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Although COVID-19 remains a real threat, it’s seems we are now progressing toward a return to normalcy thanks to the widespread availability of vaccines and tireless efforts of our health care workers.

As the country continues to reopen, vaccinated Americans are gearing up to resume normal summertime activities, such as vacations and outdoor gatherings. Because June signals the beginning of summer—bringing warmer weather—Jennifer Gershman, PharmD, CPh, discusses on page 10 how pharmacists can counsel patients with certain autoimmune conditions during summer months on ways to reduce symptom flares associated with rising temperatures.

June is also LGBTQ Pride Month, so we are examining the stark health disparities affecting LGBTQ+ individuals and how pharmacists can provide more inclusive care and services. In addition to being the medication experts, pharmacists are often the most frequent touchpoints a patient has with the health care system. Our special report on page 12 focuses on how pharmacists can best support LGBTQ+ patients and create a more inclusive environment in the pharmacy.

In this issue we also recognize National Headache and Migraine Awareness Month by highlighting how pharmacists can assist patients in prevention, treatment, and medication management. On page 16, you’ll find an overview of the various pharmacologic and nonpharmacologic therapies available for migraine.

Just a few months ago, Drug Topics® launched its Total Pharmacy® platform, a resource for independent pharmacy owners and operators. We’re excited to announce that on June 19, Total Pharmacy® will be hosting its first virtual live event focused on business solutions and innovative ideas for independent pharmacy market stakeholders. The event will feature 6 sessions, with up to 3 live continuing education credits available.

In the meantime, visit our Total Pharmacy® section on page 18 for articles on Health Insurance Portability and Accountability Act compliance and how to set your medication management services up for success.

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Join us for the Total Pharmacy Solutions Summit on Saturday, June 19th for an exclusive virtual event focused on actionable business solutions for community pharmacists.

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- Factors that influence disparities in care and cultural awareness (accredited by AdvanCE)
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For full details, hover over the QR code or visit the link below:


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We will send you updates leading up to the conference including the agenda, speaker list and key takeaways.
The FDA has authorized the Pfizer-BioNTech COVID-19 vaccine for emergency use in adolescents aged 12 to 15 years, making it the first COVID-19 vaccine available for use in this age group. The expanded emergency use authorization is based on data from a phase 3 clinical trial that demonstrated 100% vaccine efficacy in adolescent participants. The vaccine was also well tolerated in the study.

The trial enrolled 2260 adolescents aged 12 to 15 years in the United States. Eighteen cases of COVID-19 were observed in the placebo group versus none in the vaccinated group. Vaccination also demonstrated strong immunogenicity in a subset of adolescents 1 month after the second dose, eliciting antibody geometric mean titers (GMTs) of 1239.5; data showed this to be noninferior to GMTs elicited by participants aged 16 to 25 years in a previous analysis.

Participants of this trial will continue to be monitored for long-term protection and safety for an additional 2 years after the second dose. Pfizer Inc and BioNTech SE are also conducting a pediatric study to evaluate the safety and efficacy of the vaccine in children aged 6 months to 11 years.

For more information, visit drughtopics.com.

A new survey indicates that patients are looking for continued convenience and flexibility when it comes to care delivery and access offerings.

More than 50% of respondents to a Kyruus survey delayed care of some kind due to the COVID-19 pandemic, and as things begin to reopen in the coming months, many said they will seek a hybrid of virtual and in-person visits, according to a news release.

The digital care management and delivery options implemented by practices during the pandemic were embraced by patients, and the survey results indicate the practices that maintain and expand these options will be in the best position to attract and retain patients, according to the release.

For more information, visit medicaledconomics.com.

To watch the full interview, visit drugtopics.com/expert-interviews or scan the QR code.
Individuals with opioid misuse disorders are experiencing a decrease in access to naloxone during the COVID-19 pandemic, according to the results of a recent study. Published in JAMA Health Forum, the study, which was conducted by investigators from Beth Israel Deaconess Medical Center, analyzed naloxone prescription trends during the pandemic and compared them with trends in opioids prescriptions and overall prescriptions between May 2019 and December 2020. The results showed that the number of individuals filling these prescriptions dropped by more than 25% and the number of individuals with Medicare and commercial coverage filling naloxone prescriptions dropped by nearly a third. Since March 2020, there was no statistically significant recovery in naloxone prescriptions, “indicating that the number of individuals filling naloxone prescription has remained low throughout the pandemic,” the investigators wrote in the study.

For references, visit drugtopics.com
Demands on pharmacists are increasing, yet all the tasks historically part of a pharmacist’s day-to-day routine are still required. Aside from COVID-19 vaccinations and responding to overall increase in volume, medication adherence is a top concern for patients and pharmacists. Using technology solutions enables pharmacists to enhance patient safety both effectively and efficiently.

According to Gerald Finken, RPh, CEO of RxE2 Inc and a 40-year veteran pharmacist, technology-driven medication packaging is a tangible reminder for patients to take their medication as prescribed.

“Additionally, health plans, prescribers, and pharmacies are held accountable through adherence-driven quality metrics (such as proportion of days covered and medication possession ratio), and pharmacists can use packaging to improve these quality metrics,” Finken said.

Joann Seigel, RPh, vice president of pharmacy services for Masonic Villages in Elizabethtown, Pennsylvania, noted that with automated packing technology, pharmacists can confidently handle increased volume in the pharmacy without an increase in errors.

“It allows you to service a volume you could never manage manually,” she said. “Smart technologies streamline the medication process.”

For the pharmacist, smart technology ensures that all a patient’s medications are synced up and billed at the same time, explained Donald Brindisi, RPh, pharmacy manager of Masonic Villages.

“It saves headaches around the concern that a patient is taking their medications as they are prescribed,” he said. “Without technology supporting a patient (who) could have 10-plus medications in a single blister would be nearly impossible to do efficiently.”

Thomas E. Hanzel, PharmD, MBA, national vice president of long-term care/nutraceutical at Parata Systems in Durham, North Carolina, said pharmacies are starting to be held accountable and, to some level, rewarded for improving medication adherence in patients.

“The right technology can provide customizable adherence packaging that is flexible enough to be adopted by all customer types and, therefore, improve medication management,” he said. “Pharmacists can verify compliance, as the customer receives notice in a cyclical calendar format where the medications are automatically refilled. This can be on a weekly, monthly, or whatever cycle is best for the customer—therefore, decreasing the chance of missing a dose.”

Sapna Patel, RPh, director of clinical services at Mosaic Pharmacy Service in Sterling, Virginia, explained that previously pharmacists had to spend a lot of time manually counting, filling, and labeling medications. With the automation of these tasks, pharmacists have additional time for patient interaction, including counseling patients on harmful drug interactions, educating patients on disease states, and reiterating the importance of staying adherent to their medication.

“Pharmacy automation has also decreased medication errors made by pharmacists,” Patel said. “Many automation systems have a pill verification system that increases patient safety while decreasing human error.”

Therefore, adherence packaging services can increase a patient’s confidence in medication management and improve their overall health by helping them take their medications as prescribed.

**Getting Started**

If a pharmacy isn’t currently offering an adherence program, it usually is due to a lack of efficient technology. To start an adherence program, it can be helpful to have show-and-tells or introductory meetings with provider offices, discharge planners, short-term rehabilitation centers, and insurance companies, Seigel said.

“Getting key players involved early on to demonstrate the value of...
engaging with your adherence program is a great way to begin those partnerships,” she said. “Compliance packaging typically comes first and is then supported by the introduction of automation into the pharmacy.”

It will also depend on one’s customer base. For example, although smart cards are great for retail and behavioral health settings, they are not as ideal for long-term care settings.

“Knowing which patient populations you’re looking to support will dramatically change the type of adherence program and the way it is implemented,” Seigel said.

More and more seniors are staying in their own homes rather than going to a nursing home. A recent article in the Wall Street Journal reported a 15% drop in nursing home occupancy in 2019—mainly due to concerns around the COVID-19 pandemic. Seniors who live on their own may need additional support from their care providers when it comes to medication adherence.

“Adherence packaging has allowed pharmacists to help manage patients’ medications better by spending less time filling and more time managing their overall health,” Patel said.

