come home.

By Karen Appold
When patients with cancer leave the hospital, they’re usually overwhelmed with multiple items demanding their attention. Chief among them is filling their outpatient prescriptions, according to Nelly G. Adel, PharmD, BCOP, BCPS, chair of pharmacy practice and associate professor of oncology at Touro College of Pharmacy in New York, New York.

Community pharmacists play an important role in helping oncology patients manage their prescriptions. First and foremost, because these patients often take many medications, it’s important to have a medication expert review them for appropriateness. “Pharmacists can review medication lists to ensure that prescribed regimens are cost-effective, safe, efficacious, and being used for the proper indication,” said Roxane L. Took, PharmD, BCACP, clinical pharmacist at Gateway Apothecary in St Louis, Missouri, and assistant professor of pharmacy practice at St Louis College of Pharmacy at University of Health Sciences and Pharmacy in St. Louis. Although other health care providers are capable of fulfilling these roles, research has shown that pharmacist-provided services can reduce physician visits, emergency department visits, hospital stays, and overall health care costs.1

Another reason why community pharmacists are in a prime position to assist transitions of care for patients with cancer is because they’re the most accessible health care providers to the public. “Patients can call or walk in to see them without an appointment and receive professional medical advice about their medications or get referrals to appropriate higher levels of care if needed,” said Roman Fazylov, PharmD, BCPS, clinical pharmacist for internal medicine and assistant professor of pharmacy practice at Touro College of Pharmacy.

“Community pharmacists are essential in maintaining a patient’s most accurate drug profile, as well as bridging any communication gaps between the patient, hospital discharge team, cancer care team, and the specialists and primary care prescribers patients see.”

Vivianne K. Celario, PharmD


Adel
“Although it’s ideal to follow up with patients within 48 hours of discharge, it may not be ideal for your pharmacy’s workflow. You may find that it’s best to limit your service to a certain patient population, such as those aged 65 and older or patients with diabetes.”

When patients with cancer have questions about treatment plans or a medication’s adverse effects (AEs), community pharmacists are well-equipped to offer 1-on-1, in-person counseling. In addition, these patients may try self-care practices, such as taking vitamins, minerals, and herbal supplements. “While some of these may help certain ailments, some also have serious risks,” Fazylov said. “Pharmacists can advise patients on self-care strategies that are effective and carry a low risk of adverse effects.”

Community pharmacists also can provide access to hard-to-find medications, and they work with physicians and insurance companies to provide expedited drug coverage and access to novel therapies, said Kavel Bhathela, PharmD, a community pharmacist at Carolina Pharmacy in Charlotte, North Carolina. They can offer medication delivery as well as medical and household supplies needed for managing disease, making it convenient for transitioning patients. Furthermore, pharmacists can collaborate with other health care providers and monitor and optimize drug therapy for complex disease states.

Here’s a closer look at the specific roles community pharmacists can play in transitions of care for patients with cancer.

**Medication Reconciliation**

Before a patient even leaves the hospital, community-based specialty pharmacists work with the discharge team to reconcile all prescribed medications, troubleshoot prior authorizations for prescriptions, and enroll patients in copay assistance programs, said Vivianne K. Celario, PharmD, a registered community-based specialty pharmacy manager at Walgreens in New Brunswick, New Jersey. Additionally, pharmacists conduct initial consultations with patients to assess their understanding of therapy goals and potential AEs. Patients are enrolled in the pharmacy’s clinical care program, where pharmacists monitor their treatment, adherence, and AEs, and address barriers that may arise between hospital and clinic visits.

It is important for community-based specialty pharmacists to work with the discharge team to establish that any medications a patient took prior to admission, including OTC medications and supplements, continue to be safe and effective with a patient’s newly discharged medication list, Celario said. For example, newly prescribed oncology medications often have the potential for drug interactions and AEs. Pharmacists can perform drug utilization reviews and address the need for dose changes or recommend drugs to alleviate AEs to increase treatment efficacy and adherence.

Due to a rise in the use of oral and self-administered oncology prescriptions, the success of a treatment greatly depends upon the patient, which is why it’s important for patients to understand their therapy goals and potential AEs.

Community pharmacists also can review patients’ OTC and prescription medications to improve patient safety and adherence. Carolina Pharmacy offers medication strip packaging and medication synchronization services, which help patients keep up with taking all of their medications on time and appropriately. “Through these services, we can check and see how patients are doing, and address any questions or concerns they may have regarding their drug therapy and overall well-being, which helps to build trust and strong relationships with patients,” Bhathela said.

**Educational Initiatives**

Community-based specialty pharmacists receive advanced training specific to oncology to effectively educate patients about their medications and the challenges they may face during their cancer journey. Celario said. These pharmacists can perform initial patient consultations, reassessments, and cycle dosing education to monitor patient adherence. In addition to onsite counseling tools, pharmacists work with manufacturers and professional and patient cancer organizations to provide patients with medication education kits, seminars, workshops, and advocacy support.

Due to the complexity of cancer treatments, a patient’s list of prescribed medications can be extensive. Consequently, multiple drug therapies are quite common. Known as polypharmacy, this can become problematic if patients end up with medications they don’t need, Adel said. Therefore, it’s essential for pharmacists to carefully review these patients’ medication lists and counsel them accordingly.
Managing Pain and Other Comorbidities

Comorbidities are common among patients with cancer. In addition to cardiovascular conditions and diabetes, these patients may experience mental health conditions and chronic pain. This leads to patients taking multiple prescriptions and visiting multiple providers. “Community pharmacists are essential in maintaining a patient’s most accurate drug profile, as well as bridging any communication gaps between the patient, hospital discharge team, cancer care team, and the specialists and primary care prescribers patients see,” Celario said. “Furthermore, due to their accessibility, pharmacists are great resources to assist patients in managing chronic conditions and (adverse) effects that come with having cancer and getting treatment.”

Fazylov said that pharmacists also can play roles in managing insomnia, changes in bowel habits, decreases in appetite, and other comorbidities. “Many of these issues can be managed with over-the-counter therapies,” he said. Pharmacists are trained to monitor pain medications by keeping track of total dose requirements and monitoring AEs. In turn, they can make recommendations to prescribers regarding the right dose and frequency of pain medications to help optimize pain control while keeping AEs at bay.

Other Areas of Expertise

Many oncology medications are costly; community pharmacists can address any cost issues that patients may have. Pharmacists can relay concerns to the appropriate physician, and suggest cost-effective alternatives.

Community pharmacists also can provide delivery services through a “meds-to-beds” program in which the pharmacy brings a patient’s medications to them before hospital discharge. “These programs help identify and resolve barriers to adherence sooner than a typical community workflow process,” Took said. “By identifying medications that cannot be filled due to formulary restrictions or medication cost, this program also helps to decrease readmission rates.”

Getting Started

Resources are available to assist pharmacists who are looking to implement a transitions of care program. For example, the American Pharmacists Association’s Transitions of Care Toolkit was developed to help pharmacists implement or enhance their transitions of care programs in order to improve patient care, reduce health care costs, and optimize medication therapy, Took said.

Took would also encourage community pharmacies to initiate a pilot transitions of care program with patients recently discharged from the hospital, and to offer it free of charge initially. During this early phase, pharmacists can identify common characteristics of patients who are discharged, a patient populations’ needs, and a hospital’s receptiveness to working with them.

To take the program a step further, Took would advise pharmacists to work with a local hospital near their pharmacy and engage with management to develop a proposal to present to hospital leadership.

As pharmacists go through the process, they should have realistic expectations. “Although it’s ideal to follow up with patients within 48 hours of discharge, it may not be ideal for your pharmacy’s workflow,” Took said. “You may find that it’s best to limit your service to a certain patient population, such as those aged 65 and older or patients with diabetes.”

Lastly, don’t be afraid to outsource a service or even partner with another pharmacy such as a specialty pharmacy, Bhathela said. The more services and access to care and products you provide, the more your community will rely on you for their health care needs.

For references, visit drugtopics.com.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Pharmacists Can Help Manage Migraines in Patients With Psychiatric Conditions

Add value by optimizing medications, decreasing pill burden.

By Frieda Wiley, PharmD

It is no secret that psychiatric conditions may predispose individuals to various comorbidities, including migraines. Similarly, patients with migraines tend to have a higher risk of developing psychiatric complaints.1

The complexity of treating migraines is amplified when the patient also has psychiatric comorbidities. The spectrum of presentation and symptomatology in this population subset creates a prime opportunity for pharmacists to help manage these conditions.

Migraine Management Inundated with Complexity, Challenges

Migraine management in patients with psychiatric conditions must take into account the complications that plague both disease states.

“Compliance and adherence are the biggest pitfalls because studies have shown that patients [with psychiatric conditions] are more likely to over- or underuse medications,” said Rania El-Desoky, PharmD, BCPS, a postdoctoral fellow in the department of pharmacy practice and translational research at the University of Houston College of Pharmacy in Texas.

Both disease states can have severe consequences. Taking a non-steroidal anti-inflammatory drug (NSAID) or triptan either more frequently than prescribed or at a higher dose can trigger migraines—a phenomenon known as medication overuse headache.2

Conversely, medication underuse has its own set of hurdles. Such is the case with prophylactic migraine therapy, which typically takes 4 to 12 weeks before symptoms start to improve. Often discouraged by not experiencing immediate results, many patients either stop taking prophylactic medications regularly or discontinue them altogether.

Poor adherence can give rise to a prescribing cascade, and the increasing complexity of the patient’s drug regimen can often worsen outcomes. Because patients with psychiatric conditions often have multiple prescriptions, adding migraine therapy can become a delicate balancing act.

“The key here is to optimize the patients’ medications and decrease the pill burden,” El-Desoky said. She recommends choosing a preventative migraine medication that also can address other comorbidities the patients have. Venlafaxine makes a good choice for a patient who has post-traumatic stress disorder in addition to migraines. Nortriptyline and amitriptyline ease insomnia and depression as well as migraine symptoms.

Some medications routinely used in migraine management are not appropriate for certain psychiatric conditions. For instance, β-blockers and the calcium channel blocker verapamil can worsen depressive symptoms and should be avoided in patients with depression, according to Lama Al-Khoury, MD, associate clinical professor of neurology at the University of California, Riverside, School of Medicine.

Serotonin-norepinephrine reuptake inhibitors (SNRIs) should be avoided in patients who have bipolar disorder because they can trigger hypermanic episodes. Instead, a mood stabilizer such as divalproex sodium (Depakote) may be a better choice. Al-Khoury warns against the use of divalproex in women of childbearing age because of its teratogenicity.

Medications that can potentiate serotonic effects, including serotonin syndrome, should be avoided or used with care in patients with migraines. Al-Khoury advises pharmacists to educate patients taking antidepressants/serotonergic medications to limit using abortive therapies such as triptans to no more than 2 days per week to prevent dangerous serotonin levels. El-Desoky encourages pharmacists also to look for less-obvious culprits such as cyclobenzaprine and tramadol.

Opportunities for Pharmacists

Experts say pharmacists have
**PHARMACISTS CAN HELP MANAGE MIGRAINES / PAIN**

numerous opportunities to enhance patient care in this population.

Communicate. A patient’s migraine or psychiatric condition can affect their ability to remember their medication history. As a result, they may forget to mention a medication or supplement. The negative stigmas associated with migraine and psychiatric conditions may cause some patients to omit the frequency of intake. Pharmacists’ access to prescription records and their increased patient interaction can help bridge the gap.

“It’s always appreciated when pharmacists flag potential interactions in patients who may not be as forthcoming with all [their] medications, along with the frequency and dosing.”

Cristina Wohlgehagen, MD

appropriate for every patient—especially patients [with psychiatric conditions] who are already taking many medications and struggle with [adherence],” Al-Khoury said.

