

**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.
- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

*Routine vaccination is an essential preventive care service that should not be delayed because of the COVID-19 pandemic. Because of COVID-19-related reductions in people accessing vaccination services, it is important to assess vaccination status at each patient visit. Please visit CDC’s COVID-19 webpage for more information.*

**WHEN YOU POKE THEM, PROD THEM.**

When giving a COVID-19 or flu vaccine to patients 50 years and older, urge them to schedule a shingles vaccination, too.*

* *Routine vaccination is an essential preventive care service that should not be delayed because of the COVID-19 pandemic. Because of COVID-19-related reductions in people accessing vaccination services, it is important to assess vaccination status at each patient visit. Please visit CDC’s COVID-19 webpage for more information.*

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If they’re 50 years and older, it’s time to start the conversation

Patients may be coming in for their COVID-19 or annual flu vaccination. **But for patients 50 years and older, there’s another risk to watch out for—shingles.** That’s why it’s also the perfect opportunity to discuss vaccination with SHINGRIX.

![50+ YEARS]

99.5% of people aged 50 years and older are infected with varicella zoster virus

In 1 out of 3 people the virus reactivates and causes shingles

There are a lot of things that patients can’t prevent as they age—but you can help them prevent shingles. Don’t wait another day to schedule a SHINGRIX vaccination with your appropriate patients.

Download our Shingles Discussion Guide at talkshingles.com

• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• 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

• 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.

**References:**

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BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)
The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

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

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 2 to 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)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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.

Adults Aged 50 Years and Older

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 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,531 (60%) 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%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (6%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions 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 and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

Table 1. Percentage of Subjects with Solicited Local and General Adverse Reactions 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>Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td>SHINGRIX Placebo</td>
<td>SHINGRIX Placebo</td>
<td>SHINGRIX Placebo</td>
</tr>
<tr>
<td>Pain</td>
<td>n=1,315 %</td>
<td>n=1,312 %</td>
<td>n=1,311 %</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>n=15</td>
<td>n=14</td>
<td>n=11</td>
</tr>
<tr>
<td>Redness</td>
<td>n=39</td>
<td>n=38</td>
<td>n=32</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>n=3</td>
<td>n=3</td>
<td>n=3</td>
</tr>
<tr>
<td>Swelling</td>
<td>n=31</td>
<td>n=27</td>
<td>n=21</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td><strong>General Adverse Reactions</strong></td>
<td>SHINGRIX Placebo</td>
<td>SHINGRIX Placebo</td>
<td>SHINGRIX Placebo</td>
</tr>
<tr>
<td>Myalgia</td>
<td>n=1,315 %</td>
<td>n=1,312 %</td>
<td>n=1,309 %</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>n=9</td>
<td>n=1</td>
<td>n=1</td>
</tr>
<tr>
<td>Fatigue</td>
<td>n=57</td>
<td>n=20</td>
<td>n=17</td>
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<tr>
<td>Fatigue, Grade 3</td>
<td>n=9</td>
<td>n=2</td>
<td>n=1</td>
</tr>
<tr>
<td>Headache</td>
<td>n=51</td>
<td>n=46</td>
<td>n=16</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>n=6</td>
<td>n=4</td>
<td>n=0</td>
</tr>
<tr>
<td>Shivering</td>
<td>n=36</td>
<td>n=30</td>
<td>n=6</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>n=7</td>
<td>n=5</td>
<td>n=3</td>
</tr>
<tr>
<td>Fever</td>
<td>n=28</td>
<td>n=24</td>
<td>n=14</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>n=0.4</td>
<td>n=0.2</td>
<td>n=0.2</td>
</tr>
<tr>
<td>GI</td>
<td>n=24</td>
<td>n=17</td>
<td>n=9</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>n=2</td>
<td>n=1</td>
<td>n=1</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.
- 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, and 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 reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The local and general adverse reactions seen with SHINGRIX had an median duration of 2 to 3 days.

(continued on next page)
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% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited local reactions (headache, myalgia, fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 2.4%, 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 51% and 32% of subjects who received SHINGRIX (n = 14,645) or placebo (n = 14,660), respectively. 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 (4% 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 or 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%) or placebo (2.2%) from the first administered dose up to 30 days post-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-vaccination. One subject with 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 of age 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 events 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.
- 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.

### 8. USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

#### 8.2 Lactation

**Risk Summary**

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].

### 8.3 Geriatric Use

**Adults Aged 60 Years and Older**

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions 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).

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Rewriting the Future of Eczema Treatment

October is National Eczema Awareness Month, offering a powerful message of hope for the more than 31 million Americans with some form of this condition. Finding treatments that can improve outcomes for young patients is essential. Beyond experiencing the discomfort or pain associated with the itch-scratch cycle, 1 in 3 children with atopic dermatitis (AD), for example, could face a variety of comorbidities, depending on their condition’s severity. The list includes asthma, allergic rhinitis, and food allergies, as well as neuropsychiatric conditions such as attention deficit disorder, depression, anxiety, and conduct disorder and suicidal ideation, according to the National Eczema Association (NEA).

Adults with AD also face a range of risks, from asthma and ocular conditions to autoimmune and cardiac disease, which increase with AD severity. Nor are adults immune to the psychological burden. Concerns about appearance reduce self-confidence, such as during job interviews and social interactions, and lead to self-esteem issues and mental health challenges in adults as well as in children and teens, the NEA notes.

Improving the physical and mental health of patients with eczema requires more than a packed pipeline. New approaches to topical steroid withdrawal also are coming closer to addressing this major roadblock to care management.

As much as the medical side of eczema treatment is advancing, some core quality-of-life (QOL) issues will not change without increased awareness across the nonpatient community. From the sports coach to the restaurant patron to the human resources director, all individuals need to understand that eczema is not contagious and that the child or adult who has the characteristic rash or inflammation should not be isolated—or bullied. Educating the public about eczema is where the most accessible health care providers, pharmacists, can play a key role. In the interim, the advent of novel therapies brings hope that until there is a cure, control will make it easier for patients to achieve clear skin and a higher QOL.

Thank you for reading.

Mike Hennessy Sr
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of MJH Life Sciences™

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New Findings Reveal Number of US Lives Saved By COVID-19 Vaccines

By Keith A. Reynolds

NIH report shows vaccines prevented 139,000 deaths.

According to a news release from the National Institutes of Health, a study assessing the impact of state-level vaccination campaigns showed that during the first 5 months the COVID-19 vaccines were available, they prevented more than 139,000 deaths. The investigators estimated that the economic value of saving these lives was between $625 billion and $1.4 trillion.

By May 9, there were 570,000 US deaths related to COVID-19. The model used for the study projected this number would have been 709,000 deaths without the vaccine, the release says. The study was performed to assess the impact of state-level vaccination campaigns. Investigators analyzed the period from December 21, 2020, to May 9, 2021, and compared the amount of time each state took to reach a series of milestones, beginning with 5 doses per 100 adults to 120 doses per 100 adults. They also calculated the number of vaccine doses per 100 adults at the end of each week.

The reduction in deaths varied in different states, with vaccinations in New York leading to an estimated 11.7 fewer COVID-19 deaths per 10,000, whereas Hawaii saw the smallest reduction, at just 1.1 fewer deaths per 10,000, the release says.

“This study brings into focus the dramatic success of the early months of the nation's coronavirus vaccine rollout,” said Christopher Whaley, policy researcher at the RAND Corporation, who helped lead the research team.

The investigators noted that the study has limitations, such as an inability to distinguish between the role of vaccination from increases in natural immunity or social distancing policies on the number of COVID-19 deaths, according to the release.

REFERENCE
Shingrix Is Approved for Immunocompromised Adults

FDA gives OK to shingles vaccine for those at risk. By Beth Longware Duff

The recent FDA decision to expand its approval of Shingrix to include immunocompromised adults 18 years and older is the first step toward providing protection against shingles to more at-risk individuals. The vaccine, manufactured by GlaxoSmithKline (GSK), was originally approved by the FDA in 2017 for immunocompetent adults 50 years and older.¹

The FDA’s move is based on clinical studies examining the safety and efficacy of Shingrix in patients 18 years and older who had undergone an autologous hematopoietic stem cell transplant or treatment for hematological malignancies. Additional data were generated in adults who were, or were anticipated to be, immunodeficient or immunosuppressed because of known disease or therapy. This group included patients with HIV, solid tumors, and renal transplants.

