PharmacyToday

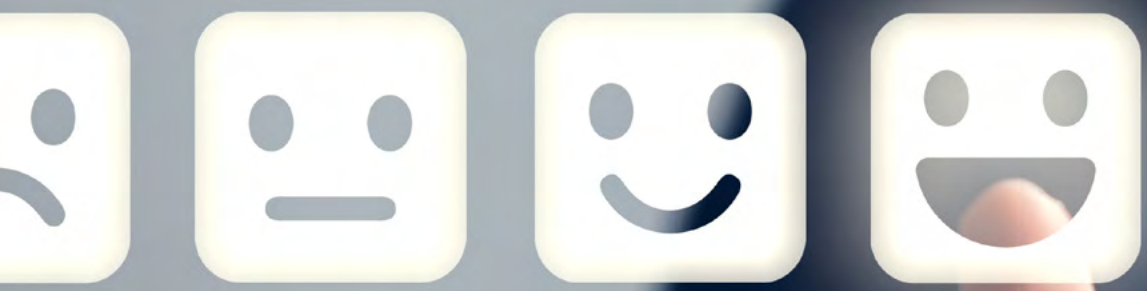
An official publication of the **American Pharmacists Association**

MAY 2023

CONTINUING PHARMACY EDUCATION

CPE

Gender-affirming care



WELL-BEING IN THE WORKPLACE FOCUSING ON SOLUTIONS

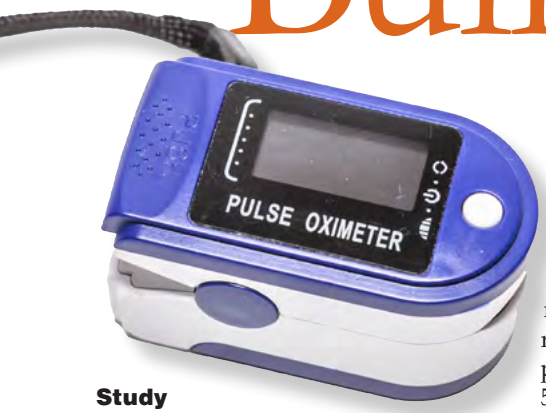
AI'S ROLE IN PATIENT DATA
Informing medical decision-making

OTC NALOXONE
Access hinges on cost

ACIP VACCINATION UPDATES
Protecting patients

APhA

BulletinToday



Study confirms racial bias with pulse oximeters

A new study in *JAMA Pediatrics* published March 20, 2023, suggests that pulse oximetry overestimated arterial oxygen saturation in Black children.

Among the study cohort of 774 white and Black children, a discordant finding of normoxemia by peripheral oxygen saturation levels on pulse oximetry (SpO_2 ≥92%), or a false negative, reached 12% of Black versus 4% of white patients. These children had true hypoxemia according to directly measured arterial blood oxygen saturation (SaO_2 <88%). However, among patients with normal SpO_2 readings, 5% of Black children and 1% of white children turned out to have hypoxemia when measured arterially.

"The discrepancy has been attributed to light absorption properties of melanin," wrote the study authors. "Race is an imperfect proxy for skin pigmentation with the inherent assumption that Black or African American patients had darker skin and more melanin than white patients."

Researchers suggest that future studies in children should prospectively evaluate the association between SpO_2 and SaO_2 with reliable, direct measurement of skin pigmentation.

Some previous studies conducted during the pandemic suggested that Black patients with COVID-19 may have experienced delays in care due to potentially inaccurate readings.

Back in November 2022 at a meeting to discuss ongoing concerns that pulse oximeters may be less accurate in individuals with darker skin pigmentations, an FDA panel said pulse oximeters are less accurate in patients with darker skin, and they urged FDA to notify patients and providers about the issue and recommend that manufacturers correct the discrepancy. ■

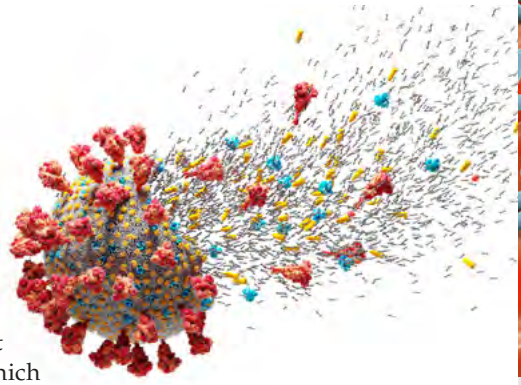
Statin alternative joins drugs that could reduce heart attack risk

A new study published March 4, 2023, in *NEJM* found that bempedoic acid (Nexletol—Esperion Therapeutics) modestly reduced the risk of heart attacks, strokes, and other complications from heart disease. However, it did not reduce the overall mortality rate. Bempedoic acid was approved by FDA 3 years ago to reduce low-density lipoprotein (LDL) levels.

The nearly 14,000 study participants included those at high risk for a heart attack or stroke who were randomly assigned to take bempedoic acid or a placebo. Their average LDL level was elevated at 139 mg/dL. At the end of the study period, the average LDL level in those taking the drug was 107 mg/dL compared with 136 mg/dL in the patients taking a placebo. After slightly more than 18 months, 819 patients (11.7%) in the bempedoic acid group had one of the heart-related complications. In the placebo group, 927 patients, or 13.3%, had such an event.

John Alexander, MD, a cardiologist at Duke Health, who wrote an accompanying editorial but was not involved in the study, said that the lack of outcome data for bempedoic acid has prompted insurers to generally not cover the drug's cost of about $140 a month.

The trial was funded by Esperion Therapeutics and led by Steven E. Nissen, MD, of the Cleveland Clinic. ■



FDA panel OKs Paxlovid as COVID-19 treatment

An FDA advisory panel backed the use of Pfizer's nirmatrelvir/ritonavir antiviral (Paxlovid) as a treatment for adults with COVID-19 who are at high risk for severe illness. The endorsement is expected to allow the drug, which is available under an EUA, to receive full FDA approval.

Pharmacists are able to order and prescribe the oral antiviral, under certain conditions, for eligible patients who have COVID-19.

The advisory panel voted 16–1 after FDA issued a new evaluation indicating that the drug reduced hospitalization and death among both unvaccinated and vaccinated people with COVID-19. Using data on COVID-19 rates in January 2023, agency researchers estimated the drug could "lead to 1,500 lives saved and 13,000 hospitalizations averted each week in the United States."

FDA's evaluation did find evidence of rebound among patients receiving the treatment. However, the data also indicated that some patients who did not receive the antiviral also experienced rebound. FDA said there was no noticeable difference in rebound rates between the two groups, and that rebound had no effect on the risk of developing severe illness. ■

Telehealth services during pandemic seemed to reduce fatal overdose risk

A new study in *JAMA Psychiatry* published March 29, 2023, shows that the wider availability of opioid use disorder (OUD)–related telehealth services and medications during the COVID-19 pandemic led to a reduced likelihood of fatal drug overdoses among Medicare beneficiaries.

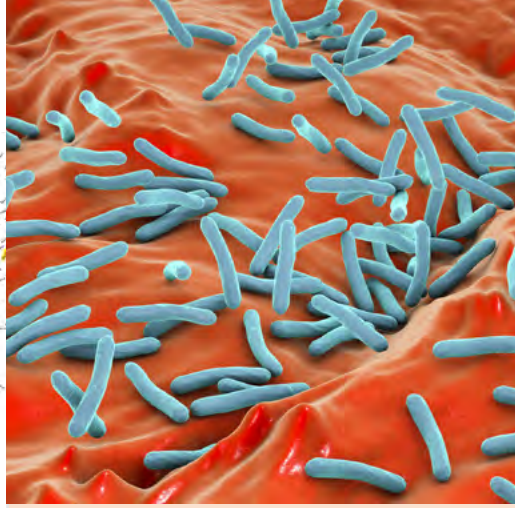
"The results of this study add to the growing research documenting the benefits of expanding the use of telehealth services for people with opioid use disorder, as well as the need to improve retention and access to medication treatment for opioid use disorder," said lead author of the study Christopher Jones, PharmD, director of the National Center for Injury Prevention and Control at CDC. "The findings form this collaborative study also highlight the importance of working across agencies to identify successfully strategies to address and get ahead of the constantly evolving overdose crisis."

For the study, researchers from CDC, CMS, and NIH examined data from two cohorts of Medicare beneficiaries to assess the use of OUD-related telehealth services, use of medications for OUD, and fatal overdoses before and during the COVID-19 pandemic.

They found that Medicare beneficiaries who commenced a new episode of OUD-related care during the pandemic and received OUD-related telehealth services had a 33% lower risk of fatal drug overdose. Medicare beneficiaries who received medications for OUD from opioid treatment programs or who received buprenorphine in office-based settings also experienced a reduced likelihood of a fatal drug overdose of 59% and 38%, respectively.

While all-cause mortality and drug overdose mortality were higher in the pandemic cohort compared with the pre-pandemic cohort, the percentage of deaths due to a drug overdose were similar between the two cohorts.

The study authors noted that just 1 in 5 Medicare beneficiaries in the pandemic cohort received OUD-related telehealth services, and only 1 in 8 received medications for OUD. These findings suggest the need for continued use of these potentially life-saving interventions across clinical settings. ■



Tuberculosis cases increased again in 2022, says CDC

New CDC data reveal that U.S. tuberculosis (TB) cases totaled 8,300 last year, an increase of 5%. CDC is urging communities at greater risk and health care providers to "Think. Test. Treat TB."

Data show that TB cases rose in 2022, although they did not return to pre–COVID-19 pandemic levels. Some public health officials were worried about the effect of missed or delayed diagnoses of TB disease in 2020, during which cases fell 20%. CDC's data now point to a rebound in cases 2 years later.

CDC noted that TB cases in children aged 4 years and younger tend to result from recent transmission rather than reactivation of latent TB infection.

CDC also advises that incarcerated individuals should be screened upon entry and yearly, as well as if they exhibit TB symptoms in a setting that raises the likelihood of outbreaks.

People from certain racial and ethnic groups are also at greater risk for TB, but recent innovations have made treatment more accessible. Today's TB treatment regimens are also shorter.

"For the second year in a row, TB disease cases in the U.S. have continued to rise, with concerning increases among young children and other groups at increased risk for TB disease. Communities, providers, and public health partners must work together to make sure we are reaching the right people with testing and treatment, so we can prevent and stop the spread of TB," said Philip LoBue, MD, director of CDC's Division of Tuberculosis Elimination, in a press statement. ■

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Take the Crossword Challenge

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See solution at pharmacytoday.org

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Wellness: A priority for pharmacists

Since the start of the pandemic, pharmacists have faced an unprecedented level of chronic stress and burnout. Many factors have contributed to this, including increased responsibilities, PBM policies, systems defects, and high pharmacist and staff turnover rates. Fortunately, this problem is getting increasing attention from employers and pharmacists alike.

What's the solution? This month's *Pharmacy Today* cover story presents some short-term and long-term strategies for success, but first digs more deeply into the cause of the problem. "What we have learned collectively is that everybody is at risk of experiencing burnout and organizations need to pay attention to sustained chronic stress," said Nancy Alvarez, PharmD, FAPhA, from the University of Arizona R. Ken Coit College of Pharmacy. "We can manage and address emerging situations—emergency situations—for short periods of time, but we can't do this for sustained periods of time."

Organizations and individuals are thinking creatively and developing solutions, from flexible work schedules and shorter workweeks to workflow redesign. Many are looking to develop new pharmacy technician roles in clinical and nonclinical activities to allow for expanded career paths for technicians… and free up a portion of the pharmacist's time.

In this issue of *Pharmacy Today*, you'll also find the latest on new drug approvals and whether arnica lives up to its hype for joint and muscle pain treatment. You'll learn about the 2023 vaccination schedules, including COVID-19, and the latest on ADHD drug shortages and OTC naloxone. Get your CPE on with this month's article on gender-affirming care and pharmacy practice.

If you are feeling a high level of stress and burnout, use evidence-based techniques that have been shown to help respond to stress productively. Focus on the moment. Breathe. Be aware that you are okay right now. Move your body to release muscle tension.

Recognize your thoughts are just that—thoughts. They are not necessarily the facts that govern your situation. In fact, your emotions can sometimes make the situation worse. Be present and focus on the realities that you can control in the moment, at every moment.

Have a great ***Today***! ■

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

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APhA2023 and pharmacy on the rise

This year's annual meeting was a resounding success. Over 3,500 attendees gathered together at APhA2023 in Phoenix in March to connect, learn, and explore. We connected with familiar faces and formed new friendships, mingling with current and emerging leaders of pharmacy. Our days were packed with sessions and events, meetings, and social gatherings.

Talk about inspiring! I'm always energized and uplifted by our annual meetings, and APhA2023 was no different. Though the very apt theme of this meeting was "In the Face of Adversity, We Rise!," the word of the meeting was "energy!" Everyone I spoke with said that they could feel a heightened level of energy around the meeting. APhA and our members never missed a beat and rode that wave of energy to rise up for our patients and our profession.

We got right back to work advocating for our patients and our profession.

The evidence is clear: patients rely on pharmacists to access essential health services, including vaccines, testing, and treatments, and to protect themselves.

While we contributed to keeping America's seniors and other vulnerable communities healthy through a pandemic, pharmacists continue to operate on a fragile foundation of temporary authorities that were put in place in response to COVID-19, and access for these patient care services at pharmacies is temporary for our nation's seniors because pharmacists are not considered providers under Medicare.

While we applaud HHS for extending PREP Act authorities for pharmacy personnel, we still need Congress to pass H.R. 1770, the Equitable Community Access to Pharmacist Services Act (ECAPS), to establish a permanent payment pathway for these services under Medicare Part B. Championed by Reps. Adrian Smith (R-NE), Brad Schneider (D-IL), Larry Bucshon (R-IN), and Doris Matsui (D-CA), the bipartisan ECAPS legislation would make permanent the temporary authorities to provide essential pharmacist services to protect seniors from the threat of COVID-19, influenza, and other infectious diseases.

Join us in ensuring our nation's seniors continue to have access to these vital pharmacist-provided patient care services. Please visit apha.us/ECAPS for an easy way to urge your congressional representatives to support H.R. 1770.

Looking forward to seeing you in Orlando for APhA2024 and celebrating our successes together! ■

ILISA BG BERNSTEIN
PharmD, JD, FAPhA
Interim Executive Vice President and CEO
American Pharmacists Association

NEW DRUGS

ZAVEGEPANT
(Zavzpret—Pfizer)

Drug class: Zavzpret is a calcitonin gene-related peptide receptor antagonist.

Indication: Zavzpret is indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventative treatment of migraine.

Recommended dosage and administration: The recommended dose is 10 mg given as a single spray in one nostril, as needed. The maximum dose in a 24-hour period is 10 mg or 1 spray. The safety of treating more than 8 migraines in a 30-day period has not been established.

Common adverse effects: The most common adverse reactions in patients being treated with Zavzpret were taste disorders, nausea, nasal discomfort, and vomiting.

Warnings and precautions: Zavzpret is contraindicated in patients with a history of hypersensitivity reaction to zavegepant or to any components of Zavzpret. If a serious hypersensitivity reaction occurs, discontinue Zavzpret and initiate appropriate therapy. Hypersensitivity reactions including facial swelling and urticaria have occurred. Avoid use in patients with severe hepatic impairment or a creatinine clearance of <30 mL/min. Avoid use of Zavzpret with drugs that inhibit or induce OATP1B3 or NTCP transporters. Avoid use of intranasal decongestants. If unavoidable, administer intranasal decongestants at least 1 hour after Zavzpret administration.

TROFINETIDE
(Daybue—Acadia Pharmaceuticals)

Drug class: The mechanism by which trofinetide exerts therapeutic effects in patients with Rett syndrome is unknown.

Indication: Daybue is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years and older.

Recommended dosage and administration: Recommended dosage is twice daily (morning and evening), according to patient weight. Daybue can be administered orally or via gastrostomy tube, with or without food. Doses administered via gastrojejunal (GJ) tubes must be administered through the G-port. Depending on the weight of the patient, doses can range from 5,000 mg (25 mL) twice daily to 12,000 mg (60 mL) twice daily.

Common adverse effects: The most common adverse reactions were diarrhea and vomiting.

Warnings and precautions: Most patients experience diarrhea during treatment with Daybue. Advise patients to stop taking laxatives before starting treatment. If diarrhea occurs, patients should start antidiarrheal treatment, increase oral fluids, and notify their health care provider. Interrupt, reduce dose, or discontinue Daybue if severe diarrhea occurs or if dehydration is suspected. Weight loss may occur in patients treated with Daybue. Monitor weight and interrupt, reduce dose, or discontinue Daybue if significant weight loss occurs. Daybue is not recommended in patients with moderate to severe renal impairment. Closely monitor for adverse reactions if Daybue is used concomitantly with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities. Avoid concomitant use with OATP1B1 and OATP1B3 substrates for which a small change in substrate plasma concentration may lead to serious toxicities.

LENIOLISIB
(Joenja—Pharming)

Drug class: Joenja is a kinase inhibitor.

Indication: Joenja is indicated for the treatment of activated phosphoinositide 3-kinase delta syndrome (APDS) in adult and pediatric patients 12 years and older.

Recommended dosage and administration: The recommended dosage is 70 mg administered orally twice daily approximately 12 hours apart, with or without food, in adult and pediatric patients 12 years and older and weighing greater than or equal to 45 kg. Verify pregnancy status in patients of reproductive potential prior to initiating treatment.

Common adverse effects: The most common adverse reactions were headache, sinusitis, and atopic dermatitis.