For example, Patel cited a recent case study on a 70-year-old man on 25 medications. The patient has an extensive medical history, which includes diabetes, hypertension, overactive bladder, hyperlipidemia, gastroesophageal reflux disease, and neuropathy. He lives alone and has a hard time remembering to take some of his medications. He became nonadherent due to cost and medication overload.

“Mosaic Pharmacy Service leverages a comprehensive care model that includes filling medications in adherence packaging to help our medically complex patients stay adherent to multiple medications,” she explained. “I switched this patient to more cost-effective medications organized by date and time of dose in adherence packaging, which helped to simplify his routine and ultimately made it easier to stay adherent.”

COVID-19 has disrupted daily processes and routines for many patients, leading to medication adherence concerns. Pharmacists have had to implement strategies to help their patients stay adherent amid a variety of logistical challenges; this includes services like curbside pickup, home delivery, and—of course—adherence packaging.

“(COVID-19) has allowed pharmacists to see the importance of adherence packaging to help manage patient’s medication regimens,” Patel said. “Having all their medication synchronized to fill once a month allows for better adherence and more time for pharmacists to focus on helping patients manage their chronic conditions.”

Who Benefits Most?
Adherence packaging is good for any patient managing multiple chronic conditions that require them to take medications multiple times per day. It is also good for patients who have a caregiver helping them manage their medication because adherence packaging makes it easy to see if the medications have been taken at the scheduled time.

The patients most likely to benefit from adherence packaging are those whose caregivers may be far too busy to manage family members’ medications.

“Home health agencies really value compliance packaging for their facilities,” Seigel said. “Patients who may be very far away from their loved ones or a power of attorney can rest easier knowing their medications are being managed safely—which provides peace of mind for both the patient and those responsible for their care.”

The senior population is also at high risk of nonadherence, which is why Patel believes seniors who are on 5 or more medications would benefit most from adherence packaging.

“A recent report put out by the Lown Institute indicates that seniors on 5 or more medications are 88% more likely to seek care for an adverse drug reaction versus those taking 1 or 2 medications,” she said.

There are plenty of benefits for the pharmacists as well. Automation allows them to better manage workflow, produce more cards, and service a much larger customer base.

“It significantly reduces stress for the pharmacists, which inherently reduces burnout,” Brindisi said.

Plus, it allows pharmacists to work with patients to reduce their overall medical spend and ensure the bestpossible treatment plan. Adherence pouch packaging also increases prescription fills and results in less audits, less direct and indirect remuneration fees, and higher reimbursement.

“Adherence technology decreases chances of medication errors and increases efficiencies, providing a high level of confidence to the pharmacist,” Hanzel said. “Automation also frees up pharmacist time and allows them to use their unique breadth and depth as experts who can then focus primarily on the patient. As a pharmacist, any way that they can improve adherence will [improve outcomes and, ultimately, reduce] total health care cost.”
PREVENTING

AUTOIMMUNE DISEASE FLARE-UPS DURING THE SUMMER

Exposure to heat and sun can worsen symptoms for certain conditions.

By Jennifer Gershman, PharmD, CPh
Pharmacists can play an important role in educating patients with certain autoimmune diseases about strategies to prevent a temporary worsening of symptoms in hot or humid weather. More than 80 diseases occur as a result of the immune system attacking the body’s own organs. Ongoing research shows that temperature changes and sunlight can exacerbate some of these conditions.

**Symptom Management**

**Multiple sclerosis (MS)**
Approximately 60% to 80% of patients with MS experience Uhthoff phenomenon, which is the temporary worsening of neurological symptoms when the body gets overheated during hot or humid weather, exercise, or fever. These symptoms improve after cooling down, typically last less than 24 hours, and may include fatigue, weakness, balance issues, blurred vision, and memory and concentration issues. Sunbathing, taking very hot showers or baths, or using saunas and hot tubs can also cause these symptoms.

Pharmacists can counsel patients to stay in air-conditioned environments during periods of extreme heat and humidity, drink cold fluids, and wear lightweight, loose, breathable clothing. Exercising in a cool pool (≤ 85°F), choosing cooler times of the day for outdoor activities, and taking a cool bath or shower to lower core body temperature following activities in heat can also prevent flare-ups.

In addition, use of cooling products such as vests, neck wraps, or bandanas can manage symptoms. The National Multiple Sclerosis Society has compiled a list of approved cooling product vendors and discount codes and may be able to provide financial assistance if the patient’s insurance does not cover the cooling equipment.

**Lupus**
Approximately 50% of patients with lupus experience photosensitivity through exposure to ultraviolet (UV) rays from sunlight or artificial light, which can cause flares such as swollen joints, fatigue, rashes (eg, characteristic “butterfly rash”), mouth and nose sores or ulcers, and leg swelling. Some of the medications used for lupus treatment, such as nonsteroidal anti-inflammatory drugs and hydroxychloroquine, also can cause sun sensitivity.

Therefore, it is important to educate patients to apply sunscreen with an SPF of 30 or higher that provides broad-spectrum protection against both UV-A and UV-B rays and to wear tightly woven clothing that covers the skin, a wide-brimmed hat, and wraparound sunglasses to help prevent lupus flare-ups from the sun.

Fluorescent and halogen bulbs should be covered with light shields or glass to filter UV rays, and UV blocking shades can be used to cover windows.

**Psoriasis and dermatomyositis**
Warm weather, accompanied by more natural sunlight and humidity, can often improve psoriasis. However, skin injuries such as sunburn can trigger flares with symptoms that include raised plaques on the skin, itching, redness, swelling, stiffness, and joint pain. Patients should apply broad-spectrum, fragrance-free sunscreen made for sensitive skin to all areas of exposed skin, including the psoriasis plaques, to prevent sunburn. Heat and sweat can also trigger flares, so patients should try to stay cool using air conditioning or a fan. Because air conditioning can dry out the skin, recommend that they use a moisturizer.

Dermatomyositis is a rare autoimmune disease that causes skin changes and muscle weakness. Even brief sun exposure can cause flares, which include a distinctive reddish-purple rash, edema surrounding the eyes, and muscle weakness. Therefore, sunscreen, sunglasses, and protective clothing are extremely important.

For references, visit drugtopics.com.
Diversity and inclusion remain a hot topic, but the embers that continue burning into the American conscience far transcend race and ethnicity. Like minority communities, the LGBTQ+ community also wrestles with its own struggles as another medically underserved populations, and pharmacists and other health care professionals who serve the LGBTQ+ community are working to establish methods to address these patients’ needs better.

“Historically, the barriers to care for LGBTQ+ individuals are complex and encompass many determinants,” said Tam Phan, PharmD, AAHIVP, assistant professor of clinical pharmacy and clinical pharmacist at the Jeffrey Goodman Special Care Clinic at the USC School of Pharmacy in Los Angeles, California. The underlying barriers hindering access to health care in the LGBTQ+ community are numerous. Discriminatory practices such as patients having been refused care simply because they are LGBTQ+ and individuals lacking access to affordable health care due to uninsured status (as a result of family rejection, unemployment, and requiring services not covered by insurance) are a few examples.

The number of individuals identifying as LGBTQ+ is on the rise, having increased from 3.5% in 2012 to an estimated 4.5% in 2017 in the United States, with millennials (defined here as individuals born between 1980 and 1999) as contributing to the majority of the uptick, according to Gallup.¹

Not only do these statistics indicate a growing number of those who identify as LGBTQ+, but they also highlight an opportunity for health care professionals to ensure the provision of inclusive services for this patient population. Pharmacists play an important role in the health care system and can work to address the health disparities that exist for their LGBTQ+ patients.

Lack of awareness regarding population-specific health challenges and negative health care provider interactions as underlying contributors in preventing the LGBTQ+ patient from experiencing an equitable and quality health care experience.

“In a busy clinic or health setting, there will be many staff members...”

“Historically, the barriers to care for LGBTQ+ individuals are complex and encompass many determinants.”

