Pharmacy Today
An official publication of the **American Pharmacists Association**
JULY 2023

"OH, THE PLACES YOU'LL GO..." NONTRADITIONAL PHARMACIST ROLES

OTC HEARING AIDS
Collaborating with audiologists

TRANSGENDER CARE
Addressing health care barriers

VALUE-BASED ARRANGEMENTS
Opportunities and advantages

CONTINUING PHARMACY EDUCATION
CPE What's on tap: 2023 Beers Update

APhA

BulletinToday

To protect infants, FDA advisers recommend RSV vaccine during pregnancy

Members of an FDA advisory panel voted in support of Pfizer's respiratory syncytial virus (RSV) vaccine (Abrysvo) for the prevention of RSV in infants via administration to pregnant women.

The panel's 14 advisers unanimously deemed the vaccine effective, while 10 out of 14 said the vaccine was safe. A study by Pfizer indicated that premature delivery was reported in 5.6% of pregnancies in the treatment group compared with 4.7% in the placebo group.

FDA officials said the difference was not statistically significant, but Pfizer said if the drug gets approved, it would track health records for cases of preterm birth and other potential health issues. However, advisers expressed doubt about a plan to use health care billing records data to monitor safety.

CDC estimates that up to 80,000 children younger than age 5 years are hospitalized with RSV each year, and up to 300 die from RSV. The vaccine was tested in approximately 7,300 pregnant people after the 24th week of pregnancy, with about one-half receiving the vaccine and one-half receiving a placebo.

A recent study in *NEJM* found that during the first 90 days after birth, six infants in the vaccination group contracted a severe case of RSV compared with 33 in the placebo group, indicating an efficacy of almost 82%. For 6 months after birth, the vaccine was found to be 69% effective. During that time, there were 19 babies who became seriously ill in the treatment group compared with 62 in the placebo group. ■

New report finds growth in illegal online pharmacies

A new report from IQVIA Institute for Human Data Science estimates that of 7,310 prescription drugs legally dispensed to U.S. patients between January 2017 and December 2022, roughly 70% (5,085) were being actively marketed and sold by illegal online pharmacies.

IQVIA researchers also estimated that 416 million prescriptions were provided to patients through illegal online pharmacies between January 2017 and December 2022, representing 1.6% of overall prescriptions dispensed from both illegal online and legal pharmacies nationwide.

However, drugs sold through illegal online pharmacies were estimated to generate 10 times higher adverse event rates compared with drugs sold through legal pharmacies, resulting in an estimated 12.6% of total extra adverse events in the United States in connection with drugs purchased through illegal online pharmacies.

These adverse events represent an estimated additional $67 billion cost for the U.S. health care system on top of the health care consequences for patients, according to the report.

From 2019 to 2022, the number of prescriptions dispensed annually through illegal online pharmacies increased from 64 million to 85 million at a compounded annual growth rate of 10%.

Categories of legal therapies with the highest volume share being sold via illegal online pharmacies included drugs used as part of cancer treatment, including hormone therapies, at 10.4% of total volume; sex hormones at 5.5%; dermatologics at 3.4%; other cardiovascular drugs at 3.7%; hormonal contraception at 2.7%; and ADHD drugs at 2.7%.

Motivations for purchasing prescription drugs through illegal online pharmacies include perceived lower prices, off-label use, and stigma. ■

Most Americans likely to seek non-emergency health care at pharmacies

A new survey from Wolters Kluwer Health reflects increasing trust in providers in nontraditional primary care settings.

The survey indicated that roughly 58% of Americans are likely to visit a local pharmacy as a first step when faced with a non-emergency medical issue, and 81% said they trust a pharmacist, nurse, or nurse practitioner to diagnose minor illnesses and prescribe medications.

Additionally, 56% and 54% of Gen Zers and Millennials, respectively, said they visited a local pharmacy to receive care in the past year, compared with 40% of Gen Xers and 35% of Baby Boomers.

About 79% of Americans said they trust their local pharmacy to provide care more than staff at health clinics inside department stores like Target or Walmart. The survey also indicated that 54% of Americans would go to a traditional physician's office only for vaccinations for children; however, for influenza and other vaccinations for adults, 62% said they would go to a local pharmacy.

Additionally, 37% of U.S. consumers said they decided not to fill a prescription because of cost, and 76% supported converting many widely used, comparatively safe prescription drugs to OTC status. Doing so would help lower costs without compromising safety, according to 74% of Americans.

The survey also revealed that 86% of Americans would receive generic medications if it meant saving money; 92% felt their physician and their pharmacist should inform them of these alternatives; and 36% said they had talked with their pharmacist in the past few months about affording their medications or to see if other options were available. ■

FDA announces updates to warning for all prescription stimulants

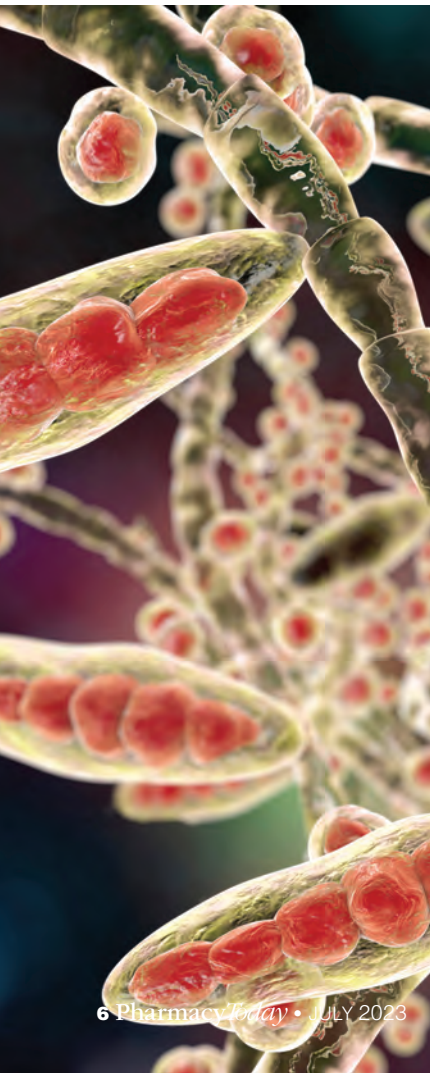
To prevent misuse, abuse, and addiction of prescription stimulants, FDA is now requiring their boxed warning—the most prominent warning—to be updated. In addition, the agency is adding more to the prescribing information for all prescription stimulants.

FDA wants to make all prescribing information consistent across this entire class of medications.

"We are adding information that patients should never share their prescription stimulants with anyone, and the Boxed Warning information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class," FDA said. "The Boxed Warning also will advise health care professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction."