Warnings and precautions: Joenja may cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. Live, attenuated vaccinations may be less effective if administered during Joenja treatment. Advise patients not to breastfeed during treatment. Use in patients with moderate to severe hepatic impairment is not recommended. Avoid concomitant use with strong CYP3A4 inhibitors, strong or moderate CYP3A4 inducers, CYP1A2 metabolized drugs with a narrow therapeutic index, and BCRP, OATP1B1, and OATP1B3 substrates.

SPARSENTAN
(Filspari—Travere Therapeutics)

Drug class: Filspari is an endothelin and angiotensin II receptor antagonist.

Indication: Filspari is indicated to reduce proteinuria in adults with

primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatine ratio greater than or equal to 1.5 g/g.

Recommended dosage and administration: Prior to initiating treatment with Filspari, discontinue use of renin-angiotension-aldosterone system inhibitors, endothelin receptor antagonists (ERAs), or aliskiren. Initiate treatment with Filspari at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated. When resuming treatment with Filspari after an interruption, consider titration of Filspari, starting at 20 mg once daily. After 14 days, increase to the recommended dose of 400 mg once daily. Instruct patients to swallow tablets whole with water prior to the morning or evening meal.

Common adverse effects: The most common adverse reactions are peripheral edema, hypotension, dizziness, hyperkalemia, and anemia.

Warnings and precautions: Filspari is contraindicated in pregnancy and patients should be advised not to breastfeed during treatment. Do not administer Filspari with angiotensin receptor blockers, ERAs, or aliskiren. Hepatotoxicity, hypotension, acute kidney injury, hyperkalemia, and fluid retention may occur. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Avoid concomitant use with strong CYP3A inhibitors and inducers. Increased sparsentan exposure may lead to adverse reactions if Filspari is used with moderate CYP3A inhibitors. Avoid use of antacids within 2 hours before or after use of sparsentan. Avoid concomitant use with acid reducing agents. Monitor for signs of worsening renal function if used with NSAIDs. If Filspari is used concomitantly with CYP2B6, 2C9, and 2C19 substrates, monitor for efficacy of the concurrently administered substrates as decreased exposure of these substrates may occur. Avoid concomitant use with sensitive P-gp and BCRP substrates. Monitor serum potassium frequently if Filspari is used with agents that increase serum potassium.

NEW INDICATIONS

ABEMACICLIB
(Verzenio—Eli Lilly and Company)

Drug class: Verzenio is a kinase inhibitor.

Indication: Verzenio is indicated in combination with endocrine therapy for the adjuvant treatment of adult patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence, in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer, in combination with fulvestrant for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Recommended dosage and administration: Verzenio tablets are taken orally with or without food. The recommended starting dose in combination with fulvestrant, tamoxifen, or an aromatase inhibitor is 150 mg twice daily. The recommended starting dose as monotherapy is 200 mg twice daily. Dosing interruption or dose reductions may be required based on individual safety and tolerability.

Common adverse effects: The most common adverse reactions were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia.

Warnings and precautions: Advise patients not to breastfeed during therapy with Verzenio. Avoid concomitant use of ketoconazole. Reduce the Verzenio dose with concomitant use of other strong or moderate CYP3A inhibitors. Avoid concomitant use with strong or moderate CYP3A inducers. Verzenio can cause severe cases of diarrhea, associated with dehydration and infections. Instruct patients at first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their health care provider. Monitor complete blood counts prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Severe and fatal cases of interstitial lung disease (ILD) and pneumonitis have been reported. Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue Verzenio in all patients with Grade 3 or 4 ILD or pneumonitis. Increases in serum transaminase levels have been observed. Perform liver function tests (LFTs) before initiating treatment with Verzenio. Monitor LFTs every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. Verzenio can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. ■

Also in this issue
Brenzavvy approved by FDA to improve glycemic control in patients with type 2 diabetes (page 21)

Beat the bloat and gas

Mary Warner

Everyone has gas; producing and passing gas is a normal part of the digestion process. According to Johns Hopkins Medicine, most people produce 1 to 4 pints of gas a day and eliminate excess gas—either by burping or passing gas (flatulence)—about 14 times a day. But when gas is trapped or not moving well through the digestive system, most patients will look for OTC relief of the resulting pain and bloating.

Intestinal gas can be caused by swallowing air, commonly from eating or drinking rapidly; the bacterial breakdown of undigested food in the colon, which produces hydrogen, carbon dioxide, and methane; and some foods such as beans. Lactose intolerance and less common diseases, such as celiac disease, can also cause intestinal gas.

Simethicone, activated charcoal, digestive enzymes, and probiotic products are the most common nonprescription medications for treating intestinal gas. Simethicone and activated charcoal relieve symptoms after gas has formed, while α-galactosidase and lactase enzymes are taken with food to prevent gas from forming.

Simethicone

Simethicone functions as a nonsystemic surfactant, decreasing the surface tension of gas bubbles in the GI tract, which coalesces and disperses the gas bubbles and allows them to be removed via flatulence or belching. FDA approved simethicone in 1952 and considers it safe and effective with no serious adverse effects, although mild diarrhea and nausea have been reported. Because simethicone is not absorbed orally, systemic adverse effects do not occur.

Simethicone is available as tablets, capsules, chewables, and liquid and is often combined with antiacids (aluminum hydroxide, magnesium hydroxide, and/or calcium carbonate). Common products include Gas-X, Phazyme, and numerous generic medications.

Activated charcoal

Although activated charcoal is promoted for relief of intestinal gas, it is not FDA approved and should be used with caution. It has been suggested that activated charcoal absorbs intestinal gas, but there is limited research into its efficacy. Activated charcoal can result in tongue discoloration, black stools, and constipation, and can interfere with absorption of some medications.

Activated charcoal is available as tablets, capsules, or loose powder. Common products include Charcoal Plus DS, CharcoCap, Nature's Way, and numerous generic forms.

α-galactosidase

The enzyme α-galactosidase relieves intestinal gas and bloating by breaking down the carbohydrates in beans and other vegetables. Derived from Aspergillus niger, α-galactosidase hydrolyzes oligosaccharides into their component parts before they can be metabolized by colonic bacteria.

Because high-fiber foods, including legumes, contain large amounts of oligosaccharides, α-galactosidase can prevent excessive intestinal gas associated with high-fiber diets.

Forms of α-galactosidase include tablets, capsules, and orally disintegrating tablets (meltaways), which should be taken immediately before, during, or after a meal. Common products include Beano, Equate, and numerous generics.

Simethicone and activated charcoal relieve symptoms after gas has formed, while α-galactosidase and lactase enzymes are taken with food to prevent gas from forming.

Lactase supplements

For those who are unable to digest lactose, lactase supplements are available to prevent gas and bloating that may occur after eating dairy products. Lactase breaks down lactose into glucose and galactose, which can be absorbed. No adverse effects have been reported.

Lactase is available as a powder and liquid drops that can be added directly to dairy products and as capsules and tablets that are taken before eating dairy products. Common products include Lactaid, Dairy Aid, and Nutricost.

Probiotics

Some patients have reported that probiotic supplements, containing *Bifidobacterium, Lactobacillus, Saccharomyces,* or *Streptococcus thermophilus*, alone or in combination, have eased their gas and bloating symptoms by introducing new bacteria into the digestive system. Because probiotic bacteria leave the intestine soon after their use is discontinued, daily administration is required to maintain the bacterial populations in the intestines. A trial of 14 days is generally recommended for patients starting a probiotic regimen.

What to tell your patients

Advise patients who complain of gas and bloating to avoid foods and drinks that introduce gas into the digestive system. If symptoms persist, lactase or α-galactosidase can be taken with food to prevent intestinal gas from forming.

Simethicone can be taken after symptoms occur, but patients should be advised to discontinue use if relief isn't achieved within 24 hours. If patients have other symptoms, they should be advised to consult a physician to determine what is causing the pain.

For further information, see Chapter 14 in APhA's *Handbook of Nonprescription Drugs*, available in the bookstore on pharmacist.com or in Pharmacy Library. ■

Arnica: Relief from aches and pains?

Mickie Cathers

Patients suffering from joint and muscle pain often turn to complementary and alternative medicine for relief. Arnica has a long history in treating numerous medical conditions such as insect bites, bruises, scars, fever, apprehension, sciatica, and rash, but it's primarily recommended for inflammation, arthritis, muscle aches, and stiffness. So, what does the science say?

Arnica is a perennial in the sunflower family (Asteraceae), as are marigolds, daisies, and chamomile. *Arnica montana* is the species most commonly used in commercial products.

A. montana is traditionally used in self-care, midwifery, and in surgery as prevention or treatment for pain, improved wound healing, and stopping bleeding and swelling. This homeopathic medicine is advertised as plant-powered pain relief from muscle aches and stiffness due to minor injuries, overextension, and falls.

Benefits of arnica use are attributed to the plant's chemical components, which demonstrate anti-inflammatory, antioxidant, and other biological activity. It is thought that the polysaccharides, flavonoids, and helenalin—among over 150 bioactive components—in arnica express anti-inflammatory and immunosuppressive effects. Cell and animal studies have shown anti-inflammatory effects from arnica extract, but these effects have not been consistently confirmed in human studies.

Is there a benefit?

Arnica has been mainly studied in patients with postoperative pain, with mixed results and divergent effects.

An October 9, 2021, review of arnica used in clinical trials by Smith and colleagues published in *Medicines (Basel)* found that arnica extract, gels, and creams show promising, but mixed, effects for pain relief.

Some studies included in the review showed significant reduction of pain after treatment with either arnica tablets or ointment compared with placebo, especially in the treatment of arthritis and lower back pain. Fresh plant gel and arnica extract gel resulted in significantly reduced pain scores after 6 weeks in patients suffering osteoarthritis. Other studies found no evidence of effects on pain relief or improvement in reducing pain after surgical procedures.

A December 23, 2014, *Cochrane Database Systematic Review* by Oltean and colleagues evaluated 14 randomized controlled trials examining 2,050 adult participants suffering from acute, subacute, or chronic nonspecific lower back pain treated with herbal medicines. Interestingly, cayenne was found to reduce pain more than placebo, while arnica presented very low-quality evidence of reduction in perception of pain and improved flexibility with application of a gel twice daily compared to placebo gel.

A December 17, 2021, systematic review and meta-analysis of 18 trials compared arnica to placebo or another active comparator in surgery. Gaertner and colleagues' *Frontiers in Surgery* study concluded that arnica had a clinically small effect compared with placebo that just misses significance in treating postoperative pain, swelling, and functional limitations, an effect equal and comparable to most anti-inflammatories and NSAIDs.

Arnica exhibited the most pain efficacy in a comparison with diclofenac and in a trial examining patients who underwent mastectomy and reconstruction and were treated with arnica, which resulted in reduced opioid intake. Arnica presents comparable activity to standard medications such as ibuprofen and diclofenac for pain management and may be a better-tolerated alternative to diclofenac and opioids. More studies are needed to confirm these findings.

Arnica presents comparable activity to standard medications such as ibuprofen and diclofenac for pain management and may be a better-tolerated alternative to diclofenac and opioids.

Dosage and availability

Arnica is sold as a cream, gel, sublingual tablets, extract, teas, dissolvable pellets, and mixed into mineral bath salts to rejuvenate joints and muscles. The supplement is widely available and ranges in strengths from 1X to 30X. (Homeopathic medicine is dosed based on tenfold dilutions, so a 30X product has been diluted in a 1:10 ratio 30 times.) Dosing is not standardized and variations in concentration levels differ between manufacturers.

What to tell your patients

Arnica is generally regarded as safe by FDA. Adverse dermatologic effects such as rash, itching, or dry skin may develop with topical therapies. Patients allergic to chamomile, chrysanthemum, dandelion, marigold, or sunflower may develop allergic skin reactions when using arnica creams or gels.

High concentrations of oral products are associated with gastroenteritis, vomiting, diarrhea, shortness of breath, and tachycardia. Arnica has anticoagulant and antiplatelet effects due to its coumarin content and is contraindicated in anticoagulant and antiplatelet drug therapies. Arnica may also lower the efficacy of antihypertensive drug therapies. Advise pregnant or breastfeeding patients to avoid use due to lack of data. ■

FDA approves Brenzavvy for type 2 diabetes

Lauren Howell, PharmD

In January of this year, FDA approved Brenzavvy (bexagliflozin—TheracosBio), a sodium-glucose cotransporter 2 (SGLT-2) inhibitor, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D). Brenzavvy is the fifth SGLT-2 inhibitor to become FDA approved.

Despite the efficacy of these medications, a study published in *JAMA* in 2021 found that 50% of patients taking SGLT-2 inhibitors stop therapy during the first year due to high cost and insurance barriers. The approval of new drugs in this promising class of medications brings hope that a more affordable option may be on the way for patients.

Recommended dosage and how it works

Brenzavvy reduces glucose levels in the blood by inhibiting the transporter that is mostly responsible for reabsorption of glucose in the renal proximal tubule.

When this transporter is inhibited, less glucose is reabsorbed into the bloodstream and more glucose is lost through urinary excretion. Brenzavvy is not indicated for use in patients with type 1 diabetes (T1D) as it may increase the risk of diabetic ketoacidosis in these patients.

The recommended dose is 20 mg once daily, taken in the morning with or without food. The tablet should not be crushed or chewed.

Renal function should be assessed prior to initiation of therapy. Volume depletion should be corrected before treatment begins.

In patients with an eGFR of <30 mL/min/1.73 m^2, use of Brenzavvy is not recommended. A higher incidence of adverse reactions was seen in relation to reduced renal function.

Additionally, Brenzavvy is not recommended for patients with severe hepatic impairment. A higher incidence of adverse reactions specifically related to volume depletion is seen in older patients.

Patients of reproductive potential should be advised of the potential risk to a fetus, especially during the second and third trimesters, since Brenzavvy is not recommended during this time. Use of this therapy should also be avoided in breastfeeding patients.

Adverse effects

The most common adverse reactions seen in patients taking Brenzavvy are female genital mycotic infections, UTI, and increased urination. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, discontinue Brenzavvy, evaluate, and treat promptly. Patients should be monitored for signs and symptoms of infection or ulcers of the lower limbs, and Brenzavvy should be discontinued if these occur. Patients should be assessed for factors that may increase the risk of lower limb amputation before treatment with Brenzavvy begins. Monitor for signs and symptoms of volume depletion during therapy as this may result in acute kidney injury. Monitor for signs and symptoms of UTIs and treat promptly, if indicated, to avoid urosepsis and pyelonephritis.

When patients are being treated with insulin or an insulin secretagogue, a lower dose of these therapies should be considered to reduce the risk of hypoglycemia when used in combination with Brenzavvy. Serious, lifethreatening cases of necrotizing fasciitis of the perineum have occurred in both females and males treated with SGLT-2 inhibitors.

Assess patients presenting with pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. Monitor and treat patients for genital mycotic infections as appropriate.

Clinical trials

Brenzavvy has been studied as a monotherapy and in combination with metformin in adults with T2D, in adults with T2D with moderate renal impairment, and in adults with T2D with established CVD or at increased risk for CVD. In these studies, treatment with Brenzavvy was found to reduce A1C compared to placebo and efficacy was noninferior to glimepiride 6 mg and sitagliptin 100 mg once daily. This A1C reduction was shown across subgroups of age, sex, race, and geographic region.

Patient counseling

Patients should be advised of the risk for ketoacidosis, lower limb amputation, volume depletion, serious UTIs, hypoglycemia with concomitant use of insulin and insulin secretagogues, necrotizing fasciitis of the perineum, and genital mycotic infections. Additionally, patients should be counseled on the signs and symptoms associated with each of the previously listed conditions.

Patients should be informed that their urine will test positive for glucose while taking Brenzavvy due to its mechanism of action.

Patients should be advised to take Brenzavvy exactly as prescribed. If a dose is missed, it should be taken as soon as possible but patients should not double their next dose. ■

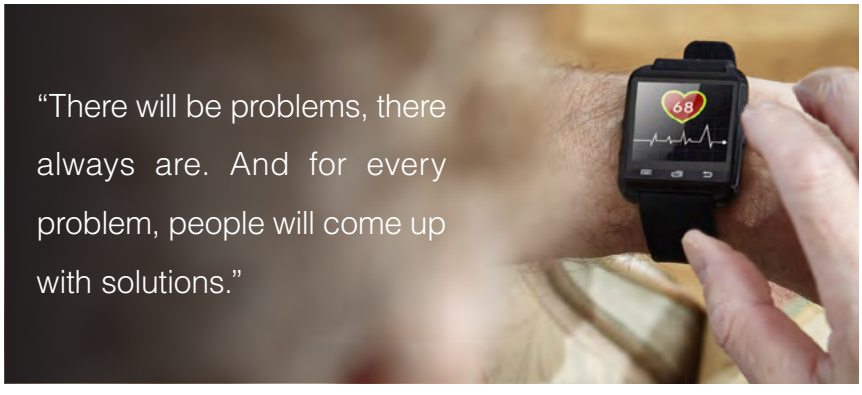
With tech rapidly advancing, understanding actionable data is key

Clarissa Chan, PharmD

"Artificial intelligence (AI) is going to seriously disrupt medical practice over the next 5 to 10 years," said Steven Charlap, MD, MBA, founder and CEO of SOAP Health, an AI-powered artificial digital human assistant that identifies, verifies, and simplifies patient-reported data collection, risk assessment, and electronic delivery.

Like physicians, pharmacists face many challenges including decision fatigue and burnout. "I like to joke that doctors don't need better technology. Technology needs better doctors who are trained to use technology more effectively and efficiently," said Charlap.