TAM PHAN, PHARM.D, AAHIVP, ASSISTANT PROFESSOR OF CLINICAL PHARMACY AND CLINICAL PHARMACIST AT THE JEFFREY GOODMAN SPECIAL CARE CLINIC
Is Your Pharmacy Inclusive of the Transgender and Gender-Diverse Community?4

The American Pharmacists Association and Human Rights Campaign Foundation recently released a new guide for pharmacies on transgender and gender-diverse inclusion. The guide, which was released on International Transgender Day of Visibility on March 31, serves as an educational tool and resource for pharmacists and pharmacy staff on how to be inclusive to transgender, nonbinary, and gender-diverse patients.

According to the guide, the 6 qualities of a pharmacy that are inclusive of transgender, nonbinary, and gender-diverse individuals are:

1. **Knowledge of key LGBTQ terms**
2. **Inclusive communication**
3. **Gender-related data management**
4. **Visible symbols of support**
5. **Staff training**
6. **Knowledge and patient-centered care**

who can interact with the patient—all of whom can either affirm or hinder the patient’s experience,” Phan said. “In many cases, problems can come from simple oversights or mistakes (from health care staff) who lack understanding—patients having reported hearing jokes or slurs and/or having received insensitive criticism about their appearance or behavior.”

Scott Nass, MD, MPA, a family physician based in Santa Rosa, California, noted that only in recent years has this started to change.

“In this context, we can’t ignore the fact that homosexuality and gender dysphoria were, for so many years, pathologized by organized health care,” he said. “Only recently has so-called conversion therapy been widely condemned.”

Nass also serves as the president of Health Professionals Advancing LGBTQ Equality (GLMA) and noted that survey data indicate that more than half of lesbian, gay, and bisexual respondents and nearly 3 out of 4 (70%) of all transgender and gender-nonconforming individuals reported having experienced some degree of discrimination when using the health care system.

Another element amplifying the complexities of serving the LGBTQ+ lies in the community’s diversity, as it transcends many other cultural identifiers such as race, ethnicities, religious affiliation, and socioeconomic class.

These complexities include lack of access to quality health care, lower rates of health insurance coverage, failure to routinely and comprehensively include questions about sexual orientation and gender identity in health surveys and other data collection, and lack of consistent nondiscrimination protections for LGBTQ+ individuals in health care, workplace, housing, and other areas of everyday life.

### Health Risks in the LGBTQ+ Community

Although HIV/AIDS is often associated with LGBTQ+ health, the community is at increased risks for many other conditions beyond this infectious disease, such as substance use, obesity, cancers, sexually transmitted diseases, cardiovascular disease, obesity, cancers, isolation, bullying, rejection, depression, anxiety, and suicide. Mental health conditions affecting the community deserve special attention, as the circumstances under which the LGBTQ+ population grows up often weigh on their mental, emotional, and psychological health throughout their lives. Children are more prone to bullying, isolation, rejection, depression, and suicide than the general population and are more likely to report suicidal ideations (30% vs 6%; *P* < 0.0001) and engage in self-harm (21% vs 6%; *P* < 0.0001) than their heterosexual and non-transgendered counterparts. In addition, LGBTQ+ patients may face societal ostracism, which also predisposes them to circumstances that threaten their health and livelihood early in life. For example, LGBTQ+ youth comprise 40% of all young individuals who experience homelessness.

“Although these are desirable developments, some patients may develop (adverse) effects such as obesity and cancers or overdose by adjusting their medications.”

Although the health issues impacting the community affect all members, LGBTQ+ youth wrestle with their own set of challenges, including increased susceptibility to substance abuse, sexually transmitted diseases, cardiovascular disease, obesity, cancers, isolation, bullying, rejection, depression, anxiety, and suicide. Mental health conditions affecting the community deserve special attention, as the circumstances under which the LGBTQ+ population grows up often weigh on their mental, emotional, and psychological health throughout their lives. Children are more prone to bullying, isolation, rejection, depression, and suicide than the general population and are more likely to report suicidal ideations (30% vs 6%; *P* < 0.0001) and engage in self-harm (21% vs 6%; *P* < 0.0001) than their heterosexual and non-transgendered counterparts. In addition, LGBTQ+ patients may face societal ostracism, which also predisposes them to circumstances that threaten their health and livelihood early in life. For example, LGBTQ+ youth comprise 40% of all young individuals who experience homelessness.

Unfortunately, inadequate data collection contributes to the inequities...
affecting the medical treatment for those who identify as LGBTQ+. Many state and national surveys fail to include questions regarding sexual orientation and gender identity.3

Establishing Best Practices for Inclusive Care

Despite the barriers hindering the provision of LGBTQ+ inclusive care, sources say there are several steps clinicians and their organizations can take to better serve the community.

For example, Perez’s institution encourages patients to self-identify. The practice allows patients to express how they want to be addressed by elucidating the pronouns they prefer. Phan also recommends incorporating certain elements into the practice setting that members of the LGBTQ+ community often seek out as indicators that the care they receive will meet their needs. Pharmacists can assess their practice site for nondiscrimination policies.

Assessment may include examining whether specific needs are met in the daily course of practice, including the following:

- Does the practice site include gender-neutral bathrooms?
- Are questions on the registration forms and electronic health records tailored to collect information for this demographic?

To help address mental health concerns, Perez encourages her pharmacist colleagues to establish a rapport with patients by engaging them in conversation. The discussions might reveal mental or psychological challenges. “The feelings of rejection, unacceptance, confusion, and loneliness are common in this patient population,” she said. And such feelings can lead to psychiatric illnesses such as depression and anxiety among many others. “A simple conversation can open up a [larger] conversation,” she added.

Perez recommends pharmacists ask their patients the following questions:

- To promote conversation: “How are you today?”
- To determine whether patients warrant referral:
  - “Do you feel little interest in doing things?”
  - “Are you feeling down and hopeless?” (a component of Patient Health Questionnaire-2, a screening tool for depression)

Nass and Phan agree that continuing education ranks among some of the most critical strategies organizations can implement to help ease clinician bias and improve patient trust by building a better rapport. For nearly 40 years, the GLMA has offered its GLMA Annual Conference on LGBTQ Health. The conference is just one of the organization’s initiatives aimed at improving LGBTQ+ health, and its programming includes workshops and research presentations for pharmacists. Phan emphasizes that all health care professionals must take steps to improve their ability to serve the LGBTQ+ and that these efforts begin with introspection.

“I think it starts with a reflection and reassessment of individual practice and conduct and then [transitions] to reflect on practice policies applied to all workers,” he said.

He encourages pharmacists to educate themselves and their colleagues about LGBTQ+ inclusive care, such as terminology and various social and health disparities. Once this has been accomplished, clinicians can then devise a plan to address these topics in their practice settings. Phan also noted that customizing care for this patient population often requires interdisciplinary and external collaboration, engaging the LGBTQ+ community itself to learn about patients’ individual experiences and needs.

However, education, training, assessment, and exploration are only part of the work. Successful implementation and practice of such LGBTQ+ inclusive policies require cadence and an ongoing commitment. Institutions must periodically reevaluate their new policies to determine how the practice has changed and the degree of effectiveness.

For references, visit drugtopics.com.

Educational Resources

Check out the following materials for more information on providing LGBTQ+ inclusive care:

- Learning resources from the National LGBTQ+ Health Education Center: https://www.lgbtqiahealtheducation.org/resources/
- Transgender and Gender Diverse Pharmacy Resource Guide from the Human Rights Campaign Foundation and American Pharmacists Association: https://www.thehrcfoundation.org/professional-resources/transgender-pharmacy-guide
- Providing LGBTQ-Inclusive Care and Services at Your Pharmacy from the Human Rights Campaign Foundation: https://www.thehrcfoundation.org/professional-resources/providing-lgbtq-inclusive-care-and-services-at-your-pharmacy
COVID-19 Vaccination Curriculum:
An Accredited Certificate Program for Pharmacists and Pharmacy Technicians to Apply CDC’s Provider Training Recommendations

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1. The Evolution of COVID-19: Where Are We Today?
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4. Safety and Efficacy of COVID-19 Vaccines: Understanding the Clinical Trials (Immunizations Credit)
5. Bloodborne Pathogens and Essentials of COVID-19 Vaccine Storage and Administration (Immunizations Credit)
6. Advancements in COVID-19 Treatment Options
7. Coping With COVID-19: Examining the Psychology of Vaccine Hesitancy and Barriers to Achieving Herd Immunity
8. COVID-19 and Vaccine Literacy: Practical Communication to Empower the Patient
9. COVID-19 Vaccine Update: Implementation and Best Practices
10. COVID-19 Post-Vaccination Considerations and Requirements (Immunizations Credit)

Updated information from the CDC’s COVID-19 Vaccination Program Interim Playbook and ACIP vaccination provider training.

