COVID-19 VACCINE TAKEAWAYS
LESSONS LEARNED
STORIES FROM PHARMACISTS ON THE FRONT LINE

A Primer on Naloxone
Self-Care for Respiratory Infections
Getting Paid for Medication Management Services
DO YOUR ADULT PATIENTS HAVE A GAP IN IMMUNIZATIONS?

HELP PROTECT YOUR ADULT PATIENTS. TAKE THE SIMPLE STEP OF ADDING Tdap TO YOUR VACCINATION PROTOCOL.ª

Help close the Tdap gap

• CDC recommends that all adults 19 years of age and older who have not previously been vaccinated with Tdap receive a dose of Tdapª

• However, only 31.7% of eligible adults in this age group are vaccinated with Tdap as of 2017²
  – By comparison, the rate for adult influenza vaccination for the 2016-2017 season was 45.4%²
  – As of 2017, pneumococcal vaccination coverage in adults 65 years of age and older was 69.0%²

ª For vaccine age indications and coadministration information, please visit www.cdc.gov.
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*For vaccine age indications and coadministration information, please visit www.cdc.gov.
Tdap= Tetanus, diphtheria, and acellular pertussis

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Questions Linger Around COVID-19’s Origin

As it natural zoonotic spillover that catapulted SARS-CoV-2 from an emerging virus into a pandemic pathogen or was it something much more sinister? Is it at all possible that a lab leak in Wuhan, China, was the spark that lit the fuse?

Early on, whispers of a potentially engineered virus quickly grew to a roar and fueled speculation that China was behind the pandemic. In February 2020, a group of 27 public health scientists published a letter in The Lancet disputing the lab leak theory and announcing their support of their counterparts in China.

“The rapid, open, and transparent sharing of data on this outbreak is now being threatened by rumors and misinformation around its origins,” wrote the authors, who all declared no competing interests in their disclosures as recommended by the International Committee of Medical Journal Editors. “We stand together to strongly condemn conspiracy theories suggesting that COVID-19 does not have a natural origin.”

Fast forward to June 2021 and new evidence that has breathed new life into those origin questions. In an update to the February 2020 letter, The Lancet has published an addendum with revised disclosure statements from virologist and investigator Peter Daszak. In the revised document, Daszak noted that his remuneration is paid solely in the form of a salary from EcoHealth Alliance, a New York-based nonprofit research foundation of which he is president. The company has reportedly worked directly with Wuhan laboratories and funded gain-of-function research at China’s Wuhan Institute of Virology.

Are these coincidences or “where there’s smoke, there’s fire” situations? It’s unclear. But they add to the bank of troublesome questions standing in the way of the truth about COVID-19.

The questions extend beyond origin theory, though. With the US FDA’s green lighting of vaccines for adolescents and young adults comes hesitation over long-term effects. The CDC’s Advisory Committee on Immunization Practices recently met to discuss instances of myocarditis or pericarditis in people aged 30 and younger who have received an mRNA COVID-19 vaccine.

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We may never know what triggered the global pandemic that has claimed more than 3.8 million lives. And we won’t know the long-term effects until enough time has elapsed. What we do know for certain is that the incredible strength and collaboration of the scientific community have allowed us to regain some semblance of normalcy. The development and rollout of multiple effective vaccine options have been the medical miracle of our lifetime. That, right now, will have to be the only answer that matters.

Thank you for reading,

Mike Hennessy Sr
Chairman and Founder of MJH Life Sciences™
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LESSONS LEARNED

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ASCO 2021: HOPA Survey Details Cancer Drug Shortages

Survey results presented during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, held virtually June 4 to 8, 2021, showed the prevalence of oncology drug shortages (Figure).¹

Oncology medication and supportive care products for patients are often in shortage, resulting in disruptions in chemotherapy treatment and medication regimens. The 34-item survey conducted by the Hematology Oncology Pharmacy Association (HOPA) among its membership, aimed to evaluate the effects of oncology-related drug shortages on patient care. Of the HOPA membership cohort, 68 health care organizations completed the survey, almost all of them pharmacists.

The top 5 oncology drugs in shortage reported in the survey were epirubicin, flutamide, decitabine, mechlorethamine, and dactinomycin.

The top 5 supportive care drugs in shortage were noted as hydrocortisone, bivalirudin, promethazine, mycophenolate sodium, and scopolamine. For references, visit drugtopics.com

FDA Approves Secukinumab for Pediatric Plaque Psoriasis

From our sister publication Dermatology Times®
By Linda Stocum

The FDA has approved secukinumab (Cosentyx; Novartis) for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are also candidates for systemic therapy or phototherapy.¹

The is the first FDA approval that secukinumab has received to treat pediatric patients. There are 5 years of adult data showing the long-term efficacy and a consistent safety profile for the treatment of moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis.

The approved dosing for secukinumab is 75 mg or 150 mg depending on patient weight and is administered by subcutaneous injection every 4 weeks after the initial dose. Once trained by the physician and given proper counseling, an adult caregiver can administer the dosage. The approval is based on 2 phase 3 studies that demonstrated that both low-dose and high-dose secukinumab were effective and safe. For reference, visit dermatologytimes.com.

EXPRESS INTERVIEWS

Leverage Technology to Maximize COVID-19 Vaccinations, Boost Clinical Services, and Transform Pharmacy Practice

Drug Topics® interviewed Jason Ausili, PharmD, chief clinical officer of FDS, Inc, about President Joe Biden’s recent announcement on using community pharmacists to reach his goal of getting 70% of Americans to receive at least 1 COVID-19 vaccine by July 4, 2021, as well as how independent pharmacists can leverage technology to save time and reinvest in clinical services now and beyond the pandemic.

The COVID-19 pandemic has shed light on just how accessible pharmacists are as health care professionals and how pharmacists are uniquely positioned to drive the COVID-19 vaccination effort. But how can small independent pharmacies keep up with demand?

To watch part 1 of this interview, visit www.drugtopics.com/expert-interviews or scan the QR code.

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It’s nearly a year since August 2020, when the US Department of Health & Human Services (HHS) authorized licensed pharmacists throughout the country to provide childhood immunizations to patients aged 3 to 18 years during the public health emergency. This is a significant, albeit temporary, expansion of pharmacist authorization to administer pediatric vaccines in many states. Although about half of states and territories allow pharmacists to administer vaccines to patients of any age, many have age limitations and other restrictions pertaining to specific vaccines. Yet it seems that most pharmacies nationwide have not gotten involved in pediatric vaccinations. “We’re trying not to bite off more than we can chew,” said Kevin Day, PharmD, president of Day’s Miami Heights Pharmacy in Cincinnati, Ohio. “[COVID-19] testing and vaccines have been plenty.”

Perhaps now that the initial rush of COVID-19 vaccination has subsided, pharmacies should consider establishing pediatric vaccination programs, as this is an opportunity that can benefit both individual pharmacists and the profession as a whole.

Why Should Pharmacists Vaccinate Kids?
The HHS authorization was intended to bolster childhood immunization levels after the CDC collected data in May 2020 indicating a significant drop in childhood vaccinations in the early months of the pandemic, raising fears of outbreaks of vaccine-preventable disease. Even if vaccination levels now appear to have returned to prepandemic levels, there may remain a backlog of patients who are behind on their immunizations, according to Jeffery Goad, PharmD, professor and chair of the Department of Pharmacy Practice at the Chapman University School of Pharmacy in Irvine, California.

Administering childhood vaccines gives pharmacists the opportunity to practice at the top of their license while improving immunization rates in their communities. “Expanding into pediatric vaccines expands the range of providers that you’re able to network with, and that creates more collaboration among providers that you may not have dealt with,” Goad noted. In addition, he said, a childhood vaccination program helps build parents’ trust in pharmacists.

Communication and Collaboration
Setting up to provide childhood vaccines should not be a major investment for most pharmacies, Goad said, as the basic infrastructure of an immunization administration area and vendors to order vaccines and supplies are already in place. “They just need to order the right vaccines,” he said.

What may require more attention is establishing the infrastructure to identify children who need vaccination, document appropriately, and communicate with other health care providers to ensure that children are not left behind.