FDA said that information on these risks is now mandatory in several sections of the prescribing information, including the Warnings and Precautions, Drug Abuse and Dependence, Overdosage, and Patient Counseling sections.

FDA will also require updates to existing patient medication guides to help educate patients and caregivers about the risks of these medications. ■



CDC identifies first-ever drug-resistant ringworm in U.S.

CDC reported that two cases of drug-resistant ringworm infections involving the fungus Trichophyton indotineae were identified in New York City, the first such cases in the country.

According to CDC, the use of conventional treatments has not been successful in treating the infections of the two patients. One of the patients, a woman aged 28 years, developed a rash in the summer of 2021 across a large portion of her upper body, while the other patient, a woman 47 years old, developed a rash across a large portion of her lower body in the summer of 2022.

The older woman was infected with the rash while in Bangladesh, while the other woman had not traveled abroad recently. This suggests that it could be a "potential local U.S. transmission," according to CDC. Neither woman had underlying health conditions. A dermatologist in New York alerted public health officials of the cases in February.

The infection is typically associated with widespread and inflamed plaques on the body. Earlier cases of drug-resistant ringworm have been reported in Europe, Asia, and Canada.

CDC advised health care providers to expect to give up to 12 weeks of treatment if this species of fungus is detected. ■

Study finds OUD med underprescribed, especially by race

Findings from a study published May 10, 2023, in *NEJM* suggest that a key treatment for opioid use disorder (OUD) is underprescribed among patients in the United States, in particular among Black patients.

Roughly more than 20% of patients diagnosed with OUD filled prescriptions for buprenorphine—the gold standard for OUD treatment—from 2016 to 2019, according to the study.

Researchers also found that within 6 months following a high-risk event such as an overdose, white patients filled buprenorphine prescriptions up to 80% more frequently compared with Black patients and up to 25% more frequently compared with Hispanic patients.

In the study, researchers from public health programs at Harvard and Dartmouth evaluated claims filed through Medicare's disability program for prescriptions of buprenorphine and other addiction treatment drugs. In the 6 months after an episode in which a health care provider had diagnosed the patient with OUD, there were claims for 23,370 patients nationwide. The data show that compared with 18.7% of Latino patients and 23.3% of white patients, just 12.7% of Black patients received any buprenorphine during that 6-month time frame.

Lead study author Michael L. Barnett, MD, who teaches health policy and management at Harvard T.H. Chan School of Public Health, pointed out that access to medical care was not the primary issue in the differences because regardless of race, patients were in contact with physicians approximately once a month. ■

Pharmacy Today regrets an error in the June 2023 issue article, "Xylazine worsens overdose rates, threatens harm reduction efforts." The word "adrenergic" was misspelled as "andrenergic." We apologize for any inconvenience caused. ■

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Pharmacists think outside the box when it comes to their careers

Entrepreneurship is on the rise in our profession. In the past, entrepreneurial ventures primarily involved independent pharmacy ownership. But as pharmacists' scope of practice has widened and workforce demands are causing decreased satisfaction, innovative (ad)ventures in pharmacy are on the rise! A recent study showed that this mindset is starting earlier than ever, with pharmacy schools equipping pharmacists for these changes by including risk-taking, strategic planning, and divergent thinking into pharmacy school curricula.

The cover story of this issue of *Pharmacy Today* highlights some of these pharmacist entrepreneurs. From Crystal Yu, PharmD, who works at L'Oréal, USA, educating pharmacists about skincare to Megan Freeland, PharmD, a medical writer who founded a business focused on health content for digital companies, opportunities abound. Tara Schneider, PharmD and owner of the Point of Care Testing Institute works with clinical pharmacists to help them set up new services. Schneider speaks to the personal satisfaction she finds in her role when she states, "It's so rewarding to help likeminded entrepreneurs grow new service lines because you know they will have a big impact on their community."

In this issue of *Today*, you'll also see recommendations for treating insect stings and bites, get the skinny on glucomannon and weight loss, and learn about new FDA-required updates to opioid prescribing information and boxed warnings. Find new streamlined COVID-19 vaccine recommendations from CDC, learn about transcending barriers to transgender care, and get an update on 2023 Beers Criteria changes in this month's CPE article.

Keep in mind entrepreneurship in pharmacy is not limited to new business ownership or establishing innovative pharmacy services. An entrepreneurial mindset can be applied in many ways. Career development: Is it time to take an online course or earn a specialized credential to expand into new roles? Creative problem solving: Could divergent thinking help you arrive at an innovative solution to an existing challenge or problem? A creative approach to career development, problem solving, and patient care are essential skills for today's pharmacist. Flex your entrepreneurial thinking muscles today. I think you'll be surprised where they can take you!

Have a great *Today!* ■

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

APhA

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VICE PRESIDENT, PUBLISHING
MARY WARNER, CAE

EDITORIAL OFFICES
PHARMACY TODAY
2215 Constitution Ave. NW
Washington, DC 20037-2985
PT@aphanet.org

EDITOR IN CHIEF
KRISTIN WIISANEN, PharmD, FAPhA, FCCP

PRODUCTION DIRECTOR
MICKIE CATHERS

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MICHELLE POWELL
ROGER SELVAGE

GRAPHIC DESIGNER
KATE ERDMANN

ADVERTISING SALES OFFICE
DISPLAY ADS
SCOTT DENICOLA
SDeNicola@amcmediagroup.com
973-214-4374

CLASSIFIED ADS
LAUREN MORGAN
lmorgan@amcmediagroup.com
267-980-6087

Passing the baton at APhA

I am honored and humbled to have served as APhA's interim executive vice president and CEO for the past 13 months during the search for a permanent CEO. It was an amazing experience leading APhA, meeting members and the broader pharmacy community, and moving our profession forward.

On July 5, 2023, Michael Hogue takes over this important role. I've known Michael for years and am excited for the passion he brings for the profession and his innovative ideas for APhA, pharmacy, and patients. Before handing off my baton, I spoke with Michael to get his perspective.

Ilisa: Our members and the broader pharmacy community have shared with me a sense of being on the cusp of providing more patient care services, but also struggling to find the time because payment incentives are not appropriately aligned. Pharmacy teams are also extremely proud of the profession's heroic efforts providing care during COVID-19—providing immunizations, testing, and treatments.

You are joining APhA with a wide range of experiences and you've seen the profession from different angles. What's your view?

Michael: This is an inflection point in our profession. On the one hand, there is unprecedented opportunity for pharmacists across the health system. Pharmacists are rapidly joining teams in outpatient clinics, specialty pharmacy, home care, and even telehealth. On the other hand, we are faced with untenable payment systems and staffing support, jeopardizing access to care in local communities. We must partner with consumers and other health care providers to improve health equity and access to care. APhA must continue to lead the profession in preparing pharmacists for new opportunities while simultaneously addressing system-based issues that threaten patient access to their pharmacists' care services.

