Mental Health
Emerging Roles for Pharmacists

Vaccines
COVID-19 Vaccine Safety Overview

Autoimmune
Rheumatoid Arthritis

Podcast Episode
What It Takes to Succeed in Pharmacy Ownership

Choosing a Wholesale Distributor

Drug Topics
Voice of the Pharmacist

May 2021
Vol. 165 No. 5
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%)
FROM YOURSELF.

THE VIRUS THAT CAUSES SHINGLES IS ALREADY INSIDE YOUR PATIENTS.¹,²

99.5% of adults aged 50 years and older are infected with the varicella zoster virus.¹,² 1 out of 3 people will get shingles in their lifetime.² Fortunately, you can do something today to prevent it.

HELP PROTECT YOUR PATIENTS AGED 50 YEARS AND OLDER WITH SHINGRIX.³

Learn more about shingles and aging by visiting WhatCausesShingles.com

Important Safety Information (cont’d)

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


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

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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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 (56° 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 (74.9%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fever (44.5%), headache (37.7%), shivering (26.8%), 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></th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX#</td>
<td>Placebo§</td>
<td>SHINGRIX#</td>
<td>Placebo§</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4%</td>
<td>14.4%</td>
<td>82.8%</td>
</tr>
<tr>
<td>Pain, Grade 3d</td>
<td>10.3%</td>
<td>0.5%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7%</td>
<td>1.2%</td>
<td>38.4%</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8%</td>
<td>0.0%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5%</td>
<td>0.8%</td>
<td>26.5%</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1%</td>
<td>0.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>General Adverse Events</td>
<td>0.15%</td>
<td>0.0%</td>
<td>0.15%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9%</td>
<td>15.2%</td>
<td>49.0%</td>
</tr>
<tr>
<td>Myalgia, Grade 3d</td>
<td>8.9%</td>
<td>0.9%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0%</td>
<td>19.8%</td>
<td>45.7%</td>
</tr>
<tr>
<td>Fatigue, Grade 3d</td>
<td>8.5%</td>
<td>1.8%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6%</td>
<td>21.6%</td>
<td>39.6%</td>
</tr>
<tr>
<td>Headache, Grade 3d</td>
<td>6.0%</td>
<td>1.7%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8%</td>
<td>7.4%</td>
<td>30.3%</td>
</tr>
<tr>
<td>Shivering, Grade 3d</td>
<td>6.8%</td>
<td>0.2%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8%</td>
<td>3.0%</td>
<td>23.9%</td>
</tr>
<tr>
<td>Fever, Grade 3d</td>
<td>0.4%</td>
<td>0.2%</td>
<td>0.5%</td>
</tr>
<tr>
<td>GI†</td>
<td>24.3%</td>
<td>10.7%</td>
<td>18.7%</td>
</tr>
<tr>
<td>GI, Grade 3d</td>
<td>2.1%</td>
<td>0.7%</td>
<td>0.9%</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: NCT01165177 and Study 2: NCT01165229.

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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 (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Lactation

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

8.5 Geriatric Use

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

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

17 PATIENT COUNSELING INFORMATION

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

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

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

Storage:

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

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May Is Mental Health Awareness Month

More than a year into the COVID-19 pandemic, the mental health burden resulting from the public health crisis is becoming more and more apparent. Social isolation amid widespread lockdowns, coupled with fear and anxiety over becoming infected by the SARS-CoV-2 virus, have undoubtedly affected the mental well-being of many individuals. In fact, the results of a recent study published in *Psychiatry Research* showed increased levels of clinical depression symptoms and a reduction in overall well-being among young adults during the lockdown.1

May is Mental Health Awareness Month, and our cover story dives into how pharmacists can address the mental health burden in their patients and communities. From specialized training and medication management to simply checking in on patients’ mental welfare when they visit the pharmacy, opportunities exist for pharmacists across health care settings. Read our story on page 10 to learn more.

It is also important for pharmacists to take care of their own mental health during these times. Tune in to our Medical World News® broadcast to catch our new “Well-being Checkup” segment for tips and tricks from peers and experts on how to practice self-care and prevent burnout. Visit www.mjhlifesciences.com/news-network to watch the program.

Additionally, as more Americans become eligible for COVID-19 vaccinations, pharmacists undoubtedly will be asked questions regarding the vaccines’ safety profiles. Pharmacists should arm themselves with the knowledge to properly educate vaccine-hesitant patients. Turn to page 24 for an overview of the current safety data for each available vaccine and what is known about the adverse effects.

You’ll also find in this issue great insights into digital health tools for diabetes, management of rheumatoid arthritis, and integrating pharmacists into the stroke care team. Check back to drugtopics.com for the latest pharmacy news, including expert interviews, podcasts, and conference coverage.

Thank you for reading.

Mike Hennessy Sr  
Chairman and Founder of MJH Life Sciences™

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Flu Vaccine Has Role in COVID-19 Infection Rates, Severity

A recent study looked at the role of the influenza vaccine in COVID-19 susceptibility and severity. The findings, which were published in the American Journal of Infection Control, showed that individuals who received the flu vaccine had a lower chance of testing positive for COVID-19 compared with those who did not receive it.

The study investigators reviewed medical charts for more than 27,000 patients who were tested for COVID-19 at Michigan Medicine between March and mid-July 2020. According to the data, the odds of testing positive for COVID-19 were reduced by 24% in those who were vaccinated against flu versus those who were not (odds ratio [OR], 0.76; 95% CI, 0.68-0.86; $P < .001$). Additionally, vaccinated patients were less likely to require hospitalization (OR, 0.58; 95% CI, 0.46-0.73; $P < .001$) or mechanical ventilation (OR, 0.45; 95% CI, 0.27-0.78; $P = .004$), and had a shorter hospital length of stay (risk ratio, 0.76; 95% CI, 0.65-0.89; $P < .001$).

However, the investigators did not find a significant difference in mortality between the 2 groups. The results also did not identify an underlying mechanism behind the association.

What It Takes to Succeed in Pharmacy Ownership

Pharmacy ownership can be an attractive choice for pharmacists looking to advance both professionally and financially, but it can also be daunting.

Drew Hegi, a loan officer with First Financial Bank (FFB), and Bob Graul, a business development officer with FFB, joined Over the Counter, the Drug Topics® podcast, to discuss first-time pharmacy ownership, transitioning into a CEO role, and more.

In the episode, Hegi and Graul cover how to succeed in the endeavor of pharmacy ownership, including tips on:
- choosing between starting a pharmacy or purchasing an existing one,
- finding available pharmacies to buy and what to look for in a prospective store,
- estimating costs of purchasing a pharmacy, and
- identifying financing needs and options for business loans.

“If you’re not financially savvy, find some partners that are that can help you appropriately value a store and then we can help,” Hegi says.

To watch the full interview, visit www.drugtopics.com/expert-interviews or scan the QR code.

COVID-19 Vaccine Recipients Experience “Vaccine Arm” Reaction

From our sister publication Dermatology Times®

By Morgan Petronelli

As the COVID-19 vaccine is being rolled out, some recipients are experiencing adverse effects (AEs), one of which includes a delayed large local reaction.

This particular reaction is characterized by pain and swelling in the upper arm located at the injection site and appears 7 to 8 days following injection. This AE is commonly being referred to as COVID arm, but experts are warning against using the term, as the reaction is not caused by COVID-19 but rather by the vaccine.

