Pharmacy Today
An official publication of the **American Pharmacists Association**
MARCH 2024

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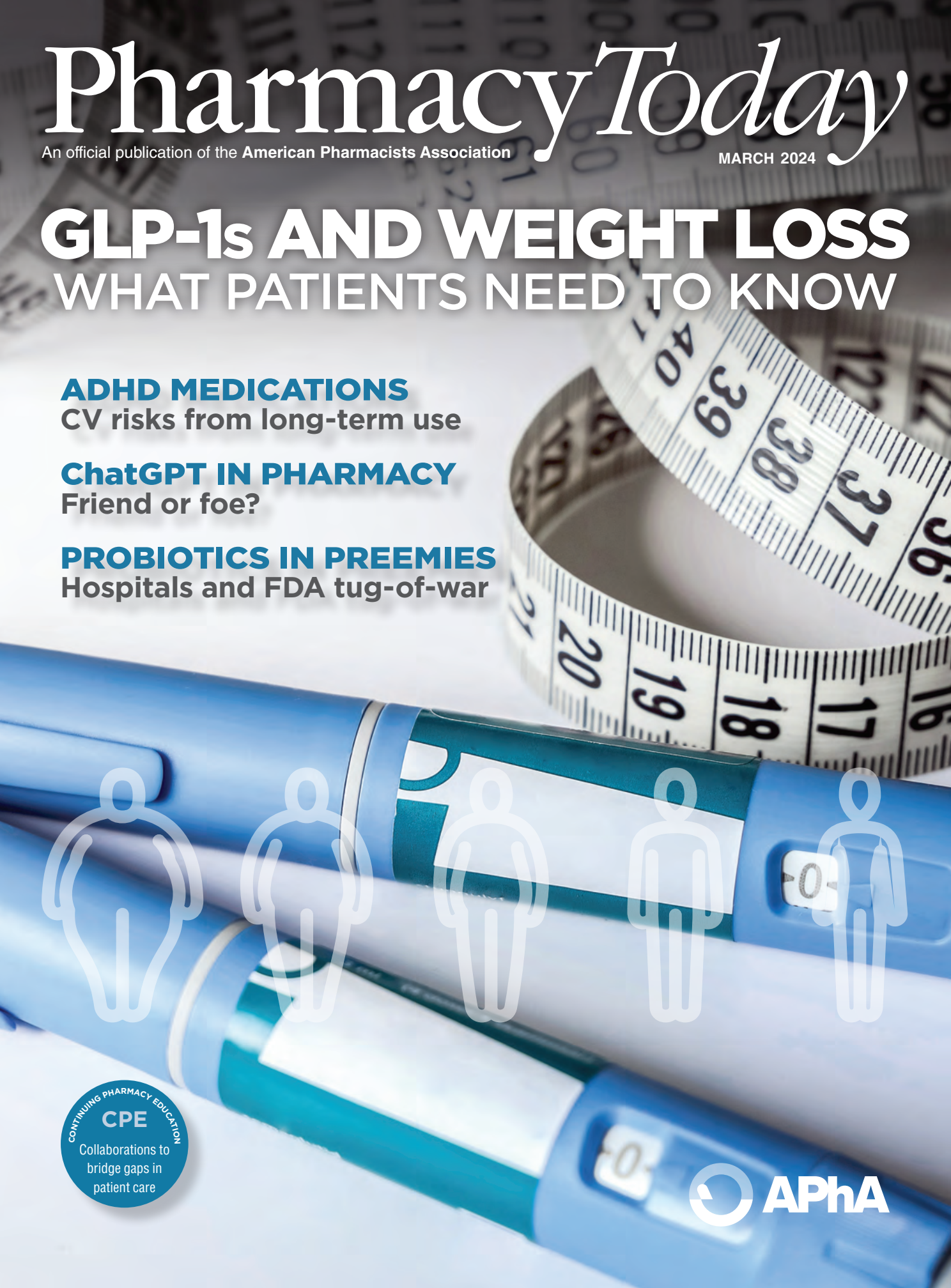
WHAT PATIENTS NEED TO KNOW

ADHD MEDICATIONS
CV risks from long-term use

ChatGPT IN PHARMACY
Friend or foe?

PROBIOTICS IN PREEMIES
Hospitals and FDA tug-of-war



CONTINUING PHARMACY EDUCATION
CPE
Collaborations to bridge gaps in patient care

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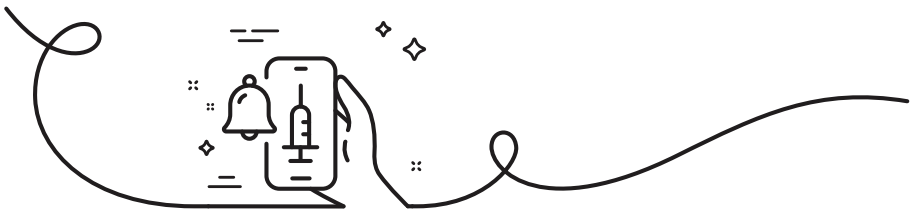
BulletinToday



CDC releases detailed adult immunization schedule for 2024, with revisions

CDC's adult immunization schedule for 2024, which was published in the *Annals of Internal Medicine* on January 12, 2024, includes updates for several vaccines, such as those for respiratory syncytial virus (RSV), meningitis, mpox, and COVID-19. The immunization schedule is based on the recommendations of CDC's ACIP.

In October 2023, ACIP voted to approve the adult immunization schedule. Specifically, the changes from the previous iteration include the removal of the bivalent mRNA-based COVID-19 vaccines, which are no longer recommended. Current mRNA-based COVID-19 vaccines are monovalent.

Also removed from the guidance are all mentions of meningococcal serogroups A, C, W, Y polysaccharide diphtheria toxoid conjugate vaccine (Menactra), which is no longer distributed in the United States. While Menactra, or MenACWY-D, is no longer recommended, pentavalent meningococcal vaccine, or MenACWY-TT/MenB-FHbp (Penbraya), is now included.

Among other changes, the schedule has been revised to now include modified Vaccinia Ankara vaccine (Jynneos) for protection against mpox.

Additionally, clarifications have been added regarding recommendations for the measles, mumps, and rubella vaccine; hepatitis A and B vaccines; HPV vaccine; and tetanus, diptheria, and pertussis vaccines.

In an accompanying editorial to the 2024 schedule in the *Annals of Internal Medicine*, Scott Ratzan, MD, and other members of the Council for Quality Health Communication cited the recent CDC alert for health care providers with an "urgent need to increase immunization coverage for influenza, COVID-19, and RSV."

In the editorial, they criticized CDC's complex written and visual presentation of the recommendations.

"The Recommended Adult Immunization Schedule article and recent CDC alert on seasonal flu, COVID-19, and RSV vaccination shortfalls are the latest warning signs that the CDC needs to upgrade its health communication capability now," they wrote. "Our nation's health and security depend on it."

The full ACIP recommendations for each vaccine are available at www.cdc.gov/vaccines/hcp/acip-recs/index.html. ■

Why are cases of syphilis soaring?

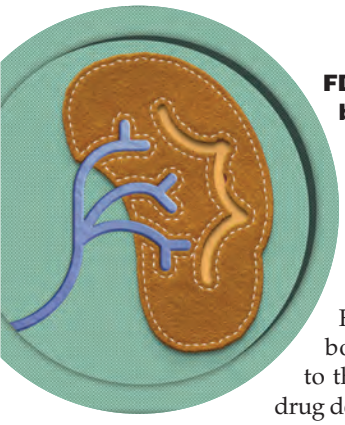
CDC has stated that the United States is seeing the highest incidence of syphilis since 1950. In its new report, the agency mapped out an astonishing comeback for a disease that had previously reached near-eradication status.

The most recent count puts the number of diagnosed new infections at more than 207,000 in 2022—a staggering 80% increase from 2018. Experts point to multiple drivers behind the trend, including a rise in substance use, which is associated with risky sexual behavior, and a dearth of sexual health clinics.

The epidemic is also affecting every age group, including newborn babies, and is having an especially pronounced impact on Black Americans and people of Native American/Alaskan Native heritage.

Without proper care, the virus can damage organs; lead to loss of eyesight and hearing; cause paralysis; and result in miscarriage, stillbirth, or developmental delays in babies.

The Biden administration has unfurled initiatives designed to address the high rate of infection, including formation of a national task force, temporary importation, an alternative syphilis intervention because Bicillin L-A is in short supply in the United States, and ongoing development of a simple test for use in clinics. ■



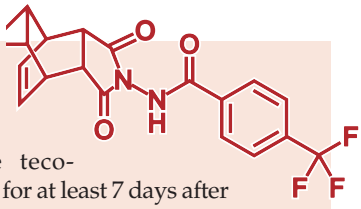
FDA adds boxed warning to denosumab for patients with advanced CKD

FDA added a boxed warning to the osteoporosis drug denosumab (Prolia). The agency's review of the drug indicated risks that warrant new prescribing information. Patients with chronic kidney disease (CKD)—especially those on dialysis or those with a concomitant diagnosis of mineral and bone disorder could develop severe hypocalcemia, or very low levels of calcium in the blood.

FDA is changing the label for denosumab to include a boxed warning to reflect the risk of hospitalization and even death for this group of patients.

Added information will provide advice to both patients and providers on strategies to curtail the risk of harm, including a recommendation to evaluate kidney function in patients before prescribing denosumab, emphasis on the importance of sufficient calcium and vitamin D intake for current users, and a recommendation for frequent monitoring of blood calcium levels for patients with advanced CKD. ■

Early tecovirimat treatment for mpox disease may benefit people with HIV



Early intervention with tecovirimat may stop an mpox infection from advancing to the stages of severe disease in people living with HIV (PWH), new research in *JAMA Internal Medicine* suggests.

Investigators followed a sample of PWH who received care for mpox at four Atlanta hospitals between June and October 2022. Two propensity-matched cohorts were formed: one including 56 patients who received tecovirimat therapy within 7 days of mpox symptom onset, and the other consisting of 56 patients who did not receive tecovirimat for at least 7 days after symptom onset or never received it at all.

Mpox disease progression was observed in 5.4% of patients in the early treatment group compared with 26.8% in the late- or no-treatment group.

Although more research is needed to validate the findings, the study results support initiation of tecovirimat therapy in all PWH at the first signs of an mpox infection. ■

FIP represents, advocates for pharmacy at WHO

The International Pharmaceutical Federation (FIP) represented pharmacy at a January 2024 session of the WHO Executive Board in Geneva, Switzerland. Some of the main themes on the agenda included universal health coverage, health emergencies, and health and well-being.

On the topic of antimicrobial resistance, for instance, FIP reminded members that as frontline health care professionals, pharmacists play a crucial role in combating antimicrobial resistance.

WHO's work in health emergencies was another widely discussed topic. The World Health Professions Alliance, which includes FIP, gathered data during the COVID-19 pandemic and because of those efforts, a new clause was placed in the WHO's Pandemic Accord, requiring parties to protect the safety of health professionals in emergencies, according to Paul Sinclair, president of FIP. This includes ensuring priority access to personal protective equipment.

FIP is the global body for pharmacy, pharmaceutical sciences, and pharmaceutical education. APhA is a member organization of FIP. ■

Study finds possible risk of birth defects with first trimester use of methadone versus buprenorphine

Both buprenorphine and methadone treat OUD, but there is limited understanding of how in-utero exposure affects infants. Researchers of a new study published in *JAMA Internal Medicine* used Medicaid data to gauge the risk of congenital malformations in neonates whose mothers received buprenorphine or methadone while carrying them.

After examining Medicaid data from more than 13,000 pregnancies during 2000 to 2018, outcomes data showed that birth defects were more prevalent overall with first trimester exposure to methadone than with similar exposure to buprenorphine. In 9,514 cases, pregnant parents received buprenorphine during the first 90 days of gestation. In 3,846 cases, they received methadone.

The relative risk reduction with buprenorphine was 18%, the equivalent of one fewer event per 100 patients compared with methadone. Similar patterns emerged when investigators looked specifically at birth defects linked with opioid use, the only exception being GI malformations, which were more likely with fetal exposure to buprenorphine.

They noted that risk of birth defects is just one factor to consider when choosing an intervention for OUD in pregnant women. Access to treatment, previous treatment success, and the odds of retention in treatment should also inform the decision, they added. ■

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CPE

45 Pharmacist and CHW collaborations to bridge gaps in patient care

Jasmine D. Gonzalvo and Ashley H. Meredith

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Take the Crossword Challenge

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See solution at pharmacytoday.org

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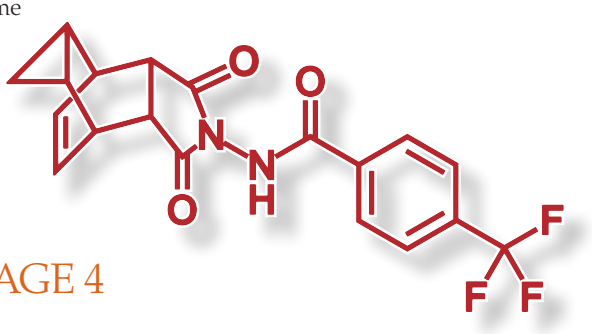

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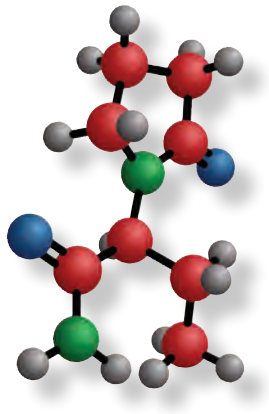
Practice & Trends

Health Systems



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GLP-1 agonists are changing the landscape of achieving optimum weight

People are increasingly using GLP-1 receptor agonists such as semaglutide to help facilitate their journey to weight loss and improved health, with a 40-fold increase in semaglutide use over the past 5 years. Studies have demonstrated significantly more weight loss when semaglutide is added to lifestyle interventions as compared with placebo. Success stories are flooding social media, which only increases patient demand. With two-thirds of American adults classified as overweight or obese, these drugs have the potential to decrease the risks of numerous chronic diseases on a large scale.

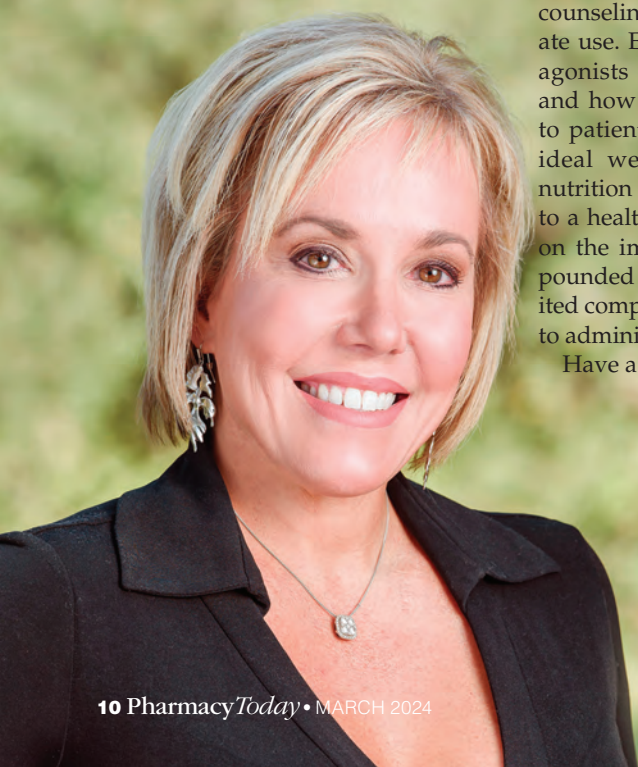
But are these truly a "magic bullet" for weight loss? This month's *Pharmacy Today* cover story weighs in on this question. Experts say yes…and no. On the plus side, GLP-1 agonists act to stimulate insulin production, decrease appetite, and lengthen the feeling of fullness after eating. They can also lead to reduced alcohol consumption and lessen other addictive behaviors in some people. These effects lead to increased weight loss and improved health, and have demonstrated a decrease in CV events in some cases.

However, they have drawbacks. Their high cost, inconsistent insurance coverage, and likely need for lifelong therapy could lead to health disparities between higher- and lower-income populations. Also, there is a potential for rare but serious adverse effects such as pancreatitis. Due to high demand, a worldwide shortage of these agents has flooded the market with counterfeits and increased the need for compounded formulations. Although many compounded forms are identical to commercially available products, they require patients to self-measure their injectable dose—leading to an increased risk for inappropriate dosing and adverse effects.

In this issue of *Today*, you'll also find new drug updates, tips for managing motion sickness, and the latest information on the CV effects of ADHD medications. Get an update on the safety of cannabis in pregnancy, whether you should use ChatGPT as part of your MTM processes, catch up on your CPE credit with this month's article about benefits of pharmacist collaborations with community health workers, and much more.

