Social Determinants of Health

Tackle Disparities From the Pharmacy

“Pharmacists see patients struggles first.”

PLUS

Respiratory Asthma Management
Vaccines COVID-19 Vaccinations
Pain Psychedelic Medicines Go Mainstream
Technology Telemedicine Insights

Enhanced pharmacy services such as home delivery, curbside services, and expanded personal patient outreach create opportunities to address social determinants of health during the pandemic.

DrugTopics.com
THINK FIRST® BEFORE YOU COMPOUND

A comprehensive FAMILY of Single-Prescription Compounding Kits

Two additional family members:

FIRST® - Metronidazole
FIRST® - Progesterone VGS

Compounding made quick & easy

✓ CONVENIENT
• Pre-weighted, pre-measured components
• One single product #/kit for easy prescription processing

✓ CONSISTENT
• Promotes accurate dosing each time
• Helps facilitate your obligations under 503A and USP <795>

Medicine that’s easy to give... AND TO TAKE

To learn more, visit FIRSTKITS.COM or call 1-800-461-7449

Azurity Pharmaceuticals™, Inc. was formerly known as CutisPharma®, Inc. Product packaging may reflect either name.
© 2020 Azurity Pharmaceuticals™, Inc. All rights reserved.
EDITORIAL ADVISORY BOARD

**EDITORIAL MISSION:** Drug Topics® is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
Cover Story
Social Determinants of Health
Tackle Disparities From the Pharmacy

“Pharmacists see patients struggles first.”

Vaccines
Pharmacies Must Prepare for a COVID-19 Vaccine
PAGE 20

Diabetes
Addressing Diabetes Management Disparities in Minority Children
PAGE 22

Self-Management Support Aids Glycemic Control in NYC Poverty Areas
PAGE 23

CAREER
COVID-19 Testing Is Not an Automatic Choice for Pharmacists
PAGE 24

Microbiome Research Calls for Due Diligence in Pharmacy
PAGE 26

Health Systems
UMass Memorial Provides Model for Curbside Medication Delivery
PAGE 29

COLUMNISTS
Go to Bat for Patients in Need
PAGE 30

Selpercatinib for NSCLC and Thyroid Cancer With RET Mutations or Fusions
PAGE 31
For 1st-line constipation relief

The gentle power of MiraLAX® (PEG 3350) is prized by both doctors and patients.1-3

AGA recommends PEG laxatives as a first-line treatment4

#1 GI-recommended laxative

96% patient satisfaction rate3

AGA=American Gastroenterological Association.

Drug Topics® Rolls Out Enhanced Website

The coronavirus disease 2019 (COVID-19) pandemic has been at the top of everyone's mind for the past several months. Pharmacies have settled into a new normal that involves many changes to the ways they serve their patients. But even as businesses reopen and we begin to feel a slight sense of normalcy, a sense of unease remains, particularly among racial and ethnic minority groups, who, according to the CDC, have been “disproportionately affected” by this illness.

In health care, providers cannot treat patients without acknowledging the treatment disparities that exist for minority communities. This month’s cover story discusses social determinants of health and the role of the pharmacist in tackling health care inequities. As pharmacists are often the first point of care, they are well positioned to see firsthand the social and economic determinants that affect patients.

On page 22, our coverage from the American Diabetes Association’s 80th Scientific Sessions discusses a range of issues related to endocrinology, including a piece on managing diabetes in minority populations.

Despite the country’s march toward reopening, COVID-19 remains omnipresent. As we prepare for a potential second wave of illness in the fall, this issue covers perspectives on the effect of an impending vaccine on pharmacies and the barriers that remain for pharmacist-provided COVID-19 testing.

Serving the pharmacy industry for more than 160 years, Drug Topics® has always dedicated itself to focusing on the individual needs of the practicing pharmacist while providing career guidance and insight into elevating the profession. As part of our ongoing efforts to evolve our platform with each generation of pharmacists, we have revitalized the Drug Topics® website to deliver additional value to our audience. The enhanced website streamlines our industry-leading content to make it more concise and reader friendly and easier to navigate. As always, the website will provide you the most timely information you need to advance your profession.

To even better serve our audience, we’ve also launched the Drug Topics® podcast series, Over the Counter. The interview-style weekly podcast features industry experts offering insights and analysis of the latest news, trends, and innovations, along with actionable tips for enhancing the practice of pharmacy. Visit drugtopics.com/podcasts to tune in.

Thank you for reading.
COMMITTED TO HIGH-QUALITY AUTHORIZED GENERICs*

SECURITY OF PRODUCT
A commitment to the integrity of our medications and the authorized distribution of each product

QUALITY
A commitment to quality and manufacturing excellence

SUSTAINABILITY
A commitment to environmental sustainability

GREENSTONE receives our product materials from a global network of suppliers. Our sites in North America and Europe manufacture 100% of GREENSTONE’S Authorized Generics.

*GREENSTONE provides Authorized Generics from other manufacturers, in addition to some generic products.

MANUFACTURING STANDARDS
GREENSTONE Authorized Generics are manufactured to the same standards and at the same facilities as the original brand-name drugs

LEgACY
GREENSTONE Authorized Generics carry the legacy of the brand-name products' years of clinical research, data, and patient and physician experience

Learn more at www.GREENSTONELLC.com
CDC Urges Routine Vaccinations Despite COVID-19 Pandemic

Although stay-at-home and shelter-in-place orders have resulted in decreased routine immunizations, the CDC is stressing the importance of continuing vaccinations, especially for the upcoming influenza season.

Influenza vaccination will be paramount to reduce the impact of respiratory illnesses in the population and resulting burdens on the health care system during the coronavirus disease 2019 (COVID-19) pandemic, CDC said in its updated Interim Guidance for Immunization Services During the COVID-19 Pandemic.

"Ensuring that routine vaccination is maintained or reinitiated during the COVID-19 pandemic is essential for protecting individuals and communities from vaccine-preventable diseases and outbreaks. Routine vaccination prevents illnesses that lead to unnecessary medical visits, hospitalizations and further strain the healthcare system," the CDC added.

Pharmacists and other vaccination providers should communicate to patients that routine vaccination is an essential preventive care service for children, adolescents, and adults (including pregnant women) that should not be delayed because of the COVID-19 pandemic.

"In light of COVID-19-related reductions in people accessing vaccination services, it is important to assess the vaccination status of all children and adolescents at each patient visit to avoid missed opportunities for vaccination and ensure timely vaccine catch-up. All vaccines due or overdue should be administered according to the recommended CDC immunization schedules during that visit, unless a specific contraindication exists, to provide protection as soon as possible as well as minimize the number of healthcare visits needed to complete vaccination," the agency said.

Regarding the flu vaccine specifically, health care providers should "use every opportunity during the influenza vaccination season to administer influenza vaccines to all eligible persons," the CDC said.

In particular, essential workers, individuals at increased risk for severe illness from COVID-19 (those 65 years and older, nursing home residents, those with underlying medical conditions), and other individuals at high risk for influenza complications should receive the flu vaccine.

Routine vaccination should be deferred for persons with suspected or confirmed cases of COVID-19, regardless of symptoms, until criteria have been met for them to discontinue isolation, the agency said.

FDA Revokes EUA for Chloroquine and Hydroxychloroquine

Shortly after the World Health Organization suspended its hydroxychloroquine study, the FDA revoked the emergency use authorization (EUA) for chloroquine phosphate and hydroxychloroquine sulfate to be used in hospitalized patients with coronavirus disease 2019 (COVID-19).

"Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA," FDA said in a press release.

The FDA is also concerned about the "ongoing serious cardiac adverse events and other potential serious side effects," it said. "The known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use."

The FDA granted the EUA on March 28 based on the science and data available at the time. "[On June 15], in consultation with the FDA, Biomedical Advanced Research and Development Authority (BARDA) sent a letter to the FDA requesting revocation of the EUA based on up to date science and data," the agency said.
New Apps Tap Into Unmet Need for COVID-19 Testing

By Gabrielle Ientile, Assistant Editor

Currently, approximately 460,000 Americans are being tested for coronavirus disease 2019 (COVID-19) each day, a mere 1.5% of the population. Experts have urged that between 900,000 and 30 million individuals need to be tested daily in order to effectively articulate the extent of the virus in the United States.

According to a commentary published in *New England Journal of Medicine*, the majority of US COVID-19 case projections have relied on incidence calculated from current COVID-19 testing, hospitalizations, and deaths. The authors asserted that these limited estimates do little to accurately depict the extent of COVID-19 in the United States for a number of reasons:

1. **Lack of uniformly collected data on a national scale**
2. **Substantial delays in reporting and aggregating data**
3. **Limited availability of testing for COVID-19**
4. **Data based on hospitalizations and death rates only capturing severe COVID-19 cases**
5. **Dearth of information on reliability, accuracy, and availability of antibody-based testing**

The commentary pointed to the opportunity to use technology-based solutions to address these limitations. With social distancing measures in place, the COVID-19 pandemic has carried telemedicine to the forefront of health care.