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Communicating with other health care providers to ensure that children are not left behind.

“Expanding into pediatric vaccines... creates more collaboration among providers that you may not have dealt with.”

Jeffery Goad, PharmD
TABLE: RECOMMENDED IMMUNIZATION SCHEDULE FOR CHILDREN AGED 3 TO 18 YEARS

<table>
<thead>
<tr>
<th>AGE</th>
<th>4 TO 6 YEARS</th>
<th>11 TO 12 YEARS</th>
<th>16 YEARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, tetanus, acellular pertussis (DTaP, age &lt; 7)</td>
<td>5th dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injectable polio vaccine (IPV)</td>
<td>4th dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR)</td>
<td>2nd dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varicella (VAR)</td>
<td>2nd dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetanus, diphtheria, acellular pertussis (Tdap, age 7+)</td>
<td>Tdap</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningococcal</td>
<td>1st dose</td>
<td>2nd dose</td>
<td></td>
</tr>
<tr>
<td>HPV</td>
<td>2- or 3-dose series*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>Yearly**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*May be given as early as aged 9 years. If the first dose is given at 9 to 14 years, 2 doses are administered 6 to 12 months apart (minimum 5 months); if the first dose if given at 15 years or older, 3 doses are administered at 0, 1 to 2 months, and 6 months (minimum 12 weeks from dose 1, 5 months from dose 1).

**2 doses separated by at least 4 weeks in children aged 6 months to 8 years who have received fewer than 2 doses before; 1 dose for children 6 months to 8 years who have received at least 2 doses before; 1 dose for children 9 years and older.

being under- or overvaccinated. This can be accomplished easily if pharmacists have access to electronic health records or if their state has a comprehensive immunization registry that pharmacists can access (in some cases, directly through their dispensing software). But not all states mandate that all providers document vaccinations in the state registry, resulting in incomplete immunization registries. Pharmacists who cannot access vaccine information electronically must find other ways to communicate with pediatricians to share immunization information (eg, faxing records).

Pharmacists who can check immunization registries while filling prescriptions can identify children who are due or overdue for specific vaccines. In fact, COVID-19 vaccinations for adolescents may provide a key opportunity for pharmacists to identify other vaccines these teens need. Importantly, although previous recommendations were to separate COVID-19 and other vaccines by 14 days, the CDC now allows COVID-19 and other vaccines to be administered without regard to timing.4

Generally, however, the major source of pediatric vaccine business is from physician referrals, so it is crucial for pharmacists to cultivate relationships with local pediatricians. Before establishing a pediatric vaccine program, pharmacists must perform a needs assessment in their community. Goad said, by reaching out to local pediatricians to find out whether “they are struggling to meet the backlog of vaccines.”

Day said a main reason his pharmacy has not jumped in on childhood vaccines is to respect relationships with pediatricians in his area who, he said, “do an excellent job.” In contrast, Travis Wolff, PharmD, owner of Med-World Pharmacy in Sapulpa, Oklahoma, reported that his local physicians find ordering and storing vaccines to be a huge barrier, so they are happy to refer their patients to the pharmacy for vaccination. Establishing which local physicians this is the case for is important.

Although the American Academy of Pediatrics came out strongly against pharmacists providing childhood vaccines at the time of the HHS announcement, Goad believes the academy’s main concern is communciation and the potential for under- or overvaccination. “We have to reassure pediatricians that we are not disrupting [the normal visits pediatricians have], that we are simply acting to help them offload some of the patients where they now are behind.” For example, he said, physicians can send their patients to the pharmacy for later doses of a multidose series of vaccines, and pharmacists should encourage parents to schedule their kids for physicals if they haven’t seen the pediatrician in a while.

Compensation Matters
Before establishing a pediatric immunization program, pharmacists must ensure they’ll be reimbursed for their services. Medicaid and commercial insurance rules vary by state. “The state of Oklahoma currently does not pay pharmacies through our state Medicaid for immunizations in patients under age 19,” said Wolff. “This has proven to be a huge barrier to vaccinating those that need it most.” And, he noted, many commercial insurers cover pediatric vaccines on the medical but not the pharmacy side.

Pharmacies can apply to participate in their state’s Vaccines for Children Program, which covers vaccine costs for children 18 years and below. For more information, go to https://www.cdc.gov/vaccines/programs/vfc/providers/questions/qa-join.html.

A Chance for Change
According to Goad, the emergency declaration has shown that you can enact a national standard, rather than what he calls “the patchwork of immunization laws” throughout the country.

“As the only pharmacist serving on our state board of health, I am working to educate and encourage reform in the practice privileges of pharmacists every day,” Wolff said. “This is a window of opportunity.” Goad concluded. “Pharmacists need to advocate to their legislators and their stakeholders that this is something they can do and they want to do, so that everyone just thinks that the pharmacy is the place to go to get a vaccine.”

For references, visit drugtopics.com.
In 2019, almost 50,000 people in the US died as a result of opioid overdose; this number includes events involving prescription pain medications, heroin, and synthetic opioids like fentanyl. The CDC estimates the annual economic burden of prescription opioid misuse at $78.5 billion. Pharmacists can be a valuable resource to patients and the community as a whole by learning about naloxone and how to treat an opioid overdose, as well as recommending naloxone to patients and counseling on its use.

This article is the first of a 2-part series on naloxone education and patient counseling for pharmacists.

What Is Naloxone?
Naloxone is an opioid antagonist. It attaches to opioid receptors, rapidly reversing an opioid overdose. Naloxone quickly restores normal breathing in a patient whose breathing has slowed or stopped because of an opioid overdose. Naloxone is effective only in opioid overdose due to drugs such as oxycodone, hydrocodone, codeine, heroin, fentanyl, and morphine.

Naloxone does not treat overdoses of nonopioid medications, and it does not have an effect on someone who has not taken opioids.

Risk Factors for Opioid Overdose
Although any opioid use can lead to overdose, some factors that may increase overdose risk include:

- combining opioids with alcohol or other drugs (such as benzodiazepines);
- taking a high daily dosage of opioids;
- taking more opioids than prescribed by the physician;
- taking illegal opioids that could contain unknown substances;
- having sleep apnea;
- having impaired hepatic or renal function; and
- being older than 65 years.

Signs of an Opioid Overdose
Signs of an opioid overdose include:

- slowed or shallow breathing (or no breathing);
- pinpoint pupils (small, constricted pupils);
- falling asleep;
- loss of consciousness;
- choking or gurgling;
- limp body; and
- skin that is pale, blue, and/or cold.

In the event of an opioid overdose (or suspected overdose), administer naloxone and call 911. Keep the person awake and talking. Another naloxone dose (or more) may be necessary. Stay with the person until emergency help arrives.

Does Naloxone Require a Prescription?
Results of studies show that naloxone distribution programs and naloxone access laws reduce opioid overdose deaths without increasing opioid use. Estimates suggest that when laypersons and emergency personnel have naloxone, 21% of opioid overdose deaths could be avoided.

Although naloxone is a prescription drug, many pharmacies in the United States have naloxone available without a prescription through a standing order. Law enforcement or emergency medical services personnel can work with local health departments to access naloxone.

Available Naloxone Formulations
Naloxone is available in 3 FDA-approved forms:

1. Prepackaged nasal spray
Naloxone nasal spray (Narcan; Sankyo) is sprayed into 1 nostril while the patient lies on their back.

Dosage and administration: One spray into 1 nostril, and then call 911. If the patient responds and goes back into respiratory depression before help arrives, or if the patient does not respond after 2 to 3 minutes, give another dose in the other nostril using a new naloxone nasal spray. If there is still no response and more doses are available, give additional doses every 2 to 3 minutes using a new naloxone nasal spray with each dose, and alternate nostrils each time, until the EMS arrives.
2. Autoinjection
Naloxone autoinjector (Evzio; Kaleo) is a prefilled autoinjection device that is injected into the thigh muscle. When it is turned on, a recording gives instructions.