Visit www.pharmacytimes.org/advance to learn more about the curriculum.
Migraine Care: Prevention, Treatment, and Medication Management

Various pharmacologic and nonpharmacologic therapies are available.

By Karen Berger, PharmD

Twelve percent of the US population experiences migraine, according to the Migraine Research Foundation. Migraine is the third most prevalent illness globally, and it affects 1 in 4 US households. Moreover, migraine can be disabling, with 90% of those affected worldwide unable to work or function normally during a migraine attack.¹

Migraine Phases and Symptoms

Although migraine is sometimes thought of as just a headache, a migraine attack can involve 4 phases of various symptoms. Not every stage is present in every migraine. Pharmacists can counsel patients to keep track of their migraines with a headache journal or app because neurologists and headache specialists may be able to pinpoint patterns and detect a migraine attack before it arrives.²

A migraine attack can manifest with any of the 4 phases:

Prodrome: This is a “preheadache” and can last several hours to several days. Symptoms include mood changes (eg, depression, irritability), sensitivity to light and sound, insomnia or fatigue, and stomach problems (eg, nausea, vomiting, diarrhea). Unique symptoms include yawning, food cravings, and increased urination.

Aura: This phase can last from 5 to 60 minutes. Symptoms include vision disturbances, such as blurry vision or vision loss, and/or seeing patterns or flashing or shimmering lights.

Headache: This phase can last from 4 to 72 hours. The hallmark symptom is pain, often on 1 side or 1 part of the head. Other symptoms like nausea, vomiting, anxiety, and sensitivity to light and sound may occur.

Postdrome: This “hangover” phase usually lasts 24 to 48 hours. Symptoms may include fatigue, body pain, dizziness, and mood changes.²

One way to remember migraine symptoms is with the acronym POUND³:

P: pulsating pain
O: 1-day duration of severe untreated attacks
U: unilateral pain
N: nausea and vomiting
D: disabling intensity

When to Consult a Specialist

It is prudent to refer patients who have frequent headaches, headaches that are increasing in severity or frequency, or headaches that interfere with functioning to a headache specialist for evaluation and a treatment plan, including preventive and acute treatment.⁴

If the patient experiences a new or unusual symptom, such as a headache that occurs within a few seconds or the worst headache they’ve ever had, refer the patient to the emergency department. Other symptoms that require emergency treatment include pain for more than 72 hours, fever, weakness, vision loss or changes, and confusion or if the patient is pregnant, is immunocompromised, or has a severe medical condition like liver or kidney disease.⁴,⁵

Migraine Treatment

Many options are available for migraine treatment. Product selection may be based on a variety of factors, including symptoms, medical history, other medications, patient preference for specific formulation(s), AEs, and cost or insurance considerations.

Pharmacists can provide counseling on the following popular first-line medications for migraine treatment.

OTC Options

For mild to moderate migraine attacks, acetaminophen and oral nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, diclofenac, ibuprofen, or naproxen may be used. Although acetaminophen is less effective than NSAIDs for migraine, it has fewer AEs. The combination in acetaminophen/aspirin/caffeine (Excedrin; Novartis) is also a first-line option.⁶

Counseling can include dosage, limitations, and the importance of avoiding alcohol. For NSAIDs and acetaminophen/aspirin/caffeine, also counsel patients on the risk of potential gastrointestinal and cardiovascular effects.⁷

Triptans

Triptans are effective as a first-line treatment for moderate to severe migraine. Triptans approved by the FDA for the treatment of migraine include the following:⁸

- Naratriptan (Amerge; GlaxoSmithKline)
- Almotriptan (Axert; Teva

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Nonpharmacologic prevention of migraine

Some nonpharmacologic migraine prevention tips for patients include8,9:

- Tracking: Keep detailed information in a headache diary or app.
- Trigger avoidance: Avoid known triggers such as odors, smoke, alcohol, stress, and food triggers.
- Sleep: Keep a regular sleep schedule by waking up and going to bed at the same times every day, including weekends.
- Diet: Eat regular, healthy meals and limit sugar. Drink plenty of water to avoid dehydration. Limit alcohol and caffeine. Avoid food triggers such as aged cheeses, chocolate, MSG, and cured meats.
- Exercise: Try to get moderate, regular exercise 3 to 5 times weekly.
- Reduce stress: Lower stress with relaxation, yoga, or stress management.

Pharmacological prevention of migraine

Patients who have 4 or more migraine attacks, 8 or more migraine days per month, or other qualifying factors may need preventive treatment.7 Many options are available, and some of the more common preventive treatment medications include the following9:

- β-Blockers (propranolol or metoprolol)
- Anticonvulsants (divalproex or topiramate)
- Antidepressants (such as amitriptyline or venlafaxine)
- β-Blockers (propranolol or metoprolol)

Calcitonin gene-related peptide (CGRP) inhibitors are a newer class of drugs that prevent migraine by targeting CGRP, which is found in higher levels during a migraine attack. CGRP inhibitors are monoclonal antibodies that block the effects of CGRP and are the first class of medications specifically designed to prevent migraine.

CGRP inhibitors approved by the FDA for the prevention of migraine are as follows10-14:

- Erenumab-aooe (Aimovig; Amgen): 70 to 140 mg injected subcutaneously once monthly
- Fremanezumab-vfrm (Ajovy; Teva Pharmaceutical Industries Ltd): 225 mg injected subcutaneously once monthly or 675 mg injected every 3 months (as 3 consecutive injections of 225 mg each)
- Galcanezumab-gnlm (Emgality; Eli Lilly and Company): 240 mg (2 consecutive doses of 120 mg) injected subcutaneously as a loading dose, then 120 mg once monthly
- Eptinezumab-jjmr (Vyepti; Lundbeck Seattle BioPharmaceuticals, Inc): 100 mg or 300 mg by intravenous infusion every 3 months

Common AEs associated with CGRP inhibitors include injection-site reactions (pain, redness, itching) and hypersensitivity reactions.10,14 Other AEs of erenumab-aooe include constipation (possibly with complications including hospitalization) and increased blood pressure. Eptinezumab-jjmr may also cause nasopharyngitis.15

Triptans have slight differences that may cause patients to respond to certain triptans but not others. Triptans are most effective when taken early in a migraine attack and are generally well tolerated. Most triptans, with the exception of almotriptan and frovatriptan, can cause fatigue, dizziness, chest pain, and nausea.8

Medication-Overuse Headache

An important consideration when talking with patients is the possibility of medication-overuse headache, also known as a rebound headache—part of a vicious cycle of having headaches and taking more and more medication to relieve them, which results in near-daily or daily headaches.15

Patients who experience headaches every day or almost every day, especially when the pain begins upon awakening, may be experiencing a medication-overuse headache. Refer the patient to a headache specialist, who can help the patient establish a new treatment plan that includes stopping acute medications, starting preventive treatment, and slowly reintroducing a limited amount of acute medicines as needed.15

Drug Interactions and Serotonin Syndrome

An essential consideration is the presence of drug interactions. Pharmacists can help patients by checking for drug interactions and being aware of the possibility of serotonin syndrome, a life-threatening condition that is more likely to occur with triptans and other medications that increase serotonin levels.

For references, visit drugtopics.com.

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Although pharmacists understand that all of a patient’s medical information is confidential and access to that information is protected by the Health Insurance Portability and Accountability Act (HIPPA) of 1996, some still have challenges staying 100% compliant. That is why independent pharmacy owners should establish a compliance checklist and ensure their staff does annual HIPPA training.