The authors brought attention to the launching of their Covid Symptom Study app, which has been used by nearly 3.5 million people in the United States, the United Kingdom, and Sweden. A cost-efficient participatory syndromic-surveillance tool, the app not only finds individuals who may have more moderate manifestations of COVID-19 infection, but is able to collect data on other potential risk factors for and outcomes of COVID-19, which can be offered to real-time epidemiologic studies, including current population-based cohort studies.

The authors additionally collaborated with Boston Children’s Hospital to adapt a web- and text message-based syndromic surveillance tool, called FluNearYou. Although the original platform allowed users to view influenza patterns, the new platform has captured upwards of 1 million individual reports, possessing the potential for identifying syndromic data and key demographic risk factors.

**Medical World News**

MJH Life Sciences™ has officially launched Medical World News®, a first-of-its-kind 24-hour online program for health care professionals, by health care professionals.

With easy viewing access on all our sites, you will be among the first to hear about the following:
- Breaking health care news
- Live updates and opinions on what's happening, with leading experts answering the tough questions
- Cross-specialty feedback for multidisciplinary approaches to treatment and guidelines

MJHLifeSciences.com/news-network

**Long Term Care and the “Unsung Health Care Heroes” of the Pandemic**

*DRUG TOPICS*: In this episode we’ll be talking about COVID-19 and issues connected to one of the viruses most vulnerable hosts. There are elderly, or the older adult population, particularly those who are residents at assisted living nursing homes or some kind of long-term care.

According to the CDC, nursing home residents have a heightened risk for infection, serious illness and death from COVID-19. The *New York Times* reported that about one third of all COVID-19 deaths in the United States are nursing home residents or those that work there.

In this unfamiliar global crisis territory, pharmacists and other health care workers and long-term care facilities must now navigate delivering care while also making sure that they and their patients are safe.

**AMIE BLASZCZYK, PHARMD**: I’ve been teaching geriatric pharmacotherapy with Texas Tech since 2005. When I graduated from my PGY 2 geriatric pharmacotherapy program at the University of Maryland, I started out with a practice site at the VA here in Dallas. And then in 2014, I transitioned to practicing within the long-term care environment. In this environment, I’ve been working with our corporate team or individual facilities consultant pharmacists on research and education initiatives for the company.

To listen to this podcast and others, visit www.drugtopics.com/podcasts.
Social Determinants of Health

Tackle Disparities From the Pharmacy

by John Schieszer

Nonmedical issues are requiring pharmacists’ attention in increasingly urgent ways, especially in light of the coronavirus disease 2019 (COVID-19) pandemic. A greater focus on social determinants of health (SDOH) may lead to a much more comprehensive approach to treating patients in the pharmacy and ultimately drive improved outcomes. Overall health is often determined by social and economic issues, and understanding how these factors affect patients is key to identifying and addressing SDOH in the pharmacy setting.

The World Health Organization (WHO) defines SDOH as the conditions in which individuals are born, grow, live, work, and age. The WHO definition also states that these circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels. SDOH can be directly related to health inequities contributing to unfair and avoidable differences in health status. However, the health care community is now addressing these issues in a much more formal way, with the COVID-19 pandemic

Enhanced pharmacy services such as home delivery, curbside services, and expanded personal patient outreach create opportunities to address social determinants of health during the pandemic.
Social Determinants of Health

placing even greater urgency on pharmacists to adopt models of SDOH.

Hannah Fish, PharmD, associate director of strategic initiatives at the National Community Pharmacists Association in Washington, DC, said pharmacists are one of the most accessible health care providers and are often the first point of care for many patients. “Pharmacists are intimately familiar with the lives of the patients in their community and often are aware of nonmedical-related concerns such as transportation, housing, and food security,” she told Drug Topics.

Fish added that because many independent pharmacies deliver medications, they can see firsthand many of the SDOH affecting their patients. Pharmacies across the country are starting to train their pharmacy technicians as community health workers. “Pharmacists have been leveraged informally as the eyes and ears of the care team, documenting what they see in their pharmacy management systems or simply just knowing their community so well. Now we’re starting to see some formality,” she said.

The CDC has recognized the importance of SDOH to public health and has established programs that partner with communities to provide a greater health impact. The CDC programs include the National Program to Eliminate Diabetes-Related Disparities in Vulnerable Populations, which helps 6 organizations plan, develop, implement, and evaluate multi-sector, community-based interventions.

Fish said some community health workers can assist with screening and assessing patients adversely affected by SDOH. These health workers can serve as a referral source to connect patients with the resources they need, such as food banking services, transportation services, and more. “A pharmacy might have helped a patient with finding these resources in the past, [and] community health workers are able to expand and expedite this service,” said Fish.

Richard Logan Jr, PharmD, Logan & Seiler, Inc L&S Pharmacy, Medical Arts Pharmacy, Charleston, Missouri, echoed Fish’s recognition of the pharmacist’s role in patient’s health care: “This relationship has been for years the cornerstone of clinical pharmacy services. From addressing access to medications for reasons clinical or financial to acting as a triage and referral site into the health care system, no one spends more eyeball-to-eyeball time with the patient than their pharmacist,” he said.

Logan noted that the best health care system in the world is of no use to a patient who cannot access it. If an individual has an appointment with a physician but has no way to get to the office, that appointment is pointless. “People who have poor access to food are worrying about their next meal, not their [high-density lipoprotein] levels,” said Logan. SDOH in various forms can create a significant barrier to health care. “[The Centers for Medicare & Medicaid Services] has recognized this and legitimized it with a whole series of ICD-10 [International Classification of Diseases, Tenth Revision] codes addressing SDOH as a barrier to care,” said Logan.

A patient with a chronic disease usually has 35 or more visits to a pharmacy in a year, making the pharmacy the logical “go-to place” to delve into how SDOH are affecting a patient’s care, according to Logan. Often the pharmacy is the canary in a coal mine for patient access to health care. “We see patient struggles first, either through conversations in the pharmacy or when we deliver to their home and step into their lives. In our practice, and others of which I’m aware, we employ trained community health workers to interact with patients, interview patients, refer patients to services, and assist them in any way possible to address their SDOH [and] access to care in a caring, compassionate, effective way,” said Logan. Logan said by focusing on SDOH, his group has had great success, in both positive patient outcomes and increased professional awareness among local health care colleagues.

Lack of Awareness

Linn Gould, MPH, executive director of Just Health Action in Seattle, Washington, said the term SDOH has existed for more than 20 years. Yet many pharmacists have never even heard of it. “From 2001 to 2003, the jargon started being adopted more widely. So it is fascinating that there are so many people who have never heard of it,” said Gould.

Medical and pharmacy schools appear to be failing in addressing SDOH. One recent article suggested that major structural and cultural transformations in medical education are warranted to address social and economic issues. The authors wrote that educators need to discuss not only poverty but also oppression, racism, sexism, and homophobia. One local pharmacist in Seattle told Drug Topics that he had never heard much about SDOH. He said he is surprised by how little attention SDOH receive and that most pharmacists have a total lack of awareness of SDOH. Yet most pharmacists would probably adopt
Social Determinants of Health

“Pharmacies delivering medications are calling their patients to see whether they need anything else, such as groceries.” Hannah Fish, PharmD

a model if they had the knowledge and were given the opportunity, he added. Unfortunately, the current operational model for retail pharmacies is now extremely transactional and, for the most part, does not allow pharmacists to take into account SDOH.

COVID-19 Effects Change
Currently, the COVID-19 pandemic is requiring that pharmacies address SDOH in many areas. Mass unemployment, for instance, has led to myriad new needs. “Pharmacies delivering medications are calling their patients to see whether they need anything else, such as groceries, before going to the home,” said Fish. She said during the current period of social distancing, calling patients once a week to check on their general well-being and mental health may be appropriate. “In addition to employing community health workers, we’ve seen pharmacies partner with local farmers’ markets to provide fresh produce for patients coming to the pharmacy. Further, insurers are recognizing the impact SDOH have on health outcomes and are expressing a desire to work with pharmacies to address these concerns,” said Fish.

Logan said pharmacists are rising to meet the challenge of remote patient care via enhanced deliveries, curbside services, expanded personal patient outreach, and an increase in those patient touch points even as patients shelter in place. Many older patients in particular are now unable to make physician visits, putting them at risk of uncontrolled chronic comorbidities. “Our pharmacies are checking in regularly with our patients with chronic conditions to make sure they are not ignoring other conditions for the sake of COVID-19,” Logan told Drug Topics.

Gould works in Seattle’s Duwamish Valley, a community with environmental justice concerns as a result of significant air pollution problems. “It has one of the highest childhood asthma hospitalization rates in the city of Seattle, and now we have evidence that the higher air pollution [is], the higher the COVID-19 death rate [is]. We have also learned that there is a link between asthma and COVID-19 rates,” said Gould.

The physical distancing measures required to slow the spread of COVID-19 are substantially more difficult for those with adverse social determinants. According to Denise Fu, PharmD, clinical programs manager in Patient Care Services at Johns Hopkins Home Care Group Pharmacy Services in Baltimore, Maryland, although many pharmacists can identify SDOH issues, they need more education regarding available resources to help them address the barriers. “For example, pharmacists may be able to assist the patient with access to prescription medication but would need to refer the patient to other resources for employment, food insecurity, or housing instability,” she said.