Esther Freeman, MD, PhD, director of global health dermatology at Massachusetts General Hospital in Boston, spoke with Dermatology Times® about her recent case series in the New England Journal of Medicine on these delayed reactions. She suggested calling the delayed reaction “vaccine arm.”

Freeman added that although most reports of the reaction have been in patients who received the Moderna COVID-19 vaccine (mRNA-1273), they have also occurred in a few individuals who received the Pfizer-BioNTech COVID-19 vaccine. These reactions are not worrisome and typically go away on their own, she said. Recommended treatments include topical steroids and oral antihistamines.

For reference, visit dermatologytimes.com.

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EMERGING ROLES IN MENTAL HEALTH CARE FOR PHARMACISTS

By Joan Vos MacDonald
“Given how common depression is, you could make the argument that pharmacists should be as well versed in depression as in diabetes, high blood pressure, and other common conditions.”

CHARLES F. CALEY, PHARMD, BCPP

early 1 in 5 US adults lives with a mental health disorder. Many are currently being treated with medication regimens that benefit from pharmacist oversight. As the antipsychotic medication landscape evolves, more opportunities are emerging for pharmacists to fine-tune their patients’ regimens and serve as important access points for individuals experiencing mental health crises.

Psychiatric Pharmacy: A Career Path in Mental Health

For a growing number of pharmacists, an interest in providing mental health care leads to a specialization in psychiatric pharmacy, also known as mental health pharmacy. Currently there are over 1300 board-certified psychiatric pharmacists in the United States and that number is expected to grow, said Charles F. Caley, PharmD, BCPP, chair and professor of pharmacy practice, Department of Pharmacy Practice, at Western New England University College of Pharmacy and Health Sciences in Springfield, Massachusetts.

“The vast majority of psychiatric pharmacists are going to be working in inpatient psychiatric hospitals or in ambulatory or outpatient clinics,” said Caley. “Depending on where you live in the country, they could be state-run facilities or federally run facilities or county-run facilities. For example, in California, the counties govern and dictate and deliver behavioral health care, but in Connecticut that is not the case. It’s the state. So wherever public health care can be delivered, there’s the potential for pharmacists to be involved.”

Medication therapy that is managed by pharmacists has been shown to improve patient adherence while cutting costs for the care provider.

“Many patients are on many, many drugs because it is much
easier for someone to add a medica-
tion than it is to take one away,” said
Stephen R. Saklad, PharmD, BCCP,
director of the Psychiatric Pharmacy
Program at The University of Texas
at Austin College of Pharmacy and a
founding member of the College of
Psychiatric and Neurologic Pharma-
cists. “Every time they change provid-
ers someone layers on another drug.
They may or may not get their pre-
scriptions from the same pharmacies,
so many pharmacies may not see the
composite picture of what they’re tak-
ing. It’s an opportunity for pharma-
cists to be able to reach in and clean
up their meds, make the patient bet-
ter, and decrease costs. Also, there are
a number of opportuni-
ties in giving long-acting antipsy-
chotics or monitoring [patients taking]
clozapine. Those are 2 areas where phar-
cists have really stepped up.”

To provide and monitor long-acting injectable drugs, such as clozapine,
pharmacists must first set up a proto-
col with the prescriber. They can then
monitor treatment and, after getting
lab results, adjust doses in collabora-
tion with the prescriber.

“The protocol will differ depending
on the state you are in,” said Saklad.
“It’s not really very difficult or tedious
but requires a few hurdles to jump
over depending on [your] state....
There’s a really big opportunity for
ambulatory care in community phar-
macy and this is being done in a
number of states around the country.”

As an associate professor at Pacific
University in Forest Grove, Oregon,
Bridget Bradley, PharmD, RPh, BCPP,
educates future pharmacists about
potential roles in mental health care.
She also works as a psychiatric pharma-
cist at Virginia Garcia Memorial Health Center, a federally qualified
health center.

“I truly love everything about my
job,” said Bradley. “I get to work side by side with physicians,
[physician assistants], NPs [nurse prac-
titioners], nurses, [medical assistants],
behavioral health providers, mental
health providers, and the amazing sup-
port staff. In Oregon, pharmacists have
the opportunity to practice at the top
of their license. I get to provide medi-
cation management for patients with
depression [and] anxiety, and support
providers with managing many differ-
ent psychiatric medications.”

Choosing psychiatric pharmacy as
a career gives pharmacists an oppor-
tunity to improve lives and fight the
stigma associated with mental health.
“Being knowledgeable about the
medications [gives you] the oppor-
tunity to connect with a patient and
help them with their medication use,”
said Bradley. “Psychiatric pharmacists
have the opportunity to help patients
understand their medications.”

Filling in the Care Gaps
According to Saklad, about a third of
all psychiatric patients in the United
States are cared for at a family prac-
tice. A family practice provider might
prescribe a selective serotonin reup-
take inhibitor or other antidepressant
and schedule a standard 3-month fol-
low-up.

“They might make 1 dose adjust-
ment and if that does not work, send
the patient to a psychiatrist,” said
Saklad. “Well, there’s not enough
psychiatrists. Three months is too long.
If you have a psychiatric pharmacist
in your practice, patients are sent to
them for a more appropriate monitor-
ing adjustment. You have them come
back in 1 to 2 weeks to see how they
are doing and maybe then make an
adjustment.”

Taking advantage of pharmacists’
expertise can do more than ease the
burden on family practice physicians
and NPs. With the shortage of psychi-
atrists expected to reach 25% of need
by 2025, psychiatric pharmacists will
be more essential than ever.2

The medication intervention and
management performed by a pharma-
cist is also valuable during telehealth
consultations. A 2020 study followed
the pharmacist-led telemental health
transitions conducted by a care clinic
at a Veterans Affairs medical center.
The aim was to improve continuity of
psychiatric medication therapy follow-
ing discharge from an acute psychi-
tric hospitalization. The study results
showed that the pharmacist-led tele-
mental health transitions improved
the likelihood of patients adhering to
antidepressant medication after hospi-
tal discharge.3

Getting Trained
Becoming a board-certified psychi-
tric pharmacist requires specialized
training. After graduating from a doc-
tor of pharmacy program accredited
by the Accreditation Council for Phar-
macy Education, pharmacists can
specialize in psychiatric pharmacy
by acquiring postgraduate residency
training, clinical experience, or a com-
bination of the 2.4 Although all phar-
macy students learn about common
mental health conditions and medi-
cations, specialization in psychiatric

For More Information on Mental Health Care

The College of Psychiatric and
Neurologic Pharmacists
offers information on careers and
training in psychiatric and neurologic
pharmacy at https://cpnp.org/.

The National Community
Pharmacists Association
offers mental health first aid training
(virtual during COVID-19) at

The National Council for
Behavioral Health
provides information on mental health
services and mental health first aid at
https://www.thenationalcouncil.org/.
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pharmacy involves rotations in a mental health setting.

“You need experience talking with these folks, talking about the illness, learning how they live and what they struggle with in order to shape how you approach them, so you are of the most benefit to them,” said Caley.

Continuing mental health education, whether that involves focusing on psychiatric pharmacy or taking a mental health first aid course, makes it easier for pharmacists to approach the topic.