In some cases, this might entail investigating underlying causes of a patient’s migraines. Stress triggers migraines in 70% of those with the condition.

Pharmacists can remind patients about potentially bothersome symptoms and teach them to recognize signs of harmful adverse effects (AEs). The teaching aspect proves particularly critical with regards to improving adherence. El-Desoky urged her colleagues to ensure patients understand the importance of taking prophylactic medications regularly as prescribed and emphasizing it may take up to 12 weeks before their symptoms improve. Patients should leave the encounter understanding the importance of not skipping doses.

Document. Both El-Desoky and Al-Khoury encourage patients to keep headache diaries to document the frequency, time, and resolution of their migraines.

Consider nonpharmacological options when possible.

“Pharmacological therapy is not

Monitor. Monitoring is critical in this patient population, as many medications have bothersome AEs or other challenges. For example, high-dose venlafaxine therapy can raise blood pressure, and the pharmacist should follow up with patients when they refill their prescriptions or visit the pharmacy for other reasons.

Similarly, pharmacists’ recurring patient encounters offer numerous opportunities to assess the patient’s progress and reinforce adherence. El-Desoky recommended encouraging patients to use pill boxes and medication organizers. Although mobile device apps, phone messages, and alarms can also serve as helpful tools, El-Desoky noted that her patients experienced greater benefit from making medication charts.

Multidisciplinary Practice

Despite the continued push toward collaborative practice, the health care industry remains largely fragmented.

“I have rarely seen multidisciplinary interactions between pharmacists and physicians outside large academic facilities where you tend to have neurologists, psychiatrists, and pharmacists on board,” Al-Khoury said.

Despite this hurdle, El-Desoky seems optimistic and encourages pharmacists to capitalize on in-pharmacy services and any other opportunities to demonstrate their value.

“Every facility has an opportunity for pharmacists and other practitioners to present their knowledge,” she said. “Tell them, I’m here and able to help.”

For references, visit drugtopics.com.
Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.
SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
• Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
You may already be vaccinating patients against shingles in your pharmacy—but are you considering ALL appropriate patients? Because no matter how healthy they may feel, people aged ≥50 years are at risk for shingles. That’s why CDC recommends you vaccinate immunocompetent adults 50 years and older with SHINGRIX. Review the CDC Recommendations below—they may help you identify patients and establish protocols.

**Important Considerations for CDC Recommendations**

- There are limited data on vaccination with SHINGRIX in patients previously vaccinated with ZVL compared to those not previously vaccinated with ZVL.
- In a phase 3 study, humoral immunogenicity was non-inferior among subjects previously vaccinated at least 5 years earlier with ZVL.
- No apparent safety differences were observed between study groups within 30 days post-dose 2 of SHINGRIX.
- Solicited local and systemic symptoms were similar between study groups.
- The levels of antibodies and immune cells that correlate with protection against shingles have not been clearly defined.
- There are no head-to-head clinical trials comparing the efficacy and safety of SHINGRIX to ZVL.

**Preferred over ZVL for the prevention of herpes zoster and related complications**

- CDC Recommendations state that SHINGRIX is recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years.
- CDC Recommendations state that SHINGRIX is not indicated for the prevention of herpes zoster-related complications.

*ACIP recommendations adopted by CDC.

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**Important Safety Information (cont’d)**

- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion.
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients.

**References:**


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Explore the efficacy data for patients 50 years and older by visiting SHINGRIXefficacy.com

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BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 28,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.3%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.9%), redness (38.1%), and swelling (25.3%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1.

Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Days of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older. (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>SHINGRIX</th>
<th>Placebo</th>
<th>SHINGRIX</th>
<th>Placebo</th>
<th>SHINGRIX</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-59 Years</td>
<td>1,315</td>
<td>1,312</td>
<td>1,311</td>
<td>1,305</td>
<td>2,258</td>
<td>2,263</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
<td>0.5</td>
<td>4.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
<td>0.0</td>
<td>3.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
<td>0.0</td>
<td>1.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
<td>0.8</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
<td>16.8</td>
<td>36.6</td>
<td>14.4</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
<td>0.8</td>
<td>3.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
<td>0.2</td>
<td>1.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
<td>0.3</td>
<td>2.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
<td>0.6</td>
<td>1.2</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

* 7 days included day of vaccination and the subsequent 6 days.

a Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

b Placebo was a saline solution.

c Grade 3 pain: Defined as signiﬁcant pain at rest; prevents normal everyday activities.

d Grade 3 myalgia: fatigue, headache, shivering, GI: Defined as preventing normal activity.

e Fever deﬁned as ≥39.5°C/103.0°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever deﬁned as ≥39.0°C/102.2°F.

f GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,860), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively; within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.1%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects aged 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions (6.1)].

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:
Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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Over the last 20 years, the price of insulin has dramatically increased, which has led to many individuals rationing this lifesaving drug. Unfortunately, there have been deaths reported in patients with diabetes due to insulin’s lack of affordability. Since about 90% of insulin sold in the United States is manufactured by 3 companies, there is limited direct competition. Pharmacists can play an integral role in helping patients access and afford insulin, especially during the coronavirus disease 2019 (COVID-19) pandemic.

Insulin Prices and Counseling Pearls

In an interview with Drug Topics®, Sandra Leal, PharmD, MPH, FAPhA, CDCES, executive vice president of Tabula Rasa HealthCare and president-elect of the American Pharmacists Association (APhA), said that APhA is examining why drug prices in general are increasing, and the organization is helping patients navigate this complex system. Even though insulin manufacturers are not experiencing drug shortages, mail order delays have slowed the delivery of medications, which could affect adherence. The American Diabetes Association (ADA) recommends that health care providers “prescribe the lowest-priced insulin required to effectively and safely achieve treatment goals.” The ADA maintains a comprehensive list of resources to help patients afford insulin products and medical devices.

“Pharmacists should always be good advocates and put the patient first,” Leal said. Amid the pandemic, Leal discussed the importance of educating patients transitioning to different insurance plans and assisting individuals who are uninsured about the best and most affordable insulin options. Individuals also should be educated about patient assistance programs (PAPs) and discount cards for insulin savings.

Insulin is now regulated as a biological product after recent regulatory changes to facilitate the approval of biosimilars. The biologic product insulin glargine injection (Semglee) vial and pen are FDA approved and recently launched in the US at a 65% discounted list price, and Mylan is seeking biosimilar status for Lantus with the FDA. Some states have approved insulin copay cap legislation, and the ADA has urged governors to implement zero-dollar copayments for insulin during COVID-19. The Trump administration signed executive orders that include lowering insulin drug costs. Additionally, Medicare Part D prescription drug plans will provide insulin at a maximum $35 copay per month.

The savings programs and recent state and federal laws are an important step in the right direction, but there is still more work to be done for expanded access to affordable insulin. For references, visit drugtopics.com.

Eli Lilly and Company has introduced the Lilly Insulin Value Program $35 copay card (monthly) for those with and without insurance, and the manufacturer has developed additional patient assistance programs (PAPs) as well. Humalog U-100, Humalog Mix75/25, and Humalog Junior KwikPen are available as lower-priced versions at a 50% discount and can be ordered through pharmacies.

Novo Nordisk is offering a free 90-day supply of insulin through their PAP to patients who have lost health insurance coverage because of a change in job status due to the coronavirus disease 2019. The My$99Insulin program provides individuals with up to 3 vials or 2 packs of FlexPen/FlexTouch/PenFill pens of any combination of Novo Nordisk insulins with a prescription for $99. Authorized generics of NovoLog and NovoLog Mix are available at 50% off the list price of brand products.

Sanofi offers copay assistance programs and an Insulins Valyou Savings Program for patients without insurance that is $99 per month for 1 or multiple insulins (up to 10 packs of pens and/or 10 mL vials per month).

MannKind Corporation has a savings card ($15 per prescription fill) for insulin human (Afrezza) inhalation powder for patients with insurance. (APhA), said that APhA is examining why drug prices in general are increasing, and the organization is helping patients navigate this complex system. Even though insulin manufacturers are not experiencing drug shortages, mail order delays have slowed the delivery of medications, which could affect adherence. The American Diabetes Association (ADA) recommends that health care providers “prescribe the lowest-priced insulin required to effectively and safely achieve treatment goals.” The ADA maintains a comprehensive list of resources to help patients afford insulin products and medical devices.

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Pharmacists Are Key Players in Improving Vaccination Rates During Pandemic

The combined landscape of flu and COVID-19 presents challenges to vaccine uptake. By Gabrielle Ientile, Assistant Editor

Under normal circumstances, pharmacists are a critical component of vaccine uptake, as well as a trusted resource for patients looking to make informed decisions about the risks and benefits of vaccination.

In March, the United States began lockdown measures and stay-at-home orders to protect the public from coronavirus disease 2019 (COVID-19) exposure. Even as restrictions lifted, many Americans continued to avoid potential exposure by social distancing, which led to decreased uptake of routine vaccinations. Now, with the “twin-demic” of the COVID-19 pandemic and influenza season under way, the pharmacy workforce, more than ever, is positioned to support vaccine uptake of flu and COVID-19 vaccines.

A session presented at the National Community Pharmacists Association (NCPA) 2020 Annual Convention held online October 18-19 tackled the effect that the pandemic has had on vaccination rates in the United States and how pharmacists can aid in improving uptake.

The Impact of COVID-19 on Routine Vaccination
David Ha, PharmD, BCIDP, infectious diseases and antimicrobial stewardship pharmacist at Stanford Health Care, in Palo Alto, California, discussed the combined landscape of influenza and COVID-19 vaccination amid the pandemic and 2020-2021 flu season.

Ha explained that following the national emergency declaration on March 13, 2020, the CDC released guidance documents highlighting pharmacies as a vital part of the health care system, with their ability to function during the pandemic being critical. However, the early recommendations included postponing and rescheduling receiving immunizations. “Suffice to say, regardless of the age group, there was a dramatic decline in pediatric and adult vaccination,” Ha said during his presentation.

This decline was documented in a CDC report published in May, in which investigators identified a notable decrease in routine pediatric vaccine ordering and doses administered following the national emergency declaration. In August, the Department of Health and Human Services made an effort to expand access by authorizing all state-licensed pharmacists to order and administer childhood vaccinations during the pandemic.

Ha also discussed the similarities and differences in influenza and COVID-19 infections, outlined below:

**Similarities:**
- Both can be transmitted through respiratory droplets.
- Both show clinical manifestations.
- Groups at high risk for infection include those of advanced age, who are obese, or who have multiple comorbidities such as diabetes; and individuals in nursing homes.

**Differences:**
- COVID-19 is much more contagious.
- COVID-19 is generally mild or asymptomatic in pediatric patients with COVID-19, compared with more severe illness in pediatric patients with influenza.

Ha mentioned the significance of similar transmission methods, as both viruses are transmitted through respiratory droplets. “This is particularly important because, potentially, some”

“Some of the infection prevention strategies that we’re using to prevent the spread of COVID-19 may also secondarily work against influenza.”

David Ha, PharmD, BCIDP
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PHARMACISTS ARE KEY PLAYERS IN IMPROVING VACCINATION RATES / VACCINES

of the infection prevention strategies that we’re using to prevent the spread of COVID-19 may also secondarily work against influenza,” Ha said.

Ha explained that COVID-19 being more contagious than influenza may change, since the data is based on nonpharmacologic intervention, infection prevention measures, and vaccinations.

Ha noted that during the Southern Hemisphere’s most recent influenza season, which aligned with the COVID-19 pandemic, the World Health Organization identified very few confirmed influenza cases.

“There are a number of different hypotheses of why this could be the case. Perhaps the lockdown, sheltering in place, masking, and other types of transmission prevention practices in the Southern Hemisphere countries during that time prevented influenza transmission. Perhaps, as well, there was a drifting in terms of testing for influenza,” Ha said.