GLP-1 agonists are here to stay, and pharmacists have an important role in counseling patients on their appropriate use. Educate patients using GLP-1 agonists on their GI adverse effects and how to administer a dose. Stress to patients that while achieving their ideal weight is important, optimal nutrition and physical activity are keys to a healthy lifestyle. Counsel patients on the importance of obtaining compounded formulations from an accredited compounding pharmacy and steps to administer the correct dose.

Have a great *Today*! ■



Kristin Wiisanen
PharmD, FAPhA, FCCP
***Pharmacy Today* editor in chief**

Michael D. Hogue
PharmD, FAPhA, FNAP, FFIP
Executive vice president and CEO of APhA

Addressing second victim syndrome

Six weeks ago, I had never heard of second victim syndrome (SVS). Then my phone rang, and I've been forever changed by the conversation.

Pharmacists are faced with systems that may not fully support optimal patient care and can place professionals in a crisis of conscious. An error happens, a patient is harmed. The worst fears any of us could have are realized in an instant. Any traumatic patient care event—medication errors, near misses, adverse patient outcomes—can lead to significant mental distress and feelings such as guilt, anger, and fear.

Unfortunately, the pharmacists, student pharmacists, and pharmacy technicians who experience these events—the "second victims"—typically suffer in isolation and silence. And this is just not something we can move past—none of us entered this profession thinking we might harm another human being. If we could take it back, we would. But often we don't even know how or why the error happened.

Some hospitals and health systems have established SVS support programs for health care professionals involved in medical or medication errors. However, these programs may not reach throughout the system beyond inpatient professionals, and pharmacists may connect with other pharmacists and be supported.

That phone conversation I had with an APhA member who is experiencing SVS was transformative for me. The pharmacist said one thing that riveted me: "Michael, there are many of us out here in practice with SVS, and we are all alone. We need support and help. Can APhA do anything?"

Without hesitation, I said "YES!" And if you are reading this editorial at the APhA 2024 Annual Meeting & Exposition, you will find the very first (to our knowledge) focused support group meeting for pharmacists who need to just talk about their experiences with SVS or related issues. Titled, You are Not Alone: Pharmacy Well-being Support, the group will meet on Friday evening (March 22) from 9:00 pm to 11 pm ET. This is for pharmacists who've had a colleague commit suicide; pharmacists who've struggled themselves; or who are supporting a colleague who is suffering from significant anxiety disorder, depression, or suicidal ideation. A licensed professional counselor and facilitator will be present to support attendees. There is no agenda, and no presentations. This is for you: a safe space for pharmacists to talk about their experiences.

Please note that this time is intended as positive, healing support. It is not a forum for airing workplace grievances.

And this is just the first step. Beginning later in March, APhA will launch a monthly online support group for pharmacists, student pharmacists, and pharmacy technician members experiencing SVS and related mental health challenges. The support group will be facilitated by an expert facilitator and attended by a licensed professional counselor. In addition to providing support, APhA is committed to providing attendees with resources and best practice examples that will help us all be supportive of each other in the session and in our workplaces. We will send members an email with Zoom login details to access the group. For those who are not members and need to join the support group, we'll provide you with a 3-month complimentary membership so that you can get support right away.

APhA is also adding new resources through our well-being web page at apha.us/APhAWBI, and through the Well-Being Index by Mayo Clinic resources tabs. New content is being added regularly.

APhA is leading the charge in supporting pharmacist well-being and workplace improvements. We are working with employers—corporate pharmacies, health systems, and others—to ensure systems support optimal patient care. And when systems fail, support for employees is there to help you get through this difficult time.

APhA is standing beside you and fighting for you.

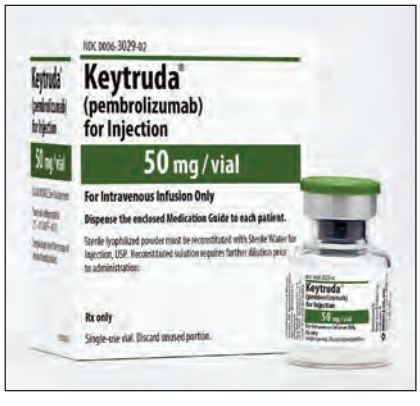
For every pharmacist. For all of pharmacy. Won't you join us? ■

NEW INDICATION

PEMBROLIZUMAB
(Keytruda—Merck Sharp & Dohme)

Drug class: Keytruda is a PD-1 blocking antibody.

Indication: Keytruda is now indicated for the treatment of patients with FIGO 2014 stage III–IVA cervical cancer in addition to previous indications for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell cancer, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial cancer, microsatellite instability or mismatch repair deficient cancer, microsatellite instability-high or mismatch repair deficient colorectal cancer, gastric cancer, esophageal cancer, recurrent or metastatic cervical cancer, hepatocellular carcinoma, biliary tract cancer, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer as well as an additional treatment for adult classical Hodgkin lymphoma and adult primary mediastinal large B-cell lymphoma.



Recommended dosage and administration: The recommended dosage varies according to the cancer being treated; see drug label for appropriate dosage. Keytruda is administered via I.V. infusion over 30 minutes after dilution.

Common adverse effects: The most common adverse reactions to Keytruda as a single agent were fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism.

Warnings and precautions: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Monitor for early identification of adverse effects and management. In the case of infusion-related reactions, interrupt, slow, or permanently discontinue infusion. Fatal or serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials. Keytruda can cause fetal harm. Advise patients of the potential risk to a fetus and to use an effective method of contraception.

BUPIVACAINE, MELOXICAM
(Zynrelef Kit—Heron Therapeutics, Inc.)

Drug class: Zynrelef is an NSAID.

Indication: Zynrelef kits are now indicated for postsurgical analgesia in adults for up to 72 hours after soft tissue and orthopedic surgical procedures in addition to previous indications.

Recommended dosage and administration: The recommended dosage is up to a maximum dosage of 400 mg bupivacaine and 12 mg meloxicam. It is applied without a needle into the surgical site following final irrigation and suction but prior to suturing. See full prescribing information for full preparation, administration, and dosage instructions.

Common adverse effects: The most common adverse reaction to Zynrelef kits in soft tissue procedures was vomiting; the most common adverse reactions in orthopedic procedures were constipation and headache.

Boxed warning: NSAIDs cause an increased risk of serious CV thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration

of use. Zynrelef is contraindicated in coronary artery bypass graft surgery. NSAIDs cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use or without warning symptoms. Older adult patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at a greater risk for serious GI events.

Other warnings and precautions: Monitor CV and respiratory vital signs and the patient's state of consciousness after application. If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient. Patients taking NSAIDs may have an impaired response to antihypertensives; monitor BP. Avoid use in patients with severe heart failure unless the benefits of using Zynrelef are expected to outweigh the risk of worsening heart failure. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function. Limit exposure to articular cartilage due to the potential risk of chondrolysis. Limit use of NSAIDs, including Zynrelef, between about 20 and 30 weeks of pregnancy due to risk of oligohydramnios/fetal renal dysfunction. Avoid the use of NSAIDs in patients who are ≥30 weeks' pregnant due to risk of oligohydramnios/fetal renal dysfunction and premature closure of the ductus arteriosus. Monitor heboglobin or hematocrit in patients with any signs or symptoms of anemia.

ALPELISIB
(Piqray—Novartis)

Drug class: Piqray is a kinase inhibitor.

Indication: Piqray is indicated in combination with fulvestrant for the treatment of adults with hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative, PIK3CA-mutated, advanced, or metastatic breast cancer as indicated by an FDA-approved test following progression on or after an endocrine-based regimen. The indication has expanded to include pre- and perimenopausal women.

Recommended dosage and administration: The recommended dose of Piqray is 300 mg taken orally once daily with food.

Common adverse effects: The most common adverse reactions to Piqray were increased or decreased glucose, increased creatinine, diarrhea, rash, decreased lymphocyte count, increased gamma-glutamyl transferase, nausea, increased ALT, fatigue, decreased hemoglobin, increased lipase, decreased appetite, stomatitis, vomiting, decreased weight, decreased calcium, prolonged activated partial thromboplastic time, alopecia, and uveitis.

Warnings and precautions: In cases of severe hypersensitivity, permanently discontinue Piqray and initiat appropriate treatment. Piqray can cause severe cutaneous adverse reactions (SCARs). Interrupt Piqray use if there are signs or symptoms of SCARs and permanently discontinue if SCARs are confirmed. Piqray can cause severe hyperglycemia; before initiation, test fasting plasma glucose, A1C, and optimize blood glucose. Consider premedication with metformin before initiation of Piqray. Piqray can cause severe pneumonitis and interstitial lung disease; monitor for clinical symptoms or radiological changes and interrupt or discontinue Piqray if severe pneumonitis occurs. Diarrhea may be severe, resulting in potential dehydration and acute kidney injury; advise patients to start antidiarrheal treatment and notify their health care provider if diarrhea occurs. Monitor for symptoms of diarrhea or colitis. Advise patients of potential risk to a fetus and to use effective contraception. Avoid coadministration with a strong CYP3A4 inducer or breast cancer resistance protein inhibitor.

DUPILUMAB
(Dupixent—Regeneron Pharmaceuticals)

Drug class: Dupixent is an interleukin-4 receptor alpha antagonist.

Indication: Dupixent is now indicated for the treatment of eosinophilic esophagitis in adults and pediatric patients 1 year and older who weigh at least 15 kg in addition to previous indications for the treatment of atopic dermatitis in adult and pediatric patients 6 months and older, as an add-on maintenance treatment for asthma in adult and pediatric patients 6 years and older with moderate to severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma, as an add-on treatment of chronic rhinosinusitis with nasal polyposis in adults, and prurigo nodularis in adults.

Recommended dosage and administration: The recommended dose of Dupixent for eosinophilic esophagitis is 200 mg injected every other week for patients who weigh 15 kg to <30 kg, 300 mg every other week for patients weighing 30 kg to <40 kg, and 300 mg every week for patients weighing ≤40 kg. For other conditions, see label.

Common adverse effects: The most common adverse reaction to Dupixent for eosinophilic esophagitis were injection site reactions, respiratory tract and herpes viral infections, and arthralgia.

Warnings and precautions: When using Dupixent for eosinophilic conditions, watch for vasculitic rash, worsening pulmonary symptoms, and/or neuropathy, especially when reducing oral corticosteroids. See label for full list of warnings and precautions.

CEFAZOLIN INJECTION
(Baxter Healthcare Corporation)

Drug class: Cefazolin is a cephalosporin antibacterial.

Indication: Cefazolin injection is indicated for the treatment of respiratory tract infections, UTIs, skin and skin structure infections, biliary tract infections, bone and joint infections, genital infections, septicemia, and endocarditis. It is now also indicated for perioperative prophylaxis in adults and pediatric patients at least 10 years old.

Recommended dosage and administration: Cefazolin is administered via I.V. injection. For perioperative prophylaxis in adults, the dosage is 1 g to 2 g 0.5 to 1 hour prior to surgery, 500 mg to 1 g during lengthy procedures, and 500 mg to 1 g every 6 to 8 hours for 24 hours after the operation. For pediatric patients, the dosage is 1 g for patients who weigh <50 kg and 2 g for patients who weight ≥50 kg 0.5 to 1 hour prior to surgery, then 500 mg to 1 g during lengthy procedures, then 500 mg to 1 g every 6 to 8 hours for 24 hours after the operation. Dosage adjustment is required for adults with CLcr of <55 mL/min and children with a CLcr of <70 mL/min. For other indications, see prescribing label.

Common adverse effects: In adult patients, the most common adverse reactions were GI and allergic reactions. In pediatric patients, the most common adverse reactions were nausea, infusion site pain, and headache.

Warnings and precautions: Hypersensitivity may occur in up to 10% of patients with a history of penicillin allergy. Mild diarrhea to fatal colitis may occur. Cefazolin may be associated with a fall in prothrombin activity; prothrombin time should be monitored in patients at risk and exogenous vitamin K administered as indicated. ■

Managing motion sickness

Mary Warner

Motion sickness can occur when riding in a car, train, airplane, boat, or even an amusement park ride. When your brain gets conflicting information from your eyes, inner ear, and body, the resulting confusion can cause dizziness, nausea, and vomiting. While avoiding situations that cause motion sickness is the best way to prevent it, that's not always possible. Fortunately, several therapeutic options are available to calm the inner turmoil.

Motion sickness is most common in women and in children ages 2 to 12 years old. A family history of motion sickness, hormonal birth control, inner ear disorders, menstrual periods, migraines, Parkinson's disease, and pregnancy can increase the likelihood of experiencing motion sickness. Common symptoms include cold sweats, dizziness, fatigue, headache, irritability, inability to concentrate, nausea, vomiting, pale skin, and rapid breathing. These symptoms generally resolve quickly once motion stops.

Common ways to avoid feeling sick include sitting in the front of a car, choosing a window seat on airplanes and trains, and looking at the horizon. Staying hydrated and eating small amounts of food frequently can also help. When these strategies are unsuccessful, medication may be needed.

Medications for motion sickness

Antihistamines are the most commonly used medications for treating motion sickness and easing symptoms. They're most effective when taken before travel or at the early onset of symptoms and are effective and generally safe in addition to being well-tolerated for relieving nausea, vomiting, and dizziness related to motion sickness. Only the first-generation antihistamines meclizine, dimenhydrinate, and diphenhydramine are approved by FDA for this purpose. These medications are well-known to cause drowsiness, and patients wishing to avoid these sedative effects should be aware that the less-sedating second-generation antihistamines are ineffective for treating motion sickness. Meclizine may be less sedating and longer-acting than dimenhydrinate or diphenhydramine.

Formulations

Pharmacy shelves are full of tablets and chewables claiming to prevent motion sickness, with most but not all containing antihistamines. For example, Dramamine, one of the most common brands of motion sickness medications, is available in several versions, including Original (dimenhydrinate 50 mg), All Day Less Drowsy (meclizine HCI 25 mg), Kids (dimenhydrinate 25 mg), and Non-Drowsy (ginger root 500 mg). Several products contain ginger, which is known to calm an upset stomach.

Two types of nonmedicated wristbands are also marketed to relieve motion sickness, though these have shown mixed results in clinical trials. The first type uses acupressure to maintain steady pressure on the P6 point, which is located on the inner arm just below the wrist, stimulating the median nerve and interrupting motion sickness signals to the brain. Wristbands can be safely used by pregnant patients and children, making them particularly helpful to these patients.

Advise patients to always face forward while traveling, stay hydrated, and avoid alcohol and spicy foods.

Another option is a battery-powered acustimulation wristband that uses electrical pulses to stimulate the median nerve and disrupt nausea signals. Conductivity gel is applied to the P6 point before putting on the wristband; the patient can then adjust the pulse strength depending on the severity of the motion sickness. Pregnant patients can safely use these wristbands, but they're far more expensive than other motion relief products.

What to tell your patients

Advise patients to always face forward while traveling, stay hydrated, and avoid alcohol and spicy foods. It can also be helpful to look at an object in the distance or at the horizon. Ensure that patients understand that only antihistamines that cause drowsiness will affect motion sickness and that children should not take meclizine, as it is not FDA-approved for children under 12 years old. Both diphenhydramine and dimenhydrinate are suitable for younger children.

Advise pregnant patients that they have increased susceptibility to motion sickness and that medications used for morning sickness can be used for motion sickness, including meclizine and dimenhydrinate.

For more information, see APhA's *Handbook of Nonprescription Drugs*, available in print from the bookstore on pharmacist.com and online in PharmacyLibrary. ■

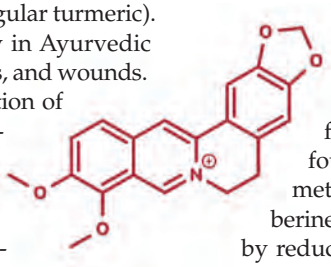
Berberine supplements

Mickie Cathers

Berberine supplements have joined the weight-loss buzz with rumors that this herb can help patients slim down. Also advertised as a means to lower blood glucose levels and support the CV system and GI and immune function, berberine supplements are rising in popularity. But is there any truth behind these claims?

Background

Berberine is an isoquinoline alkaloid compound found in certain plants such as barberry, goldenseal, Oregon grape, and tree turmeric (not to be confused with regular turmeric). This dietary supplement has a long history in Ayurvedic medicine as treatment for GI issues, infections, and wounds.



Berberine has been studied in the prevention of atherosclerosis, T2D, obesity, CV complications, and cancer. There is some evidence that berberine positively contributes to improving the regulation of glucose and lipid metabolism as well as inhibiting mitochondrial function, activating the AMPK pathway. Berberine is also known to act as an anti-inflammatory and an antioxidant by reducing reactive oxygen species accumulation.

Mild adverse effects include diarrhea, constipation, gas, and upset stomach. Patients who are pregnant or breastfeeding should avoid berberine and it should not be given to infants.

Is there a benefit?