“Pharmacy staff need to be aware of who they are providing health information to over the phone, in person, or via mail,” said Chirag Patel, PharmD, MBA, chief operating officer and brand ambassador for Carolina Pharmacy Group in Charlotte, North Carolina. “The staff also need to ensure all health information at the pharmacy—prescription vials, labels, print outs, handouts, etc—is properly disposed of. That disposal source is most often an information security company that disposes of personal health information via shred boxes.”

Arielle T. Miliambro, Esq, a partner at Pine Brook, New Jersey-based health care law firm Frier Levitt, outlined the components of HIPAA:

- The HIPAA Privacy Rule protects the privacy of individually identifiable health information.
- The HIPAA Security Rule sets standards for the security of electronic protected health information (PHI).
- The HIPAA Breach Notification Rule requires covered entities and business associates to provide notification following a breach of unsecured PHI.

Each HIPPA rule may have different requirements and exceptions. Miliambro explained that the Privacy Rule contains certain limited exceptions for which PHI may be disclosed without authorization, such as to coordinate care among health care providers or to obtain reimbursement from a patient’s health insurer or payer. For the Security Rule, covered entities such as pharmacies must regularly conduct a risk analysis, according to Miliambro. “Such an analysis must address the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI held by the covered entity,” she said.

The Security Rule does not prescribe how the analysis must be conducted or formatted. Therefore, independent pharmacists must consider the scope and characteristics of the pharmacy’s activities and proceed accordingly in their analysis.

R. Jeffrey Hedges, president and CEO of R.J. Hedges & Associates in New Florence, Pennsylvania, which helps independent pharmacies feel at ease when it comes to compliance, noted that annual training for the entire staff is vital. If you don’t have the records to back that up, pharmacy benefit managers (PBMs) can cancel contracts.

What Needs to Be HIPAA Compliant?

A pharmacy has many systems that must be HIPAA compliant.

“Any information pertaining to a patient needs to be protected,” Patel said. “That includes pharmacy software, prescription labels and bags, prescription paperwork, telephone and internet services, and our website [and/or] app.”
Russell Dowdell is director of solutions engineering for SecureLink in Austin, Texas, which provides health care organizations with a centralized solution for managing privileged access for their third-party vendors. He noted that HIPAA compliance is less about seeking a HIPAA badge of sorts and more about implementing processes and tools in a compliant manner.

“It’s not enough to just focus on purchasing and deploying tools and systems that tout HIPAA compliance, since using those tools properly is the difference between being compliant and failing an audit,” he said. “This means deploying HIPAA-compliant configurations within your systems and applications such as encryption standards, AES-128 or higher is a good starting point, and password requirements.”

Some of these HIPAA requirements are vague: not as a means of making them easy to achieve, but in recognition that security standards are constantly evolving. Sites should adhere to the latest updates of cybersecurity frameworks, such as those of the National Institute of Standards and Technology, when setting policies. With the correct tools and policies in place, user training and compliance enforcement becomes much easier.

**Common Violations**

HIPAA violations—or worse, breaches—can come from several different places. One of the biggest, according to Dowdell, involves encryption standards.

“Failure to encrypt data or the use of outdated and insufficient encryption places data in a precarious position,” he said. “Should the data, the access to them, the device they’re on, the network they’re on, or some other component of the data security be compromised in any way, PHI without proper encryption turns into a disaster. This can mean anything from an unencrypted database that third parties access to an employee’s laptop that got stolen on the train.”

Another common violation is unauthorized or unintended access.

“Preventing all access to PHI is impossible and defeats the purpose of maintaining the information; after all, the right people need access to the right information,” Dowdell said. “The right people getting to the wrong information or more than they need is a common violation and the wrong people getting access to information at all is one of the worst violations.”

Compromised PHI based on user access can be as simple as granting your users access to all the information in a system when they only needed a single patient’s or a small data set. It can also involve bringing in a vendor and granting them network access when they only need remote access to the individual devices they maintain.

Additionally, HIPAA compliance requires staff training, and getting that rolled out effectively can be difficult and cause some violations.

“An untrained staff member might be caught discussing PHI when and where they shouldn’t because they don’t know better,” Dowdell said. “Likewise, an untrained staff member might improperly use the tools they have and misplace data [digitally or physically], resulting in more violations.”

**A Checklist for HIPAA Compliance**

Dowdell recommends that pharmacists first look at the bigger picture to identify gaps in compliance. Pharmacists should take into account the following:

- Where their data reside
- Who is on the network with access
- Whether the data can be accessed off the network
- How to validate or audit access to data

**Actionable Methods for Compliance**

Pharmacies can use several methods to ensure pharmacy HIPAA compliance, but continuous training is one of the most important.

At Carolina Pharmacy Group, all new hires undergo HIPAA-related training compliance courses, as do the rest of the staff annually, according to Patel.

“We also conduct audits of each of our pharmacies once or twice a year to ensure all compliance is met,” Patel said. “A newer method we have employed is having mystery shoppers call or visit our locations and attempt to obtain health information on behalf of someone else. This shows how well trained your staff is [on] both HIPAA and company policies.”

When Hedges goes into a pharmacy for an assessment, he sits in the waiting area and listens. If he hears conversations behind the counter, he knows that’s an issue and a possible violation. He suggests adding ambient noise such as music to keep other individuals from hearing what’s being said.

“You also need to post your notice of privacy practice in a public area and up on the website,” he said. “Using a checklist to get started is a great way to start to spot gaps that you can dig a bit deeper into,” he said. “Inevitably, some detailed review of individual systems and their configurations is required.”
Getting Started With Medication Management Services

Part 1 of this 3-part series examines how to strategically integrate this alternative revenue source into the pharmacy. by Fred Gebhart

Not many aspiring professionals go to pharmacy school to learn to count by fives. Yet counting pills and other prescription-related tasks continue to dominate the daily routine for too many pharmacists. Regardless of the setting, pharmacists focused on filling prescriptions seldom have time or other resources to care for patients beyond the immediate encounter.

Medication management services (MMS) help define an area of professional clinical services distinct from dispensing medication products. Importantly, MMS activities and outcomes can be quantified, measured, and tracked for reimbursement purposes. Providing MMS and tracking results to demonstrate improved outcomes are a professionally sustainable business model moving into the future.

“Medication management services [means] being proactive, getting ahead of interactions and other drug issues we find with patients, keeping track of their health so we know if something changes that might mean a change in their meds,” said Karami Reed, PharmD, a clinical associate at Shaver Pharmacy and Compounding Center in Pocatello, Idaho. Reed is translating a recent community pharmacy fellowship from the National Community Pharmacists Association (NCPA) Innovation Center and the Community Pharmacy Enhanced Services Network (CPESN) into practice.

“We are developing new payers. We’re talking with the cardiology center at a local hospital about managing patients with heart failure. The cardiologists all want us on board. It’s just a matter of convincing administrators,” Reed said. “When you think about people visiting their pharmacy 3 times a month versus seeing a physician once a year, MMS makes total sense in terms of improving outcomes.”

Use an Appointment-Based Model

The key to successful MMS is getting paid for it. That means getting off the Rx treadmill that has pharmacists filling prescriptions as one-time events when patients walk in the door.

“We are not keeping the doors open and lights on very successfully by just filling prescriptions,” said Cheri Schmidt, PharmD, director of clinical pharmacy for Grx Holdings LLC, which operates 22 community pharmacies in central Iowa. “Finding an alternative revenue source is vital to staying in business.”

According to Flip the Pharmacy, a transformation organization founded by the Community Pharmacy Foundation, patients with 2 or more chronic conditions account for 70% of the national health care bill and 83% of pharmacy fills.1 Transforming pharmacy workflow and business models to reflect the realities of health care needs is good for patients, good for payers, and good for the sustainability of pharmacy.

The first step in flipping the pharmacy workflow is scheduling patients rather than waiting for them to appear. Medication synchronization can convert patients with chronic conditions to scheduled visits and scheduled refills.

Carlie Traylor, PharmD, associate director of strategic initiatives and student affairs for the NCRA, refers to scheduled appointments as proactive workflow.