“A lot of pharmacists want to be able to do the right thing but they’re not sure what the right thing is,” said Caley. “They also think that talking with someone who has a mental health condition might take too much time, so they don’t. Given how common depression is, you could make the argument that pharmacists should be as well versed in depression as in diabetes, high blood pressure, and other common conditions. If you’re not interested in psychiatry and you don’t do a residency, then it’s up to individual pharmacists to pursue continuing education in areas that are focused on mental illness.”

**Opportunities Exist in Community Pharmacy**

Pharmacists working in the community setting can also play an important role in mental health care. According to the National Community Pharmacists Association (NCPA), pharmacists are more likely to encounter a patient having a mental health crisis than a patient requiring basic life support or cardiopulmonary resuscitation (CPR). By offering mental health first aid, a pharmacist can provide essential support during a crisis and then refer the patient to the appropriate medical professional.

NCPA offers a course for community pharmacists about common mental health disorders and how to deal with a crisis. The training recommends that a pharmacist who notices a patient acting differently—sadder, more anxious, or perhaps more manic—might suggest a simple mental health screening. Such screenings take only a few minutes.

“It really is like CPR—where it stops short of someone providing sutures if you slice a finger,” said Hannah Fish, PharmD, NCPA’s associate director of strategic initiatives. “You’re there to understand. You need to provide some sort of compression to stop the bleeding, but then you call 911 and they’re on their way. It’s the same thing with mental health first aid, where you’re able to figure out what the issue may be or where someone might need some extra support and then extend that support to the person who needs it.”

One way to start the conversation is to post a sign letting patients know that you offer mental health screenings. It’s not unlike putting up a sign that says you offer influenza shots.

“You can say, ‘Hey, how are you doing? Are you interested in a screening today? We’re here to talk and to help,’” said Fish.

The screening is more effective if a patient receives a questionnaire during a 1-on-1 interaction with a pharmacist. A 2019 study⁴ explored whether distributing the standard Patient Health Questionnaire-9 for depression screening was more effective when added to a prescription pickup bag or when patients had a one-on-one conversation with the pharmacist at prescription pickup or during a previously scheduled medication therapy management appointment. The highest participation rate occurred during a one-on-one interaction between pharmacist and patient, according to the results.

To provide timely referrals, pharmacists need an up-to-date list of accessible mental health professionals, clinics, and services. At Saklad’s Forty Acres Pharmacy in Austin, Texas, that list is updated on a monthly basis.

“Referring someone to a dead end is a bad, potentially lethal thing to do,” said Saklad. “We also check back with all the people we refer in 2 weeks to make sure they made contact and make sure they are OK. If they didn’t make contact, we give them another referral and we may basically contact that referral while they are on the phone and get them an appointment. You have to lean in.”

A mental health crisis can happen to anyone—even to those who do not normally suffer from an ongoing mental health disorder:

“A significant portion of adults will go through some kind of mental health crisis at some point in life,” said Fish. “It’s not always permanent. Someone can have a panic attack without having a panic disorder, someone can go through a depressive period and not necessarily be clinically diagnosed with depression.”

Given the isolation prompted by a year of COVID-19 lockdowns, some individuals may be more likely to experience bouts of anxiety and depression.

“There’s a real opportunity for pharmacists to make the outreach, to just do a wellness check with folks and to normalize the mental health conversation,” said Fish.

For references, visit drugtopics.com

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**A significant portion of adults will go through some kind of mental health crisis at some point in life.**

HANNAH FISH, PHARM.D
As of 2020 in the United States, there were over 30 million individuals living with diabetes, around 7 million who had not received a diagnosis, and over 80 million with a diagnosis of prediabetes.\(^1\)

Diabetes is extremely prevalent and can lead to serious complications such as cardiovascular disease, renal dysfunction, neuropathy, diabetic retinopathy, foot ulcers or infections, and even tinnitus if it is not properly managed through medications and lifestyle adjustments.\(^2\)

General treatment recommendations include insulin for type 1 diabetes and several different classes of medications for type 2 diabetes, such as biguanides, sulfonylureas, thiazolidinediones, sodium-glucose cotransporter 2 inhibitors, dipeptidyl peptidase-4 inhibitors, and glucagon-like peptide 1 (GLP-1) receptor agonists.\(^2\)

Because primary indicators of well-controlled diabetes include blood glucose levels and glycated hemoglobin levels, it is imperative for patients to have a firm understanding of how to self-monitor and regularly check these values. In addition, they should be able to recognize the symptoms of hypoglycemia and/or hyperglycemia.

Although patients are able to check their levels at routine doctor visits, frequent monitoring can provide a more comprehensive understanding of whether their current treatment plan is effective. Through technological advancements, the ease of self-monitoring and of accessing tools through mobile health apps has increased. This trend is likely to continue as more and more healthcare providers incorporate these technologies into their practices.

### TABLE: LIFESTYLE MANAGEMENT APPS FOR DIABETES\(^3\)

<table>
<thead>
<tr>
<th>APP NAME</th>
<th>FUNCTION</th>
<th>FEATURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Livongo</td>
<td>Works with the Livongo Blood Glucose Meter, Livongo Blood Pressure Monitor, and Livongo Scale to provide a more detailed picture of overall health</td>
<td>New recipes, Insights into glucose patterns with real-time support and professional coaching from diabetes response specialists, Tracks daily steps, Allows users to order unlimited test strips and lancets at no additional cost</td>
</tr>
<tr>
<td>MyFitnessPal</td>
<td>Diet and nutrition management; contains a database of over 10 million food items for tracking</td>
<td>Nutrient and exercise tracker, Restaurant reviews, Barcode scanner for packaged food items, Weight goal customization</td>
</tr>
<tr>
<td>Glucose Buddy</td>
<td>Records and tracks blood sugar control</td>
<td>Records and tracks glycated hemoglobin levels, blood glucose, medications, exercise, blood pressure, and weight, Food database of carbohydrates</td>
</tr>
<tr>
<td>Meal IQ</td>
<td>Enhances patient understanding of the connection between their diet and management of diabetes with information about how food can affect blood glucose</td>
<td>Personalized nutrition plans, Food and exercise tracking</td>
</tr>
<tr>
<td>DiabetesConnect</td>
<td>Converts glucose data across multiple apps into standard glucose statistics, providing valuable insight into glucose trends and how well controlled patients are on their current medication regimen</td>
<td>Allows recording of blood sugar, meal, bolus insulin, basal insulin, correction insulin, basal rates, temporary basal rate changes, exercises, medication, blood pressure, pulse, and mood</td>
</tr>
<tr>
<td>Diabetes:M</td>
<td>Provides a bolus insulin calculator for use with an insulin pump or multiple daily injection insulin regimen</td>
<td>Contains a logbook, food database, and basal insulin tracker that can be converted into daily charts to be shared with health care providers</td>
</tr>
<tr>
<td>Beat Diabetes</td>
<td>Designed for patients newly diagnosed with diabetes to provide tips on how to manage blood glucose, facts about diabetes complications, and treatment options with both modern medicine and Ayurvedic practices</td>
<td>Shares lists of the best and worst foods for diabetes, Diet advice based on the American Heart Association Diet and Lifestyle Recommendations</td>
</tr>
</tbody>
</table>

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Apps and Wearable Devices
Bluetooth capability has increased the expansion of health care apps and has enabled 1 main platform to contain all a patient’s relevant health information. For example, the OneTouch Verio Flex glucose meter will automatically synchronize its data with its corresponding OneTouch Reveal app, which patients can use to track their average blood glucose readings, food intake, medication dosing, and activity data. They can also set lifestyle goals, receive alerts about low and/or high blood glucose readings, and even share their data directly with their health care providers. Similarly, the Accu-Chek Guide, Guide Me, and Aviva Connect meters can connect to the mySugr app, allowing patients to enter any relevant diet and medication information, receive an analysis of glucose readings, and predict $A_g$ levels. Other similar apps include the iHealth Smart meter and One Drop mobile app. Patients can receive instantaneous alerts as well as predictive alerts up to 60 minutes in advance for hypoglycemia and/or hyperglycemia with Medtronic’s Guardian Connect app.