As for the Northern Hemisphere’s guidance for its 2020-2021 flu season, the core recommendations have stayed the same: individuals aged 6 months or older who do not have a contraindication should get a flu vaccine.

The Pharmacist’s Role in COVID-19 Vaccination

Jeff Goad, PharmD, MPH, FAPhA, FCPhA, FCSHP, professor and chair of the Department of Pharmacy Practice at Chapman University in Orange, California, honed in on the opportunities and responsibilities for pharmacists amid the 2020-2021 flu season, citing several reasons why “pharmacy is critical and an important player in immunizations, both now and in the future,” he said.

Goad said the following are factors in pharmacists’ key role in COVID-19 vaccine distribution and uptake:

- Authorization to vaccinate
- Workforce

“The government, the public-private partnerships, everyone is counting on pharmacy to be a major hub for distribution of the [COVID-19] vaccine to a very large population.”

Jeff Goad, PharmD, MPH, FAPhA, FCPhA, FCSHP

- Access
- Storage
- Existing immunization patient relationship
- Vaccine confidence
- Documentation

“The government, the public-private partnerships, everyone is counting on pharmacy to be a major hub for distribution of the vaccine to a very large population,” Goad said.

In addition to the 300,000 licensed pharmacists working in both the chain and community settings, there also are more than 62,000 student pharmacists and interns, all of whom are critical to the COVID-19 vaccine effort.

Pharmacists also are more accessible to the American public: 86% of the US population lives within 5 miles of a pharmacy—“A unique aspect of pharmacy [which] is probably going to be very important in fitting into the lives of Americans who have to get 2 doses of a coronavirus vaccine in very short order, is the ability to access those services when they want it,” Goad said, noting that pharmacies are often open on weekends, holidays, and later into the evening, and sometimes 24 hours a day.

Goad also discussed the trend that individuals are increasingly trusting pharmacists to administer their vaccines; physicians, including all specialties, administer 34% of flu vaccinations in the US, and pharmacies administer 32%.

The presentation also touched upon the COVID-19 vaccines most likely to be authorized for distribution to the public in the United States, notably Moderna’s and Pfizer’s respective mRNA vaccines in development. Both will be administered in 2 doses; however, although Moderna’s vaccine requires storage at normal freezer temperatures (≥20 °C), Pfizer’s vaccine must be stored at -70 °C, creating a challenge for the majority of pharmacies. However, Goad stressed that the stability data is always evolving, so paying attention to developments is key.

“Innovation always rules the day, and we have seen ultracool units being developed and potentially might be a part of vaccine distribution to eliminate the need to purchase an ultracool freezer. Stay tuned, things change fast here,” he said.

Although storage temperatures could potentially create a challenge for pharmacies, according to Goad, “the toughest battle is vaccine confidence.”

Goad pointed to a Gallup survey from August 7, 2020, which reported that 1 in 3 Americans would not get the COVID-19 vaccine.1

According to Goad, myths are deadly to vaccine efforts, and pharmacists have the responsibility to address myths and provide accurate information to their customers.

“These are some of the things we need to stop right away, so that people get the correct information and can make an informed decision about the risks and benefits of vaccination that’s our job and that’s our mission as pharmacy,” Goad said.

For references, visit drugtopics.com.
Indication for AirDuo RespiClick/Authorized Generic

AirDuo RespiClick is indicated for the treatment of asthma in patients aged 12 years and older. AirDuo RespiClick is only for patients uncontrolled on an inhaled corticosteroid (ICS) or whose disease severity clearly warrants an ICS/Long-acting beta₂-agonist (LABA).

Important Limitation of Use: AirDuo RespiClick is NOT indicated for the relief of acute bronchospasm.

Important Safety Information for AirDuo RespiClick/Authorized Generic

- **Contraindications:** AirDuo RespiClick is contraindicated in:
  - Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive measures
  - Patients with known severe hypersensitivity to milk proteins or any ingredients of AirDuo RespiClick

Please see additional Important Safety Information and Brief Summary of Full Prescribing Information on the following pages.
AirDuo RespiClick® (fluticasone propionate and salmeterol) Inhalation Powder:

**ASTHMA CONTROL WITH LESS MEDICINE**

**Recommended starting dose: 1 inhalation twice daily**¹⁻³

<table>
<thead>
<tr>
<th></th>
<th>AirDuo RespiClick</th>
<th>Authorized Generic</th>
<th>ADVAIR DISKUS®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Fluticasone propionate + Salmeterol</td>
<td>55 mcg + 14 mcg</td>
<td>55 mcg + 14 mcg</td>
</tr>
<tr>
<td>Medium</td>
<td>Fluticasone propionate + Salmeterol</td>
<td>113 mcg + 14 mcg</td>
<td>113 mcg + 14 mcg</td>
</tr>
<tr>
<td>High</td>
<td>Fluticasone propionate + Salmeterol</td>
<td>232 mcg + 14 mcg</td>
<td>232 mcg + 14 mcg</td>
</tr>
</tbody>
</table>

ADVAIR DISKUS® is a registered trademark of the GSK group of companies.

Table is intended to show differences in dosing only and should not be construed to imply safety or efficacy similarities or differences.

**IMPORTANT SAFETY INFORMATION for AirDuo RespiClick/Authorized Generic (continued)**

- **Serious Asthma-Related Events – Hospitalizations, Intubations, Death:** Use of LABA as monotherapy (without ICS) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone.

- **Deterioration of Disease and Acute Episodes:** AirDuo RespiClick should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. AirDuo RespiClick is not indicated for the relief of acute bronchospasm. An inhaled, short-acting beta₂-agonist, not AirDuo RespiClick, should be used to relieve acute symptoms such as shortness of breath.

- **Excessive Use and Use with Other Long acting Beta₂-Agonists:** AirDuo RespiClick should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AirDuo RespiClick should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason.

Please see additional Important Safety Information throughout and Brief Summary of Full Prescribing Information on the following pages.
• **Local Effects of ICS:** Oropharyngeal candidiasis has occurred in patients treated with AirDuo RespiClick. If this occurs, treat with appropriate local or systemic (i.e., oral) antifungal therapy while treatment with AirDuo RespiClick continues, but at times therapy with AirDuo RespiClick may need to be interrupted. Advise the patient to rinse his/her mouth with water without swallowing following inhalation.

• **Immunosuppression:** Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use with caution in patients with the above because of the potential for worsening of these infections.

• **Transferring Patients from Systemic Corticosteroid Therapy:** Particular care is needed for patients who have been transferred from systemically active corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available ICS. Taper patients slowly from systemic corticosteroids if transferring to AirDuo RespiClick.

• **Hypercorticism and Adrenal Suppression** may occur with high doses of ICS, including fluticasone propionate, or at the recommended dose in susceptible individuals. If such changes occur, discontinue AirDuo RespiClick slowly.

• **Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors:** The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, ketoconazole) with AirDuo RespiClick is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

• **Paradoxical Bronchospasm and Upper Airway Symptoms:** If paradoxical bronchospasm occurs, discontinue AirDuo RespiClick immediately and institute alternative therapy.

• **Hypersensitivity Reactions, Including Anaphylaxis:** Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of AirDuo RespiClick. Discontinue AirDuo RespiClick if such reactions occur.

• **Cardiovascular and Central Nervous System Effects:** Salmeterol, a component of AirDuo RespiClick, can produce clinically significant cardiovascular effects in some patients as measured by pulse rate, blood pressure, and/or symptoms. If such effects occur, AirDuo RespiClick may need to be discontinued. AirDuo RespiClick should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

• **Reduction in Bone Mineral Density (BMD):** Decreases in BMD have been observed with long-term administration of products containing ICS. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care.

• **Effect on Growth:** ICS, as well as poorly controlled asthma, may cause a reduction in growth velocity, and the long-term effect on final adult height is unknown. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients.

• **Glaucoma and Cataracts:** Long-term use of ICS, including fluticasone propionate, a component of AirDuo RespiClick, may increase the risk for cataracts or glaucoma. Regular eye exams should be considered.

• **Eosinophilic Conditions and Churg-Strauss Syndrome:** Systemic eosinophilic conditions, such as Churg-Strauss syndrome, may occur. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy.

• **Coexisting Conditions:** Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

• **Hypokalemia and Hyperglycemia:** Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects.

Please see additional Important Safety Information on the previous pages and Brief Summary of Full Prescribing Information on the following pages.
AirDuo RespiClick® (fluticasone propionate and salmeterol) Inhalation Powder:

**ASTHMA CONTROL WITH LESS MEDICINE**

<table>
<thead>
<tr>
<th>Total Daily Dose</th>
<th>Fluticasone propionate + Salmeterol</th>
<th>Fluticasone propionate + Salmeterol</th>
<th>Fluticasone propionate + Salmeterol</th>
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</thead>
<tbody>
<tr>
<td>Low</td>
<td>110 mcg + 28 mcg</td>
<td>110 mcg + 28 mcg</td>
<td>200 mcg + 100 mcg</td>
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<tr>
<td>Medium</td>
<td>226 mcg + 28 mcg</td>
<td>226 mcg + 28 mcg</td>
<td>500 mcg + 100 mcg</td>
</tr>
<tr>
<td>High</td>
<td>464 mcg + 28 mcg</td>
<td>464 mcg + 28 mcg</td>
<td>1000 mcg + 100 mcg</td>
</tr>
</tbody>
</table>

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Table is intended to show differences in dosing only and should not be construed to imply safety or efficacy similarities or differences.

**IMPORTANT SAFETY INFORMATION for AirDuo RespiClick/Authorized Generic (continued)**

- **Adverse Reactions:** Most common adverse reactions (reported in greater than or equal to 3% of patients) include nasopharyngitis, oral candidiasis, headache, cough and back pain

Please see Important Safety Information on the previous pages and Brief Summary of Full Prescribing Information on the following pages.

References

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**BRIEF SUMMARY OF PRESCRIBING INFORMATION FOR AIRDUO® RESPICLICK®**

(Fluticasone propionate and salmeterol) inhalation powder, for oral inhalation and the Authorized Generic for (fluticasone propionate and salmeterol) inhalation powder

SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

**Initial U.S. Approval: 2000**

1  **INDICATIONS AND USAGE**

AIRDUO® RESPICLICK® is indicated for the treatment of asthma in patients aged 12 years and older. AIRDUO RESPICLICK should be used for patients not adequately controlled on a long term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and a long-acting beta2-adrenergic agonist (LABA).

**Limitations of Use:**

AIRDUO RESPICLICK is NOT indicated for the relief of acute bronchospasm.

2  **CONTRAINDICATIONS**

4.1  **Status Asthmaticus**

AIRDUO RESPICLICK is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required [see Warnings and Precautions (5.10)].

5  **WARNINGS AND PRECAUTIONS**

5.1  **Serious Asthma-Related Events — Hospitalizations, Intubations, Death**

Use of LABA as monotherapy (without inhaled corticosteroids (ICS)) for asthma is associated with an increased risk of asthma-related death (see Salmeterol Multicenter Asthma Research Trial (SMART)). Results from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. The findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone [see Serious Asthma-Related Events with Inhaled Corticosteroid/Long-acting Beta2-Adrenergic Agonists (LABA/LABS) Combination Therapy].