**Dosage and administration:**
Administer 1 intramuscular (IM) or subcutaneous (SQ) injection into the thigh (through clothing if necessary), then call 911. If the patient does not respond and more doses are available, doses may be repeated every 2 to 3 minutes until EMS arrives. If the patient responds and goes back into respiratory depression before EMS arrives, give another dose.

3. Injection
Naloxone injection is given by a health care professional. The route of administration may be intravenous (IV), IM, or SQ. The IV route is preferred because of its faster onset.

Depending on the opioid, dose, and route of administration that caused the overdose, the naloxone dose will vary and may require repeat doses.

Each patient who receives a naloxone product, regardless of whether it is an autoinjector or nasal spray, should receive training, read the instructions, and check the expiration date. These 2 dosage forms were designed to be easy to use by anyone in an emergency situation.

**Adverse Effects**
Naloxone may cause withdrawal symptoms. Although uncomfortable, withdrawal symptoms are not life-threatening. They may include headache, blood pressure changes, tachycardia, sweating, nausea, vomiting, tremors, irritability, nervousness, aggressive behavior, body aches, fever, runny nose, and sneezing.

For references, visit drugtopics.com.

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**PEER PERSPECTIVES ON COUNSELING OPPORTUNITIES**

**Toni Mitchell,** PharmD, of Plymouth, Massachusetts, was counseling a patient in the pharmacy. The patient, who had been prescribed hydrocodone bitartrate and acetaminophen (Norco), shared that she had naloxone on hand.

“She elaborated that her dog, which is small and very hyper, knocked the Norco bottle over and started to tear into it when she was upstairs. By the time she got to her dog, he was catatonic and foaming at the mouth—evidence of what happened was obvious, as the bottle and remaining pills were scattered about. She thought quickly and called the veterinarian, who talked her through administering the Narcan nasal spray, and [her dog] came around. She rushed him to the animal hospital right after, but it did save his life. Now, she always keeps Narcan on hand.”

Mitchell recommends pharmacists share this scenario with patients because they might not think of pets when thinking about accidental overdose. She reminds pharmacists to counsel patients to contact a poison control center or the veterinarian before administering naloxone to a pet.

**Justine Russell,** PharmD, BCPS, is a clinical pharmacy specialist in emergency medicine. In the emergency room setting, she has seen “both sides of naloxone use.” Sometimes it is too little too late, but other times she has seen it bring people back, “living up to that lifesaving description it has been given.”

She recommends patients keep 2 doses on hand at home and reminds her patients always to call 911 in an emergency situation in case more is needed. “It’s not a substitute for medical care in true emergencies,” she said. Russell explained that some patients require much higher doses of naloxone to reverse the opioids in an overdose situation. “This is why it is so important always to call 911 if administering naloxone in the community. Anybody who is even thinking they should have it on hand just in case should take steps to do so,” she recommended.

**Stefanie Toomey,** PharmD, offers naloxone to patients who take higher doses of opioids or combinations of benzodiazepines and opioids. She often contacts the insurance company before the patient arrives at the pharmacy so she can offer the naloxone prescription as well as the price with insurance. “Not all physicians bring up this conversation with their patients, so the standing order helps fill in the gaps in care that can sometimes happen,” she said. “When it comes to naloxone patient counseling, I discuss how easy it can be to forget that an opioid pill was taken, and a second dose is then taken accidentally. I then explain how naloxone can be used if you become unresponsive or stop breathing vs using the word ‘overdose’ since it can sound accusatory.” When counseling a patient, she uses the “teach-back” method. “I have them teach back to me how to use the naloxone so I know they can confidently show their friends and family members how to use it and also where it is located in the house. It can’t be used if no one knows where it is!”
Irritable bowel syndrome (IBS) is a chronic condition that affects the large intestine and can have an impact on patients’ quality of life. Treatment typically consists of dietary changes, pharmacotherapy for constipation (IBS-C) and diarrhea (IBS-D), and abdominal pain management. Pharmacists can play an integral role in IBS management through medication and dietary education.

### Treatment Overview and Guideline Update

Treatment for IBS includes medications to manage diarrhea such as rifaximin (Xifaxan; Salix Pharmaceuticals) and those for constipation like lubiprostone (Amitiza; Sucampo Pharmaceuticals and Takeda Pharmaceuticals North America, Inc). Dietary changes (eg, increasing soluble fiber) can help manage IBS symptoms. The American College of Gastroenterology (ACG) recently released updated guidelines for IBS that addressed 25 clinically important questions including new treatment recommendations.

FODMAPs include certain grains, vegetables, fruits, and dairy products that can trigger meal-related symptoms in patients with IBS. However, there is still a need for more studies evaluating a low FODMAP diet. Pharmacists can educate patients on the 3 phases of the plan:

- **Phase 1:** Substitution of foods with low FODMAP choices
- **Phase 2:** Gradual reintroduction of foods into diet while evaluating symptoms
- **Phase 3:** Personalized diet to avoid foods that trigger symptoms

The new ACG guidelines include a strong recommendation for the use of rifaximin to manage IBS-D symptoms based on clinical trials. Secretagogues such as plecanatide (Trulance; Synergy Pharmaceuticals) and linaclotide (Linzess; Ironwood and Allergan) now have high rankings in efficacy for IBS-C. Plecanatide is a guanylate cyclase-C agonist that was not available several years ago and was not mentioned in the 2018 guideline update. Linaclotide and plecanatide are both well tolerated, and the most common adverse effect (AE) is diarrhea. The serotonin type 4 (5-HT4) agonist tegaserod (Zelnorm; Sloan Pharmaceuticals) was reintroduced into the market in 2019 for IBS-C after it was voluntarily withdrawn in 2007 because of a safety signal of an increased risk of cardiovascular AEs. The ACG guidelines recommend the use of tegaserod in women younger than 65 years with < 1 cardiovascular risk factors who have failed secretagogue treatment. The use of tricyclic antidepressants (TCAs) is now also recommended for the treatment of abdominal pain as they work by acting on norepinephrine and dopaminergic receptors. Pharmacists can recommend that patients be started on a low dose of a TCA that should be titrated up gradually to achieve the best symptom management with the least amount of AEs. AEs associated with TCAs include dry mouth, dry eyes, urinary retention, constipation, and cardiac arrhythmias.

### Pipeline Drugs for IBS

Arena Pharmaceuticals reported topline results from the phase 2b CAPTIVATE clinical trial (NCT04043455) demonstrating that orlizinab, a novel full agonist of the cannabinoid receptor 2, did not meet the primary efficacy end point of statistically significant improvement in the overall average abdominal pain score from baseline to week 12 for patients with IBS-C and IBS-D. Orlizinab did demonstrate efficacy for moderate to severe pain at the higher dose studied. The company will evaluate possible future options for IBS. OrphoMed is investigating ORP-101 in a phase 2 clinical trial (NCT04129619) for IBS-D, and topline results are expected in the second half of 2021.

For references, visit drugtopics.com.
**INTRODUCING AN EHR DESIGNED FOR PHARMACY:**

- View patient’s immunization history
- Send patient consent forms through text message
- Electronically document encounters
- Identify vaccine reimbursement opportunities
- Update state IIS registries and the federal data lake for COVID-19 vaccines
- Bill immunization claims, even for out-of-network and uninsured COVID-19 vaccine patients

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**omnisys.com**
Self-care for Upper Respiratory Tract Infections

Pharmacists can offer OTC recommendations for symptom relief.

Karen Berger, PharmD

Pharmacists are an excellent resource for patients to ask questions about upper respiratory infections, especially with the ongoing COVID-19 pandemic. As trusted and accessible health care professionals, they can effectively counsel patients on appropriate OTC products and refer them to their physician when necessary.

The upper respiratory system consists of:

- Nose/nostrils
- Nasal cavity
- Mouth
- Throat (pharynx)
- Voice box (larynx)

Most upper respiratory infections are caused by a virus and include the common cold, sinusitis, pharyngitis, epiglottitis, and laryngotracheitis (see Table).

Common Cold

The common cold is the most prevalent type of respiratory infection. Usually caused by a virus, its symptoms include a stuffy or runny nose, sneezing, sore throat, and cough. Fever rarely occurs, and complications are rare. Sometimes, sinusitis or an ear infection may develop. Treatment for a common cold is symptomatic.