Ilisa: And where do you see the future state of the pharmacy profession?

Michael: The vision of pharmacists as members of the health care team responsible for ensuring appropriate medication therapy outcomes is just now beginning to come into focus.

Pharmacists in the future will be leveraging artificial intelligence, machine learning, and data analytics to predict needed health interventions at both the population and individual patient levels. Pharmacists will prepare customized immunotherapies using patient-specific genetic markers to optimize treatment and provide cures for conditions previously thought to be uncurable.

Automation, expansion of pharmacy technician training and authorities, and modernization of regulations will allow pharmacists to focus on why we entered the profession: caring for patients.

Ilisa: Ensuring pharmacy team well-being is a top priority for APhA—driving the systemic change that's needed to ensure safe workplaces and providing tools and services for pharmacy personnel to address their own well-being. Leading by example, our own well-being in a demanding job is important to maintain. As a triathlete, I run, bike, and swim to find my center calm. How do you find your center calm as you step into your new role?

Michael: Every morning I spend about an hour reflecting on my life's blessings, centering my spiritual life, and contemplating how I can best impact the world for good in the coming day. I focus more fully on my diet and exercise. I also make time to be present in the moment with my daughters and my wife. I've learned through my last five years at Loma Linda University that a whole person approach to life helps me keep my well-being in the right place.

Ilisa: Last question, which drug class would you say best describes you?

Michael: Vaccines. An ounce of prevention is worth a pound of cure, right? I'm a futurist and strategic thinker, believing that planning ahead is the best way to prevent bad things from happening and maximize the potential for positive results! ■

Ilisa BG Bernstein, PharmD, JD, FAPhA, interim executive vice president and CEO; and Michael D. Hogue, PharmD, FAPhA, FNAP, FFIP, new executive vice president and CEO of APhA

NEW DRUGS

FEZOLINETANT
(Veozah—Astellas Pharma)

Drug class: Veozah is a neurokinin 3 (NK3) receptor antagonist.

Indication: Veozah is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Recommended dosage and administration: Baseline bloodwork should be performed to evaluate for hepatic function and injury before beginning treatment with Veozah. While using Veozah, follow-up bloodwork should be performed at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms suggest liver injury. The recommended daily dosage is 45 mg (1 tablet) once daily with or without food.

Common adverse effects: The most common adverse reactions with Veozah are abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.

Warnings and precautions: Veozah is contraindicated in known cirrhosis, severe renal impairment or end-stage renal disease, and concomitant use with CYP1A2 inhibitors. Do not start therapy with Veozah if serum transaminase concentration is equal to or exceeds two times the upper limit of normal. Elevations in serum transaminase concentrations greater than three times the upper limit of normal occurred in the clinical trials.

FLOTULFOLASTAT F 18
(Posluma—Blue Earth Diagnostics)

Drug class: Posluma is a radioactive diagnostic agent.

Indication: Posluma is indicated for positron emission tomography (PET) of prostate-specific membrane antigen positive lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected recurrence based on elevated serum prostate-specific antigen level.

Recommended dosage and administration: The recommended amount of radioactivity of Posluma is 296 MBq (8 mCi) administered as an intravenous bolus injection. Initiate imaging approximately 60 minutes after administration. Scanning should start from mid-thigh and proceed to the base of skull.

Common adverse effects: The most common adverse reactions are diarrhea, BP increase, and injection site pain.

Warnings and precautions: Image interpretation errors can occur with Posluma imaging. Interpretation of Posluma PET may differ depending on imaging readers in patients with suspected recurrence of prostate cancer. Consider multidisciplinary consultation and histopathological confirmation. Posluma contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

SOTAGLIFLOZIN
(Inpefa—Lexicon Pharmaceuticals)

Drug class: Inpefa is a sodium glucose cotransporter 2 (SGLT-2) inhibitor.

Indication: Inpefa is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent care visits in adults with heart failure or type 2 diabetes, chronic kidney disease, and other cardiovascular risk factors.

Recommended dosage and administration: Correct volume status before starting Inpefa at 200 mg daily and titrate to 400 mg as tolerated. In patients with decompensated heart failure, begin dosing when patients are hemodynamically stable. Withhold Inpefa for at least 3 days, if possible, prior to major surgery or procedures associated with prolonged fasting.

Common adverse effects: The most common adverse reactions are UTI, volume depletion, diarrhea, and hypoglycemia.

Warnings and precautions: Inpefa is contraindicated in patients with a history of serious hypersensitivity reaction to Inpefa. Monitor digoxin levels if used concomitantly. Sotagliflozin exposure is reduced if taken concomitantly with uridine 5′-diphospho-glucuronosyltransferase inducers. Monitor serum lithium concentrations if used concomitantly. Advise patients of reproductive potential of the potential risk to a fetus especially during the second and third trimesters. Inpefa is not recommended while breastfeeding. Higher incidence of adverse reactions related to volume depletion have occurred in geriatrics and renal impairment. Consider ketone monitoring in patients with type 1 diabetes and consider ketone monitoring in others at risk for ketoacidosis, as indicated. Assess for ketoacidosis regardless of presenting blood glucose levels and discontinue Inpefa if ketoacidosis is suspected. Monitor patients for resolution of ketoacidosis before restarting. Before initiating therapy with Inpefa, correct volume status. Monitor for signs and symptoms of hypotension during therapy. Monitor for signs and symptoms of urosepsis and pyelonephritis during therapy and treat promptly. A lower dose of insulin or insulin secretagogue may be required if used concomitantly with Inpefa. Monitor for pain, tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise as necrotizing fasciitis of the perineum may occur. Discontinue Inpefa and treat urgently. Monitor and treat genital mycotic infections as appropriate.

SULBACTAM AND DURLOBACTAM
(Xacduro—Entasis Therapeutics)

Drug class: Xacduro is a copackaged

product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, which is a beta lactamase inhibitor.

Indication: Xacduro is indicated in patients 18 years and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex. Xacduro is not indicated for the treatment of HABP/VABP caused by other pathogens. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xacduro and other antibacterial drugs, Xacduro should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Recommended dosage and administration: Admister Xacduro (1 g of sulbactam, 1 g of durlobactam) every 6 hours by intravenous infusion over 3 hours in patients with creatine clearance of 45–129 mL/min. Dosing regimen adjustments are recommended for creatine clearance <45 mL/min or ≥130 mL/min. Administer all doses of Xacduro by intravenous infusion over 3 hours.

Common adverse effects: The most common adverse reactions with Xacduro are liver test abnormalities, diarrhea, anemia, and hypokalemia.