Four large, 28-week, randomized, blinded, active-controlled clinical safety trials were conducted to evaluate the risk of serious asthma-related events when LABA were used in fixed-dose combination with ICS compared with ICS alone in subjects with asthma. Three (3) trials included adult and adolescent subjects aged 12 years and older, and 1 trial compared budesonide/formoterol to budesonide, 1 trial compared fluticasone propionate/salmeterol inhalation powder to fluticasone propionate inhalation powder, and 1 trial compared mometasone furoate/formoterol to mometasone furoate. The fourth trial included pediatric subjects aged 4 to 11 years and compared fluticasone propionate/salmeterol inhalation powder to fluticasone propionate inhalation powder. The primary safety endpoint for all 4 trials was serious asthma-related events (hospitalizations, intubations, death). A blinded adjudication committee determined whether events were asthma-related. The 3 adult and adolescent trials were designed to rule out a risk margin of 2.0, and the pediatric trial was designed to rule out a risk margin of 2.7. Each individual trial met its hazard ratio of time to first event compared to ICS based on the prespecified risk margin (2.7), with an estimated baseline hazards stratified by each of the 3 trials. These reports to determine whether salmeterol contributed to these events.

When beginning treatment with AIRDUO RESPICLICK, patients who have been taking oral or inhaled, short-acting beta2-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs.

5.3  **Excessive Use of AIRDUO RESPICLICK and Use with Other Long-Acting Beta2-Agonists**

AIRDUO RESPICLICK should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AIRDUO RESPICLICK should not use another medicine containing a LABA (e.g., fluticasone propionate and salmeterol) because the healthcare provider should also prescribe an inhaled, short-acting beta2-agonist (e.g., albuterol) for treatment of acute symptoms, despite regular twice-daily use of AIRDUO RESPICLICK.

When beginning treatment with AIRDUO RESPICLICK, patients who have been taking oral or inhaled, short-acting beta2-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs.

5.4  **Local Effects of Inhaled Corticosteroids**

In clinical trials, the development of localized infections of the mouth and pharynx with Candida albicans has occurred in subjects treated with AIRDUO RESPICLICK. When such an infection develops, it should be treated with appropriate local or systemic therapy. If a patient is exposed to chickenpox, prophylaxis with varicella-zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG) may be indicated. If a patient is exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IM) may be indicated. (See respective package inserts for complete VZIG and IM prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.6  **Transferring Patients from Systemic Corticosteroid Therapy**

AIRDUO RESPICLICK should be transferred to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.
Patients who have been previously maintained on 20 mg or more of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastrointestinal), or other conditions associated with severe electrolyte loss. Although AIRDUO RESPICLICK may improve control of asthma symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of corticosteroid systemically and does NOT provide the mineralocorticoid activity that is necessary for coping with these emergencies. During periods of stress or a severe asthmatic attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physician for further instruction. These patients should also be instructed to carry a medical identification warning card indicating that they may need supplemental systemic corticosteroids during periods of stress or a severe asthma attack.

Patients requiring systemic corticosteroids should be weaned slowly from systemic corticosteroids prior to conversion to AIRDUO RESPICLICK. Lung function (mean forced expiratory volume in 1 second [FEV₁], or morning peak expiratory flow [AM PEF]), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of systemic corticosteroids. Some patients may experience symptoms of systemically active corticosteroid withdrawal (e.g., joint and/or muscular pain, lassitude, depression) despite maintenance or even improvement of respiratory function.

5.7 Hypercorticism and Adrenal Suppression
Fluticasone propionate, a component of AIRDUO RESPICLICK, will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since fluticasone propionate is absorbed into the circulation and can be systemically active at higher doses, the beneficial effects of AIRDUO RESPICLICK in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose. A relationship between plasma levels of fluticasone propionate and inhibitory effects on stimulated cortisol production has been shown after 4 weeks of treatment with fluticasone propionate inhalation aerosol. Since individual sensitivity to effects on cortisol production exists, physicians should consider this information when prescribing AIRDUO RESPICLICK.

Because of the possibility of significant systemic absorption of inhaled corticosteroids, patients treated with AIRDUO RESPICLICK should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response. It is possible that transfer to corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients who are sensitive to these effects. If such effects occur, AIRDUO RESPICLICK should be discontinued immediately; and alternative treatment, consisting with accepted procedures for reducing systemic corticosteroids, and for management of asthma symptoms.

5.8 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors
The CYP3A4 (CYP3A4) inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, neflinavir, saquinavir, ketoconazole, telithromycin) with AIRDUO RESPICLICK is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur [See Drug Interactions (7.1)].

5.9 Paradoxical Bronchospasm and Upper Airway Symptoms
As with other medicines, AIRDUO RESPICLICK can produce paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs following dosing with inhaled fluticasone propionate/salmeterol medicines, it should be treated promptly with an inhaled, short-acting bronchodilator; inhaled fluticasone propionate/salmeterol medicines should be discontinued immediately; and alternative therapy should be instituted. Upper airway symptoms of taryngal spasm, irritation, or swelling, such as stridor and choking, have been reported in patients receiving inhaled fluticasone propionate/salmeterol medicines.

5.10 Hypersensitivity Reactions, Including Anaphylaxis
Inhalation of the test aerosol (e.g., artichoke, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of AIRDUO RESPICLICK. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder products containing lactose; therefore, patients with severe milk protein allergy should not use AIRDUO RESPICLICK [see Contraindications (4)].

Excessive beta-adrenergic stimulation has been associated with seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, palpitation, nausea, dizziness, fatigue, malaise, and insomnia [see Overdosage (10)]. Therefore, AIRDUO RESPICLICK, like all products containing sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
6.1 Clinical Trials Experience in Asthma

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In two placebo-controlled, 12-week, clinical studies (Trials 1 and 2) a total of 1,364 adolescent and adult patients with persistent symptomatic asthma despite ICS or ICS/LABA therapy were treated twice daily with either placebo; fluticasone propionate, 113 mcg or 232 mcg; or fluticasone propionate (113 mcg or 232 mcg) with AIRDUO RESPICLICK (hereafter referred to as fluticasone propionate MDPI); or AIRDUO RESPICLICK 55 mcg/14 mcg, 113 mcg/14 mcg, or 232 mcg/14 mcg. Ninety percent of patients were female and 80% of patients were white. The average duration of exposure was 82 to 84 days in the fluticasone propionate MDPI and AIRDUO RESPICLICK treatment groups compared with 75 days in the placebo group. Table 2 displays the incidence of most common adverse reactions in pooled Trials 1 and 2.

| Table 2: Adverse Reactions with ≥3% Incidence with AIRDUO RESPICLICK, and More Common than Placebo in Subjects with Asthma (Trials 1 and 2) |
|-----------------|------------------|-----------------|-------------------|-----------------|
| Adverse Reaction | Fluticasone Propionate MDPI (n=129) | Fluticasone Propionate MDPI (n=133) | Fluticasone Propionate MDPI (n=148) |
| | % | % | % |
| Nasopharyngitis | 5.4 | 5.6 | 4.8 |
| | 4.6 | 3.9 | 4.4 |
| Oral candidiasis* | 5.4 | 4.9 | 4.8 |
| | 2.2 | 3.4 | 2.7 |
| Headache | 16.8 | 16.7 | 18.5 |
| | 2.5 | 2.5 | 3.7 |
| Cough | 16.0 | 16.0 | 17.1 |
| | 3.3 | 3.3 | 4.8 |
| Back pain | 1.6 | 1.6 | 1.8 |
| | 1.4 | 1.1 | 1.8 |

* Oral candidiasis includes oropharyngeal candidiasis, oral fungal infection, and oropharyngitis.

Other adverse reactions not previously listed (and occurring in ≥3% of patients and in three or more patients on AIRDUO RESPICLICK) that were reported more frequently by patients with asthma treated with AIRDUO RESPICLICK compared with patients treated with placebo include the following:

Sinusitis, oropharyngeal pain, pharyngitis, dizziness, influenza, rhinitis allergic, rhinitis nasale, rhinitis anginose, abdominal pain upper, myalgia, pain in extremity, dyspepsia, laceration, dermatitis contact, and palpitations.

Long Term Safety Study: This was a 26-week, open labeled study of 674 patients previously treated with ICS who were treated twice daily with fluticasone propionate, 113 mcg or 232 mcg; AIRDUO RESPICLICK 113 mcg/14 mcg or 232 mcg/14 mcg; fluticasone propionate and salmeterol inhalation powder (250 mcg/50 mcg), or fluticasone propionate and salmeterol inhalation powder (500 mcg/50 mcg). The types of adverse reactions were similar to those reported above in placebo controlled studies.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been identified during post approval use of fluticasone propionate and/or salmeterol regardless of indication. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to their seriousness, frequency of reporting, or causal connection to fluticasone propionate and/or salmeterol or a combination of these factors.

Cardiac Disorders: Arrhythmias (including atrial fibrillation, extrasystoles, supraventricular tachycardia, premature tachycardia).

Endocrine Disorders: cushing’s syndrome, Cushingoid features, growth velocity reduction in children/adolescents, hypertension.

Eye Disorders: Blurred vision and central serous choriorretinopathy.

Gastrointestinal Disorders: Abdominal pain, dyspepsia, xerostomia.

Immune System Disorders: Immediate and delayed hypersensitivity reaction (including very rare anaphylactic reaction). Very rare anaphylactic reaction in patients with severe milk protein allergy.

Infections and Infestations: Esophageal candidiasis.

Metabolic and Nutritional Disorders: Hypoglycemia, weight gain.

Musculoskeletal Disorders: Connective Tissue, and Bone Disorders: Arthralgia, cramps, myositis, osteoporosis.

Nervous System Disorders: Parathesia, restlessness.

Psychiatric Disorders: Agitation, aggression, depression. Behavioral changes, including hyperactivity and irritability, have been reported very rarely and primarily in children.

Respiratory, Thoracic, and Mediastinal Disorders: Chest congestion; chest tightness, dyspnea; facial and oropharyngeal edema, immediate bronchospasm; paradoxical bronchospasm; tachyphnea; wheezing; reports of upper respiratory symptoms of laryngeal spasm, irritation, or swelling such as stridor or choking.

Skin and Subcutaneous Tissue Disorders: Eczematoses, photodermatitis.

Vascular Disorders: Palpitations.

7. DRUG INTERACTIONS

AIRDUO RESPICLICK has been used concomitantly with other drugs, including short-acting beta-agonists, and intransal corticosteroids, commonly used in patients with asthma via MDPI 55 mcg, 113 mcg. No formal drug interaction trials have been performed with AIRDUO RESPICLICK.

7.1 Inhibitors of Cytochrome P450 3A4

Fluticasone propionate and salmeterol, the individual components of AIRDUO RESPICLICK, are substrates of CYP3A4. The use of strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, HIV protease inhibitors) with AIRDUO RESPICLICK is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur.

Ritonavir: Fluticasone Propionate: A drug interaction trial with fluticasone propionate aqueous nasal spray in healthy subjects has shown that ritonavir (a strong CYP3A4 inhibitor) can significantly increase plasma fluticasone propionate exposure, resulting in significantly reduced serum cortisol concentrations. During postmarketing use, there have been reports of clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects such as Cushings syndrome and adrenal suppression.

Ketoconazole: Fluticasone Propionate: Co-administration of orally inhaled fluticasone propionate (1,000 mcg) and ketoconazole (200 mg once daily) resulted in a 1.9-fold increase in plasma fluticasone propionate exposure and a 45% decrease in plasma cortisol area under the curve (AUC) but had no effect on urinary excretion of cortisol.

Salmeterol: In a drug interaction trial in 20 healthy subjects, co-administration of inhaled salmeterol (50 mcg twice daily) and oral ketoconazole (400 mg once daily) for 7 days resulted in greater systemic exposure to salmeterol (AUC increased 1.9-fold and Cmax increased 1.4-fold). Three (3) subjects were withdrawn due to beta-agonist side effects (2 with prolonged QTc and 1 with palpitations and sinus tachycardia). Although there was no statistical effect on the mean QTc, co-administration of salmeterol and ketoconazole was associated with more frequent increases in QTc duration compared with salmeterol and placebo administration.