Before joining NCRA, Traylor was clinical director for Chancy Drugs, a 6-store independent pharmacy in South Georgia. She used MedSync to create a predictable workflow that let pharmacists focus on immunizations, adherence, patient education, and other nondispensing services.

“When you get about 40% of your volume being dispensed in a proactive workflow, it’s like flipping a light switch,” Traylor said. “That’s when you suddenly see you have the time and the resources to start bringing enhanced clinical services on line.”

MedSync also improves adherence and boosts refill numbers, said Cody Clifton, PharmD, director of clinical services at Duvall Family Drugs in Duvall, Washington. And just as technicians handle most of the dispensing workload, techs handle routine MedSync calls.

“Having your MedSync program down pat, maximizing it and continually enrolling patients, gives you the time and the cash flow to implement additional services and line up payers,” Clifton said.

MTM as a Springboard

Maximizing Part D Medication Therapy Management (MTM) is another opportunity to shift the business model.

“CMS (Centers for Medicare & Medicaid Services) has a standardized format for comprehensive medication reviews and targeted medication reviews under MTM,” said Jessica Frank, PharmD, vice president for payer solutions at OutcomesMTM, a Cardinal Health company that designs and administers Part D–compliant MTM programs. “But the conversation can—and should—be tailored to the patient. There are payable intervention opportunities for Medicaid and commercial payers as well as interventions for Medicare members outside the mandated Part D MTM program.”

Think flu shots and pneumococcal vaccinations, both reimbursable, said Jordan Ballou, PharmD, clinical assistant professor of pharmacy practice at the University of Mississippi School of Pharmacy.

COVID-19 vaccination is another reimbursable opportunity. Although
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3 Revenue Opportunities for 2021 with “on demand” adherence pouch-packaged medication.

“Just three months in, we’re over 150 patients, and that’s only prescription patients. We have a ton of patients packaging their supplements with us, and our supplement business has actually grown by more than five times. “

– Easton Bryant, Owner, North Century Pharmacy
Medication Management Services: What’s in the Name?

William S. Apple, executive director of the American Pharmacists Association from 1959 to 1983, advocated for pharmacists to manage medication therapy in the 1970s. That early term, medication therapy management (MTM) so encapsulated the concept of moving beyond dispensing medications to managing their use that policy works throughout health care added it to their vocabulary. The idea of pharmacists working individually with patients to manage medications and improve outcomes was incorporated into the Medicare Part D program. And MTM has never been the same.

On the upside, Part D MTM was the first population-based national program that reimbursed pharmacists for providing medication-related services rather than dispensing. On the downside, Part D MTM transformed what had been an inclusive concept of managing medication use at the patient level into a circumscribed set of medication reviews prescribed by the Centers for Medicare & Medicaid Services (CMS). If a medication-related service wasn’t included in the CMS definition, it wasn’t MTM.

So what was it? In 2018, the Joint Commission of Pharmacy Practitioners (JCPP) came up with the term medication management services (MMS) to describe the spectrum of services pharmacists offer to help patients better manage their medications. Rather than prescribing specific activities, JCPP laid out 4 key elements that define MMS:

1. A patient-centered approach that is individualized for every patient, focused on the patient’s needs and concerns, and involves the patient in the care process
2. An assessment of medication appropriateness, effectiveness, safety, and adherence, including accessibility and cost
3. A collaborative approach involving patient, caregiver(s), pharmacists, and other providers
4. A focus on health outcomes

most Medicare recipients have already received at least 1 dose of a COVID-19 vaccine, they will need the second dose if indicated. Those same patients may have younger family members, relatives, friends, and acquaintances who are eligible but not yet fully vaccinated.

“Part D MTM is a springboard to other services,” Ballou said. “It’s not just vaccines. We’re an accredited provider of DSME [diabetes self-management education]. I can remind patients that we offer diabetes education through Medicare. Yes, MTM is limited, but it’s an opportunity to learn what other services that particular patient might find useful. MedSync and using MTM as a bridge to non-Medicare services are ways to transform your business plan.”

Creating a Sustainable Business Model
Pharmacy has been talking about transforming itself for decades.

“Bill Apple made the case for separating product from service reimbursement when he was CEO at the American Pharmacists Association [APhA] in the 1970s,” said Lucinda Maine, PhD, RPh, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP).

Colleges of pharmacy have been pushing to separate pharmacy services and products almost as long. The Accreditation Council for Pharmacy Education cited the growing role of clinical services when it replaced the bachelor of science with the doctor of pharmacy as the sole professional practice degree in 1997.

Just like there is no one-size-fits-all medication regimen, there is no 1 business model that fits all pharmacies. AACP and CPESN created the Academia-CPESN Transformation (ACT) Pharmacy Collaborative to develop and publicize a variety of business models. The collaborative has collected more than 120 different practice models. Several are included in an inaugural ACT Patient Casebook.

Independent pharmacies have long focused on clinical services to differentiate themselves. What goes into the service mix depends on what payers and patients need. Successful MMS is about solving problems for both.

“COVID-19 has provided a lot of opportunities to boost clinical services like telehealth and consultations when physician offices were closed,” noted Anne Burns, BSPharm, RPh, APhA vice president of professional affairs. “The way pharmacies jumped into [COVID-19] testing and immunizations has opened a lot of eyes to the kinds of services we can provide that have a real impact on people’s lives and health.”

Paid Beats Free
It all comes back to getting paid.

“We’ve always given our services away,” said Becky Sneed, RPh, executive vice president and CEO, National Alliance of State Pharmacy Associations. “Free is a hard thing to transition away from, whether you are a pharmacist or a payer.”

Payers won’t cover MMS until they see it in action, and pharmacists can’t provide MMS until they get reimbursed for it, noted Clifton, who is also CPESN’s director of practice transformation and clinical programs.

“You don’t offer a payer, maybe a self-insured business, a hospital, a medical practice, or a health insurer your whole library of services,” Clifton explained. “You offer the services that are tailored to their individual pain points. Payers don’t care that you are a highly skilled pharmacist. They care that you can solve their specific problems. Easing payers’ pain points is the sustainable business model. And it’s starting to happen.”

For references, visit totalpharmacy.com.

Next month, part 2 of this series will dive deeper into reimbursement for MMS.

Resources to Get Started

- NCPA Innovation Center/CPESN Community Pharmacy Fellowship: https://ncpa.org/fellowship
- Flip the Pharmacy: https://www.flipthepharmacy.com/
- CPESN: https://cpesn.com/
- Academia-CPESN Transformation (ACT) Collaborative: https://www.actforpharmacy.com/
- ACT Patient Casebook: https://tinyurl.com/kdzkzc79
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A n increasing number of pharmacists are now prescribing birth control, further expanding their role as public health service providers.

Lincoln Alexander, PharmD, residency program director in Portland, Oregon, for Albertsons Companies, has been prescribing birth control for just over 5 years and has received a positive response from his patients.

"Patients are highly appreciative of the service. Nowadays, [pharmacists prescribing birth control] seems like second nature to many, which is a testament to the effective rollout we have had here in Oregon," said Alexander, who is also president-elect of the Oregon State Pharmacy Association.

Oregon isn’t alone. Allie Jo Shipman, PharmD, MBA, director of state policy for the National Alliance of State Pharmacy Associations, said 13 states and the District of Columbia currently allow pharmacists to prescribe oral contraceptives independently.

"There are also 13 states with legislation pending this session that would allow for the same thing," she said.

Although the prescriptive authority, age limits, and requirements for each state vary, the overall message is clear: Pharmacies in all practice settings are stepping up to the challenge.

**Differences Among States**

In 2013, California became the first state to pass a bill allowing pharmacists to “furnish” contraception without a physician prescription. However, Oregon was the first state to implement independent pharmacist-prescribed contraception.

"We had a physician legislator, Dr [Knute] Buehler, who just decided this is an access issue for patients," said Paige Clark, RPh, director of alumni relations and professional development at Oregon State University College of Pharmacy in Corvallis.