The data collected, which include current glucose levels with trends and glucose history can be shared with health care providers. Patients who have type 1 diabetes may be in need of more substantial monitoring of their insulin input and blood glucose levels. Apps such as Dia- beo and Diabetes Interactive Diary contain a recording option for self-monitoring blood glucose and an insulin bolus calculator: The calculator is comprehensive, using an algorithm to consider self-monitored blood glucose values, carbohydrate intake, and physical activity. It also takes into account clinician-set parameters for the insulin-carbohydrate ratio, correction factor, and basal insulin dose. If patients routinely check their blood glucose levels with the Accu-Chek meter, they can download the Accu-Chek Connect App, which will directly sync readings and results from the meter. Patients will also be able to take advantage of the insulin bolus calculator and photographic food diary in the app.

Technological advances in recent years have provided incredibly innovative methods through which patients can monitor their own health. In 2017, the FDA approved the FreeStyle Libre flash glucose monitor, a disklike sensor inserted into the upper arm and worn there for up to 14 days. Once the sensor has been inserted, a reader can be passed over it, providing real-time glucose levels, trends, and even alarms for dangerously low or high glucose levels in some versions of the monitor.

**Glucagon App**
Patients who routinely administer insulin have a high probability of hypoglycemia. As a preventive measure, glucagon kits may be given to those who are prescribed insulin. Eli Lilly created and released the Lilly Glucagon Mobile App, which shows users how to properly administer glucagon, provides frequent reminders about practicing and preparing for glucagon use, and contains drug safety information and indications. Because glucagon is generally not used except in emergencies, this app can be helpful for reminding patients and their caregivers how to properly administer it if there is ever a need.

**Lifestyle Apps**
In addition to medication therapy and medical management of diabetes, certain lifestyle modifications can be made to help patients better manage their symptoms and long-term outcomes. Similar to the several apps available for patients to monitor their blood glucose levels and current medications, there are lifestyle management apps that provide insight into diet and exercise.

This past year has posed unique challenges. Thanks to technology we have been able to remain connected through various platforms, which have been instrumental in health care. We have seen telehealth expand, and mobile apps such as the ones mentioned throughout this article have allowed patients and their health care providers to communicate with one another on a regular basis. For patients with diabetes, an increased accessibility to self-monitor and regularly communicate with their providers may help optimize their treatment plans and decrease the risk of long-term complications.

For references, visit drugtopics.com.

**Sandhya Vijapurapu** is a PharmD candidate at Duquesne University School of Pharmacy in Pittsburgh, Pennsylvania, who anticipates graduating in spring 2021.

**Jonathan Ogurchak**, PharmD, CSP, is the CEO and cofounder of STACK, a pharmacy information management platform. He also serves as preceptor for a virtual advanced pharmacy practice experiential rotation for specialty pharmacy.

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Rheumatoid Arthritis Management

Pharmacists can play an important role as part of an interdisciplinary team in treating patients with rheumatoid arthritis.

By Jennifer Gershman, PharmD, CPh

Rheumatoid arthritis (RA) is a chronic autoimmune disease that causes joint pain, stiffness, swelling, and decreased joint movement. Pharmacists are well equipped to help patients select the most appropriate RA treatment option and educate them about potential drug and disease state interactions as well as lifestyle modifications to improve symptoms (see Table 2-6).

Treatment Options and Drug Interactions
Pharmacologic treatment options for RA include conventional disease-modifying antirheumatic drugs (DMARDs), biologic DMARDs, corticosteroids, and nonsteroidal anti-inflammatory drugs (NSAIDs). Therapies are available orally, as injections, or as intravenous infusions. The American College of Rheumatology (ACR) recommends using the treat-to-target approach, which involves setting a therapeutic goal and working with patients to achieve the best health outcomes. Conventional DMARDs can take several weeks for patients to experience the full benefits, but they improve active RA symptoms, slow the disease course, and improve radiographic outcomes. Examples of conventional DMARDs include methotrexate (eg, Rheumatrex, Trexall), sulfasalazine (Azulfidine), leflunomide (Arava), and hydroxychloroquine (Plaquenil).

Conventional DMARDs
The ACR recommends methotrexate as the first-line DMARD for RA because most patients continue to take the therapy after 5 years based on its efficacy and tolerability. Pharmacists should advise patients to take methotrexate once weekly and not daily to prevent toxicity; many fatal errors have been reported to the Institute for Safe Medication Practices. As methotrexate can cause hepatotoxicity, patients should limit alcoholic beverages to no more than 1 to 2 per week. Folic acid supplementation can help reduce the incidence of hepatotoxicity and of gastrointestinal (GI) adverse effects (AEs) associated with the drug. Patients should avoid taking the antibiotic trimethoprim because it can increase methotrexate levels and cause nephrotoxicity and myelosuppression (low blood counts). If trimethoprim is necessary in the event there is no alternative antibiotic, the methotrexate should be held that week. Caution should be exercised if NSAIDs are used with methotrexate because of an increased risk of methotrexate toxicity; patients should be closely monitored. The herbal supplement echinacea purpurea also can cause hepatotoxicity and its use should be avoided with methotrexate.

Concomitant use of sulfasalazine and NSAIDs can increase the risk of GI bleeding. Patients taking leflunomide should limit alcohol consumption because it can cause liver damage. Higher doses of hydroxychloroquine for COVID-19 treatment has been associated with QTc prolongation. However, evidence suggests that lower doses of the drug for RA treatment should not itself increase the risk of QTc prolongation or the fatal arrhythmia torsades de pointes. Pharmacists should review patients’ medication profiles for possible drugs that could cause QTc prolongation in individuals taking hydroxychloroquine, especially those with heart conditions. Medications that can cause QTc prolongation include: antipsychotics (eg, haloperidol, ziprasidone, risperidone); antiarrhythmics (eg, amiodarone, quinidine); antibiotics (eg, azithromycin, fluoroquinolones); antidepressants (eg, amitriptyline); methadone; and ondansetron.

Biologic DMARDs
Tumor necrosis factor (TNF) inhibitors were the first biological DMARDs to be approved for the treatment of RA. TNF inhibitors include the following:
- etanercept (Enbrel; Amgen, Inc);
- infliximab (Remicade; Janssen Biotech, Inc);
- adalimumab (Humira; AbbVie Inc);
- certolizumab pegol (Cimzia; UCB, Inc); and
- golimumab (Simponi; Janssen Biotech, Inc).
COUNSELING POINTS FOR NONPHARMACOLOGIC MANAGEMENT OF RHEUMATOID ARTHRITIS

### TABLE

#### TABLE 1

**Exercise benefits and tips**

- Exercise is one of the key components of RA treatment to reduce disability and boost strength and flexibility.
- Weight-bearing exercises (eg, walking) can prevent osteoporosis that can be caused by RA.
- If RA has severely damaged the hips or knees, low-impact exercises can also help (eg, swimming, walking, bicycling, water aerobics).
- Physical and occupational therapists also can assist with exercises and discuss ways to make daily activities easier.