7.2 Monoamine Oxidase Inhibitors and Tricyclic Antidepressants

AIRDUO RESPICLICK should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of these agents, because the action of salmeterol, a component of AIRDUO RESPICLICK, on the vascular system may be potentiated by these agents.

7.3 Beta-Adrenergic Receptor Blocking Agents

Beta-blockers not only block the pulmonary effect of beta-agonists, such as salmeterol, a component of AIRDUO RESPICLICK, but may also produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents for these patients. Beta-adrenergic blocking agents could be considered, although they should be administered with caution.

7.4 Non-Potassium-Sparing Diuretics

The co-administration and/or hyperkalemia that may result from the administration of non-potassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as salmeterol, a component of AIRDUO RESPICLICK, in patients when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of AIRDUO RESPICLICK with non-potassium-sparing diuretics.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no randomized clinical studies of AIRDUO RESPICLICK or individual monoprodcts, fluticasone propionate and salmeterol, in pregnant women. There are clinical considerations with the use of AIRDUO RESPICLICK in pregnant women [see Clinical Considerations]. Animal reproduction studies are available with the combination of fluticasone propionate and salmeterol as well as individual components. In animals, teratogenicity characteristic of corticosteroids, decreased fetal body weight and/or skeletal variations, in rats, mice, and rabbits were observed with subcutaneously administered maternal toxic doses of fluticasone propionate less than the maximum recommended human daily inhaled dose (MRHID) on a mcg/m² basis [see Data]. However, fluticasone propionate administered via inhalation to rats decreased fetal body weight, but did not induce teratogenicity at a maternal toxic dose less than the MRHID on a mcg/m² basis [see Data]. Experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroids than humans. Oral administration of salmeterol to pregnant rabbits caused teratogenicity characteristic of beta-adrenoceptor stimulation at maternal doses approximately 700 times the MRHID on a mcg/m² basis. These adverse effects generally occurred at large multiples of the MRHID when salmeterol was administered by the oral route to achieve high systemic exposures. No such effects occurred at an oral salmeterol dose approximately 420 times the MRHID [see Data].

The estimated risk of major birth defects or miscarriage for the indicated population is unknown. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

In women with poorly or moderately controlled asthma, there is an increased risk of several perinatal adverse outcomes such as preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. Pregnant women with asthma should be closely monitored and medication adjusted as necessary to maintain optimal asthma control.
In two embryo/fetal development studies, pregnant rats received salmeterol by oral administration at doses ranging from 100 to 10,000 mcg/kg/day during the period of organogenesis. Salmeterol produced no maternal toxicity or embryo/fetal effects at doses up to 5000 times the MRHDID (on a mcg/m² basis at maternal oral doses up to 10,000 mcg/kg/day).

In embryo/fetal development study in pregnant rats dosed by the oral route from late gestation through delivery and lactation, salmeterol at a dose 3500 times the MRHDID (on mcg/m² basis with a maternal oral dose of 10,000 mcg/kg/day) was fetotoxic and decreased the fertility of survivors. Salmeterol xinafoate crossed the placenta following oral administration to mice and rats.

8.2 Lactation

Risk Summary

There are no available data on the presence of fluticasone propionate or salmeterol in human milk, the effects on the breastfed child, or the effects on milk production. Other corticosteroids have been detected in human milk. However, fluticasone propionate and salmeterol concentrations in plasma after inhaled therapeutic doses are low and therefore concentrations in human breast milk are likely to be correspondingly low. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for AIRDUO RESPICLICK and any potential adverse effects on the breastfed child from AIRDUO RESPICLICK or from the underlying maternal condition.

Data

Animal Data

Subcutaneous administration of trifluoromethylated fluticasone propionate at a dose in lactating rats approximately 0.2 times the MRHDID for adults (on a mcg/m² basis) resulted in reduced maternal body weight and increases in maternal subcutaneous fat. Neither fluticasone propionate nor salmeterol at a dose approximately 2900 times the MRHDID for adults (on a mcg/m² basis) resulted in measurable levels in milk.

Bone Development

In a three-generation study in rats, fluticasone propionate (5 mcg/kg/day, p.o.; maternal oral dose of 30 mcg/kg/day) was assessed. No effects were noted on bone development.

Animal Drug Metabolism

Fluticasone propionate was teratogenic in both species. Omphalocele, decreased cranial bones, and skeletal variations were observed in mouse fetuses when combining fluticasone propionate at a dose approximately 0.2 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 30 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). The rat no observed adverse effect level (NOAEL) was observed when combining fluticasone propionate at a dose 0.6 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 30 mcg/kg/day) and a dose of salmeterol at approximately 350 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 1000 mcg/kg/day).

In an embryo/fetal development study with pregnant mice that received the combination of subcutaneous administration of fluticasone propionate and oral administration of salmeterol, maternal toxicity, at a dose approximately 2 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 100 mcg/kg/day) and a dose of salmeterol at approximately 3500 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day). The NOAEL was observed at approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 30 mcg/kg/day). Cleft palate and skeletal variations were observed in mouse fetuses at a dose approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 45 mcg/kg/day). The mouse NOAEL was observed at 0.16 times the MRHDID (on a mcg/m² basis at a maternal subcutaneous dose of 20 mcg/kg/day).

In an embryo/fetal development study with pregnant rats that were dosed by the inhalation route throughout the period of organogenesis, fluticasone propionate produced decreased fetal body weights and skeletal variations, in the presence of maternal toxicity, at a dose approximately 0.5 times the MRHDID (on a mcg/m² basis with a maternal inhalation dose of 5.5 mcg/kg/day).

In an embryo/fetal development study in pregnant rabbits that were dosed by the subcutaneous route throughout organogenesis, fluticasone propionate produced decreased fetal body weights and skeletal variations, in the presence of maternal toxicity, at a dose approximately 0.2 times the MRHDID and higher (on a mcg/m² basis with a maternal subcutaneous dose of 0.37 mcg/kg/day). Teratogenicity was evident based upon a finding of 1 fetus at a dose approximately 0.2 times the maternal NOAEL (on a mcg/m² basis at a maternal subcutaneous dose of 4 mcg/kg/day). The NOAEL was observed in rabbit fetuses at a dose approximately 0.004 times the MRHDID (on a mcg/m² basis with a maternal subcutaneous dose of 0.08 mcg/kg/day).

Fluticasone propionate crossed the placenta following subcutaneous administration to mice and rats and oral administration to rabbits. Salmeterol, from embryo/fetal development studies, pregnant rabbits received oral administration of salmeterol at doses ranging from 100 to 10,000 mcg/kg/day during the period of organogenesis. Pregnant Dutch rabbits administered salmeterol doses approximately 42 times the MRHDID (on a mcg/m² basis at maternal oral doses of 1000 mcg/kg/day and higher), fetal toxic effects were observed characteristically resulting from beta-adrenoceptor stimulation. These included precocious eyelid openings, cleft palate, delayed ossification of the frontal cranial bones. No such effects occurred at a salmeterol dose approximately 420 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 600 mcg/kg/day). New Zealand White rabbits were less sensitive since they delayed ossification of the frontal cranial bones was seen at a salmeterol dose approximately 7000 times the MRHDID (on a mcg/m² basis at a maternal oral dose of 10,000 mcg/kg/day).

8.3 Reproduction

8.4 Congenital Malformations

Fluticasone propionate and salmeterol, individually and in combination, were non-mutagenic in a variety of standard in vitro and in vivo assays. Fluticasone propionate and salmeterol individually at a dose 1/3000 and 1/100 of the MRHDID (on a mcg/m² basis at maternal oral doses of 100 and 1000 mcg/kg/day), respectively, were devoid of genotoxic effects in a series of in vitro genotoxicity tests using Chinese hamster ovary cells. Fluticasone propionate at the same dose was negative in an in vivo micronucleus assay in mice. Fluticasone propionate was negative in a battery of genotoxicity tests at a dose of 3 mg/kg/day in the Ames test in a two-generation study in rats.

8.5 Mutagenicity

Formal pharmacokinetic studies using AIRDUO RESPICLICK have not been conducted in patients with hepatic impairment. However, since both fluticasone propionate and salmeterol are predominantly cleared by hepatic metabolism, impairment of liver function may lead to accumulation of fluticasone propionate and salmeterol in plasma. Therefore, patients with hepatic impairment should be closely monitored.

8.6 Hepatic Impairment

Cardiac monitoring is recommended in cases of overdose.

Fluticasone propionate chronic overdosage of fluticasone propionate may result in signs/symptoms (see Warnings and Precautions (5.7)). Inhalation by healthy volunteers of a single dose of 4,000 mcg of fluticasone propionate inhalation powder or single doses of 1,780 or 3,520 mcg of fluticasone propionate CFC inhalation powder was well tolerated. Fluticasone propionate given by inhalation aerosolized doses of 1,320 mcg twice daily for 7 to 15 days to healthy human volunteers was also well tolerated. Repeat oral doses up to 60 mg daily for 10 days in healthy volunteers and repeat oral doses up to 20 mg daily for 42 days in subjects were well tolerated. Adverse reactions were of mild or moderate severity, and incidences were similar in active and placebo treatment groups.
AIRDUO® RESPICLICK® (fluticasone propionate and salmeterol) inhalation powder

Salmeterol
The expected signs and symptoms with overdosage of salmeterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms of beta-adrenergic stimulation (e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, insomnia, hyperglycemia, hypokalemia, metabolic acidosis). Overdosage with salmeterol can lead to clinically significant prolongation of the QTc interval, which can produce ventricular arrhythmias.

As with all inhaled sympathomimetic medicines, cardiac arrest and even death may be associated with an overdose of salmeterol.

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This brief summary is based on the AIRDUO® RESPICLICK® full prescribing information AIRDP1-005.
How Pharmacists Can Make the Most of Their Technicians’ Skills

Pharmacists can support technicians through training, incentives, and motivation. By Fred Gebhart

Good technicians can be the backbone of pharmacy operations. They answer the phone, ring up sales, input scripts, refill dispensing machines, and shepherd claims through adjudication, which allows pharmacists to focus on their job.

“Our analogy is the primary care provider,” explained Tripp Logan, PharmD, second-generation owner of L&S Pharmacy in Charleston, Missouri, and 2 other stores. “The physician doesn’t do intake or billing or all of those other essential, nonclinical tasks. We try to replicate that in pharmacy to free up our pharmacists to do what they are really good at, clinical work, and let our techs do the work they’re really good at, which is just about everything else that keeps the store running smoothly and our patients coming back.”

So how can pharmacists best use their technicians? By helping their techs work at the top of their own jobs with plenty of training, incentives, and motivation.

“I came here from a chain store, and this approach is 100% different,” said community pharmacy resident Heather Jarvis, PharmD, MBA, who works at L&S. “So many of the things I was used to doing at the chain store the techs handle as a matter of course. I had no idea technicians could give me so much more clinical time.”

That’s no surprise for Jody McConkey, MPA/HCM, CPhT, pharmacy standards and process controls senior manager for Banner Health in Phoenix, Arizona. For too many technicians, especially in retail, pharmacy is a job, not a career.

Pharmacy technicians, like other employees, try to meet expectations. Setting low expectations, with minimal support and no career path, is a prescription for low performance.

“Providing standardized training and the opportunity for professional growth not only engages technicians, it helps them grow and develop and support the pharmacist more effectively,” said McConkey, who is the head of the Pharmacy Technician Certification Board Certification Council. “Developing your techs, helping them develop themselves, can add real value to the pharmacist, make the pharmacist’s job easier, and improve patient care.”

Logan adopted that kind of support-the-technician approach several years ago. He dropped his company’s annual cost of living raise to instead focus on incentive raises based on professional education and credentials.