Fu also said that improving information technology can help by filling in the gaps with SDOH data. One published study suggested that a lack of policy standards around SDOH data may be hindering adoption. However, commercial vendors are interested in collaboratively discussing policy solutions such as standards and guidelines. The investigators evaluated the development of electronic health record (EHR) software products that allow health care providers to identify and address patients’ SDOH. They conducted interviews with 6 EHR vendors with large market shares in both ambulatory and inpatient settings. The study results showed that SDOH appear to be an area for growth and that vendors offer a wide range of SDOH-related products with various levels of sophistication.

“If health care providers are able to collect and document SDOH risk factors, technology can help by seeing how many and to what extent of the 5 SDOH domains a particular patient is experiencing. If a patient is unable to keep the water on in their house or food on the table for their family, they are most likely not going to be able to afford and take their medicines,” said Fu.

A century ago, helping individuals with SDOH made a significant impact against tuberculosis, another highly infectious disease. At that time, better housing, a reduction in overcrowding, and improved nutrition saved countless lives. Now pharmacy is stepping up to formally address SDOH to help lower both morbidity and mortality during the current pandemic and beyond.

For references, go to drugtopics.com
Pharmacists can play an important role in helping patients with asthma manage their disease through drug therapy assessment and education.

**Asthma Pharmacotherapy and Counseling Pearls**

Pharmacists should ensure that patients have a written asthma action plan that includes their medications with directions, steps to take if symptoms worsen, and means of accessing medical care. Pediatric patients will generally need nebulizers, pressurized metered dose inhalers, or face masks attached to a metered dose inhaler, depending on age, to ensure the correct dose of medication is delivered into the lungs. Patients should continue taking their current asthma medications and discuss any concerns with their pharmacist and other health care providers during the COVID-19 pandemic.

Pharmacists can also help ensure that patients have an adequate supply of medications. The Global Initiative for Asthma recommends that all adults and adolescents with asthma receive inhaled corticosteroids (ICSs) as long-term control medications; experts consider these the most effective anti-inflammatory drugs because they reduce the risk of exacerbations, hospitalizations, and death. Examples include fluticasone (Flovent HFA), budesonide (Pulmicort Flexhaler), and beclomethasone (Qvar RediHaler), and they have a low risk of adverse effects (AEs). Local AEs may include oral candidiasis and dysphonia (hoarse voice), which patients can minimize by using a spacer and rinsing with water and spitting out after inhalation.

Long-acting beta_2_ agonists (LABAs) are bronchodilators that practitioners can add to an ICS if patients require combination therapy. Combination ICS-LABA inhalers include fluticasone-salmeterol (Advair Diskus), budesonide-formoterol (Symbicort), and formoterol-mometasone (Dulera). Importantly, patients must always use LABAs with ICSs because evidence shows that LABAs used alone may increase the risk of a severe asthma attack. AEs associated with LABAs include tachycardia, headache, and cramps.

Leukotriene receptor antagonists such as montelukast (Singulair), zafirlukast (Accolate), and zileuton (Zyflo) are another option for controller therapy, specifically in children. The FDA recently issued a drug safety communication about the addition of a boxed warning for montelukast because of the risk of serious mental health AEs, including suicidal thoughts or actions. Practitioners should weigh the benefits and risks before prescribing montelukast for patients with asthma. Patients taking montelukast should discontinue the medication and contact their pharmacist and other health care providers immediately if they experience any behavior- or mood-related changes.

Rescue medications provide rapid, short-term symptom relief during an asthma attack. Patients should take short-acting beta_2_ agonist bronchodilators (SABAs) such as albuterol (ProAir HFA, Ventolin HFA) and levalbuterol (Xopenex) only as needed and at the lowest dose, and SABAs should not be used without an ICS. Patients may experience tremor and tachycardia with initial use of SABAs, but tolerance develops with regular use. Ipratropium (Atrovent) is a short-acting anticholinergic inhaler that is less effective than SABAs as a rescue medication, with dry mouth as a common AE. Practitioners should prescribe systemic corticosteroids (eg, prednisone, methylprednisolone) only short term to treat severe asthma symptoms, as long-term use can cause serious AEs, including diabetes, hypertension, osteoporosis, and cataracts. Corticosteroid use should be tapered if the treatment duration is longer than 2 weeks. Short-term use of corticosteroids may cause hyperglycemia, insomnia, increased appetite, and mood changes.

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

Important Safety Information
- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
HOW MANY PATIENTS CAN YOU PROTECT FROM SHINGLES?

• Age-related decline in immunity is a dominant driver of shingles²-⁴
• SHINGRIX is recommended by the CDC for the prevention of shingles⁵

Learn how YOU can protect your patients at VisitSHINGRIXPHARM.com

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

• Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)

• SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

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

BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

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

1 INDICATIONS AND USAGE

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

Limitations of Use:

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

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

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

2.3 Dose and Schedule

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

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

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fever (44.5%), headache (37.7%), shivering (26.8%), fatigue (20.5%), and gastrointestinal symptoms (17.3%), respectively.

Unsolicited Adverse Events

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

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

<table>
<thead>
<tr>
<th>Age Group</th>
<th>SHINGRIX</th>
<th>Placebo</th>
<th>SHINGRIX</th>
<th>Placebo</th>
<th>SHINGRIX</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged 50-59 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,311</td>
<td>n = 1,305</td>
<td>n = 2,258</td>
<td>n = 2,263</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
<td>11.1</td>
<td>69.2</td>
<td>8.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
<td>0.5</td>
<td>4.0</td>
<td>0.2</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
<td>1.6</td>
<td>37.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
<td>2.6</td>
<td>0.0</td>
<td>3.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
<td>1.0</td>
<td>23.0</td>
<td>1.1</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
<td>0.0</td>
<td>1.3</td>
<td>0.0</td>
</tr>
<tr>
<td>General Adverse Events</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,309</td>
<td>n = 1,305</td>
<td>n = 2,252</td>
<td>n = 2,264</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
<td>49.0</td>
<td>11.2</td>
<td>35.1</td>
<td>9.9</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>8.9</td>
<td>0.9</td>
<td>5.3</td>
<td>0.8</td>
<td>2.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
<td>45.7</td>
<td>16.8</td>
<td>36.6</td>
<td>14.4</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>8.5</td>
<td>1.8</td>
<td>5.0</td>
<td>0.8</td>
<td>3.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
<td>39.6</td>
<td>15.6</td>
<td>29.0</td>
<td>11.8</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>6.0</td>
<td>1.7</td>
<td>3.7</td>
<td>0.2</td>
<td>1.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
<td>30.3</td>
<td>5.7</td>
<td>19.5</td>
<td>4.9</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>6.8</td>
<td>0.2</td>
<td>4.5</td>
<td>0.3</td>
<td>2.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
<td>23.9</td>
<td>3.4</td>
<td>14.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>GI*</td>
<td>24.3</td>
<td>10.7</td>
<td>16.7</td>
<td>8.7</td>
<td>13.5</td>
<td>7.6</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2.1</td>
<td>0.7</td>
<td>0.9</td>
<td>0.6</td>
<td>1.2</td>
<td>0.4</td>
</tr>
</tbody>
</table>

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

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

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.

Placebo was a saline solution.

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

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

Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as >39.0°C/102.2°F.

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

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

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

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

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 16,465) and placebo (n = 16,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pruriitus (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 0.0% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (0.01%) reported lymphadenitis and 1 subject (0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

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

Deaths

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

Potential Immune-Mediated Diseases

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

Dosing Schedule

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

6.2 Postmarketing Experience

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

General Disorders and Administration Site Conditions

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

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

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

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk.

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

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 16,465), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (48.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

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

17 PATIENT COUNSELING INFORMATION

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

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

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

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

Trademarks are owned by or licensed to the GSK group of companies.

Manufactured by GlaxoSmithKline Biologicals Rixensart, Belgium, U.S. License 1617, and Distributed by GlaxoSmithKline Research Triangle Park, NC 27709
©2019 GSK group of companies or its licensor. May 2019 SHX3BRS
©2019 GSK or licensor. SGXJRNA190015 July 2019
Produced in USA.
Psychedelic Medicines for Pain Go Mainstream

Once largely stigmatized, illicit substances are breaking into the field of pain management. By Frieda Wiley, PharmD

A n estimated 32 million individuals 12 years and older used psychedelic medicine in the United States in 2010, according to a US population survey.1 As the opioid epidemic has eclipsed concerns about illegal drugs in recent years, the medical community and the federal government alike have begun reexamining certain illicit drugs as potential alternatives to opiates in pain management.

Cannabis
Perhaps no other “illicit” substance has played a greater role in turning the tides recently than medical cannabis. Its slow but steady serial legalization and decriminalization at the state levels to treat a variety of complaints, including pain, have helped bring cannabis, cannabis products, and other stigmatized drugs to the forefront.