Several studies have shown that berberine stimulates glycolysis, thereby improving insulin secretion, and inhibiting gluconeogenesis and adipogenesis in the liver. Berberine acts as an antisclerotic, lowering low-density lipoprotein (LDL), and testosterone levels as well as exhibiting an anti-inflammatory property by stalling the expression of COX-2 and PGE2. Berberine acts as an anticancer option by inducing apoptosis and influencing mitogen-activated protein kinase and transcription regulation. Berberine has been shown to prevent the development of atherosclerosis, T2D, and CV disorders, and the anti-obesity action of berberine is well-documented. However, high-quality, large clinical trials in humans are limited.

Hernandez and colleagues published results of a systematic review and meta-analysis of berberine's impact on lipoprotein, triglycerides, and total cholesterol in the *Journal of Dietary Supplements* on May 14, 2023. The authors evaluated 42 randomized clinical trials including 4,838 patients over the course of 8 to 18 weeks of berberine therapy. Results showed berberine, alone or with other additives, significantly reduced total cholesterol and may provide a modest positive impact on lipid concentrations.

Another systematic review and meta-analysis of randomized clinical trials published in *Frontiers in Pharmacology* on April 26, 2021, reported on the efficacy and safety of berberine for several metabolic disorders. Ye and colleagues found a positive therapeutic effect of berberine on metabolic diseases. The authors concluded that berberine may affect obesity and improve hyperlipidemia by reducing triglycerides, total cholesterol, LDL, HDL, homeostasis model assessment-insulin resistance, and fasting glucose in both patients with metabolic disorders as well as in healthy participants.

However, despite the reported beneficial effects and high safety profile, berberine suffers from poor bioavailability, limiting its clinical application.

Dosage and availability

This low bioavailability may explain why berberine supplements are often combined with black pepper, Ceylon cinnamon, and turmeric. Other additives include MCT oil, artichoke leaf, and milk thistle. Berberine is available as capsules and gummies on store shelves and online. Dosages vary from 1,000 to 1,500 mg and upwards to 4,700 mg daily in some supplements.

What to tell your patients

While berberine is generally considered safe, it can interact with prescription medications due to its effects on specific enzymes in the blood. There is a potential for hypoglycemia in patients with diabetes, those taking metformin, and those on other medications that lower blood glucose levels. Those interested in supplementing with berberine should speak with their health care provider first. Remind patients that supplements are not FDA-regulated, and the safety, efficacy, and actual contents may not reflect what is on the label. ■

Researchers take close look at long-terms effects of ADHD meds on heart

Loren Bonner

When taken for a long period of time and at a high dose, ADHD medication use was associated with an increased risk for some cardiovascular diseases, according to a research study published November 22, 2023, in *JAMA Psychiatry*.

Not only are more individuals being prescribed ADHD medication, but there's a growing trend in the long-term use of the drugs.

The number of individuals receiving ADHD medications has increased worldwide, said a 2018 *Lancet Psychiatry* study, and the prevalence of ADHD medication use among children has risen over time in all countries and regions.

Clinicians should be vigilant in monitoring signs and symptoms of cardiovascular diseases, particularly among those receiving higher doses.

"These medications are typically started in childhood, but function-impairing symptoms often continue into adolescence and adulthood, and thus treatment is continued," said Julie Dopheide, PharmD, a professor at the University of Southern California School of Pharmacy and Keck School of Medicine, who was not involved with the research.

Pharmacists are in a position to monitor prescriptions of ADHD medications to promote safe, therapeutic doses and discourage their use in individuals who have significant CV risk factors, said Dopheide.

Researchers of the new study examined data from several Swedish nationwide databases that included 300,000 individuals in Sweden ages 6 to 64 years. Using these data sets, their aim was to track the cumulative use of ADHD medication for up to 14 years and the risk of CVD. Previous studies haven't looked past a 2-year mark in investigating the association between long-term ADHD medication use and the risk of CVD.

Specific outcomes, limitations

The research team found that longer cumulative duration of ADHD medication use was associated with an increased risk of CVD—particularly hypertension and arterial disease—compared with nonuse. They also found a correlation between ADHD medication dosage and an increased risk of CVD.

The dosage analysis showed that the risk of CVD associated with each year of ADHD medication use increased with a higher average defined daily dose. For example, among individuals with a mean defined daily dose of up to 1.5 to 2 times the standard dose, each 1-year increase in ADHD medication use was associated with a 4% increased risk of CVD.

While study findings indicated a 4% increased risk with each 1-year increase in ADHD medication use, the first 3 years of use were associated with the highest risk, after which the risk stabilized. The corresponding increased risk for the first 3 years was 8%. The research team observed similar results when examining children and adults separately.

Findings of the study also suggest that increasing cumulative durations of the specific ADHD medications methylphenidate and lisdexamfetamine, and at higher doses, were associated with incident CVD.

"Clinicians should be vigilant in monitoring signs and symptoms of cardiovascular disease, particularly among those receiving higher doses," said lead author Le Zhang, PhD, from the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet in Stockholm, Sweden.

But, he noted, the study is observational and does not infer causal interpretations.

Dopheide said that the severity of ADHD was not looked at, nor were lifestyle factors that could have contributed to the risk.

"Stimulants are still effective for many people," Dopheide said. "I just think the risks need to be understood."

"Treatment decisions, as always, should be based on careful weighing of potential benefits and risks at an individual patient level, rather than simple one-size-fits-all recommendations," said Zhang.

Takeaway

"I think ADHD meds are crucial treatments for people and they can help with self-esteem, but if we can keep the dose in check, or use behavioral interventions and other lifestyle modifications to decrease the dosage, that is best," said Dopheide. "Multimodal treatment is best to find lowest stimulant dose."

She said pharmacists can also talk to prescribers if they see a patient is exceeding a maximum dose.

Likewise, pharmacists can ask patients if they want to know more about the risks. ■

Loneliness should be considered a health risk factor for older adults

Loren Bonner

Almost one year ago, United States Surgeon General Vivek Murthy, MD, released an advisory calling attention to the public health crisis of loneliness and isolation. While this can affect all age groups, older adults are at increased risk for loneliness and social isolation because they are more likely to live alone, have chronic illness, or face other limiting factors.

CDC noted that social isolation significantly increases a person's risk of premature death from all causes, a risk that may rival that of smoking, obesity, and physical inactivity.

While all this may have been known prior to 2020, the COVID-19 pandemic put a unique spotlight on loneliness as a health risk factor.

"Before the pandemic, this topic was usually glazed over. It felt like a social issue," said Ashwin Kotwal, MD, assistant professor in the division of geriatrics at the University of California, San Francisco. "But after the pandemic, I no longer had to make the case for my research."

Kotwal led a research study that found a link between loneliness in older adults and higher pain medication use, including use of opioids and NSAIDs. Older adults had twice the frequency of using antidepressants, sleep medications, and benzodiazepines.

"Loneliness was a common predicator for all these medications that fall along different pathways," said Kotwal. "We consider these things in isolation—sleep, depression, even polypharmacy. We think about these things separately, and loneliness may be a factor tying these together," said Kotwal, whose 2021 research paper was published in *JAMA Internal Medicine.*

Common psychosocial stressor

"I don't want to overmedicalize loneliness, but it's not a good state to be in," said Kotwal. "Loneliness in general causes wear and tear on our bodies."

According to a 2020 report from the National Academies of Sciences, Engineering, and Medicine, social isolation was associated with about a 50% increased risk of dementia. The report also found that poor social relationships, characterized by social isolation or loneliness, were associated with a 29% increased risk of heart disease and a 32% increased risk of stroke. Loneliness among heart failure patients was associated with a nearly fourfold increased risk of death, 68% increased risk of hospitalization, and 57% increased risk of emergency department visits, according to the report. Loneliness has also been associated with higher rates of depression, anxiety, and suicide.

Loneliness strongly predicts the development of pain, fatigue, and depression as well as the cluster of all three symptoms several years later.

In a 2022 study published in the *Journal of the American Geriatrics Society*, researchers from the University of Michigan investigated whether loneliness predicted the development of pain, fatigue, depression, and this symptom cluster over time. "Pain, fatigue, and depression frequently co-occur as a symptom cluster. While commonly occurring in those with cancer and autoimmune disease, the cluster is also found in the absence of systemic illness or inflammation. Loneliness is a common psychosocial stressor associated with the cluster cross-sectionally," the study authors wrote.

Using data from the Health and Retirement Study—a large, nonclinical sample of older American adults—the research team found that loneliness strongly predicts the development of pain, fatigue, and depression as well as the cluster of all three symptoms several years later.

"It is possible that interventions which address loneliness in older adults may prevent or mitigate the cluster of pain, fatigue, and depression," wrote study authors.

Normalize talking about loneliness

"When I talk to clinicians about [our study] findings, it resonates," Kotwal said. "We see a lot of lonely people in the clinic."

Kotwal has noticed that when he asks about a patient being lonely, they appreciate it.

While Kotwal agrees that clinical interventions that address loneliness in older adults could prevent or mitigate symptoms of pain, fatigue, or depression, it's "a hard ask" for busy clinicians to do in practice.

There is also a stigma associated with loneliness, making it hard to talk about. "It's easier to talk about your sleep habits than being lonely," Kotwal said.

"But we—any clinician, even pharmacists—can try to be a good first step to talk about this. We can try to normalize this, and I am hopeful we can start to incorporate social interventions into our clinical care," he said. ■

Cannabis use tied to higher risk of unhealthy pregnancy outcomes

Loren Bonner

Tori Metz, MD, frequently gets questions from her patients about using cannabis during pregnancy. For Metz and other clinicians, this has been a hard question to answer.

But findings from a study published December 12, 2023, in *JAMA* led by Metz and fellow researchers at the University of Utah Health, can hopefully inform clinicians as they talk to patients about the risks of cannabis use.

Metz and her research team conducted a study of more than 9,000 pregnant patients from eight medical centers across the United States and found that for the individuals who had cannabis metabolite in urine samples, there was a higher risk of adverse outcomes, especially low birth weight for the baby, compared to nonexposure.

Higher levels of cannabis exposure over the course of pregnancy were associated with higher risks.

"I think that these findings really just reiterate that we need to continue advising pregnant people to abstain from cannabis use during pregnancy," said Metz, vice chair of research of obstetrics and gynecology at University of Utah Health, during a press conference.

For all the adverse outcomes the researchers examined that were related to placental function, they found that cannabis exposure was associated with a 1.3-fold increase in risk after the impacts of other factors were removed. Higher levels of cannabis exposure over the course of pregnancy were associated with higher risks.

"Higher frequency of use, higher concentrations of use, were associated with more adverse outcomes," said Metz. "I think we can even tell patients that stopping at any point is helpful."

The greater risk seen at higher levels of exposure is concerning. Today, cannabis products contain more THC and are stronger than the products that were available when the study data was collected over 10 years ago.

Cannabis and Pregnancy

CANNABIS-EXPOSED PREGNANT PEOPLE
Have a higher rate of unhealthy birth outcomes

25.9% vs. 17.4%

HIGHER EXPOSURE = HIGH RISK
Higher exposure is associated with higher risks

SAFE ALTERNATIVES TO CANNABIS ARE AVAILABLE

FOR NAUSEA:
- Zofran
- Diclegis

FOR ANXIETY:
- Therapy
- Exercise
- Meditation
- SSRIs

These unhealthy outcomes can all be caused by reduced placental function:

- Low birth weight
- Medically induced preterm birth
- Stillbirth
- Pregnancy-related blood pressure disorders

Adapted from University of Utah Health press release, December 12, 2023.

The health impacts of these more concentrated products remain largely unknown.

Strong data and design

Medical cannabis use in Americans has more than doubled over the past decade as legalization of cannabis has become more common. For self-reported maternal cannabis use, results from a 2019 study published in *JAMA* found that it doubled as well. Data came from women who participated in a survey from 2002 to 2017.

Metz said she believes their study is unique because they didn't rely on self-reporting. They were able to take a large cohort of women and actually look at cannabis metabolites in urine samples across the course of the pregnancy and examine those outcomes.

Using medical record data, the adverse outcomes—or composite outcomes—related to placental function included small-for-gestational-age birth, medically indicated preterm birth, stillbirth, or hypertensive disorders of pregnancy.

Specifically, they found that 26% of people who used cannabis during pregnancy had one of those adverse outcomes compared to 17% who did not use cannabis. When they analyzed for "no exposure," "exposure only during the first trimester," or "ongoing exposure," they found that only using cannabis during the first trimester was not associated with the primary composite outcome. However, ongoing cannabis use was associated with the primary composite outcome.

Advice for clinicians

Natalie DiPietro Mager, PharmD, PhD, MPH, said it is important to talk to all patients about the risks of cannabis exposure on pregnancy outcomes, especially as cannabis use increases with more states legalizing it for both recreational and medicinal use.

Patients often use cannabis to relieve nausea or anxiety during pregnancy.

"I think pharmacists can play a key role in education and counseling for pregnant patients or patients considering pregnancy. Per the American College of Obstetricians and Gynecologists, use of marijuana for nausea and vomiting or other medicinal purposes during pregnancy is not recommended," said DiPietro Mager, who is a professor of pharmacy practice at Raabe College of Pharmacy at Ohio Northern University. "Rather, patients should be advised to use therapies with better pregnancy-specific safety and efficacy data."

"Clinicians need to have open conversations because there are safe alternatives we can use to treat those conditions during pregnancy," said Metz.

Both clinicians and patients need to know how important it is to talk about this, said Metz. "Be open about it and be willing to talk to patients about the risks. Understanding that we don't know everything, but this study adds to literature and gives us information about cannabis use in pregnancy." ■

Semaglutide prescriptions have increased 40-fold over the last 5 years.

Weight-loss injectables enjoy exploding popularity among the 2 in 3 American adults who are overweight or obese

Sonya Collins

Corena Hughes, a 45-year-old veterinary technician, weighed in at 215 pounds when she decided she had to try something different.

It had been easier to lose weight with diet and exercise when she was in her 20s and 30s. It also didn't hurt that at that time she had lived in places like Honolulu and San Diego, where she felt motivated to get outside and move. Now Hughes was over 40 and living in Richmond, Maine, a region with long winters and short days. She was battling depression after a recent divorce and hormonal changes brought on by a hysterectomy and hypothyroidism. Her need to lose weight was made more urgent by her rising BP.

But, she said, "I just couldn't shed a pound. So, at my next physical exam, I said, 'Doctor, I need some sort of help.'" Hughes knew what kind of help she wanted; she had seen it on TikTok. It was an injectable drug called semaglutide (Wegovy), and her physician prescribed it.

Hughes began shedding weight at a clip of 1 to 4 pounds a week. Within a year, she had lost 30% of her body weight. She last weighed in at about 150 pounds. Her BMI had plummeted by 10 points, from "obese" to "normal." These results surpass even the expectations set by the literature.

"After the first week, I thought, 'What is this magic?'" she said.

In a landmark study published March 18, 2021, in *NEJM*, 1,961 adults with a BMI of 30 or greater and without diabetes were randomized to 68 weeks of once-weekly S.C. semaglutide at a dose of 2.4 mg or a placebo, plus lifestyle intervention. Those in the semaglutide group lost an average of 15% of their body weight compared to a loss of 2.4% in the placebo group. Additional studies published since then have had similar results.

Like Hughes, the public is seeing these dramatic results on social media, in magazines, and on TV and movie screens. Semaglutide prescriptions have increased 40-fold over the last 5 years, according to an analysis by Epic Research which was shared exclusively with CNN. About 1 in 60 Americans were prescribed the drug in 2023.

GLP-1 receptor agonists such as semaglutide may indeed be the "magic" weight loss drug that undoubtedly many people with overweight or obesity—which amount to two-thirds of American adults—have dreamt of. If so, they could bring dramatic population health benefits—at least to the segment of the population who can afford it. Others may take big risks to find an alternative that fits within their budget.

The rich get thinner, the poor stay sick

As GLP-1 agonist makers such as Novo Nordisk and others rake in money and the stock market braces itself against the aftershock, many people who could benefit from the drug cannot afford it. People with lower incomes are typically more likely to have overweight or obesity than their wealthier counterparts, and they are harder hit by the subsequent chronic conditions as well. Increasing use of weight loss injectables among those who can afford them could substantially increase health disparities between the haves and have-nots over time.

Growing use of these drugs has also pushed them into worldwide shortage. Many who find the price of the brand-name drugs out of reach or simply don't want to pay the high price have turned to compounded versions.

Hughes' insurance covered 6 months of Wegovy. After that, her cost would have been $1,400 per month. At that price, she couldn't even afford to titrate down slowly as her physician recommended, so she quit cold turkey.

"I went from being perfectly satisfied eating a pickle and a few olives for dinner to suddenly wanting to eat my arm off," she said.

Hughes immediately sought out a cheaper compounded semaglutide so she could get her weight management back on track.