With advances in conversational AI, generative AI, and machine learning, computers may soon provide tools to help health care professionals make better medical decisions so they can focus on the patient, Charlap said.



Importance of actionable data

"I don't know how many physicians have asked for the data that come from most wearables," said Charlap. "Doctors don't have time to process the information patients fill out on written forms. How are they meant to process these huge amounts of data until clear indications emerge to help inform medical decision-making? Most wearable data is limited in usefulness, but this will evolve."

Data from wearable devices often are not actionable. "There's nothing magical about 10,000 steps. Contrary to popular opinion, there's no study that shows that 10,000 versus 9,000 versus 11,000 steps makes any ultimate difference in your health," said Charlap. "So I think people are attracted by the novelty, but then they get tired of it."

Understanding and evaluating data

"The downside to OTC [ECG] devices is that patients are often anxious when they receive a notification indicating AFib. False positives are not uncommon. Devices may not be working effectively," said Brittany Messer, PharmD, CTTS, AACC, cardiology pharmacist at Marshall Health in Huntington, WV. "Patients may panic thinking they are in danger when the heart is actually functioning properly. Proper diagnosis and follow-up with a physician is necessary to confirm an abnormal heart rhythm."

Health care providers will need to know how to use data—how to process, analyze, and understand it. "Other than looking at bloodwork, pathology, and radiographic results in medical school, I don't know that medical school teaches a course on data processing. Most physicians aren't even taught how to read a research paper," said Charlap.

Over 100 years ago, physicians didn't use blood chemistry testing to make diagnoses. In fact, they thought it was worthless because they didn't know how to correctly use laboratory testing. And now it's an indispensable part of medical practice, Charlap noted.

"Why? Because it took time for them to learn how to use it, and later the results became more reliable and the reference ranges of normal and abnormal were better defined. [For example, they learned a] white blood count above 11 was indicative of infection, with an even higher count possibly indicating cancer," he said. "If someone didn't know what it meant, it meant nothing."

Continued improvement in technology and society adapting

"People tend to think linearly, when in fact innovation is constant and ongoing and evolving," said Charlap. "There will be problems, there always are. And for every problem, people will come up with solutions."

When the first portable ECG machines that had computer analysis came out, Charlap said the analysis was not up to par and physicians by and large ignored them. They used the portable machine to generate the ECG, but then still did manual measurements. Today, machines are exceptionally good, and people rely on the output. This will be the case for tomorrow's wearable technologies, Charlap said.

For now, "patients with an unknown heart arrhythmia [who may wear] OTC [ECG] devices can detect episodes of atrial fibrillation, which is the most commonly reported arrhythmia I hear patients report," said Messer. "It is vital that patients see a medical provider to see if they, in fact, are in AFib." With these [wearable OTC] devices, patients can proactively take action to get further workup for an accurate diagnosis and to prevent adverse events like strokes.

In the future, people may wear sensors in the form of patches or injections that collect far more accurate and actionable data such as blood glucose levels, metabolic rates, and waste products—but today's wearables are more of a passing fad, said Charlap. ■

2023 CDC immunization schedules include COVID-19 vaccine recommendations and more

Olivia Welter, PharmD

In February 2023, CDC released its immunization schedules for 2023. Both adult and childhood/adolescent schedules received updates, with changes covering recommendations for COVID-19; measles, mumps, and rubella (MMR); hepatitis B; pneumococcal vaccines; and more.

Bringing pharmacy to the table

This cycle, APhA had the opportunity to suggest recommendations, review, and provide support for the adult immunization schedule specifically.

This marks the first instance of pharmacy being an actively engaged participant in this process.

"This is a recognition of and tribute to the large impact that pharmacists have had and will continue to have in the provision of vaccine and vaccination-related activities," said Brigid Groves, vice president of pharmacy practice at APhA.

Several pharmacy leaders affiliated with APhA served as subject matter experts for the adult vaccine schedule. APhA is listed alongside other notable health care organizations on the printable document, right next to the instructions for using the schedules.

COVID-19 vaccines: A new standard

The adult and childhood/adolescent immunization schedules show that CDC now recommends the COVID-19 vaccine series for the general population and for individuals who are moderately to severely immunocompromised. This change to the recommendations is perhaps the most anticipated since ACIP voted unanimously in October 2022 to add the COVID-19 vaccine to the new adult and childhood/adolescent immunization schedules.

Pfizer–BioNTech's Comirnaty, Moderna's Spikevax, and Novavax's COVID-19 vaccines are the monovalent COVID-19 vaccines recommended within the schedules. The bivalent versions of the vaccines from Pfizer–BioNTech and Moderna have also made it onto the list of recommended immunizations to be administered as booster doses. However, Janssen's single-dose monovalent vaccine is excluded from the recommendations.

Additionally, an FDA advisory committee voted in early 2023 to recommend "harmonizing" the primary series and booster doses of COVID-19 vaccines so that all will eventually contain the same ingredients, making vaccine selection an easier process.

Child-specific updates

Two newly licensed vaccines have made their way into the childhood immunization schedule. Priorix (GlaxoSmithKline) for MMR prevention and a 15-valent pneumococcal vaccine called Vaxneuvance (Merck) are included in the recommendations for the 2023 edition. The updated schedule also noted that the 15-valent vaccine can be used interchangeably with the 13-valent vaccine for children in both routine and catch-up pneumococcal vaccination series.

Adult-specific updates

The updated adult schedule also explores use of pneumococcal vaccines. As one of the vaccine types with the most frequently changing guidance, pneumococcal vaccines require clinicians to refer back often to CDC immunization schedules to ensure they are appropriately selecting which one to use.

In the 2023 edition of the adult schedule, the notes section reflects substantial changes regarding pneumococcal vaccines when considering prescribing the 15-valent and 20-valent version of the pneumococcal vaccine for someone who has already received other types of pneumococcal vaccines.

In addition, the schedule makes it easier for clinicians to make decisions by providing links to a guidance document and a mobile app designed specifically for pneumococcal vaccine recommendations.

Influenza recommendations for older adults are another major focus of the 2023 adult schedule. For individuals 65 years and older, the updated schedule notes that 3 versions of the vaccine are preferred: high-dose inactivated influenza vaccine, quadrivalent recombinant influenza vaccine, and quadrivalent adjuvanted inactivated influenza vaccine.

While the 2023 CDC childhood and adult immunization schedules underwent several notable changes, advisory committees are already considering new recommendations for the next edition.

Future schedule considerations (RSV, mpox, rotavirus)

While the 2023 CDC childhood and adult immunization schedules underwent several notable changes, advisory committees are already considering new recommendations for the next edition.

A potential RSV vaccine is in the works, and both Pfizer and GSK received votes from an FDA group in favor of recommending their products for approval. If approved, the RSV vaccine may be added to future immunization schedules.

At a February 2023 ACIP meeting, a CDC immunization advisory committee voted to recommend the Jynneos vaccine for adults who are at risk for contracting mpox.

Other vaccine updates to look out for in the future include rotavirus, meningococcal, and further recommendations for COVID-19 vaccines and booster doses. ■

Shingles linked to increased cardiovascular risk

Lauren Howell, PharmD

According to a study published in the *Journal of the American Heart Association* on November 16, 2022, herpes zoster (more commonly known as shingles) is associated with an almost 30% higher long-term risk of a major cardiovascular event. This new information highlights the importance of herpes zoster vaccination and the role it may play in preventing more than just the virus itself.

Background information and study findings

Most individuals who are older than 50 years living in the United States have been infected with the varicella zoster virus (VZV), which is also called chicken pox. All of these individuals are at risk for developing herpes zoster.

There is a multitude of information to show that serious chronic complications such as postherpetic neuralgia and opthalmicus can occur following a herpes zoster episode. Because VZV has been found to replicate in arteries and lead to vasculopathy, many have hypothesized that herpes zoster may be associated with an increased risk of cardiovascular events.

Previous data have shown an elevated risk of a major cardiovascular event in the weeks following herpes zoster infection. Despite previous evidence, this study of the association between herpes zoster and major cardiovascular events was the first to include a long duration of follow up, control for potential confounding cardiovascular risk factors, and capture individuals who may not have sought out medical attention for herpes zoster.

Curhan and colleagues found that herpes zoster was significantly and independently associated with higher long-term risk of stroke and congenital heart disease (CHD). This increased risk was found to persist for far longer than symptoms, and for greater than 12 years after the herpes zoster episode. This risk of a major cardiovascular event was found to be potentially even greater among individuals with immunocompromising conditions or on immunosuppressive regimens.

Impact on pharmacist practice

As easily accessible health care providers, pharmacists are in the best position to discuss vaccination status, recommend appropriate vaccinations, and provide these vaccinations to patients.

The availability of a safe and effective vaccine enhances pharmacists' ability to reduce the burden of herpes zoster and reduce the risk of subsequent cardiovascular complications among their patients. It is crucial that pharmacists are knowledgeable about vaccines, particularly herpes zoster vaccines, and are able to counsel patients confidently on them.

Patients do not need to wait a certain amount of time following a herpes zoster episode before receiving Shingrix.

CDC recommends 2 doses of Shingrix (recombinant zoster vaccine–GlaxoSmithKline) separated by 2 to 6 months for the prevention of herpes zoster in immunocompetent adults aged 50 years and older. This recommendation is applicable whether or not patients report a prior episode of herpes zoster and whether or not they have received a prior dose of Zostavax (Merck).

In those aged 19 years or older who are or will be immunodeficient or immunosuppressed, CDC recommends 2 doses of recombinant zoster vaccine. While it is preferable for the second dose to be given 2 to 6 months after the first dose, if the patient would benefit from completing the series over a shorter span of time, the second dose can be administered 1 to 2 months after the first dose.

Patients do not need to wait a certain amount of time following a herpes zoster episode before receiving Shingrix. It is important, however, that patients do not receive the vaccine during an acute episode.

What to tell your patients

When counseling patients on the Shingrix vaccine, it is important to inform them that most people experience a sore arm after receiving the vaccine.

Additionally, patients can have redness and swelling of the arm, fatigue, headache, fever, stomach pain, or nausea. Due to these adverse effects, patients should be advised to plan to avoid strenuous activities for a few days after vaccination.

Pharmacists should be aware that if a patient has a reaction to the first dose of Shingrix, it does not guarantee that they will have a reaction to the second dose. Additionally, if a patient does not have a reaction to the first dose, they may or may not have a reaction to the second dose.

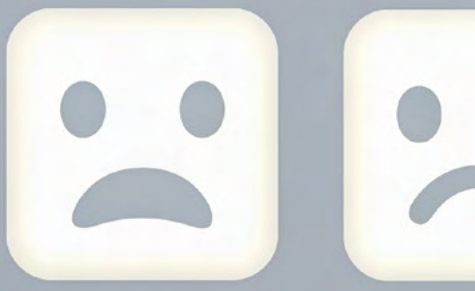
While these symptoms may be inconvenient to patients, pharmacists may remind them that these effects only last 2 to 3 days whereas complications from herpes zoster, including major cardiovascular events, can be detrimental to their overall health and well-being.

Pharmacists can also help patients mitigate these symptoms by encouraging them to take OTC pain medicine to ease discomfort after receiving Shingrix. However, it is not recommended that patients take these medications before vaccination. ■

Pharmacists can visit apha.us/ShingrixVaccine for more information about the Shingrix vaccine and resources for speaking with patients about the vaccine.

PHARMACISTS' WELL-BEING:

SOLUTIONS FOR THE SHORT TERM, PLANS FOR THE LONG TERM



LOREN BONNER

The initial shock of the COVID-19 pandemic has worn off. Fast forward 3 years later to today, and a clearer picture has emerged of both the individual as well as broader organizational effects of prolonged stress from the pandemic. Some pharmacy personnel are leaving, others are experiencing apathy, and there are clear threats to patient safety.

"What we have learned collectively is that everybody is at risk of experiencing burnout and organizations need to pay attention to sustained chronic stress," said Nancy Alvarez, PharmD, FAPhA, from the University of Arizona R. Ken Coit College of Pharmacy. "We can manage and address emerging situations—emergency situations—for short periods of time, but we can't do this for sustained periods of time."

While workplace issues and the need to improve pharmacy staff's well-being are not new problems, the pandemic put a public spotlight on them.

"These problems and burnout are a big problem across many practice settings, yet lived experiences of pharmacy personnel do not seem to be characterized solely by burnout." said Alvarez. "It appears that there is a gap in our understanding of how moral distress and moral injury apply to pharmacy personnel similar to what has been described for veterans who return from war."

As all health care personnel across the board are facing these challenges right now, organizations representing them are all trying to find solutions to well-being—for the short term and the long term.

While workplace issues and the need to improve pharmacy staff's well-being are not new problems, the pandemic put a public spotlight on them.

The problem

Workplace conditions continue to be the primary reason cited for prolonged stress and burnout in the nearly 1,300 reports submitted to the Pharmacy Workplace and Well-being Reporting (PWWR) portal since it launched in October 2021. The portal, developed jointly by APhA and the National Alliance of State Pharmacy Associations (NASPA), is a confidential and anonymous way pharmacy personnel can report positive and negative experiences in pharmacy practice as well as suggest solutions. Comments are collected and analyzed by a patient safety organization to afford legal confidentiality protections.

Many organizations recognize that systems issues within a workplace are a major cause for burnout among health care professionals, and call for the focus to be on correcting them. In their National Plan for Health Workforce Well-being, for example, the National Academy of Medicine singles out government, payers, industry, educators, health care leaders, public health leaders, and those in other sectors to help drive policy and systems change.

In the PWWR reports, pharmacy personnel have said that employers may have well-being resources on hand, but workplace issues are still not being addressed.

"I think that many of the issues are systemic and do not enable rank-and-file people to care for the issues,"

said Alvarez, who was chair of the APhA/NASPA workgroup whose work included PWWR, a state-based national survey, and the Pharmacists' Fundamental Responsibilities and Rights document.

Other key findings that have emerged as the PWWR reports have been analyzed quarterly, include

- Harassment by patients, coworkers, and pharmacy and nonpharmacy managers is a real problem.
- Two-way lines of communication are not perceived to be open.
- Positive experiences have a long-term positive effect on well-being.

Even in the context of workplace and systems issues needing to be addressed by organizations in the long term, Alvarez asks, "What small things can an individual do today?"

Short-term solutions

Pharmacists report "unimaginable" stress from interruptions, aggressive patients, increased workload, and staffing issues. It's a concern across practice settings and in all roles of pharmacy.

Cynthia Knapp Dlugosz, BSPharm, NBC-HWC, a certified mindfulness teacher and one of the first national board-certified health and wellness coaches in the United States, said there are ways pharmacists can manage stress and anxiety in the moment while at work.

"Stress and anxiety are tied to our prehistoric threat defense system," said Knapp Dlugosz.

What is moral injury?

Moral injury was first described in service members who returned from the Vietnam War with symptoms resembling PTSD, but who exhibited symptoms beyond that diagnosis and did not respond to standard PTSD treatment.

Research revealed a different driver behind the two, wherein those with PTSD experienced a real threat to their mortality, and those with this different presentation had experienced repeated insults to their morality. They had been forced, in some way, to act contrary to what their beliefs dictated as moral beings.

Moral injury can happen when one perpetuates, bears witness to, or otherwise fails to prevent an act that transgresses deeply held personal moral beliefs. In the health care space, this can include the oath taken as health care providers to put the needs of patients first. ■

"Our fight-or-flight reaction gets triggered, and our thoughts keep us stuck there."

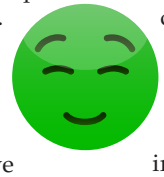
At APhA2023 in Phoenix this year, Knapp Dlugosz led a session—"Right Here, Right Now: Managing Stress and Anxiety in the Moment"—in which she shared evidence-based techniques for shifting from sympathetic to parasympathetic activity, to respond to stress and anxiety more productively.

Here are the 5 steps she recommends pharmacy staff can take:

1. **Reclaim your attention.** The most important first step is to return your focus to the present moment.
2. **Breathe for calm.** Breathe from your diaphragm rather than chest and make the exhalations twice as long as inhalations (e.g., breathe in for a count of 2 and out to a count of 4).
3. **Notice you are all right.** As you inhale and exhale, say to yourself "Right now, I am all right"—because in that moment, you probably are.
4. **Shake it out.** Dissipate the fight-or-flight energy by shaking your body for a few seconds or tensing up all of your muscles tightly and then releasing them.
5. **Reset thoughts.** In a calmer state, you can examine the thoughts that are fueling stress and anxiety. You have to start appreciating your thoughts as mental events and not facts. Ask yourself: how are my thoughts making the situation worse?

Some pharmacy settings have attempted to correct workplace issues that are causing stress.

Lam Nguyen, PharmD, from Oregon Health & Science University Hospital, said that his pharmacy department worked with the hospital's human resources department to develop new concepts for workload. They designed a workweek with 4 full-time equivalents (FTEs) that were needed rather than four 1.0 FTEs. "We actually realized 'why not create five 0.8s?'



This allowed our staff to have more balance in [their] workload, and it's been well-received," said Nguyen, who spoke on an APhA podcast about burnout.

On the same podcast, Jessica O'Brien, CPhT, a community practice pharmacy supervisor at Mayo Clinic, said she believes staffing issues are the main contributor to burnout among employees across all of health care. In the pharmacy department where she works, they are putting stay interviews into practice with employees, giving them a chance to share what is working well and where there are opportunities to improve. "I feel this helps give [employees] a voice and helps them feel valued as an employee, that we are listening to their concerns," she said.