“Older age and being immunocompromised are the most common risk factors for shingles disease,” explained Thomas Breuer, chief medical officer of GSK Vaccines, in a prepared statement. “GSK is committed to this important patient population at increased risk for shingles disease and its complications by bringing them a vaccine option that can help prevent this painful condition.”

A cross-sectional analysis of data from the 2013 National Health Interview Survey administered by the US Census Bureau revealed that more than 4% of adults surveyed had been told by a physician that they were immunocompromised. Almost 3% of those surveyed reported current immunosuppression. The rate was highest in women, White individuals, and people aged 50 to 59 years.²

Immunocompromised individuals are at greater risk for developing opportunistic infections and experiencing the reactivation of chronic infections, as well as other health problems. In addition, patients are often unable to receive vaccines because of their condition.

Immunocompromised individuals are at greater risk of developing shingles and associated complications, including postherpetic neuralgia, than immunocompetent individuals. Age, gender, race, and overall health are risk factors for developing shingles in the general population.

In his statement, Breuer noted that in addition to the immunocompromised patient population, more than 100 million adults 50 years and older in the United States also are eligible to receive Shingrix.¹

Virtually all individuals over age 40 carry the varicella zoster virus associated with shingles. The virus initially causes chickenpox and then lies dormant in an individual’s nervous system for decades before reactivating to cause shingles.

Shingrix is administered in 2 doses given 2 to 6 months apart. For immunocompromised adults who would benefit from a shorter vaccination schedule, GSK states that the dosing schedule can be changed to 1 to 2 months.

Shingrix is included on the 2021 vaccination schedule for adults issued by the CDC’s Advisory Committee on Immunization Practices (ACIP). The committee is reportedly considering recommendations for the vaccine’s use in immunocompromised adults.

Shingrix is not contraindicated in immunocompromised persons but is not recommended by ACIP, according to the CDC.³ The committee will review evidence for modifying its vaccine policy as it becomes available.¹

The guidance states that Shingrix can be administered to individuals who are taking low-dose immunosuppressive medication or are anticipating immunosuppression, and to those who have recovered from an immunocompromising illness.●

For references, visit drugtopics.com.

More than 4% of adults were told by a physician that they were immunocompromised, according to a 2013 National Health Interview Survey administered by the US Census Bureau.
According to results from a new study on the effect of Shingrix in individuals with inflammatory bowel disease (IBD), the recombinant zoster vaccine (RZV) is associated with a decreased risk of shingles infection among the 2 age groups studied.1

The authors of the retrospective cohort study, which was conducted in the Veterans Affairs (VA) health care system, noted that individuals with IBD are at an increased risk of herpes zoster (HZ) infection. Their greater susceptibility to the varicella zoster virus, which causes shingles, is linked to the immunosuppressive treatments they receive for their disease.

The study investigators acknowledged that although the efficacy of the Shingrix vaccine has been proved to be high among immunocompetent individuals, little was known about its effect among immunosuppressed individuals with IBD.

“Previous literature has suggested that the risk of herpes zoster is 1.2 to 1.8 times higher in the IBD group compared with the general population, with higher risks among patients using thiopurines, a combination of anti-TNF [tumor necrosis factor] and thiopurines, and corticosteroids within the previous 30 days,” wrote lead author Nabeel Khan, MD, of the Department of Gastroenterology at Corporal Michael J. Crescenz VA Medical Center in Philadelphia, Pennsylvania.

The study involved patients who had received an IBD diagnosis on or before January 3, 2018, the earliest date the RZV was administered. The investigators collected data on 2 groups of eligible patients: 7008 in the 50- to 60-years group and 26,292 in the over-60-years group.

“We identified veterans who received RZV and compared the incidence of HZ between vaccinated vs unvaccinated individuals,” the authors wrote. “We performed multivariable Cox regression with time varying analysis to determine the risk of HZ among the vaccinated [full dose and single dose separately] vs unvaccinated cohort, stratified by IBD medications.”

They reported that compared with the unvaccinated group, the crude HZ incidence rate after a full-dose vaccination of RZV was lower in both the 50- to 60-years group (0.00 vs 3.93 per 1000 person-years) and the over-60-years group (1.80 vs 4.57 per 1000 person-years).

Shingrix vaccination was associated with a significantly lower risk of HZ among those aged 50 to 60 years and among those older than 60 years, though the finding was limited by low HZ event rates. The authors concluded that greater efforts should be made to vaccinate all patients with IBD with Shingrix, the only shingles vaccine available in the United States.

The majority of the 3 million adults in the United States with IBD received their diagnosis in their 20s and 30s, decades before reaching the current age requirement of 50 for receiving Shingrix, according to the CDC.2 The agency recommends Shingrix for the prevention of shingles and related complications in adults 50 years and older, particularly for individuals with chronic medical conditions, unless a contraindication or precaution exists.3

The Crohn’s & Colitis Foundation reports that as many as 70,000 new cases of IBD are diagnosed in the United States annually.4 There may be as many as 80,000 children in the country with IBD. All these individuals are at a potentially greater risk for developing shingles, which could be prevented through vaccination.

For references, visit drugtopics.com.
The first population-based vaccine registry in the United States launched in Delaware in 1974 and did not begin to flourish until the Robert Wood Johnson Foundation launched their All Kids Count program in 1991. Government funding for immunization registries became available when President Bill Clinton included immunization registries in his Childhood Immunization Initiative in 1993. There are currently 63 registries, now called immunization information systems (IISs), in the United States. These include state-, island-, and city-based IISs, each operating independently under its respective local and state policies with their own rules around collection and use of data, analysis, and operational routines. Figure 1 shows the percentage of children under 6 participating in a state-based IIS as of 2019.

What Is An ISS?
An ISS is a confidential, population-based, computerized database that records all immunization doses administered by participating providers within a geographic area. ISSs provide a consolidated record of administered vaccines for the benefit of the patient, their family, and the greater public health. An ISS keeps a record of vaccinations given, dates, and manufacturing details, and can identify when a future or missed vaccination should be given.

ISSs have many advantages; they can improve immunization rates, reduce vaccination errors, identify opportunities to vaccinate, provide epidemiological insights when there is a community outbreak of a vaccine-preventable disease, and allow access by patients, families, schools, and other health care providers. An ISS can also reduce time spent entering data and track vaccine inventory, especially if it is connected through your electronic health record (EHR) system. An ISS can make a child’s immunization portable when the family changes practices, moves from one location to another, or seeks care outside the medical home. (Figure 2)

How do IISs work?
The administering site is credentialed by the individual ISS under licensed providers who can designate access for data entry and/or viewing by staff. Access to view is allowed for the patient, parents, and specified agencies, such as schools, pharmacies, urgent care facilities, and hospitals. There are federal requirements for documenting vaccines established by the CDC, which includes the specific vaccine, manufacturer, lot number, the date and location, and that the patient and/or family was given a vaccine information statement (VIS) to...
review with its publication date. Most systems will identify when a dose of a specific vaccine should be given and have specific time intervals that are not forgiven when a sequential dose is given too early.

It is the responsibility of the administering site to enter the required data, and it can be a burden to staff when they need to enter the data in multiple locations, such as the registry, the EHR, and the patient vaccination card. Most pediatric-specific EHRs are certified and connect with a local IIS, requiring only 1 point of data entry that will be shared with the IIS, the medical record, and the patient copy.

**Are IISs effective?**

There is significant evidence that IISs improve vaccination rates and reduce missed opportunities for administering immunizations. Australia implemented a national IIS in 1996 and demonstrated an increase in full immunization among 2-year-old children from 64% in 1997 to 93% in 2007. Australia has a national health care system that facilitates implementation and utilization of IISs. Although the United States has yet to implement a national IIS, studies have repeatedly demonstrated that IISs improve vaccination rates, reduce missed opportunities for vaccinations, and facilitate responses to community outbreaks of diseases.

The most significant problem with existing vaccine registries in the US is the lack of interoperability between them. Few nonpediatric-specific EHRs can currently extract data from local and state registries, or deposit immunization information directly into them. This necessitates office staff performing double entries of immunizations into the office EHR and the local IIS, which is time-consuming and unwieldy.