Hughes gets the drug for a few hundred dollars a month rather than over a thousand. She's experienced no adverse events and has faced the same GI adverse effects that are expected with the branded drugs.

The most common adverse effects of GLP-1 receptor agonists are nausea and constipation. There have been some reports of acute pancreatitis, which is believed to be a result of the drug ramping up insulin secretion by the pancreas. Previous concerns about the risk of suicidal ideation were recently called into question by a large retrospective cohort study of EHRs published January 5, 2024, in *Nature Medicine* that found no correlation between these weight-loss drugs and suicidal thoughts.

Desperate measures

Saving money with compounded semaglutide may come at a high price.

FDA has received adverse event reports after patients used compounded semaglutide. In 2023, United States poison control centers fielded some 3,000 calls about semaglutide—a 1,500% increase since 2019. It's suspected that patients may be accidentally overdosing on compounded versions of the drug, which they must measure themselves as opposed to the branded medications that come in pre-measured pens.

> Patients who have only had success losing weight on GLP-1 agonists may expect to stay on them for life.

"What we've noticed at the New Mexico Poison and Drug Information Center is that patients are having symptoms consistent with the adverse effects of a normal therapeutic dose, but more severe vomiting and nausea so bad that some patients aren't able to eat or drink for a few days. That's when they consider going to the emergency department to get help," said Joseph Lambson, PharmD, DABAT, director of the University of New Mexico Health Poison Center.

FDA has also issued warnings about some compounders using salt forms of the drug, which is different from the FDA-approved medication. In addition, FDA alongside other agencies worldwide recently sounded alarm bells when counterfeit semaglutide made its way onto pharmacy shelves.

The risks of compounded GLP-1 agonists may increase as the sources of it do.

"There've been reports of people going to med spas and getting it," said Jennifer Clements, PharmD, a clinical professor and director of pharmacy education at the University of South Carolina College of Pharmacy. "People are doing this because they want the product, but can't afford it."

Pharmacists should seize opportunities, she said, to counsel patients seeking compounded semaglutide on the importance of getting it from an accredited compounding pharmacy.

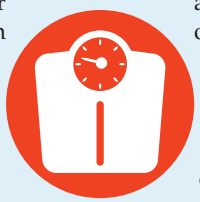
But while educating patients on where to source compounded drugs could help them avoid adverse events, it doesn't solve the problem, Clements said.

"The reason we see people pay so much, or try to save money by going through a back door, is because payers are not covering these medications," she said. "Obesity is not a cosmetic condition. It's a chronic condition that affects so many other aspects of health and can lead to further complications. People need that medicine to help them because they have tried other things and have not been successful."

In concert with lifestyle changes

Patients who have only had success losing weight on GLP-1 agonists may expect to stay on them for life, said Daniela Hurtado, MD, PhD, an endocrinologist whose research examines the brain's regulation of food intake and the benefits of semaglutide.

"The understanding that we have is that in order to maintain the weight loss and treat this chronic disease effectively, there is a very high likelihood that patients will need to stay on the drug long-term. We are treating obesity as a disease, like any other disease such as diabetes or high BP. Once we start an intervention, the plan will be to be on it long-term." Hurtado sees patients in Mayo Clinic's Precision Medicine for Obesity program in Jacksonville, FL.



But long-term use of weight loss drugs does not negate the need for lifestyle changes. While patients may lose significant amounts of weight on GLP-1 receptor agonists without making other lifestyle changes, they should be reminded that good nutrition and physical activity are critical to optimum health, not just optimum weight.

In addition to counseling patients on the GI adverse effects and how to administer the drugs, "pharmacists need to tack on that they still have to make lifestyle modifications—changes in what they eat and drink and to be active—because that's part of weight loss," said Clements. She added that it's unclear whether some of the GI distress patients feel on GLP-1 agonists is from the drug itself or from continuing to eat unhealthy foods.

Eat less, feel fuller longer

GLP-1 receptor agonists such as semaglutide entered the market as diabetes medications, but it was soon clear that this powerful medication did more than stimulate insulin production.

"We also found that it can act at the level of the brain to suppress appetite and at the level of the stomach to delay how fast food is emptied from it. So it not only decreases the hunger sensation and appetite, but also gives you a sensation of fullness, or satiety, for a longer period of time," said Hurtado.

Hughes said the drug not only killed her appetite almost completely, but it also put her off what she considered her Achilles heel when it came to weight management: red wine. "It was my weakness and the culprit of all my weight gain. I would just drop bottles of red wine like it was nothing. And now, I can't. I don't like it."

Hughes' experience is borne out in preliminary research, too, which suggests semaglutide may help reduce alcohol consumption and curb other addictive behaviors.

David Soliman, a 43-year-old financial adviser in New Orleans, described the appetite suppression he got from tirzepatide (Mounjaro, Zepbound) as a silencing of "food noise."

"I had to be munching on something or thinking about my next meal all the time," he said. "It was really remarkable—just kind of like a switch flipped. My relationship with food and my thoughts about food were completely different. The noise is something you don't even realize is there until it's not anymore."

Soliman weighed 250 pounds when he started the drug. In 8 months, he lost 55 pounds. These days, he can forget to eat entirely. On a typical day, when he remembers, he has two protein shakes and a small meal.

Research is beginning to show that these drugs may affect other weight-related health conditions, too. In the SELECT trial, adults with obesity who didn't have diabetes and received semaglutide were 20% less likely than those on placebo to have a CV event. This benefit arose earlier in the study period than weight loss did. The drugs may improve obstructive sleep apnea, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, and diabetic kidney disease.

Like Hughes, Soliman and his wife are on a compounded formulation, too. They get the drug for a few hundred dollars a month rather than over a thousand.

Market disruptor

Given their potential to dramatically suppress chronic disease rates as well as the population's collective appetite, semaglutide, some predict, may be a major economic disruptor, too. In October of last year, Truist analyst Bill Chappell downgraded his rating for Krispy Kreme from a "buy" to a "hold," citing the overwhelming use and popularity of appetite-suppressing GLP-1 agonists. That same month, it was reported that the drug's successes had triggered a sell-off of shares in Dexcom, the maker of continuing glucose monitoring systems, and DaVita, the manufacturer of dialysis machines.

Long-term use of weight loss drugs does not negate the need for lifestyle changes.

On a microeconomic level, Soliman has certainly seen demand for high-calorie foods plummet in his household. He and his wife, who is also on tirzepatide, buy less at the grocery store, dine out less often, and when they do they order less food.

"We're splitting an appetizer and maybe an entrée as opposed to two apps and two entrées, and we're not ordering out as much. It's curbed all of that," he said.

But the financial adviser is as struck by the broader market impact of the drugs as he is by the changes he's seeing in his own waistline and wallet.

"The level of disruption these drugs are creating within industry is fascinating," he said. "Weight Watchers acquired a telemed company simply so they could start prescribing this stuff to their client base. Medical device companies have seen an extreme dip in their stock prices. The health care industry would save trillions a year if you could actually start eradicating obesity and related ailments." ■

Diabetes care AIDed by new digital technologies

Olivia C. Welter, PharmD

Patients with diabetes have been using devices such as insulin pumps and continuous glucose monitors for many years, but automated insulin delivery (AID) technologies appear to be the next big tool in the progression of diabetes technology.

In a new consensus recommendation on AID systems published in the April 2023 issue of *Endocrine Reviews*, Phillips and colleagues provided not only key information for clinicians to consider when evaluating AID systems as a treatment option, but also emerging knowledge on upcoming enhancements to AID systems.

Benefits of AID systems

AID systems are some of the most recent digital technologies available to patients with diabetes, adding sophisticated algorithms to closed-loop systems. Such algorithms can continuously adjust insulin delivery in response to real-time glucose levels obtained from the sensor component of the AID system. Additionally, newer versions of AID systems have sensors that do not require calibration, and automatic corrective doses of insulin are provided in response to improved adaptive algorithms. Patients can even observe in real-time how their lifestyle can affect their blood glucose level.

Studies such as the one published in *NEJM* on November 30, 2023, by Hughes and colleagues highlight real-world results from individual patients. Some benefits of AID systems, noted the study, include rapid decrease of measured glycated hemoglobin, better quality of life due to an easier injection process, and improved user comfort with managing extremes of blood glucose measurements.

The researchers said that AID therapy can increase the time that a patient spends in target glucose range without triggering hypoglycemia as well as reduce the burden of diabetes management among both patients with diabetes and their support system.

Target populations for AID

The study provided recommendations for which type of patients should be considered for AID system use. All patients with T1D are the primary target population, including children 7 years or older, adolescents, and adults.

Clinicians should consider recommending AID systems to older adults, children under 7 years old, and pregnant patients with T1D as well. Authors of the recommendation suggested that AID systems be permitted in hospital settings under supervision in an effort not to complicate care or confuse patients, as some institutions may revert patients back to insulin injections when hospitalized.

Barriers with digital technologies

The recommendations emphasized that although AID systems are highly beneficial for patients, there are certain barriers to using them. Clinicians must emphasize to patients that AID systems can only help make diabetes management easier, not completely replace basic skills.

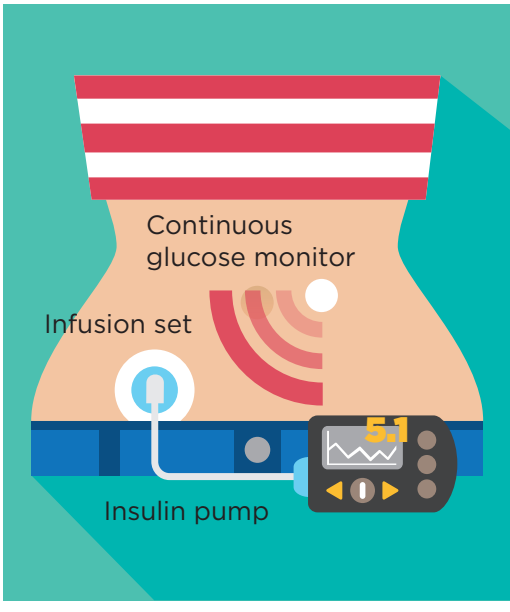
Patients using AID systems as well as health care providers must be properly trained in how to use AID devices and how to troubleshoot if issues arise.

According to the authors, multifactorial racial and ethnic disparities exist in prescribing AID system technologies, meaning that some individuals who would be appropriate candidates for AID systems may be overlooked due to preconceptions and unconscious biases about the individual, their family, or their psychological attributes.

Diabetes technologies can be fairly expensive, which could cause individuals to opt out of using AID systems to save money. In addition, cost-effectiveness studies on AID technologies are scarce and little data are available to payers as they try to determine whether they will cover such systems.

New developments in AID technologies

Newer versions of AID systems that could incorporate glucagon or pramlintide delivery in addition to insulin are currently under development. These would address not only elevated blood glucose levels, but also hypoglycemia.



The researchers noted that AID systems may soon become fully automated, with inputs such as motion sensing, meal detection, and disturbance anticipation used to control blood glucose levels falling outside of target glucose ranges after a meal or during exercise.

In order for AID systems to continue being accepted by patients with diabetes as treatment options, the authors highlighted that size, shape, battery life, and customizations of AID hardware and software are crucial factors. Looking toward the future, diabetes technology companies should consider how they can continue improving these key features of their systems. ■

How reliable is ChatGPT as a tool for MTM?

Elizabeth Briand

Every day seems to bring with it another new use for ChatGPT, the artificial intelligence (AI)–driven chatbot created by OpenAI. Experts have speculated that AI could help pharmacists improve safety, predict health risks, and more. A new study published in the November/December 2023 issue of *JAPhA* suggested that ChatGPT might one day play a significant role in medication therapy management (MTM).

Researchers of the study sought to determine whether ChatGPT could be used to identify medication interventions by integrating patient and drug databases—and specifically to see how effective it was in MTM for simple, complex, and very complex cases.

ChatGPT engages in MTM by collecting and processing sensitive patient data.

Putting AI to the test

Investigators took 39 sample cases—with 13 each designated as simple, complex, and very complex by a team of clinical pharmacists—and assessed ChatGPT's responses to each case based on three criteria: its ability to identify the interactions between drugs, diseases, substances, and supplements; its precision in recommending alternatives; and its appropriateness in devising management plans. Using a predetermined formula, ChatGPT's responses were considered valid if it could accurately provide 70% of the clinical points from each criterion when compared to the previously researched answers. This threshold was based on the passing score requirements for the United States Medical Licensing Examination and NAPLEX.

ChatGPT's responses earned a 39 out of 39. It did very well in the simple and complex cases, but the very complex cases required more informational support for it to achieve the correct answers. Overall, the study found that "ChatGPT was able to identify potential interactions and provide reasonable management plans, but limitations existed in recommending alternative medical therapy and specifying medication recommendations."

Don Roosan, PharmD, PhD, lead author of the study from Western University of Health Sciences in California, who is a proponent of the use of informatics and technology in medicine, was surprised at the full spectrum of results. "One of the reasons MTMs are so unique is because they take years of experience [to do them well]," he said. For ChatGPT, which is continuing to evolve every day, to achieve a perfect score was eye-opening.

"Achieving a 100% success rate in simple cases was expected to some extent, given the access to all available online databases, but maintaining a commendable accuracy even in complex and very complex cases was particularly surprising," said Yanting Wu, PharmD, a postdoctoral fellow with Indiana University School of Medicine's Division of Clinical Pharmacology, who also worked on the study.

Looking at potential benefits down the road

Findings of the study suggest that in the not-too-distant future, the use of ChatGPT in MTM could help enhance patient safety, lower health care costs, and help providers identify potentially harmful drug interactions. These applications, in turn, could assist increasingly busy health care providers and pharmacists by decreasing the time needed to create MTM plans.

"Beyond this, patients stand to gain additional benefits, experiencing more personalized and effective MTM," Wu said. "By analyzing extensive datasets, ChatGPT can deliver tailored recommendations based on individual patient characteristics, leading to improved treatment outcomes, reduced risks of adverse effects, and enhanced overall health."

AI may also benefit patients directly. "Medical knowledge and data have been kind of a monopoly where only doctors and pharmacists can access that information," Roosan said. "This can help empower patients to understand [their care]. They don't have to Google something and get gibberish. They can ask questions and get information."

The study also acknowledged a number of hurdles that must be overcome before using ChatGPT for MTM. "It's crucial to acknowledge the challenges and limitations for using AI tools in health care, particularly regarding ethical considerations, privacy concerns, and the need for continuous refinement and integration into existing health care systems," said Wu.

ChatGPT engages in MTM by collecting and processing sensitive patient data. Because of that, the study authors noted, "opportunities for data breaches and unauthorized access to this information could compromise patient privacy and confidentiality."

In addition, ChatGPT's accuracy and consistency could be elevated even further by giving it access to more major reference management materials such as Lexicomp, building on the data already readily available to it online.

While there is still much work to be done, Roosan believes in the value of AI as a potentially valuable tool in health care. "Large language-based models are completely going to transform medicine, nursing, and pharmacy," Roosan said. "We can't fear this technology, we have to embrace it." ■

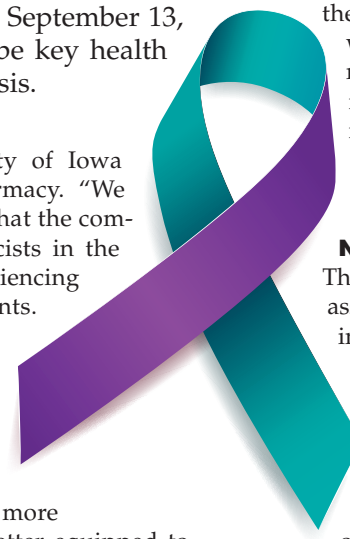
Community pharmacists are finding their patients in distress

Ronald Levinson III, PharmD

Pharmacists are an accessible point of contact for patients to discuss their health needs, and a study published September 13, 2023, in *JAPhA* suggested that pharmacists may be key health care professionals in the growing mental health crisis.

Researchers examined Iowa community pharmacists' encounters and confidence levels as they related to patients with suicide warning signs. The study also explored the growing need for pharmacist training in this area. One hundred and sixty-one community pharmacists in rural and suburban Iowa completed the survey used for the purposes of the study.

"During COVID-19, there was a lot in the news about older adults experiencing distress, such as loneliness, anger, or even thoughts of suicide," said lead author Matthew J. Witry, PharmD, PhD, associate professor at the University of Iowa College of Pharmacy. "We wanted to see what the community pharmacists in the state were experiencing with their patients. We were hoping to learn about what we could target with future initiatives to help pharmacists feel more confident and better equipped to help."



Pharmacists reported a high number of encounters with patients with suicide warning signs. Most encounters described patients in distress, ranging from expressions of hopelessness to anger.

"Certainly a striking element in the data was how universal it was among pharmacists to report encountering patients in distress, including hearing about their negative life events, loneliness, and displays of anger," Witry said.

