Care at the Counter
WOMEN’S HEALTH IN THE PHARMACY

DIABETES
Point-of-Care Testing for HbA1c

CAREER
The Women of Pharmacy

TOTAL PHARMACY
Drug Price Distortions

DRUGTOPICS.COM
MAY 2022 VOL. 166 NO. 5

Inside Cannabis Pharmacy
Are adults in your pharmacy at increased risk for invasive pneumococcal disease (IPD)?

Indications and Usage

VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.

**VAXNEUVANCE** is an option for pneumococcal vaccination in a broad range of patients at increased risk, including older adults, adults with chronic medical conditions or behavioral risk factors, and certain immunocompromised adults.b

A strong immune response to 15 *S. pneumoniae* serotypes, including noninferior immune responses for the 13 serotypes shared with PCV13, and

**62%** higher immune response1,a than PCV13 against serotype 3—the leading cause of IPD in the US1

Study Design: Double-blind, active comparator-controlled study in which pneumococcal vaccine-naïve participants 50 years of age and older were randomized to receive either VAXNEUVANCE (N=604) or PCV13 (N=601). VAXNEUVANCE also elicited superior immune responses for 2 unique serotypes, 22F and 33F, vs PCV13.

*a GMT ratio vs PCV13: 1.62 (95% CI: 1.40-1.87).

*b For example, adults aged 65 years or older; those with diabetes, chronic heart disease, chronic lung disease, or chronic liver disease; smokers or those with alcoholism; or adults living with HIV.

Randomized controlled trials assessing the clinical efficacy of VAXNEUVANCE compared to PCV13 have not been conducted.

Select Safety Information

Do not administer VAXNEUVANCE to individuals with a severe allergic reaction (eg, anaphylaxis) to any component of VAXNEUVANCE or to diphteria toxoid.

Some individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE.

Pneumococcal Serotypes

The polysaccharide capsule of *S. pneumoniae* forms the basis for classifying pneumococci by serotypes and antibody-mediated responses are unique to each serotype.2,3 One hundred *S. pneumoniae* serotypes had been documented as of 2020, but fewer serotypes cause most pneumococcal infections.3
Select Safety Information (continued)

The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age were: injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%), and arthralgia (12.7%).

The most commonly reported solicited adverse reactions in individuals 50 years of age and older were: injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%), and arthralgia (7.7%).

Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

Please read the adjacent Brief Summary of the Prescribing Information.

PCV13, 13-valent pneumococcal conjugate vaccine.

References:

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ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age were injection-site pain (75.8%), fatigue (54.6%), headache (26.9%), injection-site swelling (21.7%), injection-site erythema (15.1%) and arthralgia (12.7%).

The most commonly reported solicited adverse reactions in individuals 50 years of age and older were injection-site pain (66.8%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%) and arthralgia (7.7%).

Safety Assessment in Clinical Studies

The safety of VAXNEUVANCE was assessed in 7 randomized, double-blind clinical studies conducted in the Americas, Europe, and Asia Pacific, in which 5,630 adults 18 years of age and older received VAXNEUVANCE and 1,808 adults received Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Pneumococcal CRM®_197 Protein]). In Studies 1-3 (NCT03950622, NCT03950856, and NCT04038763), a total of 3,032 adults 50 years of age and older with no history of pneumococcal vaccination received VAXNEUVANCE and 1,154 participants received Prevnar 13. In Study 4 (NCT03547167), adults 18 through 49 years of age with no history of pneumococcal vaccination, including individuals with increased risk of developing pneumococcal disease, received VAXNEUVANCE (N=1,134) or Prevnar 13 (N=378), followed by PNEUMOVAX 23 six months later. In Study 5 (NCT02573181), adults 65 years of age and older previously vaccinated with PNEUMOVAX 23 (at least 1 year prior to study entry) received VAXNEUVANCE (N=127) or Prevnar 13 (N=126). In Study 6 (NCT03615482), adults 50 years of age and older received VAXNEUVANCE concomitantly with a seasonal inactivated quadrivalent influenza vaccine (Fluarix Quadrivalent; QIV) Group 1, N=600; or nonconcomitantly 30 days after QIV (Group 2, N=585). In this study population, 20% of individuals had a history of prior vaccination with PNEUMOVAX 23. In Study 7 (NCT03480082), HIV-infected adults 18 years of age and older received VAXNEUVANCE (N=152) or Prevnar 13 (N=150), followed by PNEUMOVAX 23 two months later.

The clinical studies included adults with stable underlying medical conditions (e.g., diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease), received VAXNEUVANCE (N=1,134) or Prevnar 13 (N=378), followed by PNEUMOVAX 23 six months later. In Study 5 (NCT02573181), adults 65 years of age and older previously vaccinated with PNEUMOVAX 23 (at least 1 year prior to study entry) received VAXNEUVANCE (N=127) or Prevnar 13 (N=126). In Study 6 (NCT03615482), adults 50 years of age and older received VAXNEUVANCE concomitantly with a seasonal inactivated quadrivalent influenza vaccine (Fluarix Quadrivalent; QIV) Group 1, N=600; or nonconcomitantly 30 days after QIV (Group 2, N=585). In this study population, 20% of individuals had a history of prior vaccination with PNEUMOVAX 23. In Study 7 (NCT03480082), HIV-infected adults 18 years of age and older received VAXNEUVANCE (N=152) or Prevnar 13 (N=150), followed by PNEUMOVAX 23 two months later.

The safety assessment was conducted as follows: 72.3% were White, 9.9% were Asian, 8.1% were Black, 3.0% were Hispanic or Latino ethnicity. In all studies, safety was monitored using a Vaccination Report Card (VRC) for up to 14 days postvaccination. Study investigators reviewed the VRC with the participants 15 days postvaccination to ensure consistency with protocol definitions.

The analyses presented in Tables 1-3 below reflect the information based on the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination. The table represents the final assessment by the study investigators upon follow-up up to 14 days postvaccination.
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### Table 1: Percentage of Participants with Solicited Local and Systemic Adverse Reactions in Pneumococcal Vaccine-Naïve Adults 18 to 49 Years of Age With or Without a History of Pneumococcal Infection

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE (%)</th>
<th>Prevnar 13 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>55.1</td>
<td>55.1</td>
</tr>
<tr>
<td>Erythema</td>
<td>0.8</td>
<td>0.8</td>
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<tr>
<td>Swelling</td>
<td>14.2</td>
<td>6.3</td>
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<tr>
<td>Systemic Reactions</td>
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<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>18.1</td>
<td>19.0</td>
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<tr>
<td>Headache</td>
<td>13.4</td>
<td>15.9</td>
</tr>
<tr>
<td>Myalgia</td>
<td>15.7</td>
<td>11.1</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>5.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Fever</td>
<td>&gt;38.0°C and &lt;38.5°C</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>≥38.5°C and &lt;39.0°C</td>
<td>0.0</td>
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<tr>
<td></td>
<td>≥39.0°C</td>
<td>0.0</td>
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</tbody>
</table>

### Table 2: Percentage of Participants with Solicited Local and Systemic Adverse Reactions in Pneumococcal Vaccine-Naïve Adults 65 Years of Age and Older

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE (%)</th>
<th>Prevnar 13 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>83.5</td>
<td>84.0</td>
</tr>
<tr>
<td>Erythema</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>28.8</td>
<td>18.7</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>21.7</td>
<td>19.0</td>
</tr>
<tr>
<td>Headache</td>
<td>15.7</td>
<td>11.1</td>
</tr>
<tr>
<td>Myalgia</td>
<td>13.4</td>
<td>15.9</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7.7</td>
<td>8.7</td>
</tr>
<tr>
<td>Fever</td>
<td>&gt;38.0°C and &lt;38.5°C</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>≥38.5°C and &lt;39.0°C</td>
<td>0.0</td>
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<tr>
<td></td>
<td>≥39.0°C</td>
<td>0.0</td>
</tr>
</tbody>
</table>

### Table 3: Percentage of Participants with Solicited Local and Systemic Adverse Reactions in Adults 65 Years of Age and Older with Previous Pneumococcal Vaccination (Study 5)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE (%)</th>
<th>Prevnar 13 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>75.8</td>
<td>75.8</td>
</tr>
<tr>
<td>Erythema</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Swelling</td>
<td>10.9</td>
<td>10.9</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>21.7</td>
<td>21.7</td>
</tr>
<tr>
<td>Headache</td>
<td>18.7</td>
<td>18.7</td>
</tr>
<tr>
<td>Myalgia</td>
<td>15.7</td>
<td>15.7</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>8.7</td>
<td>8.7</td>
</tr>
<tr>
<td>Fever</td>
<td>&gt;38.0°C and &lt;38.5°C</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>≥38.5°C and &lt;39.0°C</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>≥39.0°C</td>
<td>0.0</td>
</tr>
</tbody>
</table>

### Nonclinical Toxicology

Carcinogenesis, Mutagenesis, Impairment of Fertility

VAXNEUVANCE has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility in animals. VAXNEUVANCE administered to female rats had no effect on fertility.