Warnings and precautions: Xacduro is contraindicated in patients with a known history of severe hypersensitivity to the components of Xacduro or other beta-lactam antibacterial drugs. Serious and occasionally fatal hypersensitivity reactions have been reported with beta-lactam antibacterial drugs. Hypersensitivity was observed in patients treated with Xacduro. If an allergic reaction occurs, discontinue therapy.

Clostridioides difficile–associated diarrhea has been reported with nearly all systemic antibacterial agents, including Xacduro. Evaluate if diarrhea occurs. Concomitant administration with OAT1 inhibitors may increase plasma concentrations of Xacduro. Concomitant administration is not recommended.

NEW INDICATIONS

BREXIPIPRAZOLE
(Rexulti—Otsuka Pharmaceutical)

Drug class: Rexulti is an atypical antipsychotic.

Indication: Rexulti is indicated for use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults, treatment of schizophrenia in adults and pediatric patients ages 13 years and older, and treatment of agitation associated with dementia due to Alzheimer disease. Though indicated for daily treatment, Rexulti is not indicated as an as-needed treatment for agitation associated with dementia due to Alzheimer disease.

Recommended dosage and administration: Adminster Rexulti once daily with or without food. For treatment of major depressive disorder in adults, the starting dosage is 0.5 mg/day or 1 mg/day, with a recommended target dosage of 2 mg/day and maximum dosage of 3 mg/day. For treatment of schizophrenia in adults, the starting dosage is 1 mg/day with a recommended target dosage of 2 mg/day to 4 mg/day and a maximum dosage of 4 mg/day. For treatment of schizophrenia in pediatric patients, the starting dosage is 0.5 mg/day with a recommended target dosage of 2 mg/day to 4 mg/day and a maximum dosage of 4 mg/day. For treatment of agitation associated with dementia due to Alzheimer disease, the starting dosage is 0.5 mg/day with a recommended target dosage of 2 mg/day and a maximum dosage of 3 mg/day. In moderate to severe hepatic impairment or a creatine clearance of <60 mL/min, the maximum recommended dosage is 2 mg once daily for patients with major depressive disorder or agitation associated with dementia due to Alzheimer disease and 3 mg once daily for patients with schizophrenia.

Common adverse effects: The most common adverse reactions with Rexulti in adults were increased weight, somnolence, akathisia, nasopharyngitis, and dizziness.

Warnings and precautions: Rexulti is contraindicated in known hypersensitivity to Rexulti or any of its components. Extrapyramidal and withdrawal symptoms may be seen in neonates with third trimester exposure. If taken with strong CYP2D6 or CYP3A4 inhibitors, administer half of the recommended dosage. If taken with strong/moderate CYP2D6 with strong/moderate CYP3A4 inhibitors, administer a quarter of the recommended dosage. In known CYP2D6 poor metabolizers taking strong/moderate CYP3A4 inhibitors, administer a quarter of the recommended dosage. If taken with strong CYP3A4 inducers, double the recommended dosage and further adjust based on clinical response. There is an increased incidence of cerebrovascular adverse reactions in older patients with dementia-related psychosis. Manage neuroleptic malignant syndrome with immediate discontinuation and close monitoring. If tardive dyskinesia occurs, discontinue if clinically appropriate. Monitor for hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. If pathological gambling or other compulsive behaviors occur, consider dose reduction or discontinuation. Perform complete blood counts in patients with pre-existing low white blood cells count or history of leukopenia or neutropenia. Consider discontinuing Rexulti if a clinically significant decline in white blood cell count occurs in absence of other causative factors. Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope of the risk for orthostatic hypotension and syncope. Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. ■

Be prepared for insect bites and stings

Mary Warner

Stinging and biting insects seem to be everywhere during the summer months, and usually cause only a local reaction. But for patients who are sensitive to compounds in the insect's saliva or venom, bites and stings can cause reactions ranging from swelling to life-threatening anaphylaxis. Fortunately, there are numerous ways to relieve the pain and other symptoms of insect stings and bites, including local anesthetics, topical antihistamines, hydrocortisone, and counterirritants. Because reactions to bites and stings often occur in places where treatment may not be readily available, it's important to be prepared for whatever insects you may encounter, either in your back yard or on a wilderness hike.

The best, and easiest, way to protect against insect bites and stings is to avoid them altogether. Wearing light clothing and avoiding colognes; perfumes; and scented soaps, shampoos, and deodorants is also helpful. When that isn't possible, using an insect repellent can be extremely helpful in preventing insects from biting or stinging. (For more information on safe use of insect repellents, see the OTCs Today article in the July 2022 issue of *Pharmacy Today*.)

Treatment options for insect stings and bites include local anesthetics, topical antihistamines, protective agents, and hydrocortisone.

Stings

Bees, wasps, hornets, yellow jackets, and fire ants inject venom to defend themselves or to kill other insects, and their interactions with humans are usually accidental or reactive. The injected venom contains various allergenic proteins, which vary considerably among insects. Most of these proteins act by releasing histamines.

Most patients don't experience systemic symptoms following an insect sting, but instead complain of pain, itching, and irritation at the site. However, patients who are allergic to insect stings may experience hives, itching, swelling, and burning sensations, and those with severe allergies may experience anaphylaxis within 10–15 minutes of the sting.

Bites

Unlike insect stings, bites from mosquitoes, fleas, ticks are nonvenomous, with irritation resulting from salivary secretions. Mosquitoes inject an anticoagulant saliva into the victim, which causes the characteristic welt and itching. Although anaphylaxis is rare, mosquitoes can spread serious infections—including malaria, West Nile virus, and Zika virus—through this saliva, so it's important to be alert to other symptoms from bites.

Fleas are most often found in humid climates and usually affect pets, who can pass them on to their human companions. Fleas bite to obtain blood from their hosts, and while their bites are annoying, they are rarely serious in Western countries. Flea bites are characterized by a reddened region around the puncture and intense itching.

Ticks also feed on the blood of animals, including pets and humans who are exposed to affected animals. A tick bite involves attachment to the skin; if not removed, the tick becomes engorged with blood before finally dropping off. Local reactions to tick bites include itching papules that generally disappear within a week. Some ticks can transmit systemic diseases such as Rocky Mountain spotted fever and Lyme disease, usually after the tick has been attached for 36 hours or more. Thus, it's important to check for ticks regularly and remove them promptly.

Spider bites, though less common than bites from mosquitoes, fleas, or ticks, can result in serious reactions. Although all species of spiders are venomous, most are unable to penetrate the skin, with only the black widow, brown recluse, and hobo spiders as exceptions.

Black widow bites can result in redness of the skin or a halo-shaped lesion, delayed intense pain, muscle spasms, abdominal disturbances, fever, chills, and dyspnea, while brown recluse bites result in just a local reaction with itching and redness of the skin. Hobo spider bites typically present with a moderate to severe, slow-healing wound.