Sinusitis

Sinusitis is an acute inflammation of the paranasal sinuses and can be caused by viruses or bacteria. Symptoms include pain, pressure, and tenderness around the sinus, as well as nasal discharge. Patients may feel tired and have a slight fever. Symptomatic treatment with analgesics and moist heat, as well as a decongestant, can be helpful. If an antibiotic is needed, amoxicillin/clavulanic acid is a first-line treatment.

Pharyngitis

Pharyngitis is an inflammation of the pharynx (throat), which can be caused by bacteria, virus, or fungus, or by smoking. Most cases are viral and occur with a common cold or flu. Symptoms include a red, sore, or “scratchy” throat. Fever, fatigue, muscle pain, or headache may occur, as well as swollen lymph nodes and difficulty swallowing. Treatment is symptomatic unless the virus is caused by herpes simplex, in which case acyclovir is used. If an antibiotic is needed, a penicillin or macrolide is often used.

Epiglottitis and Laryngotracheitis

Epiglottitis or laryngotracheitis (croup) is an inflammation of the upper

DR TAVEL’S TIPS

For a viral illness, Morton Tavel, MD, clinical professor emeritus of medicine at Indiana University School of Medicine, recommends the following:

- Plenty of fluids, especially water and chicken soup
- Saltwater gargle (1/4 tsp salt dissolved in 8 oz warm water)
- Saline nasal spray or drops to loosen mucus in the nasal passages
- Steam inhalation to alleviate congestion (or cold or warm steam humidifiers)
- Plenty of rest to combat fatigue and malaise

Tavel advises telling patients that “remaining at rest is important to prevent the spread of infection. As a rule of thumb, stay away from work or school while you do not feel well.”

In terms of OTC medications, Tavel recommends the following:

- Antihistamines: second-generation products such as fexofenadine or cetirizine (Allegra or Zyrtec), which are less sedating and can relieve watery eyes, runny nose, and sneezing
- Decongestants, preferably the nasal form, such as oxymetazoline (Afrin), used for 3 days or less to prevent rebound congestion
- Acetaminophen (Tylenol) to alleviate pain and reduce a high fever
airway. The diagnosis depends on location, symptoms, and pathogens.⁴

Epiglottitis, most often caused by *Haemophilus influenzae* type b, is less common in adults and can be associated with viral or bacterial infections. Laryngotracheitis is usually viral. Epiglottitis symptoms begin with sudden onset of fever, sore throat ("cherry-red" epiglottitis), hoarseness, drooling, and difficulty swallowing. It can quickly progress to severe respiratory distress and can be fatal. Epiglottitis is a medical emergency, especially in children, who need immediate emergency care including intubation and antibiotics (against *H influenzae*).

Symptoms of laryngotracheitis (croup) include a runny nose, fever, sore throat, and mild cough, progressing to tachypnea, a barking cough, and stridor. Treatment includes observation, fluids, and humidified air.

The *H influenzae* type b conjugate vaccine (and immunization against diphtheria) is recommended in all children for prevention.

**Other Common Infections**

Lower respiratory infections include bronchitis, bronchiolitis, and pneumonia. They are often bacterial in nature, requiring antibiotics in such cases.²

Otitis media, or middle ear infection, is another common infection, especially in children. It may be bacterial or viral and should be referred to the pediatrician or internist.

**OTC and Self-Care Recommendations**

Morton Tavel, MD, is a clinical professor emeritus of medicine at Indiana University School of Medicine. Tavel reminds pharmacists that “despite the discomfort from the sneezing, sore throat, cough, and runny nose of a viral infection, happily it gets better on its own without requiring any special treatment, usually within a week but sometimes a bit longer.”

Chris Schiller, PharmD, is the CEO of Economy Pharmacy, Inc, in Muskogee, Oklahoma. He recommends guaiifenesin or guaiifenesin-pseudoephedrine (Mucinex or Mucinex-D), depending on symptoms, as well as humidifiers and camphor-eucalyptus oil-menthol (Vicks VapoRub). “My primary focus is on immune system health,” he said. He recommends supplements such as probiotics and immune support products, which combine vitamin D, vitamin C, zinc, and quercetin.

Tavel says pharmacists should discuss other conditions the patient has that may not be compatible with a recommended OTC medication (for example, patients with hypertension should not use an oral decongestant).

**Antibiotic Use**

According to the CDC, at least 47 million unnecessary antibiotic prescriptions are issued every year in the United States, which can lead to adverse effects and antibiotic resistance.¹ When counseling patients, pharmacists should remind them that antibiotics do not treat viral infections. “[Seeing] they have no effect on the culprit viruses, contrary to the almost universal misconception, antibiotics should not be employed,” Tavel said. “Using them will neither shorten the cold’s duration nor prevent its spread to others. Moreover, the more we take antibiotics, the greater chance of producing resistant bacteria that could create mischief to others at a later time.”

Instead, Tavel recommends that patients consult their physician if their cold lasts for over a week or causes a moist cough, or if a fever lasts for more than 2 days. Antibiotics are needed for certain bacterial infections, such as pneumonia or sepsis. They are also necessary for high-risk patients, such as those with severe kidney disease or who are undergoing chemotherapy.¹

Patients should visit their internist if symptoms persist or are severe. The internist can perform an examination, order labs and cultures if warranted, and decide if an antibiotic is needed.

For references, visit drugtopics.com.
LES S O N S  L E A R N E D  F R O M  T H E
COVID-19 VACCINE
ROLLOUT
Pharmacists reflect on their takeaways from the experience and how to move forward. By Keith Loria
Kevin DeMass, RPh, owner of the Apothecary Shoppe in Salt Lake City, Utah, has more than 30 years of experience in the field. He noted that the important lesson he learned from the vaccine rollout was the need for patience. “It seems that phase 1 took forever and we were in constant communication with our patients, providers, and even the Department of Health to find out what was going on,” he said. “And it certainly wasn’t a smooth process from the get-go.”

For instance, the state’s website crashed almost daily with patients trying to make appointments, and the vaccine supply ebbed and flowed with no predictability. Plus, he found many of his regular patients didn’t want to go into a mass immunization center and wanted his pharmacy to administer the vaccine. “They were frustrated with the system, and we were as well,” DeMass said. “In many places in our country, patients were asked to go to a strange place to receive a strange drug that they knew nothing about. We haven’t really done anything like that before. Independent pharmacies have built a relationship and trust with their patients for years, and they relied on us, but we didn’t have anything to give them.”

Although that was frustrating to him, he knew not to let that show, as he didn’t want that frustration to spill over to his patients. He described an encounter with a longtime African American customer who refused to allow anyone but DeMass to administer the vaccine because of uncertainty and fear. DeMass worked with him to make that happen as soon as the pharmacy received doses.

“I did a lot of reading online, looked at journals, called friends in New York and California to see what they were doing…and learned from them,” DeMass said.

He also learned not to compare what he was doing to pharmacies in different cities.

“We’re all going at different paces,” DeMass said. “You need to know what you can do with your staff to make the experience as smooth as possible. We took lessons we saw from others and improved efficiencies as we went into phase 2.”
"If we could go back, equitable distribution to all states should be the standard."

Ghaidaa Najjar, PharmD, PhD, community pharmacist for Rite Aid in Plymouth, Michigan, added that the process was confusing and inefficient at the beginning for both patients and the pharmacy.

“I had [older] patients walking in, thinking they would be automatically signed up for the vaccine,” she said. “They did not have smartphones; they may not have children or grandchildren who can help due to the social distancing, and they struggled because of isolation.”

She believes there should have been cohesive alignments in terms of eligibility among federal, state, and county entities when pharmacies had to serve the public based on certain criteria.

“People were confused, because a mile from where you live, your neighbors could be getting vaccine way ahead of you,” Najjar said. “Inequality was manifested by preferring some states to get vaccines before others. The category differences within the same state and local counties were also discriminating people and added more confusion. If we could go back, equitable distribution to all states should be the standard.”