### Patient Counseling Information

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Discuss the following with the patient:
- Provide the required vaccine information to the patient.
- Inform the patient of the benefits and risks associated with vaccination.
- Inform the patient that vaccination with VAXNEUVANCE may not protect all vaccine recipients.
- Instruct the patient to report any serious adverse reactions to their healthcare provider who in turn should report such events to the vaccine manufacturer or the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967, or report online at www.vaers.hhs.gov.

For more detailed information, please read the Prescribing Information. uspi-v114–2107000

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Women’s Health is Everyone’s Health

It has long been known that women are the primary health care decisions makers for their families. According to the Harvard Business Review, a survey of over 9000 global respondents found that health care consumers are “overwhelmingly female,”¹ and data released by the United States Department of Labor indicate that women—mothers in particular—make approximately 80% of health care decisions for their children, and are more likely to be the caregiver if those children are ill.²

But despite these statistics, women are frequently overlooked in the health care system. In this month’s issue, we shine a spotlight on women’s health care in the pharmacy, sharing suggestions for the types of services that pharmacists can provide to the women in their communities, including contraception access, menstrual pain management, and routine vaccinations. Turn to page 18 to read the full story.

Elsewhere in this issue, learn more about some of the women changing pharmacy practice for the better. Their hard work and dedication to their communities is a testament to the talent that exists throughout the pharmacy profession.

As always, thank you for reading.

Mike Hennessy Jr
President and CEO

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As of February 2022, 37 states permit the use of medical cannabis products. These products are used to treat a variety of medical conditions, including cancer, epilepsy, glaucoma, and chronic pain. 

Cannabis, however, is still illegal on the federal level, so each state can determine if and how medical cannabis is available. For example, in New York state, dispensaries must have a licensed pharmacist on-site to counsel patients on the treatments available to them.

On a recent episode of Inside the Practice, Jeff Lombardo, PharmD, a Drug Topics editorial advisory board member and a research assistant professor at University at Buffalo School of Pharmacy and Pharmaceutical Sciences, joined us to discuss the ins and outs of working in cannabis pharmacy in New York.

Drug Topics: Do pharmacists need a more comprehensive education to inform them about the medical benefits of cannabis and the endocannabinoid system?

Jeff Lombardo, PharmD: Pharmacists can draw on their pharmacology training. If you look at the endocannabinoid system, it’s a system. And if you look at the way that cannabinoids work… I equate it to the way that some blood pressure medications (work), with binding affinities with cannabinoid receptors—CB1, CB2; [it’s] very similar to β-blockers.

If you think about it in that context, I think you’ll want more information on how cannabinoids work. There are some good journals out there; Cannabis and Cannabinoid Research is one of the better ones, somewhat evidence-based and has some really good articles. Another thing that pharmacists can do is...look at some of the research for various indications. Read through the abstracts, read through the design. That gives a better understanding of how cannabinoids may be beneficial in certain patient populations. If you focus on the pharmacology, that’s a good place to start.

Is the sentiment toward medical cannabis changing? Might that impact the role of pharmacists at dispensaries?

I think sentiment is changing, thought is changing. I go back to the pharmacology question: defining how the compounds are working in the body. You have this endocannabinoid system that we’re just learning about. I think education and good solid research, conferences, seminars to talk about it [are] a good thing.

CBD [cannabidiol] falls under the Farm Bill, but still, federally, it’s Schedule I. A lot of the academic institutions face this problem. We have funding from NIH [National Institutes of Health], and we don’t want to jeopardize that funding. But when some of those regulations change a little bit...you can do some of the prospective, randomized controlled trials and really answer the question in a way scientifically that evidence-based practitioners want to know.

If cannabis goes recreational—which it is in New York state—there [will be changes]. I don’t know what’s going to happen...Maybe cannabinoids move into the pharmacy. You’ve heard about Epidiolex; it’s an islet CBD, [and] it’s a specialty pharmacy drug. It’s in the pharmacy. If other companies go through the same [approval] pathway, you’ll see those medications moved from a dispensary to a pharmacy. They’ll be covered by insurance, and they’ll be much more economical. That’s a funny question, as far as pricing...But it could be covered on a patient’s [insurance] benefits. That’s where I think you might see the change. Maybe not tomorrow, but maybe in a couple of years.

For references, visit drugtopics.com.
If your pharmacy does not yet provide point-of-care testing services, the prospect of adding these offerings can seem daunting. This month, Drug Topics® spoke with 2 pharmacists offering hemoglobin A₁c (HbA₁c) testing, who break down the point-of-care process into attainable steps.

**Prepare and Train**
Before embarking on any point-of-care services journey, Nicole C. Pezzino, PharmD, BCACP, CDCES, associate professor of pharmacy practice, director of community outreach and innovation, and director of the postgraduate year 1 Community Pharmacy Residency Program at Wilkes University Nesbitt School of Pharmacy in Wilkes-Barre, Pennsylvania, and a pharmacist at Weis Markets, recommends that pharmacists look first at state law. A Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver is always necessary for point-of-care testing, but in Pennsylvania, where Pezzino practices, a lab license is also necessary.

Pezzino’s pharmacy already had an accredited diabetes self-management education and support (DSMES) program and a CDC-recognized diabetes prevention program. Because these programs already required routine blood glucose monitoring, adding HbA₁c testing was a no-brainer, Pezzino explained. Weis Pharmacy began with an employee diabetes monitoring program called Live Well With Weis. After the success of the employee program became apparent, Pezzino began to expand HbA₁c testing services to pharmacy patients.

Pezzino works under a protocol from a local physician and suggested that other pharmacists do the same by finding a physician with whom they have a good relationship. If this is an issue, “there are many protocol companies that you can employ to sign the protocol for you,” she said, adding that “physicians are generally very receptive to participating.” The protocol outlines when the test can be ordered, what to do with the results, and how frequently the pharmacist will communicate with the health care provider. And because all employees who perform tests must be trained, Pezzino and her staff check both fasting blood glucose and HbA₁c. “We address blood glucose in real time,” she said. “If the patient is hypoglycemic, we give glucose tablets.” Patients who are above range are referred to the DSMES program, and patients who are critical are referred for a same-day appointment with their health care provider.

Because diabetes is one of the top 5 most prevalent chronic diseases in the United States—and one of the top 10 most expensive for payers to treat—Pezzino’s pharmacy offers HbA₁c testing as a cash-pay service. “It is convenient for patients to come in and do a quick finger stick,” she said, adding that the pharmacy also offers free blood glucose screening. “The EmbracePro meter is less than $1 per test and helps raise awareness and enroll patients in our programs.”

For HbA₁c testing, Pezzino prefers PTS Diagnostics’ A1CNow+ test kit. “Be sure you purchase the professional kit, not the single-use kit, and make sure it’s a CLIA-waived kit,” she advised. These kits can be purchased from a medical supply company. She also suggested that pharmacists check with their state and county health departments, as well as their state pharmacy association, for available grant money for point-of-care testing.

In terms of marketing these services, Pezzino has seen the greatest impact through word of mouth. But, she added, patients can also be reached through marketing channels like social media, partnerships with local gyms, and advertisements in local newspapers.

“HbA₁c testing...is a nice tool to connect patients to other services and programs and [to] help people in the community because they don’t always have access to health care.”
Get Buy-in From Patients, Support Staff

Heather Ferrarese, PharmD, is the owner and pharmacist in charge at Bartle’s Pharmacy in Oxford, New York. Her pharmacy provides HbA1c testing through an initiative from the Community Pharmacy Enhanced Services Network (CPESN). Ferrarese and her team screen eligible patients by identifying those who are late on medication refills or who have weight issues. During patient consultations, Ferrarese emphasized the need to approach patients in a way that makes them feel good. For example, Ferrarese and her staff understand that in some rural areas, such as theirs, harsh weather and bad roads can make it difficult at times to get out and exercise or to go out and buy fresh produce. “We tell patients, ‘We can do better for you. We noticed you’re a little late taking your meds.’ We phrase it as ‘We can help you’—in a nonconfrontational way—and they are willing to open up,” Ferrarese explained.

Ferrarese utilizes CPESN to find a physician to sign the protocol and to source equipment. Her team reports back to that physician and explains the results to the patient. “We calculate HbA1c back to an average blood glucose number, which makes it easier to understand. We talk about results and how to improve them... Most people are very receptive because they know we are trying to help them,” she said.

Ferrarese suggested involving support staff as much as possible. These staff members can help with identifying patients, scheduling, and outreach. “[I]t’s OK to use support staff appropriately. They are more than capable and can really help speed the process along,” she said. “It also makes them feel included in the process and that they’re making a difference, so it’s a win-win for everyone.” Another win-win, Ferrarese said, is that HbA1c testing helps decrease the pharmacy’s direct and indirect remuneration fees.

Point-of-Care Testing 101

In addition to glucose monitoring and testing for hemoglobin A1c (HbA1c), pharmacies can provide a slew of point-of-care testing services, including tests for acute infectious diseases (influenza, group A Streptococcus), chronic disease screening (HIV, hepatitis C, lipids), and chronic disease monitoring (HbA1c, international normalized ratio). A full list of Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests is available from the FDA.