One method of speeding up data entry is the integration of barcode scanning into EHRs (online Figure 3). After receiving a shipment of vaccine, the shipment form is scanned into a vaccine inventory, which is integrated into the EHR. When vaccines are ordered for a patient, the barcode on the vial is scanned again and screened by the connected IIS. Warnings appear if the vaccine is being given too soon, is not age appropriate, is attributed to the wrong funding source (eg, Vaccines for Children Program), or has expired. The staff manually enters the other vaccine administration details into the EHR and the information is electronically sent to the appropriate IIS. Over the next few years, it is anticipated that a growing number of EHRs will have this capability.

**The way forward**

There is no uniform rule requiring an administering site to enter that data into the IIS, which further complicates the potential for interoperability. However, the COVID-19 pandemic and the CARES Act may be creating a new opportunity for data sharing between EHRs and the IISs. All sites administering COVID-19 vaccines must report all vaccinations into a database that allows for capturing the event and providing reminders for a second dose as indicated by the vaccine given. It may open the opportunity to connect all vaccine registries into a national database, accessible from anywhere.

For references and online figure, visit drugtopics.com.

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The authors have nothing to disclose.

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Pandemic Response, Pharmacists’ Role Among Key Topics at 2021 NACDS Total Store Expo

This year’s Total Store Expo identified opportunities for growth and facilitated collaboration between retailers and manufacturers.

With lingering COVID-19 effects and responsibilities, including the CDC’s plan for offering COVID-19 booster shots to the public starting now, it is more important than ever that pharmacists collaborate with industry to expand services, and provide patient care.

That was one of the key takeaways from the 2021 National Association of Chain Drug Stores (NACDS) Total Store Expo (TSE), which ran August 23 through August 25.

NACDS Chair Colleen Lindholz, president of Kroger Health, noted that retailers, suppliers, and health care providers should be working together to push through the pandemic and prioritize patient care, she explained.

The 3-day virtual conference was geared toward retailers and manufacturers and designed to find fitting business partners and build valuable relationships. The interactive virtual platform was tailored to each participant and offered both retailer and exhibitor resources, as well as a marketplace exchange. Retailers and manufacturers used personalized, functional dashboards to discover new product trends, collaborate in teams, and schedule meetings.

NACDS TSE included 2 sessions featuring industry experts who presented the challenges, trends, and opportunities that have been top of mind for pharmacies given the quick pace of change within health care and the pharmacy industry.

In Session I, Steven C. Anderson, FASAE, CAE, IOM, president and CEO of NACDS; Colleen Lindholz, NACDS chair and president of Kroger Health; and Mark M. Zandi, chief economist and cofounder of Moody’s Analytics, discussed valuable insights on current economic issues and successes that have influenced pharmacies over the course of 2020 and 2021. Talking points included NACDS initiatives, such as a bold new approach to public health issues, as well as legislative successes over the past year.

“So far in 2021, we have seen over 60 individual improvements in state laws and how pharmacy teams can serve people,” Anderson noted during the session. For example, NACDS’ own efforts and collaboration with the National Community Pharmacists Association (NCPA) helped land a major win in the US Supreme Court—Rutledge v Pharmaceutical Care Management Association. The unanimous decision upheld that states had the authority to prohibit pharmacy benefit managers (PBMs) from reimbursing pharmacies at a lower rate than what pharmacies pay to fill prescriptions. The ruling has created a ripple effect of new state efforts to do the same, Anderson said.

In that session, Lindholz discussed the changes to the pharmacy industry that have been witnessed during this pandemic.

In Session 2, Wendy Liebmann, chief executive officer and chief shopper at WSL Strategic Retail; Doug Long, vice president of industry relations at IQVIA; and Scott Biggs, director of supplier services at IQVIA, expanded on the retail and industry trends that pharmacists should be aware of and incorporate into their practice.

The COVID-19 pandemic ushered in a wholly new shopping experience, according to Liebmann. “The pandemic changed the shape of retailing,” she said. “Shopping occurred in a completely different environment. How and when a shopper decided to shop and how a retailer attracted and provided for the shopper evolved at supersonic speed.” But the new retail landscape isn’t an end in itself, Liebmann explained. Now retailers must ramp up innovation through the 2021 shopper’s lens.

The presentation included interviews with real consumers whose goals included saving time and money and reducing stress. In response to these consumer needs, Liebmann suggested, retailers should work on creating a more efficient shopping experience. Offering more checkout counters, self-checkouts, and contactless pay; placing essential products in a convenient location; and having curbside pickup were some of her recommended solutions.

Long and Biggs discussed the latest pharmaceutical trends, services, issues, and forecasts for the industry. Their presentation touched on COVID-19 case and death counts in the United States, which had been on the rise through the end of the August (and have been decreasing through September) but were nowhere near the numbers experienced in 2020. COVID-19 vaccination rates peaked in April 2021, declined through July, and are again on the upswing, according to Long. As for the demographic of vaccinated individuals, an estimated 90% of senior citizens have had 1 dose of a COVID-19 vaccine and roughly 80% have received both doses.

Regarding those who have not received their COVID-19 shot, the data showed that individuals between the ages of 20 and 55 years have been least likely to get vaccinated. In addition, “people who have been vaccinated tend to be lower-income people in high-density [housing] situations,” Long said. According to data from IQVIA, the White population has received the least vaccinations. “…The Black population and Hispanic population [particularly] have really stepped up and gone out and got their vaccinations in the last 14 days more than the White population,” Long noted.

Long and Biggs additionally touched on the upcoming influenza (flu) season and potential impacts of the pandemic. In 2020 the flu season in the United States was virtually nonexistent, mainly due to COVID-19 precautions. For 2021, the presenters highlighted data from Australia’s flu season, which spans May to November. Although 71% of the Australian population received their flu shot last year, only 45% did so this year. “We’ll have to see, but my feeling is [the United States is] not going to reach the vaccination levels of last year, maybe by a considerable amount,” Long said.

For more insights, features, and interviews from NACDS TSE 2021, check out the NACDS Total Store Expo 2021 spotlight on DrugTopics.com.
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DIVERSIFY YOUR REVENUE STREAMS

Pharmacies can take advantage of alternative revenue opportunities to boost their bottom line.

By Keith Loria
A successful pharmacy is one that doesn’t rest on its laurels and continues to be innovative and opportunistic. After all, even though things may be going well now, that can always change, and a pharmacy owner should have alternative revenue streams coming in to combat any challenges.

Today’s pharmacies must install diverse or alternative revenue opportunities to boost profits. This can mean revamping their front end, expanding on services such as specialty pharmacy medications, or partnering with health care providers or hospitals in the area. It can even entail offering tailored services to their patients such as smoking cessation, weight-loss counseling, or nutrition guidance.

“In the changing landscape accentuated by pharmacy benefit managers, the profit margins that have previously supported pharmacists’ salaries and the cost of running independent retail pharmacies have been borne on the spread of the product,” says Paige Clark, RPh, vice president of pharmacy programs and policy at Prescriptive Health. “That reimbursement model, in many cases, can no longer support independent pharmacies.”

Therefore, building a robust and significant clinical services provision is essential to the success of all community pharmacies. Jennifer Donovan, PharmD, vice president of clinical services at Shields Health Solutions in Stoughton, Massachusetts, notes there is a need to balance how to deliver high-quality care while offsetting the costs of caring for patients who are underinsured or not insured.
“Finding alternative ways to generate revenue is necessary to ensure all patients have access to high-quality health care,” Donovan says.

**Avenues to Explore**

JoAnn Sanborn, BSPharm, owner and vice president of operations for Hudson Pharmacy in Hudson, Michigan, notes that due to decreasing profits for prescription drugs, which are the main source of business, she often looks to outside sources to help stay in business. These include point-of-care testing, immunizations, hormone replacement therapy consultations, medication therapy management, and complimentary medicine consultations.

Shelley Roberts, PharmD, owner of Grassroots Pharmacy in Lexington, Kentucky, shares that during the first part of the COVID-19 pandemic, the pharmacy’s front-end sales were severely depressed, although prescription sales went up. “The reduction in cash flow that resulted really drove home the point of how important those sales truly are,” Roberts says. “We have a thriving smoothie business and gift shop that bring in cash daily versus waiting on insurance reimbursement checks. It is so important to diversify all aspects of your business to account for when one piece is affected.”