“If you want to become a certified pharmacy tech, we’ll cover the cost of the training and then give you a raise,” he said. “Every opportunity for training and credentialing comes with an incentive raise. Our techs can choose the courses they want, based on their own interests as well as our strategic goals for the pharmacy practice. Looking at our techs as part of the team has been very beneficial.”

Turning techs into team members gives what William Schimmel, executive director and CEO of the Pharmacy Technician Certification Board, calls a triple win.

“The pharmacist or the employer wins because they have strong performers. Individual technicians win by being rewarded for advancing through their careers. And most importantly, patients win by getting better care, which means better outcomes. The possibilities to support technicians and get more from technicians are endless as pharmacy evolves and technicians evolve with it,” Schimmel said. “For references, visit drugtopics.com.”

For the Latest Technician Certification Changes:
The Pharmacy Technician Certification Board (PTCB) has 5 specialty certificates:

- Controlled Substances Diversion Verification,
- Technician Product Verification,
- Medication History,
- Hazardous Drug Management, and
- Billing and Reimbursement.

A certificate program in immunization is in the works, and it will be followed by point-of-care testing and community health worker programs.

Any certified pharmacy technician who earns at least 4 certificates, or 3 certificates plus PTCB’s Compounded Sterile Preparation Technician (CSPT) Certification, can become an Advanced Certified Pharmacy Technician (CPhT-Adv). There is no additional fee or testing required for CPhT-Adv, but the credential must be recertified every 2 years with continuing education.

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SPECIAL REPORT

The Pharmacist’s Guide to CBD

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Cannabidiol (CBD) 101: Overview and Potential Interactions

By Joseph P. Nathan, PharmD, MS

During the past several years, the US market has seen an explosion in the popularity of cannabidiol (CBD)-containing products. These products are readily available to consumers through various retailers. Additionally, Epidiolex, a natural form of CBD, is available as a prescription drug for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients aged 1 year and older. Under US federal law, cannabis-derived products with very low levels of ∆-9-tetrahydrocannabinol (THC; < 0.3%) are considered “industrial hemp.” Per the Agriculture Improvement Act of 2018 (the 2018 Farm Act), cannabis plants and derivatives that contain no more than 0.3% THC are not considered controlled substances. It is important to note that CBD-containing products currently are not classified by the FDA as dietary supplements.

As the use of CBD-containing products continues to rise, it is imperative pharmacists be familiar with the clinical implications of CBD’s use, especially in patients who use other pharmacologically active substances.

Pharmacology

The cannabis plant possesses many compounds, including cannabinoids, terpenoids, flavonoids, nitrogenous compounds, and other molecules. Three major cannabinoids are ∆-9-THC (the psychoactive component associated with the intoxicating effects of cannabis and primarily involved in its recreational use), cannabiol (CBN), and CBD. The pharmacology of CBD is not fully understood. Studies suggest that its effects are related to its interaction with the endocannabinoid system. Some of its effects, however, are attributed to other mechanisms; for example, its anticonvulsant activities may involve a number of mechanisms, including blockade of G protein-coupled receptor 55 (GPR55) and T-type voltage-gated calcium channels, as well as stimulation of 5-HT1a and 5-HT2a receptors.

Clinical Use

CBD-containing products are marketed as remedies for various conditions, such as joint pain, back pain, insomnia, stress, depression, inflammation, mood elevation, immunity enhancement, improved brain activity, maintenance of hormonal balance, and indigestion. Many, if not most, of these claims have not been substantiated. In contrast, there are conditions for which limited evidence does exist that CBD may be of benefit. Examples include psychosis and schizophrenia, substance use disorders, seizure disorders, Parkinson disease and spasticity, and anxiety disorders. It is important to recognize that much of the clinical evidence for the use of CBD stems from case reports.

Pharmacokinetic Interactions With CBD

Based on in vitro data, pharmacokinetic interactions are predicted with:

- CYP1A2 substrates (eg, theophylline, caffeine),
- CYP2B6 substrates (eg, bupropion, efavirenz),
- CYP2C8 and CYP2C9 (eg, phenytoin) substrates,
- Uridine 5’-diphosphoglucuronosyltransferase 1A9 (UGT1A9) substrates (eg, diflunisal, propofol, fenofibrate), and
- UGT2B7 substrates (eg, gemfibrozil, lamotrigine, morphine, lorazepam).

As the use of CBD-containing products continues to rise, it is imperative pharmacists be familiar with the clinical implications of CBD’s use, especially in patients who use other pharmacologically active substances.
and/or from a small number of studies that often carry significant limitations. Moreover, the clinical implications of effects identified in case reports and studies cannot always be ascertained. Likewise, the source of CBD (eg, synthetic or plant extract) used in these case reports and studies is not always specified. All these limitations preclude drawing firm conclusions on the benefits of CBD in the clinical management of these conditions in the general population.

**Adverse Effects**

Based on clinical trials data described in Epidiolex’s prescribing information, the most common adverse effects (AEs) occurring in at least 10% of patients treated with Epidiolex and to a greater extent than with placebo in patients with Lennox-Gastaut syndrome or Dravet syndrome are somnolence, decreased appetite, diarrhea, transaminase elevations, fatigue, malaise, asthenia, rash, insomnia, sleep disorder, and infections. The most common AEs in patients with tuberous sclerosis complex are diarrhea, transaminase elevations, decreased appetite, somnolence, pyrexia, and vomiting.1

**Pharmacokinetics**

CBD has an estimated oral bioavailability of 6% and is highly lipophilic, readily crossing the blood-brain barrier.2 High-fat/high-calorie meals significantly increase the maximum concentration and the area under the curve.4 CBD has a large volume of distribution and is greater than 94% protein bound.3 At steady state, the time to peak plasma concentration occurs between 2.5 and 5 hours.5 CBD is primarily metabolized in the liver (and to some extent in the gut) through cytochromes P450 (CYP2C19 and CYP3A) and uridine 5'-diphospho-glucuronosyltransferase (UGT1A7, UGT1A9, and UGT2B7 isoforms).3 CBD has 1 active metabolite, 7-OH-CBD, which is metabolized to the inactive metabolite, 7-COOH-CBD.4 CBD is almost exclusively excreted in the feces and has an elimination half-life of 56 to 61 hours.5

**Drug Interactions**

CBD's pharmacokinetic and pharmacologic properties have implications on its potential to interact with other pharmacologically active substances. Much of what is known about these potential interactions comes from data available for the prescription drug Epidiolex.4 Additionally, in vivo data show that coadministration of CBD increases plasma concentrations of CYP2C19 substrates (eg, clozapam, diazepam) or their metabolites, and thus may increase the risk of AEs from these agents. Conversely, concurrent use with a strong CYP3A4 and CYP2C19 inducer (eg, rifampin) will result in a substantial decrease in CBD's plasma concentration. As such, an increase in CBD's dose should be considered when everolimus, sirolimus, or tacrolimus; or other substrates (eg, clobazam, diazepam) are coadministered.1

Concomitant use of CBD and valproate has resulted in liver enzyme elevations. Reports in the literature also suggest that CBD administration resulted in increased serum levels of everolimus, sirolimus, or tacrolimus; the mechanism of this interaction is not clear. Likewise, concomitant use of CBD with other CNS depressants may increase the risk of sedation and somnolence.1

Much of the data concerning the potential interactions between CBD and other pharmacologically active agents is derived from studies and observations involving Epidiolex, a standardized form of CBD subject to strict FDA regulations and requirements. It is important to note, though, that CBD-containing products that are readily available to the consumer may not be subjected to the same rigorous quality assurance measures (eg, standards for growth, production, testing/analysis). Such issues have been identified in the past and found to result in variable amounts of CBD among marketed CBD-containing products. There are limited data on the bioavailability of CBD following oral administration of various CBD-containing dosage forms. This limits the ability to predict CBD's pharmacokinetic parameters (ie, absorption, distribution, metabolism, excretion) as well as its pharmacologic and clinical effects, including its potential to interact with other agents.

Pharmacists and other health care professionals must be aware that these issues may affect exposure to CBD and affect concurrent pharmacologically active therapies. Pharmacists must carefully monitor drug therapy in patients using any form of CBD. While the clinical significance of the potential interactions between CBD and other agents is not certain, it is important for pharmacists to be mindful of them and recommend appropriate courses of action.6

Joseph P. Nathan, PharmD, MS, is the director at the International Drug Information Center and associate professor at Arnold & Marie Schwartz College of Pharmacy and Health Sciences, Long Island University.
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Cannabidiol (CBD) may be the biggest business booster pharmacy has seen in years. Statista forecasts $1.9 billion in CBD sales in the US by 2022, up from $535 million in 2018.1

“The reality is that CBD is a drug,” said Tim Gregorius, RPh, vice president of operations for PRS Pharmacy Services in Latrobe, Pennsylvania. “There are drug interactions, there are [adverse] effects, there are dosing considerations. The clerk at the gas station and the nice lady at the convenience store should not be selling CBD. CBD belongs in a pharmacy.”

**Price and Profits**

Don’t try to compete on price, warned Mike Bellesine, RPh, owner of El Dorado TrueCare Pharmacy in El Dorado, Kansas.

“You can buy CBD from any smoke shop, from Amazon,” he said. “We have brought our prices down somewhat, but we focus on the professional aspect. We are the CBD specialists.”

Pharmacists can build financial success with CBD around 3 elements:

1. good product selection,
2. good marketing, and
3. good patient conversations.

**Product Selection**

Pharmacy regulations for CBD products vary by state. California, for example, does not explicitly permit sale of ingestibles in pharmacies, said Ken Thai, PharmD, chief executive officer of K & B Pharmacy Associates in Los Angeles.

“We used to carry a full line of CBD products in our stores, but have cut back to topicals because state board inspectors are inconsistent. Some are fine with gummies and tinctures, some are not.”

Some CBD products also contain THC, which may not be noted on the product label. Kansas allows up to 5% THC in CBD products, according to Bellesine. Still, employers can terminate employees who test positive for THC. Bellesine uses only manufacturers that certify their products contain no THC, then sends samples to a local lab for confirmation.

“The only acceptable level of THC for us is 0,” Bellesine said. “Our suppliers know it, our customers know it, their employers know it. That has brought a lot of customers to our doorsteps.”

PRS also screens manufacturers. Products can be sold only to pharmacies or similar health care outlets, and packaging cannot carry marijuana leaves or similar deceptive elements. All products must be free of THC, certified by the manufacturer and a third party certificate of analysis, then verified by another lab selected by PRS.

**Marketing and Advertising**

Judy Leventhal, president of Leventhal Productions in St. Louis, Missouri, spent 3 years hammering out advertising guidelines with TV networks and streaming services. Leventhal is the only advertising agency devoted exclusively to independent pharmacies.

“Essentially, we can’t show products, we can’t talk benefits,” she explained. “What we can do is position the pharmacist as the CBD expert and education resource. This can be tremendously effective, especially with older audiences.”

The most successful CBD marketing focuses not on patients and customers, but on prescribers. Pharmacists can be the go-to source for CBD information, just as they are for drug information.

“We advise focusing on prescribers in town,” Gregorius said. “Tell them about your CBD knowledge and your certified THC-free products.”

Bellesine’s only CBD pitch is to local physicians. Window signs and sandwich boards advertise his THC-free product lines. Inside, products are arranged on clear shelves behind a plastic barrier that separates a technician line from the rest of the store.

“Customers can see product clearly, but they have to ask for it,” he explained. “That gives us an easy opening to talk about how CBD might help. That kind of low-key, in-store positioning is cheap, easy, and it works.”

**Patient Conversations**

Patients are bombarded by a bevy of purported benefits, but pharmacists may not make therapeutic claims.

“I can’t tell you that CBD is a sleep aid,” Bellesine said. “But I can tell you that other customers have told me that it helps them sleep better. And I can tell them that CBD doesn’t work for everyone, but this is what it did for me.”