#### Nutrition tips

- Evidence demonstrates that a Mediterranean diet consisting of many fruits, vegetables, whole grains, and healthy fats can help reduce RA symptoms.
- Fatty fish (eg, salmon, tuna, sardines, herring), which are rich in omega-3 fatty acids, can help control inflammation.
- Nuts (eg, pine nuts, pistachios, hazelnuts, almonds) are good for heart health, and walnuts are high in omega-3 fatty acids. Pharmacists should counsel patients about these nutrition tips.
- Whole grains (eg, oats, whole wheat, brown rice, quinoa) can reduce inflammation and lower the risk of heart disease.
- In patients with heart disease or renal impairment, 8,9 their long-term use should be avoided, especially in patients with heart disease or renal dysfunction. Corticosteroids should be used short term for treatment and tapered before discontinuation.8,12 They can increase blood glucose levels, so patients with diabetes should be closely monitored. Individuals can also develop osteoporosis.8 Patients with a history of mental illness may be at risk of developing neuropsychiatric AEs with corticosteroid therapy, but these symptoms can also occur in those without such history.8

For references, visit drugtopics.com.
Independent community pharmacists must keep pace with rapidly changing industry trends, from shifting reimbursement models and prescription drug costs to COVID-19 vaccination.

Amid policy changes and cultural shifts, pharmacists who want to know how to navigate the business and how to get ahead of legislation that could shake up their day-to-day operations should tune in to a recent episode of Over the Counter, the podcast from Drug Topics®, brought to you by Total Pharmacy® and New Jersey–based Omega Pharmacy Group. Omega Pharmacy Group represents independent pharmacies, leveraging buying power to help them access pharmaceuticals at the best prices. As a buying group, Omega provides contract negotiations and vendor relationship management, analytical reporting, and marketplace trend reporting.

In the episode, Jonathan Kurtz, chief executive officer of Omega Pharmacy Group, and Anthony Reznik, director of government and public affairs with Omega Pharmacy Group, walk us through industry trends they find compelling, including Medicaid Fee-For-Service (FFS) updates, COVID-19 vaccination, direct and indirect remuneration fees, and more.

Kurtz and Reznik first provide their perspectives on Medicaid FFS.

“What a lot of states [that have switched over to Medicaid Managed Care] have found over the course of the past 10 years...is that instead of saving money, they've been losing money,” Reznik shared. “Medicaid beneficiaries have been paying more money for their prescription drugs. Pharmacies have been reimbursed less, yet the state's cost of the prescription drug benefit for Medicaid has been increasing exponentially. And, for instance, in New Jersey, we're talking about hundreds of millions of dollars in the state budget. And as a result, taxpayers are paying more money. Beneficiaries in the Medicaid program are also paying more money for their prescription drugs. At the same time, the independent pharmacies that serve these communities are being reimbursed less and less and less.”

Because of this, Reznik said, there has been more discussion about returning to an FFS in many states. West Virginia, for example, recently went back to an FFS system in its Medicaid program.

“In the first year, they saved $50 million in their Medicaid program. And they were able to make the independent pharmacies in West Virginia whole by increasing their reimbursement rates,” Reznik said.

“And when you look at the scope of the dollars spent on Medicaid—let's take the state of New York—and we're talking about full Medicaid, not just the prescription divor,” Kurtz added. “In the state of New York, they spend $59 billion on Medicaid participants. That's a huge number. So, we feel that it needs to go to [an FFS]. It's a win for the state that you're in, it's a win for the independent pharmacy owner, and it's a win for the patient.”

Later in the episode, Reznik and Kurtz talk COVID-19 vaccines. Although specific challenges exist when it comes to resources for administering the vaccines, both agreed that independent pharmacies can play a crucial role in getting these shots to the general public.

Reznik and Kurtz pointed to Omega Pharmacy Group's monthly update, available to all members, which has been focused on the COVID-19 vaccines and testing. Because news about the vaccines and regulations change quickly, independent pharmacists can stay on top of the latest information with these updates. Those who are interested in becoming certified to administer vaccines can also contact Omega Pharmacy Group for more information.
Choosing a Wholesale Distributor

An independent pharmacy’s relationship with a wholesaler is about more than drug costs.  

by Aine Cryts

The number of independent pharmacies continued its decline in 2019, to 21,683 stores, according to the 2020 National Community Pharmacists Association’s Digest report.1 Drug Topics® reported in July 2019 that there were 23,106 independent pharmacies in 2011, a number that fell to 21,909 in 2017.2

Of course, there are efforts around the country by independent pharmacists—often orchestrated by the Community Pharmacy Enhanced Services Network—to provide services that not only affect the communities they serve but generate the revenue needed to support their businesses. However, it is an independent pharmacy’s relationship with a wholesale distributor that is pivotal to its success. Stacy Ramirez, PharmD, a clinical assistant professor at Oregon State University College of Pharmacy in Corvallis, explained that although the cost of drugs is part of the equation, many wholesale distributors also offer pharmacy software and inventory services, and facilitate arrangements with payers.

“If you get it wrong, it’s not just about switching to another wholesale distributor; it’s about switching your entire operation. That’s where the challenge is,” said Ramirez, who also serves as director of pharmacy at Community Health Centers of Benton and Linn Counties in Oregon. “You’d have to be really dissatisfied to take that step. If you’re a new independent pharmacist, you have invested a certain amount of time and capital into that decision. It makes it difficult to walk away,” she said.

Importance of Drug Costs

Because wholesale distributors offer more than drugs, Ramirez encourages new independent pharmacists not to look at the cost of drugs as their first consideration. “Oftentimes, there’s not much variation...it’s usually a few pennies in either direction,” she said.

Instead, she encourages new independent pharmacists to ask about the level of service the company can provide. For example, in metropolitan areas, such as New York, New York, a pharmacist can get “spoiled” with access to deliveries 6 days a week, said Ramirez. Independent pharmacists in rural areas may need to base their decision on a wholesale distributor’s ability to deliver more often than 1 or 2 days a week. If it takes 4 or 5 days to get a drug, that could have a negative impact on customers, she explained.

Christopher J. Daly, PharmD, MBA, BCACP, a clinical assistant professor at the University of Buffalo School of Pharmacy and Pharmaceutical Sciences in New York, said the cost of drugs is an important consideration. “There are [independent pharmacy] owners out there who will shop vast and wide [to buy cheaper drugs],” he said.

To remain viable as a business, independent pharmacists should consider not being loyal to a single wholesaler, advised Daly, who’s a third-generation pharmacist. Amelia Arnold, PharmD, director of pharmacy operations at Augusta, Maine–based Community Pharmacies and an adjunct assistant clinical professor at the University of New England School of Pharmacy in Portland, Maine, said pharmacist-owners need to consider the cost of goods, possible rebates, ordering thresholds that must be maintained, and payment terms.

In addition, pharmacists should ask about exclusions for the cost of goods. For example, they should ask whether a particular specialty drug will have a different payment term, said Arnold.

Beyond the Cost of Drugs

Daley describes the decision about working with a particular wholesale distributor as multifactorial. The primary characteristic pharmacy owners should look for in a wholesaler is their being invested in the pharmacy’s outcomes. Specifically, Daly points to a company’s ability to provide access to contracts through its pharmacy services administrative organization (PSAO).