In Kentucky, there are numerous board-approved protocols that the pharmacy is beginning to delve into to create multiple revenue streams. “From the beginning, we have looked for ways to be different—the look of our store, the offerings, the atmosphere,” Roberts says. “To be successful, you either have to be unique or do the same thing better than everyone else. With the big boxes’ hold on the market, it is hard to beat them on price, so we don’t try to.”

In many states, public health departments are highlighting the fact that community pharmacists are trusted and highly accessible resources.

Under the crisis of COVID-19 and the Public Readiness and Emergency Preparedness Act, all pharmacists can provide testing services to detect COVID-19. Additionally, as of September, pharmacists are empowered to provide monoclonal antibody treatment to patients who are positive for or have been exposed to the disease. “So we now truly have...testing, treatment, and immunization services that are comprehensive for serving our communities in the fight against COVID-19,” Clark says. “This is a great revenue opportunity to look into right now.”

“The state of Oregon was among the early adopters of the concept of pharmacists being enabled to provide subcutaneous injections of REGEN-COV (casirivimab and imdevimab) to COVID-19–positive patients,” Clark continues. “As such, the Oregon Board of Pharmacy with leading subject matter experts built a comprehensive clinical protocol to guide pharmacists through patient care. We have incorporated that resource into our turnkey solution at Prescriptive. Not only is the protocol available for utilization, Prescriptive has then built the model policies and procedures needed for independent retail pharmacies to operationalize this...service.”

Among other revenue opportunities, 15 states have extended pharmacists’ ability to provide birth control services to patients in some form. Other states have allowed pharmacists to provide services for tobacco cessation and post-exposure and pre-exposure prophylaxis for HIV prevention.

“In all cases, expanding clinical services and pharmacist scope of practice relate to meeting unmet public health needs,” Clark explained. “My tendency is to advise pharmacists to move into areas that are directly reimbursable at a state level by Medicaid, such as birth control prescribing.”

Trieu Bao, PharmD, of Soleil Pharmacy in Glen Burnie, Maryland, notes that pharmacists have excellent training that goes beyond filling prescriptions. “As clinicians, we are driven to provide many other services for the overall health of our clients, thus improving patient outcomes,” he says. “As [many of us are] immigrants, we understand the unique needs of those from a multitude of cultures and provide culturally competent care. Then, we want to...
be sure they know where and how to get access to other elements of their health care.”

As a Clinical Laboratory Improvement Amendments–certified pharmacy, Soleil Pharmacy offers COVID-19 testing. They also provide international normalized ratio and glycated hemoglobin tests when appropriate for the patient and their care plan.

“We offer and deliver in our pharmacy—or in other locations—many types of vaccines,” Bao says. “We are currently finalizing a plan to have primary care telehealth available in our pharmacy or in the homes of the uninsured population in our community.”

As recent recipients of the National Community Pharmacists Association Diabetes Prevention Program grant, the pharmacy is also expanding its diabetes services in 3 languages.

“We have found if you focus on the unmet needs in your community and the unique strengths of your staff, you can create something pertinent and of great value,” Bao says.

Soleil Pharmacy focuses on vaccinations, common medications, and supplies that support hospital discharge and make the discharge process easier for patients and caregivers.

“We have reconsidered the products we carry and removed the feeling of being crowded in the front of our store,” Bao says. “We are intentionally making it easier for the pharmacist or technician to acknowledge the patient upon entry and for patients to have access to items that will benefit their health journey.”

Clark adds that pharmacies that have not carved in private patient services are available for free for most individuals, so she hasn’t instituted any programs.

“Early on in the pandemic, before we were able to obtain product, both the local health department and hospitals offered vaccines for us to vaccinate the elderly in long-term care facilities [who had been] missed, as part of a federal initiative,” Sanborn says. “We have been partnering with the health departments in both counties to schedule and run clinics and obtain vaccines. We’re basically on call whenever they need help and it’s been very profitable; there’s administration money available from insurance companies to do this work.”

The pharmacy has also worked with hospitals to offer a continuum of care for when patients leave the hospital and transfer to long-term care facilities or back home.

“We’re there making sure there’s a proper coordination of care and to offer counseling,” Sanborn notes.

Partnering With Hospitals and Health Care Facilities

In some cases where collaborative practice agreements (CPAs) are required, partnering with other providers or organizations can be helpful in bringing in new revenue.

“Partnering with health care providers and health systems allows for the best patient care,” Donovan says. “The patient stays integrated within the health system and information is accessible by all health professionals in the multidisciplinary team. Integrating pharmacy services into care is necessary to drive meaningful changes in patient outcomes.”

One strategy Donovan has found to be successful is aligning specialty pharmacy programs with the health system’s accountable care organizations and at-risk populations to further drive quality and value.

“Developing programs and strategies to help the at-risk population has [been] shown to improve patient care and lower total medical cost,” she says.

Hudson Pharmacy has a practice agreement and offers point-of-care testing with a local physician.

“Early on in the pandemic, before we were able to obtain product, both the local health department and hospitals offered vaccines for us to vaccinate the elderly in long-term care facilities [who had been] missed, as part of a federal initiative,” Sanborn says. “We have been partnering with the health departments in both counties to schedule and run clinics and obtain vaccines. We’re basically on call whenever they need help and it’s been very profitable; there’s administration money available from insurance companies to do this work.”

The pharmacy has also worked with hospitals to offer a continuum of care for when patients leave the hospital and transfer to long-term care facilities or back home.

“We’re there making sure there’s a proper coordination of care and to offer counseling,” Sanborn notes.

Tailoring Personal Services

Pharmacists should also consider helping with things such as smoking cessation and weight-loss counseling.

“The pharmacist can play a crucial role in these conditions as there are tremendous short-term and long-term benefits to their health and the health care system,” Donovan says.

“Even within our specialty pharmacy program, we stress the importance of smoking cessation, weight reduction, stress management, and nutrition as part of an overall care plan to ensure we are helping our patient today and in the future.”

Hudson Pharmacy once tried offering diabetes management but found that it was very difficult to get insurance companies to pay for the service. In addition, it was something that people weren’t as willing to pay for.

“Now we’ve been doing hormone replacement therapy consultations,” Sanborn says. “And that the patients are happy to pay for directly, so that’s been successful.”

According to Roberts, because the pharmacy is located in a city with multiple large hospital settings and a thriving health department, these services are available for free for most individuals, so she hasn’t instituted any programs.

“This could definitely work in other locations, though,” she says.

“What has been more helpful than anything is doing [adherence] packaging for their patients. This is what we were trained to do, and what we can excel at.”

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Telehealth has been a life-saver for practices hammered by the COVID-19 pandemic, but new data show that its use may be on the decline. According to a news release from health care data firm FAIR Health, national telehealth use dropped by 10% from May to June 2021. It decreased from 5% of medical claim lines in May to 4.5% in June. Telehealth use is measured as a percentage of all medical claim lines. This came after its use rose by 2% nationally from April to May and decreased each month from February to April, says FAIR Health.

Telehealth claim lines fell across all 4 US Census regions. The sharpest decline occurred in the Northeast, which saw an 11.9% drop from May to June 2021.

The same period also saw changes to the top 5 telehealth diagnoses given via telehealth. Joint/soft tissue diseases and issues saw a rise in the rankings nationally (from No. 4 in May to No. 3 in June) and in all regions except for the West. Acute respiratory diseases and infections also rose from third to second place in the same period. Meanwhile, mental health conditions remained at the top nationally and in every region.

In the South, urinary tract infections rose to fifth place among telehealth diagnoses in June, after not appearing on regional or national lists since the beginning of the pandemic. The diagnoses had been common prior to COVID-19, according to the release.

The same period also saw changes to the top 5 telehealth procedure codes by utilization. CPT 99214 (established patient outpatient visit, total time 30-39 minutes) rose from third to second place, whereas CPT 99213 (established patient outpatient visit, total time 20-29 minutes) fell from second to third place, according to FAIR Health.

Although June seemed bleak for telehealth, the service remains a key tool in the arsenal of those physicians treating patients who are most at risk during the pandemic.

According to a study prepared by survey and market research firm SSRS on behalf of the Bipartisan Policy Center, 31% of the general US population had a telehealth visit within the past year. Among Medicare beneficiaries, 44% reported having a telehealth visit within the past year.