“It is most surprising that even though cannabis has been used for a number of ailments for thousands of years—even dating back to the 28th century BC—it is now being recognized as a valid treatment option,” said Swathi Varanasi, PharmD, an integrative health pharmacist and medical cannabis consultant in Los Angeles, California. “However, because of the way cannabis has been criminalized, it hasn’t been integrated into standard treatment algorithms.”

Regulatory issues aside, pharmacists and other members of the medical profession often wrestle with safety when assisting patients who use cannabis for medicinal purposes. Cannabis has been studied extensively for numerous uses, including its potential benefits in neuropathic pain, chronic pain, and inflammation. A 2014 study found that most patients cited relief from chronic pain as the most common reason for their medicinal use of cannabis.2 Yet the plant’s psychoactive properties continue to draw concerns regarding abuse potential, owing to the effects of 1 phytochemical, ∆9-tetrahydrocannabinol, known for its psychoactive properties.

However, these are not the only challenges pharmacists face when it comes to assisting patients.

“The biggest pitfall in advising patients on cannabis is that dosing is so difficult to standardize,” said Victoria Starr, RPh, a cannabis pharmacist at Sage Life, LLC, in Portland, Oregon, told Drug Topics. “Cannabis for medicinal purposes is highly complex, largely because of its high number of phytochemicals, called constituents. To date, the plant has been found to contain more than 560 constituents. When individuals consume these as the whole plant, the chemicals offer synergistic and therapeutic benefits while mitigating potential toxicities, what’s known as the entourage effect. Synthetic cannabis typically contains only 1 active ingredient and lacks additional chemicals that can help regulate undesirable effects. However, customizing cannabis dosing to even the individual patient is no small feat.”3

“Besides attaching medical benefits to each of these components, the combination of synergistic benefits needs to be determined, along with the proper ratio and dose,” Starr explained. “So unlike Western medicine, in cannabis, there exists a multitude of different medications—with a wide range of potencies, targeting a vast array of medical conditions—made up of varied combinations of cannabinoids, terpenes, and flavonoids.”

Psilocybin
Psilocybin, the primary ingredient found in mushrooms that produce...
Psychedelic medicines for pain go mainstream

Psychedelic effects, is enjoying an increased share of popularity and renewed exploratory use.

“It’s exciting that patients are starting to ask their pharmacist about psilocybin,” said Emily Kulpa, PharmD, an integrative health pharmacist and psychedelic medicine consultant based in Milwaukee, Wisconsin.

Although psychedelic mushrooms have been used for millennia, they gained popularity in the United States for recreational use during the 1960s and had spawned some academic interests as well. From 1960 to 1962, psilocybin, along with psychedelic relatives lysergic acid diethylamide (LSD) and mescaline, became the focus of a series of trials known as the Harvard Psilocybin Project. At the time, these drugs were legal. Criminalization of these drugs would later erupt in the following decade as safety concerns grew.

Fast-forward to the new millennium. Psilocybin sparked some interest in its potential analgesic effects in cluster headaches and migraines. Psilocybin, along with psychedelic relatives lysergic acid diethylamide (LSD) and mescaline, became the focus of a series of trials known as the Harvard Psilocybin Project. At the time, these drugs were legal. Criminalization of these drugs would later erupt in the following decade as safety concerns grew.

Kratom
Indigenous to Thailand, Malaysia, Myanmar, and other regions of Southeast Asia, kratom (Mitragyna speciosa) belongs to the coffee family and also exhibits dose-dependent sedative and stimulatory effects. The plant is typically consumed in pill, capsular, or extract form, although some individuals brew dried or powdered leaves as a tea. Others may chew, smoke, or consume the leaves in food. However, because of kratom’s harmful adverse effects and abuse potential, the FDA warns individuals against using the substance.

Kratom contains mitragynine, an alkaloid bearing a tryptaminelike structure that exhibits µ- and δ-opioid receptor agonist activity that results in dose-dependent stimulatory and analgesic effects. In lower doses, mitragynine produces stimulatory effects, whereas higher doses result in opioid-like activity. However, its metabolite, 7-Q-hydroxymitragynine, exhibits significantly stronger µ-opioid receptor agonist behavior.

Although kratom is not an opioid, the CDC found an association between kratom use and overdose deaths, also involving opioid and nonopioid use, in the State Unintentional Drug Overdose Reporting System. Moreover, based on toxicology results, medical examiners or coroners determined kratom as the culprit in deaths in 11 states from July 2016 to June 2017 and 27 states during the last 6 months of 2017.

“There is no legitimate medical use for kratom in the [United States],” the Drug Enforcement Administration (DEA) wrote in a report on its website. On August 16, 2016, the DEA announced its intent to classify kratom as a Schedule I controlled substance, noting that the plant had been “abused for its ability to produce opioidlike effects” and “was often marketed as a legal alternative to controlled substances.”

Pharmacists should be aware of the potential harms.

Psychedelic Medicine in the Near Future
Varanasi believes the importance of cannabis in pain management will continue to grow. “Preliminary evidence demonstrates cannabis’ ability to provide significant pain relief as well as [to help individuals] taper off opioids [particularly in the setting of addiction],” she said. “Though the research is inconclusive, patient anecdotes support the continued use of cannabis in pain management.”

In Oregon, the Oregon Psilocybin Program Initiative will appear on ballots in November 2020. “If passed, it would [be] the first state-sanctioned program for the administration of psilocybin services between a certified practitioner and a patient,” Varanasi said. “This would not only set the standard for other states but also support published studies reporting that a strong patient-practitioner relationship improves overall health outcomes.”

In the meantime, patients and practitioners alike will have to wait to see how these and other psychedelics will alter integrative medicine and the world of health care.

For references, visit drugtopics.com.
In a recent video interview with Drug Topics®, Richard Scholz, RPh, chief strategy officer of ERxDirect in Columbus, Ohio, explained the prominence of telemedicine during the coronavirus disease 2019 (COVID-19) pandemic and the lasting implications.

Drug Topics®: Can you break down how telemedicine works? Is its nature to replace the health care maze or more to supplement current practice?

Scholz: First of all, [it is to] clearly supplement; I think replacement would be a far overreach. I think there are a lot of things we can do through telemedicine within the current practice. First of all, the current practice of health care is professional dependent. Professional conditions, professional pharmacists, professional dietitians, professional and behavioral health [specialists]—all these professionals are on the mosaic that brings us to health care. The key is how we get them to the [patients] more effectively and more efficiently. So that’s truly a supplemental role. We see that as not replacing. Health care providers are the key, and empowered patients are the key to health care. So our goal is not to replace; our goal is to enhance. I think it’s important to understand, at least from my perspective, what telemedicine is. All my experience has been in the outpatient world, so we’re not talking telestroke in the hospital, those kinds of care. Those are different. Our arena for telehealth is a clinical encounter in a basic sense, and the patient is in one location and the provider is in a different physical location. And the connectivity in those end points has great diversity even within our world. And I’d like to [mention that] some of that diversity, if I may, is [through] Health in Motion Network, a model of care delivery that focuses on wellness through innovation [and] improving health management. And we do that through personalized care, and that’s personalized care with your provider. That’s the goal, for [patients] to have that relationship with [their] provider. Our goal is to enhance that relationship and multiple relationships and then coordinate them so that maze we talked about earlier is not so complex.

New technologies are creating a more portable health care system. By Drug Topics® staff

Our care spaces are hallmark virtual clinics. This is a clinic designed to put on an employer’s work site. It’s also used in campus care environments and in our connected health hub clinical sites, which are actually brick-and-mortar clinics with dedicated rooms for digital health and for virtual health and telemedicine. That allows those brick-and-mortar sites to now enhance their offerings to local patients, so they can now host an in-person practice but also host a visit for a patient with a specialist who may be at a tertiary care facility 60 miles away. That patient doesn’t have to interrupt their day and go get that additional clinical care through a specialist.

What we’re looking at really is enhancing portability. [For] our care spaces, the hallmark is...synchronous communication of medical data to the provider. So the professional clinicians get real-time heart and lung sounds; they get real-time, detailed, high-resolution pictures. There’s a nurse at the bedside, at the exam table, helping with the medical devices and working with the physician [to provide] hands-on care that may be needed...for the physician to make the proper diagnosis. So it’s a very, very large scope of care. We also have the direct-to-consumer components, where the physician can do a virtual visit directly with the consumer on a personal device. But again, that has utility but not as robust diagnostic utility as the care space does. So we see a place for all of that. We see a pharmacist as part of that health care team. We see a pharmacist being imported into each of those different environments to bring that pharmacy knowledge to that encounter and to that patient as part of that health care team.

Drug Topics®: Can you take us through the steps for a pharmacist who is interested in implementing ERxDirect’s telemedicine service? What changes
would they have to make to their current practice?

Scholz: The first piece of ERxDirect telemedicine that we’re rolling out through Epic Pharmacies is connectivity. They can implement this on various devices depending on their desired workflow. We have some pharmacies right now during COVID-19 where there’s a pharmacist who is actually part of the vulnerable population and chooses not to come into the pharmacy, and appropriately so. So they do all their work [and their consultations] on a personal device from their home, much as you and I are working from offices that are atypical [compared with those of] our normal day. And this enables those practitioners to participate in that market as robustly as [they would] if they were in their pharmacy.