Ready for launch? Follow the steps below to get your testing program off the ground:

- Enroll with the Centers for Medicare & Medicaid Services as a CLIA-waived testing site.
- Consider the logistics, including specific services, target market, team training, and advertising; costs, payment, and reimbursement options; and goals for follow-up care.
- Budget for the applicable certificate fees, paid every 2 years.
- Ensure that CLIA regulations are followed and that tests are administered according to manufacturer instructions.

Launch Point-of-Care Services With CPESN

Q: What kind of support does CPESN offer network pharmacies who want to start offering point-of-care testing services?

A: In coordination with the New York State Department of Health, CPESN NY is expanding services to patients with diabetes. We are operating on 2 main objectives: 1, expanding the pharmacist role in the care of patients with diabetes and 2, screening and identifying patients with uncontrolled diabetes (HbA1c >9%), and referring them to diabetes self-management education and support (DSMES) services or other appropriate clinical care.

We are creating a clinical protocol under a nationwide medical director...[that] allows a pharmacy to operate a [limited services laboratory] with a more diverse array of tests, [including] HbA1c. When screening a patient, a pharmacy can perform a point-of-care HbA1c test if the patient has not had this test in the last 3 months. We will also use point-of-care HbA1c testing on follow up to see if a patient has had an HbA1c reduction by attending DSMES classes or through other supportive methods or pharmacy interventions.

Chris Daly, PharmD, MBA, BCACP, is the vice president and secretary of CPESN New York, as well as a network facilitator for Upstate New York and Western New York.

Any pharmacists who are interested in providing HbA1c testing as a point-of-care service should join their state CPESN network; Ferrarese said. “There are many tools and resources available. We work smarter and pool resources,” she explained.

Although pharmacists might face challenges along the way, providing HbA1c testing is worth it. “Diabetes is the seventh leading cause of death. No matter what setting, we all treat patients with diabetes, and doing this empowers them to take care of their health,” she said. “It is one of the best things you can do for them.”

For references, visit drugtopics.com.

Karen Berger, PharmD, is a graduate of the University of Pittsburgh School of Pharmacy. Her experience includes chain and independent pharmacy and medical writing and reviewing.
Cystic fibrosis (CF) is a progressive genetic disease that causes pulmonary and digestive system issues and affects more than 30,000 children and adults in the United States and more than 70,000 individuals worldwide. CF symptoms include a persistent cough that produces thick mucus, wheezing, exercise intolerance, repeated lung infections, chronic sinusitis, intestinal blockage, and poor weight gain and growth.

Multidisciplinary teams for CF management typically include specialists like pulmonologists, gastroenterologists, palliative care specialists, respiratory therapists, nurses, social workers, dietitians, psychologists, and pharmacists who can work to improve health outcomes and patient quality of life.

Pharmacists on the Care Team

Patients with CF require a complex, life-long pharmacotherapy regimen that may include, on average, 10 medications, making pharmacists a vital member of the CF care team. Pharmacists can manage therapies that might include CF transmembrane conductance regulator protein modulators, inhaled antibiotics, bronchodilators, pancreatic enzymes, supplemental vitamins, inhaled mucolytics, and anti-inflammatories. CF is also associated with comorbidities, including diabetes, liver disease, depression, and anxiety—all of which add to a patient’s medication burden.

In 2020, the Cystic Fibrosis Foundation published the most recent consensus guidelines for managing patients with advanced CF lung disease, the most common cause of death in this population. The 22 panelists, which included pediatric, adult, and transplant pulmonologists; a gastroenterologist; a palliative care specialist; a pharmacist; a respiratory therapist; a nurse coordinator; a social worker; a dietician; a methodologist; one parent; and 2 patients with CF—met to discuss pulmonary management, comorbid condition treatment, symptom management, and psychosocial issues.

According to these guidelines, intermittent inhaled antibiotics (28 days on/off) are the standard of care for patients with CF and chronic airways infection. Pharmacists can also recommend drug dosages for a trial of continuous alternating inhaled antibiotics—generally alternating between 2 different drugs—appropriate for treatment based on bacterial pathogens identified in respiratory culture, which is one of the recommendations based on evidence demonstrating additional benefit in patients with advanced disease.

Antimicrobial resistance has become a growing concern for patients with CF and pulmonary infection. Appropriate use of antibiotic therapy is critical in this population. Ototoxicity and nephrotoxicity related to antibiotics (eg, aminoglycosides) can be monitored by pharmacists. Tobramycin is the preferred aminoglycoside in patients with Pseudomonas aeruginosa infections.

Patients with CF may also develop chronic kidney disease. Pharmacists are critical in making antibiotic renal dose adjustments to prevent toxicity. Pharmacists can also monitor patients with advanced CF lung disease who require opioid therapy for pain management for adverse effects such as respiratory depression; provide education about drug administration, storage, and proper disposal;

“Including a pharmacist who can monitor regimen effectiveness, simplify pharmacotherapy dosing schedules and ensure medication access can improve outcomes in both inpatient and outpatient settings.”
monitor bowel function for constipation prevention; and consult with pain and/or palliative care specialists. Patients with anxiety should be treated with a stepped-care model, using psychological interventions as first-line treatment and reserving short-term benzodiazepines for refractory symptoms—with close monitoring to prevent disease exacerbation and respiratory failure. Pharmacists should educate other health care providers to avoid coprescribing benzodiazepines and opioids, which interact and can lead to a drug overdose.

Medication adherence challenges in CF can lead to increased health care costs, disease complications, depression, anxiety, and hospitalizations. Studies have shown that CF medication adherence can be as low as 50%, especially in pediatric populations. Because daily administration of CF medication therapy can take between 1 and 2.5 hours, including a pharmacist who can monitor regimen effectiveness, simplifying pharmacotherapy dosing schedules and ensuring medication access can improve outcomes in both inpatient and outpatient settings.

Barriers to effective treatment can include poor motivation, suboptimal dose delivery due to inadequate training on inhalation technique, difficulty coping with CF diagnosis, poor understanding of the treatment regimen, and comorbidities.

The Role of Specialty Pharmacy

Specialty pharmacists can provide 1-on-1 patient counseling for patients and caregivers to improve adherence through hospital discharge education and follow-up. Additionally, collaborative practice agreements are an important tool for pharmacist involvement on CF multidisciplinary teams. These agreements give pharmacists the authority to change drug therapy without physician oversight to ensure there are no delays in access to care.

Patients with CF typically use multiple payers, such as primary and secondary insurances, along with specialty and mail-order pharmacies, to access medications. Because not all pharmacies stock common CF medications, therapy delays can occur. Pharmacists can assist with prior authorizations and take care of insurance-related issues to ensure that patients can access their medications in a timely manner. Pharmacists can also provide support in navigating patient assistance programs to help with CF drug therapy coverage. Compass, a personalized service provided through the Cystic Fibrosis Foundation, can assist patients with insurance issues and offer financial assistance for medical care.

More than 130 accredited CF care centers, located at teaching and community hospitals across the United States, provide comprehensive treatment programs. In addition, AllianceRx Walgreens Prime is an accredited specialty and mail service pharmacy that provides drug therapy services for CF. The AllianceRx Walgreens Prime Connected Care CF patient management program was established in 2014 and utilizes a multidisciplinary team that includes pharmacists, pharmacy technicians, patient care advocates, and insurance specialists. This team provides a range of services, including drug utilization reviews, patient counseling, medication refill reminders, drug administration and storage education, adverse effect monitoring, and financial assistance, and pharmacists receive comprehensive CF training on pharmacotherapy and disease-state management.

For references, visit drugtopics.com.

Research Spotlight

In 2019, AllianceRx Walgreens Prime partnered with Duquesne University School of Pharmacy to analyze data from patients with cystic fibrosis (CF) prescribed CF transmembrane conductance regulator (CFTR) modulator medications to examine medication adherence and the financial impact of drug therapy through a retrospective cohort study. Specialty pharmacy data were analyzed in a sample of 2548 patients from September 2017 to August 2018 for CFTR modulators including ivacaftor (Kalydeco), lumacaftor/ivacaftor (Orkambi), and tezacaftor/ivacaftor and ivacaftor (Symdeko).

The average adherence rate using proportion of days covered (PDC) for all 3 medications was 0.86, demonstrating good patient adherence. Previous studies indicated that PDC greater than 0.80 is a surrogate marker for patient adherence.

“This research validates all of the work AllianceRx Walgreens Prime’s operations team does to support these patients,” Rick Miller, MS (Pharm), MBA, BS (Pharm), CSP, vice president of clinical and professional services at AllianceRx Walgreens Prime, said in a press release. “Kudos to the respiratory team, our dedicated CF team, and all operations team members who support our CF population. The research reinforces the value of our patient management process by proving our hypothesis that the Connected Care CF program positively impacts PDC.”

Jennifer Gershman, PharmD, CPh, is a drug information pharmacist and medical writer residing in South Florida.
New career paths are appearing in pharmacy, and these career paths are digital ones. The FDA is approving growing numbers of digital products to monitor and treat patients, building on a growing acceptance of wearable products to monitor health, health apps to guide daily activities, smart pill dispensers to monitor and improve adherence, and much more.

“Technology is changing the patient journey,” said Timothy Aungst, PharmD, associate professor of pharmacy practice at the Massachusetts College of Pharmacy and Health Sciences in Worcester. “Digital health is mainstream, accelerated by the COVID-19 pandemic and telehealth. We need to catch up with digital resources, not stay tied to legacy approaches. Digital health needs digital pharmacists.”