The service is also proving to be effective, as 8 of 10 adults said their primary health issue was resolved through a telehealth visit. This isn’t surprising, as 63% of telehealth visits were for a preventive service or prescription refills, or were routine visits for chronic illness. In these cases, audio-only visits were as likely to resolve patient issues as video visits.

Thirty-five percent of rural residents and 42% of older adults reported technology-related barriers to accessing telehealth, with access to high-speed internet or broadband being an obstacle. Overall, 45% of respondents reported that some type of technical issue had been an obstacle to their taking advantage of telehealth visits.

For references, visit drugtopics.com.
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Women with limited health literacy consider pain the predominant harm of a mammography screening, whereas primary care providers (PCPs) and experts emphasize the harm of false positives, according to a survey. The survey in *Medical Decision Making Policy & Practice* sought to clarify areas of divergent and convergent input across stakeholder groups in developing a breast cancer screening decision aid for younger women with limited health literacy.

Individual qualitative interviews were conducted in 2018 and 2019 with 25 patients (13 mammogram-naive and 12 having undergone at least 1 mammogram) with limited health literacy and 20 PCPs at 6 outpatient primary care practices located at a safety-net hospital (Boston Medical Center). The purpose of the interviews was to glean mammography counseling experiences, including the provider’s goals for counseling and the patient’s desired information.

In addition, a modified online Delphi panel of 8 experts in breast cancer screening (5 medical doctors or nurses in internal medicine and 3 researchers without clinical degrees) rated 57 statements for inclusion in a breast cancer screening decision aid over 3 rounds between May and July 2020. All 3 groups of stakeholders identified 4 informational needs: the benefits and harms of screening, various screening modalities, the experience of mammography, and communication about breast cancer risk.

Patients, but not PCPs or experts, believed that information about the process of obtaining a mammogram was important. Conversely, PCPs believed that mammography was the only evidence-based screening modality, whereas patients felt breast self-examination was also important for screening.

All stakeholders cited the need to incorporate personal risk information into a breast cancer screening decision aid, but this information is seldom used by PCPs in practice. There were 5 items that the Delphi panel unanimously rated as important: women can choose not to get a mammogram or schedule one at a future date; describing the benefits of screening; conveying the harms of screening; describing false positives as a possible screening harm; and that overdiagnosis is a possible screening harm.

Experts noted the challenges in communicating false negative and true positive rates. After the 3 rounds, the panel was unable to reach a consensus on what women need to do to prepare for a mammogram and on the process. They also unanimously rated as unimportant the inclusion of breast self-exam as a screening option.

Most decision aids include patients to refine content, according to the authors. Excluding patients as advisers or partners in the design and maintenance of decision aids may cause a disconnect in priorities, such as the differing values stakeholders placed on including mammography process information. Community-engaged research with patients of lower socioeconomic status and limited health literacy can lead to more efficacious measurement tools and user-friendly education materials for breast cancer care decision-making.

Two limitations of the study are that participants were recruited from 1 hospital, thus perhaps reflecting local practices, and the Delphi sample size was small. “Our findings will contribute to both the development of a decision aid responsive to the preferences of women with limited health literacy and the broader goal of building tools that enhance health equity,” wrote the authors, adding that “more evidence is needed to guide integration of multiple stakeholder perspectives into the content of decision aids.”

Kronemyer is a freelance writer for Drug Topics®.

**REFERENCE**


Community-engaged research with patients can lead to more user-friendly education materials.
FDA Official Clarifies Differences Between Biosimilars, Interchangeables

With the recent approval of insulin glargine-yfgn (Semglee; Mylan Pharmaceuticals) for diabetes as the first interchangeable biosimilar for insulin, pharmacists understandably have questions on biosimilars and interchangeable medications in general.

To help clear up some of the confusion, the National Association of Boards of Pharmacy recently hosted the webinar Biosimilar and Interchangeable Products: What Do Pharmacists Need to Know?

A biosimilar is a biological product that is highly similar to a reference product already approved by the FDA. An interchangeable biosimilar is one that may be substituted for the reference product at the pharmacy level.

However, the agency's approval of an interchangeable biosimilar product does not indicate a higher standard of biosimilarity, said Sarah Yim, director of the Office of Therapeutic Biologics and Biosimilars, Center for Drug Evaluation and Research at the FDA, during the webinar.

Patients and health care providers do not need to wait for a biosimilar to "become" an interchangeable product, she explained. "Biosimilars are as safe and effective as the biological product they were compared to."

To support an agent's approval as an interchangeable biosimilar, pharmaceutical manufacturers must submit specific data. This is "to allow it to be substituted for the reference product at the pharmacy level without consulting the health care provider, depending on state pharmacy laws," Yim said.

The manufacturer's application must demonstrate that switching between their proposed product and the reference product does not increase patients' safety risk or decrease treatment effectiveness, Yim noted. The required "switching study" data compare using the reference product without switching with using the reference product and switching to the proposed biosimilar interchangeable medication.

A "comprehensive comparative analytical assessment supports a proposed biosimilar or interchangeable product as highly similar to a reference product with little or no residual uncertainty," Yim said.

Meanwhile, a biosimilar drug is highly similar to its reference product and has no clinical meaningful differences from the existing FDA-approved reference product, according to Yim.

An abbreviated approval pathway is necessary for biosimilars and biosimilar interchangeable medications vs generics, Yim noted, due to the difference in molecular structure of the 2 medications.

Generics contain the same active ingredient as the reference product. The process is often much simpler than with biosimilars. "...It's typically just one chemical, and they just need to show that the formulation of the product results in the same exposure," Yim said.

Biosimilars are a mixture of variants of the reference products, so assessing product sameness involves more than a definitive yes or no answer, according to Yim. "Because the molecular variant mixes are always a little different, they cannot be copied." As a result, the therapeutic standard is "no clinical meaningful differences" between the biosimilar and reference product, she added.

"[The] abbreviated pathway has a goal of identifying biosimilarity or interchangeability for a reference product. Studies are not for the purpose of efficacy and safety, only to provide observations for any variations of the 2 products," Yim said.
The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 created an abbreviated licensure pathway for biological products that are demonstrated to be interchangeable with an FDA approved biological product. Biosimilars provide patients with additional treatment options at lower costs. Typically, biosimilars marketed in the United States have initial list prices that are 15% to 35% lower than the existing FDA-approved biologic (reference product). Biosimilar products have no clinically meaningful differences from their reference product, and they undergo safety, efficacy, and quality evaluations. Pharmacists can play an important role in educating health care professionals and patients about biosimilars to improve access to and enhance their knowledge about these medications.

Biosimilar New Product Update Semglee
As of August 21, 2021, the FDA approved 30 biosimilars, with the most recent being the first interchangeable biosimilar insulin product in the United States, Semglee (insulin glargine-yfgn). The reference product for Semglee is Lantus, a long-acting insulin. Semglee is approved for the treatment of type 1 diabetes in children and adults and for type 2 diabetes in adult patients. This is a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs,” said FDA Acting Commissioner Janet Woodcock, MD, in a press release. This will help to make insulin more affordable for patients as the cost has skyrocketed. Semglee is administered subcutaneously once daily at the same time each day. In patients with type 1 diabetes, Semglee must be used with short-acting insulin. The recommended starting dose in patients with type 2 diabetes who are not currently treated with insulin is 0.2 units/kg or up to 10 units once daily. In patients switching from once-daily insulin glargine injection 300 units/mL to once-daily Semglee, the recommended initial dose is 80% of the insulin dose being discontinued. As with Lantus, the most common adverse effects reported with Semglee include hypoglycemia, edema, weight gain, allergic reactions, and injection site reactions.

Riabni
Riabni (rituximab-arrx) received FDA approval in December 2020 as a biosimilar to Rituxan for the treatment of adult patients with non-Hodgkin lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (inflammation of the blood vessels), and microscopic polyangiitis. Riabni is administered as an intravenous infusion by a health care professional. Prior to initiating treatment with Riabni, patients should be screened for hepatitis B infection. Riabni carries a boxed warning for fatal infusion-related reactions and it is critical to monitor patients closely as fatalities within 24 hours of infusion have occurred. Riabni infusions should be discontinued for severe reactions. Other boxed warnings include severe mucocutaneous reactions, hepatitis B virus reactivation, and progressive multifocal leukoencephalopathy.