According to Heather Ferrarese, PharmD, owner of Bartle’s Pharmacy in Oxford, New York, no one is ever really prepared for something like a global pandemic, even when they think they are. From her perspective, careful communication and planning are most important in adapting to the unpredictable a public health crisis brings.

“To anticipate having the vaccine, then to have it delayed time and time again, was definitely something we learned from, especially about how to plan and communicate,” she explained. “Once we did get the vaccine, it was a complete learning curve to pull off vaccinations on such a large scale and figure out where to vaccinate so many people. Those were some of the key takeaways from this experience. Thankfully, most people have been very gracious. They understand this is something none of us have ever been through before.”

For many pharmacies, implementing COVID-19 vaccinations was a significant trial-and-error process that resulted in plenty of mistakes. Pharmacies had to adjust their workflows and services to fit their community’s needs.

“The 2 biggest areas were workflow improvement in the pharmacy and improving efficiency and capacity during vaccinations,” said Mark McCurdy, RPh, an independent pharmacist from Mark’s Pharmacy in Cambridge, Nebraska.

Being in a rural area, the pharmacy works closely with the local health department. It offered vaccination events in multiple locations across 4 of the 9 counties in its service area.

“The goal was to identify the highest-risk and highest-need patients and provide them easy access to care,” McCurdy said. “So aside from the original crush of patients seeking vaccine, we also faced with logistics of site coordination, travel, and time on making these events happen. Once supply outpaced demand, the biggest challenge has been maintaining interest in receiving the vaccine and filling available appointments. We have struggled to get information to the right places and reach the right people.”

Jasmine Chan, PharmD, chief operating officer at Central Avenue Pharmacy in Pacific Grove, California, said because her pharmacy was a little late in getting vaccines, she was able to learn from the challenges that others were facing, notably with schedules and communication with patients.

“I got to marinate on how we could do it better;” she said. “Organization was key. I like lists, I [like] Excel sheets, but very quickly we learned we can’t overorganize this. We had to be flexible and roll with it.”

She feels the biggest thing she learned was how to navigate to the need of the individual patient. For example, the pharmacy served a lot of hospice patients, so Chan needed to best figure out appointments, transportation, and all the logistics in getting the vaccine to those patients.

“There were people with language barriers, those with no legal status in the United States, so we had to change our process for each of those barriers and break them down to make sure everyone was properly serviced,” Chan said. “Many of these people couldn’t leave during their workday, yet many clinics were only open 10 to 4.”

Chan’s pharmacy set up clinics near workplaces, such as golf courses for greenskeepers and even in homes where maids were employed, to help improve access to those patients.

Correcting Mistakes

Miscalculating the time needed to process paperwork, distribute vaccine cards to patients, and schedule second appointments proved to be one of the biggest mistakes, according to Ferrarese.

“We have been administering vaccines for many years, so we thought we had that down, but we weren’t prepared for all of the questions that
In an effort to adapt to the increasing but now patients are using it daily. The vaccine is free to everyone, but pharmacies have to cover the costs. The vaccine was distributed to eligible patients through walk-up vaccination locations, which were run by our community’s trusted health care provider. "Now more than ever, the local pharmacy is a trusted health care provider," said Aaron Gilbert, Ph.D., a pharmacist who has been preloading COVID-19 prescription pads and we had all the information, scheduling, and insurance companies were very gracious volunteering their time. Some achieved a high knowledge of the COVID-19 vaccine because the Flu shot is so important. The Flu shot is very important. The Flu shot is a public health crisis and it’s a public health crisis. The Flu shot is a public health crisis. The Flu shot is a public health crisis.
DON’T BE OUT OF THE LOOP ON OUT-OF-POCKET COST

LET PATIENTS KNOW THE AVERAGE OUT-OF-POCKET COST MAY BE LESS THAN THEY THINK

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

LESS THAN*

$5

*Average out-of-pocket cost for commercially insured patients.

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
When it comes to healthcare, coverage and cost are often big concerns for patients. But as you’ll see, cost doesn’t need to be an obstacle to receiving quality care. In fact, for most commercial plans, the out-of-pocket cost to patients is usually minimal.

Nationally, payers covering 96% of commercial medical benefit enrollees cover SHINGRIX. The Affordable Care Act (ACA) requires all Health Insurance Marketplace plans and most other private health insurance plans to cover all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines, including SHINGRIX, with no cost sharing (deductibles, copayments or coinsurance) if administered in-network.

90% of privately insured patients pay no or limited out-of-pocket cost with the average cost being less than $5 per dose.

Individual access may vary by geography and plan benefit design.

What you need to know:
Coverage, coding, cost to patient, reimbursement amount for product, and administration fee will vary by payer, plan, patient, professional setting, or services rendered and are subject to change without notice. Cost to patients may vary. Coverage and reimbursement decisions are made by individual payers following receipt of claims from providers. Providers must follow payer documentation and billing requirements.

†SOURCE: Managed Markets Insight & Technology, LLC, Database as of June 2021. “Coverage” is formulary access without restrictions, which means reimbursement from a health plan with no accompanying step edits or prior authorizations. Veterans Affairs (VA) and Indian Health Service (IHS) lives have been omitted when calculating the percentage of lives for this geography.

Important Safety Information (cont’d)
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients


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.

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

To see additional information about cost and coverage go to CoverageSHINGRIX.com

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SGXJRNA210005 April 2021
Produced in USA.
SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

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

1 INDICATIONS AND USAGE

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

Limitations of Use:

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

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

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

2.3 Dose and Schedule

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

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 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (0.6%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); 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>
<thead>
<tr>
<th>Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events within 7 Daysa of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Olderb (Total Vaccinated Cohort with 7-Day Diary Card)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
</tr>
<tr>
<td><strong>SHINGRIX</strong></td>
</tr>
<tr>
<td>Pain</td>
</tr>
<tr>
<td>Pain, Grade 3c</td>
</tr>
<tr>
<td>Redness</td>
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<tr>
<td>Redness, ≥100 mm</td>
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<tr>
<td>Swelling</td>
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<tr>
<td>Swelling, ≥100 mm</td>
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<tr>
<td><strong>General Adverse Events</strong></td>
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<tr>
<td><strong>SHINGRIX</strong></td>
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<tr>
<td>Myalgia</td>
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<tr>
<td>Myalgia, Grade 3d</td>
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<tr>
<td>Fatigue</td>
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<tr>
<td>Fatigue, Grade 3d</td>
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<td>Headache</td>
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<td>Headache, Grade 3e</td>
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<td>Shivering</td>
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<td>Shivering, Grade 3e</td>
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<td>Fever</td>
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<td>Fever, Grade 3f</td>
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<tr>
<td>GI</td>
</tr>
<tr>
<td>GI, Grade 3f</td>
</tr>
</tbody>
</table>

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

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

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

c Placebo was a saline solution.

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

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

f 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.

g 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 (24.5% 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)
Safety:
second dose administered anytime between 2 and 6 months later. (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal (both doses combined) were pain (78.0%), redness (38.1%), and

Across both studies, the percentages of subjects aged 50 years the majority of subjects were white (74.3%), followed by Asian Latin America, Europe, Asia, and Australia. In the overall population, (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects administered according to a 0- and 2-month schedule. At the time The safety of SHINGRIX was evaluated by pooling data from 2

1 dose of SHINGRIX in 17 clinical studies. Vaccination-related adverse reactions. Appropriate medical treatment

6 hours. Discard reconstituted vaccine if not used within 6 hours. Refrigerated between 2° and 8°C (36° and 46°F) and use within

After reconstitution, administer SHINGRIX immediately or store

6 ADVERSE REACTIONS

2 DOSAGE AND ADMINISTRATION

3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events
Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), 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 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

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

Serious Adverse Events (SAEs)
In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) 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 last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule
In an open-label clinical study, 238 subjects 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 hospitalized GBS 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 (14.3) 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

• Informs 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.