Specific to pharmacy technicians, pharmacy leadership within Mayo Clinic has worked to make the pharmacy technician profession more than just a job. They employ a career ladder concept in which pharmacy technicians can choose multiple pathways for their career, such as education or research, and obtain additional training in those chosen areas.

"I really think this is going to change the profession for pharmacy technicians [because] they will be able to grow in their career and it gives more meaning to their work," O'Brien said. "They can see the big picture and the impact they are having on people." She believes it will help decrease technician turnover, too.

According to Long Trinh, PharmD, former senior director of pharmacy at Providence in Portland, OR, the financial impact of turnover in hospitals is a top CEO concern today.

"One of the biggest moves is seeing pharmacy technicians having a much greater voice and seeing boards of pharmacy allow technicians to perform more nonclinical roles."

His hospital quantified the cost of turnover and estimated that for every one pharmacy technician turnover, it would cost $25,000 to $35,000 per turnover. The average cost of a pharmacist or leader turnover is 4 to 6 times greater than that of a technician.

"For a large health system with a 40-technician turnover per year, this could incur an estimated cost of 1 to 1.4 million dollars annually—so there's a financial impact," said Trinh, who also

spoke on APhA's podcast about burnout.

Lemrey "Al" Carter, PharmD, RPh, executive director of the National Association of Boards of Pharmacy (NABP), believes one of the most recent positive steps forward in improving pharmacy workplace conditions has been giving technicians more authority.

"One of the biggest moves is seeing pharmacy technicians having a much greater voice and seeing boards of pharmacy allow technicians to perform more nonclinical roles," Carter said.

Long-term solutions

Remedying workforce issues in both community and health-system

PBMs play big role in negative working conditions

Jonathan Little, PharmD

Well-being in pharmacy is affected by workplace conditions, PBM practices, and burnout—all of which may be related.

APhA and the National Alliance of State Pharmacy Associations' Pharmacy Workplace and Well-being Reporting (PWWR) tool, an online anonymous service for pharmacy personnel to submit their experiences, conveys several eye-opening findings on the difficulties that pharmacy team members must deal with in their practice settings.

In new findings released by APhA in March 2023, working conditions were the most commonly cited source of negative experiences for pharmacists. This could include anything from prescription workload, vaccination demands, staffing levels, number of hours worked, lack of breaks, and/or other issues.

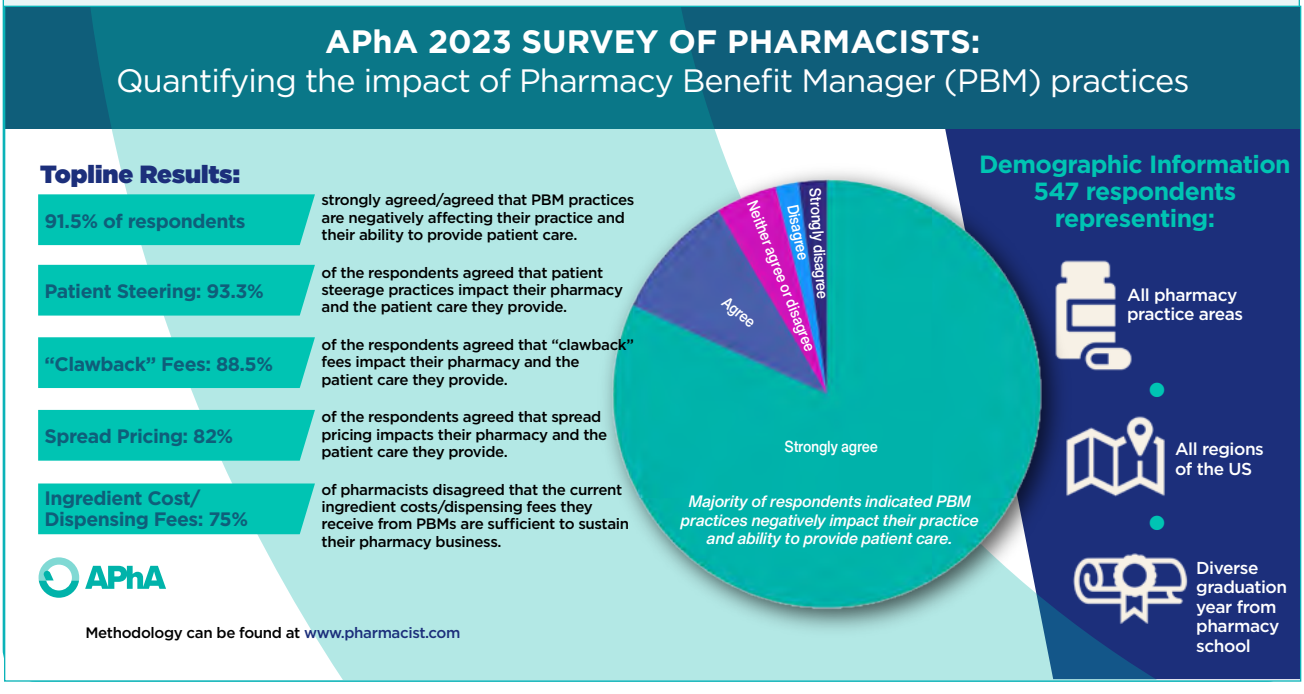
Many anecdotal stories about poor well-being are supported by the most recent APhA Pharmacy Workplace Survey, in which the authors conclude "pharmacy personnel's workplace issues and their relationship to personal well-being continue to be a critical, complex issue across all practice settings."

If pharmacists are unable to provide the exceptional patient care that they are capable of providing, patients lose in the end. This, too, is supported by data, as pharmacists recently described several issues that interfere with their ability to provide patient care in APhA's survey on PBM practices.

Respondents overwhelmingly described the negative effect that PBM practices have on their ability to provide patient care. While PBMs may not be the only source affecting well-being issues in pharmacy, there is little doubt of the large role they play. This is yet another contributing piece to the problem of impaired well-being in pharmacy.

Recent research conducted by the University of Illinois Chicago found that "nearly 9 in 10 pharmacists were found to be at high-risk for burnout," and the reasons for this are multifactorial.

Pharmacists are extremely valuable members of the health care team, but the impact that pharmacists can make in patient care is highly related to the pharmacist's own well-being. Improving these issues—especially workplace conditions, PBM practices, and burnout—in pharmacy will in turn improve pharmacy team members' well-being, which ultimately will allow for the delivery of high-quality patient care. ■



pharmacy won't happen overnight.

Trinh said to address burnout, leaders must go back to the fundamental principles of workforce planning and design and look for opportunities to redesign work.

Questions leaders should ask, according to Trinh, are

- Do we have enough people to do the work?
- Are people adequality trained to do the work they are expected to do?
- Are people compensated equitably to the market for the work they are being asked to do?

"By addressing these, I feel, long-term, we will be able to cover and renew and rebuild a sustainable workforce," said Trinh.

Carter said partnerships are vital going forward in order to achieve any meaningful change.

"Partnerships have to happen because there are so many issues at play here," said Carter.

For instance, NABP and other pharmacy organizations need to continue working with the American Association of Colleges of Pharmacy. An NABP workgroup identified schools and colleges of pharmacy as being integral stakeholders in developing a new pharmacy practice model, "as enrollment has significantly decreased while the need for pharmacists has increased," noted the report the NABP workgroup published in 2022. "If these trends continue, there will not be enough pharmacists to meet the health care needs of communities throughout the country, especially in more rural areas."

"With working conditions and well-being, it takes a village and we are working with all the pharmacy associations and partners on the state and federal level," said Carter.

The NABP report cited some specific and achievable solutions as pharmacy partners envision and collaborate on a new pharmacy practice model. They include

- Providing pharmacy staff with opportunities to work from home with fewer interruptions to complete nonpatient-facing tasks, including data entry, data verification, and third-party adjudication
- Encouraging employers and state boards of pharmacy to support efforts to increase the use of call centers that provide patients the convenience and time to discuss concerns and ask questions while freeing up staff in the community setting for more clinical tasks
- Suggesting that central fill operations should be used to relieve busy pharmacies and that the central fill pharmacies should be permitted to mail medications directly to patients rather than having to ship them back to the originating pharmacy
- Identifying and setting meaningful standards for lunch breaks, shift lengths, well-being of pharmacy personnel, and practice standards for clinical functions through stakeholder collaborations

Having a voice

According to WHO, not feeling valued or heard is a hallmark symptom or risk that can lead to burnout.

In the PWWR reports as well as in APhA's Well-being Index for Pharmacy Personnel, pharmacy staff report over and over that they are not being heard or valued when they're trying to speak with a supervisor.

According to the latest PWWR findings, two-thirds of those who submitted comments about negative experiences involving lack of open communication channels said they offered recommendations to management, but 83% of those individuals said their recommendations were not considered or applied, causing them to feel ignored and unvalued.

"Just giving [staff] a voice so they feel heard and valued is really going to help in the long run for your whole team," said O'Brien.

While it's distressing for pharmacy personnel and the profession to be at this point, Alvarez said it's an opportunity to name the lived experiences for what's happening and act in such a way that the profession, including those who have influence to affect systems changes, will have collective resilience.

"We can advance as a profession out of this," Alvarez said. "Not only pharmacists, but all those involved so that pharmacists and pharmacy personnel are able to safely and effectively help people use medications for optimal health and wellness." ■

NABP recommendations

The National Association of Boards of Pharmacy (NABP) 2022 workgroup report on workplace safety, well-being, and working conditions, recommended that

1. NABP collaborate with stakeholders to
   a. Identify new practice models that support pharmacists' ability to provide patient care services
   b. Identify/set meaningful standards for staffing to include but not be limited to
      i. Lunch breaks/shift lengths
      ii. Well-being
      iii. Clinical functions
      iv. Use of automation technology
      v. Use of pharmacy technicians
2. NABP review the Model Act to identify model act language that can create barriers to care and suggest edits to submit to the Committee on Law Enforcement/Legislation
3. NABP encourage industry stakeholders to amplify current messaging to educate patients about pharmacy operations to manage expectations
4. NABP encourage boards of pharmacy to consider pathways to innovation such as automation and central fill, reimagine new delivery models that support pharmacists' ability to provide patient care services, and address staffing shortages
5. NABP encourage boards of pharmacy to review and revise regulations to utilize pharmacy technicians to augment the role of the pharmacist and to identify current pharmacist-only duties that could be safely and competently performed by nonpharmacist personnel ■

ADHD drug shortages will continue to be felt

Sonya Collins

Last October, Adderall (amphetamine/dextroamphetamine) and its generics entered shortage status. As prescribers scrambled to find alternatives for their adult and pediatric patients with ADHD, many other central nervous system stimulants have seen intermittent shortages as well. Though drugmaker Teva Pharmaceuticals said production of fast-acting, brand-name Adderall tablets is now up to speed, the residual effects of the shortage continue to be felt across brand and generic ADHD medications in all classes and formulations. Some drugmakers expect their shortages to persist through the spring of 2023.

"It's not just Adderall. At some point, with all stimulants, we've seen that patients have been unable to get them at the pharmacy," said Sterling Ransone, MD, a family physician in Deltaville, VA, and board chair of the American Academy of Family Physicians.

Until the supply is once again able to meet demand, patients, prescribers, and pharmacists must work together to find solutions. Here are some strategies they have tried.

Going cold turkey

Some adults are making the decision to go off their ADHD medication until it becomes available again.

When pharmacists discuss this decision with patients, they might mention that "for those [who] have been taking these medications consistently for a long period of time and at a higher dosage, they may see some fatigue and depressed mood with an abrupt discontinuation of therapy," said Brigid Groves, PharmD, vice president of pharmacy practice at APhA. "Those symptoms usually dissipate within a week or two."

Parents are less willing to drop their child's medications due to concerns about the impact on the child's behavior and ability to concentrate at school. Even adults feel a negative impact when they discontinue their ADHD medications.

"One patient who took that strategy came back to my office and said, 'We have to do something about this because I'm having problems at work and I need some help,'" Ransone said.

Until the supply is once again able to meet demand, patients, prescribers, and pharmacists must work together to find solutions.

Different doses, formulations, or fewer pills

When the desired drug is available in some form, pharmacists might have to request that prescribers rewrite prescriptions to allow the pharmacist to dispense the drug in different doses. "If the patient is on 25 mg and the pharmacist has a 10 [mg] and 15 [mg pill], we'll have to rewrite the prescription accordingly," Ransone said.

Patients are also finding that their pharmacy doesn't have a full month's supply of their ADHD medication, in which case they ask their prescriber to call in another prescription for 15 pills.

"In that case, because these medications do have the potential for abuse—and there have been instances when parents have taken their children's medication—we always like to verify that with the pharmacy or check the [prescription drug monitoring program] or both," Ransone said.

Pharmacists may also try to fill these prescriptions with chewable tablets or liquid formulations. When those options are not available, pharmacists might ask prescribers about switching from extended-release to short-acting or immediate release Adderall, but that's not ideal due to added adverse effects and the need to take more than one pill per day.

"In our schoolchildren, having to leave at lunchtime to take your medicine can be stigmatizing, and we want to avoid that for patients if we can," Ransone said.

Different drug class

While it's not preferable, when supply dictates, sometimes Ransone switches patients from a prodrug to another type of drug.

"Pharmacists should counsel patients or parents on how the medication might kick in faster or that it might not last as long," Ransone said.

Changing drugs altogether, however, can be costly, though prescribers might not realize it, Groves said. "Vyvanse is more closely related to Adderall than Ritalin is, but it's expensive and insurers might not cover it," she said.

Advice for pharmacists

It's likely that pharmacy inventory, patients' needs, prescribers' preferences, and insurance benefits don't align. This can add up to multiple phone calls back and forth between pharmacists and prescribers.

"It would be great if pharmacists could list what they have in stock in the patient's [electronic health record] so that the physician could see what was available and make the best choice," Ransone said. But, until that day comes, he said, "My preference would be that the pharmacist leaves a message that says 'We don't have Vyvanse. These are the alternatives. Do you have a preference?'" ■

OTC naloxone could save scores of lives—if the price is right

Sonya Collins

In March 2023, FDA approved naloxone for OTC sale in a move that public health experts hope will dramatically increase access to the nasal spray and slash opioid overdose deaths.

Drug-related deaths in the United States topped 100,000 in each of the last two years. An estimated 75% of these deaths are attributable to opioids.

"Making it available alongside products like Tylenol was something that the experts thought could reduce stigma and encourage a broader set of people to obtain this and carry it around."

While every U.S. state has laws that allow pharmacists to dispense naloxone without a patient-specific prescription, the number of doses dispensed at pharmacies is low relative to the total number dispensed each year.

In 2021, of the nearly 17 million doses of naloxone distributed, just 2.64 million originated at pharmacies, according to the March 2023 Naloxone Economic View, a report released by the Reagan-Udall Foundation for FDA.

Experts expect that naloxone's OTC status will make pharmacies a safe and easy point of access—but only if this price is right.

"The idea that Narcan [the brand name for naloxone] could become available OTC was overwhelmingly supported by the experts," said Rosanna Smart, PhD, an economist at RAND Corporation, whose recent research involved surveying an expert panel of clinicians, social service practitioners, policymakers, advocates, and researchers on naloxone access. "They think it could have a big impact in terms of getting naloxone out to communities."

OTC naloxone's expected impact

Despite pharmacists' authority to stock and dispense naloxone without a patient-specific prescription, not all pharmacies keep the opioid antidote on their shelves. In some states, around half of pharmacies stock it, but in others that number may be closer to just a quarter of pharmacies.

Among those that do include naloxone in their inventories, research suggests that many pharmacists are uncomfortable dispensing it. In some surveys, pharmacists have cited lack of training; other studies have shown that, at least in rural areas, pharmacists incorrectly believe patients need a prescription for the drug.

"There are also views out there about naloxone producing moral hazard effects, and that may act as a personal barrier to dispensing," said Evan Peet, PhD, an economist at the RAND Corporation whose research focuses on the opioid crisis.

OTC naloxone would ostensibly resolve those types of gaps in access and address other barriers, too.

Even in pharmacies that dispense naloxone, there's no guarantee that patients who need it will walk out with it. Stigma may play a role in this discrepancy, as patients still must approach the pharmacy counter and ask for the lifesaving drug.

"Making it available alongside products like Tylenol was something that the experts thought could reduce stigma and encourage a broader set of people to obtain this and carry it around," Smart said.

The question of cost

Drugmaker Emergent Biosolutions has not yet announced what their OTC product will cost.

For Medicaid beneficiaries, and some who carry private insurance, prescription naloxone comes at no cost. For those who must make a copayment, the average is $25, according to a September 29, 2022, study in *Substance Abuse* by Messinger and colleagues, which speculated that this cost alone was a deterrent for many people who might need the antidote.

Uninsured patients on average paid $73.62 for Narcan and $67.99 for generic naloxone in 2018, according to an August 19, 2022, study in *JAMA Health Forum* coauthored by Peet.

Should the cost of an OTC product be similar to the latest cash prices for the prescription drug, price would be a barrier for a major segment of the potential market. People living below the poverty line account for 1 in 4 opioid overdose deaths. Nearly 40% of those who die by overdose rent their homes, a quarter did not complete high school, and more than a third have no more than a high school diploma or GED.

Prescription injectable naloxone will continue to be available in pharmacies and at the charitable organizations that give it away for free—with the same pre-existing barriers to access. OTC naloxone is expected to be available this summer. Just how much it will help curb opioid overdose deaths depends on just how much it costs. ■

Community health workers in pharmacies help address social determinants of health

Loren Bonner

The community pharmacy may be the very place where addressing social determinants of health (SDOH) can be a reality, not just a concept.