Treatment of stings and bites

Treatment options for insect bites and stings include local anesthetics, topical antihistamines, counterirritants, hydrocortisone, and protective agents.

Local anesthetics such as benzocaine, pramoxine, benzyl alcohol, lidocaine, dibucaine, and phenol are FDA approved in topical preparations for relief of itching, irritation, and pain caused by insect bites and stings. These preparations are available as creams, ointments, aerosols, and lotions and can be applied to the bite area 3–4 times daily for up to 7 days.

Topical antihistamines such as diphenhydramine hydrochloride are approved for temporary relief of pain and itching related to minor insect bites. They're available in several dosage forms in concentrations of 0.5%–2% and can be applied to the affected area up to 3–4 times daily for no longer than 7 days. Because topical antihistamines can cause photosensitivity and hypersensitivity reactions, they should not be used for more than a week to avoid the possibility of contact dermatitis.

Counterirritants such as camphor and menthol at low concentrations (0.1%–3% for camphor and <1% for menthol) are also used in some topical analgesic products to relieve itching and irritation. Like topical anesthetics and antihistamines, they can be applied to the sting or bite area 3–4 times daily for up to 7 days.

Topical preparations (0.5% or 1.0%) of hydrocortisone, a low-potency corticosteroid capable of vasoconstriction, are indicated for temporary relief of minor insect bites and stings. A wide variety of topical hydrocortisone formulations are available and should be applied as directed to the bite area 3 or 4 times daily for up to 7 days.

Finally, protective agents such as zinc oxide and calamine lotions and creams in concentrations of 1%–25% can be applied to insect bites to reduce inflammation and irritation. Zinc oxide works as a mild astringent with weak antiseptic properties, while both zinc oxide and calamine absorb fluids from weeping lesions.

What to tell your patients

Advise patients to remove bee stingers by scraping them away with a fingernail or the edge of a credit card to stop release of venom, then apply an ice pack or cold compress to slow venom absorption and reduce itching, swelling, and pain. An OTC topical antihistamine, protective agent, or hydrocortisone should then be applied to the affected site to relieve pain and itching. Patients who know they are sensitive to stings should carry epinephrine or oral antihistamines with them at all times. Patients should seek prompt medical attention if they develop hives, excessive swelling, dizziness, vomiting, or difficulty breathing.

For further information on the pathophysiology and treatment of insect bites and stings, see Chapter 37 of APhA's *Handbook of Nonprescription Drugs*, available via the bookstore on pharmacist.com or in PharmacyLibrary. ■

Selected nonprescription products for insect bites and stings

Local anesthetics	
Lanacane First Aid Aerosol Spray 2-in-1 Fast Acting Pain Relief	Benzocaine 20%; benzethonium chloride 0.2%
Solarcaine Pain Relieving Aerosol Spray	Lidocaine 0.5%; aloe, vitamin E
Topical antihistamines	
Benadryl Itch Stopping Cream	Diphenhydramine HCl 2%; zinc acetate 0.1%
Benadryl Itch Stopping Gel, Extra Strength	Diphenhydramine HCl 2%
Counterirritants	
Blue Star Ointment	Camphor 1.24%
Sarna Anti-itch Lotion Original	Camphor 0.5%; menthol 0.5%
Corticosteroids	
Aveeno Active Naturals Anti-Itch Maximum Strength Cream	Hydrocortisone 1%; aloe vera
Cortizone-10 Intensive Healing Anti-Itch Cream	Hydrocortisone 1%
Cortizone-10 Easy Relief Liquid	Hydrocortisone 1%; aloe vera
Combination products	
Aveeno Anti-Itch Concentrated Lotion	Pramoxine HCl 1%; calamine 3%; dimethicone
Benadryl Extra Strength Anti-Itch Cooling Spray	Diphenhydramine HCl 2%; zinc acetate 0.1%
Caladryl Clear Lotion	Pramoxine HCl 1%; zinc acetate 0.1%; camphor
Campho-Phenique Gel	Camphor 10.8%; phenol 4.7%; eucalyptus oil
Chigarid External Analgesic	Camphor 2.6%; phenol 1.5%; menthol 0.1%; eucalyptus oil 0.5% in collodion
StingEze Insect Bite Relief	Benzocaine 5%; phenol 1.35%, camphor
Sting-Kill Swabs	Benzocaine 20%; menthol 1%

Adapted from Chapter 37 of the *Handbook of Nonprescription Drugs*.

Glucomannan and weight loss

Mickie Cathers

Weight loss is big business with multiple supplements on the market advertising promising results. Glucomannan is one weight loss supplement gaining popularity in patients seeking to reduce cravings and control appetite as a way to lose weight. What's behind the hype?

Background

Glucomannan is a water-soluble dietary fiber found in the root of the konjac plant. Konjac, also known as elephant yam, is grown in parts of Asia and is best known for its starchy bulb root, a tuber-like part of the stem that is used to make low-carb noodles and rice, similar to riced cauliflower. Shirataki noodles have a gelatinous texture and are commonly used in Japanese cooking.

In January 2020, FDA approved glucomannan for labeling as a dietary fiber. FDA determined that glucomannan met the standards of naturally occurring fibers in plants and that the available scientific evidence suggested that glucomannan can help reduce blood cholesterol.

Dietary fiber does more than alleviate constipation. A high-fiber diet helps maintain bowel health overall, lowers cholesterol levels, helps control blood glucose levels by slowing the absorption of glucose, and can aid in achieving a healthy weight. As fiber is more filling and energy-dense, it may lead people to eat less and feel satisfied longer.

Is there a benefit?

Much like other soluble fibers found in oats, chia seeds, apples, carrots, peas, beans, citrus fruits, barley, chicory root, and psyllium, the hypoglycemic and lipid-lowering effects of glucomannan are widely known.

A meta-analysis published February 15, 2023, in *Nutrients* evaluated the effects of glucomannan supplementation on blood lipid-related indicators, blood glucose-related indicators, BP, and bodyweight in patients suffering from T2D. Zhang and colleagues analyzed six randomized controlled trials evaluating glucomannan and T2D. The authors found statistical significance that glucomannan reduced total cholesterol, low-density lipoprotein levels, fasting blood glucose, fasting insulin, and serum fructosamine levels compared with the control groups.

Glucomannan is thought to aid in weight loss by forming a viscous gel in the stomach, slowing gastric emptying, and increasing the feeling of satiety and fullness. However, the data here are inconsistent. A September 2020 review in *Obesity Medicine* by Mohammadpour and colleagues evaluated six randomized clinical trials and concluded that glucomannan resulted in significant reduction in weight in studies over 8 weeks with more than 30 adults who are overweight and obese.