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

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

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

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The mechanics of getting paid for nondispensing services are shrouded in myths and lies. Conventional wisdom says pharmacists have always given away their clinical, nondispensing services and payers won’t reimburse what they can get for free. “We have always gotten paid for non-dispensing services,” said Troy Trygstad, PhD, PharmD, MBA, executive director of the Community Pharmacy Extended Services Network (CPESN) USA. “The problem is we have gotten paid through the product margin spread and dispensing fees,” Trygstad said. “And because we were getting paid on product margin, our services never became standardized and the adjudication superhighway never developed the way it did for dispensing. We’re changing that.”

Pharmacists have been managing patients with hypertension, asthma, diabetes, heart failure, and other conditions at least since the 1980s, providing immunizations since the 1990s and point-of-care testing since the 2000s, and prescribing oral contraceptives and smoking cessation since the 2010s. Generations of pharmacists have integrated durable medical equipment and diabetes education into their stores. All are reimbursable as medical benefits. Medical claims are typically paid at a higher rate than pharmacy claims, and they are not subject to direct and indirect remuneration clawbacks.

“Vaccines, as just 1 example, can be billed 3 and 4 times higher through medical benefits than through pharmacy benefits,” said Jenny Arnold, PharmD, BCPS, CEO of the Washington State Pharmacists Association. In this 3-part series, Total Pharmacy® explores what it takes to turn your medication management skills into a successful and profitable pharmacy service. In part 2, we offer tips on getting paid for medication management services (MMS).

Recognize the Tools
COVID-19 transformed pharmacist and payer attitudes, according to Arnold. Scheduling appointments and billing

“Local pharmacists resonate with local providers, businesses, and employers looking to support their high-risk populations.”

Tripp Logan, PharmD

A content source designed specifically for pharmacy industry professionals practicing in (or interested in moving to) an independent pharmacy. Total Pharmacy® provides trusted resources and actionable business solutions to effectively maximize profitability, minimize costs and improve patient experience.
medical benefits for COVID-19 testing and vaccination became standard. Payers, led by the Centers for Medicare and Medicaid Services, acknowledged that pharmacists provide valuable, reimbursable services.

“The 2020 Pharmacy Quality Alliance Industry Trend Report tells us that 70% of health care payers would contract with pharmacies today if they could get data and claims in a standardized way,” Trygstad said. “We have the documentation and billing tools to do that in the Pharmacist eCare Plan.”

All 50 states recognize pharmacists as providers, said Rebecca Snead, RPh, executive director of the National Association of State Pharmacy Associations, but payer status does not always translate into payment or scope of practice. Some states reimburse pharmacists directly for Medicaid or other state-run programs. Eight states have payment parity laws that prohibit payers from excluding pharmacists from provider contracts. Elsewhere, pharmacists are building their own paths to payment.

**Provider Status**

After Ohio recognized pharmacists as providers in 2019, the Ohio Pharmacists Association and Ohio Medicaid launched a pilot program with public and commercial payers.

“Four of our 8 stores were picked because we had a larger population of patients without insurance,” said Andrea Kowalski, PharmD, director of clinical services for Shrivers Pharmacy in Athens, Ohio. “We were responsible for developing and implementing a clinical service, documenting outcomes, for developing and implementing a clinical service, documenting outcomes, for developing and implementing a clinical service, documenting outcomes.”

**Information Technology Solutions**

Information technology (IT) is a key barrier to payment for nondispensing services. Pharmacy benefit managers (PBMs) process pharmacy benefits and medical vendors handle medical benefits. The 2 benefits require different data elements, vocabularies, and coding systems. No one system can handle both—not yet. Here are 3 approaches to working around IT gaps.

1. **Pharmacy Benefit**

Multiple pharmacy management vendors use Pharmacist eCare Plan to automate clinical service workflows, but generating medical claims remains awkward. That could change with a new IT standard called Fast Healthcare Interoperability Resources (FHIR). The federal Office of the National Coordinator for Health Information Technology wants electronic health record vendors, health plans, health systems, pharmaceutical manufacturers, and other industry players to adopt FHIR.

The goal, said Josh Howland, PharmD, MBA, vice president of clinical strategy for PioneerRx, is for pharmacies to adopt the latest eCare Plan version that can talk with other FHIR-compliant partners.

“You are going to bundle all the clinical documentation and clinical codes and send that off to a clearinghouse that routes the claim to Blue Cross, UnitedHealthcare, or whoever, for payment,” Howland said. “If you dispensed a drug as part of the visit, the system routes that piece to the PBM for adjudication. But seamless IT is going to come in baby steps, not next month.”

2. **Medical Benefit**

Some medical clinical documentation vendors saw the potential of pharmacy before COVID-19. Simeon Roth, PharmD, selected Azova for his Invara Pharmacy + Clinic in Sultan, Washington, because its clinical modules can be readily customized for his acute care workflow, unlike his pharmacy management system. Although both systems support eCare Plan, they cannot talk to each other or use a common database.

“None of these vendors play nice with each other,” Roth said. “Every system comes with their own ancillary services and apps they want you to use. I’m having lengthy discussions about building my own proprietary software that does it all.”

3. **Proprietary Ecosystem**

Cardinal Health did just that with Outcomes. The platform combines Cardinal’s existing Medication Therapy Management (MTM) program administrator OutcomesMTM with mscrips for digital communication services and TelePharm for telepharmacy. The announced goal is to help pharmacies, payers, and pharmaceutical companies address the challenge of medication adherence and close critical gaps in health care.

“It’s 1 platform to learn across multiple payer programs, said Jessica Frank, PharmD, vice president, payer solutions, OutcomesMTM, “which simplifies staffing and makes integrating MTM into workflow easier. Documenting on our platform isn’t complex like a doctor’s office with a team of billing specialists, and you don’t have to learn billing requirements for multiple plans. A pharmacist or technician enters the results of the service and Outcomes pays the pharmacy for services provided.”

Outcomes is exploring ways to integrate with other frameworks such as Pharmacist eCare Plan.
and submitting claims.”

Shrivers focused on improving behavioral health outcomes for patients taking antidepressant and antianxiety medications. Pharmacists administered standardized tests to assess patient status, counseled patients on interventions such as lifestyle changes and recommended medication adjustments.

In Camden, Ohio, pharmacists started with smoking cessation, opioid and naloxone use, diabetes, and asthma services.

“Those were the conditions of interest to our primary Medicaid payer, CareSource,” said staff pharmacist Penny Nerdeman, RPh, Camden Village Pharmacy. “Once you’re accredited, you bill directly for services, just like any other provider.”

Medicaid is no path to riches, but it’s an improvement over losing money on too many scripts.

“Provider status means I get paid for providing the clinical services we’ve all been trained to do,” said Danielle Hubbard, RPh, partner at Franklin Pharmacy in Warren, Ohio. “That makes a huge difference in our bottom line.”

**Payment Parity**

Washington required commercial payers to pay pharmacists at the same rate as other providers in 2014. Health system and ambulatory care pharmacists soon began billing medical benefits. Independents are catching up.

“I opened Invara Pharmacy + Clinic in 2019 as a hybrid pharmacy/acute care clinic right out of pharmacy school,” said owner Simeon Roth, PharmD, in Sultan, Washington, a small, rural town outside Seattle.

“We help fill the gap in acute care medical services with point-of-care testing, vaccinations, chronic care for diabetes, hypertension, and hyperlipidemia, and treatment for things like herpes, human and animal bites, urinary tract and yeast infections, and a lot more.”

Pharmacists can expect midlevel provider fees similar to those of nurse practitioners, Roth said. Dispensing has a gross margin of about 20%, vs 50% for nondispensing services.

“That’s the same margin I get selling toys,” he said. “And there is no cost of goods sold on services.”

**On Their Own**

Tripp Logan, PharmD, taps into multiple local, state, and national payers.

“Local pharmacists resonate with local providers, businesses, and employers looking to support their high-risk populations,” said Logan, vice president for SEMO Rx Pharmacies, with 3 stores in southeast Missouri.

SEMO pharmacists are accredited Medicaid providers, but county public health departments can be even more valuable. Public health funds programs such as diabetes self-management education (DSME) but lacks access to patients. Pharmacists have the patients but lack program funding. “We tried DSME 3 times but couldn’t figure out how to financially sustain the service,” Logan said. “Public health has those same programs and struggles to fill them. We’re natural partners.”