As far as what they have to adjust, it’s really easy because it’s a workflow. First of all, they have to have a viable device with a camera, which is quite common now. We have an environment that is compliant with the Health Insurance Portability and Accountability Act, so you wouldn’t want to do a consult in a public area. I think the biggest change from a workflow standpoint is for pharmacists and community pharmacists...to set aside time in their day to schedule consultations. They’re so used to ad hoc consultations and on-demand workflow that scheduled consultations are somewhat of a new arena for them from a workflow standpoint.

Drug Topics®: Why do you think it’s important to continue to improve telemedicine technologies, and what changes will this create for pharmacy?

Scholz: I think that that’s a critical question and a good question based on the fact that yes, this will come to an end, and we’re hoping for a very quick end to it. I think...[this pandemic has] spotlighted the fact that we have a vulnerable society...with comorbidities and some chronic diseases. I believe the spotlight...on those chronic disease states will have a lingering effect [on] how we approach and practice population health going forward. That’s going to take implementation of a health care team....What we’re doing through ERxDirect telemedicine is making sure that our pharmacists are enabled to fully participate on that team. [For example,] urgent care providers actually [have] a care space or a clinic in a public school. The school nurse becomes the enabler and the care coordinator for the student. It’s really fascinating.

I think we’ll see a bigger focus on this post COVID-19....We’ve seen that by bringing the team together and facilitating that collaboration, the magic of increasing the access and the quality comes in. So there’s going to be a lot more focus on chronic conditions and how the different components of the professions work together for the betterment of that patient.

Drug Topics®: What are the biggest takeaways from this?

Scholz: The biggest takeaway from my perspective, and this is as a pharmacist and as a health care professional, is that in more than 45 years in the industry, I’ve come to 1 really basic conclusion....Informed [and empowered] patients, regardless of how they got the credible information—through physician connectivity, pharmacy counseling, credible patient-oriented content, health coaching—are the most critical team members in the management of chronic disease. Everything we can do to reach into the lives of these patients and make those lives better, to make that maze a little less daunting, [will help]. That will be for successful management of chronic health care, and [I hope] not [only] management but prevention also. The tools that we’re bringing to market, again, [are] not replacing anyone in health care; they’re enhancing what they do every day and [making] it more portable and more viable in the future.

Visit drugtopics.com for the full video interview.

Editor’s note: This interview transcription has been edited for style and clarity.
Pharmacies Must Prepare for a COVID-19 Vaccine

Despite some anticipated hesitancy, demand for the novel coronavirus vaccine will be significant when it becomes available.

By Christine Blank

A lthough community pharmacies are the ideal locations to provide a vaccine for coronavirus disease 2019 (COVID-19) after it is developed, they must overcome barriers that include state regulations and patient objections. One recent survey found that only 3 in 4 Americans would choose to receive the COVID-19 vaccine when it becomes available.1

“Vaccine hesitancy is a major barrier to vaccine uptake and the achievement of herd immunity, which is required to protect the most vulnerable populations,” wrote the authors of a recent JAMA Viewpoint article.2 “Given that certain individuals will be ineligible for COVID-19 vaccination because of age, immunocompromised status, and other preexisting medical conditions, a vaccine refusal rate greater than 10% could significantly impede attainment of this goal.”

However, experts with the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) believe demand for the COVID-19 vaccine will be significant and that pharmacies should prepare now to administer it. “We are operating under the assumption that the demand for a COVID-19 vaccine will be high, when available,” said Kathleen Jaeger, RPh, senior vice president of pharmacy care and patient advocacy for NACDS. NACDS’ recent poll conducted by Morning Consult found that 86% of Americans say pharmacists should be allowed to provide a COVID-19 vaccine.3 “This, combined with the tremendous trust that patients place in pharmacists, suggests that Americans will continue to look to these highly educated health professionals for reliable information,” Jaeger said.

Pharmacists are in a “great position” to administer the vaccine, according to John Beckner, RPh, senior director of strategic initiatives at NCPA. “If you want to mass-immunize the population, you want to use pharmacists,” he told Drug Topics. It is not too early to begin educating patients about the vaccine, which practitioners can do now while providing other routine vaccinations, Beckner said.

However, Beckner acknowledged that some patients will have concerns. “Like anything new, there is probably going to be some pushback. There are going to be antivaxxers, and there are always going to be folks thinking they can get the flu from the vaccine, for example. It is really important to educate them,” Beckner said.

Community pharmacies need to work with their state associations, who will partner with local and state health departments, to break down barriers to pharmacists’ vaccinations in certain states—and to communicate that they are set up to administer the new vaccine. Some states have age restrictions on pharmacists who can administer vaccines. “NCPA has been pushing for pharmacists to administer all American Council on Immunization Practices–approved vaccines,” Beckner added.

NACDS is advocating for the federal and state governments to take “swift action” to ensure the population can rely on pharmacies and pharmacists for the COVID-19 vaccine, Jaeger said. The organization has engaged with the Trump administration’s Operation Warp Speed to make the case for pharmacy’s role, based in large part on the industry’s proven track record during the H1N1 pandemic.

For references, visit drugtopics.com
Never miss a thing.


Sign up for the Drug Topics® eNewsletter.

Take us anywhere.
New research presented virtually at the American Diabetes Association 80th Scientific Sessions determined key low-intensity initiatives that address disparities in diabetes management for African American and Hispanic children in the United States. The study, presented by Ashley Michelle Butler, PhD, associate professor of pediatrics at Baylor College of Medicine and clinical psychologist at Texas Children’s Hospital discussed the significant gaps in glycemic control among African American and Hispanic children compared with nonminority children.

“We have a focus within our organizations on preventing complications of diabetes,” Butler said. “That’s because we know that if we don’t address these potential difficulties before they occur, the burden to families can be devastating, and the health care costs are tremendous.”

According to investigators, the 2 main considerations in diabetes management disparity are how long the child has had diabetes and when diabetes was diagnosed. Results of recent studies show disparities in glycemic control begin early for Black and Hispanic youth with type 1 diabetes—as early as 1 year from diagnosis. For example, 1 parent expressed concern that she is unable to check her phone during work, making it difficult to be contacted by her child’s school. Minority children are also less likely to have a written plan for managing their diabetes and are even less likely to have a nurse at their school.

Butler pointed to 3 universal strategies for influencing diabetes outcomes in this population:

- Community outreach
- Social needs screening and resource linkage
- Low-intensity social and behavioral support

Outreach events specifically tailored to this population, particularly children aged 5 to 10 years, have demonstrated success through gauging the needs of families of children with diabetes. During these outreach programs, many families highlighted their interest in getting to know other families in their situation. Personalized, written community resources that use inclusive language and images in their materials can also improve child health outcomes and reduce unmet social needs.

Low-intensity social and behavioral support is of particular significance for Black and Hispanic children with diabetes. When support is made more convenient, families are more likely to participate. Convenience has recently taken the shape of telemedicine, and Butler similarly put forth the potential for telehealth resources to mitigate unmet social needs. Some initiatives have offered low-intensity at-home sessions, sometimes through videoconferencing of up to 5 families at one time. However, ease of access to these resources is also an important consideration, as socioeconomic status can also affect a child’s access to broadband and online resources.

“There really is a need to develop and implement low-intensity strategies for minority youth, particularly those [with] newly diagnosed [disease] as well as families of younger children, and that multidisciplinary teams can use their expertise and innovation to implement...tailored community outreach, social needs screening, and personalized resources, as well as behavioral interventions that can be assessed while the families are at home,” Butler concluded.

For reference, visit drugtopics.com.
A study presented at the virtual American Diabetes Association 80th Annual Scientific Sessions reported success in decreasing glycated hemoglobin ($A_1c$) levels through self-management support in individuals living in poverty areas in New York, New York.

Study investigator Jeffrey S. Gonzalez, PhD, professor of psychology and medicine at Albert Einstein College of Medicine and director of the New York Regional Center for Diabetes Translation Research in Bronx, New York, explained New York City’s distinct socioeconomic layout, noting that the city bears huge disparities between rich and poor.

South Bronx, as well as the area around the border of Brooklyn and Queens, have the highest rates of poverty in the city. The diabetes prevalence rate in Manhattan is 4.1% to 8.9%, but rates in South Bronx and other impoverished areas were much higher, at 13.6% to 14.6%. Those living with diabetes in these regions are also more likely to have poor glycemic control.

The study used New York City’s $A_1c$ registry to identify individuals with poor $A_1c$ control. The study implemented self-management support initiatives in 2 randomized control arms: One arm received print resource materials, and the other received telephonic intervention.

Demographic data of the 841 participants found a predominantly Latino and black population, with the majority of participants able to speak Spanish. Sixty-nine percent were born outside the United States, and 76% had household incomes of less than $20,000. Only 14% of participants reported ever having any diabetes education prior to the study’s program.

Results of the study found the telephonic arm to be superior in leading to $A_1c$ improvement. Additionally, those with $A_1c$ levels above 9% at baseline showed clinically significant improvements on the $A_1c$ scale.