CBD price may be an issue for some customers. Bellesine offers 2 options.

One is a high-dose formulation, cheaper per use but more costly at the register. The other is a low-dose formulation, which is cheaper at the register but more expensive per use.

“If CBD doesn’t help, they’re not out a lot of cash with the low-dose choice,” he said. “And if it does work, they come back for the higher dose bottle to save money. Either way, I’ve helped my customer.”

By Fred Gebhart

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1. Statista forecasts $1.9 billion in CBD sales in the US by 2022, up from $535 million in 2018.
BRINGING CBD TO YOUR CUSTOMERS

Plant-based, natural, third-party tested
Our CBD products include topical and supplement options for Everyday Wellness, Sleep, Stress, and Pain. We offer broad-spectrum, broad-spectrum plus isolates, and full-spectrum options for a variety of customer uses and needs. All products are plant-based, made with the cleanest ingredients, and third-party tested for potency, pesticides, residual solvents, microbials, and heavy metals.

Perks of Joining Our Wholesale Program
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Buy with confidence. Plant Therapy offers CBD at competitive prices that are even better for wholesale members. Our prices and third-party testing gives you and your customers confidence that you are investing in high-quality CBD products. Learn more about our extensive CBD line at PlantTherapy.com/CBD

Join Our Wholesale Family at PlantTherapy.com/wholesale-program
Use This Checklist To Select Your Product

What pharmacists need to consider before selling CBD in their stores. By Tim Gregorius, RPh

Don’t have time to evaluate which of the thousands of cannabidiol (CBD) brands on the market to sell in your pharmacy? How do you make wise choices about which brands and products to carry on your shelves? What criteria should you use to ensure you are offering your patients quality CBD products from reputable manufacturers?

CBD is a product that belongs in a pharmacy, and it should be sold with the same care you employ to sell every other OTC medication to your customers.

Packaging and Labeling
The product should be professionally packaged and look like it belongs in a pharmacy. The label should be simple and easy to understand, and it should have the same information you expect on other OTC products. Is it for ingestion or sublingual use? Strength in milligrams of CBD per dose must be clearly printed on the label, not just total milligrams per bottle.

Marketing Claims
The label and any marketing materials cannot include statements that are banned by the FDA, such as ones making therapeutic claims or advertising the product’s use as a food additive. Avoid brands that make claims or insinuate that the product may lead to certain health outcomes.

Manufacturer Credibility
Choose companies owned and/or operated by pharmacists or physicians. There are plenty of them out there.

Types of Delivery Methods
Remain alert for new developments in technology that provide enhanced delivery of CBD to target tissues. These developments are taking place seemingly overnight. Sublingual (SL) oils have been the prominent dosage form since the introduction of CBD on the market, mainly due to its greater absorption profile. Most oral CBD capsules undergo first-pass metabolism, which diminishes blood levels since CBD is not water soluble. However, there are now enhanced biodelivery methods that allow oral CBD to be absorbed at levels well above SL oils and are 10 to 20 times greater than oral dosage forms not utilizing these new technologies. In the near future, we can make CBD as easy for customers to take as vitamins and other supplements.

Product Quality
The CBD must be sourced from hemp that is grown, cultivated, processed, and distributed in the United States. Manufacturers who are concerned about the purity of their products should only use hemp that is produced compliant with FDA and US Department of Agriculture guidelines, as well as sometimes stricter state laws. There are conflicting and inconsistent rules that affect hemp grown overseas, but using hemp sourced in the US ensures that the THC levels, contaminants such as pesticides, and trace heavy metals are regulated by US agencies.

Moreover, are the products independently tested by a third-party laboratory? CBD companies should have the certificate of analysis (CoA) readily available for every product they sell, but that CoA is only meaningful if provided by a reputable laboratory. There are documented instances where unreliable CBD companies have published counterfeit CoAs.

Remember, the products you sell can reflect positively or negatively on you and your business. You should only sell CBD from trusted and reliable companies. As Harry Lattanzio, RPh, president of PRS Pharmacy Services, has said, “It’s the Wild West out there. Make sure you know what is in that bottle you’re handing to patients!”

Tim Gregorius, RPh, is vice president of operations for PRS Pharmacy Services.

Go to NCPACBDSource.com to learn everything you need to know about how and why CBD works, and what that means for your patients and pharmacy. NCPACBDSource.com is the premier learning center for pharmacists wishing to learn about CBD’s mechanism of action, drug interactions, side effects, dosing, CBD for pets, legal implications, new technologies, product selection, and more.
Questions About CBD?

NCPACBDsource.com Has The Answers

A comprehensive source of pharmacist-centered CBD education, products, and marketing. Created by pharmacists for pharmacists, and backed by names you can trust...NCPA and PRS.

- **Pharmacist-Centric CBD Education:** A clinical based educational resource designed exclusively for pharmacists. So you can feel more confident when advising patients about CBD.

- **CBD Marketing Support & Materials:** Multimedia CBD marketing kits designed by pharmacists, NOT a CBD brand. Created to help you inform your customers and local physicians that you are knowledgeable about CBD.

- **CBD Product Selection:** We evaluated dozens of brands and then had those we selected independently tested for potency and purity. We did the work to help save you time.

“Because The Community Pharmacist Should Be The Community CBD Expert…”

Connect With Tim Gregorius, R.Ph.
CBD For Pharmacy Expert

NCPACBDSource@PRSRx.com
or call 833-786-6522
A Look at the Legal Landscape

Regulations and laws governing CBD products. By Joan Vos MacDonald

Although the booming demand can make CBD products a profitable addition to any pharmacy inventory, some questions remain about the legal compliance factors when carrying CBD products in the pharmacy.

CBD oil and CBD-infused products first began to appear on pharmacy shelves after the passage of the federal Agriculture Improvement Act of 2018, also known as the Farm Bill, which declassified hemp as a Schedule I drug under the Controlled Substances Act (CSA). By 2019, both independent pharmacies and pharmacy chains such as CVS and Walgreens were selling a variety of CBD products. However, these products are regulated by a tangle of federal and state regulations that can be challenging to decipher.

“The main thing to know is that the federal 2018 Farm Bill removed hemp (defined as less than or equal to 0.3% THC) from the definition of ‘marijuana’ in the Controlled Substances Act, and hence from the prohibitions of that act,” said Mark K. Osbeck, JD, clinical professor of law, legal practice program, at the University of Michigan in Ann Arbor, and coauthor of Cases and Materials on Marijuana Law.

Although CBD derived from hemp gained a significant measure of legal protection in 2018, hemp-derived products are still subject to active regulation by the US Department of Agriculture and the FDA. The Farm Bill specifically provides that states may have different regulations governing sales.

“Every state has an equivalent of a bureau or department of cannabis control, and their websites will answer many of these questions,” said Robert Solomon, JD, clinical professor of law at The University of California, Irvine, School of Law, and cochair of the UCI Center for the Study of Cannabis. Research into the therapeutic possibilities of hemp-derived medicine is ongoing, but to date the FDA has approved only 4 hemp-derived treatments for US distribution: nabilone (Cesamet), cannabidiol (Epidiolex), and tetrahydrocannabinol (Marinol and Syndros). Pharmacists can safely dispense these medications if they comply with the federal and state requirements, such as registering with the Drug Enforcement Administration (DEA).

The approved uses of these hemp-derived treatments—combined with the increasing presence of CBD in OTC products—might suggest that all uses of CBD oil are permitted. Yet under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, the FDA does not permit the addition of CBD to food, beverages, or cosmetics, or allow it to be sold as a dietary supplement.

“The Farm Bill did not affect the FDA’s jurisdiction over drugs, supple-

“Pharmacists should pay attention to enforcement actions taken against companies with misleading or false labels, and seek out products that have been independently verified by third-party sources.”

KURT PROCTOR, RPH
ments, food additives, and cosmetics,” Osbeck said. “According to the FDA, CBD cannot be included legally as a food additive because the FDA has approved Epidiolex, whose active ingredient is CBD, as an approved drug for the treatment of childhood seizure disorder, and food additives may not contain FDA-approved drugs. The FDA has also not approved CBD as a drug. And its position with respect to designation as a supplement is that CBD does not meet the definition of a supplement because it contains an approved drug.”

If CBD oil were an FDA-approved supplement, the required labeling would have to list ingredients and dosage information. To that end, Rep Kurt Schrader of Oregon and Rep Morgan Griffith of Virginia filed H.R. 8179, known as the “Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020,” in the House of Representatives. The bill proposes that hemp derivatives be regulated and sold as a dietary supplement, with accurate FDA-required labeling. However, as Osbeck noted, defining CBD as a supplement, when CBD is already an ingredient in an approved drug, may be complicated.

Because CBD products are not regulated, pharmacists must exercise caution when promoting claims about the often-touted, but as yet scientifically unsubstantiated, benefits. CBD oil has been cited as a remedy for a variety of conditions—including anxiety, acne, and arthritis—but until more testing is done, the claims remain anecdotal.

“There are significant risks associated with making claims of medical efficacy with respect to CBD, whether such claims ultimately turn out to be true or not,” Osbeck said. “The FDA regulates as drugs substances about which health claims are made, and therefore such claims are subject to FDA approval following appropriate clinical tests. Thus, any claims about CBD’s efficacy absent such approval are deemed unsubstantiated, and therefore (they) violate FDA regulations.”

What does this mean for pharmacists? To date the FDA has done little to crack down on unsubstantiated claims by pharmacists, but it has issued a number of warning letters to manufacturers and marketers who make some of the boldest claims (for example, that CBD can fight cancer). However, there is no assurance that in the future pharmacists will be safe from the repercussions of making unproven claims.

“Any claims regarding CBD products or benefits may lead to private lawsuits from consumers or investigations from regulating bodies,” Proctor said.

Safety is always a concern in products not vetted by the FDA. Since CBD oil contains both pharmacodynamic and pharmacokinetic properties, using CBD products can prompt interactions with other common medications, including immunosuppressives, antidepressants, and blood thinners. In some cases, a combination may have adverse effects. Proctor suggests that pharmacists encourage patients to confirm any CBD usage with their physicians.

“Pharmacists should also inform customers that CBD products are not intended to prevent, diagnose, treat, mitigate, or cure diseases or disorders,” Proctor said.

Because state and national regulations governing hemp-based products don’t necessarily synchronize, pharmacies that stock CBD products can potentially face stricter scrutiny from the DEA, which can lead to increased pharmacy audits and inspections. In addition to the usual compliance measures that pharmacies adopt, pharmacies that fill CBD prescriptions, if they are legal under that state’s laws, should adopt measures specific to CBD compliance. Failure to comply with applicable laws can leave pharmacists vulnerable to substantial fines and, potentially, criminal prosecution.

“I think the takeaway is that CBD is sold in most states and is legal, subject to state regulations, under the laws of those states,” Osbeck said. “And while CBD derived from hemp is no longer an illegal substance under federal law, it is still subject to federal regulation. Thus, sellers assume certain risks when they market CBD in violation of these federal regulations, particularly when they make unsubstantiated claims about the safety or efficacy of CBD.”

If a pharmacy decides to carry CBD products, there are ways to determine the most reliable sources.

“Pharmacists should pay attention to enforcement actions taken against companies with misleading or false labels and seek out products that have been independently verified by third-party sources,” Proctor said. “Pharmacists can visit ncppachdsourc.com for CBD products that have been independently tested to confirm the accuracy of the labels and ingredients.”

For references, visit drugtopics.com.
Improving Pharmacist-Physician Collaboration

Shared information and continued communication can build a cohesive partnership.  

By John Schieszer

Operational barriers and lack of shareable patient-specific documentation are systemic obstacles to effective collaboration between pharmacists and physicians. However, there are some simple steps that go a long way in improving collaboration between pharmacists and physicians.