Aungst explored ways that pharmacists can move practice into the digital world during his presentation at the American Pharmacists Association 2022 Annual Meeting & Exposition in San Antonio, Texas. 1

Digital health is hardly a new concept, he explained. Digital monitoring and mechanical health alerts have long been standard for cars and trucks in the United States. In humans, though, digital health includes a growing variety of sensors, mobile apps, telehealth applications, artificial intelligence, voice assistance, robotics, and automation. Most patients—80%, Aungst noted—already use the internet to search for health information, and 42% of adults use digital health tracking devices. The first smart toilets—to monitor urine and feces for glucose, blood, and other biomarkers—are poised to enter the market soon, he said.

“Patients have become consumers of health, and the home is becoming the center of care,” Aungst said. “We need to move away from a product-based model toward a focus on services empowered by digital technology, meeting patients where they are and adopting a consumer-first mentality. This is the future of how we will deliver care for patients.”

The broad umbrella of digital health includes multiple overlapping technologies, approaches, audiences, and uses such as:

• platforms for health care systems, clinics, and other enterprise settings, including pharmacy;
• technology platforms and support systems for clinicians and support staff;
• patient-facing products that capture, store, or transmit health related data;
• products to diagnose, guide diagnosis, or monitor patients directly; and
• products that deliver medical interventions and therapies.

When it comes to regulatory oversight, guidance varies. Most digital health platforms and products don’t require clinical evidence or regulatory oversight. Digital medicine, evidence-based software and/or hardware that measure or intervene in human health may require regulatory oversight, and digital therapeutics (DTx) that deliver evidence-based therapeutic
interventions do require regulatory oversight based on product claims of risk, efficacy, and intended use. “The goal of all this technology is to have it work in the background of our lives and only intervene when needed,” Aungst said. “We have more in our tool kit to help patients. It’s not just medications anymore.”

For example, EndeavorRx, the first FDA-cleared game, treats attention-deficit/hyperactivity disorder as an adjunct to therapy, medications, and/or education programs. Reset, the first FDA-approved prescription DTx, and Reset-O are used with pharmacologic therapy for substance use disorder and opioid use disorder. “There are other DTx products in chronic disease management, oncology, ophthalmology, and [women’s] health,” Aungst said. “We need to incorporate all of these developments into patient care within the pharmacy space.”

That means rethinking pharmacy services. Current health monitoring is intermittent—when the patient visits the pharmacy for a refill and maybe a blood pressure check. Data collection is spotty and can be subjective. Digital health integrates real-time patient monitoring to detect and treat problems at an earlier stage to improve outcomes; data collection is continuous and objective.

“Digital health is mainstream, accelerated by the COVID-19 pandemic and telehealth. We need to catch up with digital resources, not stay tied to legacy approaches. Digital health needs digital pharmacists.”

TIMOTHY AUNGST, PHARMD

Most patients with asthma do not use inhalers correctly, Aungst noted. Apps can provide real-time technique feedback to improve drug delivery and outcomes. Diabetes is similarly poised for digitally guided outcomes.

“We have the tools today and more are coming,” Aungst said. “Digital health–guided medication management is what we need to latch onto for better medication management and better outcomes.”

Just as consumers expect retail sellers to offer digital access, pharmacy patients expect a digital front door into health-related services, medications, and interactions. The pharmacy may no longer be the sole source of medications, Aungst cautioned, but pharmacy can expand as the hub of medication management and related services. Payers are already moving to digital, and pharmacists have a clear role for medication optimization.

“It’s time for us to meet patients where they are and adopt a consumer-first mentality,” Aungst concluded. “And we need to show payers that we can do this. Otherwise, we’re not going to get paid. We need data showing not just clinical impact, but data that [show] economic impact as well.”

For references, visit drugtopics.com.
Care at the Counter

WOMEN’S HEALTH IN THE PHARMACY

Pharmacists can improve quality of life for the women they care for by offering advice, education, and other point-of-care services.

By Aine Cryts
on contraceptive access just is one area in which pharmacists can help women, said Veronica Vernon, PharmD, assistant professor of pharmacy practice at Butler University College of Pharmacy & Health Sciences in Indianapolis, Indiana. Access to a pharmacist can also help women who experience menstrual disorders, including menstrual pain, irregular periods, and heavy or unusual bleeding. Access to care for women with menstrual disorders was particularly acute during the COVID-19 pandemic, noted Vernon, who is also a clinical pharmacy specialist in ambulatory care for gynecology and primary care at Richard L. Roudebush Veterans Affairs Medical Center in Indianapolis. More women than men missed recommended preventive services, including yearly checkups and routine tests, and women with low incomes were more likely to have missed these preventive health services.

A variety of factors make care access challenging for women with lower incomes, including inconsistent transportation, lack of childcare, limited insurance coverage, and a work schedule that prevents them from going to medical appointments, according to a commentary published in Pharmacy. "Equipping community pharmacies with specialized skills in family planning will increase their ability to meet patient and community needs and subsequently reduce barriers to access. Newly developed learning resources...are a bridge to successfully implementing practices [that] reduce stigma, increase patient satisfaction, and improve health outcomes," wrote the authors, one of whom was Sally Rafie, PharmD, BCPS, APH, founder of Birth Control Pharmacist and a pharmacist specialist at University of California San Diego.

Pharmacists’ Role in Women’s Health

Because 91% of Americans live within 5 miles of a community pharmacy, pharmacists are in a unique position to fill these health care gaps. "[Pharmacies] can be a public health hub in their communities," Vernon said.

Pharmacists also play a meaningful role in the inpatient environment. Kayla Popova, PharmD, a clinical pharmacist specialist in obstetrics and gynecology at Michigan Medicine in Ann Arbor, spends her days rounding with obstetrics specialists who see women with menstrual disorders and other health issues.
women with high-risk pregnancies. “It’s very important to have a pharmacist on the women’s service,” Popova said. “When a woman is pregnant, there are certain medications that can’t be taken. They’re not safe in the first trimester, but they may be safe in the second or third trimester.” And because of some women’s past medical history, taking birth control with a lot of estrogen isn’t an option because it can lead to thrombosis, added Popova, who is also an adjunct clinical instructor in pharmacy at University of Michigan.

Providing Contraceptive Access
Pharmacists face hurdles in providing access to contraception. Without a collaborative practice agreement, pharmacists can only prescribe contraceptives in 20 states. Pharmacists, however, are aware that women experience challenges accessing birth control. “We’ve all received those panic[ed] phone calls,” Rafie said.

The pharmacist’s role is to serve as a resource to patients who need birth control, Rafie explained. That includes counseling and helping patients pick the contraception method that works best for them. And in states where pharmacists can prescribe contraception, that role includes writing a prescription. “This is a public health challenge,” she said. “It’s critically important that women have autonomy over their own bodies and their own health.”

Rafie, founder of the San Diego–based Pharmacists Clinic, provides contraception and other clinical services in a community pharmacy environment. Educating patients about the pharmacist’s ability to prescribe birth control is important as well. “I definitely encourage pharmacists to make it very apparent that they’re offering this service,” she said. Education opportunities include sharing posts on social media, wearing buttons that promote the service, and using counter tents. Rafie also recommended providing a private or semiprivate space—or at least a sound barrier—to support women speaking with a pharmacist about birth control options.

Addressing Menstrual Pain
Pain, psychological complaints, and tiredness are the most common symptoms associated with menstruation, and during menstruation, 1 in 3 women refrain from daily activities due to these symptoms. When a pharmacist sees a woman browsing the menstrual pain–relief section of the pharmacy, it’s a great opportunity to approach and ask questions, Vernon said. She recommends using this conversation starter: “You’re here looking for menstrual pain relief. What are your symptoms? How long has this been occurring?”

“You’re not going to have 20 [or] 30 minutes for this conversation,” Vernon said. “But you can have a 2-minute conversation with a patient to ask a few questions and determine if there’s something more going on than menstruation…such as overlooked endometriosis.” She also recommends using this opportunity to connect the woman with a gynecologist if she doesn’t already have one. Of course, this requires doing some research in advance to develop a list of obstetricians-gynecologists.

Beyond “Bikini Medicine”
In her talk at a 2014 TEDxProvidence event, Alyson McGregor, MD, now the associate dean of faculty affairs and development at the University of South Carolina School of Medicine Greenville, discussed the mistake of merely focusing on reproduction when it comes to women’s health.

“Women’s health became synonymous with reproduction: breasts, ovaries, uterus, pregnancy.” McGregor said in her talk. “It’s this term we now refer to as ‘bikini medicine.’ And [it] stayed this way until…the 1980s, when the concept was challenged by the medical community and the public health policymakers, when they realized that by excluding women from all medical research studies, we actually did them a disservice—in that apart from reproductive issues, nothing was known about the unique needs of the female patient.”

Vernon agrees. Women’s health should also focus on tobacco-cessation management, cardiovascular health, and osteoporosis. And crucially, pharmacists must also be prepared to provide women’s health services to patients who aren’t cisgender women; transgender individuals require these services as well.