Hulio
The FDA approved Hulio (adalimumab-fkjp), the sixth biosimilar to Humira, in July 2020; it is expected to launch in July 2023 in the United States. Hulio is approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn disease, ulcerative colitis, and plaque psoriasis. The agent is administered as a subcutaneous injection, and it carries a boxed warning for serious infections (eg, active tuberculosis [TB] and invasive fungal, bacterial, and viral infections) and malignancies (eg, lymphoma). Patients should be tested for TB prior to starting Hulio and monitored closely for any signs of infection during treatment.

Nyvepria
Nyvepria (pegfilgrastim-apgf) received FDA approval in June 2020 as a...
biosimilar to Neulasta. It is a leukocyte growth factor indicated to decrease the incidence of infection in patients with nonmyeloid malignancies who are receiving myelosuppressive anticancer drugs associated with an increased incidence of febrile neutropenia.9 Nyvepria is administered as a subcutaneous injection. Serious adverse effects can include spleen rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions, sickle cell crises in patients with sickle cell disorders, kidney injury, capillary leak syndrome, leukocytosis, malignancies, and inflammation of the aorta.9 Nyvepria should be discontinued in patients experiencing ARDS, serious allergic reactions, sickle cell crises, or inflammation of the aorta.9

**Biosimilar Forecast and the Pharmacist’s Role in Education**

According to an IQVIA report, biosimilar medications are expected to lower drug costs by $100 billion over the next 5 years.10 The development and approval of biosimilars has increased over the past 2 years.10 Since the passage of the BPCI Act, $17 billion in biosimilar spending has been associated with a savings of $37 billion.10 The following biosimilars launched in 2019 achieved significant uptake within their first year: bevacizumab (42%), trastuzumab (38%), and rituximab (20%).10 There are 108 biosimilars across 22 molecules in development, with some in the pipeline for the near future (Table).10,13 President Biden is working to improve access to biosimilar medications by promoting drug competition to drive down costs and facilitate the development and approval of biosimilar and interchangeable products.11 Pharmacists can assist in educating health care professionals and patients about biosimilars and the approval process to improve uptake. The FDA determines biosimilarity based on the “totality of evidence” provided in the marketing application submission.3 Animal, human pharmacologic, immunologic, and additional clinical data are added in a stepwise approach.3 Semglee being the first approved interchangeable biosimilar product provides further opportunities for education.4

An interchangeable biosimilar meets additional requirements and may be substituted for the reference product at the pharmacy, which can help increase patient access to these medications.3 The process is similar to the manner in which generic drugs are routinely substituted for brand products. For approval of an interchangeable biosimilar, manufacturers must provide additional data that reflect how the product can be used in clinical practice with patients.3 Studies generally evaluate the safety of patients’ alternating between the reference product and interchangeable biosimilar compared with those being treated with the reference product alone.3 Additionally, the results must reveal that there is no decrease in efficacy or increase in adverse effects with switching.3 Pharmacists can inform patients that biosimilars are safe and effective medications used to treat a variety of conditions, such as psoriasis, irritable bowel syndrome, Crohn disease, arthritis, kidney conditions, and cancer.7 The same benefits and adverse effects are expected with biosimilars compared with their original biologic product because they are made with the same types of natural resources and have the same strength and dosage recommendations. In addition, biosimilar medications can be used regardless of whether patients were first treated with the reference product. Emphasize to patients that biosimilars may provide them with more access to important treatments at lower costs. Further, the FDA monitors the safety and effectiveness of all biosimilar medications after their approval.3 Explain that there are similarities and differences between biosimilars and generic drugs. For example, both are compared to a reference (original) product for approval,3 and both are versions of previously FDA-approved medications. Biosimilars and generics go through a thorough review process and receive FDA approval through different abbreviated pathways.3 One difference is that biosimilars are made from natural and living ingredients, whereas generics are generally made from chemical ingredients.3 As biologic medications cannot be replicated exactly, more information is required to show that a biologic is biosimilar to another biologic than that required for a generic drug.3

**TABLE. BIOSIMILAR DRUG PIPELINE**

<table>
<thead>
<tr>
<th>BIOSIMILAR</th>
<th>MANUFACTURER</th>
<th>BRAND NAME DESIGNATION</th>
<th>REFERENCE PRODUCT</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>Avrotech</td>
<td>AVT02</td>
<td>Humira</td>
<td>Submitted to FDA with decision expected in 2021</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Celltrion</td>
<td>CT-P17</td>
<td>Humira</td>
<td>Submitted to FDA in November 2020 with approval decision expected in 2021</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Coherus BioSciences</td>
<td>CHS-1420</td>
<td>Humira</td>
<td>Submitted to FDA with approval decision expected in 2021</td>
</tr>
<tr>
<td>Bevacizumab</td>
<td>Bio-Thera Solutions</td>
<td>BAT-1706</td>
<td>Avastin</td>
<td>Submitted to FDA with approval decision expected in 2021</td>
</tr>
<tr>
<td>Ranibizumab</td>
<td>Samsung Bioepis/Bioepis Biogen</td>
<td>SB11</td>
<td>Lucentis</td>
<td>Submitted to FDA with approval decision expected in 2021; would be first Lucentis biosimilar</td>
</tr>
</tbody>
</table>
There is one magic way to guarantee positive growth for your pharmacy. Are you interested in learning this secret? Anxiety and uncertainty stem from living without a plan for the future. It quickly becomes exhausting when you wake up every day and just hit the balls coming at you. So what’s the magic way? You need to create a growth plan. That isn’t a super sexy answer but it is the truth.

Luckily for pharmacy owners, there isn’t just one strategy to create a thriving pharmacy—there are hundreds of ways. At DiversifyRx, we teach about the 6 pillars of pharmacy profitability:

- Cash-based revenue
- Non-pharmacy benefit management (PBM) revenue
- PBM optimization
- Marketing
- Team development
- Key performance indicator optimization

Any strategy you can do to improve your pharmacy’s profitability will fit into 1 (or more) of the above pillars. When you narrow down the tactics you want to implement, you will have to engage in marketing for the strategy. Marketing is a cornerstone of every successful pharmacy. Because of its importance, let’s focus on the information you will need to create a marketing plan.

**Putting a Plan Together**

It would be great to sit down and knock out a plan with no work beforehand. But sorry, that ain’t happening. Before creating a marketing plan for your pharmacy, you need to know some concepts and basic information. The marketing umbrella is huge and there is no way to cover everything in 1 article. Let’s focus on filling in the most common gaps.

**Ideal Customer**

A marketing plan doesn’t have to be a complicated, tedious strategy. At its core, it should simply describe the value you can bring, the problems you can solve for your ideal customer, and how you will let them know. If you aren’t familiar with the term *ideal customer*, here’s a brief description: ideal customer is your perfect customer. It is a fictitious person, an avatar, for whom you are the perfect pharmacy. It could be a single mom without insurance, working 2 jobs, who has 2 kids and no car. Or it could be a 60-year-old affluent man looking to make his next 20 years his best and wanting the latest in dietary supplements and medications.

Knowing your ideal customer will help you decide where to spend your marketing capital. Marketing can be expensive, which makes mistakes very costly, but some of the best is practically free. Using the right combination of both paid and free is what DiversifyRx recommends. Fantastic books on marketing and advertising are available, such as Seth Godin’s *Purple Cow*, Allan Dib’s *1-Page Marketing Plan*, and anything by Tom Feltstein.

*It is essential to understand the varying terminology: marketing, advertising, and sales.*

- Marketing is about your name and branding. Some also refer to it as the look and feel of your pharmacy service. Marketing is telling people who you are and what you do.
- Advertising is usually about highlighting products, services, or discounts. You should advertise specifics: flu shots, delivery service, or your grand opening.
- Sales are always about closing the deal—getting a first-time customer to come into your store and fill a prescription, then turning them into a repeat customer.

**CONTINUED ON PAGE 28**
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- Your staff, processes, and systems will be your sales team. They are essential for giving your customers a truly remarkable experience that will make them come back. For some owners, marketing will be easy. If it isn’t easy for you, get help. This area is definitely one you can’t afford to fail in.

Marketing Plan
Many pharmacy owners practice what we like to call the Field of Dreams Marketing Approach...you build it, they will come. This approach is a plan to fail. You could have the best location, the best products, and the best service, but if people don’t know who you are or what you offer, they will drive right on by.