Tom Wadsworth, PharmD, BCPS, assistant dean for Alaska programs and an associate professor at Idaho State University College of Pharmacy in Pocatello, encourages pharmacy owners to realize they’re also picking a business model

Author: Aine Cryts

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that has control over the cost of generic and brand-name drugs. “You’re choosing your identity and how you’re going to run your business. This includes the sign outside your store and the wholesaler’s purchasing group,” he added.

Previously, Wadsworth led a company that included 3 independent pharmacies. When he bought the first pharmacy, which was located inside a grocery store, the gross profit was $22 per prescription. When he sold the pharmacies 10 years later, the gross profit was approximately $7.80 per prescription. He advises pharmacy owners to track this metric on a weekly, monthly, and yearly basis and then adjust their business model in response.

Daly said new pharmacy owners should consider a wholesale distributor’s interest in serving as a capital partner. This can help by the partner’s providing access to lines of credit, which allows the pharmacy to purchase fixtures, shelving, and everything else a new owner needs.

Arnold also stressed the importance of the agreement signed with the PSAO, which negotiates contracts on behalf of the pharmacy with health insurers. For example, it’s important to know the terms of the contracts and, specifically, whether the pharmacy is listed in a Part D preferred network; otherwise, the pharmacy could lose out on volume, she said.

Other services of interest to independent pharmacists can include marketing and help with training and regulatory requirements, added Arnold.

According to Daly, it’s important to work with a wholesaler that can vet medications to the FDA’s standards. He said pharmacy owners should ask about the company’s ability to comply with the FDA’s “track and trace” program, which ensures that suspect and illegitimate products don’t enter the supply chain.

“There are people out there who have a passion for independent pharmacy. You don’t have to do this alone.” Amelia Arnold, PharmD

**Exclusive or Primary Relationships With Wholesalers**

Ramirez said pharmacy owners already have a lot of responsibility. She made that observation because, although financial savings are possible when working with more than 1 wholesale distributor, each one of those companies represents another relationship to manage and another set of invoices to pay.

“A new pharmacy owner has a lot of balls in the air. It probably makes more sense to have a primary wholesaler,” she noted. But maintaining relationships with wholesalers who have items not sold by the primary wholesaler can be a good idea. Independent pharmacists in rural areas should consider partnering with more than 1 wholesaler if a company delivers only 1 or 2 days a week, added Ramirez.

**Outsourcing**

Wadsworth stresses that pharmacists who are also owners should hire a business manager who’s responsible for sorting through the nonclinical aspects of running the pharmacy. This can include managing relationships with wholesale distributors and reviewing contracts. “It’s hard to be the owner and the staff pharmacist,” he explained.

It may be appropriate to outsource reading contracts or regulatory issues to an attorney, or training and other employment issues to a human resources consultant. But any aspects of the pharmacy that are customer facing must be kept in house, insisted Wadsworth.

One way independent pharmacists can continue to distinguish their stores from Amazon’s PillPack or large chains is by ensuring the phone is picked up quickly by a staff member—or even better, by the pharmacist. “[You won’t get that] at a larger store; there you get a voice recording,” said Wadsworth.

Tapping the expertise of your state’s pharmacist association also helps. Specifically, Arnold recommends that pharmacist-owners seek out a mentor. “There are people out there who have a passion for independent pharmacy. You don’t have to do this alone,” she observed.

**Secure a Go-to Contact at the Wholesaler**

Long after a contract has been signed, problems will occur. Issues can range from a manufacturer falling behind in the production of drugs or syringes or a shipment getting lost. That’s why Arnold insists it’s important to have a named contact at the company to troubleshoot issues.

“My pharmacy can call customer service about a return, but what happens if we don’t understand the answer or we’re getting the runaround?” she said. The go-to contact could be a sales representative or another person at the company.

Daly advises new independent pharmacists to work with a wholesaler that’s active in their state’s pharmacists association. It’s a measure of the company’s role as an advocate for pharmacists and shows an investment in the profession, he said.

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Back in December 2020, the FDA issued an emergency use authorization for Pfizer-BioNTech's COVID-19 vaccine, followed by authorization for the Moderna and Janssen (Johnson & Johnson) vaccines. Many Americans have yet to be vaccinated, with the most common reasons for refusing being fear of potential adverse effects (AEs) and concerns about the rapid vaccine development process. Pharmacists must be familiar with the safety profiles of the vaccines to assure the public of their safety.

**COVID-19 Vaccines Available in the United States**

Three vaccines are currently available on the US market. The Pfizer and Moderna vaccines are both messenger RNA (mRNA) vaccines, whereas the Janssen (Johnson & Johnson) vaccines. Ongoing surveillance has identified additional AEs, but it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure (see Table). This point can be illustrated by the reporting in mid-April 2021 of a few cases of thrombocytopenia with cerebral venous sinus thrombosis in individuals who had received the Janssen COVID-19 vaccine. Although these cases appear to be very rare, as of the time of this writing, the FDA and CDC have recommended a pause in the use of this vaccine until this matter is thoroughly investigated.

The more commonly reported AEs associated with the use of COVID-19 vaccines are usually related to the vaccine’s pharmacology and not considered immune-mediated or allergic reactions. Anaphylaxis is a severe acute-onset immunologic reaction, generally immunoglobulin E (IgE) mediated, which typically occurs in response to preformed IgE antibodies. Acute-onset immunologically mediated reactions commonly manifest as urticaria, swelling, gastrointestinal upset, respiratory distress, or cardiovascular collapse associated with severe cases of anaphylaxis. The onset of acute allergic reactions generally to be more intense after the second dose of the mRNA vaccines and are more likely to occur in younger individuals. Ongoing surveillance has identified additional AEs, but it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure (see Table). The more commonly reported AEs associated with the use of COVID-19 vaccines are usually related to the vaccine’s pharmacology and not considered immune-mediated or allergic reactions.
Drug Topics® May 2021

occurs within 30 minutes of exposure, although a reaction may also develop hours to days later, in which case it usually presents as a cutaneous reaction. Generally, the mRNA, DNA, or other antigen components in vaccines are not the culprits for allergic reactions. Allergic reactions are usually attributed to other product components such as stabilizing agents and adjuvants, and, rarely, to latex in the vial’s rubber stopper. The Pfizer and Moderna COVID-19 vaccines contain mRNA, lipids, polyethylene glycol (PEG) 2000, electrolytes, sucrose, and a saline diluent. Although the etiology of anaphylaxis to the COVID-19 vaccines is not known, PEG and related polysorbates have been associated with cases of anaphylaxis to other agents. Individuals who exhibit signs of allergic reaction after COVID-19 vaccination are advised to avoid new PEG exposure and to undergo further evaluation with a board-certified allergist or immunologist. The Pfizer and Moderna COVID-19 vaccines contain mRNA, lipids, polyethylene glycol (PEG) 2000, electrolytes, sucrose, and a saline diluent. Although the etiology of anaphylaxis to the COVID-19 vaccines is not known, PEG and related polysorbates have been associated with cases of anaphylaxis to other agents. Individuals who exhibit signs of allergic reaction after COVID-19 vaccination are advised to avoid new PEG exposure and to undergo further evaluation with a board-certified allergist or immunologist. Although cases of anaphylaxis were not reported in clinical trials with the mRNA vaccines, 21 incidents of possible anaphylaxis were subsequently reported with the Pfizer vaccine (11.1 cases per million doses), with 70% occurring within 15 minutes of administration. Ten cases of possible anaphylaxis were reported after vaccination with the Moderna vaccine (2.5 cases per million doses) and 1 case of anaphylaxis was reported with the Janssen vaccine. The less extensive use of the Janssen vaccine to date prohibits a comparative assessment of the overall safety of this vaccine relative to the mRNA vaccines.