Investigators also linked the participants to a statewide database that captures hospital discharges, evaluating 2 years prior to participation and 4 years post participation in the program. Individuals who received telephonic intervention showed lower all-cause hospitalizations and lower hospitalizations related to diabetes. But according to Gonzalez, these changes could not be attributed to improvement in $A_1c$.

A follow-up study incorporated diabetes distress and depression levels. It evaluated another high-poverty area in New York City through participation of 812 adults with $A_1c$ levels above 7.5. Participants were randomized to receive either print materials by mail or print materials along with 6 to 12 tele-SMS calls, depending on their $A_1c$ and distress levels. In this population, 7% reported receiving prior diabetes education. Seventy-eight percent spoke Spanish, and 87% identified as Hispanic or Latino, with similarly high poverty levels.

Although investigators are still working through their data analysis, Gonzalez reported the $A_1c$ levels were significantly improved in both study arms: ~0.8% in the telephonic arm and ~0.7% in the print-only arm.

Data failed to reveal any difference in diabetes distress or depression, something that Gonzalez said might hint that some mismatch existed between the distress protocol and the needs of the study’s patients.

The New York City Department of Health and Mental Hygiene has decided to disseminate the study’s Care Calls telephonic approach in several ways. It has begun a pilot and feasibility study to train medical assistants in the city’s Care Calls delivery. Amid the pandemic, the department is also conducting telephonic outreach to adults with chronic illness using the Care Calls protocol, Gonzalez said. ■
COVID-19 Testing Is Not an Automatic Choice for Pharmacists

Preparation taking place in some pharmacies, but clarification is still needed. By Fred Gebhart

Are you testing for coronavirus disease 2019 (COVID-19)? A recent National Community Pharmacists Association (NCPA) survey found that most pharmacists want to be part of the testing process, but few pharmacies offer sample collection or onsite testing.1

"There are so many different barriers. One thing gets cleared, and then there's another step and then another," said pharmacy owner and California Pharmacists Association President Ken Thai, PharmD. "Especially if you are an independent pharmacy wanting to do testing, you have to find your own channels to get it going. And then it comes down to economics. Billing mechanisms seem to be in place, but they aren't necessarily functional. There are still a lot of questions before we can start widespread testing in pharmacies."

Some pharmacists have opted not to test. In the Atlanta suburb of Johns Creek, Good Neighbor Pharmacy affiliate Lily's Pharmacy focused on existing patients and the flood of discharge patients as Emory Johns Creek Hospital cleared its wards.

"The pandemic hit hard and fast," said co-owner Jennifer Shannon, PharmD, BCPS. "Our volume went sky-high for the first 6 weeks of COVID-19—really sick patients who needed a lot of pharmacist attention. We started curbside pickup, ramped up delivery, and set up new protocols as hospitals and doctors closed. Relationships with our providers have been strengthened, and we are caring for patients at a higher level than just a few months ago. I'm amazed at how many people are coming by to say they never realized how much they needed a local pharmacy."

Other pharmacists built their own testing programs. In rural Sourgoinsville, Tennessee, Beth Bryan, PharmD, was the first pharmacist in the state and one of the first in the country to offer COVID-19 testing. Her Sourgoinsville Pharmacy began offering appointment-only, drive-up testing in mid-April 2020. Pharmacy staff collected nasopharyngeal swabs and sent them to a lab for processing. Bryan said there are clear public health, community service, and professional advancement arguments for providing COVID-19 testing. And she didn't have to worry about the business case. Her pharmacy partnered with the state health department to obtain sample collection kits, the local fire department to acquire hazmat suits, and a local welder for face masks. Community members donated N95 masks.

"Without community support, we would not have been able to obtain test kits or PPE [personal protective equipment]," Bryan said. "There is no good pathway to reimbursement. We're working on it, [the US Department of Health & Human Services (HHS)] is working on it. There is a learning curve for all of us, just like there was with immunizations. But if somebody is looking for a big moneymaker, COVID-19 testing isn't it."

In West Sacramento, California, Capitol Pharmacy is building relationships, not profits. The Health Mart pharmacy has yet to be reimbursed for testing. Health Mart, part of McKesson, was part of an HHS pilot program to test community pharmacies as sample collection sites for molecular testing. The test manufacturer provided sample collection kits, McKesson provided PPE and supplies, and pharmacies provided space and personnel.

"We're not paying for testing supplies," said Capitol Pharmacy owner Thomas Bui, PharmD. "When we agreed to be a testing site, we got supplies over-night, but we didn't have time to prepare, to communicate to the community that we would be offering COVID-19 testing. We're just trying to give back to the community. It's the right thing to do."

Economics made a huge difference at the University of Southern California (USC), said Richard Dang, PharmD, RPh, BCACP, assistant professor of clinical pharmacy. Plans to test the entire
USC community—students, faculty, and staff—went on hold when the university saw cost estimates for test kits, PPE, and supplies. “They were not expecting the budgetary impact of testing,” said Dang, a California Pharmacists Association COVID-19 Taskforce chair and speaker. “They had sticker shock.”

“I’m amazed at how many people are coming by to say they never realized how much they needed a local pharmacy.”

JENNIFER SHANNON, PHARMD, BCPS

And then there is the murky question of regulatory authority.

On April 8, HHS authorized licensed pharmacists to order and administer FDA-authorized COVID-19 tests, including serology tests.² By mid-May, about two-thirds of states were allowing pharmacists to play a role in testing.

On May 19, the agency issued an advisory opinion (20-02) declaring that states and localities may not establish, enforce, or continue in effect any legal requirements that prohibit licensed pharmacists from ordering and administering FDA-authorized COVID-19 tests. HHS cited the Public Readiness and Emergency Preparedness Act as precluding them, “We are focusing on molecular tests where you collect samples and send them to a lab for processing. Many independent pharmacies just don’t have the resources to do that.”

The need for pharmacy testing is clear, especially as flu season approaches. Influenza and COVID-19 share multiple signs and symptoms. Pharmacists cannot practically identify one for treatment without ruling out the other. Respiratory syncytial virus is another potential confounder.

“The diseases are so similar in presentation that you want to be able to test for all three to advise the best course of action,” said Hannah Fish, PharmD, CPHQ, associate director for strategic initiatives at the NCPA. “We are seeing some of that preparation already taking place in pharmacies. We need clarification on pharmacists’ ability to offer testing and to bill for tests.”

For references, visit drugtopics.com.

**RELIABLE TESTING REMAINS IN QUESTION**

The reliability of existing tests is another consideration. The FDA released independent evaluations of 5 COVID-19 serological tests in early June, including 1 that had been voluntarily withdrawn from the market. Among the marketed tests, positive predictive values ranged from 100% to 63.7%. Negative predictive values ranged from 100% to 99.5%.

AmerisourceBergen is not distributing any of them.

“We just haven’t been comfortable with the accuracy of tests that have been FDA approved, so we are not distributing them,” said Rich Tremonte, executive vice president and president of community and specialty pharmacy at AmerisourceBergen. “We know that some of our independent pharmacy customers are administering tests and some of our chain customers are doing testing. They are focusing on molecular tests where you collect samples and send them to a lab for processing. Many independent pharmacies just don’t have the resources to do that.”

The need for pharmacy testing is clear, especially as flu season approaches. Influenza and COVID-19 share multiple signs and symptoms. Pharmacists cannot practically identify one for treatment without ruling out the other. Respiratory syncytial virus is another potential confounder.

“The diseases are so similar in presentation that you want to be able to test for all three to advise the best course of action,” said Hannah Fish, PharmD, CPHQ, associate director for strategic initiatives at the NCPA. “We are seeing some of that preparation already taking place in pharmacies. We need clarification on pharmacists’ ability to offer testing and to bill for tests.”

For references, visit drugtopics.com.

**RELIABLE TESTING REMAINS IN QUESTION**

The reliability of existing tests is another consideration. The FDA released independent evaluations of 5 COVID-19 serological tests in early June, including 1 that had been voluntarily withdrawn from the market. Among the marketed tests, positive predictive values ranged from 100% to 63.7%. Negative predictive values ranged from 100% to 99.5%.

AmerisourceBergen is not distributing any of them.

“We just haven’t been comfortable with the accuracy of tests that have been FDA approved, so we are not distributing them,” said Rich Tremonte, executive vice president and president of community and specialty pharmacy at AmerisourceBergen. “We know that some of our independent pharmacy customers are administering tests and some of our chain customers are doing testing. They are focusing on molecular tests where you collect samples and send them to a lab for processing. Many independent pharmacies just don’t have the resources to do that.”

The need for pharmacy testing is clear, especially as flu season approaches. Influenza and COVID-19 share multiple signs and symptoms. Pharmacists cannot practically identify one for treatment without ruling out the other. Respiratory syncytial virus is another potential confounder.

“The diseases are so similar in presentation that you want to be able to test for all three to advise the best course of action,” said Hannah Fish, PharmD, CPHQ, associate director for strategic initiatives at the NCPA. “We are seeing some of that preparation already taking place in pharmacies. We need clarification on pharmacists’ ability to offer testing and to bill for tests.”