“I believe there often is a disconnect between the patient care that pharmacists and physicians provide, especially in the community pharmacy setting,” said Michelle Jeon, PharmD, who is an assistant professor in the department of pharmacy practice at the University of Health Sciences and Pharmacy in St Louis, Missouri.

In an email to Drug Topics®, Jeon said pharmacies have crucial patient information that most physicians don’t have direct access to, such as medication out-of-pocket costs and refill histories. Pharmacies may serve as a central repository for medications prescribed by several different prescribers, and pharmacists can identify potential drug interactions and duplications in therapy. However, Jeon said pharmacists often don’t have access to diagnoses and patient information, such as weight, in order to ensure optimized patient-specific medication doses.

Jeon and her colleagues have been investigating how pharmacists can improve collaboration with physicians and overcome systemic barriers. Collaborative drug therapy management (CDTM) is permitted between a physician and pharmacist in Missouri. This allows pharmacists to modify, initiate, or discontinue noncontrolled medication therapies under a written protocol. However, Jeon’s team surveyed 103 community pharmacists and 23 outpatient physicians and found that pharmacists identified operational barriers of time and reimbursement. Physicians reported concern with clinical risks, including potential disconnect between providers and inadequate pharmacist training.

Jeon said physicians need a better understanding of the clinical role of pharmacists working in the community setting. “Most pharmacies conduct adherence calls on a regular basis, providing an opportunity to uncover barriers to optimal medication habits and educate patients about their medications,” Jeon said. “If physicians tapped into these pharmacist-led services through referrals or shared documentation, patient outcomes and overall care could drastically improve.”

Brian Caswell, RPh, the 2019-2020 president of the National Community Pharmacists Association and owner of Wolkar Drug in Baxter Springs, Kansas, said that pharmacists can find it difficult to track down a physician with questions and vice versa. “If I leave a message with an office, these questions can be so technical that the message can get lost in translation before it gets to the doctor,” Caswell said.

He would like to see pharmacists and physicians set up recurring group conversations to discuss common issues, such as prior authorizations and how to streamline processes. Caswell said the coronavirus disease 2019 (COVID-19) pandemic has compounded some issues. “Pharmacists and physicians are so busy, especially right now. In my view, time is the biggest barrier to collaboration,” Caswell said.

There are reimbursement hurdles. On the pharmacy end, there are state and federal rules on the prescription order. You can’t assume anything,” Clifford Young, RPh, CGP, president of the California Pharmacists Association, said. “It is more complex than it appears and should be. You can go into a phone queue from hell to get a clarification.”

According to Young, the very high costs of some newer agents has added even more complexity. “Most pharmacists need to know the restraints the physician is under. The payment to physicians is a challenge, just like it is to the pharmacists. If the physicians understood that we are really the patient advocate, that would help,” Young said. “It is about relationships.”

For references, visit drugtopics.com.

5 Ways to Foster Better Pharmacist-Physician Collaboration

1. Improve shareable patient-specific documentation.
2. Identify operational barriers.
3. Set up recurring group conversations.
4. Understand each other’s time constraints and reimbursement hurdles.
5. Better recognize the clinical role pharmacists have at the community pharmacy.
Implementing a dedicated inpatient pharmacy-based pain management service through electronic consultations (e-consults) can help improve patient outcomes, according to a poster presented during the PAINWeek 2020 Live Virtual Conference, held September 11-13, 2020.¹

In 2018, The Joint Commission published updated recommendations regarding the use of opioids, with the guidance that hospitals create and establish policies and procedures for review of pain regimens by pain specialists.

“In the inpatient setting, studies have shown that more than 60% of inpatients experience incomplete or inadequate pain relief,” study author Chung De (Derek) Joe, PharmD, with the VA Long Beach Healthcare System (VABLHS), reported.

To address inappropriate opioid prescribing, VABLHS implemented an Inpatient Pain Pharmacist E-Consult Service. The service involves the review of patients electronic medical records and strategies to reduce high-dose opioid analgesics and provides recommendations for complex pain-management cases.

The data highlighted the role of the pharmacy-based pain management service in an inpatient setting. In particular, the study demonstrated the effect of the e-consult service at VABLHS on changes in morphine equivalent daily dose (MEDD) at discharge and post discharge.

In the study, which consisted of a retrospective database chart review, the investigators examined patients who received an inpatient pain pharmacist e-consult from January 1, 2018, to August 31, 2019. To evaluate clinical outcomes, these patients also were matched to a cohort of patients receiving long-acting/extended-release (ER) opioids (fentanyl transdermal system, morphine sustained-release, methadone) who did not receive an e-consult within the same period.

Overall, 75 patients received an inpatient pain pharmacist e-consult: 372 pharmacologic and 56 nonpharmacologic recommendations were made, with acceptance rates of 51.3% and 41.1%, respectively.

Key results from the study showed:

- The most common opioid therapy changes accepted by inpatient providers included immediate-release (IR) opioid taper (76.2%), IR opioid titration (50%), and IR opioid initiation (46.2%).
- The most common nonopioid therapy changes were for nonsteroidal anti-inflammatory drug (NSAID) discontinuation (71.4%), anticonvulsant initiation (67.5%), and topical analgesic initiation (61.3%).
- Pharmacologic recommendations such as antidepressant taper/discontinuation, APAP/tramadol taper/discontinuation, and NSAID initiation were not commonly accepted.
- Top accepted referrals were to substance abuse (84.6%) and outpatient pain clinics (75%).
- Recommendations for physical therapy, palliative care, and psychiatry/mental health were not as commonly accepted.

The average MEDD for the e-consult group was 70.5 mg/day at admission, 65.2 mg/day at discharge, and 50.1 mg/day at 90 days post discharge. In the non-e-consult group, the average MEDD was 68.8 mg/day at admission, 70.0 mg/day at discharge, and 63.1 mg/day at 90 days post discharge, the results showed.

The investigators concluded that, regardless of the time point, patients who received inpatient e-consult services demonstrated significant reductions in MEDD from baseline compared with patients who did not receive these services.

“In terms of future directions, we would like to establish a dedicated inpatient pain pharmacist team to monitor patients longitudinally,” Joe concluded.² For references, visit drugtopics.com.
Neuromyelitis optica spectrum disorder (NMOSD) is a rare autoimmune disease characterized by inflammatory lesions that primarily affect the optic nerve and spinal cord. NMOSD attacks can lead to permanent vision impairment and paralysis, along with pain, fatigue, sensory loss, and bladder dysfunction. Recently, eculizumab and inebilizumab were approved by the FDA for the treatment of NMOSD in adults in 2019 and 2020, respectively. Prior to their approval, no medications were approved to treat this disease. On August 14, 2020, the FDA approved satralizumab-mwge (Enspryng; Genentech) for the treatment of NMOSD in adult patients who are anti–aquaporin-4 (AQP4) antibody positive. The exact mechanism of satralizumab in NMOSD is unknown, but it involves the inhibition of interleukin-6 (IL-6) mediated signaling, which is thought to play a key role in NMOSD pathogenesis.

SAKURASTAR trial (NCT02073279) included 95 patients, of which 64 were anti-AQP4 positive. Patients received either satralizumab (N = 41) or placebo (N = 23) subcutaneously at weeks 0, 2, 4, and once every 4 weeks after. Results showed that satralizumab reduced the number of NMOSD relapses by 74% in patients who were anti-AQP4 positive compared with placebo. In the satralizumab group, 82.9% and 76.5% of patients were relapse free at 48 and 96 weeks, respectively.

The SAKURASKY trial (NCT02028884) randomized anti-AQP4 positive patients to receive satralizumab plus immunosuppressive therapy (IST) with corticosteroids, azathioprine, or mycophenolate mofetil (N = 26) or placebo plus IST (N = 26) at weeks 0, 2, 4, and once every 4 weeks after. Satralizumab reduced the number of relapses by 78% compared with placebo. 91.1% of patients in the satralizumab arm were relapse free at both 48 and 96 weeks.

**Efficacy**

The SAKURASTAR trial (NCT02073279) included 95 patients, of which 64 were anti-AQP4 positive. Patients received either satralizumab (N = 41) or placebo (N = 23) subcutaneously at weeks 0, 2, 4, and once every 4 weeks after. Results showed that satralizumab reduced the number of NMOSD relapses by 74% in patients who were anti-AQP4 positive compared with placebo. In the satralizumab group, 82.9% and 76.5% of patients were relapse free at 48 and 96 weeks, respectively.

**Safety**

Satralizumab’s prescribing information includes a warning for increased risk of infections, specifically potential reactivation of hepatitis B and tuberculosis. Satralizumab is contraindicated in patients with hepatitis B infection, or active or untreated latent tuberculosis. Satralizumab also has been shown to increase liver enzymes, decrease neutrophil counts, and increase the risk for hypersensitivity reactions. The most common adverse effects include rash, arthralgia, nasopharyngitis, headache, upper respiratory tract infections, gastritis, joint pain, extremy pain, fatigue, and nausea. Live attenuated or live vaccines are not recommended during treatment and should be administered at least 4 weeks prior to initiating therapy.

**Dosing and Administration**

Satralizumab is intended for self-administration and dispensed as a 1 mL single-dose prefilled syringe. Initial dosing is 120 mg given subcutaneously every other week for a total of 3 injections, followed by maintenance doses of 120 mg once every 4 weeks. Prior to use, patients or caregivers should remove the prefilled syringe from the refrigerator and allow the syringe to sit at room temperature outside of the carton for 30 minutes. The solution should be clear and colorless to slightly yellow. Patients should inject the full amount of the syringe into the abdomen or thigh, and rotate injection sites with each administration.
Clinical Skills Help Pharmacists Emphasize Their Value to Patients

Pharmacists go beyond merely dispensing drugs to provide higher levels of care.

In today's fast-paced health care landscape, where most patients spend 15 minutes in their physician's office maybe 4 times a year, the pharmacist, who is the most accessible health care professional, is leaned on more and more to triage patients needing a higher level of care.

For instance, pharmacists provide prescription therapy directed at clot prevention. Today it is rather commonplace to see triple therapy consisting of an anticoagulant and 2 antiplatelets (aspirin/clopidogrel), depending on the source of the clot. I drill into my physician assistant students the differences between antiplatelet therapy for “white clots” and anticoagulant therapy for “red clots.” If a patient needs protection from deep vein thrombosis and pulmonary embolism, it is commonplace to use aspirin/clopidogrel plus aspirin.

Last month, I received a call from the wife of 1 of my patients. She said her husband, Steve, was given a prescription for apixaban (Eliquis), and she was wondering about the drug’s potential adverse effects (AEs). I asked, “Is there anything in particular that he is experiencing?” She replied, “Is shortness of breath an adverse effect of Eliquis therapy? He can hardly get off the couch.”

I didn’t even have to pull a reference or the package insert. I said, “You get him to the hospital NOW, preferably 10 minutes ago.”

She took my advice and took him to the emergency department immediately. They whisked him to the X-ray department and did a CT scan that showed bilateral pulmonary emboli. She called back later to tell me of their findings and that I had saved his life. A week later, Steve came to the pharmacy and told me he slipped while fishing, developed a blood clot in his lower left leg, and was put on anticoagulant therapy. He also confirmed that it was my forceful advice that got him from the couch to the emergency department.

Although we are the experts in drug therapy, this case illustrates how we must also excel in disease state management. Pumping out 40 prescriptions an hour with minimal tech help does not lend itself to an optimal level of patient care.

I doubt that we made $10 on the Eliquis prescription, which has a wholesale acquisition of $470. After the direct and indirect remuneration fees, we probably lost a few dollars. Pharmacists, the frontline health care professionals who are the most accessible and provide advice for free, are valuable members of the health care team. Just ask Steve and his wife.

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