Through partnerships between community pharmacists and community health workers (CHWs), some pharmacies have been able to help close gaps that lead to poor health outcomes for the most complex patients.

"Patients are willing to discuss their social needs at the pharmacy," said David Jacobs, PharmD, PhD, lead author of a new study in *JAPhA*, published January 10, 2023, that examined the feasibility of CHWs within a pharmacy to address health-related social needs.

Jacobs and his colleagues tested a CHW model in an independent community pharmacy in Buffalo, NY. Through partnerships with three community-based organizations, including one experienced in CHW programs, pharmacy staff were able to successfully screen patients for social needs and refer them to an embedded CHW within the pharmacy. The embedded CHW then assessed and referred patients to community resources and followed up as needed.

Eighty-seven social needs were identified among the patients in the study. The most common SDOH domains included issues with the neighborhood and built environment at 31%, and economic stability challenges at 30%, according to the study results. The CHW spent an average of 33 minutes per patient from initial case review through follow up.

After the intervention, patients completed a survey regarding their program experience. All respondents reported a positive perception of the program, and 70% agreed that community pharmacies should help patients with their social needs.

"There is movement toward community health workers in different settings, and this is one avenue," said Jacobs, who is from the University at Buffalo School of Pharmacy and Pharmaceutical Sciences. "It's feasible for a community health worker to be embedded in a pharmacy and in screening and [patient] navigation."

The American Public Health Association defines a CHW as "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community serviced. 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."

CHWs are credentialed through local certificate training programs, and they often share the same cultural understanding as their patients, which allows them to more easily identify barriers patients face when it comes to taking medications.

> In the community pharmacy setting, SDOH are the difference between a patient being able and not being able to access or manage their medications

A study published March 4, 2020, in *JAPhA* by Segal and colleagues found that a majority of patients revealed information to a CHW of which the pharmacist wasn't aware. The study evaluated the effect of CHWs in a community pharmacy in Florida on patient's adherence to antihypertensive medications.

Accessing medications

To put their Buffalo, NY, CHW program in place, Jacobs and fellow researchers collaborated with Tripp Logan, PharmD, from L & S Pharmacy in Charleston, MO. Logan's pharmacy was the first in Missouri to train CHWs through a pharmacy-based training program. His team equips their pharmacy delivery drivers with home assessments and patient assessments in order to find out if a patient should be referred to a CHW.

"This is all part of outcomes-based care, value-based care," said Logan. "Pharmacies are in the outcomes business now, and we don't talk about that enough. This is the secret weapon for getting into value-based care arrangements."

In the community pharmacy setting, SDOH are the difference between a patient being able and not being able to access or manage their medications. Medication cost, literacy, transportation, and other SDOH issues all play into this.

Training

As with any new idea or model of care, there are always next steps. According to Christopher Daly, PharmD, coauthor of the *JAPhA* study, there are gaps to address with CHW training.

"Training requirements are different per state," said Daly, who is from the University at Buffalo School of Pharmacy and Pharmaceutical Sciences. "There are partnerships with community-based organizations to accomplish training. Materials are adapted and pharmacy-centric to increase effectiveness."

Pharmacy technicians can be—and have been—trained to be CHWs. Logan said they discovered that it's easier to train a pharmacy technician in-house than hire an outside person and give them pharmacy-specific training.

Through their nationwide course, Logan's team has trained roughly 90 pharmacy technicians in 2022 to become CHWs, and they are on track to train at least another 180 this year. ■

First aid and oral care

Many patients seek OTC relief for skin injuries each year. Pharmacists are in a prime position to offer self-care recommendations for minor burns, sunburn, and insect stings and bites. Oral hypersensitivity and pain relief for oral issues is often considered urgent by the one suffering from this particular discomfort. Pain from skin or oral issues can vary in intensity and pharmacists can help point patients in the right direction for OTC relief of skin or oral hypersensitivity.

First aid

Bandages ..... (n = 551)

Band-Aid	70%
Nexcare	3%
Walgreens	2%
CVS Health	1%
Equate	1%

Sunburn relief..... (n = 621)

Solarcaine	13%
Banana Boat	6%
Demoplast	5%
Alocane	2%
Sun Bum	2%

Burn treatment..... (n = 468)

Neosporin	11%
Solarcaine	7%
Alocane	5%
CVS Health	1%
Foille	1%

Insect bite/Sting relief ..... (n = 592)

Benadryl	15%
After Bite	13%
Cortizone 10	10%
Off	3%
StingEze	3%

Oral care

Toothpaste for sensitivity ..... (n = 591)

Sensodyne	72%
Crest	6%
Colgate	6%
Sensodyne Pronamel	1%
Arm & Hammer	1%

Cold sore relief ..... (n = 574)

Abreva	64%
Orajel	3%
Carmex	2%
Herpecin-L	2%
Campho-phenique	1%

Dry mouth relief ..... (n = 619)

Biotene	52%
XyliMelts	3%
Therabreath	1%
ACT	1%
Good Neighbor Pharmacy	1%

Oral pain relief..... (n = 610)

Orajel	50%
Anbesol	8%
Tylenol	6%
Advil	3%
Motrin	2%

Sore gum relief ..... (n = 464)

Orajel	41%
Anbesol	12%
G.U.M.	1%
Colgate	1%
DenTek	1%

Denture cleaner ..... (n = 500)

Polident	21%
Efferdent	10%
Fixodent	2%
Colgate	1%
CVS Health	1%

Denture adhesive ..... (n = 482)

Fixodent	17%
Polident	10%
Super Poligrip	9%
Sea-Bond	4%
PreviDent	1%

Self-care survey redux

This section of *Pharmacy Today*'s Self-Care Product Survey is reprinted from the full survey results published in the January 2023 issue of the magazine and available online at pharmacytoday.org.

The current survey was conducted using scientifically valid methodology and determines those nonprescription products most often recommended by pharmacists in the United States to consumers.

The winners were selected based on a survey of 1,682 pharmacists practicing in the United States who gave their unaided write-in opinions on which brands they'd recommend to patients in 86 categories. The highest share of citations as Most Trusted in the category determined the winner. If the margin of citation share between the leading brands did not exceed the estimate of sampling error at 90% statistical confidence, a tie was declared.

The n value given for each category represents the total number of responding pharmacists' recommendations.

Please also see APhAs *Handbook of Nonprescription Drugs*, the definitive source of professional information about OTC products. The Handbook is available online at PharmacyLibrary.com or in print in the bookstore at www.pharmacist.com.

These data may not be used without the prior permission of APhA.

Court rules statute restricting consultation content is unconstitutional

David B. Brushwood, BSPharm, JD

A federal court in Missouri recently granted a pharmacist's motion for a preliminary injunction after the pharmacist asserted that her constitutional right to free speech was infringed by a recently enacted state statute.

Background

The statute challenged by the pharmacist says "a pharmacist shall not contact the prescribing physician or the patient to dispute the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets for human use unless the physician or patient inquires of the pharmacist about the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets."

The pharmacist sued the Missouri Board of Pharmacy and its members, contending that the new statute placed her in jeopardy for disciplinary action by the Board if she were to engage in professional consultation activity that she claimed was protected by the First Amendment of the United States Constitution.

The pharmacist's lawsuit requested that the court grant a preliminary injunction against enforcement of the state statute. Attorneys representing the Board of Pharmacy moved for dismissal of the case.

Rationale

The court first noted that "if a party shows a likely violation of his or her First Amendment rights, the other requirements for obtaining a preliminary injunction are deemed to have been satisfied."

The court explained that the key issue was whether the new statute "infringes the free speech rights of the plaintiff and other Missouri pharmacists by threatening to impose liability based on the viewpoint of their speech."

Government attorneys representing the Board of Pharmacy contended that the statute does not engage in viewpoint discrimination because the statute regulates conduct and not speech. In response, the court said, "this argument is unavailing because the statute does not prohibit initiating contact with patients or doctors (a regulation of conduct). Nor does it prohibit initiating contact with patients or doctors to speak on any matter at all (a content-neutral regulation of speech). Nor does it prohibit initiating contact with patients or doctors to talk about a particular subject matter, such as any discussion of either drug (a content-based regulation of speech).

Rather, the provision bans initiating contact only if the contact is to express the viewpoint that the drugs are not effective for human use. Hence, it is viewpoint discrimination."

The court explained that "since the statute engages in viewpoint discrimination, that is the end of the matter."

The court cited prior cases from the Supreme Court of the United States recognizing that "the government may not discriminate against speech based on the ideas or opinions it conveys," that "discrimination against speech because of its message is presumed to be unconstitutional," and that government restrictions "based on viewpoints are prohibited."

The court further explained that but for the new statute, the pharmacist "would be able to freely fulfill her professional duties and protect patients by communicating her concerns without the fear of disciplinary consequences for expressing her professional opinion."

Furthermore, even if the Board were to assure the pharmacist that they would not enforce the new statute, the pharmacist's speech "would be chilled" because she "would not feel comfortable speaking freely with physicians and patients" for fear of "complaints or other professional liability."

The pharmacist's motion for a preliminary injunction was granted.

Takeaways

The factual context of this case is relatively narrow. It evaluates one pharmacist's challenge to a law in one state where politicians sought to limit the consultations by pharmacists with regard to the therapeutic appropriateness of two drugs.

The United States Constitution protects the right of pharmacists to engage in consultations with patients and prescribers regarding the risks and benefits of medications.

The legal principle in the case is very broad. The United States Constitution protects the right of pharmacists to engage in consultations with patients and prescribers regarding the risks and benefits of medications.

The government cannot forbid the expression of a professional viewpoint by a pharmacist during such consultations.

The professional judgment of pharmacists cannot be hijacked by politicians whose goal is to promote a political agenda. ■

Prevent administration of ear drops into the eyes

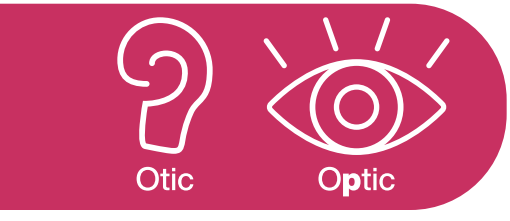
Institute for Safe Medication Practices, Horsham, PA

When a practitioner, patient, or caregiver accidentally instills ear drops into the eye, it may lead to an immediate burning and/or stinging sensation, and the patient may later experience pain, redness, swelling, or blurred vision. Patients may need to flush their eyes with water or normal saline and/or apply warm or cold compresses. Others may need to go to the emergency department, an ophthalmology clinic, or their eye doctor for care.

In one recent case, a telehealth provider prescribed what they thought was neomycin sulfate 3.5 mg/mL, polymyxin B 10,000 units/mL, and hydrocortisone 1% ophthalmic drops for a patient with conjunctivitis.

After picking up the medication and instilling 4 drops into their eye, the patient felt severe burning. They read the label and realized the product was an otic suspension. The patient flushed their eye with water, but it did not relieve the pain.

Aside from look-alike eye and ear medication names and containers, another reported reason for this type of error is confusion between the words "optic" and "otic."



Also, practitioners and patients sometimes use the term "eyedropper" when referring to the container used to instill both eye and ear drops, which could invite an error in which the person reading the label fails to see unexpected information in plain sight, such as the product formulation, a warning, or a picture/icon of an eye or ear.

While ear drops should never be used in the eyes, eye drops are made to be gentle and are sometimes used in the ears due to cost or availability. This practice can contribute to practitioners using products interchangeably.

While barcode scanning can prevent administration to the wrong patient and confirm the right product, it does not ensure the medication will be given via the correct route.

Safe practice recommendations

To reduce the risk of administering ear drops into the eyes, consider the following recommendations.

Storage

Keep medications in their original cartons, as icons of an ear or eye are sometimes on boxes but not on dropper bottles. Separate the storage areas for bottles of ear drops and eye drops on pharmacy shelves and in automated dispensing cabinets.

Prescribing

Build order sets/sentences in the electronic health record to guide prescribers to select the appropriate route, and automatically link the order with the corresponding product formulation. Specify the route of administration (e.g., right eye, left eye, each eye) and never use the abbreviations OD, OS, or OU, which can be mistaken as AD, AS, or AU (e.g., right ear, left ear, each ear). (Please see ISMP's list of error-prone abbreviations at www.ismp.org/node/8.) Restrict prescribers from ordering ear drops for the eye.

Dispensing

Utilize barcode scanning before dispensing. Consider placing an auxiliary label with a photo of an ear or eye on the dropper bottle to specify ear or eye drops.

While ear drops should never be used in the eyes, eye drops are made to be gentle and are sometimes used in the ears due to cost or availability.

Administration

When possible, administer ear drops and eye drops on different schedules (e.g., if given once daily). Use barcode scanning before administration and confirm the medication, route, and indication with the patient before administering ear drops or eye drops. Immediately dispose of any discontinued product.

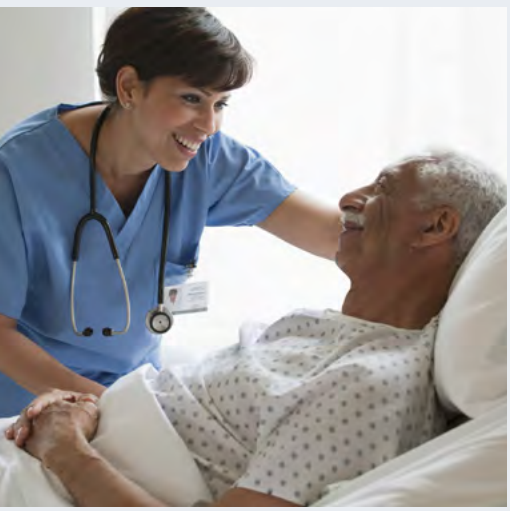
Patient education

Confirm the expected route with the patient. Counsel patients using the teach-back method to reinforce the route. Educate patients to keep ear drops and eye drops in the carton, store them in separate locations at home, and discard any leftover medication. ■

Inpatient*Insights*

How prevalent is discontinuation of antipsychotic medication use following infection-related hospitalization?

Delirium, or acute onset of disturbance of consciousness and cognition, occurs in up to 45% of older adults hospitalized for infections such as influenza, pneumonia, UTI, and COVID-19. Although antipsychotic medications (APMs) are commonly prescribed to manage the behavioral disturbances caused by delirium, clinical consensus recommends that APMs should be used with caution in older adults and should be discontinued as soon as possible.

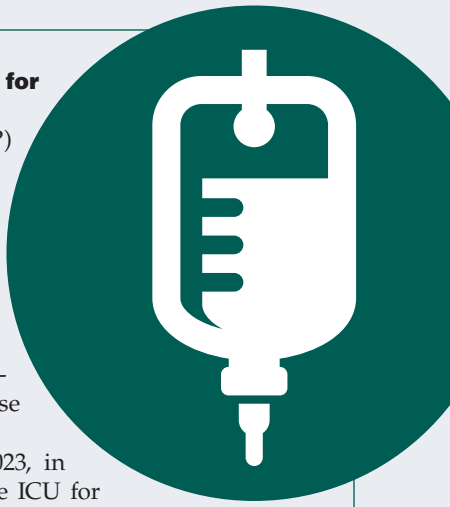


Researchers from Harvard Medical School conducted a cohort study using U.S. claims data from January 1, 2004, to May 31, 2022, to investigate patient characteristics and discontinuation rates of APMs used to treat delirium following infection-related hospitalization among older adults. The study, which included 5,835 patients with no prior use of oral haloperidol and atypical APMs (aripiprazole, olanzapine, quetiapine, and risperidone), was published on February 17, 2023, in *JAMA Network Open*. The primary outcome was APM discontinuation, defined as a gap of more than 15 days following the end of an APM regimen.

The findings of the study showed discontinuation rates of only 11% for new atypical APM users and 52% for new haloperidol users by 30 days after initiation following infection-related hospitalization. The researchers also found that dementia and prolonged hospitalization were inversely associated with discontinuation of haloperidol and atypical APMs.

Their findings suggest that contrary to clinical recommendations, APM discontinuation rates following infection-related hospitalization are low overall and lower for atypical APMs than for haloperidol. ■

Hydrocortisone may improve outcomes for patients with severe CAP

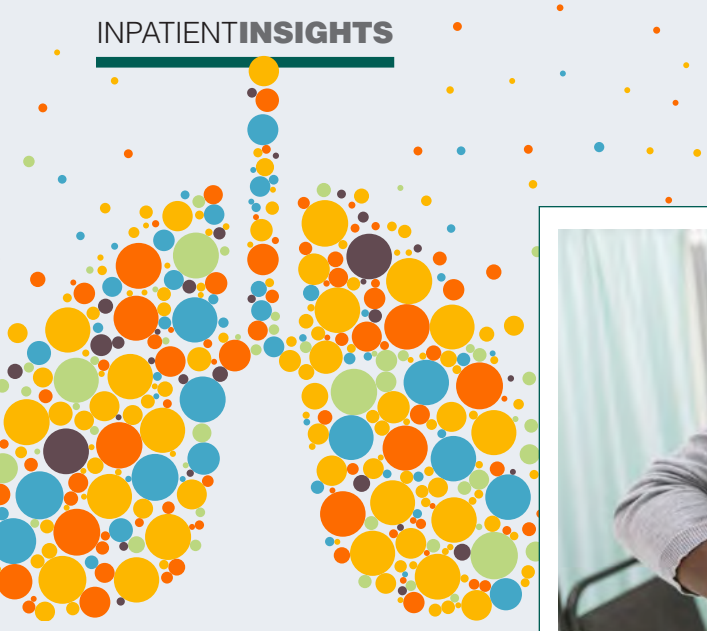


Community-acquired pneumonia (CAP) remains a leading cause of hospitalization and mortality, with many patients admitted to the ICU for treatment, which includes antibiotics and supportive care. Researchers participating in the CAPE COD study conducted a phase 3, multicenter, double-blind, randomized, controlled trial to determine whether the anti-inflammatory and immunomodulatory effects of glucocorticoids decrease mortality among patients with severe CAP.