Below are different marketing channels to consider for your plan. Although a diverse approach is typically more effective, never feel as if you have to start with everything. It is better to master 1 strategy than try to implement them all and fail. We have categorized these by free/low-cost and paid channels. Undoubtedly, there are many more under each umbrella, but we narrowed it down to those most impactful to pharmacy owners.

Free and ultra-low-cost marketing tactics:

- Relationship marketing is building relationships with different professionals in your community by joining various clubs or organizations, such as the chamber of commerce, or starting a club that attracts your ideal customers.

- Customer referral programs are a favorite type of marketing. A good customer referral program includes something of value to the referrer as well as the one referred. Just think how busy you would be if each current patient brought in 1 more new patient.

- Getting your audience to follow you on social media is a great way to connect with your patients and community. You can use social media to let your audience know about promotions, community events, business events, business changes, and even industry news. Many people make a major mistake in using their social media only to advertise (no one wants to follow you to be sold to all the time). Find a way to provide meaningful and authentic content that your ideal customer will want to have in their feed. Bonus points if you post Facebook Live videos.

Paid Advertising

- Video, video, video. Did we say video? Video has an 80% higher engagement rate than any other marketing form right now, and it is only growing. If you are going to pay for advertising, you may want to start with video views on Facebook. These types of ads can bring the highest return. Also, you don’t need expensive, professionally made videos. Just use your phone.

- Several opportunities exist for targeting your local audience digitally by using social media advertising. You can specifically target who your ads are seen by with platforms such as Facebook for future patients and LinkedIn for prescribers.

- Leveraging radio ads and getting a radio endorsement from a local host can be a good investment, depending on your audience. Radio is one way to share your message with a wide audience. Make sure you pick a channel and a host that match your ideal customer. In our pharmacies, talk radio performed exceptionally well, whereas music radio bombed.

- Direct mail is seeing a resurgence in marketing. As the quantity of mail decreases, the chances of your marketing being noticed increase. Be sure to provide value through education, entertainment, or cost savings to increase engagement with your mailer.

- Hosting events in your community is a great way to give back and market simultaneously. One of our favorites is to host a Nacho Average Pharmacy customer appreciation day. Gather other local businesses to join in the fun and help spread the word. Another great idea is to host events for physicians and a separate event for their staff.

There are lots of ideas here to help get your brain thinking. What stood out to you? Ideally, you want your marketing to reflect your style and branding. An essential rule of thumb to follow is always provide value. Value can be educational (teach about a supplement), entertaining (showing behind-the-scenes compound machines), or cost saving (coupon or sale). As a locally owned business, your most valuable asset is often you, the owner. Use this to your advantage and be authentic in everything you do. People always prefer to do business with someone they know and trust. Let your community get to know you.

For more marketing ideas for independent pharmacies, check out our blog. Please reach out with any questions to info@diversifyrx.com.

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American Pharmacists Month: 
4 Pharmacists Helping Their Communities

By Karen Berger, PharmD

In honor of American Pharmacists Month, here are 4 pharmacists making a significant difference in the communities they serve.

Greg Clyde, PharmD, opened Clyde Pharmacy in Oklahoma City, Oklahoma, in March 2019. “When we opened, one of the core values of my desire to open a store was to be more active in the community,” he says. Clyde is involved in numerous projects to help his community.

Pre–COVID-19, in an effort to increase immunization against influenza, Clyde partnered with Putnam City North High School’s band in a fundraiser to give back $5 for each influenza shot. They raised over $5000 in both 2019 and 2020. In August 2021, the pharmacy partnered with the high school and local church in a community service project. They closed the store for 4 hours so the staff could cook meals for church members and help the school prepare for fall.

Clyde recently sponsored an ID tag program at the elementary school in which ID tags match up parents’ cars with children’s backpacks for safety. He also sponsors various events at the Healthy Living Wellness Center and talks to members at the health fair.

During COVID-19, Clyde noticed that there was an abundance of misinformation. He took the opportunity to step up as a reliable source of information, writing weekly updates on the pharmacy’s Facebook page, which quadrupled in followers. Clyde worked closely with the Department of Health to secure COVID-19 vaccines, becoming one of the first pharmacies in the state to get vaccines.

Clyde is getting ready to run for the state house. “There is a need for pharmacists to step up in leadership roles. I’m in a good spot to make a difference,” he says. He hopes to continue his work on education advocacy and work on policies related to pharmacy and patient choice, “so patients have a real choice in their pharmacy.”

Mariamawit Desta, PharmD, is the owner and pharmacy manager of Apex Pharmacy in Aurora, Colorado, a suburb of Denver. She opened her pharmacy in November 2020. As a minority health care provider, Desta was alarmed to learn how COVID-19 affected minorities and wanted to serve a diverse community.

Desta started out by focusing on cardiovascular education and awareness. She found that many of her patients did not know what medications they were taking. Desta educated patients on why they were taking the medications and concentrated on adherence and medication therapy management. “We focused on preventive health and eradicating misinformation,” she explains. Soon after, the availability of the COVID-19 vaccine changed everything and the focus shifted to vaccinating the community.

“Vaccines were a great opportunity to get involved with the community,” Desta says. When the pharmacy started offering vaccines, they created an online scheduling tool. Desta soon realized that most of the vaccine appointments were booked by affluent patients outside the area. She realized she needed to target those in the community and promptly met with community leaders. They set up unadvertised walk-in clinics every day from noon to 4 pm. During these clinics, Desta and her staff helped patients fill out forms and educated patients, providing them with data when they were hesitant about the vaccine.

Soon, Desta and her staff were giving up to 200 vaccines per day. As of now they have vaccinated more than 4500 people, “the majority being from the local community,” Desta says. Their patients are mostly local community members who feel safe with and trust the pharmacy staff. Word of mouth also is a significant factor. According to Desta, 1 person may come in and then bring 2 friends the next day for their vaccines. “This is the kind of relationship that I hope and plan to build here,” Desta says of her vaccine program.

When COVID-19 slows down, Desta plans to continue working on preventive health, including mental health. “We want to end the stigma,” she says. She plans to collaborate with nonprofit mental health centers, creating a safe space to help patients with adherence.

Arun Tandon, BPharm, has always been involved in the community, taking every opportunity to go out and educate citizens about various health topics. As COVID-19 hit, he

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brought community involvement to the highest level. “When COVID-19 started, we knew we could help the community, even though many others were scared,” he says.

Tandon increased delivery capacity to meet demand and gave hazard pay to all staff members. At the time, the only available testing was at the hospital, which took over a week for results. Tandon partnered with a local lab to become the first pharmacy to offer polymerase chain reaction testing. To accommodate the volume, the staff began to provide drive-through testing in the parking lot. They were carrying out 300 tests daily. When the weather became too cold to work outside, Tandon opened up another storefront in the same strip mall as his pharmacy, tripling his staff.

In addition to offering testing at the new location, he also went to various small businesses, doctor’s offices, and nursing homes to provide testing. “Not many people raised their hands to help, but we knew infection control and we knew the needs of the community,” he notes. “I don’t think there’s anyone in this town who has not been through our testing center.” Tandon says the pharmacy staff has done over 50,000 tests.

Once the vaccines were available, Tandon was approved for the 2500 first doses and 2500 second doses. He was required to commit to giving out the 2500 first doses in 2 weeks. Tandon was approved for the grant. “In 6 days, we did 2700 vaccines. We got extra doses out of each vial and did not waste a single vaccine,” he says. “It is so humbling to see small pharmacies do so much to prevent illness and death. It was such a feeling of doing something worthwhile.”

Kristen M. Clancy, PharmD, MHA
Since graduating from pharmacy school more than 10 years ago, Kristen M. Clancy, PharmD, MHA, volunteered and worked for nonprofit organizations in multiple settings including hospitals, clinics, and community health facilities. Her passion for service pushed Clancy to pursue organizations that provide free medical treatment to patients. “Texas is a Medicaid nonexpansion state, so there is a large population of patients who make too much money for Medicaid but don’t make enough money for Obamacare. Being able to provide care for those patients has always been my goal. Every patient should have access to competent, compassionate health care regardless of their income.”

Hurricane Harvey drastically changed Clancy’s career trajectory while she was working as a pharmacist in Houston at a charity clinic in 2017. Her clinic was spared, but other nearby charity clinics sustained damage. “Humanitarian relief organizations used our facilities as a hub, to coordinate service...and store medical supplies for other clinics. It really opened my eyes to the possibilities available for charity clinics,” she recalls. With the help of an amazing pharmacy staff and volunteers, Clancy helped distribute prescription medications totaling nearly $2 million, medical supplies, and equipment to her patients and the teams participating in cleanup and recovery efforts in the area.