Immunizations, preventive care, medication management, and lifestyle changes are all services that pharmacists can provide. “Starting with immunization is a great way to focus on women’s health,” Vernon said. Pharmacists can ensure that all patients get their yearly flu vaccine and are up-to-date on human papillomavirus immunization as well, which prevents multiple types of cervical cancer in cisgender women and genital warts, anal cancers, and cancers of the mouth, throat, neck, and head in both women and men.

“Everything we look at in medicine is centered on a male lens,” Vernon said. Increasing awareness of these issues, in the pharmacy and beyond, is the first step to more equitable health care for everyone.

For references, visit drugtopics.com.
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CAREER

Women in Pharmacy Make Their Mark on the Profession

Three pharmacists share their stories, challenges, and lessons learned.

By Aine Cryts

Elizabeth Gooking Greenleaf blazed a trail as the first female pharmacist in the United States, opening a Boston apothecary shop in 1727—the only one helmed by a woman in the entirety of the New England colonies.

Since then, many thousands of women have joined same ranks as Greenleaf. According to the US Bureau of Labor Statistics, 57.8% of all practicing pharmacists in 2020 were women,

and data from that same year from the American Association of Colleges of Pharmacy showed that women made up 64.6% of the total number of pharmacy students enrolled in their first professional degree program.

Today, Drug Topics® shares the story of 3 women making their own mark on the industry.

Upholding a Legacy

For Zarina Jalal, PharmD, community pharmacy runs in the family. Her earliest role model was her father, who owned Lincoln Pharmacy in Albany, New York, when she was growing up.

“I was always surrounded by pharmacy,” said Jalal, who is now supervising pharmacist at Lincoln Pharmacy, which has served the Albany community since 1935 and has been owned by her family since 1988. “I’m the youngest of 3 [siblings]. When my mom needed a break, she’d drop me off at the pharmacy,” she joked.

She remembers taking countless naps in her dad’s office at the pharmacy. Today, however, her days are spent managing the team of pharmacists and pharmacy technicians.

“I always loved coming to the pharmacy and seeing what my Dad did,” she said. “I didn’t like the hours; he was always at work. Growing up, he didn’t have a backup pharmacist—he was always running the entire show.”

Although that experience gave Jalal pause when pursuing a career as a community pharmacist, she has relief help from the other pharmacists on her team. That help enabled her to spend a day recently serving as a luminary for the Community Pharmacy Enhanced Services Network (CPESN)—a clinically integrated, nationwide organization of local networks made up of individual community-based pharmacies working to empower community pharmacy practice—and helping with the Flip the Pharmacy initiative. This practice transformation initiative “aims to ‘flip’ community-based pharmacies away from point-in-time, prescription-level care processes and business models to longitudinal and patient-level care processes and business models through the use of hands-on coaching.”

That same day, Jalal also popped back into the pharmacy to give the pharmacist “a bit of a break,” coached a pharmacy technician on her team, and ended the day at a fundraiser for a local assemblyman who is also a pharmacist.

Jalal is no stranger to advocating for community pharmacy. In October 2020, she wrote an opinion piece published in Albany’s Times Union urging the New York Legislature to sign a bill regulating pharmacy benefit managers (PBMs).

“Like [then–New York Governor Andrew] Cuomo, I have followed in my father’s footsteps to a profession where I proudly serve my community,” she wrote, referring to Cuomo’s father, Mario Cuomo, who served as New York governor from 1983 to 1994. “I also grew up in my father’s shadow and take great pride in upholding my father’s legacy I want the same for my children. I want them to have the option of upholding the legacy of Lincoln Pharmacy and serving the community that has supported us for so many years.”
The American Association of Colleges of Pharmacy showed that women made up 64.6% of the total number of pharmacy students enrolled in their first professional degree program.3

New York Governor Kathy Hochul announced in January 2022 that she had signed a bill requiring the licensure and registration of PBMs.6 “This landmark law creates the most comprehensive regulatory framework in the country for [PBMs], increasing transparency for consumers and shedding light on the cost of prescription drugs,” Hochul said in a news release. “Navigating costs associated with medications and insurance can be difficult, so I am proud to sign this legislation to make it that much easier.”

Looking back on her life and career so far, Jalal said she understands the “virtue of patience.” “I’m someone who likes to see results for my actions—I want to see my results instantly,” she noted. “But you have to lay a foundation and do the groundwork. You won’t see the results immediately. It may be a year or two later.”

Passionate About Smoking Cessation
Michelle Farrell, PharmD, BCACP, grew up on a dairy farm in a small town in Wisconsin. She credits the now-retired Connie Kraus, PharmD, of University of Wisconsin Hospitals and Clinics in Madison, with inspiring her to become a pharmacist.

Today, Farrell is a pharmacist and owner of Boscobel Pharmacy in Boscobel, Wisconsin, and Center Pharmacy in Richland Center, Wisconsin. Within her practices, smoking cessation programs are one of her passions, she explained. Farrell’s mother, who was a smoker, passed away in 2006 due to lung cancer.

Farrell describes herself as a “strong tobacco-cessation advocate.” That means she actively engages in conversations with patients to get them to quit smoking. That conversation might take place when a patient shows up at her pharmacy with a prescription to address bronchitis or for chronic obstructive pulmonary disease brought on by smoking. “The copays and the drugs are adding up. The pill burden is adding up. They’re really amenable to accepting recommendations for change,” said Farrell, who’s a CPESN luminary for Wisconsin.

Her approach with patients is simple: Farrell asks, “Have you considered quitting smoking?” Often, the question prompts a longer conversation about the cost of quitting and the patient’s inability to tolerate smoking-cessation medication in the past, she explained. “That’s a great opportunity to have a conversation and immediately adjudicate a claim with their health insurer to see what’s covered and [to] get them set up for that ‘quit event,’” Farrell said.

Farrell’s advice for early-career pharmacists? “Be a sponge; soak in all the information around you,” she said. “Identify what you enjoy and what you don’t enjoy.”

Endings and New Beginnings
Brooke Kulusich followed her older sister into the pharmacist profession. “I was very inspired by her journey,” she said. “I remember how much she studied and how hard she worked—the initial semesters that she was in school and how hard they were. I really saw her persevere and grind through it.”

Kulusich is a PharmD candidate at the University of Pittsburgh School of Pharmacy in Pennsylvania, graduating in 2022. She also serves as the 2021 to 2022 American Pharmacy Association-Academy of Student Pharmacists speaker of the house.

“We had quite a bit of illness in our family,” said Kulusich about her decision to go to pharmacy school. “I watched our grandparents get sick and be in the hospital, [and] I remember how my parents would struggle to play doctor or pharmacist. I wanted to play that role as a pharmacist and help families.”

Next up for Kulusich is a job at a management consulting firm in Chicago, where she’ll be “putting the white coat away.” Kulusich will work on a team that provides strategic business advice to health plans and biotechnology companies to help them improve their sales and marketing efforts.

As she prepares to embark on that journey, Kulusich has one piece of advice for her younger self: “Step outside your comfort zone. That’s where you’ll find the most growth and meaning.”

For references, visit drugtopics.com.

Did we miss any upcoming pharmacy trends for 2022? Email your comments to libiscaldi@mjhlifesciences.com.
Flip the Pharmacy Transforms Community Practice, One Pharmacy at a Time

As payment models change, pharmacies must adapt to receive reimbursement for the services they offer. **By Lauren Biscaldi**

Navigating the future of community pharmacy practice requires pharmacists to be creative, agile, and ready to adapt. Even for those well-versed in the art of innovation, it can be challenging to keep up with the rapid changes in the health care, but initiatives like Flip the Pharmacy can help.

“Flip the Pharmacy is a practice transformation initiative that aims to ‘flip’ community-based pharmacies away from point-in-time, prescription-level care processes...to longitudinal and patient-level care processes and business models through hands-on coaching,” said Cody Clifton, PharmD, Director of Practice Transformation and Clinical Programs at Community Pharmacy Enhanced Services Network (CPESN). “The initiative focuses on identifying and adopting best practices for workflows that promote delivery of enhanced clinical services.”

Through change packages—monthly instructional guides for pharmacies—Flip the Pharmacy enables pharmacies to implement sustainable workflow changes with staff across the 4 most common community pharmacy focus areas. From there, Clifton explained, each topic area is broken down into multiple domains, ranging from leveraging the appointment-based model to optimizing technology and electronic care plans and establishing working relationships with other members of the patient’s care team.

Each of these domains, he added “[are] important to community pharmacy. It’s just as important to document the care that is provided to patients in order to show the value of patient care provided at the community pharmacy practice level.”

In the current practice environment, it can be difficult for community pharmacies to receive reimbursement for the services. “Payment models are changing, and adapting to value-based payment models is an area where community-based practice has an opportunity to provide value, and [to be] rewarded for that value [and] care that is provided to patients,” said Clifton. Ensuring multiple patient touch-points—when medication is dispensed, through medication synchronization processes, and with appointment-based models—helps empower pharmacy staff to control workflow, increase efficiencies, and provide enhanced services to meet community needs.