For references, visit drugtopics.com.
Microbiome Research Calls for Due Diligence in Pharmacy

By Joan Vos MacDonald

Why are some individuals prone to developing certain health conditions? Why do some have a more robust immune system than do others? These are only 2 of the many questions that research into the microbiome—the complex community of bacteria, fungi, and viruses that live in and on the human body—may answer.

Microbiome studies, the latest wave of health research, explore the role of the microbiome in a host of chronic conditions and examine how it affects metabolism, regulates the immune system, and protects against pathogens. “Over 2000 years ago, Hippocrates, the father of medicine, said all disease begins in the gut,” said Suzanne Keyes, PharmD, IFMCP, FACA, of Keyes Compounding and 180 Wellness in Elk City, Oklahoma. “Now, with advances in medical technology, in testing and analysis, we can see that link clearly.”

Emerging Therapeutic Areas

Currently hundreds of pharmabiotics companies are engaged in more than 650 active research programs. At least 3 companies have microbiome-related treatments in the trial phase. The first microbiome-targeted products likely to win FDA approval are expected to be treatments for skin or gastrointestinal (GI) conditions.

“Emerging therapeutics are following the path of least resistance in terms of access to the therapeutic area and the regulatory path,” said Sandrine Miller-Montgomery, PharmD, PhD, executive director of the Center for Microbiome Innovation and professor of practice, bioengineering, at the Jacobs School of Engineering, University of California, San Diego. “In terms of therapeutic areas, skin diseases have quite a significant amount of product in development; the same is true for GI diseases. What will likely lag behind in reaching the market are therapeutics targeting organs. The notable exception will likely be in the cancer field, as it is starting to be well documented that microbes play a significant role in the effectiveness [of and] responsiveness to chemotherapy.” Research suggests that modulating the gut microbiome may help boost the immune system in patients with cancer and also reduce the adverse effects of some cancer treatments.

Antibiotics: A Path to Resistance

The balance of the microbiome is vulnerable to a variety of factors, including medication and environmental exposure. One example is overexposure to antibiotics. “According to the latest statistics in 2017, the average 2-year-old has had 3 rounds of antibiotics,” said Keyes. “By the time a child is 17, they’ve had 21 rounds of antibiotics.”

Prolonged or frequent antibiotic use can lead to an increase in the number of antibiotic-resistant microbes. Individuals who frequently take antibiotics for an underlying condition are often prone to recurrent Clostridoides difficile infections, which damage the lining of the large intestine, causing diarrhea. Such infections affect half a million Americans every year.

A proposed donor stool therapeutic uses microbes to help restore a healthy microbiome balance, enabling the gut to fight the infection. Ferring Pharmaceuticals’ nonantibiotic therapeutic RBX2660 is currently in phase 3 clinical development for the prevention of recurrent C. difficile infections. Fecal transplants may one day also play a role in correcting the microbiome imbalance, which has been suggested as a possible link to obesity and diabetes.

Gaps in Research, Development

In the past 2 decades, microbiome research has accelerated thanks to less

Prepare to counsel patients on microbiome-related products.

Suzanne Keyes, PharmD, IFMCP, FACA

“At the end of the day, the gut microbiome will be key in how we identify disease, monitor progression, and ultimately treat disease.”
Microbiome Research Calls for Due Diligence in Pharmacy  /  CAREER

invasive sampling techniques and more efficient means of analysis. But development of microbiome-based treatments remains complicated. Not only is an individual’s microbiome unique, but it also features trillions of organisms, making the determination of cause-and-effect relationships difficult. Sequencing an individual’s microbiome as a diagnostic tool has become increasingly popular, but it may not always provide useful information.

“Although there are some companies that have taken advantage of this market need, they are still not offering true insights, as we are still in the observation phase when it comes to understanding the microbiome,” said Miller-Montgomery. “Sure, we have made humongous leaps in better understanding at the population scale the diversity of a microbiome profile, but translating this into something that works at the individual level despite the claims of some service providers—we are surely not there yet.”

For references, visit drugtopics.com.

Although patients may ask pharmacists to recommend a probiotic supplement, it’s not a 1-size-fits-all remedy. Probiotic products sold as dietary supplements don’t require FDA approval, so quality may vary. Products also contain different strains, the most common being Lactobacillus, Bifidobacterium, Saccharomyces, Streptococcus, Enterococcus, Escherichia, and Bacillus.5

“Make sure to stock probiotics that you trust are stable and have data to show that they are still active once they get to the small intestine and the colon,” said Melody Hartzler, PharmD, PhD associate professor of pharmacy practice at Cedarville University School of Pharmacy in Ohio. “There are some commercial products that have been shown in multiple clinical trials to have benefits. Find those products that you know are backed by good research and are strain specific to conditions you would recommend them for.

“The other thing you need to think about when you talk about probiotics is prebiotics. Prebiotics are the food that grows the good bacteria, so if we take probiotics and we don’t eat any fiber, it’s not going to be as helpful to our microbiome as [also] eating prebiotic fibers in our diet. People who don’t get enough in their diet…may need a prebiotic supplement. Some probiotics are mixed with prebiotics.” However, the effects of probiotics are usually not permanent. “When you take a probiotic, you take them every day,” said Suzanne Keyes, of Keyes Compounding and 180 Wellness. “The growth that is happening is very short lived.”

Studies investigating soil microbes suggest the effect of these microbes may last longer, said Hartzler. The effects of fecal microbe transplants may also be permanent. “Fecal transplants are definitely a big area of research, but there are 2…high-dose probiotics that are already available for doctors to prescribe: VSL#3 and Visbiome,” said Hartzler.

Although pharmacists may not yet encounter a slew of microbiota-targeted medications, they can help patients achieve and maintain a healthier microbiome by exercising antibiotic stewardship, recommending probiotics, and encouraging a healthier lifestyle.

“Diversity of your microbiome is key, and commercially available probiotics usually [comprise] only a few strains,” said Sandrine Miller-Montgomery, of the Center for Microbiome Innovation. “So it will always remain crucial to eat a diverse diet and include a large variety of fermented food as well. Although pharmacists—and I am one by training—are always looking forward to providing a miracle pill to their patients, they need to keep in mind that having a healthy microbiome at the individual level starts with advising patients to have a good quality of life: a diverse and nutritious diet, quality sleep, appropriate amount of exercise, and a stress reduction practice.”
Why stop at the last page?

Visit Drug Topics® online. The magazine in your hands is only the beginning. Breaking news, topic centers, event coverage and engaging partner content make drugtopics.com an ideal resource for the smart pharmacist.
Since Governor Charlie Baker of Massachusetts issued a stay-at-home advisory in response to the coronavirus disease 2019 pandemic, UMass Memorial Health Care in Worcester, Massachusetts, has dispensed more than 5000 medications to patients and employees using its curbside prescription service.

The top 3 medications filled are those for blood pressure, cholesterol, and acid reflux, said Jackie Breeds, PharmD, RPh, pharmacy supervisor at the health system.

UMass Memorial offers the service at 2 separate locations, both in downtown Worcester. Patients and employees start the pickup process by entering an order in the patient portal or calling the pharmacy team, said Breeds. In either case, they are prompted to call the pharmacy team to schedule a pickup and discuss paying co-pays by credit card or cash.

A pharmacy order takes approximately 2 hours to fill, although the turnaround time can depend on the current volume of prescription requests; Mondays are the busiest days, Breeds said. Patients park in 1 of 2 designated parking spots at each location, and a sign instructs them to call the pharmacy. The pharmacy staff captures information about the make, model, and color of the patient’s or employees’ car, which makes identifying them easier. The staff also verifies their birthdate to ensure the individual is getting the correct medication. The staff typically brings out the medications within 3 to 5 minutes.

“[Staffers] stay far back from the car window,” said Breeds. “They don’t want to sneak up on people. They wait until [the person] unrolls their window.” Staffers are required to wear masks, she added, and they use hand sanitizer upon reentering the building.

When a medication order is generated, a pharmacy staffer bills insurance and determines the patient co-pay. If they come across any formulary issues, they call the patient’s doctor to make changes or ask questions.

Some of UMass Memorial’s pharmacy techs have been furloughed. The staffers bringing medications to patients’ cars are typically recent nursing school graduates and medical assistants from clinics with reduced patient volume, said Neil Gilchrist, PharmD, BCPS, DPLA, senior director of pharmacy services. Nonpharmacy tech employees can serve in these roles during the state of emergency declared by Governor Baker on March 10. For opioid-based medications, the prescribing physician sends the order to UMass Memorial electronically, said a health-system spokesperson. The pharmacy staff tells the patient that they’ll need to show photo identification at pickup. During pickup, the staff verifies the patient’s birthdate and photo to ensure the correct individual receives the medication.

Because of the positive response from patients and employees, many of whom have been working remotely during the pandemic, UMass Memorial is considering continuing the program when the health system returns to steady-state operations.

“Staffers stay far back from the car window. They don’t want to sneak up on people.”

Jackie Breeds, PharmD, RPh

“The staffers bringing medications to patients’ cars are typically recent nursing school graduates and medical assistants from clinics with reduced patient volume.”