**Prevention and Management of Anaphylaxis**

The CDC recommends that the COVID-19 vaccines not be administered to individuals who have a history of severe or immediate allergic reaction to any vaccine component (e.g., PEG in the case of the mRNA vaccines, polysorbate in the case of the Janssen vaccine). Patients who experienced a severe or immediate allergic reaction to a COVID-19 vaccine should not receive subsequent doses. The CDC recommends a postvaccination observation period of 30 minutes for those at high risk for anaphylactic reactions and 15 minutes for all other individuals.

**Counseling and Education**

When providing counseling, it is important to emphasize the vaccine’s efficacy. Individuals receiving the mRNA vaccines also should be counseled on the importance of completing the vaccination series with the same product. They should be counseled on the expected postvaccination symptoms: Of those receiving the mRNA vaccines, local symptoms are experienced by 80% to 89%, and systemic symptoms by 55% to 83%; of those receiving the viral-vector vaccine, local symptoms are experienced by 50%, and systemic symptoms by 55%. Reassure recipients that systemic postvaccination symptoms are generally mild to moderate in severity, occur within the first 3 days of vaccination, and resolve within 3 days of onset. Advise recipients that antipyretic or analgesic medications can be taken for postvaccination local or systemic symptoms.

The available COVID-19 vaccines are effective in reducing the spread of the disease. Serious reactions are rare, and the public should be educated on the overall safety of these vaccines.

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### TABLE. ADVERSE EFFECTS (%) REPORTED IN CLINICAL TRIALS INVOLVING CURRENT COVID-19 VACCINES IN THE UNITED STATES^6–8

<table>
<thead>
<tr>
<th>ADVERSE EFFECT</th>
<th>PFIZER-BIONTECH COVID-19 VACCINE</th>
<th>MODERNA COVID-19 VACCINE</th>
<th>JANSSEN COVID-19 VACCINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at injection site</td>
<td>84.1</td>
<td>92.0</td>
<td>48.6</td>
</tr>
<tr>
<td>Fatigue</td>
<td>62.9</td>
<td>70.0</td>
<td>38.2</td>
</tr>
<tr>
<td>Headache</td>
<td>55.1</td>
<td>64.7</td>
<td>38.9</td>
</tr>
<tr>
<td>Muscle pain</td>
<td>38.3</td>
<td>61.5</td>
<td>33.2</td>
</tr>
<tr>
<td>Chills</td>
<td>31.9</td>
<td>45.4</td>
<td>-</td>
</tr>
<tr>
<td>Joint pain</td>
<td>23.6</td>
<td>46.4</td>
<td>-</td>
</tr>
<tr>
<td>Fever</td>
<td>14.2</td>
<td>15.5</td>
<td>3.1-12.8*</td>
</tr>
<tr>
<td>Injection site swelling</td>
<td>10.5</td>
<td>14.7</td>
<td>2.7-7*</td>
</tr>
<tr>
<td>Injection site redness</td>
<td>9.5</td>
<td>10.0</td>
<td>4.6-9.0*</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.1</td>
<td>23.0</td>
<td>14.2</td>
</tr>
<tr>
<td>Malaise</td>
<td>0.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>0.3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>-</td>
<td>19.8</td>
<td>-</td>
</tr>
</tbody>
</table>

*Depending on age group studied
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Medications used to treat stroke are complex, and their preparations are complicated. Pharmacists’ knowledge and familiarity with these brain-saving medications are crucial in the typically narrow time windows to effectively treat patients with stroke, according to Deborah Sadowski, MHA, BSPharm, RPh, director of pharmacy services at Deborah Heart and Lung Center in Browns Mills, New Jersey.

“The pharmacist is uniquely positioned to assess the safety and appropriateness of these medications for each patient as well as dose and prepare them in a safe and expedient manner,” Sadowski said.

As a result, including pharmacists in stroke care teams can greatly improve patient outcomes. They can be incorporated into a stroke patient care team in a variety of practice settings, including inpatient units, outpatient clinics, and community pharmacies, in addition to emergency departments.

At Mount Sinai Hospital in New York, New York, clinical pharmacist Nicole Davis, PharmD, BCCCP, an assistant professor in the Department of Pharmacy Practice at Touro College of Pharmacy, also in New York, said the pharmacy team is alerted when a patient with stroke arrives in the emergency department. When this occurs, a pharmacist will bring a thrombolytic directly to the bedside to assess eligibility as well as to compound the medication. The patient is then transferred to the neurology intensive care unit (ICU) or to a step-down unit or floor bed depending upon their condition, where they are followed by an ICU-trained pharmacist or inpatient pharmacist.

Kristina Stein, PharmD, a neurology clinical pharmacist at the University of Alabama at Birmingham Hospital, is part of a multidisciplinary team that responds to “code strokes.” She receives an alert when a patient has a neurologic change or event that could be concerning for a stroke. “Pharmacists can identify candidates for thrombolytic therapy and reduce time to thrombolytic therapy,” she said. Furthermore, they can facilitate adjunctive therapy, such as blood pressure control or reversing anticoagulation therapy in the case of hemorrhagic strokes.

Pharmacists can also participate in medication reconciliation, secondary stroke prevention, risk reduction, patient counseling and education, and transitions of care initiatives. Stein attends transition-of-care rounds, where she meets with an interdisciplinary group to review each patient with stroke. She also counsels patients who start oral anticoagulants during their hospitalization or who will start one after discharge, works with providers to choose the best agent for patients, and helps monitor heparin, enoxaparin, and warfarin.

Stein advises that smaller organizations train some inpatient pharmacists in stroke care. Choose someone who is interested in this effort to take ownership and be responsible for developing house-wide education, she recommends. The 2019 update to the Guidelines for the Early Management of Patients With Acute Ischemic Stroke is a great place to start when developing education.

If an institution is looking for other ways to incorporate pharmacists into stroke care, opportunities exist with developing or reviewing stroke electronic order sets; completing competencies in stroke identification, management, and thrombolytic therapy administration; participating in stroke simulation education experiences; and serving on stroke committees, Stein added.

Getting a Pharmacist On Board

When looking to make a change, such as adding a pharmacist to a stroke care team, it’s helpful to have a physician promote it. After a pharmacist has joined the team, Alyssa Bernard, PharmD, a patient care pharmacist in the stroke unit and neurosensory ICU at Jefferson Hospital for Neuroscience in Philadelphia, Pennsylvania,
Practical Considerations for Stroke Interventions

Nicole Davis, PharmD, BCCCP, offered the following best practice tips for pharmacists on stroke care teams:

- **Know the patient’s correct weight.** As both alteplase and tenecteplase are weight based for stroke treatment, an incorrect weight could lead to under- or over-dosing.

- **Assess a patient’s blood pressure (BP) and be familiar with agents rapidly available if BP becomes uncontrolled.** If using continuous infusions such as clevidipine or nicardipine, know how to titrate them and how to use your hospital’s pumps. “I have programmed pumps for nurses when they are trying to place a line or manage multiple patients—so it’s helpful to know how to react in emergent situations,” Davis said.