At this year’s American Pharmacists Association Annual Meeting and Exposition, pharmacy leaders from pharmacy schools across the country presented their research on the Flip the Pharmacy program through a qualitative analysis of community pharmacy practice transformation. “Community pharmacy practice advancement is dependent on transformation efforts focused on identifying and adopting best practices for workflows to deliver patient care services,” the authors wrote.

The researchers identified several recurring themes related to the reach, effectiveness, adoption, implementation, and maintenance of Flip the Pharmacy programs. “Each of the domains are necessary for practice transformation,” they noted, adding that “[pharmacy transformation teams] found Flip the Pharmacy...effective in moving practice transformation forward.”

Pharmacists interested in joining Flip the Pharmacy can learn more at www.flipthepharmacy.com, which hosts an extensive content library, including change packages with workflow solutions and best practices. “Change doesn’t happen overnight,” said Clifton, “which is why it is important to focus on changing workflow today so that we can be ready for additional payer opportunities in the near future. Payers are interested in community-based pharmacy enhanced services that help improve patient care. In order to be ready for these additional payer opportunities, pharmacy staff must be prepared to implement a program and document the care provided, which is what Flip the Pharmacy helps to do.”

For references, visit drugtopics.com.
Community Pharmacies Make Care Possible in Medical Deserts

We take the care to our customers who lack easy access to basic, high-quality health care services. by Mark McCurdy, RPh

Cambridge, Nebraska is the largest city in Furnas County, with just over 900 residents, according to the 2020 Census. In fact, the 7 counties that surround Furnas—5 in southern Nebraska and 2 in northern Kansas—have an average of fewer than 5000 people in the entire county. Cambridge is nearly 80 miles from the nearest level 2 trauma hospital, located in Kearney, making the area a medical desert.2,3

The difficulty for patients who live in a medical desert is decreased access and quality of care coupled with increased health care costs. As one of the most accessible health care resources in our county, the staff at Mark’s Pharmacy is committed to caring for both the people living in Cambridge and those living miles and miles beyond city limits.

Many communities across south-central Nebraska with small medical clinics or nursing homes do not have a local pharmacy. We are committed to meeting the needs of the people living in those communities by offering hand delivery to the patients’ doorsteps and locally administered well-care services, including vaccines and health screenings. We take the care to our customers.

Like many other medical deserts, this rural area faces multiple barriers to consistent, quality care. A lack of public transportation, nontraditional workdays, much longer than normal mail delivery, and isolation (eg, living on a farm or in a smaller community with no medical services) are ever-present barriers that our pharmacy staff sees each and every day. On top of those challenges, a high percentage of our population consists of older adults who are less tech savvy, making mobile-friendly websites and intuitive health care apps mostly ineffective with many of our patients.

These barriers challenge us to think differently and provide a “high touch” level of care. We feel an obligation to improve access to medicines and quality of care, even as we are confronted with the reimbursement controls of pharmacy benefit managers. When dispensing, we focus on medication synchronization and adherence packaging to make it easier for patients to manage their medications and limit our need for extra deliveries. Before it was trendy, we adopted a community wellness approach and focused on well-care services to help our patients remain healthy, rather than simply providing medications to treat illnesses. We are a community care access point with services that supplement and complement the entire health care delivery system.

Before COVID-19, we provided blood pressure devices to patients who were called each month and instructed to bring the devices back to the pharmacy or to send back with deliveries. Results were downloaded and sent to their general practitioners and specialists. We also performed health screenings and administered vaccinations locally and at outreach locations. During COVID-19, we worked closely with the health department to offer regional testing and vaccinations. We also served as a minor medical triage provider. Area medical clinics were often inundated with sick patients and would refer minor medical cases to our pharmacy. We expanded our COVID-19 testing and vaccine administration to local communities by holding events at area schools and recreation centers. During these events, we would often visit homebound patients.

We have also seen a significant reduction in nursing home and assisted-living beds in many local communities, including a recent closure.4 We provide many services to help patients stay in their home environment for as long as possible. Our mantra of taking care to our customers has expanded to include additional pharmacy care services “at home” instead of “in a home.” Hand delivery to patient doorsteps, adherence packaging, vaccinations, and ongoing medication management are examples of pharmacy care services we provide.

Being the primary health care destination in a rural area does come with challenges, including weekend and after-hours requests for antibiotics and prescription changes. These challenges are just a small obstacle in our overall effort to improve the health of every patient in the communities we serve while increasing patient satisfaction and building customer loyalty in the process.

We believe that reimbursement for the enhanced patient care and medication use services we provide is the future of community-based pharmacy practice. We have a small payer contract with one of the medical providers to reimburse us for some of the enhanced services we provide. Through our work with Community Pharmacy Enhanced Services Network (CPESN) Nebraska, known in the state as Nebraska Enhanced Services Pharmacies, we hope to continue to show our pharmacy’s value to the insurance companies and contract directly for the services that reduce their overall costs.

For references, visit drugtopics.com.

Mark McCurdy, is the owner of Mark’s Pharmacy in Cambridge, Nebraska, and a CPESN Nebraska Luminary.

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Hidden rebates and other pricing strategies can affect pricing structure. **by Fred Gebhart**

It’s easy to ask what a drug costs. Patients ask every day. It’s tough, though, for health care providers to give them an accurate answer.

“There is no ‘price’ for a drug in the United States,” said Antonio Ciaccia, senior adviser for disruptive innovation and practice transformation for the American Pharmacists Association (APhA) and president of 3 Axis Advisors, during his session at the APhA 2022 Annual Meeting and Exposition. “Price varies by time and your place in the distribution chain. Drug prices are hidden, set by contract, and manipulated by pharmacy benefit managers.”

Pharmacy benefit managers (PBMs) began as intermediaries and claims processors between insurers and pharmacies. Today, 3 PBMs control approximately 80% of the United States pharmaceutical market via vertically integrated organizations that include insurers, pharmacies, rebate aggregators, and other industry players.

Every organization and level in the distribution chain, from manufacturers to patients, have their own private contracts and rebates. “PBMs advertise that they are the only entity working to control prescription drug costs, but data show that PBM profits generated off prescription drug transactions heavily distort their incentives to control drug spending for their clients,” he said. The reality, he continued, is that formulary placement fees and other rebates give PBMs incentives to distort prices and increase profits. Each PBM promotes utilization of different mixes of drug products for different health plans. Different utilization mixes trigger different mixes of rebates and fees, making it more difficult to compare real costs.

Another problem: The entire drug distribution system is based on fake prices. List prices are artificial, Ciaccia explained; so is the average wholesale price. “We need a benchmark that isn’t set by somebody who makes money off those drugs,” he said.

Today’s pricing structure leaves cash-pay patients and small employers paying list price or close to it. Large employers pay a bit less, followed by Part D plan sponsors, the big 4 federal buyers—Department of Veteran Affairs, Department of Defense, Public Health Service Commissioned Corps, and Coast Guard (who all have federal ceiling price protection)—and Medicaid.

An analysis concluded by 3 Axis Advisors found that a group of small, self-insured employers with combined drug spend of more than $110 million in 2018 received approximately $5 million in rebates. Based on the Federal Supply Schedule, a proxy for the best commercial price, they should have received about $30 million in rebates. PBMs pocketed the difference.

The rebate retention is governed by rebate aggregators owned by or affiliated with, the 3 largest PBMs. Clients get rebate guarantees off list price on a per claim basis. But rebates are increasingly recategorized as mail-order purchase discounts, market share incentives, promotional allowances, commissions, market share utilization, drug pull-through programs, formulary placement fees, administrative fees, data fees, price concessions, volume-based incentives, and other payments not covered by rebate guarantees. “The higher list prices rise, the more price concessions a PBM can collect and retain,” Ciaccia said. PBMs are also involved with Medicare Part D. In early 2019, the patient price for imatinib mesylate—the generic of Gleevec—ranged from $9.62 per pill to $315.74. A national study of dimethyl fumarate found that the largest insurers and PBMs were steering patients to the branded product at $8,275 per month instead of toward a generic option for $184 per month.

“We need to rein in PBM abuses,” Ciaccia said. “Strategies include Medicaid carve outs or a single PBM; pass-through pricing with full transparency; prohibitions on patient steering; bans on spread pricing, gag clauses, co-pay clawbacks, and copay accumulators; pushing rebates through to patients; reverse auctions, and real fiduciary requirements.

“As list prices for drugs continue to rise, those who can engage in price setting in the middle, PBMs, can continue to benefit significantly at great cost to drug purchasers.”

For references, visit drugtopics.com.

In 2018, Dave Yost, Ohio’s state auditor at the time, reported that PBMs pocketed 31% of the state generic drug spend—$208 million in one year. In 2021, Yost, now attorney general of Ohio, accepted an apology and a check for $88 million from PBM Centene Corp over alleged drug markups of more than $11 per prescription. The company settled similar claims with Mississippi for $55 million and set aside more than $1.1 billion for other states. “In Florida, about 60% of all calcipotriene spending came from one managed care organization. Its PBM billed as a brand, then classified it as a generic for pharmacies and clawed more than $1000 per claim,” Ciaccia said.