Need for training

The research team reported the association between prior training in suicide prevention and supportive behaviors such as pharmacists asking patients directly about suicide and referring them to resources.

A third of survey respondents had previous suicide prevention training, which was significantly associated with high levels of confidence and patient interventions. Most respondents expressed interest in obtaining training on intervention strategies and knowing where they could refer patients.

"These findings are consistent with other reports from pharmacists," said Witry. "It adds to the evidence supporting the role of training for frontline personnel who are interacting with the public."

Witry noted that pharmacists already perform interventional behaviors in their regular line of work, such as counseling on medications that can increase suicidal ideations, safe medication storage and disposal, and withholding medications because of potential harm risks.

"It is powerful to see how pharmacists are supporting patients in their communities, especially given the constraints of the workplace," Witry said. However, additional training in suicide prevention and how these interventions can be part of an action plan can contribute to more confident pharmacists who are able to respond to patients at risk for, or currently experiencing, mental health crises. ■

Resources and tools

- American Foundation for Suicide Prevention (AFSP): AFSP is a voluntary health organization with educational resources about mental health and suicide prevention.
- For Your Health: Managing Chronic Stress to Prevent Burnout: This APhA online knowledge-based CPE activity offers pharmacists information about how to manage stress and prevent burnout in the workforce.
- CDC Prevention Partner Toolkit: CDC's Injury Center created a Suicide Prevention Month Social Media Toolkit, which includes sample social media graphics and messages centered around the key role personal connections play in preventing suicide.
- Mental Health First Aid: This skills-based training course teaches participants to identify, understand, and respond to mental health and substance use challenges.
- QPR Training: QPR stands for Question, Persuade, and Refer—the three simple steps anyone can learn to help save a life from suicide. People trained in QPR learn how to recognize the warning signs of a suicide crisis and how to ask questions and persuade and refer someone to seek help.

APhA 2019 Policy: Pharmacists' Role in Mental Health and Emotional Well-Being

- APhA encourages all health care personnel to receive training and provide services to identify, assist, and refer people at risk for, or currently experiencing, a mental health crisis.
- APhA encourages employers and policy makers to provide the support, resources, culture, and authority necessary for all pharmacy personnel to engage and assist individuals regarding mental health and emotional well-being.
- APhA supports integration of a mental health assessment as a vital component of pharmacist-provided patient care services. (*JAPhA.* 2019;59(4):e16) ■

Pharmacy walkouts lead to beginnings of pharmacy union

Mickie Cathers

During the fall of 2023, pharmacy personnel staged walkouts at Walgreens and CVS stores citing unhealthy and unjust working conditions that put patient safety at risk. These protests by pharmacists and pharmacy personnel, which also included pharmacy labor advocates, led to the launch of the Pharmacy Guild, a formal unionization effort for pharmacy workers.

In response to the walkouts, companies such as Walgreens and CVS have said they are committed to developing sustainable action plans to support both pharmacists and patients. However, the pace of change can be slow.

"I absolutely value and support the work of our associations in this battle to improve working conditions. But the recent walkout events have proven that pharmacists and technicians needed a protective voice when standing up to fight for themselves and their patients," said Bled Tanoe, PharmD, founder of #PizzaIsNotWorking and union advocate. "Having the support of a union will probably ensure a strong hold in fighting for better working conditions."

The Pharmacy Guild is an organization of pharmacy professionals focused on changes to staffing and workload standards as well as legislative and regulatory action to ensure safe patient care. It is an independent effort affiliated with IAM Healthcare, a union of health care professionals, working with grassroots leaders and pharmacy professionals to organize with true collective power and accountability.

Patients first

Patients may not have any idea about what's happening behind the counter, or what other responsibilities a pharmacist has taken on.

"There is a unique bond between patients and their local pharmacists," said Tanoe. "I believe pharmacists need to be honest with patients with the struggles they are facing. The lack of awareness from patients leads to assumptions and blame shifting toward our pharmacists and technicians who are desperately trying to serve their communities."

The most impactful thing any pharmacy professional can do right now to help patients is to stand up and organize for change with coworkers.

Motivated by patient safety

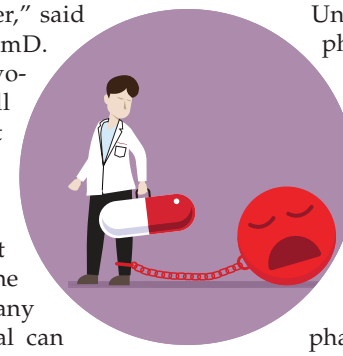
"So many pharmacy professionals are taking action right now in every region of the country because we know our patients deserve better," said Maurice Shaw, PharmD. "We must be their advocate. Our union will ensure we have a seat at the table to do that."

Shaw, who is the founder of RXComedy, a humor podcast on YouTube, said the most impactful thing any pharmacy professional can do right now to help patients is to stand up and organize for change with coworkers.

Unsafe working environments, stores closing, budgets shrinking, public harassment from agitated and frustrated customers, and uncompromising performance metrics—such as how quickly they answered the phone or the number of prescriptions filled for 90 days—has created a powder keg of pharmacists suffering from anxiety, stress, and pressure, which has had a direct impact on patient care.

"When we're forced to work at unsafe speeds in environments where our quotas and workload far outstrip what's safe, those dangerous staffing levels inside create huge risks for our patients from delays in being able to fill patients' lifesaving medications in a timely manner, up to the risk of serious or even fatal medical errors," said Shaw.

"We're organizing together to save our profession," said Shaw. "We refuse to stand by and watch our profession decline any further so we're taking action to use our collective voice to advocate for the changes that our industry needs."



Union leaders believe that a pharmacy union will result in appropriately staffed pharmacies and, said Shaw, "allow pharmacists to focus on providing excellent care to our patients instead of being bombarded with non-clinical tasks."

As the clinical role of pharmacists continues to expand, Shaw continued, it is important that pharmacies are staffed appropriately so that pharmacists are allowed to safely practice at the top of their profession. ■

The knowledge requirement in a case alleging False Claims Act violations

David B. Brushwood, BSPharm, JD

In the July 2023 issue of *Pharmacy Today*, I summarized a pharmacy case from the Supreme Court of the United States in which the court ruled that the knowledge requirement in the federal False Claims Act (FCA) refers to "actual knowledge and subjective beliefs—not to what an objectively reasonable person may have known and believed." A recent case from a United States District Court in Virginia provides additional guidance on the FCA standard.

Background

The United States sued a pharmacy corporation, alleging a violation of the FCA due to falsification of prior authorization (PA) forms by a Clinical Pharmacy Manager (CPM). The pharmacy provided medications to Medicaid patients for the treatment of hepatitis C. The state Medicaid program's PA form asked questions about a patient's medical history, laboratory values, and drug test results. The CPM allegedly volunteered to complete the PA forms for a physician group if the group agreed to send their patients to the CPM's pharmacy. The CPM allegedly completed these forms with false information, leading to coverage of Medicaid patients who did not meet criteria for payment.

According to the court, the pharmacy revenues were just over $1.5 million for the first month, in which it received "payment based on falsified documentation submitted by [the CPM] or at her direction." Fifteen months later, the pharmacy revenues had increased to over $5 million.

The CPM explained to her supervisor that she was "an expert in customizing appeal letters based on a plan's criteria." In the CPM's performance review, her supervisor congratulated her for having "developed our site to have a reputation of one that will go the extra mile." A colleague later admitted that she had "falsified prior authorization records at [the CPM's] request."

The CPM pled guilty to the crime of health care fraud. The pharmacy corporation moved to dismiss its case, contending that it had no knowledge of its employee's unlawful conduct.

Rationale

The court first noted that the FCA makes liable "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment." The term "knowingly" is defined under the FCA as "actual knowledge," "deliberate ignorance," or "reckless disregard of the truth or falsity."

The pharmacy corporation argued that it had "good faith reasons" to believe that the pharmacy's revenues had increased for "proper reasons." However, the court reasoned that the corporation received notice of the large increase in revenue because it was a topic of conversation between the CPM and her supervisor. In fact, this large increase in revenue was the event that prompted the CPM to explain to the supervisor the reason behind it.

The court also described how the corporation "employed a bonus program that incentivized higher sales" and noted that this program could "incentivize to increase revenue numbers by any means necessary."

The pharmacy corporation's motion to dismiss was denied, although the ultimate outcome of the case is undetermined at this time.

Takeaways

Pharmacists supervise medication acquisition and use to promote safe and effective outcomes for patients. Pharmacists also assure compliance with pharmaceutical payment plans to promote economic efficiency in patient care. Both of these professional responsibilities lead to legal difficulties if they are not met.

PA programs can be annoying and may seem inequitable when some patients are denied coverage. Nevertheless, any temptation to game the PA system "for the benefit of the patient" must be resisted. Patients receive a benefit when rules are followed.

Any time a colleague requests that an unlawful act be committed, this request must be reported to a supervisor. Pharmacy supervisors should be open to receiving such information objectively and confidentially.

Pharmacy supervisors should have their curiosity piqued by any unexpected event, including good news about any unanticipated increase in pharmacy revenues. Confirming a legitimate explanation can prevent liability for knowingly allowing fraudulent activity. ■

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Safeguarding the filling process using automated dispensing technology

Institute for Safe Medication Practices, Horsham, PA

Recently, paroxetine 20 mg tablets were found in a prescription bottle along with the prescribed promethazine 25 mg tablets. Upon investigation, it was determined that multiple bottles of paroxetine had been added to the automated dispensing technology's (e.g., vial-dispensing robot) cell containing promethazine 25 mg.

Selection and storage errors

The pharmacy had been in the process of adding additional technology, and as a result, the shelves were compacted and medications rearranged. The promethazine and paroxetine bottles looked similar and were stored beside each other on the shelf.

Additional bottles of medications, behind the front-facing promethazine and paroxetine bottles, were likely mixed together. A pharmacy team member intended to grab multiple bottles of promethazine to refill the robot, but they mistakenly picked up bottles of both promethazine and paroxetine. The pharmacy determined that the original refilling error occurred about a month before it was discovered. All patients who potentially received the wrong medication were contacted.

In a second case, a pharmacy was in the process of refilling one of the robot's cassettes with trazodone 50 mg tablets. The person refilling the machine retrieved two 500-count medication bottles from a storage shelf, but without realizing it, one of the containers held topiramate 50 mg, not trazodone 50 mg. Both medications were manufactured by Zydus Pharmaceuticals, and the bottles and tablets looked nearly identical.

Also contributing to the selection error was the fact that one bottle had been sitting right behind the other where they were stored. Fortunately, before anyone received the wrong medication, a pharmacist caught the filling error while verifying a prescription for trazodone 50 mg when she recognized that the two drugs appeared to be mixed together in the prescription vial.

Before anyone received the wrong medication, a pharmacist caught the filling error while verifying a prescription for trazodone 50 mg when she recognized that the two drugs appeared to be mixed together in the prescription vial.

While automated dispensing technology software commonly requires (or allows for) barcode scanning when adding medication to a cell, most only require the scanning of a single bottle. If multiple bottles are used to refill the cell, the technology can be bypassed by scanning just one bottle. That is, if you are trying to add 500 tablets and the medication comes in 100-count bottles, you can scan just one of the bottles and then pour the remaining four bottles—even if they are the incorrect medication—into the dispensing robot cell.

Takeaways

Pharmacies with robotic dispensing capabilities need to address situations in which multiple bottles of tablets are used to refill a cassette. Visual checks are important, but, as described above, cannot be solely relied upon for proper identification of bottle contents.

Check with your technology manufacturer to learn what is recommended to address situations in which multiple bottles are used to refill a cassette. Ideally, the filling process should require a scan of the barcode printed on the label of each stock bottle before it is added.

Establish standard work practices to barcode scan each stock bottle. Use only unopened stock bottles to ensure the national drug code number, lot number, and expiration date match for all tablets.

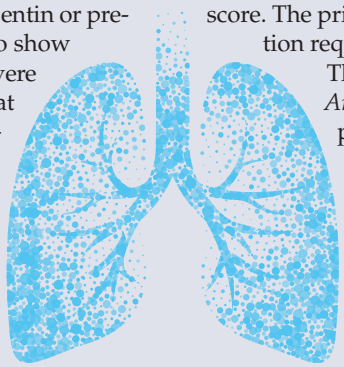
Complete the entire process of filling one cell before moving to the next cell and corresponding drug bottle(s). Restrict privileges to make modifications, adjustments, or changes in the bin contents of automated dispensing systems to properly trained staff members.

Pharmacy managers and/or regional personnel for chain pharmacies should periodically perform quality control checks by observing the processes involving automation to ensure adherence to the standardized work practices. If at-risk behaviors, such as scanning only one bottle or scanning the same bottle twice, are observed, coach staff to see the potential for error and the importance of scanning each bottle. ■

Inpatient*Insights*

Gabapentinoids pose risk for patients with COPD

Health agencies in both North America and Europe, including FDA, have warned of severe breathing problems in patients with COPD who are also using gabapentin or pregabalin. In the first population-based study to show association between gabapentinoid use and severe COPD exacerbations, Rahman and colleagues at McGill University and the Université de Montréal (Canada) evaluated insurance records from the Régie de l'assurance maladie du Québec.



The time-conditional propensity score–matched, new-user cohort study involved records from a base cohort of patients with COPD between 1994 and 2015. Patients starting gabapentinoid therapy due to epilepsy, neuropathic pain, or other chronic pain were matched one-to-one with patients not taking gabapentinoids based on COPD duration, indication for gabapentinoids, age, sex, calendar year, and time-conditional propensity score. The primary outcome was severe COPD exacerbation requiring hospitalization.

The study, published on January 16, 2024, in *Annals of Internal Medicine*, showed that compared with nonuse, gabapentinoid use was associated with increased risk for severe COPD exacerbation for patients with epilepsy (HR 1.58), neuropathic pain (HR 1.35) and other chronic pain (HR 1.49), with an overall HR of 1.39. The authors suggest that these results support the warnings from regulatory agencies and highlight the importance of considering this potential risk when prescribing gabapentin and pregabalin to patients with COPD. ■

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Which antiseptic is best for use before surgery to repair a fractured limb?

Preoperative skin antisepsis is particularly important in preventing infection after surgical repair of a fractured limb, but questions remain as to whether alcohol solutions containing iodine povacrylex or chlorhexidine gluconate are most effective for patients undergoing this surgery. In the PREP-IT trial, investigators used a cluster-randomized crossover trial to examine the efficacy and safety of iodine povacrylex or chlorhexidine gluconate antiseptic solutions among patients with either closed or open extremity fractures.

The trial involved 25 hospitals in the United States and Canada, which were randomly assigned to use a solution of 0.7% iodine povacrylex in 74% isopropyl alcohol (iodine group) or 2% chlorhexidine gluconate in 70% isopropyl alcohol (chlorhexidine group) as preoperative antisepsis for surgical procedures to repair extremity fractures. Every 2 months, the hospitals alternated interventions. The primary outcome was surgical-site infection, including superficial incisional infection within 30 days or deep incisional or organ-space infection within 90 days. The study was published on February 1, 2024, in *NEJM*.

Among patients with a closed fracture, surgical-site infection occurred in fewer patients in the iodine group than in the chlorhexidine group. Among patients with an open fracture, the results were inconclusive. The frequencies of unplanned reoperation, 1-year outcomes, and serious adverse events were similar in the two groups. ■

Buprenorphine in ED could lead to follow-up OUD treatment

Does access to buprenorphine for patients with OUD improve engagement in follow-up care? Researchers at Highland General Hospital–Alameda Health System and the University of California investigated the uptake of buprenorphine among emergency department (ED) patients with OUD and how frequently these patients engaged in treatment after discharge

The cohort study of 464 patients with OUD, published online in *JAMA Network Open* on January 29, 2024, showed that patients who received buprenorphine in the ED were two times more likely to engage in follow-up OUD treatment.

The multisite cohort study was conducted in seven California EDs participating in a statewide implementation project to improve access to buprenorphine treatment and included 464 adult ED patients with OUD. All participants were offered buprenorphine treatment for OUD (either in-ED administration, prescription, or both). The primary outcome of the study was engagement in OUD treatment 30 days after the ED visit, determined by patient report or clinical documentation.

The results of the study showed that interest in buprenorphine treatment was high, with 85.8% of patients receiving buprenorphine treatment. Follow-up at 30 days after the ED visit showed that 49.7% of patients who received ED buprenorphine treatment remained engaged. The authors note that implementing low-threshold access to medications for OUD in the ED was associated with a substantially higher likelihood of follow-up treatment engagement one month later. They suggest that future research should investigate techniques to optimize both the uptake and effectiveness of buprenorphine initiation in low-threshold settings such as the ED. ■

Phenobarbital may reduce hospital stays for patients suffering from severe alcohol withdrawal

Preliminary data suggest that phenobarbital is as effective as benzodiazepines at managing withdrawal in patients with severe alcohol withdrawal direct activation of the γ-aminobutyric acid receptor and modulation of glutamate-mediated stimulation of the *N*-methyl-D-aspartate receptor. Although benzodiazepines have long been considered standard of care, instances in which alcohol withdrawal syndrome (AWS) is resistant to benzodiazepines has been reported, prompting researchers at the University of New Mexico Hospital to evaluate the effect of phenobarbital compared with protocolized, symptom-driven benzodiazepine administration on hospital length of stay in patients experiencing severe withdrawal.