In the study, published on March 21, 2023, in *NEJM*, adults who had been admitted to the ICU for severe CAP were assigned to receive I.V. hydrocortisone (200 mg daily for either 4 or 8 days as determined by clinical improvement, followed by tapering for a total of 8 or 14 days) or placebo. All patients continued to receive standard therapy, including antibiotics and supportive care. The primary outcome was death at 28 days.

Data from 795 patients were analyzed, showing that by day 28, death had occurred in 25 of 400 patients (6.2%) in the hydrocortisone group and in 47 of 395 patients (11.9%) in the placebo group. Among the patients who were not undergoing mechanical ventilation at baseline, endotracheal intubation was performed in 40 of 222 patients (18.0%) in the hydrocortisone group and in 65 of 220 patients (29.5%) in the placebo group. The frequencies of hospital-acquired infections and GI bleeding were similar in the two groups.

The authors concluded that early treatment with hydrocortisone should be considered for patients admitted to the ICU with severe CAP. ■



Increase in lung function seen in patients with pulmonary hypertension treated with sotatercept

Pulmonary arterial hypertension results from narrowed, thickened, or stiff arteries in the lungs, and can cause shortness of breath, fatigue, and dizziness. According to the authors of a paper published on March 6, 2023, in *NEJM*, disease-associated morbidity and mortality remain high despite therapeutic advances.

The STELLAR Trial investigators conducted a multicenter, double-blind, phase 3 trial to determine if sotatercept, a fusion protein that traps activins and growth differentiation factors involved in pulmonary arterial hypertension, improved exercise capacity.

The study included over 300 adults with WHO functional class II or III pulmonary arterial hypertension who were receiving stable background therapy. Patients were randomly assigned in a 1:1 ratio to receive subcutaneous sotatercept (starting dose, 0.3 mg/kg body weight; target dose, 0.7 mg/kg body weight) or placebo every 3 weeks. The primary end point was the change in 6-minute walk distance from baseline at week 24.

Nine secondary end points included multicomponent improvement, change in pulmonary vascular resistance, change in N-terminal pro–B-type natriuretic peptide level, improvement in WHO functional class, time to death or clinical worsening, French risk score, and changes in the PAH-SYMPACT Cognitive–Emotional Impacts domain scores.

The median change from baseline at week 24 in the 6-minute walk distance was 34.4 m in the sotatercept group and 1.0 m in the placebo group. The first 8 secondary end points were significantly improved with sotatercept compared with placebo, although the PAH-SYMPACT Cognitive–Emotional Impacts domain score was not. Some adverse events, including epistaxis, dizziness, telangiectasia, increased hemoglobin levels, thrombocytopenia, and increased BP, occurred more frequently with sotatercept than with placebo. ■

Sufentanil-based analgesia may offer improved relief for children after surgery

Adequate control of postoperative pain is critical in infants and small children. Options for pediatric patients are limited because many analgesics commonly used in adult patients are not approved for use in children. In a study published on February 10, 2023, in the *Journal of Clinical Pharmacology*, researchers from Sichuan University (China) investigated the use of sufentanil, a fentanyl derivative that relieves pain quickly, for patient-controlled analgesia (PCA) in children following major surgery.

A total of 963 children (average age of 4 years old) who received sufentanil-based PCA following major surgery to repair congenital hip dislocation and hypospadias were included in the study. Patients were divided into 3 groups and received sufentanil 4 µg/kg + tramadol 10 mg/kg, sufentanil 4 µg/kg, or sufentanil 5 µg/kg. After tramadol was banned in April 2021, it was removed from the PCA regimen and the study continued with the 2 doses of sufentanil.

Caregivers or children were trained in pain assessment preoperatively and were instructed on how to use the device to maximize analgesia by pressing the PCA button if the children presented pain. The primary end point was the incidence of moderate to severe pain during rest and activity (defined as a score of ≥4 at any time within 72 hours after surgery).

Results of the study showed that the incidence of moderate to severe postoperative pain during rest was significantly lower in the group who received 5 µg/kg sufentanil and the group who received sufentanil plus tramadol. The number of effective PCA administrations within 72 hours was significantly higher in the 4 µg/kg sufentanil group than in the sufentanil/tramadol group or 5 µg/kg sufentanil group, but there was no statistical difference in total usage of opioids among the three groups.

The authors concluded that sufentanil-based PCA could be effectively and safely used for pain relief in children after major surgery without increasing opioid-related adverse effects and that the 5 µg/kg dosage is superior to the 4 µg/kg dosage. ■

Experts update vaccination recommendations for patients with rheumatic and musculoskeletal diseases

Ariel L. Clark, PharmD

Vaccinations are widely viewed as one of the greatest success stories in the history of public health. From development of the first smallpox vaccine to the continual research into a vaccine for various cancers and immunodeficiencies, they continue to protect people across the globe. Unfortunately, those with rheumatic and musculoskeletal disorders (RMDs) often may not achieve the same level of protection from infection as those without. The drugs that are used to treat RMDs put patients at an inherently higher risk for infection from diseases.

In developing new vaccination guidelines for adults and children with RMDs, the American College of Rheumatology (ACR) published recommendations in 2022 for influenza vaccination, pneumococcal vaccination, HPV vaccinations, and more.

Influenza vaccination

In the new guidelines, ACR recommends that patients with RMDs receive a quadrivalent influenza vaccine over the standard dose.

However, this recommendation should not prevent patients from getting vaccinated. If pharmacists and other health care providers do not have the quadrivalent in stock, patients should be advised to obtain any flu shot over no flu shot at all.

Pneumococcal vaccination

Vaccination against pneumococcal infection is strongly recommended by ACR. For those taking immunocompromising medications who are under the age of 65, CDC recommends vaccination with pneumococcal conjugate vaccine (PCV13), followed by polysaccharide vaccine (PPSV23).

Adults over the age of 65 with RMD who do not know or who do not have access to their vaccine records should receive booster doses. CDC currently recommends a pneumococcal conjugate vaccine (either 13- or 15-variant) followed by a dose of polysaccharide vaccine at least 2 months later.

Varicella zoster vaccination

Patients with RMDs are at higher risk for herpes zoster than older adults, according to the guideline authors. Vaccination has been proven effective in patients who have undergone transplants, including those of kidneys and stem cells; it is therefore strongly recommended. However, providers should discuss the possibility of mild disease flares with patients who are thinking about getting vaccinated.

HPV vaccination

For patients taking immunocompromising medications, there may be an increased risk for uterine cancer development, so HPV vaccination is universally recommended in this update.

Live vaccines

The guideline authors advise providers to refrain from giving live vaccines until patients have ceased using their medications for an "appropriate period before and 4 weeks after live attenuated vaccinations." The appropriate period before depends on the agent being used by the patient, and providers should review the guideline for each patient, particularly for infants who were exposed to RMD drugs while in utero.

Treatment drugs and whether or not to hold them

Methotrexate is one of the most commonly used drugs for RMDs. Other medications can include glucocorticoids and injectable biologic agents like rituximab.

Methotrexate can be continued without interruption for vaccinations other than influenza. For flu vaccines, the ACR guidelines recommend providers hold methotrexate for up to 2 weeks due to the risk of reduced flu vaccine effectiveness. However, vaccination should not be delayed and providers are encouraged to use shared decision-making based on disease activity.

According to this update, rituximab injection may be given on schedule when the patient receives a flu vaccine. But providers should delay other vaccines, including pneumococcal vaccines, until the next dose is due, and they should have the patient delay the dose after the shot by 2 weeks.

Glucocorticoid schedule interruption is based on what dosage the patient is taking. Providers should consult the ACR update and assess their patient's individual case.

Providers are encouraged to listen to patient concerns, particularly about disease flare-ups. Although studies have not shown an increased rate of flare-ups, shared decision-making can help ease patient apprehension.

Protecting patients with RMDs via vaccinations is critically important, both for their health and for global health. This guideline update may better aid providers in understanding when and how to follow traditional vaccine schedules and when to deviate from them in order to best protect their patients. ■

New hospital process initiative sees massive cost savings by reducing injectable drug waste

Corey Diamond, PharmD

Drug waste costs U.S. insurers billions of dollars annually, with Medicare Part B spending increasing year by year as a result. But a new process improvement project could provide insight into how institutions can optimize injectable drug waste production and significantly reduce costs.

The improvement process was detailed in the February 2023 issue of the *American Journal of Health-System Pharmacy*. Trovato and colleagues found that the implementation of a "grouper" with intelligent medication selection logic and custom dose rounding in the electronic health record (EHR) for three high-cost drugs—bevacizumab-bvzr, carfilzomib, and ipilimumab—resulted in drug waste savings of over $800,000 within a 3-month period.

Since the introduction of the JW modifier in 2007, CMS has been rigorously tracking injectable drug waste to ensure appropriate use of single-dose vials—a particular challenge for health institutions. There are no thorough processes in place to ensure Medicare Part B billing requirements are met each time staff prepare a dose of an injectable drug, resulting in excess drug waste.

Process improvement

Trovato and colleagues conducted a pre–post study design over a 6-month period. The authors identified 2 key process gaps at their institution. Firstly, the EHR failed to list available vial sizes or combination of vials to use when preparing an injectable dose, with the staff having to rely on their own knowledge to make decisions on which vial sizes to use to minimize drug waste. Secondly, their institution did not have a dose-rounding policy to allow staff to automatically round patient-specific doses to the nearest vial size.

To remedy these problems, the hospital's informatics team implemented a grouper functionality within their EHR that used an intelligent algorithm to automatically select the optimum combination of vial sizes for an ordered dose. The optimal vial size or vial size combination would display on the "Dispense Preparation" screen in the clean room. A dose-rounding policy was also approved in the postimplementation phase to automatically round injectable doses to the nearest vial size if the ordered patient-specific dose was within 10% of the vial size.

To obtain the best snapshot of the potential cost savings of these process improvements, the authors initially limited their process improvement implementation to three drugs—bevacizumab-bvzr, carfilzomib, and ipilimumab—that would reasonably produce waste at an amount greater than necessary.

Overall, the authors evaluated a total of 826 claims to Medicare Part B for the three drugs prior to the process improvement implementation versus 1,075 claims afterward. The authors found that there was a reduction in waste of approximately 34% for all three drugs (55.1% prior to implantation vs. 20.8% after 3 months postimplantation).

The total estimated cost savings—calculated using the wholesale acquisition cost—was approximately $828,396 ($1,397,437 in 3 months prior to project implementation vs. $569,041 after 3 months postimplementation).

Limitations

The authors could not, unfortunately, assess the efficacy of the implementation of the grouper alone. The study could only assess its efficacy within the context of being used in combination with a dose-rounding policy. "Around the same time as grouper implementation, staff received notice that certain commercial payors might begin requiring dose rounding. Pharmacy staff sought approval from organizational leadership to implement dose rounding based on this information," the authors explained. "Even though the department knew that dose rounding would confound assessment of the efficacy of the grouper alone, they wanted to implement it as soon as possible, rather than wait another two and a half months until the grouper implementation phase was over."

The total estimated cost savings—calculated using the wholesale acquisition cost—was approximately $828,396.

The authors went on to explain that although having both features helped reduce drug waste and improve billing compliance, this was a major limitation in understanding the true effect of the grouper alone on reducing waste.

Despite only containing 3 months' worth of efficacy data, Travato and colleagues' study may help inspire similar programs for other health systems in the future. ■

A minute with ...

Eric Pham, 2023 PharmD candidate, University of Mississippi, Jackson, MS

Member since 2018

"Since joining APhA as a member, one of the most valuable moments was the opportunity to serve as operation immunization chair of the University of Mississippi (UM) chapter of APhA–ASP. Being the chair during the height of the pandemic brought its set of challenges, but I was not afraid to jump right in to help our community and represent pharmacists and students pharmacists. We had our gracious volunteers of student pharmacists, pharmacists, and other UM School of Pharmacy staff willing to jump into serving our community and patients. In addition, I had the opportunity to collaborate with other APhA–ASP chapters around the nation to discuss their challenges and how they were adapting their Operation Immunization efforts."

How has APhA helped you establish meaningful connections?

In attending my first Midyear Regional Meeting (MRM) in Fall 2019, I established meaningful student connections from other APhA–ASP chapters. I still keep in touch with some of those people on social media platforms regarding their internships, APPEs, and residencies.

When I hosted a pediatric residency information session, I was able to reach out to Kelli Jo Welter, 2019–2020 APhA–ASP national president; she was so willing to come speak to our students about her interest in pediatric pharmacy and share her advice on prioritizing her residency search.

How has APhA helped prepare you for your career as a pharmacist (e.g., experiences in patient care projects, leadership opportunities, advocacy, etc.)?

Serving in my role as operation chair of The UM School of Pharmacy's APhA–ASP chapter during the COVID-19 pandemic has been one of the most rewarding experiences in preparation as a future pharmacist.

During the preparation of the influenza and COVID-19 vaccine clinics, I was able to use my clinical knowledge of the vaccine and vaccine administration techniques as well as my operational procedures knowledge to communicate to our team and help run a smooth, successful clinic.

What excites you about the profession of pharmacy?

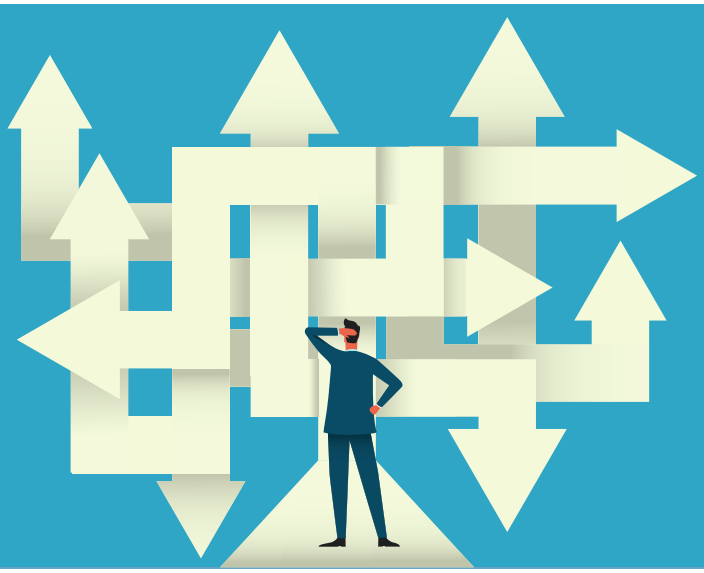
Personally, I am very excited about the growth of the profession. In spite of the pandemic, recognition of the pharmacy profession brought into greater light the accessibility and knowledge of pharmacists.

As I am pursuing a postgraduate pharmacy residency, I am excited to gain more clinical knowledge and diversify my skillsets through various medication use evaluations and projects.

Can you share a meaningful story about a time you interacted with a patient? Perhaps a time you felt like you really made a difference for them?

This may not be a single-patient interaction, but during our drive-thru flu clinic and COVID-19 immunization clinics, we had so much feedback on how logistically sound and accessible the vaccine was.

There is a lot of background work that happens in order to achieve successful outcomes and knowing that the patients of the UM community were able to notice the details of the clinic, made me feel like I made a difference in providing comfort and ease in getting vaccinated. ■



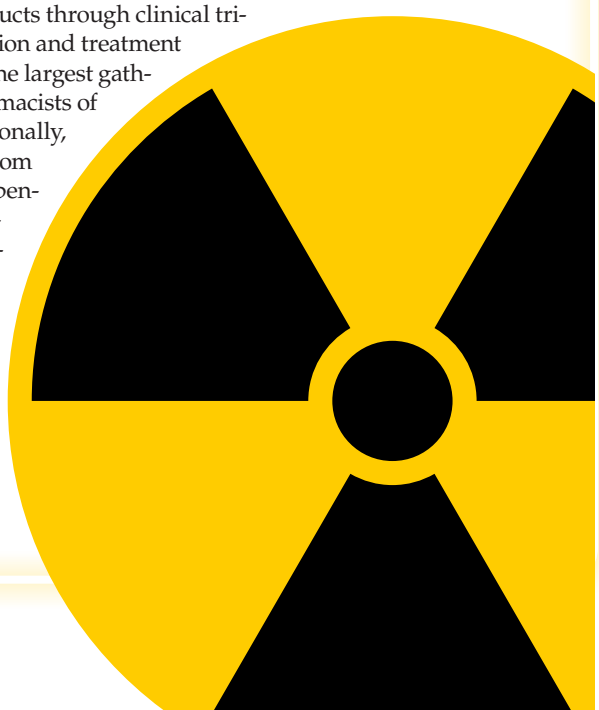
ICYMI: Career planning home study

APhA recently held a webinar entitled "Explore Your Own Pharmacist Career Planning." The recording of this webinar is now available as a self-paced learning activity that can be completed for CPE credit at apha.us/Career-Planning. During this webinar, speakers Lynette Bradley-Baker, PhD, CAE, RPh, and Nidhi Gandhi, PharmD, BS, discuss how pharmacists can effectively plan for the various facets and stages of their career through utilizing many concepts and actions including continuing professional development, networking, mentorship, and goal setting. ■

Get involved

The primary purpose of the APhA–APPM Nuclear Pharmacy Practice Special Interest Group (SIG) is to serve pharmacists involved in the specialty practice of nuclear pharmacy by providing an avenue in which to fulfill individual professional goals and support the goals of the academy. "As we approach the 50-year anniversary of nuclear pharmacy as the first pharmacy specialty recognized by APhA, we have more radiopharmaceuticals for both therapeutic and diagnostic applications in development or newly released than ever before," said David Barnes, SIG coordinator. "This allows the Nuclear Pharmacy Practice SIG to provide education and share practical experience that our members attain in helping bring these new products through clinical trials to commercialization and treatment of patients daily. As the largest gathering of nuclear pharmacists of any organization nationally, our members come from national chains, independent nuclear pharmacies, academic institutions, and industry with a goal to help bring new pharmacists into the profession and advance the practice of nuclear pharmacy."