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**The average wholesale price for 20 mg of omeprazole magnesium (Prilosec) in 2021 ranged from $0.30 per unit to nearly $9.**
Although tapentadol has a lesser effect on µ-opioid receptors, both tapentadol immediate release (IR) and oxycodone IR are associated with similar rates of gastrointestinal adverse drug events in patients hospitalized after orthopedic surgery, according to results published in Pain Physician.1

In a retrospective cohort study, researchers evaluated postoperative outcomes to determine the rates of these gastrointestinal adverse drug events with tapentadol IR vs oxycodone IR.

Electronic medical records were evaluated for patients admitted to the hospital between January 2018 and June 2019. Included patients received only tapentadol or oxycodone and did not receive the sustained-release form of these drugs, or other opioids during their stay.

The primary study outcome was gastrointestinal adverse drug events that occurred after surgery but during the patient’s hospital stay.

A total of 236 patients met inclusion criteria; 199 were included in the final cohort (tapentadol n=99; oxycodone n=100). Mean patient age was 66±12 years (56% women). Those in the tapentadol group were older, more likely to be women, and more likely to be undergoing a total hip arthroplasty. Surgeries included total knee arthroplasty (n=91; 46%), total hip arthroplasty (n=63; 32%), shoulder surgery (n=26; 13%), or other surgeries (n=19; 10%). Before hospitalization, 11% of patients were taking opioids, in doses of less than 50 mg morphine milligram equivalents per day. Median length of hospital stay was 4 days (interquartile range [IQR], 4 days).

All patients were prescribed either 50 mg to 100 mg tapentadol IR or 2.5 to 10 mg oxycodone IR for pain.

Adverse drug events included constipation, nausea or vomiting, and pruritus. In the tapentadol group, 51% of patients experienced gastrointestinal adverse drug events, compared with 53% in the oxycodone group (between-group difference, 2%; 95% CI, 11%-16%). Following adjustment for potential confounders, tapentadol use was “not associated with a significant reduction of [gastrointestinal adverse drug events]” (odds ratio, 0.62; 95% CI, 0.32-1.20).

No instances of dizziness, dysphoria/hallucinations, respiratory depression, or death were reported.

In the tapentadol group, total median dosing was 300 mg (IQR, 150 mg-500 mg; dose/day, 75 mg [IQR, 33 mg-125 mg]). Total median dose of postoperative oxycodone was 50 mg (IQR, 23 mg-95 mg; dose/day, 16 mg [IQR, 8 mg-24 mg]). Total median postoperative oral morphine milligram equivalents were 95 mg and 75 mg in the tapentadol and oxycodone groups (IQR, 45 mg-165 mg and 41 mg-150 mg, respectively). Per day, the total median postoperative oral morphine milligram equivalents were 25 mg and 23 mg, respectively (IQR, 11 mg-40 mg and 13 mg-35 mg).

Study limitations include the use of only 1 referral hospital to create the patient cohort, the retrospective nature of the research, and potential issues with accuracy of medical record data.

“These results need to be replicated in clinical trials,” the researchers concluded. “Future studies should also investigate the patient population that may benefit most from the use of tapentadol for postoperative pain.”

For references, visit drugtopics.com.
IN MY VIEW / DISPENSED AS WRITTEN

Pharmacy’s “New Dirty Little F-Word”

Government money to pay for COVID-19 vaccines has run out, but pharmacists are still obligated to provide these services without compensation.

Have you heard about the college student who ran out of money? They went to the chancellor and said, “Since I’ve been here a while and have paid you—and I know you have lots of money—I’ll continue to sit in class, take exams, and graduate without any more money going to you.” Neither have I. It never happens.

Have you heard about the guy who walked into a physician’s office, or physical therapy clinic, or nursing home and did the same? Neither have I. It never happens. No one who provides a service does it for free. Professionals administer these services, and payment is expected.

Have you heard about the uninsured person who walked into the pharmacy to get their second or third or fourth COVID-19 shot? The billing mechanism for these patients—the Health Resources and Services Administration—is now out of money, and yet we, the pharmacists, are expected to take care of these patients.

In the pharmacy where I work, we use 3 different platforms to complete 1 COVID-19 shot. Drawing up the injection and sticking it in a patient’s arm is the easy part. Reporting the required data to federal government programs, billing the administration fee, and reporting to the state immunization information system takes almost 15 minutes if a patient is new to your pharmacy. Our people in Fayette County, the poorest county in Pennsylvania, appreciate the fact that we do not require online registration. Unlike at the “big chains,” our people show up without appointments and are taken care of.

According to the Pennsylvania Pharmacists Association website, “pharmacists have administered more than two-thirds of COVID-19 vaccines. I suspect that number is even higher, given the number of pharmacists—like my daughter Gretchen Kreckel Garofoli—who helped head the vaccination effort in West Virginia. Also included in that count would be my wife, Denise Kreckel, who ran clinics for Centre Volunteers in Medicine, administering 2400 vaccines on a Saturday.

According to the CDC website, “[The] COVID-19 vaccine is free of charge for everyone. Participating pharmacies will bill private and public insurance for the vaccine administration fee. For uninsured patients, this fee will be reimbursed through the Health Resources and Services Administration’s Provider Relief Fund.”

At least half the patients who come into the pharmacy will ask why we need their insurance card. “These shots are supposed to be free,” they say. I explain to them that it takes at least 15 minutes of our time to administer a shot, and even though the vaccine is “free”—and even the alcohol pads and syringes are “free”—there is still a cost.

Through December 31, 2021, Medicare was paying for the vaccine. After the first of this year, Medicare Advantage plans had to pay, and again, we battle to get claims paid. Some Medicare Advantage plans have different billing parameters than others, and some just outright refuse to pay. Centers for Medicare & Medicaid Services does not require managed care plans to cover out-of-network providers unless the Medicare Advantage plan has an out-of-network benefit. And now, the Health Resources and Services Administration plan has run out of money, so there is no longer a mechanism for pharmacies to get paid for services provided to the uninsured. Even though COVID-19 shots are way down, we still see uninsured patients come in expecting to be cared for, even though there is no money available to pay for our time, our liability insurance, and all our fixed costs required to keep the lights on.

The government has said that COVID-19 vaccines are free, and we as pharmacists are obligated to administer them at no charge. We community pharmacists have been—and still are—the heroes of the vaccine administration efforts. My store has taken care of plenty of uninsured patients. We’ve administered vaccines for “free” to the Medicare Advantage plans that refuse to pay us.

Free has become my new dirty little F-word.

For references, visit drugtopics.com

Peter A. Kreckel, RPh, practices community pharmacy in Lemont Furnace, Pennsylvania.

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Abrocitinib for Atopic Dermatitis

The drug’s approval was based on the results of 3 clinical trials.

Hooman Kashi, PharmD candidate; and Kevin Ho, PharmD candidate

On January 14, 2022, the FDA approved abrocitinib (Cibinqo) for the treatment of adults with refractory, moderate to severe atopic dermatitis (AD) not adequately controlled with other systemic drug products, including biologics, or for patients in whom the use of those therapies is inadvisable. Abrocitinib is a Janus kinase inhibitor and is not recommended for use in combination with other Janus kinase inhibitors, biologic immunomodulators, or other immunosuppressants. Abrocitinib is approved at doses of 50 mg, 100 mg, and 200 mg.

Abrocitinib was approved based on the results of 3 randomized, double-blind, placebo-controlled studies: Trial-AD-1 (NCT03349060; n = 387; abrocitinib monotherapy), Trial-AD-2 (NCT03575871; n = 391, monotherapy), and Trial-AD-3 (NCT03720470; n = 837; combination therapy). In the 2 monotherapy trials, participants 12 years and older were randomly assigned to either placebo, 100 mg, or 200 mg groups. In the combination therapy trial, adult participants were randomly assigned to receive either oral or injectable placebo, abrocitinib 100 mg or 200 mg, or dupilumab (Dupixent) 300 mg. Abrocitinib efficacy was compared with dupilumab in terms of pruritus relief at 2 weeks. All participants in this trial also received background topical corticosteroids.

In all 3 studies, the 12-week coprimary outcome measures were the percentage of participants achieving Investigator’s Global Assessment (IGA) response of clear (0) or almost clear (1) and a reduction of greater than or equal to 2 points from baseline and the percentage of participants achieving Eczema Area and Severity Index response of greater than or equal to 75% improvement. At the end of the 12-week period, both abrocitinib doses met the IGA end point (IGA, 0 or 1) vs placebo.

The most common adverse events reported in greater than or equal to 5% of patients in the abrocitinib 100 mg, abrocitinib 200 mg, and placebo groups, respectively, included nasopharyngitis (12.4%, 8.7%, 7.9%), nausea (6%, 14.5%, 2.1%), and headache (6%, 7.8%, 3.5%). Abrocitinib prescribing information contains boxed warnings for increased risk of serious bacterial, fungal, viral, or opportunistic infections, including tuberculosis, leading to hospitalization or death. Additionally, major cardiac adverse events, malignancies, and thromboses have occurred with abrocitinib therapy in clinical studies for AD.

The recommended abrocitinib dose is 100 mg once daily, administered orally. In patients who do not respond to the 100-mg dose, dosing may be increased to 200 mg once daily. A 50-mg dose is approved for patients with moderate renal impairment (estimated glomerular filtration rate, 30–59 mL/min), for patients who are known or suspected to be poor metabolizers of cytochrome P450 (CYP) 2C19, or for patients receiving inhibitors of CYP2C19.