Contracting with major players is harder.

“Our 3 pharmacies can’t move the needle for the Blues [Blue Cross and Blue Shield] of Missouri or United-Healthcare,” Logan said. “That’s where networks like CPESN help. With more than 3000 pharmacies, CPESN can improve outcomes for any big payer. Being part of the network makes us part of large-scale health plan initiatives with revenue opportunities that we can’t touch on our own.”

**Recognize the Potential**

Don’t obsess over the obvious like direct payer billing, advised Sandra Leal, PharmD, MPH, CDCES, executive vice president of SinfoniaRx.

“There are other ways to get compensated,” said Leal, who is also president of the American Pharmacists Association. “Maybe it’s a fee-for-service contract or a per-member-per-month arrangement for specific interventions.”

The reality that pharmacies were often the only health care facilities to remain open during the COVID-19 pandemic was not lost on payers, she added.

“(COVID-19) clearly showed that pharmacists can provide services, document, and bill on the medical side,” said Josh Howland, PharmD, MBA, vice president of clinical strategy for PioneerRx.

“That puts your foot in the door. Now it’s time to pull the door open and jump through it.”

For references, visit totalpharmacy.com.

Next month, part 3 of this series will provide tips on delivering your medication management services to patients.

**Resources to Get Started**

**CPESN:** https://cpesn.com/


Pharmacist eCare Plan: https://www.eccareplaninitiative.com/

Ohio Pharmacists Association provider status resources: https://www.ohiopharmacists.org/aws/OPA/pt/sp/provider-status

Washington State Pharmacist Association payer resources: https://www.waspax.org

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The Evolution of Pharmacogenomics

Pharmacogenomics provides an opportunity for pharmacists to enhance their role in patient care.

By Rachel Pearlman, PharmD candidate; Colin Turnbull, PharmD candidate; and Jonathan Ogurchak, PharmD, CSP

At one point in our education, we all learned about Watson and Crick discovering the double helix structure of DNA in the 1950s. Although Watson and Crick did not know it at the time, this groundbreaking discovery would be the start of evaluating a patient's specific DNA for more personalized pharmacological treatment.

After Watson and Crick's discovery, there was a gold rush for DNA. Many new inventions and discoveries would follow years after. Half a century later, the Human Genome Project was launched in 1990 and completed in 2003. The goal of the Human Genome Project was to map and identify all of the human DNA base pairs and genes. Branching from the Human Genome Project is now the newer use of pharmacogenomics for medication therapy.

The first example of using DNA sequencing for disease treatment was the discovery of the human epidermal growth factor receptor 2 (HER2)-positive breast cancer mutation in the 1990s. Physicians were now able to screen for this HER2 mutation in patients with breast cancer. If the breast cancer expressed the protein HER2/neu, the patient would be receptive to trastuzumab (Herceptin), and therefore treatment would lead to a much better outcome. This proved to be a lifesaving discovery, and it inspired testing like this to continue.

Since then, testing for genetic variations has become a standard of practice in several areas of health care, including cancer, cystic fibrosis, and HIV. The cost per human genome continues to decrease with technological advancements and more data. Therefore, conducting this testing has become more standardized and less expensive (see Figure).

Currently, pharmacogenomics testing is used for various pharmacokinetic and pharmacodynamic properties, mainly focused on the metabolism of different medicines. The pharmacogenomic results regarding metabolism express whether a patient will be predisposed to a lack of response due to a lower concentration of medicine, normal response, or toxicities from a higher concentration of medicine.

As developments in pharmacogenomics progressed over the years, several initiatives attempted to standardize pharmacogenomic medication information and guidelines. Because of this demand, the Pharmacogenomics Global Research Network and PharmGKB teamed up to develop a shared project termed the Clinical Pharmacogenetics Implementation Consortium (CPIC). CPIC addresses the need for guidelines to instruct clinicians on how to modify drug therapy based on genetic information. CPIC provides information on the proven genetic variations and the variations' effects on medication therapy in 1 concise, clear guideline. CPIC information should be referred to and used by clinicians when applicable to select appropriate medications and doses for patients with genetic variations. As of this publication, there are over 40 medications with CPIC guidelines.

Optimizing Medication Use

Through CPIC and other sources of pharmacogenomic data, prescribers can now use this information to optimize medication therapies for patients. Genetic variations can cause a patient to have altered responses to medications. The common area where these genetic variations are seen is in the metabolism of the particular medication. If a patient metabolizes a medication for elimination at a slower rate than expected, the patient can be predisposed to toxic concentrations when given standard doses of the medication. Additionally, if a patient metabolizes a medication for elimination at a faster rate than expected, the patient can be predisposed to a subtherapeutic concentration of the medicine. The opposite of these responses will happen when the medication in question is a prodrug, which is an inactive medication metabolized to an active pharmacologic agent in the body, i.e., faster metabolism = toxic concentration; slower metabolism = subtherapeutic concentration.

Medication therapy can be optimized when a patient's DNA sequence is evaluated for known genetic variations associated with certain medications. Personalizing medication choices and doses to the specific needs of a patient's genetic results will lead to the correct therapeutic drug concentrations while avoiding toxicities or subtherapeutic concentrations.

Pharmacogenomics can not only optimize therapy through proper dose and drug selection but also lead to optimization in other areas of health care. If a patient experiences toxicities leading to adverse effects (AEs) from a medication, they often have to receive additional care either through emergency services or through additional...
medication to control the AEs. If pharmacogenomics is considered at the time of prescribing, the therapy can be optimized from the start and additional treatment can be avoided. This saves time for the patient and saves health care dollars overall.

The Role of the Pharmacist Across Care Settings

Today, pharmacists are the drug experts within the medical field, with extensive education in medication therapy including a heavy focus on pharmacokinetics and pharmacodynamics. Pharmacists have the knowledge and community presence to counsel patients about their genetic results, as well as educate other health care professionals. Through this education, pharmacists can help physicians make recommendations at the time of prescribing. These recommendations can include genetic testing to be done before new medication orders, as well as adjustments to be made on current medication orders.

Additionally, pharmacists can help address pharmacogenomic components as the last point of intervention before dispensing the medication to the patient. If a new prescription arrives for a patient with an established AE profile, the pharmacist may be the last person to verify if genetic testing has been done. Detrimental AEs can be avoided through intervention at this point in the prescribing process.

Furthermore, pharmacists can serve as advocates for this area of health care. The only way to collect data on additional genetic variations and their associations with medications is through clinical trials. There is a lack of financial incentive for pharmacogenomic clinical trials to be conducted and many clinicians do not understand the importance of this area of research. Pharmacists can encourage health care professionals to begin trials to expand their knowledge of pharmacogenomics and its application in health care.

The Future of Pharmacogenomics

Though pharmacogenomics in health care has come a long way from where it started, there is still a great deal of growth in this field and there are many more barriers to be crossed. One barrier in pharmacogenomics is the issue of where to store a patient’s genetic information. With genetic results being protected by the Health Insurance Portability and Accountability Act, it is hard to determine an easily accessible place where genetic information can be seen and used by all parties within the health care system. A potential suggestion some physicians have made is an electronic health record pop-up alert on a patient’s profile at the point of prescribing, but development is still needed in this area.

In addition, there is an ethical component when testing a patient’s genetics. Scientists could come across a mutation the genetic test was not indicated for. This is a gray area to decide whether the patient should be informed of the findings since they did not originally consent to search for that mutation. There is also the question of testing for 1 specific gene variation vs testing a multigene panel on a patient. Once again, this is an area that needs more discussion and development.

As previously mentioned, clinical trials are imperative to the development and success of using pharmacogenomics in health care. There is no other way to get the information than to test a patient’s genes and evaluate them for their medication use. Pharmacists play a key role here in educating for clinical trial needs and advocating for more research.

Overall, pharmacogenomics is an exciting and growing area of health care. Through additional research and a commitment to using pharmacogenomic findings, this information can eventually be brought to the bedside of every patient to optimize medication therapies for all.