Visit apha.us/NuclearSIG to learn more. ■



Did you know?

Burnout is real. APhA offers a free online screening tool, the Well-Being Index (WBI), to evaluate fatigue, depression, burnout, anxiety, stress, and mental and physical quality of life to assess your well-being. This research-validated tool invented by the Mayo Clinic is 100% anonymous and confidential. The WBI for Pharmacy Personnel measures 9 dimensions of distress including likelihood of burnout, meaning in work, severe fatigue, work-life integration, and more. In just 5 minutes, see your assessment, scores, and resources for each dimension. Assess as often as you like to track your well-being over time. This is not a one-time survey!

Visit apha.us/APhAWBI to access this free resource that's open to all. ■

Gender-affirming care and pharmacy practice

Jay Holloway, PharmD, AAHIVP, is a pharmacist for Walgreens in Los Angeles.

Over 1.6 million people 13 years and older in the United States identify as transgender.[1] However, student pharmacists might enter the workforce or residency with little knowledge of transgender and gender-diverse (TGD) patients as well as a lack of confidence to provide adequate care.[2] TGD patients exist regardless of which specialty a pharmacist is in, so it is important to be familiar with the standards of gender-affirming care that a patient may need. Pharmacists can address these health disparities and barriers to care by educating themselves on community terminology, learning about best practices, and implementing changes in their practice to create an affirming, inclusive, and equitable space.

Definitions

TGD

Most individuals are assigned a sex at birth, which is usually determined by visual inspection of the genitals or prenatal chromosome testing. Some individuals are also intersex, or have a difference in primary or secondary sexual characteristics from what is considered typical for their assigned sex at birth.[3] About 1.7% of people are born intersex and may or may not identify as transgender.[3]

Gender identity, on the other hand, is an internal sense of gender which can include but is not limited to being a man, woman, a combination of those, a different gender identity, or of no gender. There are also suprabinary gender identities specific to certain cultures; these include but are not limited to culturally specific gender identities such as the Lakȟóta wíŋtke, the lhamana of the Zuni tribe, and baté of the Crow nation.[4,5]

Individuals whose gender identity aligns with their sex assigned at birth are cisgender, while being transgender (also shortened to trans) encompasses individuals whose gender identity does not match their sex assigned at birth. However, it is important to note that whether or not a person identifies as transgender will be up to the individual. Transgender people, gender nonconforming people, nonbinary individuals, and culturally specific gender identities are often referred to under the umbrella of TGD people.[6]

Some people may experience gender euphoria, or a feeling of joy or fulfillment from feeling aligned with their gender identity.[7] But other TGD people may feel a marked, persistent incongruence between their gender identity and sex assigned at birth. The distress that may be caused by this incongruence is known as gender dysphoria.[6] Gender dysphoria can involve feelings about one's own body or how people perceive the individual. In order to alleviate the incongruence, an individual may transition socially, legally, or medically.[6] These changes can include using a name and pronouns that match their gender, changing their style of dress and appearance, or updating identity documents.

Overlapping with transition is gender-affirming care (GAC). However, it is important to note that the absence of gender incongruence/dysphoria, or the lack of desire or ability to pursue transition, does not invalidate one's transgender identity.[6]

GAC

GAC, also known as gender affirmative care, refers to the umbrella of social, medical, psychological, and behavioral care that is provided to trans and gender-diverse people in order to align with their gender identity.[8]

Learning objectives

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

- Define gender-affirming care (GAC) and relevant related terminology.
- Identify health disparities and barriers to care experienced by people who seek GAC.
- Recognize best practices for providing GAC.
- Discuss strategies for inclusive communication and pharmacy practice when caring for patients who seek GAC.

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. Select the correct statement regarding terminology for TGD patient populations.

a. Transgender identity is defined by the presence of incongruence/dysphoria between sex assigned at birth and gender identity.
b. "Gender nonconforming" relates to gender expression and may or may not overlap with transgender identity.
c. Culturally specific gender identities fall under the umbrella of transgender, as they are different from "man" and "woman."
d. Intersectionality refers to the dissonance an individual may feel as a member of 2 marginalized identities.

2. Select the correct statement regarding health disparities that those seeking GAC may face.

a. Rates of health care discrimination are even between TGD people of color and TGD people as a whole.
b. Coverage of GAC by Medicaid is standardized across all 50 states.
c. Transgender patients experience higher levels of unemployment than cisgender individuals.
d. Access to GAC did not decrease rates of depression, anxiety, and suicidality.

3. Which of the following is an example of health care discrimination a patient may face?

a. A gender care clinic allows for a chaperone in procedures that cause dysphoria.
b. A patient is unable to afford their hormone replacement therapy after being fired.
c. A patient is asked questions about their genitals when being examined for lower back pain.
d. A pediatric patient in Arkansas has to travel to Illinois for GAC.

The medical concept of GAC is not new. In 1910, Magnus Hirschfield, MD, defined the desire to express one's gender differently than their assigned sex as "transvestite" (a now-obsolete term) and was among the first to provide medical and surgical interventions at the Institute for Sexual Science in Berlin; however, most of his research was destroyed in May 1933 during the first Nazi book burning.[9] GAC began advancing in the 1940s in the United States by researchers such as Alfred Kinsey, BS, ScD, and later by Harry Benjamin, MD.[9] In 1979, the first edition of the World Professional Association for Transgender Health (WPATH) Standards of Care was published.[9]

The WPATH Standards of Care continues to be updated, with the eighth volume released in September 2022.[6]

When talking about TGD populations and GAC, it is essential to be aware of intersectionality, which was originally coined by Kimberlé Crenshaw to describe the experiences of Black women. Intersectionality is the concept that different facets of identity such as race, gender identity, sexual orientation, disability, economic status, and others can interact, leading to overlapping areas of discrimination.[10] For example, among trans and gender-diverse people of color, the rates of poverty were even higher than those of TGD people in general.[11] In the intersection of gender identity and neurodivergence, transgender autistic people may have their identity called into question or may be denied GAC, regardless of their capacity for making decisions regarding their care.[12] Gender identity and economic class can also intersect; some states ban GAC from being covered by Medicaid, which limits access for low-income and disabled TGD individuals.[13]

Because of these marginalizations that may intersect with gender identity, GAC cannot be addressed in a vacuum of pharmacologic interventions. Pharmacists must do more than be merely knowledgeable about GAC; they must also address the systemic barriers, starting with the individual level and working up toward the practice setting and systemic changes.

Barriers and health disparities

Access to GAC by TGD individuals is limited by reduced health care access, medical discrimination, legislative bans, and risk of interpersonal and systemic violence.

TGD people experience high rates of violence. According to the TransPop survey, 76% of respondents were verbally abused or insulted, and 48% were physically attacked or sexually assaulted.[14] Additionally, 8% were kicked out of their homes, while 10% left, which contributes to 1 in 3 TGD people having experienced housing insecurity in their lifetime.[11] According to the gender minority stress model, which was adapted from Meyer's 2003 minority stress model, external stressors including nonaffirmation of one's identity and internal stressors such as internalized transphobia, expectations of negative experiences, and concealment contribute to poor health outcomes as well as increased depression and thoughts of suicide.[15]

Conversely, the gender minority stress model also posits that connection with the community and pride in one's identity may provide resilience to minority stress.[15] Access to GAC and relief of dysphoria was found to be associated with improved well-being

and lowered thoughts of suicide.[6,16,17] GAC is supported by 29 health care organizations, including the American Medical Association, American Academy of Pediatrics, and American Psychological Association.[18]

TGD people experience fewer opportunities for employment, insurance coverage, and economic mobility. In the 2015 U.S. Transgender Survey, 29% of respondents reported living in poverty and 33% of respondents to a 2020 by the Center for American Progress (CAP) reported an annual household income of under $25,000.[11,19] In 2020, 27% reported being unemployed compared to 15% for cisgender people.[19] Similarly, 15% of respondents in the 2015 U.S. Transgender Survey and 28% in the CAP 2020 survey reported being insured through Medicaid, which may not cover GAC depending on the state.[11,13,19]

Resources

APhA–HRC Transgender Pharmacy Resource Guide: apha.us/InclusiveCare

Medical discrimination on the individual and systemic level also occurs at an alarming rate for transgender individuals. The 2015 U.S. Trans Survey reported 33% of respondents having at least one negative experience with a health care provider related to their gender identity in the past year, while the CAP 2020 survey reported 47% of overall respondents.[11,19] The 2015 U.S. Transgender Survey reported 23% and the CAP 2020 survey reported 22% of respondents did not seek necessary treatment for fear of discrimination.[11,19] The 2020 CAP survey found that 18% of respondents had a doctor refuse to see them outright due to their gender identity.[19] Additionally, 7 states have targeted exemption laws, thereby allowing medical professionals to decline to provide GAC.[20] TGD individuals may also experience "trans broken arm syndrome," in which the individual is either subjected to irrelevant, invasive questions about their gender identity or have their chief (often unrelated) complaint entirely attributed to their identity and medical transition.[21] Even in circumstances in which a provider is supportive, 1 in 4 transgender people had to educate their providers on gender identity and how to provide affirming care.[11]

TGD individuals also experience difficulties in insurance coverage when seeking GAC. The 2015 U.S. Trans Survey reported 25% of respondents faced difficulties getting coverage for GAC; the CAP survey reported 46%.[11,19] With higher rates of unemployment than cisgender people, TGD people may also have less access to employee health insurance programs.[19] Nine states have also written into law bans on Medicaid coverage for GAC for all individuals, while Arkansas and Mississippi's Medicaid policies exclude care for minors only.[13] Arkansas law permits all insurance providers in the state to refuse to cover GAC.[13]

Finally, on the state level are laws banning GAC entirely for TGD youth. Seven states have passed laws banning medical and surgical care, while Arizona bans surgical care.[22] All 7 bills which ban GAC also make an exception for surgeries performed on intersex infants and children.

Best practices for providing GAC

In this article, the elements of medical transition, with emphasis on hormone replacement therapy and supplemental therapies, will be the main focus. While there may be overlaps in experience, each TGD person may have different transition goals.

The 3 main guidelines in order of most recent update for GAC are[6,23,24]

- World Professional Association of Transgender Health's Standards of Care 8 (WPATH SOC8), last updated September 2022
- Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (Endocrine Society), last updated September 2017
- Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, Second Edition (UCSF), last updated June 2016

In addition to medically transitioning, a person may opt to socially transition. Social transition involves changing one's name, pronouns, clothing, hair, or other aspects of their gender presentation. This may also involve coming out to friends, family, and others.[6] Social transition may occur before or after medical transition, and it is no longer required as a prerequisite for medical interventions.[6] For children who are prepubescent, social transition is the only method of transition provided, as medical interventions are not started until puberty.[6]

GAC can affect fertility, and some patients may wish to be able to have children. A patient's fertility goals should be brought up in the course of GAC and discussed with the patient, their care team, and their parents/caregivers if applicable. Additionally, while hormone therapy can affect fertility, testosterone and estrogen therapy are not 100% effective contraceptives. In individuals participating in intercourse in which pregnancy could occur, additional methods should be used.[6]

A concern that is often brought up in GAC is the concept of "detransition," or an individual transitioning back to a gender identity aligning with sex assigned at birth. While a small percentage of individuals may go back to living as their sex assigned at birth, it is often temporary.[11] The most common reason for detransition is a lack of supportive environment; only 5% of those who detransitioned did so because they felt it did not reflect their gender identity.[11] Throughout the process of transitioning, in order to provide optimal outcomes, the SOC8 recommends that a patient's gender care involves a multidisciplinary team and a safe, inclusive space for an individual to explore their gender identity and affirmation goals.[6]

Children and adolescents

The first step of GAC for children and adolescents is social transition, in which a child is able to explore and articulate their gender identity and expression.

Once a child begins to exhibit signs of puberty and continues to exhibit a marked and persistent sense of gender identity different than the sex assigned at birth, they may be eligible for a gonadotropic-releasing hormone (GnRH) agonist, which is also called a "puberty blocker."[6]

GnRH agonists are only started after the patient reaches Tanner Stage 2 of puberty.[6] Tanner staging is an objective classification system to track the development of secondary sex characteristics in children and adolescents.[25] At stage 2, breast bud development begins in people with ovaries, and the growth of testes to over 2.5 cm for those with testes.[25] GnRH agonists have been used for precocious (early) puberty in cisgender children since 1981, and have been studied since 1998 for the use of GAC.[6,26]

GnRH agonists—the most commonly used being leuprolide (Lupron Depot—AbbVie Inc.)—work by providing a constant supply of GnRH to the anterior pituitary, which then releases follicle stimulating hormone (FSH) and luteinizing hormone (LH) to the ovaries and testes, releasing estrogen and testosterone, respectively.[27] This process, also known as the GnRH-pituitary cascade, occurs during puberty in pulses; with a consistent application of GnRH, the pituitary becomes less sensitive and eventually halts FSH and LH production, stopping the release of estrogen or testosterone and preventing puberty effects.[27] GnRH agonists provide a delay in endogenous puberty in order to reduce distress from puberty characteristics until the child, their family, and care team make a decision regarding whether to continue endogenous puberty or affirmed puberty and sex hormone therapy.

1 in 4 transgender people had to educate their providers on gender identity and how to provide affirming care.

GnRH agonists are reversible. If a child decides that they wish to identify with their sex assigned at birth, then the GnRH agonist is discontinued and the child will continue with their endogenous puberty. GnRH decreases the rate of bone mineralization due to the suppression of sex hormone, but this was found to recover upon discontinuation.[6]

If the child, with the support of their care team, decides that they would like to go forward with their affirmed puberty, a taper of either estrogen or testosterone is introduced, with a dosage increase every 6 months until the adult dose is reached, and then continued through adulthood.

If the child began GnRH agonists and hormone therapy early in puberty, a growth spurt may occur. In adolescents for whom GnRH agonists and hormone therapy is initiated later, height will not be affected as endogenous puberty has concluded bone development.[6]

When dispensing this medication, it is important to emphasize staying adherent to the dosing schedule. Due to the mechanism of action, there will be an initial surge of sex hormones prior to the sensitization of the pituitary.[28] Patients with severe dysphoria may experience a temporary increase in dysphoric symptoms prior to relief, and thus they should be made aware of this.

While on a GnRH agonist, patients should be monitored for height, weight, BP, and Tanner stage every 3–6 months; FSH, LH, estradiol, and testosterone levels every 6–12 months; and a bone density scan (DXA) and X-ray bone age scan on the left hand every 1–2 years.[23]

Common gender terms and definitions[3,6,8]

- **Sex, sex assigned at birth:** the designation of male, female, intersex, or another sex assigned at birth by visual inspection of external genitalia. AFAB is often used as shorthand for "assigned female at birth," while AMAB is an abbreviation for "assigned male at birth."
- **Intersex:** an umbrella term for individuals with differences in primary or secondary sexual characteristics different from what is considered typical for their sex assigned at birth.
- **Gender identity:** one's deeply felt, intrinsic sense of their own gender.
- **Gender expression:** the way a person expresses their gender through appearance, dress, and behavior.
- **Cisgender:** an individual whose gender identity matches their sex assigned at birth.
- **Transgender (trans):** a diverse group of people whose identity does not match their sex assigned at birth.
- **Gender nonconforming:** a gender expression that does not conform to prevailing societal standards for their gender. This may overlap with transgender identity, but not always.
- **Transgender man (trans man, transgender male, transmasc):** a person who was assigned female at birth but whose gender identity is masculine and/or a man.
- **Transgender woman (trans woman, transgender female, transfem):** a person who was assigned male at birth but whose gender identity is feminine and/or a woman.
- **Nonbinary:** an umbrella encompassing gender identities outside of strictly "man" and "woman." Some identities that may fall under this are "genderqueer," "bigender," or "agender" (an absence of gender). May also be used as an identity label itself.
- **Transgender and gender-diverse (TGD):** a term used to describe people with gender identities and expressions different than social and cultural expectations attributed to their sex assigned at birth.
- **Pronouns:** how one refers to self and others. May include he/him, she/her, they/them, or neopronouns (neologistic pronouns beyond the common he/him, she/her, and they/them. Examples may include ze/hir and ey/em/eir.)
- **Transition:** the process in which a person changes their gender expression to better match their gender identity.
- **Gender-affirming care:** social, medical, psychological, and/or behavioral care that is provided to transgender and gender-diverse people in order to align with their gender identity.

Table 1. Testosterone therapies

Drug	Form	Dosage	Adverse reactions	Additional counseling
Testosterone cypionate, testosterone enanthate	Injection	50–100 mg S.C. or I.M. weekly, 100–200 mg S.C. or I.M. every 2 weeks	Injection site reaction, headache	Requires 18 g needle to draw up, 22–25 g needle to inject Vial good for 28 days after opening
Testosterone undecanoate	Injection	1,000 mg I.M. every 12 weeks, 750 mg I.M. every 10 weeks	POME (REMS program), anaphylaxis acne, injection site pain, insomnia, mood swings	REMS program required for dispensing Must be administered by a hospital professional, then observed for 30 minutes
Testosterone gel 1%, 1.6%, 1.62%	Topical gel	50–100 mg daily	Skin irritation at application site	Secondary exposure risk—see black box warning Must allow it to dry before putting on clothing and wait 2 hours before showering

Abbreviation used: POME, pulmonary oil microembolism.