According to Shipman, state policies are typically structured using 1 of 3 types of prescriber authority:

- General prescriber authority, for which the pharmacist is the prescriber of record
- Statewide protocol, for which the pharmacist serves as the prescriber of record but the overall protocol is developed and approved by a state pharmacy board
- A statewide standing order

Under the last option, the state offers a statewide blanket prescription issued by a medical official in the department of health, who is often the chief medical officer. That official is considered the prescriber of record, but pharmacists are responsible for consulting and making clinical decisions.

Although some states have no age limits in place, Shipman said others only allow pharmacists to prescribe to those 18 years or older. Alternatively, they may allow prescribing to patients younger than 18 only if they have had a previous contraception prescription.

**Capitalizing on a Need for Public Health Service Providers**

A growing number of states are exploring options that go beyond collaborative practice agreements for birth control prescribing. The move follows a larger trend of enlisting pharmacists to provide public health services to patients for areas that don’t require a diagnosis.

"I think the pandemic has shown just how pharmacists have shined in a time of a public health emergency where pharmacies have stayed open… when other providers have closed," said Veronica Vernon, PharmD, an assistant professor of pharmacy practice at Butler University in Indianapolis, Indiana. "We have seen during the pandemic that access to contraception has been a significant concern."

Pharmacists can bring their unique set of skills to address what Vernon referred to as “contraception deserts,” geographic regions where access to birth control prescribers might be limited. They can also save states significant money in public costs.

One study examined the policy’s impact on Oregon’s Medicaid program in the first 2 years since it went into effect in 2016. According to the results, published in *Obstetrics & Gynecology*, pharmacist prescription of contraception averted more than 50 unintended pregnancies and saved the state an estimated $1.6 million in public costs.

**Payment Challenges**

Pharmacist contraception prescription may come with big benefits, but it also brings its own set of challenges. Not least among these is ensuring that pharmacists are getting paid for their services.

"We want to remove barriers for patients and we can be a more cost-effective approach for patients when
accessing contraception, but you want to make sure you are not giving away the service for free,” Vernon said.

Clark said that in Oregon the Medicaid system has put pharmacists in the provider lane, allowing them to use billing codes that are also available to physicians and physician assistants. However, to date, their adoption hasn’t been widespread because of the systems many pharmacies need to put into place in order to process medical billing.

“There are some hoops they have to jump through, and there are some connectivity issues,” she said.

Vernon said patient consultations and assessments can last up to 20 minutes or more. This makes it essential that pharmacists are paid not only for dispensing the medication but also for their time to properly assess the patient.

“If you are going to do this, make sure there is a payment pathway in place and that you are meeting with insurance companies in your state to talk about what this would look like. The states that have been most successful in pharmacists’ prescribing of contraception have ensured that there is a pathway for payment for pharmacists’ time,” she explained.

**Putting It Into Practice**

Vernon recommends having a designated space within the pharmacy to conduct patient assessments in community pharmacy settings.

She also stressed the need to evaluate the workflow within the pharmacy to manage day-to-day responsibilities and billing. It will most likely mean using technicians to their highest skill levels to increase overall efficiency.

“I think including them in your workflow so that the pharmacist can step away from checking prescriptions and counseling on other prescriptions to spend time with the patient...would be really helpful,” Vernon said.

For example, one pharmacy she talked with had tasked their lead technician with medical billing to streamline the workflow. Alexander echoed Vernon’s comments, saying one of the biggest challenges he has seen in practice is adapting the workflow.

“Time constraints with performing a contraceptive consultation with the patient can sometimes make this service a challenge to fit into the workflow, especially with the ongoing COVID-19 pandemic and vaccination efforts,” he said.

To accommodate all the workflow demands, Alexander said he has done his best to educate patients on the best time of day to come to the pharmacy for prescribing services, such as in the mornings when there is pharmacist overlap. However, he also has found that patients are generally “amenable [to] a short wait” if he clearly communicates to them the other demands going on at the time.

“It starts with treating each person that walks through our doors with courtesy, dignity, and respect,” he noted. He also stressed the importance of training pharmacy technicians, interns, and other associates on workflow procedure.

“Though these associates cannot make prescribing or consultation decisions, they are very helpful in onboarding the patient,” he said. He added that they can check IDs, gather insurance cards, or ask the patient to begin by filling out a self-screening questionnaire.

As an employee of the public state university in Oregon, Clark and her team were tasked with developing a thorough training program for pharmacists in the state and other areas.

She recommends that pharmacists who assume the new role invest in an educational program, even if it isn’t specifically required in their state.

“We have a 4-hour course that literally [covers] the entire process from the beginning of that patient walking in the door all the way through all the safety guidelines,” she said. The course makes it very doable for frontline pharmacists to begin offering the service, she added.

When working with patients, Vernon said, most states require pharmacists to follow the CDC’s US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016 and the US Selected Practice Recommendations For Contraceptive Use, 2016 to guide patient eligibility and selection.

Many states also require pharmacists to administer a patient questionnaire that can be a “great jumping off point” to begin a conversation with the patient, she continued.

“The best option is what the patient decides on, and so using a shared decision-making approach with the patient is really crucial,” she said. Having patient buy-in on the product will generally overlap. However, he has also found that patients are generally “amenable [to] a short wait” if he clearly communicates to them the other demands going on at the time.

“The best option is what the patient decides on, and so using a shared decision-making approach with the patient is really crucial,” she said. Having patient buy-in on the product will likely increase consistent adherence, she pointed out.

The last step is to find ways to successfully advertise the new services.

“It’s not if you build it, they will come, you also have to let patients know that you are doing this,” Vernon said.»

For references, visit drugtopics.com.
The American Society of Health-System Pharmacists (ASHP) announced plans to update its set of guidelines on preventing drug diversion during the 2021 to 2022 timeframe.

Drug Topics® spoke with Patrick Yoder, PharmD, cofounder and CEO of LogicStream Health, for insights on what health systems can expect from the upcoming updates.

**Drug Topics®:** First, can you give us a little overview of these updates?

**Yoder:** They last updated those guidelines [ASHP Guidelines on Preventing Diversion of Controlled Substances] in 2017, so a lot has changed since then. Some of the things that we expect them to highlight and really add to those guidelines are a more comprehensive view of the potential spots of diversion in a health system, all the way from procurement of the drug to administration and waste, so something on the order of 1000 different places where drugs could be diverted.

We also expect them to recommend 100% review of transactions in that flow, from procurement to administration and waste, which is a large change from previously. And then we expect some...commentary about newer technologies in this particular space. Examples might be automation, machine learning, artificial intelligence, radio-frequency identification, [and] probably some others as well.

**Drug Topics®:** What do you see as some of the potential effects of the new guidelines?

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**Drug Topics®:** What do you see as some of the potential effects of the new guidelines?

**Yoder:** Health systems are going to have to figure out new and creative ways to basically build out their diversion processes to match these new guidelines. I’m excited about them. I think, at the end of the day, diversion is about people. In talking with our customers, it excites me a lot that they think about diversion not in a policing-type way or “find the diverter and put them in jail,” but more if we can prevent it and get ahead of it far enough, we can help those colleagues...get the help they need to basically solve that problem for them personally, if they’re using drugs, and as part of their diversion activities.

**Drug Topics®:** How can hospitals build effective diversion processes using proven best practices?

**Yoder:** What we’ve seen from our work is that there are really 3 areas that tend to be the focus. Those are audit, consult, and technology.

The audit piece is really partnering with an independent third-party consultant or a contractor that has worked with lots of health systems and really looking at your current processes, your current people, your current committees, and the way that you do your diversion today. And basically, [they compare] that to what they’ve seen...as best practices across all of their customers and really [develop] gap analysis, so to speak, of what you should consider [changing as a health system]. The consultant piece is having that same party or another consultant work with your teams in parallel, so together with your diversion management committee, [to fill in] those gaps—updating policies and procedures, making sure roles and responsibilities are well defined.

The third part is technology. What we believe is going to be part of the ASHP recommendations and others as well—so it’s not only ASHP [but also other organizations including] the Joint Commission that actually assesses and accredits hospitals systems—is a recommendation to review all transactions. Technology is going to be a requirement in that world. What we know is [that] most hospitals actually spot check 10% or 20% of their transactions on a monthly basis. Going from that to 100% transaction review is going to require new innovative automation technology and, really, data to basically make all that happen much, much more efficiently so that health systems can achieve that goal.