In contrast, an August 2019 randomized, double-blind, placebo-controlled trial published in the *Journal of Pediatrics* assessed the efficacy of glucomannan on the BMI of 96 children with overweight or obesity. Participants received 3 g/day of glucomannan or placebo for 12 weeks and were followed up for the next 12 weeks. The authors concluded that glucomannan supplementation compared with placebo had no effect on weight reduction.

A December 30, 2013, trial in the *Journal of Obesity* evaluated the safety and efficacy of glucomannan. Participants were randomly assigned to take 1.33 g of glucomannan or placebo with 8 oz of water one hour before breakfast, lunch, and dinner for 8 weeks. Results revealed no significant difference between glucomannan and placebo with respect to weight loss, body composition, and hunger/fullness in overweight and moderately obese individuals.

More trials are needed to assess any significant beneficial effect of glucomannan on body weight.

Glucomannan is a water-soluble dietary fiber found in the root of the konjac plant.

Dosage and availability

Glucomannan is available as gummies, powder, and capsules as well as mixed into supplemental powders advertised as detox blends for herbal cleanses and gut health support. As a powder, glucomannan can be used to thicken soups and sauces in much the same way cornstarch is commonly used. Shirataki noodles and riced konjac are available in Asian markets or the Asian food section of the supermarket. These products are so fiber-rich that their net carbs per serving are listed as zero, making them popular among those following a keto lifestyle. Glucomannan has also started showing up on the ingredients list of gluten-free baked goods.

Daily recommended fiber for adults ranges from 21 to 38 grams, but more than 90% of Americans do not meet recommended daily levels.

What to tell your patients

While it's generally better to get one's fiber through switching to whole grains and incorporating more fruits and vegetables into the diet, fiber supplements such as glucamannon are generally regarded as a safe addition. Caution patients to add supplemental fiber incrementally over a few weeks. Adverse effects of adding fiber too quickly include intestinal gas, abdominal bloating, and cramping. Advise patients to select supplements certified by credible organizations such as NSF International, ConsumerLab, or the US Pharmacopeial Convention.

Also counsel patients taking glucomannan to drink plenty of water. Be aware that the powder has the potential to be a choking hazard and block the stomach. ■

FDA requires updates to opioid prescribing information, boxed warning

Sonya Collins

FDA announced several required updates to opioid prescribing information in April 2023. The changes apply to both immediate release (IR) and extended release/long-acting (ER/LA) opioid pain medications.

"The updated labeling finally notes the risks of concurrent CNS depressant use and opioids in terms of overdose and respiratory depression risk," said Chris Herndon, PharmD, a professor of pharmacy practice at Southern Illinois University Edwardsville School of Pharmacy. "Additionally, the class-wide labeling changes now bring to focus the phenomenon of opioid-induced hyperalgesia."

The most prominent changes will be seen in the boxed warning, which will put more emphasis on the risk of life-threatening respiratory depression and the risks associated with using opioids along with benzodiazepines or other CNS depressants.

FDA said that prescribing information should also note that

- IR opioids are not to be used for extended periods except when pain is severe enough to require them and alternative treatment is insufficient.
- Many acute pain conditions treated in the outpatient setting, including postsurgical pain and musculoskeletal injuries, require no more than a few days of opioids.
- ER/LA medications should be reserved for severe, persistent pain that requires extended treatment with daily medication and for which alternatives were insufficient.
- ER/LA and IR opioids come with the risk of opioid-induced hyperalgesia (OIH), which differs from opioid tolerance and withdrawal.

Manufacturers will need to make changes to several other sections of the prescribing information, including to the Indications and Usage, Dosage and Administration, and Warning and Precautions sections. Further required changes to patient Medication Guides are expected to help educate patients and their caregivers about opioid-related risks.

Pharmacists should be aware that while the amended information shines a brighter light on the inherent life-threatening risks of opioid use, they will not necessarily change prescribing or reduce patients' access to these drugs.

Many acute pain conditions treated in the outpatient setting, including postsurgical pain and musculoskeletal injuries, require no more than a few days of opioids.

In fact, FDA's changes may still leave room for inappropriate prescribing, whether it is under- or over-prescribing of these pain medications. "I am concerned that the ambiguity around severe versus not severe pain, as it is worded in the prescribing information, could open the door to inappropriate interpretation by pharmacists, prescribers, nurses and payers," Herndon said.

OIH

New prescribing information will bring OIH to the forefront. This is an increase in, or greater sensitization to, pain rather than a reduction in it after acute or long-term opioid use.

Patients who do not get relief from a dose increase but rather experience greater pain in response to the larger dose may have OIH. When patients fill a prescription for a higher dose, pharmacists should screen for symptoms of OIH.

"Educate patients that opioids can, in fact, increase the sensitivity of pain transmitting nerves or change the way the pain signal is conducted and potentially worsen pain symptoms," Herndon said. "The take-home is that some patients will be exposed to opioid analgesics for pain, and the paradoxical effect of worsening pain can actually result."

Opioids and CNS depressants

FDA's required changes underscore the life-threatening risks of concurrent use of opioids and CNS depressants. Pharmacists should stress to patients that both drug classes depress the CNS and can lead to sedation, impaired thinking, slowed response time, and, critically, slowed or difficult breathing and death.

"Even though an individual has been on an opioid for pain for years, or even decades, the risk of oversedation, respiratory depression, overdose and even death still exists," Herndon says.

Counseling points

In addition to highlighting the risk of overdose and OIH, pharmacists should make patients aware that opioid use disorder (OUD) has a genetic component and having a first-degree relative with a history of OUD raises the patient's own risk, too.

All of this is in addition to the standard counseling points, including possible constipation and pruritus, risk of sexual dysfunction, and education about naloxone.

"Discussing with patients that OIH does exist, along with discussions about naloxone, can oftentimes open the door to more frank conversations about the risks versus benefits of opioids."

The life-threatening risks that come with opioid use cannot be overstressed, Herndon said. "These medications should be treated like a loaded firearm and stored judiciously in a locked environment such as a lockbox or lockable cabinet." ■

APhA offers tools and resources, as well as training and webinars, at www.pharmacist.com/Practice/Patient-Care-Services/Opioid-Use-Misuse to help pharmacists treat patients using opioids.

OTC hearing aids: Pharmacists can help improve access and affordability

Clarissa Chan, PharmD

According to a randomized clinical trial published April 2023 in *JAMA Otolaryngology–Head & Neck Surgery*, self-fitted OTC hearing aids demonstrated similar clinical outcomes to audiologist-fitted hearing aids using best practices in patients with mild-to-moderate hearing loss within a 6-week period.

FDA-approved OTC hearing aids became available for purchase in October 2022 at pharmacies. The arrival of these items on pharmacy shelves is an opportunity for pharmacists and audiologists to collaborate. In fact, a recent article from the May/June 2023 issue of *Audiology Today* suggests models for collaborative working relationships between audiologists and pharmacists to help improve access and affordability for patients with hearing care needs.