The study, published in the January 2024 issue of *JAPhA Pharmacotherapy*, involved a retrospective chart review of patients evaluated in the ED for the treatment of severe AWS, which was defined as a Clinical Institute Withdrawal Assessment for Alcohol–Revised score of 20 or greater during their visit. The primary outcome was the difference in length of hospital stay between patients receiving phenobarbital and those receiving continuous lorazepam infusions. Secondary outcomes included ICU admission, ICU length of stay, the need for mechanical ventilation, and incidence of oversedation.

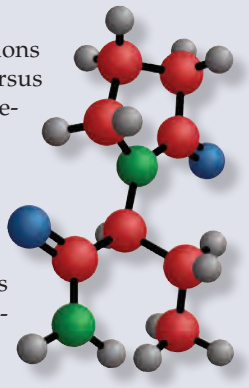
The results of the study showed that patients who received lorazepam infusion had a significantly greater length of stay than the patients who received phenobarbital. Patients treated with lorazepam also had increased admissions to the ICU and higher rates of oversedation. No differences in ICU length of stay or the need for mechanical ventilation were observed between the two groups. The authors suggest that phenobarbital should be considered as an alternative to benzodiazepine infusions for patients suffering from AWS. ■

Study suggests undiluted levetiracetam is safe for pediatric patients

Corey Diamond, PharmD

Levetiracetam has emerged as a favored choice for severe seizures due to its favorable profile, minimal adverse effects, few drug interactions, and lack of a necessity for therapeutic drug monitoring. Recent studies indicate the safety and tolerability of the rapid, undiluted administration of levetiracetam in adults, but the evidence for pediatric patients remains scarce.

Researchers of a retrospective cohort study published December 2023 in *Pharmacotherapy* sought to evaluate the safety and tolerability of undiluted levetiracetam administration. The researchers found that undiluted levetiracetam, when administered at high doses (up to 4,500 mg over 5 minutes) to pediatric patients, did not show a higher occurrence of adverse effects compared to its diluted counterpart.



"Our results support the findings of other retrospective studies that demonstrated undiluted levetiracetam is well tolerated and safe when given faster than the recommended package labeling."

Design

Price and colleagues conducted a retrospective cohort analysis at the Cincinnati Children's Hospital Medical Center, a 622-bed academic institution. Their final analysis included charting data of over 250 pediatrics patients who were administered over 350 doses of levetiracetam from May 6, 2020, to July 31, 2022. The median age of the patients included in the study was 2 years old, ranging from 1 day to 32 years old. The average patient weight was 20.1 kg in both groups. Levetiracetam was used most for status epilepticus and acute seizures. The study included undiluted doses of 60 mg/kg, up to a maximum of 4,500 mg.

The primary outcome of the study was a composite of incidences of hemodynamic disturbances and infusion-related reactions in the undiluted versus the diluted levetiracetam group. Hemodynamic disturbances were defined as incidences of hypotension and bradycardia.

Hypotension was defined as a mean arterial pressure of less than the gestational age in neonates born earlier than 37 weeks; systolic BP of less than 60 mm Hg in neonates born at 37 weeks or later; less than 70 mm Hg in infants or children aged 1 to 10 years; and less than 90 mm Hg in children older than 10 years.

Bradycardia was defined as a heart rate of less than 100 bpm for infants and children up to 3 years old, less than 60 bpm in children aged 3 to 10 years, and less than 50 bpm in children older than 10 years. Infusion related reactions included extravasation, infiltration, phlebitis, loss of I.V. access, occlusion, or line complications.

Outcomes

Ultimately, the researchers found no significant differences in the occurrences of hemodynamic disturbances or infusion related reactions between the undiluted (24.6%) and diluted (26.3%) levetiracetam group.

Additionally, in order to compare the timeliness of antiseizure medication delivery, the authors measured the time between first-line antiseizure medication and second-line antiseizure medication when levetiracetam was used as a second-line agent in status epilepticus patients. The analysis revealed that the median time to levetiracetam administration after first-line agent failure was 18 minutes in the undiluted group versus 36.5 minutes in the diluted group. This difference was statistically significant.

Lastly, the authors found that diluted levetiracetam lead to significantly more waste and drug cost per year. The authors estimated that the diluted group cost their hospital an average of over $16,000 per year versus less than $300 per year in the undiluted group.

Relevance

"Our study is the only retrospective study that evaluated the safety and tolerability of undiluted levetiracetam in pediatric patients and adds to the minimal available literature that evaluated full rescue doses needed in status epilepticus, up to 4,500 mg," stated the authors. "Our results support the findings of other retrospective studies that demonstrated undiluted levetiracetam is well tolerated and safe when given faster than the recommended package labeling."

The authors cautioned that the administration of levetiracetam in diluted form carries the risk of safety obstacles, such as crucial delays in therapy administration, at elevated doses. Additionally, there is a possibility of medication administration errors occurring when dispensing volumes of diluted levetiracetam, particularly those exceeding 300 mL within a 5-minute timeframe. "Undiluted levetiracetam vials stored in automated dispensing cabinets allows for rapid availability throughout the hospital with little manipulation regarding preparation and administration," wrote the authors. ■

How do SGLT-2 inhibitors compare for HFpEF treatment?

Ariel L. Clark, PharmD

In the realm of CV conditions, treatment options that reduce hospitalizations are critical to providing care for patients with heart failure. CDC estimates that over 6 million Americans suffer from heart failure.

Treatment plans for patients with heart failure with preserved ejection fraction (HFpEF) are patient-specific and can be complicated by a number of factors. Previous studies into treatment options for HFpEF, including EMPEROR-preserved, showed that SGLT-2 inhibitors were an effective treatment option to reduce hospitalizations and even death when compared to placebo treatment. These results led the American Heart Association (AHA) to include treatment with SGLT-2 inhibitors into its 2022 guideline update.

New research by Riaz and colleagues, published in May 2023 in *Pharmacotherapy,* attempts to help practitioners understand the differences between the SGLT-2 inhibitors' effectiveness so that they can make the best choice when designing treatment plans. Study authors were the first to investigate and summarize which of the SGLT-2 inhibitors resulted in fewer HFpEF- and non-HFpEF–related hospitalizations.

Study design and outcomes

Researchers from the University of Florida analyzed insurance claims data from commercial and Medicare payers from 2012 through 2020. They identified any patient whose insurance was billed for an outpatient claim related to HFpEF. Patients who had previous claims related to heart failure were excluded.

Claims data were narrowed further to those who were treated with canagliflozin, dapagliflozin, or empagliflozin after diagnosis and who remained enrolled in their health plan for at least an additional 6 months.

To ensure results were comparable between the SGLT-2 inhibitor cohorts, researchers adjusted for age, sex, coexisting conditions, and treatment for HFpEF with other drug classes, including ACE inhibitors and beta blockers. Using the claims data, researchers designed three cohorts for head-to-head comparison. Cohort 1 included dapagliflozin versus canaglifozin; cohort 2 included empagliflozin versus canagliflozin; and cohort 3 included dapagliflozin versus empagliflozin. Using the ICD-9/10 codes, investigators searched the data for two types of outcomes: first for HFpEF-related hospitalizations and then for hospitalization from any cause.

In the head-to-head comparisons, researchers found that empagliflozin resulted in nearly 50% less HFpEF-related hospitalizations than canagliflozin. Similarly, patients treated with dapagliflozin had 25% fewer HFpEF-related hospitalizations compared to canagliflozin, though these results were not statistically significant. And between empagliflozin and dapagliflozin, there were 50% more hospitalizations in those treated with dapagliflozin.

All-cause hospitalizations

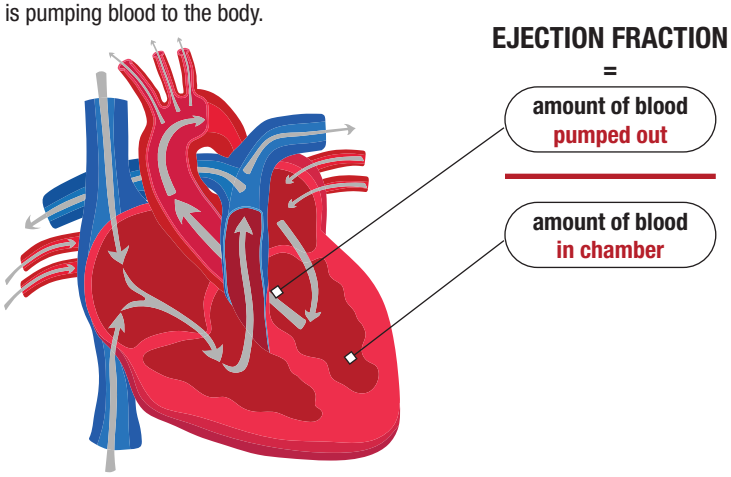
To determine the difference in all-cause hospitalization rates, this study used the crude incident rates of all-cause hospitalization within each cohort. Investigators found hospitalizations occurred less in the dapagliflozin and empagliflozin treatment groups when compared to canagliflozin—by 16% and 18%, respectively.

Dapagliflozin treatment resulted in 5% more hospitalizations than treatment with empagliflozin, though this result was not statistically significant. Empagliflozin was more effective than dapagliflozin and canagliflozin in lowering HFpEF-related and all-cause hospitalizations.

The 2022 update to the AHA treatment guidelines and the results of this study show that management of HFpEF has advanced significantly. These results have the potential to empower practitioners with insights that can be translated into personalized care. It can also build a roadmap for future studies. ■

Heart failure and ejection fraction

The ejection fraction compares the amount of blood in the heart to the amount of blood pumped out. The fraction, or percentage, helps describe how well the heart is pumping blood to the body.



Adapted from www.heart.org/HF.

FDA warns hospitals not to give preterm infants probiotic products

Loren Bonner

For years, clinicians in hospital NICUs have been giving preterm infants probiotic products to prevent a life-threatening illness called necrotizing enterocolitis, which causes tissues in the lining of their bowels to become inflamed and die. The mortality rate associated with necrotizing enterocolitis is as high as 50%, but the condition can also lead to serious infection, long-term disability, and developmental problems.

In a new warning, FDA advised health care providers to stop giving preterm infants probiotic products, which are not FDA-regulated, due to the bacteria and fungi found in probiotics that might put preterm infants at risk of invasive and potentially fatal infections.

The warning comes on the heels of a preterm infant's death. Through an FDA investigation, genomic sequencing data found the bacterium that caused sepsis in this infant was a genetic match to the bacteria contained in the commercial probiotic product Evivo with MCT Oil (Infinant Health). FDA sent warning letters to Infinant Health, which voluntarily recalled their product, as well as to Abbott Laboratories for its product Similac Probiotic Tri-Blend. Abbott has agreed to discontinue sales of Similac Probiotic Tri-Blend and is working with FDA to take additional corrective actions.

"We want to warn parents, caregivers, and health care providers that if these products are used for the prevention or treatment of disease, they have not undergone the agency's rigorous premarket process to evaluate their safety, effectiveness, and quality for these medical uses," said Peter Marks, MD, PhD, director of FDA's Center for Biologics Evaluation and Research, in an FDA statement.

But what are health care providers supposed to do without an alternative?

Trials are underway for an FDA-approved probiotic product for preterm infants, but the timeline to market is not clear.

The literature

"Necrotizing enterocolitis is so devastating, and multiple factors are thought to be the cause, including overgrowth of intestinal bacteria," said Jamie Miller, PharmD, from the University of Oklahoma College of Pharmacy. She said hospitals seem split on using probiotics or not using them to prevent necrotizing enterocolitis.

Several studies have shown the benefit of probiotics in preventing the condition. Some institutions adopted the practice when there was a big push for it years ago. The main concern, as FDA has stated, is the risk of sepsis and the fact that the products are not regulated.

"Meta-analyses have shown definite benefit," said Miller, who also practices at Oklahoma Children's Hospital OU Health. Her institution decided not to administer probiotics to preterm infants. "The issue is it's just not a regulated product," she said. When the topic came up a while back at Oklahoma Children's, they did have one probiotic on their formulary, but it was not one that showed a benefit for prevention of necrotizing enterocolitis. "That's the other thing: you have to determine if the probiotic on formulary is one that has been shown to be beneficial. Having an FDA-regulated product would help things considerably," said Miller.

Probiotics are added to milk feeds and Miller said there were also practical issues using it, including dosing.

A July 2023 meta-analysis in *Cochrane Review* which involved 60 trials and roughly 11,000 preterm infants concluded that giving preterm infants probiotics, compared with giving them placebo or no treatment, may reduce their risk of necrotizing enterocolitis and probably decreases an infant's risk of death. However, researchers said most trials included in the analysis were small and had design flaws that might have biased the findings and that there is a need for further large, high-quality trials to inform policy and practice.

An analysis published in *JAMA Pediatrics* from October 2023 of more than 100 studies and roughly 25,000 preterm infants found that probiotics containing multiple strains of bacteria were associated with reduced necrotizing enterocolitis and deaths.

"FDA understands there are conflicting data in the literature on the safety and effectiveness of probiotics for the prevention of necrotizing enterocolitis, and that the study of the use of probiotics has been complicated by several factors, including the use of different probiotics in different trials," FDA said in a statement.

According to a 2021 report from the American Academy of Pediatrics (AAP), three of the earliest randomized trials of probiotics in preterm infants suggesting benefit were conducted outside the United States. The authors noted that the studies are hindered by methodological differences among study protocols, including different strains and combinations of therapy. Different countries have different organism strains.

"It is not clear whether it is appropriate to pool data from trials by using different strains of probiotics, leading many investigators to urge caution in interpretation of meta-analyses of probiotics for the prevention of morbidity in preterm infants," the authors of the AAP report wrote.

Which way forward?

The AAP report from 2021 stressed that clinicians should not use probiotics until there's an FDA-regulated product to ensure that the preparations are appropriate. Even after this warning, many hospitals continued the practice. Miller thinks the FDA warning, however, could have a stronger impact since institutions won't want to be liable if something happens. ■

A minute with ...

Adrian Quezada Gonzalez
Student Pharmacist, Los Robles Hospital and Medical Center, Thousand Oaks, CA, and President of APhA–ASP chapter at West Coast University, Los Angeles, CA
Member since 2019

"APhA–ASP is truly the organization for student pharmacists to succeed throughout their pharmacy school experience. There's a spot for every student within the association, and no matter the role, you will have support from local, regional, and national leaders. As a member of this professional pharmacy organization, I have access to many resources, including networking opportunities, educational events, and leadership development programs. APhA–ASP has offered numerous opportunities to get involved in the community, including health fairs and other outreach events, which have allowed me to develop my patient care skills and give back to the community. Overall, my involvement in APhA–ASP has helped me to develop both personally and professionally, and has provided me with the skills and resources needed to succeed in my future career as a pharmacist."

How has APhA helped you establish meaningful connections?

APhA–ASP has helped me to connect with practicing pharmacists who can serve as mentors and provide me with insight into the profession. Through these connections, I have gained a deeper understanding of the pharmacy profession and the various career paths available to me. Overall, my involvement in APhA–ASP has allowed me to establish meaningful connections with other student pharmacists and professionals, which has been instrumental in my personal and professional growth.

How has APhA helped prepare you for your career as a pharmacist?

Through my involvement in patient care projects and other outreach events, I've gained valuable experience working with patients and developing my patient care skills.

This has included providing medication therapy management services, conducting health screenings, and promoting medication adherence.

APhA–ASP has also provided me with numerous leadership opportunities, including serving as a chapter officer and organizing events and activities for the organization. These experiences have helped me to develop my leadership and communication skills, and hone my ability to work as part of a team.

What excites you about the profession of pharmacy?

Pharmacy is a diverse and dynamic field that offers a wide range of career opportunities. Pharmacists play a crucial role in patient care, working closely with other health care professionals to ensure that patients receive the most appropriate and effective medication therapy.

As medication experts, pharmacists are uniquely positioned help improve patient outcomes and prevent medication-related problems. Additionally, the pharmacy profession is constantly evolving, with new medications, therapies and technologies emerging all the time.

Can you share a meaningful story about a time you interacted with a patient?

The most meaningful experience in pharmacy school and my time with APhA–ASP was assisting a patient with the use of a glucose monitoring device. During a health fair, I showed a patient how to properly use their glucose monitor—which they'd used incorrectly for years—step-by-step, in their preferred language, Spanish.