This interview has been edited for length and clarity.

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Social Media Incites the COVID-19 Misinformation Epidemic

Many Americans still do not want to get vaccinated. Vaccine myths spread on the internet are a major part of the problem.

I have never golfed in my life. However, my 4-year-old grandson Luke lives near a golf course, and one of our favorite activities is walking through the woods searching for golf balls. Luke describes these golf balls as the ones hit by “bad golfers.” We have collected more than 250 golf balls, and about 200 of them are white. Therefore, Luke feels it is safe to conclude that bad golfers buy white golf balls, since that is the predominant color we find. If you want to be a great golfer, don’t buy white golf balls.

As failed as this logic appears, we have individuals with vaccine hesitancy applying the same logic. Many nonexperts frequently take to social media to express their antivaccine views, with virtually no understanding of virology or immunology. It’s like getting golf advice from a 4-year-old.

One simple statistic should persuade everyone who is reluctant to get the COVID-19 vaccine. According to an analysis conducted by the Kaiser Family Foundation, “Since vaccinations began in mid-December 2020, the number of COVID-19 deaths in long-term care facilities across all states in this analysis has declined by 89% as of April 2021.”

Currently, our nation doesn’t have half of our citizens fully vaccinated. Community pharmacists are seeing vaccine hesitancy with the same zeal we saw for getting the vaccine 6 months ago. I’ve even had discussions with pharmacists who have no interest in getting vaccinated. For the first 4 months of this year, there has been little movement of getting the “definitely nots” vaccinated. According to epidemiologists, we need to vaccinate 80% of the population to reach herd immunity. And to think we have 13% of Americans who are “definitely nots” that will never accept vaccination. Will we ever reach herd immunity?

In my 40 years of health care, I’ve seen nothing like this. I remember that mysterious disease in the 1980s that devastated many communities in our nation. Three years after the first cases were reported, the etiology was discovered and named human immunodeficiency virus. Yes, it took a worldwide effort of 3 years to even name and elucidate the cause of HIV. It took another dozen years to have effective treatment protocols to include combinations of different HIV drugs to save lives. Today, treating HIV is easier than treating type 2 diabetes; patients simply need to be adherent to their medications.

Here we are 15 months after the pandemic, and we have a vaccine that is 95% effective in preventing disease and nearly 100% effective in preventing death due to COVID-19. We pharmacists are struggling to find arms to get vaccines into from our overstocked refrigerators and freezers. Individuals read posts on social media, get advice from family members and friends and apply it to their decision whether to get the vaccine or not. Thanks to social media, everyone is an expert and has a forum to post their unsubstantiated opinions.

I’m glad that in the middle of the HIV epidemic in the 1980s and 1990s, we had no such venue as social media. We listened to the experts and waited for the scientists to come up with treatment protocols and then treated our patients accordingly.

We are blessed to have a number of COVID-19 vaccination options, all efficacious, with the only substantial differences among them being storage requirements. We community pharmacists need to engage our patients and encourage them to get vaccinated; we don’t need them to turn to social media.

If they believe everything on social media and they need to improve their golf game, I know a 4-year-old who can give them advice from his scientific study. Don’t buy white golf balls.

For references, visit drugtopics.com.

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.
**RECOMMENDED READING:**
**THE CDC RECONS**

**THEY MAY HELP YOU IDENTIFY PATIENTS FOR SHINGLES VACCINATION**

**SHINGRIX**  
(Zoster Vaccine Recombinant, Adjuvanted)

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**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.
- In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX.
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).
- 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.

**Please see Brief Summary of Prescribing Information for SHINGRIX on the previous pages.**

**References:**  
7. Prescribing Information for SHINGRIX.

You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

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SGXJRNa210011 April 2021
Produced in USA.
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 to 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.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

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 29,305 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 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,631 (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 = 4,486 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 (78.0%), redness (38.1%), and swelling (26.5%); 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>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
<td>11.1</td>
<td>69.2</td>
<td>8.8</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</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
<td>1.6</td>
<td>37.7</td>
<td>1.2</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</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
<td>1.0</td>
<td>23.0</td>
<td>1.1</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</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
<td>11.2</td>
<td>35.1</td>
<td>9.9</td>
</tr>
<tr>
<td>Fatigue</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</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
<td>15.6</td>
<td>29.0</td>
<td>11.8</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</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
<td>5.7</td>
<td>19.5</td>
<td>4.9</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</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
<td>3.4</td>
<td>14.3</td>
<td>2.7</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</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
<td>8.7</td>
<td>13.5</td>
<td>7.6</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.4</td>
<td>1.0</td>
<td>1.7</td>
<td>0.8</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.
* 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: NCT01165577 and Study 2: NCT01165229.
* Placebo was a saline solution.
* Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
* Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.
* Fever defined as >37.5°C/99.5°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.
* GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

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 (continued on next page))
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 52.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), 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 0.1%), 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 (<0.01%) reported lymphadenitis and 1 subject (<0.01%) 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 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 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.

Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalization among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

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 temporarily 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 Vaccine 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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New Nonstimulant Medication Is Approved for ADHD in Children

By Kathryn Wheeler PharmD, BCPS

On April 2, 2021, the FDA approved viloxazine (Qelbree; Supernus Pharmaceuticals, Inc) for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged 6 to 17 years. Viloxazine is a selective norepinephrine reuptake inhibitor and is the first new nonstimulant medication for treatment of ADHD in children in more than 10 years.1

The FDA evaluated the safety of viloxazine in 3 randomized, placebo-controlled trials. Studies 1 and 2 included participants aged 6 to 11 years and lasted either 6 or 8 weeks that included a titration period to achieve maintenance dosing of 100 mg, 200 mg, or placebo daily (study 1) and 200 mg, 400 mg, or placebo daily (study 2). Participants aged 12 to 17 years were titrated to 200 mg or 400 mg or placebo in study 3. The primary end point in each study is a change in total score on the ADHD Rating Scale, comparing baseline to the end of the maintenance period assessments. The change in Clinical Global Impression-Improvement (CGI-I) score from baseline was a secondary end point in each study. Patients administered viloxazine showed statistically significant improvements in ADHD rating scale scores and in CGI-I scores compared with those given placebo.

In trials, the most common adverse effects (AEs) included nausea, vomiting, insomnia, irritability, decreased appetite, and somnolence. The most common AEs leading to treatment discontinuation included somnolence, nausea, fatigue, decreased appetite, headache, tachycardia, and irritability. Viloxazine carries a boxed warning regarding higher rates of suicidal thoughts and behaviors among patients administered viloxazine in clinical trials compared with patients administered placebo. Patients treated with viloxazine should be monitored for suicidal ideation or behaviors, particularly when initiating or increasing therapy. Viloxazine may activate mania in patients at risk for bipolar disorder. Patients should be screened prior to initiating therapy for a history of suicide, depression, or bipolar disorder. Viloxazine may cause an increase in blood pressure and heart rate. A patient’s blood pressure and heart rate should be assessed at baseline when initiating therapy and periodically throughout treatment. Concomitant administration of viloxazine with monoamine oxidase inhibitors is contraindicated due to an increased risk of hypertensive crisis. Viloxazine strongly inhibits cytochrome P450 1A2 (CYP1A2) and will increase exposure to concomitant CYP1A4 substrates and increase the risk of AEs to those medications. In addition, viloxazine weakly inhibits CYP2D6 and CYP3A4.

In patients aged 6 to 11 years, the recommended starting dosage of viloxazine is 100 mg once daily and may be titrated in 100-mg increments weekly to a maximum dosage of 400 mg once daily. The recommended starting dosage for patients aged 12 to 17 years is 200 mg once daily. In this age group, the dosage may be titrated up in 1 week to the maximum recommended dosage of 400 mg once daily. Capsules may be swallowed whole with or without food or may be opened and contents sprinkled on applesauce. The capsule or applesauce with sprinkled medication must not be chewed. Medication mixed with applesauce must be used within 2 hours of mixing and cannot be stored for later use.
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