For references, visit drugtopics.com.

Rachel Pearlman and Colin Turnbull are PharmD candidates at Duquesne University School of Pharmacy in Pittsburgh, Pennsylvania, with anticipated graduation in spring of 2022.

Jonathan Ogurchak, PharmD, CSP, is the CEO and cofounder of STACK, a professional information management platform. He also serves as a preceptor for a virtual advanced pharmacy practice experiential rotation for specialty pharmacy, technology, and entrepreneurship.
The year 1981 was a special one for my wife, Denise, and me. We graduated from the University of Pittsburgh School of Pharmacy in April. We got married on the Fourth of July and took our first jobs as licensed pharmacists in August. Like all new graduates, we were ready to apply our new knowledge and patient counseling skills to help our patients. It didn't take long to realize that the dream was becoming a nightmare.

After a couple of months working with a major chain, I came home one night and told my new wife, “If this is retail pharmacy, I made a serious mistake choosing this profession.” When I begged for more tech help, my district manager said, “I've watched you work, Pete, and if you stop talking to those customers, you will have [a lot] of time to get my paperwork done.” As good fortune would have it, we later found 2 great jobs for an independent pharmacy chain. As I always tell my student pharmacists: “Your license hangs on the wall by a nail. If you are unhappy in your current position, you will have [a lot] of time to get my paperwork done.” As good fortune would have it, we later found 2 great jobs for an independent pharmacy chain. As I always tell my student pharmacists: “Your license hangs on the wall by a nail. If you are unhappy in your current position, you will have [a lot] of time to get my paperwork done.”

I found another great nail at a different independent pharmacy and had 12 great years of community practice there. I staffed the bench, and later on, I staffed a physician’s office 2 days per week. By most pharmacists’ standards, this was a dream job. However, I left that job to fill a position as director of clinical services at Nickman's Drug store in Lemont Furnace, Pennsylvania. I chose this nail not only because of the owner’s interest in providing clinical services, but most importantly the nail would be closer to my family I had landed another dream job.

Did you notice that all 3 times I left a job, money had nothing to do with my career move? It was all about conditions outside the paycheck. The major chains have yet to learn this. Wave the big bucks in front of the newbies and get them signed up. After a short time, the joy of the big paycheck is overshadowed by lack of staffing, unattainable metrics, and long hours. As a result, these experienced pharmacists move on to lower-paying jobs with much more opportunity.

Brenda, a pharmacist who lives just up the lane from us, left her chain job for a pay decrease to be part of the West Virginia University community. She now gets to be a mom as well as a pharmacist. Mike, another neighbor of mine, left his job with a major chain shortly after he got married. He took a job with an insurance company doing medication therapy management for a few years and also became a member of the university community. He is now on the national circuit discussing opioid therapy and pain management. Like Brenda’s, Mike’s career moves involved a salary decrease for better conditions and opportunities.

I often compare the big chains to my beloved Pittsburgh Pirates. The Pirates develop players like Andrew McCutchen, Gerrit Cole, Josh Bell, and Josh Harrison, who move on to bigger and better opportunities. The New York Yankees, Washington Nationals, and Los Angeles Angels are grateful to the Pirates for developing the very best players available to them.

Similarly, independent pharmacies and academic universities appreciate the chains developing the future stars of our profession. By providing better working conditions, staffing, and opportunities, the chains could keep these future stars for their own benefit.

As I celebrate my 40th year in this amazing profession, I’m sure that nail No. 4 will be my last. My extended family is always asking me, “When are you going to retire?” My answer is simple: “When [I]m darn good and ready.” I love this profession and get great satisfaction going to work every day.

Peter A. Kreckel practices pharmacy in Lemont Furnace, Pennsylvania.
Novel Antifungal Treatment Approved for Vaginal Candidiasis

By Kathryn Wheeler PharmD, BCPS

On June 2, 2021, ibrexafungerp (Brexafemme; Scynexis, Inc) was approved by the FDA for vulvovaginal candidiasis (VVC) in adult women and girls who have begun menstruating. Ibrexafungerp is a triterpenoid antifungal that works by inhibiting the formation of the fungal cell wall. Ibrexafungerp (pronounced eye-BREX-ah-FUN-jerp) is the first approved drug of a novel class of antifungals.

Efficacy

Two randomized placebo-controlled clinical trials evaluated the safety and efficacy of ibrexafungerp. Participants were postmenarche, nonpregnant females with VVC. In trials, a diagnosis of VVC is defined as a minimum composite vulvovaginal signs and symptoms (VSS) score greater than or equal to 4 and a minimum of 2 moderate signs or symptoms (score of 2 or greater), positive microscopic examination in a sample demonstrating yeast, and a normal vaginal pH. Signs and symptoms were scored along a scale: 0 (absent) to 3 (severe). Median VSS scores at baseline in trials 1 and 2 were 9 and 10, respectively, at baseline; range, 4 to 18. In both trials, the majority of cultures were positive for Candida albicans. Participants received two 150-mg tablets (300-mg dose) of ibrexafungerp or placebo 12 hours apart in a single day, a total daily dose of 600 mg. Participants were reassessed at a test-of-cure (TOC) visit between days 8 to 14 and a follow-up visit between days 21 to 29. Participants with a positive culture for Candida who had at least 1 dose of the study drug were included in a modified intention to treat analysis. Compared with placebo, a greater percentage of participants on ibrexafungerp demonstrated negative cultures at the TOC visit ($P < .001$) and VSS scores of 0 (ie, complete clinical response) at the TOC ($P = .001$ and .009) and follow-up visits ($P = .007$ and .006).

Safety

In trials, a total of 545 participants were exposed to a dose of ibrexafungerp. The most common adverse effects (AEs) noted in participants administered ibrexafungerp are diarrhea (16.7%), nausea (11.9%), abdominal pain (11.4%), dizziness (3.3%), and vomiting (2.0%). For comparison, the most common AE noted in participants administered placebo in trials is abdominal pain (5.1%). Ibrexafungerp is metabolized by cytochrome P450 (CYP3A). Concomitant administration of strong inhibitors or moderate to strong inducers of CYP3A may alter the patient’s exposure to ibrexafungerp. A reduced dose of ibrexafungerp, 150 mg (1 tablet), should be given when concomitantly administered with strong CYP3A inhibitors. Ibrexafungerp is potentially teratogenic. The use of ibrexafungerp is contraindicated in pregnant women. A patient’s pregnancy status should be confirmed prior to use. The manufacturer recommends the use of contraception for 4 days after the last dose of ibrexafungerp for all women of reproductive potential. If a woman is pregnant or pregnancy is detected within 4 days after the last dose of ibrexafungerp, patients should report the pregnancy to the manufacturer to include in an ongoing safety analysis by calling 1-888-982-7299.

Dosing

The recommended dosage of ibrexafungerp for treatment of VVC is 300 mg. This dose is provided as two 150-mg tablets. To complete a full course of therapy, patients should take two 150-mg tablets for the first dose and two 150-mg tablets 12 hours later. This medication may be taken with or without food.
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Tony Hayslip, ABR/AREP
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“Tony and Ernie’s ability to find qualified buyers and help independent owners sell their pharmacies to other independent owners has had a positive impact in our industry.”

-Phil Woodward, RPH, Executive Director  
Oklahoma Pharmacy Association

Here’s what some of our clients have to say . . .

“Your knowledge of the business climate allowed me to get top dollar for my pharmacy.”

-Jim Angell, Kerrville TX

“My experience with Tony Hayslip and Ernie Zost was very positive. I appreciate their honesty, fairness, integrity and professionalism.”

-Robert Guy, Super “D” Drugs, Greenville MS

“Hayslip & Zost’s knowledgeable staff and expertise allowed us to get a great price for our pharmacy. I strongly recommend their company to represent you throughout the selling process.

-Helen T., RPH, CEO Yuba City CA

“Tony and Ernie did an outstanding job representing our pharmacy. I received top dollar thanks to them!”

-D. Cox, CEO- Boise ID

Endorsed by State Pharmacy Associations

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