- **Identify which bolus blood pressure medications are most beneficial for each patient.** Ensure that the physicians treating the patient are familiar with your recommendations as well as the dosing and monitoring parameters.

- **Remain calm.** Davis also emphasized the importance of remaining calm when compounding alteplase or tenecteplase. “Because both are time-sensitive medications, you’ll want to make the correct dose as soon as possible, but never at the expense of causing an error,” she said.

Ameliorating Secondary Prevention Strategies

Pharmacists also need to be aware of the different outcome measures for preventing future strokes. Ensuring that patients have good outpatient poststroke discharge plans is important to make sure they are monitored for high blood pressure, high cholesterol, diabetes management, smoking cessation, and other health maintenance concerns, according to Sarah Clark, PharmD, BCPS, a senior pharmacy manager for neurology, psychiatry, and emergency medicine, at Mayo Clinic in Rochester, Minnesota. Outpatient pharmacists can play a role in the ongoing medication management of these patients.

By working collaboratively with providers, pharmacists can build mutual trust and confidence with them. This partnership will benefit patients and provide them with optimum care through team collaboration, Sadowski said.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Technology Advances Are Needed to Advance the Profession

Innovation is everywhere, but cumbersome pharmacy technology remains an issue.

One day, my wife, Denise, and I went to our local bank with a plastic card and put it in the machine. We had the option of withdrawing either $25 or $50 from our checking account. The money dropped down in an envelope with the cash inside. This was amazing technology for 1981. I then went to work and pulled out the Smith Corona typewriter and started typing prescription labels.

Yesterday, I went to our warehouse club and pulled up to the gas pumps. I took out my phone and waved it at the QR code on the screen. I began pumping my gas without ever getting my wallet out of my pocket. I checked my email and saw I had spent $28.54 on pump No. 4 at 7:46 AM. I went to the pharmacy, fired up the computer, and began my working day.

A new patient needed a shingles vaccine. She handed me her 2 prescription cards. We had to enter all the insurance data by hand, making sure we typed in the right bank identification, processor control, ID, and group numbers. After we submitted the claim, it was denied and we needed to use the Medicare Part D card. Next, we entered the alphanumeric information carefully to make sure all the letters and digits were correct. I got out my cheat sheet to make sure I added 4 additional fields, including administration fee, because this was for a vaccine. Then we went to another website to print out her prescreening form, and logged in the site of administration, lot number, and expiration date of the vaccine.

Two outstanding pharmacists who are working to make massive changes in our profession are Stephanie McGrath, PharmD, and my daughter Gretchen Garofoli, PharmD, BCACP. Both are working tirelessly to have pharmacists get paid for their clinical expertise through CPESN-USA. Their focus is on e-care plans, which enable pharmacists to show what interventions they have made that will produce optimal outcomes for our patients.

The biggest challenge with e-care plans is that the technology is clunky at best. Like anything else in healthcare, it takes more time to document your actions than to carry them out. I’m familiar with 3 of the major e-care plans and I’m not impressed with any of them. The one I use to bill for services to a provider requires 5 different systematized nomenclature of medicine clinical terms (SNOMED CT) codes to be documented. Whether you are documenting hypertension, chronic obstructive pulmonary disease, or asthma, you should not have to search through layers and layers for the appropriate 5 SNOMED codes.

The very best pharmacy software I was ever exposed to was in the late 1990s. It was built by a couple of pharmacists. To this day, I have yet to see a pharmacy filing system that was more pharmacist friendly than that one. I would love to see more pharmacists on the ground floor of software development. If only our pharmacy software could be as intuitive as the iPhones we all carry with us. When’s the last time you read the user manual for your smartphone?

When I stand in front of my pharmacy computer for 10 hours at a time, I often wonder why this technology seems so far behind the other technology I use daily. If we want to move this profession toward more patient-centric care, we must have the tools to do that. All I ask is that my pharmacy computer have the same technology as my gas pump.

If we want to move this profession toward more patient-centric care, we must have the tools to do that.

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.
Melphalan Flufenamide for Relapsed or Refractory Multiple Myeloma

Kendall Szulimowski, 2021 PharmD candidate; Samantha Troy, 2021 PharmD candidate; Lisa M. Holle, PharmD, BCOP, FHOPA, FISOPP

On February 26, 2021, melphalan flufenamide (Pepaxto; Oncopeptides AB) in combination with dexamethasone received accelerated approval from the FDA for adult patients with relapsed or refractory multiple myeloma (MM).1 Relapsed or refractory multiple myeloma is defined in patients who have received at least 4 prior lines of therapy and whose disease is refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD38-directed monoclonal antibody. Melphalan flufenamide, a peptide-drug conjugate, targets aminopeptidases and selectively releases alkylating agents into tumor cells.2 Melphalan flufenamide is taken up by myeloma cells because of its lipophilicity. It is rapidly hydrolyzed by peptidases, and cross-linking of DNA is involved in the antitumor activity. Melphalan flufenamide shows synergistic cytotoxicity with dexamethasone in both melphalan-resistant and -nonresistant multiple myeloma cell lines.3

Approval was based on results of the phase 2 HORIZON trial (NCT02963493).1 Patients were required to have relapsed or refractory MM and have received 2 or more prior lines of therapy and been refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD38-directed antibody. The primary end point was overall response rate (ORR).2 The ORR was 29% in the all-treated population (95% CI, 22%-37%), with 26% in the triple-class-refractory population (95% CI, 18%-35%). In the all-treated population, median duration of response was 5.5 months (95% CI, 3.9-7.6 months), median progression-free survival was 4.2 months (95% CI, 3.4-4.9 months), and median overall survival was 11.6 months (95% CI, 9.3-15.4 months) at a median follow-up of 14 months.2

Efficacy

The most common adverse effects were fatigue (55%), nausea (32%), diarrhea (27%), pyrexia (24%), and respiratory tract infection (24%). The most common grade 3 or 4 laboratory abnormalities were decreases in leukocytes (88%), platelets (80%), lymphocytes (95%), neutrophils (82%), and hemoglobin (50%).3 Melphalan flufenamide carries warnings for thrombocytopenia, neutropenia, anemia, infections, secondary malignancies, and embryo-fetal toxicity. This medication should not be interchanged with regular melphalan hydrochloride, such as when prescribed in high doses for conditioning regimens for hematopoietic stem cell transplantation, as higher-than-recommended doses of melphalan flufenamide may be associated with mortality.4 Complete blood counts with differential should occur at baseline, during treatment, and as clinically indicated to monitor for thrombocytopenia, neutropenia, and anemia. Melphalan flufenamide should be withheld if the patient’s platelet count is less than 50 × 10^9/L or neutrophil count is less than 1 × 10^9/L.

Safety

The recommended dosage of melphalan flufenamide is 40 mg intravenously over 30 minutes on day 1 of each 28-day treatment cycle in combination with dexamethasone. A serotonin (5-HT3) receptor antagonist, such as ondansetron, or other antiemetics may be taken to prevent nausea and vomiting.1 If needed because of adverse effects, the first dose reduction would be to 30 mg of melphalan flufenamide and the second dose reduction would be to 20 mg. If the patient cannot tolerate 20 mg, melphalan flufenamide should be permanently discontinued.1
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