Source: Adapted from References 24, 29–35.

Adult GAC

Testosterone

Testosterone is the primary drug for masculinizing hormone therapy. It is an endogenous sex hormone available as an injectable suspension and topical gel. Dosage forms, dosing, drug specific adverse effects, and counseling considerations are shown on Table 1.

Testosterone can increase the risk of erythrocytosis and clotting, so hemoglobin and hematocrit is monitored during the course of therapy.[6] While it may cause cessation of periods, it is not a 100% effective contraceptive and is contraindicated in pregnancy. If a person on testosterone therapy is engaging in activity where they could become pregnant, additional methods of contraception, such as barrier methods, intrauterine device, or progesterone-only birth control are recommended.[6,24]

At the initiation of testosterone therapy, testosterone levels as well as hemoglobin and hematocrit should be evaluated every 3 months for the first year, then annually afterward.[6] Testosterone can also increase the chance of acne, edema, and sleep apnea. Although testosterone can potentially change weight, BP, cholesterol, and blood glucose, these can be monitored with the primary care provider as part of regular care.[6] Estrogen levels do not need to be monitored as estrogen levels fluctuate during the menstrual cycle, and the cessation of menses is thought to be a sign of sufficient estrogen suppression.[6,24,36] In the event of testosterone failing to suppress menses, a progesterone-only contraceptive may be suggested. Testosterone therapy may also cause vaginal dryness or atrophy; in this case, a water-based lubricant or topical estrogen cream may be used.[6]

Some individuals may use a binder, which is a compression top used to slim the chest profile and create a more masculine appearance. Using improper binding techniques, such as with elastic bandages or duct tape, can cause lung or rib injuries.[37] When sizing a binder, it should be snug but not painful, and the person should be able to take it on and off unassisted.[37] Advise the patient to only wear a binder for as long as needed, and to take frequent breaks.[37]

A person may also opt to use a packer, a phallic prosthesis placed in the underwear to give the contour of a penis and scrotum. Like a binder, the packer should only be worn as needed and be taken out if any irritation occurs. Packers should also be washed frequently with nonirritating soap and water, and then dusted with cornstarch after drying.[38]

Considerations for testosterone therapies[24,29–35]

- Class effects: skin oiliness, facial/body hair growth, scalp hair loss, increased muscle mass, fat redistribution, deepened voice, clitoral enlargement, cessation of menses*
- Class adverse effects: acne, androgenic alopecia** (i.e., hair loss), hypertension, hyperlipidemia, sleep apnea, weight gain, increased CV risk, vaginal atrophy
- Contraindications/warnings: pregnancy, unstable coronary artery disease, untreated polycythemia with hematocrit (Hct) >55%, active hormone-sensitive cancer, erythrocytosis, history of hormone-sensitive cancer

*Cessation of menses may not occur in all people receiving testosterone therapy.

**Hair loss incidence and extent depends on family history, genetics, dose, and duration of therapy.

Estrogen+ therapy

Estradiol is the form of estrogen that is used as the primary drug for feminizing therapy. It is also an endogenous sex hormone available as an oral pill, transdermal patch, and injectable suspension. Estrogen is typically used

Table 2. Estrogen+ therapies

Drug	Form	Dosage	Adverse reactions	Additional counseling
Estradiol	Oral tablet	2–6 mg daily	VTE, headache, breast tenderness, nausea, hair loss, fluid retention	Highest VTE risk due to first-pass metabolism
	Transdermal patch	0.025–0.2 mg daily; patch changed weekly	—	Recommended for those with risk/history of VTE
Estradiol valerate	Injection suspension	2–10 mg I.M. weekly or 5–30 mg I.M. every 2 weeks	Injection site reaction	Thick suspension, supply 18 g needles to draw, 22 g to inject
				Vial good for 28 days
Spironolactone	Oral tablet	100–300 mg daily	Urination, dizziness, reduced blood pressure, increased potassium, lowered sodium	Counsel on signs of hyperkalemia, low BP, low sodium
Leuprolide	Injection	3.75–7.5 mg S.C./I.M. monthly, 11.25/22.5 mg S.C./I.M. every 3 or 6 months	Injection site reaction, hot flashes	Adult dose of leuprolide is different from pediatric dose

Abbreviation used: VTE, venous thromboembolism.

Source: Adapted from References 23–24, 29.

alongside an androgen-blocking drug such as spironolactone or leuprolide. See Table 2 above.

Estradiol carries a risk of venous thromboembolism (VTE), especially in older patients and those with a previous VTE.[6] Transdermal estradiol is associated with a lower risk of VTE than oral estradiol, as it bypasses first-pass metabolism. Conjugated estrogens and ethinyl estradiol are not recommended due to increased risk of VTE and difficulty in measuring accurate serum estradiol levels.[6,24,39] Breast cancer risk should be evaluated on an individual patient basis, depending on family history, dose, and duration of estrogen therapy.[6]

The primary drug used for androgen blocking in GAC is spironolactone. It is used at higher doses than that for BP reduction in order to utilize the antiandrogen effects.

Due to the higher doses used, individuals using spironolactone for GAC should be counseled on potential dizziness.

Spironolactone is also a potassium-sparing diuretic, so patients should be counseled on the signs of high potassium (e.g., heart palpitations, muscle fatigue/weakness, tiredness) as well as low sodium (e.g., nausea/vomiting, headache, fatigue, muscle weakness, and spasm).[40] Kidney function should also be monitored.[39]

Leuprolide can also be used as an antiandrogen in individuals receiving concurrent estrogen therapy.

Patients on leuprolide should be monitored for bone density—especially those with a family history of osteoporosis—as well as mood changes.[27] Patients should be monitored for physical changes, estradiol, and testosterone levels every 3 months for the first year and 1–2 times yearly thereafter.[6]

Considerations for estrogen+ therapies

- Class effects: softened skin/decreased oiliness, breast growth, redistribution of fat, decreased muscle mass, decreased libido, decreased spontaneous erections, decreased sperm count and testicular volume, decreased terminal hair growth, increased scalp hair, hair loss*
- Adverse effects: increased clotting risk, weight gain, gallstones, hypertriglyceridemia, fluid retention
- Contraindications/warnings: active deep vein thrombosis, pulmonary embolism, active estrogen-sensitive cancer, previous venous thromboembolism, history of estrogen-sensitive cancer

*Scalp hair and hair loss are dependent on family history and genetics.

Shapewear such as breast forms may also be used to create a more pronounced chest. Patients may also move the testes into the inguinal canal and the penis and scrotum toward the back in a process known as "tucking;" these are then held in place with underwear.[41] Tucking should also only be done as long as necessary, and medical adhesive should be avoided to reduce skin irritation. If pain occurs, tucking should be stopped.[41]

Supplemental therapy and surgical procedures

Patients on testosterone therapy, and some on estrogen therapy prior to androgen blockade, may experience androgenic alopecia, which is commonly known as "male-pattern baldness." For all individuals, OTC minoxidil as well as prescription finasteride can be used to address this.[39]

As all hormone therapy can lead to increased risk of clots as well as increased risk of smoking due to minority stress, all patients on GAC should be offered resources for smoking cessation.

Some TGD patients may also benefit from voice therapy in order to reduce incongruence and dysphoria.

A TGD patient may decide to pursue surgical transition. While it is not desired for all individuals, some state laws may require gender-affirming surgeries in order to have the gender marker on a birth certificate or driver's license changed, regardless of the individual's goals.

Surgical procedures are generally conducted for individuals 18 years and older, though for younger individuals with severe dysphoria a decision might be made after discussion with the patient, parents, and care team.[6]

Masculinizing surgical procedures may include[24]

- Mastectomy, a.k.a. "top surgery": removal of breast tissue to create a flatter chest profile
- Metoidioplasty: creation of a penis using local genital tissue
- Phalloplasty: creation of a penis using clitoral tissue and graft tissue from forearm or thigh
- Oophorectomy, vaginectomy, hysterectomy: removal of ovaries, vagina, and uterus, respectively

Feminizing surgical procedures may include[24]

- "Bottom surgery": removal of testes (orchiectomy), penis (penectomy), and construction of a neovagina (vaginoplasty) using penile and scrotal tissue
- Hair removal via electrolysis
- Breast augmentation
- Facial feminization surgery: procedure to soften the face profile

WPATH SOC8 recommends at least 6–12 months of hormone therapy prior to surgery for optimal surgical outcomes, for example, to ensure sufficient clitoral growth prior to metoidioplasty.[6]

Pharmacists can contribute to the GAC team after the procedure by managing medications to ensure proper relief of pain, promoting healing, and preventing postsurgical complications.

Inclusive communication and practice

Pharmacists can facilitate inclusive communication and practice environments for GAC on 3 levels: individual patient interaction, pharmacy practice environment, and pharmacy systems at large.

Due to the high incidence of medical discrimination that TGD people face, an effort must be made by pharmacists to do the initial outreach. Providing an inclusive practice must be not a one-time change, but an active, ongoing dialogue with the communities who seek GAC in order to address their evolving needs. When interacting with patients, use the initial point of contact as a way to establish you are an inclusive space.[29]

Practice must also utilize trauma-informed care, which is care that acknowledges patients' life experience and impact on health, as well as provide a safe and empowering environment.[42]

For example, introduce yourself with your name and pronouns. If in the course of operations you accidentally misgender a patient or colleague, offer a brief apology and correction, and then move forward.

Changes can also be made to the pharmacy practice environment to be more inclusive to TGD patients. For example, provide visible signage around your practice setting that patients can be open about their gender identity and use gender-neutral language in labeling, such as "menstrual/reproductive care" instead of "women's health" for OTC products such as pads, tampons, and pregnancy care.

When interacting with the pharmacy team, patients should have the option to be called forward by their affirmed name. In the event that a person must present a legal document with an incongruent name, such as in

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the case of picking up testosterone, respect and care should be given. Pharmacy professionals should also contribute their skills and resources to local communities to mitigate the barriers to access of care. This allows not only increased access to GAC through programs such as free clinics; it also acknowledges the history of medical discrimination and serves as a gesture of repairing relationships and reparations.[29]

A pharmacy that is providing inclusive practice to people seeking GAC also requires inclusive systems. Pharmacies' electronic health records should contain text fields for affirmed name and pronouns in the event that it is different from their legal name.[29]

Intake forms should contain separate fields for sex assigned at birth versus gender identity as well as text fields which allow individuals to further articulate their gender identity.[44] It is important to consider why information is being requested; if it is not required for the patient's care, there is not a need to ask.

There is no single universal form, so TGD people must be consulted to develop a form that addresses the practice and community needs. Pharmacy systems can also develop pipelines to uplift TGD pharmacy professionals, have TGD people present in all levels of the practice, and implement steps to transition resources to TGD experts. TGD people should be actively involved in the development of policies and procedures.[43]

GAC cannot be discussed strictly in an academic vacuum, as its access and patients requiring it are subject to discrimination, violence, and legislated restriction to care. Pharmacists must not only educate themselves on how to provide care, but the systemic barriers and health disparities that limit access to it.

Providing care must also encompass recognizing the history of medical discrimination, and reforming systems that continue to bar access to care. As providers, pharmacists can utilize their positions of authority as health care workers to uplift the voices of and advocate for TGD patients.

Gender-affirming language recommendations[29]

- Introduce yourself with your name and pronouns
  - "Hello, my name is Laura, and I use she/her and ze/hir pronouns."
  - "Hello, I'm Stephan, any pronouns, and I will be providing your vaccination today."
- Do not assume pronouns/prefixes based on appearance.
- Ask "how may I refer to you?," as it provides an open-ended, opt-in question for the patient to direct how they are referred.
- Do not comment that a person "doesn't look transgender or nonbinary." There is no one way to look or express one's gender.
- Pronouns should be offered as an option, not a requirement. Not everyone will feel comfortable sharing pronouns.
- If a person tells you their pronouns, use them. Continuing to use another pronoun, or even neutral pronoun afterward is misgendering, which is invalidating and may cause dysphoria.
- If you misname or misgender a patient
  - Quickly offer an apology and correction, and then continue.
  - Do not emphasize how hard it is to use correct/name pronouns.
  - Do not request a TGD person to allow "an exception."
- Do not ask questions not related to care or unnecessary/invasive questions such as
  - "What is your 'real' name?"
  - "Are you gay/straight?"
  - "What surgeries have you had?"
  - "What genitals do you have?"

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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. Select the correct statement regarding terminology for TGD patient populations.

a. Transgender identity is defined by the presence of incongruence/dysphoria between sex assigned at birth and gender identity.
b. "Gender nonconforming" relates to gender expression and may or may not overlap with transgender identity.
c. Culturally specific gender identities fall under the umbrella of transgender, as they are different from "man" and "woman."
d. Intersectionality refers to the dissonance an individual may feel as a member of 2 marginalized identities.

2. Select the correct statement regarding health disparities that those seeking GAC may face.

a. Rates of health care discrimination are even between TGD people of color and TGD people as a whole.
b. Coverage of GAC by Medicaid is standardized across all 50 states.
c. Transgender patients experience higher levels of unemployment than cisgender individuals.
d. Access to GAC did not decrease rates of depression, anxiety, and suicidality.

3. Which of the following is an example of health care discrimination a patient may face?

a. A gender care clinic allows for a chaperone in procedures that cause dysphoria.
b. A patient is unable to afford their hormone replacement therapy after being fired.
c. A patient is asked questions about their genitals when being examined for lower back pain.
d. A pediatric patient in Arkansas has to travel to Illinois for GAC.

4. For a prepubertal (Tanner stage 1) patient, what is the recommendation for GAC?

a. Begin a GnRH agonist.
b. Begin an estrogen or testosterone taper.
c. Defer care until Tanner stage 2.
d. Begin social transition.

5. Which of the following statements are correct regarding testosterone hormone therapy?

a. Testosterone cypionate requires a REMS program for pulmonary oil microembolism and anaphylaxis.
b. Erythrocytosis is an absolute contraindication for testosterone therapy.
c. Testosterone cypionate multidose vials are good for 14 days after opening.
d. Testosterone topical gel carries a black box warning of secondary exposure.

6. Which of the following statements are correct regarding testosterone hormone replacement therapy and pregnancy?

a. Patients on testosterone therapy who are at risk of becoming pregnant should receive a combined oral contraceptive therapy to prevent pregnancy.
b. Patients on testosterone therapy who are at risk of becoming pregnant should use a progesterone-only contraceptive, barrier method or IUD to prevent pregnancy.
c. Patients on testosterone therapy who are at risk of becoming pregnant should add a GnRH agonist.
d. Patients on testosterone therapy for at least 1 year are not capable of becoming pregnant unless therapy is discontinued.

7. Select the correct statement regarding estrogen and related care.

a. Estradiol and conjugated estrogens have similar clot risk profiles in GAC.
b. Spironolactone decreases serum potassium levels, so patients should be counseled on low potassium.
c. Estradiol valerate is administered either subcutaneously or intramuscularly.
d. Estradiol patches are the preferred dosage form for those with higher risks of clotting.

8. Which dosage form of estradiol has the highest risk of clotting and causing VTE?

a. Injection suspension
b. Transdermal patch
c. Oral tablet
d. Topical gel

9. Which of the following statements are correct regarding inclusive communication?

a. Pharmacy professionals should have an ongoing dialogue with the TGD communities they serve.
b. Pronouns must be recorded from a patient in order to provide inclusive care.
c. Neutral pronouns should continue to be used after a patient states their affirmed pronouns.
d. During patient intake, ask a patient for their "real" name in case there is an insurance discrepancy.

10. When developing pharmacy practice, which of these ways would provide an inclusive, affirming space for those seeking GAC?

a. A health fair event on breast cancer awareness titled Women's Week.
b. A text field in an electronic health record which allows patients to write in their pronouns.
c. A policy requiring patients in the waiting room be addressed by their legal name.
d. A pharmacy intake form that has 2 options for patients' gender.

Across

1 Combining drugs to make a medication for a specific patient
7 Agency that recommends vaccination schedules
9 Demolished
10 Product used to remove dead skin cells
11 Commonly used NSAID
12 Anatomical horn, ancient Roman brass instrument
13 Vitamin A_1
15 Method to administer a vaccination
18 You may do this to an 8 Down
20 Hair that protects against dust and debris in the eye
23 Bone prefix
24 Anticonvulsant medication
26 Medication that inhibits yeast growth...right away
27 Pharmacies hopefully do not run _____ of the state board of pharmacy's rules
28 Organization that monitors pollution (abbr.)
29 Anxiety, uneasy state

Down

1 Insects may be _____ of disease
2 Pesky pest that may spread malaria, dengue fever, or zika
3 Kingdom, phylum, class, _____, family, genus, species
4 Necessary, as in "do the _____"
5 Young patients
6 With glucose, simple sugar component of lactose
7 Energy points that may become "blocked"
8 Helps keep scurvy at bay
14 Theories derived from the scientist who discovered gravity
16 Medication that can reverse an opioid overdose
17 Often painful rash treated with an antiviral
19 Whistle blower
20 Energy prefix or a Marvel supervillian
21 Morning caffeine source
22 Muscular immobility, especially during REM sleep
25 Age measurement

Solution is available online at pharmacytoday.org.