Helping a patient to effectively manage their diabetes can have a significant, positive impact on their overall health and well-being, which can be a very rewarding and meaningful experience for a student pharmacist and any health care professional. ■

Get involved

The opioid epidemic and subsequent increase in SUD has been a prevalent concern within health care for the past decade. At the same time, ensuring patients get proper pain management has also become somewhat of an obstacle due to concerns surrounding the overprescribing of opioids. The APhA Pain, Palliative Care, and Addiction (PPCA) Special Interest Group (SIG) strives to educate pharmacists and student pharmacists on how to care for patients with all types of pain and patients who may experience SUD.

"The PPCA SIG focuses on very current and relevant topics in contemporary pharmacy practice," said Larry Selkow, RPh, BSPharm, and PPCA SIG coordinator. "As the name of the SIG shows, pain, palliative care, and addiction are subjects all pharmacists should know about and focus on in their practice. I enjoy very much communicating with my fellow SIG members on Engage, and I especially enjoy working with the SIG leadership. Our Committee Chairs are an amazing bunch of pharmacists!" Visit apha.us/PPCA_SIG to learn more.

BCGP recertification

Board certification demonstrates superior knowledge and expertise beyond that of a licensed pharmacist. As a BCGP-certified pharmacist, you know how important it is to keep older adults in your community healthy. APhA will soon offer BPS-approved recertification courses that you can use to keep up with all your CPE requirements. APhA and the American Society of Consultant Pharmacists are collaborating to offer board prep and recertification education for the geriatric credential. APhA's offerings will include a monthly clinical case study through which learners are given the opportunity to practice identifying medication-related problems and making recommendations related to help keep older adults safe.

Coming this year, our program will offer webinars, case studies, trending topics, podcasts, and more, all developed directly from leaders in the industry. Visit apha.us/BCGP for more information and available offerings.

PWWR and safeguarding pharmacy

Embark on the new year knowing that your workplace experiences and insights are valid. At APhA, we understand that pharmacists and pharmacy teams may have concerns and ideas to offer but are often held back by fears of potential repercussions. The Pharmacy Workplace and Well-being Reporting (PWWR) tool is an online portal developed by APhA and the National Alliance of State Pharmacy Associations. This tool provides a secure and confidential platform for the entire pharmacy community to anonymously share positive and negative workplace experiences.

Your contributions to PWWR are indispensable and help shape aggregated, nonidentifiable data that informs and influences pharmacy leaders. Please visit apha.us/PWWR to share your truth and actively contribute to driving meaningful changes geared toward enhancing the pharmacy work environment and ensuring patient safety.

PWWR
PHARMACY WORKPLACE & WELL-BEING REPORTING

Pharmacist and CHW collaborations to bridge gaps in patient care

Jasmine D. Gonzalvo, PharmD, CDCES, FADCES, Chris and Theresa Dimos Director of Purdue University Center for Health Equity and Innovation and clinical professor of pharmacy practice, Purdue University College of Pharmacy, Indianapolis, IN; **Ashley H. Meredith PharmD, MPH, CDCES, FCCP,** clinical professor of pharmacy practice, Purdue University College of Pharmacy, Indianapolis, IN

The traditional health care model requires the patient to seek care by coming to the health system (e.g., office, hospital, pharmacy, etc.). Health care providers often do not represent or have the lived experiences of the communities they serve, which can lead to overt and implicit bias within the health care system.[1,2] These structural and political determinants of health further reinforce relationships that contribute to a problematic power dynamic that exacerbates long-standing health disparities primarily for communities who are underserved, notably Black, Indigenous, and people of color populations. Health disparities may evolve due to multiple reasons, including language barriers, cultural divide/differences, mistrust, and barriers related to the social determinants of health (SDOH).[3–6] Underlying systemic racism exacerbates these aforementioned factors. Pharmacists can play an integral role in beginning to mitigate long-standing health disparities by building bridges between communities and health systems.

Community health workers can be an important and trusted partner for pharmacists. A community health worker (CHW) is defined as "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served" by the American Public Health Association.[7] Furthermore, "this trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery."[7]

CHWs can take on varied roles and responsibilities that allow them to address disparities and improve outcomes.[8] CHWs may be involved in multiple facets of program delivery, including outreach (e.g., conducting health screenings, making follow-up calls, networking with community peers, etc.), provision of culturally sensitive care (e.g., serve as translator or interpreter, develop culture-specific health materials, etc.), and serving as a health advocate (e.g., serve as role model, mentor enrolled participants, etc.).[9] CHWs are able to fill the role of trusted messenger, particularly for communities that are underserved, and act as liaisons between individuals and health care providers. It is through these roles and responsibilities that CHWs are able to improve the health of populations in an evidence-based, cost-effective manner, often resulting in stronger health systems.

Positive outcomes are consistently demonstrated when CHWs are included in providing support for chronic conditions and preventive care recommendations.[10–13] For example, one CHW program in a low-income population with multiple chronic conditions found improvements in multiple clinical markers (A1C, BMI,

Learning objectives

At the conclusion of this knowledge-based activity, the pharmacist will be able to:

- Identify the current gaps in health care that can be addressed by the community health worker (CHW) workforce.
- Describe collaborative models used for successful integration of CHWs and pharmacists.
- Recognize existing models showcasing the impact of pharmacist–CHW collaboration.
- Discuss key factors that contribute to successful pharmacist–CHW collaborative models.

Preassessment questions

Before participating in this activity, test your knowledge by answering the following questions. These questions will also be part of the CPE assessment.

1. **What community pharmacy staff member has demonstrated success when cross-trained as a CHW?**
   a. Cashier
   b. Technician
   c. Pharmacist
   d. Manager

2. **What types of outcomes have been improved when CHWs are involved in patient care?**
   a. Decreased medication adherence
   b. Increased hospital readmissions
   c. Enhanced preventive care
   d. Higher patient dissatisfaction levels

3. **What factor is important to include when developing a pharmacist–CHW collaboration?**
   a. Staying within traditional health care delivery models
   b. Replicating only programs that have been tried already
   c. Creating mutually respectful community partnerships
   d. Moving programs forward without a sustainable financial plan

cigarettes per day, systolic BP) and non-clinical markers (self-rated mental health, quality of care) when compared to people who did not have CHW support.[10]

Another program found that a CHW-led diabetes self-management education showed a greater reduction in A1C and systolic BP after 1 year compared to those who did not participate in the CHW-driven program.[11]

When involved in an asthma control program for low-income adults with uncontrolled asthma, CHW home visits were associated with an increase in symptom-free days and quality of life.[12]

CHWs have also demonstrated success in improving childhood immunization rates for participants of a home-based program.[13]

These are just a few examples that highlight the impact of CHWs on conditions in which disparities exist and in which pharmacists are often involved; however, CHWs have demonstrated broad impact across myriad conditions and settings.[3–5,14–17]

Pharmacist–CHW collaboration

Existing published models highlighting the benefit of a pharmacist–CHW collaboration take place in traditional care settings (e.g., pharmacy, clinic).[18–22] A fundamental shift is needed across the pharmacy landscape that takes pharmacists out of traditional settings into places where access to health care services is most limited. Pharmacist–CHW relationships are critical to the success of this shift to bridge gaps between health services and community members.

CHW relationships with the community are fundamental to build rapport, establish trust, and maintain engagement to optimize health outcomes. Innovative strategies and models will be required to facilitate this community-focused shift. Contextualizing care, strong communication between CHWs and pharmacists, and adapting traditional health care services to meet the needs of diverse communities should be a priority.

While a robust amount of evidence exists to support the impact of the CHW workforce across myriad conditions, limited published data describe collaborative models between CHWs and pharmacy teams. Pharmacists, pharmacy technicians, and pharmacies have the opportunity to mitigate health disparities, explore opportunities for innovative income streams, and optimize health and wellbeing for their communities through collaboration with CHWs.

Much of the available literature describing CHW and pharmacist integration has taken place in the community pharmacy setting.[18–22]

CHW integration with community pharmacy

Community Pharmacy Enhanced Services Networks (CPESN) Health Equity is a national organization that has prioritized training hundreds of pharmacy technicians as CHWs to facilitate screenings, referrals, care coordination, education, outreach, and improved health care access.[20,21] Participating community pharmacies pay a nominal monthly fee to participate in the CPESN Health Equity network of pharmacies and gain access to relevant continuing education, health equity consulting services, and other supportive educational materials.[22] CPESN Health Equity has helped implement CHW–pharmacy-based programs in Missouri, Wyoming, Arkansas, and New York, with promising outcomes and reimbursement data.[18,22] These CHW-driven programs are helping to mitigate health disparities through

hosting community clinics, conducting health screenings, and administering vaccinations, among other services that improve health access while avoiding disruptions to daily operations of a community pharmacy.[22] CPESN Health Equity pharmacies have worked with state health departments, government insurers, and performance incentive contracts to support reimbursement for CHW efforts in community pharmacies.

In 2019, the Missouri pharmacy program mentioned above cross-trained pharmacy technicians as CHWs who also became responsible for continued program implementation and evaluation. The CHWs administered SDOH screening assessments and subsequently connected anyone in need with community-based organizations to help make appointments and followed up with the patient to ensure that their issues were resolved. These responsibilities were integrated into the normal workflow to avoid significant interruptions in daily productivity. Over the 3-month study period, a total of 28 screenings were conducted, with 16 SDOH challenges identified. These challenges were related to affording daily needs, transportation, or health care system navigation or management.[23] This program successfully implemented and sustained a team of over 30 CHWs.

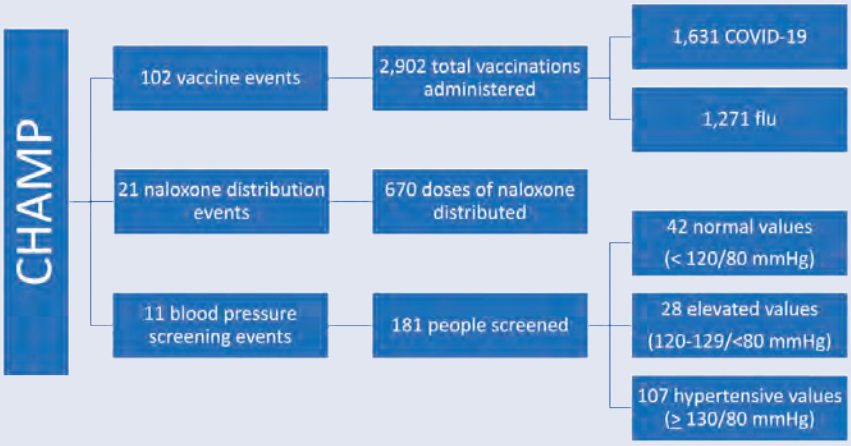


Figure 1. CHAMP outcomes June 2021 to September 2023

CHW initiatives also included the development and dissemination of culturally appropriate COVID-19 education and vaccination information during the pandemic. These CHW-driven efforts resulted in almost 80,000 education touchpoints through outreach events and almost 15,000 vaccinations administered.[24]

In 2020, this program also successfully integrated the work of the CHWs into their BP monitoring program. These CHW initiatives demonstrate the clear impact of cross-training pharmacy technicians as CHWs. Overall, staff perceptions of the program were positive.[24]

Table 1. Preliminary outcomes from the Free Clinic-CHEqI Program (February 2023–August 2023)

Patient demographics[a]		
Characteristic	**Result**	
Mean age, years (SD)	57 (11)	
Ethnicity, n (%)		
Hispanic/Latino/LatinX	3 (25)	
NOT Hispanic/Latino/LatinX	9 (75)	
Race[b], n (%)		
Black/African American	8 (80)	
White	2 (20)	
Health insurance[c], n (%)		
Private health insurance	1 (12.5)	
Medicare	2 (25)	
Not insured	4 (50)	
Other	1 (12.5)	
Primary language spoken, n (%)		
English	8 (67)	
Spanish	3 (25)	
Haitian Creole	1 (8)	
Effectiveness: Clinical outcomes		
BP[a]	Initial visit	Visit three
Systolic BP, mean mm Hg (SD)	153 (21.2)	146 (14.5)
Diastolic BP, mean mm Hg (SD)	98 (14.2)	94 (9.7)

CHW integration outside of community pharmacy

The opportunity to optimize health outcomes more efficiently exists when a pharmacist in any setting has access to SDOH information. The Purdue University Center for Health Equity and Innovation (CHEqI) has developed multiple innovative programs that emphasize collaborative efforts between a pharmacist and CHW outside of the community pharmacy with a focus on working alongside community-based organizations, acquiring necessary resources, and providing the infrastructure to design, implement, and evaluate programs that are deemed beneficial to the communities they serve. Details of three programs

Table 1. Preliminary outcomes from the Free Clinic-CHEqI Program (February 2023–August 2023) cont'd

Statin initiation[d]	Number of patients	Number of statins started
ASCVD risk, n (%)		
Low (<5%)	5 (12)	2 (40)
Borderline (5–7.4%)	2 (5)	1 (50)
Intermediate (7.5–19%)	11 (26)	4 (36)
High (>20%)	2 (5)	1 (50)
Did not assess/unable to calculate	23 (53)	2 (7)
Patient-centeredness: SDOH outcomes		
CHW referrals[e]	Number of referrals	
Referral type, n (%)		
Medical services	20 (65)	
Food resources	6 (19)	
Rent/utility assistance	5 (16)	

[a]n = 12.
[b]n = 10.
[c]n = 8.
[d]n = 43.
[e]n = 31.
Abbreviations: ASCVD, atherosclerotic cardiovascular disease; CHW, community health worker; SD, standard deviation; SDOH, social determinants of health.

are included to serve as generative inspiration for the types of collaborative models that can be created: 1) collaboration with free clinics, 2) partnership with food banks and homeless shelters, and 3) establishment of an SDOH clinic within a health system.

Collaboration with free clinics

One CHEqI program has demonstrated a successful collaboration between a clinic-based pharmacist and CHW focusing on CV risk reduction (CVRR) in partnership with a free clinic. This free clinic has provided free, quality, accessible, and compassionate patient-centered health care for persons experiencing homelessness or lacking established health care regardless of insurance enrollment for almost 40 years. The clinic provides care across multiple sites, including two permanent/stationary medical clinic sites, one mobile medical clinic with multiple partner sites, one dental clinic, and three health recovery homes for men and women experiencing homelessness. The clinic's primary care hub is housed within a food pantry where this pharmacist–CHW partnership takes place. This location is within a neighborhood that experiences the highest per capita poverty rates in the county and has the lowest life expectancy compared to the state life expectancy rate.[25]

In approaching the development of this new clinic, CHEqI recognized the critical need for care beyond what is traditionally provided by a clinic-based pharmacist. As a result, a full-time CHW was hired in January 2023. The pharmacist–CHW CVRR clinic aims to meet patient's heart health needs through CVRR interventions (e.g., medication access and optimization, patient education, etc.) managed by the pharmacist with integral wrap-around support (e.g., screening for SDOH barriers, patient navigator and advocate, benefits enrollment, transportation assistance, etc.) provided by a CHW. The pharmacist works under a CPA for the management of hypertension, dyslipidemia, and smoking cessation.

The clinic began offering its services in February 2023, with the pharmacist–CHW team available on-site at the free clinic one day per week. During a typical clinic day, 6 to 8 patients are scheduled for visits. The pharmacist performs a medication management appointment, reviewing home BP values, discussing medication use, ordering and reviewing any pertinent blood work, providing disease state and lifestyle modification education, and adjusting medications as needed. Medications are dispensed free of charge as part of the visit, with a supply provided to last until the next expected follow-up. Each patient completes a Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) screening form to identify any SDOH concerns that exist.[26] The CHW reviews the form with the patient and provides necessary referrals and connections to resources that may be needed. Outside of clinic hours, the CHW is available to patients via phone or text for problems or concerns that may arise.

While data collection and analysis is ongoing, preliminary data for the first 6 months of the program's delivery highlight the early success of the pharmacist–CHW collaboration at the free clinic. Outcomes were categorized according to the select Institute of Medicine Healthcare Quality domains of effectiveness (BP measurements, statin initiation rate) and patient-centeredness (referrals to social and health services).[27] Available data include demographics and BP outcomes for patients that had completed at least three appointments (n = 12), and statin initiation and CHW activities for all patients seen at least once (n = 43) (Table 1).[28] Unpublished data show that as of December 2023, 49 patients have been enrolled in the program, with those patients who have attended at least five appointments achieving mean BP values of 134/83 mm Hg.