As Clancy connected with other charity clinics and nonprofit pharmacies, she found that many were unaware of the relief organizations such as Americares, Direct Relief, Dispensary of Hope, and others. In 2018, she started her own company—Texas Recovery Network Solutions—with the goal of providing information about these resources to other charity clinics and relief organizations. “I actually provide all the information about these opportunities for free on my website. I want the information out there and easy to access,” Clancy says.

Although Texas Recovery Health Network Solutions was founded to address the post-Harvey recovery efforts, Clancy had other long-term goals. “I had always envisioned using these resources to help organizations that provide treatment for substance use disorders. For patients that are seeking treatment or are new in recovery, the ability to maintain their physical health at the same time as their recovery is equally important,” she explains.

With this goal in mind, Clancy was able to pivot her organization to assist recovery organizations. She was asked to lead the Behavioral Health Integration workgroup for the Houston Recovery Initiative, a coalition that provides resources for recovery groups and facilities in the Houston area. Clancy also founded a nonprofit, RxRecovery, with the mission of reducing opioid overdose rates.

“The state of Texas ranks fifth in the United States in regard to overdose, yet less than half of Texas community pharmacies are willing to dispense buprenorphine products. As pharmacists, we really need to get involved in fighting the other epidemic that exploded while we were busy fighting COVID-19,” Clancy says.

RxRecovery aims to educate healthcare professionals, reduce stigma, increase patient access to buprenorphine, and reduce the overdose rates plaguing Texas and beyond. Clancy hopes to find solutions for Texas and also provide a pharmacist’s input on tough cases. “Sometimes there will be a Zoom meeting with 20 people but I’m the only pharmacist. I hope by participating I can encourage other pharmacists to participate and be a part of the solution.”

Volunteering for the American Red Cross during a pandemic and the most active hurricane season in recorded history was one of the most challenging yet rewarding opportunities of her career. “This past year, I won a service award from the Red Cross, and I was nominated for the Distinguished Alumni Award from Texas A&M [Irma Lerma] Rangel College of Pharmacy for my efforts in the recovery community. I never in my wildest dreams would have imagined my life as a pharmacist would look like this, but I’m so grateful for how it has all come together.”
IN MY VIEW / DISPENSED AS WRITTEN

One of the most colorful commentators on health care is Zubin Damania, MD, a University of California, San Francisco and Stanford University–trained physician. Known as “ZDoggMD,” he has a huge following of health care professionals. His programs on Facebook and YouTube have focused on the COVID-19 pandemic over the past 18 months. But as so many of us are experiencing COVID-19 fatigue or psychosis, I would like to refer to one of his older programs, in which he chastises the major pharmacy chains (https://www.youtube.com/watch?v=AFzi4dQOiiI).

In this 12-minute video he lambastes the major chains about performance metrics, understaffing, and “expecting pharmacists to do more with less. In this country we don’t reward safety and quality—we reward volume.” He notes that chain pharmacies dispense 70% of the prescriptions in the United States.

I would venture to say that patients, not by choice, aren’t getting the care they need because of these chains’ performance and understaffing. Most pharmacists I talk to are passionate about providing quality care; however, most major chain pharmacists are unable to provide quality care if they want to stay employed. I learned this lesson well back in October 1981 when I requested an increase in staffing levels. The district manager said, “Pete, I’ve watched you work and if you quit talking to the patients, you will have plenty of time to get your paperwork done.” Six weeks later my license was hanging on a new nail.

Last Tuesday while doing an intervention for one of the local health plans, I noticed that a patient with chronic obstructive pulmonary disease (COPD) hadn’t had his budesonide/formoterol (Symbicort) filled for 5 months. I called him on the phone and he told me he was mad at his doctor (and everyone else) and was so glad I had called. He was getting dizzy on the inhaler and had told his doctor. His doctor was supposed to send in a new prescription but hadn’t done so. I told him I would investigate and finished up his COPD interview.

I checked our dispensing system, and indeed his doctor had submitted a new prescription for tiotropium/olodaterol (Stiolto Respimat), but it was not covered by the patient’s Medicaid program. Because I sit on the Pharmacy and Therapeutics Committee for the State of Pennsylvania, I called the physician’s office and spoke with a nurse. I recommended umeclidinium/vilanterol (Anoro Ellipta), another combination product with the same mechanism of action that was covered by the formulary. The patient was delighted, just knowing that someone in health care was looking out for him.

At my pharmacy, Nickman’s, we are in full stride filling naloxone (Narcan) prescriptions to our at-risk population. We are using the standing order for naloxone to prevent overdose, as issued by Denise A. Johnson, MD, physician general for Pennsylvania. I spend at least 5 minutes with every medication-assisted treatment patient or others at risk discussing morphine milligram equivalents and the appropriate use of naloxone. My patients are most grateful and are experiencing compassionate care, which would not be possible with flashing screens pushing us to do more with less.

“I spent at least 5 minutes with every medication-assisted treatment patient or others at risk discussing morphine milligram equivalents and the appropriate use of naloxone.”

Can Technology Get in the Way of Patient-Centered Care?

Pharmacist explores how too much reliance on technology may affect patient care

By Peter A. Kreckel, RPh

October 2021

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FD A Approves Belumosudil (Rezurock) for the Treatment of Patients With Chronic Graft-Versus-Host Disease (cGVHD)

Marrium Z. Qureshi, PharmD; and Kevin W. Chamberlin, PharmD

**Efficacy**

The ROCKstar study (NCT03640481) demonstrated significant efficacy across all affected organs in patients after the failure of at least 2 prior lines of systemic therapy. Investigators in the phase 2, open-label, randomized, multicenter study evaluated belumosudil 200 mg once daily and 200 mg twice daily in patients who had received 2 to 5 prior therapies. The primary end point was best overall response rate (ORR) as defined by the 2014 National Institutes of Health Consensus Development Project on Criteria for Clinical Trials in Chronic Graft-versus-Host Disease. The best ORR (95% CI) in patients receiving belumosudil 200 mg once daily and those receiving 200 mg twice daily was 74% (62%-84%) and 77% (65%-87%), respectively. An ORR of 30% was considered clinically meaningful in the study population characterized as being refractory to other treatments.

**Safety**

The safety and tolerability data come from 2 open-label clinical trials. Adverse events were similar among cGVHD patients receiving steroids and immunosuppressants. The most common adverse reactions included infection (53%), asthenia (46%), nausea (42%), diarrhea (35%), dyspnea (33%), cough (30%), lymphocytopenia (29%), decreased serum phosphate (28%), edema (27%), hemorrhage (23%), abdominal pain (22%), musculoskeletal pain (22%), hypertension (21%), increased gamma glutamyl transferase (21%), and headache (21%). Adverse events leading to dose discontinuation occurred in 18% of patients and those leading to dose interruptions occurred in 29%.

**Belumosudil**

Belumosudil is an inhibitor that targets inflammatory and fibrotic processes associated with cGVHD. It is an inhibitor of rho-associated, coiled-coil–containing protein kinase (ROCK) and predominantly inhibits ROCK2 over ROCK1. Belumosudil decreases activation of STAT3, causing the downregulation of Th17 and T follicular helper cells, which leads to the downregulation of pro-inflammatory cytokines. Inhibition of ROCK2 also increases phosphorylation of STAT5, causing the upregulation of regulatory T cells to reduce inflammation. Belumosudil downregulates fibrosis by preventing the polymerization of globular actin to fibrous actin by ROCK2.

**Dosing**

The recommended dose of belumosudil for patients with cGVHD is 200 mg once daily until unacceptable toxicity or progression of disease requiring new systemic therapy. Patients should be instructed to take belumosudil with a meal at the same time every day. The tablets must be swallowed whole with water. As belumosudil has not been studied in patients with preexisting severe renal and hepatic impairment, both risks and benefits should be considered before starting therapy in this population. Modifying the dosage is recommended with hepatotoxicity or other adverse reactions during treatment. When coadministering belumosudil with strong cytochrome P450 3A inducers or proton pump inhibitors, increase the dosage to 200 mg twice daily.