For references, visit drugtopics.com
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What is SEMGLEE® (insulin glargine-yfgn) injection 100 Units/mL?

SEMGLEE is a prescription long-acting man-made-insulin used to control high blood sugar in adults and children with type 1 diabetes and in adults with type 2 diabetes.

• SEMGLEE is not for use to treat diabetic ketoacidosis.

It is not known if SEMGLEE is safe and effective in children less than 6 years of age with type 1 diabetes.

IMPORTANT SAFETY INFORMATION

Do not share your pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

Do not use SEMGLEE during episodes of low blood sugar or if you are allergic to insulin glargine or any of the ingredients in SEMGLEE.

Do not share needles, insulin pens, or syringes with others. Do NOT reuse needles.
Before using SEMGLEE, tell your healthcare provider about all your medical conditions including if you:

- have liver or kidney problems.
- take other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with SEMGLEE.
- are pregnant, planning to become pregnant, or are breastfeeding. It is not known if SEMGLEE may harm your unborn baby or breastfeeding baby.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start using SEMGLEE, talk to your healthcare provider about low blood sugar and how to manage it.

Change (rotate) your injection sites within the area you chose with each dose to reduce your risk of getting lipodystrophy (pitted or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites. Do not use the same spot for each injection or inject where the skin is pitted, thickened, lumpy, tender, bruised, scaly, hard, scarred or damaged. Tell your doctor if you have any new or worsening symptoms of heart failure, including shortness of breath, swelling of your ankles or feet, sudden weight gain.

SEMGLEE should be taken once a day at the same time every day. Test your blood sugar levels while using insulin, such as SEMGLEE. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made cautiously and only under medical supervision.

Do NOT dilute or mix SEMGLEE with any other insulin or solution. It will not work as intended and you may lose blood sugar control, which could be serious. SEMGLEE must only be used if the solution is clear and colorless with no particles visible. Always make sure you have the correct insulin before each injection.

While using SEMGLEE, do not drive or operate heavy machinery until you know how SEMGLEE affects you. You should not drink alcohol or use other medicines that contain alcohol.

The most common side effect of insulin, including SEMGLEE, is low blood sugar (hypoglycemia), which may be serious and life threatening. It may cause harm to your heart or brain. Signs and symptoms that may indicate low blood sugar include dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change and hunger.

SEMGLEE may cause serious side effects that can lead to death, such as severe allergic reactions. Get medical help right away if you have: A rash over your whole body, trouble breathing, a fast heartbeat, sweating, swelling of your face, tongue, or throat, shortness of breath, extreme drowsiness, dizziness, or confusion.

Other possible side effects may include swelling, weight gain, low potassium levels, injection site reactions, including changes in fat tissue at the injection site, and allergic reactions.

Important Safety Information for SEMGLEE (insulin glargine-yfgn) injection pen

SEMGLEE pen is a disposable single-patient-use prefilled insulin pen. Please talk to your healthcare provider about proper injection technique and follow instructions in the Instruction Leaflet that accompanies the pen.

These are not all the possible side effects of SEMGLEE. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

This summary does not include all the information about SEMGLEE and is not meant to take the place of a discussion with your healthcare provider about your treatment.

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SEMI-2021-0080
DRUG FACTS for SEMGLEE® (insulin glargine-yfgn) injection for subcutaneous use

**Rx Product**

Active ingredient in the injection solution
Insulin glargine-yfgn 100 units/mL (U-100)

**Purpose**

Used for control of high blood sugar in adults and pediatric patients (6 years of age and older) with Type 1 diabetes and in adults with Type 2 diabetes

**Uses:** Prescription SEMGLEE is a long-acting man-made-insulin used for control of high blood sugar in adults and pediatric patients (6 years of age and older) with Type 1 diabetes and in adults with Type 2 diabetes.

SEMGLEE is not for use to treat diabetic ketoacidosis.

- It is not known if SEMGLEE is safe and effective in children less than 6 years of age with type 1 diabetes.
- It is not known if SEMGLEE is safe and effective in children with type 2 diabetes.

**Warnings**

What is the most important information about SEMGLEE?

Do not share your SEMGLEE pen or syringe with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

Do not use SEMGLEE if you are having an episode of low blood sugar (hypoglycemia).

Do not use SEMGLEE if you have an allergy to insulin glargine products or any of the ingredients in SEMGLEE.

Before using SEMGLEE tell your doctor:

- If you have liver or kidney problems.
- If you take other medicines, especially ones called TZDs (thiazolidinediones).
- If you have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with SEMGLEE.
- If you are pregnant, planning to become pregnant, or are breastfeeding.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start using SEMGLEE, talk to your healthcare provider about low blood sugar and how to manage it.

Do not use SEMGLEE:

- If it is cloudy or slightly colored, or if you see particles in the solution.
- In an insulin pump or inject SEMGLEE into your vein (intravenously).
- On exact same spot for each injection. Where the skin has pits, is thickened, or has lumps. Where skin is tender, bruised, scaly or hard, or inject into scars or damaged skin. For a condition for which it was not prescribed. After the expiration date printed on the label of the pen or on the carton. Do not mix SEMGLEE with other insulins.

When using SEMGLEE, the following serious side effects may occur:

- Low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:
  - Dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change and hunger.
  - Severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:
    - A rash over your whole body, trouble breathing, a fast heartbeat, or sweating.
  - Low potassium in your blood (hypokalemia).
  - Heart failure. Taking certain diabetes pills called TZDs (thiazolidinediones) with SEMGLEE may cause heart failure in some people. This can happen even if you never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with SEMGLEE. Your healthcare provider should monitor you closely while you are taking TZDs with SEMGLEE. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
    - Shortness of breath, swelling of your ankles or feet, sudden weight gain.

Treatment with TZDs and SEMGLEE may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

Get emergency medical help if you have:

- Trouble breathing • Shortness of breath • Fast heartbeat • Swelling of your face, tongue, or throat, • Sweating • Extreme drowsiness • Dizziness • Confusion.

The most common side effects of SEMGLEE include:

- Low blood sugar (hypoglycemia) • Weight gain • Allergic reactions, including reactions at your injection site • Skin thickening or pustules at the injection site (lipodystrophy).

**Directions**

- Read the detailed Instructions for Use that come with your SEMGLEE insulin vial or single-patient-use prefilled pen. Use SEMGLEE exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much SEMGLEE to use and when to use it. Know the amount of SEMGLEE you use. Do not change the amount of SEMGLEE you use unless your healthcare provider tells you to. Check your insulin label each time you give your injection to make sure you are using the correct insulin. If using the vial, always use a syringe that is marked for U-100 insulin. Only use SEMGLEE that is clear and colorless. Do not use SEMGLEE if it is cloudy or slightly colored, or if you see particles in the solution; return it to your pharmacy for a replacement. SEMGLEE comes in a single-patient-use prefilled pen, which you may use to administer your SEMGLEE dose. The dose counter on your pen shows your dose of SEMGLEE. Do not make any dose changes unless your healthcare provider tells you to. • SEMGLEE also comes in a multiple-dose vial. Do not use a needle to remove SEMGLEE from your disposable prefilled pen. Do not re-use needles. Always use a new needle for each injection. Re-use of needles increases your risk of having blocked needles, which may cause you to get the wrong dose of SEMGLEE. Using a new needle for each injection lowers your risk of getting an infection. • You may take SEMGLEE at any time during the day, but you must take it at the same time every day. SEMGLEE is injected under the skin (subcutaneously) of your upper legs (thigh), upper arms, or stomach area (abdomen). • Do not use SEMGLEE in an insulin pump or inject SEMGLEE into your vein (intravenously). • Change (rotate) injection sites within the area you chose with each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites. • Do not mix SEMGLEE with any other type of insulin or liquid medicine. • Check your blood sugar levels. Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Other information:

- For subcutaneous (under the skin) use • Store unused SEMGLEE vials and prefilled pens in the refrigerator between 36° to 46°F (2° to 8°C) until the expiration date. If your unopened SEMGLEE vial or prefilled pen is stored at room temperature up to 86°F (30°C), it should be thrown away after 28 days. • Store in-use (opened) SEMGLEE vials in a refrigerator or room temperature and in-use (opened) SEMGLEE prefilled pens at room temperature up to 86°F (30°C). The SEMGLEE vials and prefilled pens you are using should be thrown away after 28 days, even if it still has insulin left in it. Do not freeze SEMGLEE. Keep SEMGLEE out of direct heat and light. If vials and prefilled pens have been frozen or overheated, throw them away. • Protect your SEMGLEE from dust and dirt. • You can clean the outside of your SEMGLEE by wiping it with a damp cloth. • Do not soak, wash, or lubricate the pen as this may damage it. • Keep SEMGLEE and all medicines out of the reach of children.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Inactive Ingredients: • zinc chloride, • glycerol, • polysorbate-20, • metacresol, and • water for injection.

These are not all the possible side effects of SEMGLEE. To learn more, talk about SEMGLEE with your health care provider or pharmacist. The FDA-approved product label can be found at DailyMed - SEMGLEE insulin glargine injection, solution or call 1-877-446-3679.