This pharmacist–CHW CVRR clinic is one of the first programs at the free clinic meant to engage people with chronic disease in an intentional, longitudinal manner. The model has achieved initial success due to mirroring what is seen in other primary care settings—providing in-depth disease counseling, ensuring patients can monitor their BP at home, scheduling routine follow-up appointments, outreaching when patients miss scheduled appointments, providing

Table 2. CHAMP participant demographics (June 2021–September 2023)

Characteristic	Result	Indianapolis census comparison
Age in years[a], mean (range)	44.3 (3–101)	
Gender[b], n (%)		
Female	1,417 (50.0)	51.50%
Male	1,414 (49.9)	48.50%
Nonbinary or gender nonconforming	3 (0.1)	
Prefer not to respond	2 (0.1)	
Ethnicity[c], n (%)		
Not Hispanic or Latino	1,393 (57.0)	
Hispanic or Latino	1,024 (41.9)	10.80%
Unknown	21 (0.9)	
Prefer not to respond	7 (0.3)	
Race[d], n (%)		
White	840 (34.5)	57.70%
Black or African American	819 (33.6)	28.80%
Other/prefer to self-describe	627 (25.7)*	
Asian	113 (4.6)	3.90%
American Indian or Alaska Native	25 (1.0)	0.20%
Native Hawaiian or Pacific Islander	7 (0.3)	0.00%
Prefer not to respond	5 (0.2)	0.00%

[a]n = 2,793.
[b]n = 2,836.
[c]n = 2,445.
[d]n = 2,436.
*Out of the 627 individuals that self-identified as "Other," 416 (66.3%) identified as Hispanic/Latino.

access to medications that will last the expected time in between appointments—and adding in the additional social support provided by the CHW.

Most patients (36, 74%) have had two or more appointments, which highlights that patients are finding value in this program.

In addition to the time spent at the free clinic, the CHW has also participated in other CHEqI projects to connect patients to the free clinic and the CVRR program, when needed. The CHW regularly attends the CHEqI Community Health Access Model Partnerships (CHAMP) events. The CHW has also partnered with a local high school to support students and families with Medicaid applications and additional resources (i.e., rent and utility assistance). The CHW engages with students during lunch by providing health education and passing out healthy snacks.

While this collaboration models the traditional ambulatory care collaborative practice model for pharmacists, placing the pharmacist on-site at a free clinic located within a food bank removes barriers of access and cost for people who would not otherwise receive care from traditional health systems.

Partnership with food banks and homeless shelters

CHAMP began as the CHEqI Community Vaccination Model (CVM) and has since evolved to include services beyond vaccinations. In June 2021, CHEqI received a grant from the county health department to address racial inequities in COVID-19 response. Groups more likely to live in COVID-19 high-impact county ZIP codes include people of color and people living in poverty.[29] The CVM was created through a partnership with one of the largest Midwest food banks to offer free vaccinations alongside food distribution.[30] Additional community partnerships were then created with other food pantries and homeless shelters.

At the core of this innovative model, the goal was to advance public health and meaningfully improve patient care and community health outcomes by providing accessible, convenient, and culturally contextualized practices to optimize the reach and quality of services. Initial partners expressed interest in leveraging this model to expand health services beyond vaccination—such as screening for hypertension, SUD education, and wrap-around support (e.g., person-centered education, referrals to accessible health and social services)—to help mitigate the disparate needs of communities they serve. Using the framework of the CVM, CHAMP events were developed to offer additional services at community partner sites during publicly accessible hours (Table 2 and Figure 1).[31] Services provided may include BP screening (Figure 2), naloxone training and distribution, tobacco cessation counseling, and education on various health topics.

Since joining the CHEqI team in January 2023, a CHW has regularly attended CHAMP events, where they help provide health education and assist people with housing, food, medical, Special Supplemental Nutrition Program for Women, Infants, and Children (also called WIC), and utility resources. In addition, the CHW has helped event attendees apply for Supplemental Nutrition Assistance Program (also called SNAP) and Medicaid and provided referrals to online higher education opportunities for those seeking additional education.

Establishment of an SDOH clinic within a health system

Pharmacists and CHWs are central to the success of an innovative model recently implemented to improve nutrition insecurity for patients with

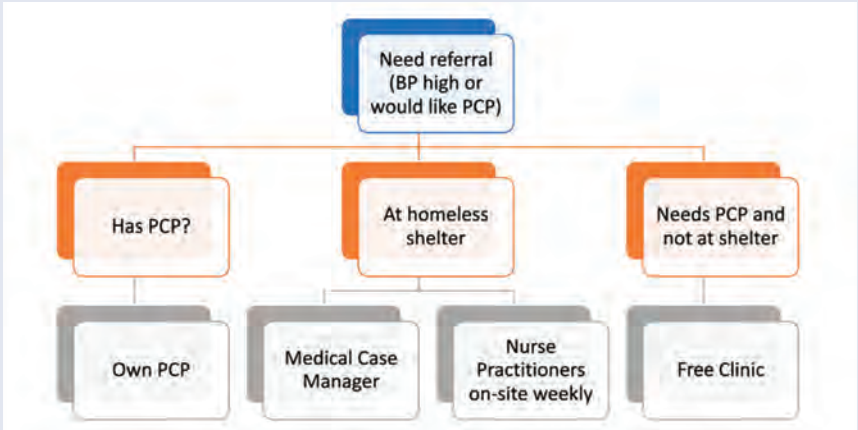


Figure 2. CHAMP blood pressure screening referrals

high CV risk.

A health system in Indianapolis, in collaboration with an area food bank, established an SDOH clinic with an integrated nutrition hub. This hub consists of refrigerated lockers in an effort to reduce the risk of heart disease through improved patient access to nutritious foods. Patients utilize a mobile application to order and receive a weekly supply of perishable and nonperishable foods from the local food bank that is delivered to the nutrition hub lockers. Pharmacists helped drive the initiative by convening relevant parties, securing grant funding, contributing expertise from existing global initiatives, developing data collection strategies, providing services in the hospital-based SDOH clinic, and collaborating with the SDOH clinic CHW. The SDOH clinic CHW interacts with patients at the nutrition hub to identify and address additional needs, and the clinic-based pharmacist serves as an additional touchpoint for chronic disease management and SDOH navigation.[32] This effort is currently recruiting patients who would benefit from improved nutrition access.

While perhaps nontraditional, the function for this pharmacist in such a collaboration represents a growing opportunity to create collaborative public health pharmacy roles.

A similar program was previously implemented in Western Kenya, where a positive impact on health outcomes for patients enrolled in an HIV care and treatment program who were also experiencing nutrition insecurity was demonstrated.[33] This pharmacist–CHW collaborative effort exemplifies the idea of bridging gaps in patient care through mitigation of SDOH-related barriers.

Factors for success

A reasonable first step for many programs looking to integrate CHWs into pharmacy care may be to make adjustments to the existing community pharmacy model, as exemplified by the success of CPESN Health Equity. When pharmacy technicians are cross-trained as CHWs within community pharmacies, they are able to take on expanded responsibilities to screen clients for barriers related to the SDOH, provide basic disease state education, or connect customers with community resources. This helps to strengthen the role of community pharmacies as champions of public health in rural and urban communities.[34]

Pharmacy technicians who come from and live in the communities who they serve are perfect candidates for the CHW role. They may have first-hand knowledge of the geographic environment, relationships with local community-based organizations, and familiarity with community resources that may address housing or nutrition security, for example. Technicians are eligible to complete local CHW certification programs with core competencies that aim to enhance their communication skills, navigate cultural mediation, provide coaching and social support, conduct outreach, and participate in evaluation and research, among others.[35]

The innovative CHEqI pharmacist–CHW collaborative care models described have common factors contributing to initial successes, with no one factor being more important than another. Each of the programs describes pharmacists going into and working closer to the communities they wish to serve, with the administrative support needed to do so. This is shifting the pharmacy role away from traditional dispensing and clinical roles to identify new public health pharmacy roles.

Tied directly to these emerging roles is the ability to think outside the box. None of the programs were restricted by what a pharmacist is "supposed to do" or "has always done." Instead, the intended goals are identified and then the model is shaped and modified to achieve those goals.

Goals are created in direct partnership with the community organizations with which trusting respectful relationships have been built. This mutual respect results in organizations determining what the needs of their communities are, while aligning priorities between all relevant organizations.

Sustainable financial resources are necessary to support this model. Many organizations may be hesitant to trial a pilot program without any plan for sustainability. Grant funding may be an opportunity to help launch a program while long-term planning occurs. Long-term strategies may include contracting with commercial payers to improve beneficiary outcomes, implementing Medicaid and Medicare policy changes for both CHW and pharmacist reimbursement, or other innovative funding opportunities that have yet to be well-defined.

One additional factor that cannot be overlooked is support for the CHW. This might take the form of connecting the CHW with any state CHW organizations for peer networking and access to additional resources or providing ongoing training opportunities to enhance the skills and impact of the CHW.

When starting a new pharmacist–CHW collaboration, these factors will be critical to address in ways that make sense for the objective of each program and cannot be applied in a "one-size-fits-all" approach.

What we have presented here is disrupting the traditional structure of health care delivery by centering innovations around the health needs prioritized by communities. CHWs facilitate improved access to resources that address the barriers related to the SDOH, allowing for a chance at optimal health. The profession of pharmacy needs to create innovative, forward-thinking, and sustainable pathways that more fully integrate pharmacists into community activities.

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Advisory board: Maya Harris, PharmD, Executive Resident, APhA; Katie Meyer, PharmD, Director, Content Creation, APhA, Washington, DC.

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CPE information

To obtain 1 hour of CPE credit for this activity, complete the CPE exam and submit it online at www.pharmacist.com/education. A Statement of Credit will be awarded for a passing grade of 70% or better. You have two opportunities to successfully complete the CPE exam. Pharmacists and technicians who successfully complete this activity before March 1, 2027, can receive credit. Your Statement of Credit will be available online immediately upon successful completion of the CPE exam.

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3. Select "Enroll Now" or "Add to Cart" (click "View Cart" and "Check Out").
4. Complete the assessment and evaluation.
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Assistance is available Monday through Friday from 8:30 am to 5:00 pm ET at APhA InfoCenter by calling 800-237-APhA (2742) or by e-mailing infocenter@aphanet.org.

CPE Assessment

This assessment must be taken online; please see "CPE information" in the sidebar on the previous page for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. **What community pharmacy staff member has demonstrated success when cross-trained as a CHW?**
   a. Cashier
   b. Technician
   c. Pharmacist
   d. Manager

2. **What types of outcomes have been improved when CHWs are involved in patient care?**
   a. Decreased medication adherence
   b. Increased hospital readmissions
   c. Enhanced preventive care
   d. Higher patient dissatisfaction levels

3. **What factor is important to include when developing a pharmacist–CHW collaboration?**
   a. Staying within traditional health care delivery models
   b. Replicating only programs that have been tried already
   c. Creating mutually respectful community partnerships
   d. Moving programs forward without a sustainable financial plan

4. **Which one of the following responsibilities is most appropriate to assign to a CHW?**
   a. Conducting health screenings
   b. Diagnosing medical conditions
   c. Counseling on adverse effects of medications
   d. Delegating tasks to other health care professionals

5. **Which one of the following issues needs to be addressed to support sustainability of the CHW workforce?**
   a. Lack of health disparities for a CHW to address
   b. Inconsistent reimbursement policies and practices
   c. Limited evidence supporting the impact of the work of CHWs
   d. Recruiting more female CHWs

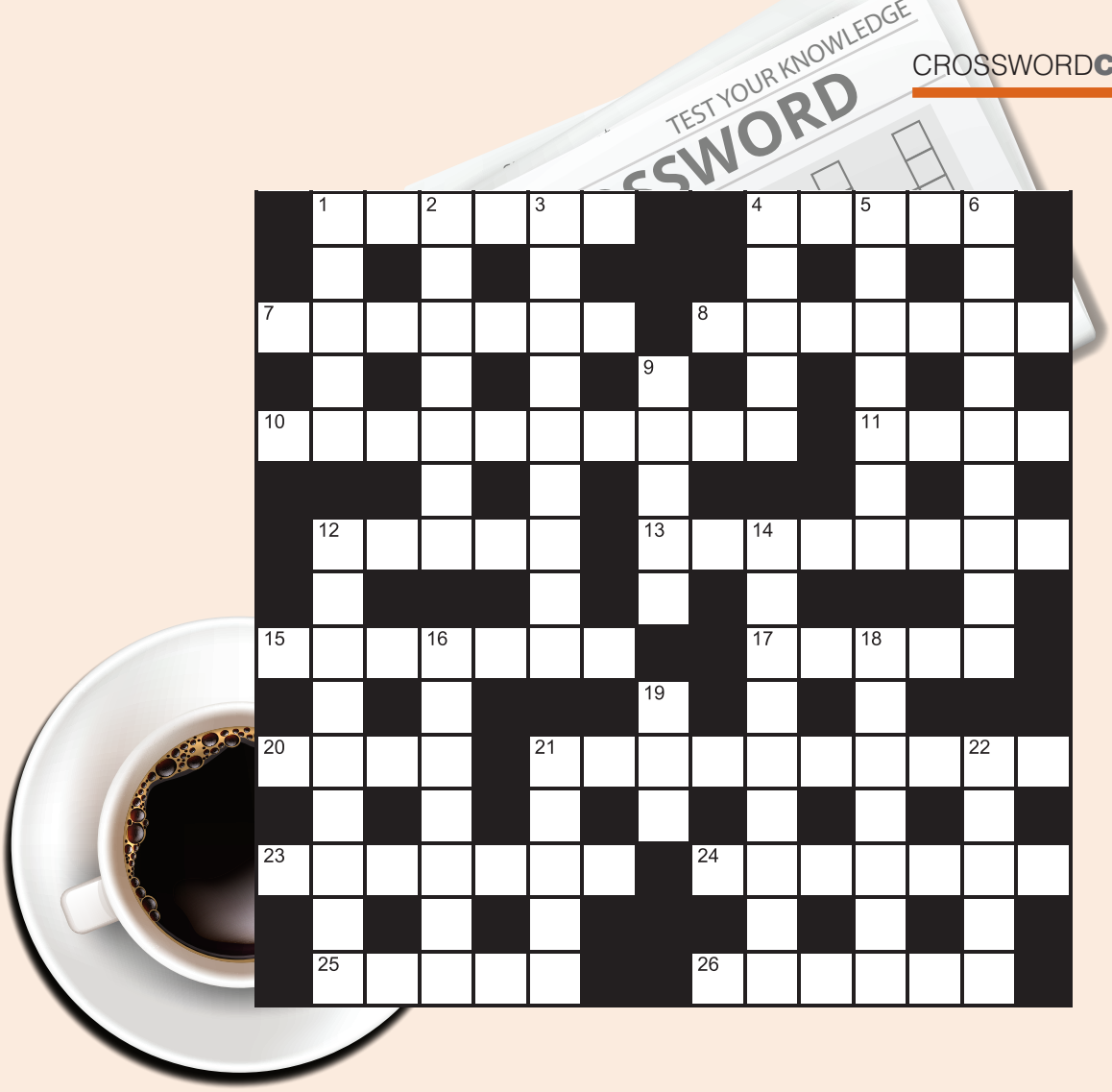
6. **CHWs can partner with _____ to improve barriers related to the social determinants of health.**
   a. Pharmacies
   b. Restaurants
   c. Banks
   d. Clothing stores

7. **What does CHW stand for?**
   a. Community health worker
   b. Community helping woman
   c. Caring helpful worker
   d. Central healthcare woman

8. **Which one of the following is an important factor of innovative CHW–pharmacist models?**
   a. Access to electronic medical records
   b. Traditional pharmacy dispensing roles
   c. Pharmacokinetic competency
   d. Public health focused responsibilities

9. **What CHW–pharmacist collaboration has been associated with improvements in BP?**
   a. Free clinic
   b. Nutrition hub
   c. Community health access events
   d. Pop-up clinics

10. **What Institute of Medicine Domain of Healthcare Quality is most relevant to the work of CHWs?**
    a. Safe
    b. Effective
    c. Patient-centered
    d. Efficient



Across

1 Justification
4 Beginning, as for a symptom
7 Really, really bad
8 One pharyngeal tonsil
10 Bar codes can be used as an _____
11 Adderall target, briefly
12 You may lose your sense of this if you have COVID-19
13 GLP-1 _____ agonists are increasingly used in weight loss
15 The "A" in ACTG
17 Obesity can do this to BP
20 Science, tech, engineering, and math (abbr.)
21 Concisely
23 A drug prescribed as H.S. should be taken in the _____ at bedtime
24 This form of an NSAID can still cause systemic adverse effects
25 Amphetamine _____ are used to treat 11 across
26 Its loss is an effect of semaglutide

Down

1 Like an animal foaming at the mouth, maybe
2 Hypertension is known as the "silent killer" because of the _____ of symptoms in many patients
3 One of the penicillins
4 _____ adults may be at risk for polypharmacy
5 Helpful to those with SAD
6 Femur
9 At a _____ fee, very small
12 Benzodiazepines, phenobarbital, and lorazepam, for example
14 Its injectable form is often used to treat inflammation, as in a joint
16 Presumed or supposed
18 Common symptom of exposure to poison ivy
19 Angiotensin-converting enzyme, in short
21 Using a neti pot may help clear this
22 Not the greatest

Solution is available online at pharmacytoday.org.