Collaborate to improve access

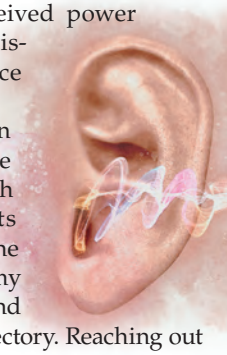
"Pharmacists and audiologists can collaborate in many different ways," said Lucas Berenbrok, PharmD, one of the authors of the *Audiology Today* article and an associate professor at the University of Pittsburgh School of Pharmacy. "Pharmacists can refer to local audiologists when patients are not candidates for OTC hearing aids, when they require refined customization, and when their needs are not met by OTC devices."

He added that audiologists can refer patients to pharmacists for the purchase of OTC hearing aids, hearing aid batteries, hearing protection, and self-treatment of earwax buildup.

Since self-fitted and audiologist-fitted hearing aids show clinically similar results, it is up to pharmacists and audiologists to collaborate and merge expertise to increase access to hearing care. According to Berenbrok, it is important for pharmacists to know when and how to make referrals to audiologists for more complex cases.

"We will need to trust that pharmacists can be trained to recognize red-flag conditions excluding patients from OTC hearing aid use and make referrals in the interest of supporting patient outcomes," wrote the authors in *Audiology Today*.

Often this might mean overcoming interprofessional collaboration obstacles to patient care, including turf boundary concerns, communication breakdown, lack of trust in provider competence, perceived power differential, and distance from practice sites.



Pharmacists can take the initiative to connect with local audiologists by searching on the American Academy of Audiology's Find an Audiologist directory. Reaching out to audiology colleagues with questions on when and how to refer patients to their offices will open lines of communication to benefit patient care.

"Collaborative working relationships between pharmacists and audiologists are essential for the success of OTC hearing aids in America," said Berenbrok.

Questions pharmacists should consider when helping patients with OTC hearing aids:

- Is this a quality brand?
- What are the features it offers that are important for my patient's needs?
- How do I fit the device? Does it provide a level of customer support that could help my patient, if needed?
- What is the warranty and return policy?
- What can I do if the device breaks?
- What is the cost and how long is it expected to last?
- Will this be appropriate for my patient's type and degree of hearing loss?
- What's the next step if this option does not work for my patient?

How pharmacists can advise patients

"There are two categories of hearing aids available," said Karina De Sousa, PhD, project coordinator in the Department of Speech-Language Pathology and Audiology at the University of Pretoria in South Africa.

OTC devices can be self-fitted or preset, both of which are regulated by FDA. Pharmacists may view self-fitting as a feature that some consumers may prefer over preset, said Berenbrok.

> The arrival of these items on pharmacy shelves is an opportunity for pharmacists and audiologists to collaborate.

Pharmacists should look for the "self-fitting" label on hearing aid packaging and confirm that they are FDA compliant to weed out bad products. A guide to purchasing OTC hearing aids can be found at apha.us/HearingAids.

A defining characteristic of FDA-registered OTC hearing aids is the availability of patient adjustability features that do not need intervention from licensed hearing aid professionals.

Prescription hearing aids require a licensed hearing aid professional to perform needed services, like managing the customization, features, and fine-tuning of the hearing aid, according to Elaine Mormer, PhD, who coauthored the *Audiology Today* article with Berenbrok and is professor and audiologist at the University of Pittsburgh.

"Help patients decide if they are potential candidates. Patients will not qualify for an OTC hearing aid if they have a history of complex ear pathologies like recurrent ear infections, requiring more specialized care by an audiologist. If hearing loss is too severe, patients may also not benefit from an OTC option," said De Sousa. ■

CDC streamlines COVID-19 vaccine recommendations

Olivia C. Welter, PharmD

While COVID-19 continues to evolve, recommendations for vaccinating against it are changing as well. From initial anticipation for vaccine development in 2020 to new booster dose indications in 2023, CDC and other national regulatory agencies have released multiple updates to ensure the various COVID-19 vaccines remain as safe, accessible, and efficacious as possible.

Highlights include blanket recommendations of bivalent vaccines from CDC, allowing older adults and immunocompromised patients to receive additional bivalent booster doses for added protection, and HHS announcing continued vaccine accessibility for uninsured patients.

Primary vaccination

In the beginning of the pandemic, the primary vaccine series included one dose of the Janssen viral vector vaccine or two doses of either the Pfizer or Moderna monovalent mRNA vaccine.

Vaccine technology developed quickly and, as of May 2023, CDC recommends only bivalent mRNA vaccines for completing the primary vaccination. Just one dose of either the Pfizer or Moderna bivalent COVID-19 vaccine completes the primary vaccination for adults and children aged 12 years and older who are not immunocompromised. These bivalent mRNA vaccines are currently available under an EUA and offer greater protection against COVID-19. Their monovalent counterparts from Pfizer and Moderna have received full approval by FDA but are no longer recommended for use. The Novavax protein subunit vaccine remains available under EUA as an alternative to mRNA vaccines. Though monovalent, this vaccine expands patients' choices.

Just one dose of either the Pfizer or Moderna bivalent COVID-19 vaccine completes the primary vaccination for adults and children aged 12 years and older who are not immunocompromised.

CDC has a notice on their Novavax-specific webpages that some doses may have expired or may be expiring soon. They are directing vaccine providers to check expiration dates weekly and never administer an expired dose.

All doses of the Janssen single-dose vaccine expired on May 7, 2023. CDC has issued an announcement directing vaccine providers to dispose of any remaining doses they may have on hand.

Booster doses

The bivalent Pfizer and Moderna vaccines were originally developed as booster doses intended to supplement coverage of monovalent primary series doses. Now, they can be used both to complete the primary vaccination and for booster doses.

In April 2023, FDA authorized adults aged 65 and older to receive a second booster dose of bivalent vaccine. This demographic, as well as immunocompromised patients, are the only populations who are currently able to receive additional bivalent booster doses.

The Novavax vaccine may serve as a booster dose in addition to being an option for primary series completion.

Cost of vaccines

When the first COVID-19 vaccines were developed, the federal government partnered with vaccine manufacturers to purchase bulk vaccine supply. These doses have been distributed to states, allocated to vaccine providers, and given to patients at no cost. Now, some COVID-19 vaccines are commercialized, and the government is no longer universally covering costs for vaccine ordering and administration.

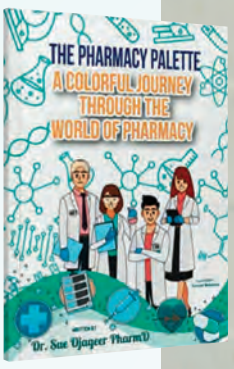
Kaiser Family Foundation released an analysis in early 2023 detailing how much commercial doses of COVID-19 vaccine could cost. They anticipated that $110–130 per dose would be standard, compared to the federal purchase rate of around $20–26 per dose.