Neil Gilchrist, PharmD, BCPS, DPLA
Go to Bat for Patients in Need

My elderly patients always remark on my ability to communicate with them. They tell me that I speak loudly and clearly and enunciate, that I never mumble.

My grandpa, a blacksmith, was “stone deaf.” I remember speaking, loudly and clearly, into his Beltone hearing aid that he kept in his shirt pocket, the wires running up to his left ear. I learned that if I wanted Grandpa to understand me, I had to speak and enunciate. I’ve applied this tactic when counseling many of my elderly patients, and it has never failed me—except for 1 patient.

“Dave,” a 75-year-old, longtime patient with type 2 diabetes, is hearing impaired. He came into my pharmacy after his wife, also hearing impaired, called me about issues concerning her husband’s insulin injections. We had recently switched him from the expensive brand-name pen needles to a generic. We discussed the need for such cost savings; she said it was not the needles but the pens. Insulin glargine (Lantus Solostar) pens have been around for years, and I thought I’d misunderstood. Dave and his wife lived a mere 2 blocks from the pharmacy, so I asked whether I could speak with her husband in person.

Dave visited the pharmacy, his box of Lantus Solostar pens in tow. Keeping an 8-ft distance between me and himself, Dave requested that I take off my mask so he’d be able to read my lips. I complied, and he then explained that he was struggling with his new devices and that he wanted the “old” insulin pens he had used previously. After analyzing his file, I found an order for insulin degludec (Tresiba FlexTouch) pens that were formulario last year. Dave’s dexterity issues made the Solostar pens problematic, but he was able to work the Tresiba FlexTouch and get accurate dosing. Mystery solved! I called his physician’s office to explain what Dave needed.

The office sent a new order for Tresiba, which needed a prior authorization from the insurance company. I provided the details and even a script of what to say, and the office sent a prescription for Toujeo (glargine)—the same device. Five days later, I was notified that Dave’s prescription hadn’t been authorized. He has 2 insurance providers for Medicare D, both of which had not given permission to fill insulin. Concerned, I called both providers, and they informed me that the physician’s office hadn’t responded to them. As I left another message with the physician’s office, my patience was wearing thin. “For God’s sake, he needs insulin, not some monoclonal antibody,” I remember muttering.

I called the secondary insurance, PACE, a state prescription assistance program funded by the Pennsylvania Lottery. PACE told me that the primary must pay first. Frustrated and concerned for my patient, I pleaded my case for Dave. The provider gave me the perfunctory apology but no action.

Two days later, I received a call from PACE, asking for Pete. Dave’s wife, who’d just called the PACE representative, instructed her to ask for me. Again, I described Dave’s situation.

“I get it, you have rules. But how can I be the only person here [who cares about their patients]? The primary insurance doesn’t care, the physician’s office doesn’t care, and your organization doesn’t seem to care either,” I told her.

I suggested that a PACE representative visit my pharmacy to witness the desperation felt by our patients when insurance companies and pharmacy benefit managers (PBMs) deny the medications they need. Seemingly convinced, she told me she would consult the next level of PACE management.

About 1 hour later, the PACE rep called and assured me that she’d secured authorization for a 1-year approval of Dave’s insulin. I immediately filled Tresiba for a 90-day supply, barely breaking even, but Dave’s ear-to-ear smile and thumbs-up were compensation enough for me. I just hope that pharmacists’ judgment can soon be a contributing factor in pharmacotherapy decisions made by PBMs and insurance companies. For now, it was just nice to win one.

IN MY VIEW

By Peter A. Kreckel, RPh

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.
Selpercatinib for NSCLC and Thyroid Cancer With RET Mutations or Fusions

By Lisa M. Holle, PharmD, BCOP, FHOPA, FISOPP

On May 8, 2020, the FDA granted accelerated approval to selpercatinib (Retevmo; Eli Lilly and Company).1 Selpercatinib is now indicated for (1) adults with metastatic RET-fusion–positive non–small cell lung cancer (NSCLC), (2) adults and pediatric patients 12 years or older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, and (3) adults and pediatric patients 12 years and older with advanced or metastatic RET-fusion MTC who require systemic therapy and who are refractory to radioactive iodine. Selpercatinib inhibits wild-type RET and multiple mutated forms of RET as well as VEGFR1/3 to ultimately inhibit tumor cell proliferation promoted by these pathways.2

Efficacy
Accelerated approval of selpercatinib stemmed from results of the multicenter phase 1/2 LIBRETTO-001 trial (NCT03157128), which evaluated selpercatinib in patients with RET-driven cancer.3 The trial enrolled both treatment-naïve and heavily treated patients with solid tumors, including those with RET fusion-positive NSCLC (n = 144) and MTC (n = 27) and RET-mutant MTC (n = 143). The primary end point of overall response rate (ORR; complete and partial responses) was 85% (95% CI, 70-94) of patients with treatment-naïve RET fusion-positive NSCLC; in treatment-experienced patients, the ORR was 64% (95% CI, 54-73). The ORR was 73% (95% CI, 62-82) in treatment-naïve patients with RET-mutant MTC versus 69% (95% CI, 55-81) in treatment-experienced patients. In those with RET fusion–positive MTC, the ORR was 100% (95% CI, 63-100) in treatment-naïve patients and 79% (95% CI, 54-94) in experienced patients. The median duration of response has not yet been reached for most of these patients. Selpercatinib is also effective in patients with RET fusion–positive NSCLC and measurable brain metastases, with a reported central nervous system ORR of 91% and a duration of response of 6 months or longer.

Safety
The most common adverse reactions (>25%) were dry mouth, diarrhea, hypertension, fatigue, edema, rash, and constipation. Common laboratory value abnormalities (>25%) included level increases in aspartate aminotransferase, alanine aminotransferase, glucose, alkaline phosphatase, cholesterol, and creatinine and decreases in leukocytes, albumin, calcium, platelets, and sodium.2 Because of these adverse events, routine monitoring of liver function enzymes at baseline, every 2 weeks during the first 3 months, and then monthly thereafter, and monitoring of blood pressure at baseline, after week 1, and monthly thereafter are recommended. Patients are also at risk for QTc prolongation, so monitoring of electrolyte and thyroid stimulating function levels at baseline and periodically is also recommended. Additionally, because selpercatinib can inhibit VEGFR, hemorrhage and impaired wound healing can occur. Drug-drug interactions can occur with acid-reducing drugs, strong and moderate cytochrome P450 (CYP) 3A4 inhibitors and inducers, and CYP2C8 and CYP3A substrates. Practitioners should avoid each of these if possible; otherwise, they may need to dose-adjust.

Dosage and Cost
Dosing is based on weight; for patients 50 kg or greater, the dose is 160 mg by mouth daily. For those less than 50 kg, the dose is 120 mg by mouth daily.2 A 40-mg capsule costs $137.33, and an 80-mg capsule costs $206.4.

Patients may take selpercatinib with or without food. Dose adjustments are recommended for severe hepatic impairment, adverse drug reactions, and some drug interactions.4

References
SELLING YOUR PHARMACY?
WHAT YOU DON’T KNOW CAN LOWER YOUR SALE PRICE.

EXPERTISE
Work with a licensed and insured broker, who has personally sold and closed over 140 pharmacy transactions in 42 states.

ADDED VALUE
Our proven, confidential, proprietary process means a higher price, less stress and lower risk for you.

FREE CONSULTATION
Call 888.808.4774 before disclosing any information to a potential buyer.

Daniel J. Lannon, RPh, Broker
Representing pharmacy owners nationwide.

Call 888.808.4RPH (4774)
Text 651.769.4932
Email dan@pharmacycbs.com
Web pharmacycbs.com

CREATE FUTURE VALUE.
Call today for a free Cost of Goods Sold-Profit Analysis.

For information, email Eric Temple-Morris at ETemple-Morris@mmhgroup.com

Content Licensing for Every Marketing Strategy

Marketing solutions fit for:
Outdoor
Direct Mail
Print Advertising
Tradeshow/POP Displays
Social Media
Radio & TV

Leverage branded content from Drug Topics to create a more powerful and sophisticated statement about your product, service, or company in your next marketing campaign.
Contact Eric Temple-Morris to find out more about how we can customize your acknowledgements and recognitions to enhance your marketing strategies.

© 2020 Pharmacy Consulting Broker Services.
Selling Your Pharmacy?
Maximize Your Value
Minimize Your Worry

HAYS LIP & ZOST
Pharmacy Sales Experts Ready to Help You!

www.RxBrokerage.com

Tony Hayslip, ABR/AREP
713-829-7570
Tony@RxBrokerage.com

Ernie Zost, RPH
727-415-3659
Ernie@RxBrokerage.com

Call Hayslip & Zost Pharmacy Brokers LLC for a free consultation. We have helped hundreds of independent pharmacy owners nationwide get the maximum value for their pharmacies. For more information about us, please visit our website.

MARKETPLACE CAN WORK FOR YOU!
We represent independent pharmacies, leveraging our buying power to help them access pharmaceuticals at the best prices.

To evaluate and compare your current price file for free, please write to us at info@OmegaRxGroup.com

Contract negotiations and vendor relationship management
Analytical Reporting

www.OmegaRxGroup.com