Insured patients can still expect to receive the vaccine for free. COVID-19 vaccine manufacturers have previously stated that the vaccine will remain free for those without insurance, although they have not released any details or plans for achieving this.

In April 2023, HHS announced their Bridge Access Program For COVID-19 Vaccines and Treatments. This program creates a public–private partnership that will maintain access to COVID-19 vaccines for uninsured patients. The federal government intends to partner with a network of pharmacies, both chains and independents, to provide per-dose payments for each vaccine administered to a qualifying patient.

The Biden administration expects that the Bridge Access Program will launch in fall 2023. Limited funds are available to support this program through December 2024. ■

ON THE COVER



LOREN BONNER

The Pharmacy Palette: A Colorful Journey Through the World of Pharmacy, is a coloring book that features over 50 pharmacy specialties: a poison control pharmacist, a military pharmacist, a quality assurance pharmacist, and a veterinary pharmacist—just to name a few.

Sue Ojageer, PharmD, dreamt up the concept as a fun way to "reintroduce" pharmacy to the world.

"Pharmacists have so many opportunities to practice, and I want the world to see that," said Ojageer, who started her entrepreneurial career after 14 years practicing in retail pharmacy. "I know there's burnout, but there are still many options to utilize your pharmacy license and provide exceptional patient care."

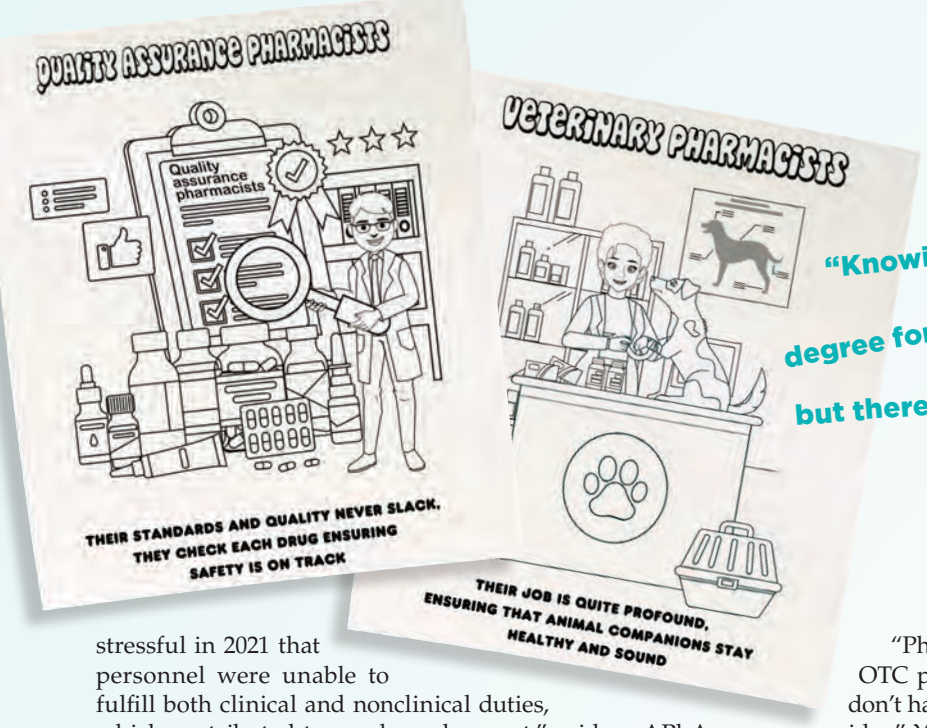
The places pharma

A look at some

Results from the 2021 APhA/NASPA National State-Based Pharmacy Workplace Survey found that 75% of pharmacists from various practice settings disagreed with the statement "Sufficient time is allocated for me to safely perform patient care/clinical duties." Additionally, 71% said there were not enough pharmacists working to "meet patient care/clinical duties," and 65% said "payment for pharmacy services" did not support their "ability to meet clinical and nonclinical duties."

"The findings show that pharmacy workplaces were so

cists are going: nontraditional careers



"Knowing that you have this advanced degree forces you to want to be the expert, but there are so many roles pharmacists can be fantastic in."

stressful in 2021 that personnel were unable to fulfill both clinical and nonclinical duties, which contributed to employee burnout," said an APhA statement from May 2022, when the findings were released. "While the majority of pharmacy workplaces have cultures of patient safety, pharmacy personnel are at a breaking point when adjustments to team training, roles, and responsibilities are not made quickly enough to adapt to change and meet all of their responsibilities."

In this current environment, pharmacists might be looking to take an unconventional or nontraditional career path. *Pharmacy Today* profiled seven pharmacists who have done just that. Their stories are in no way exhaustive of what's out there for pharmacists, but they can serve as examples of the various career paths pharmacists have taken.

Crystal Yu, PharmD, educating pharmacists about skincare

Skincare became part of Crystal Yu's life when she began treating her infant daughter's severe eczema. Skincare is also what Yu specializes in at L'Oréal USA. Yu, PharmD, graduated from Mercer University College of Pharmacy in Georgia and started her career at a local grocery store chain pharmacy, where she built close relationships with her patients and felt valued by her community.

But when her daughter was born, she longed for a change. Not only was she searching for a different skillset; Yu also needed more opportunities as a working mom. She gained new skillsets in a long-term care pharmacy and then in pharmaceutical affairs before discovering an opportunity at L'Oréal.

"The L'Oréal job opening was the perfect fit with my health care background and the experience I had with my daughter's eczema," Yu said. "I was the first PharmD to be part of the integrated health team at L'Oréal."

As the senior manager of integrated health for L'Oréal brands CeraVe, La Roche-Posay, and Vichy, a big part of Yu's job involved educating and empowering pharmacists.

According to Yu, these brands are deeply rooted in dermatology and scientific evidence.

"Pharmacists play a big role in recommending OTC products, and there are many patients who don't have access to a dermatologist or a clinic provider," Yu said. "There's an educational gap in skin health for pharmacists, although many patients come with questions about skincare."

In fact, Yu developed a L'Oreal professional resource site to provide pharmacists with support, such as accredited continuing education and access to free product kits (Learn more: www.lorealdermatologicalbeauty.us/pharmacy).

Yu recently transferred roles within L'Oréal and is now senior manager for medical affairs for SkinCeuticals.

Yu will precept a PGY-4 student from the University of North Carolina at Chapel Hill this summer, and her peer at L'Oréal, Lyndsay Zotian, PharmD, has also launched a first-of-its-kind fellowship through the Medical University of South Carolina College of Pharmacy: SkinCeuticals MSL Fellowship. (Learn more: apha.us/SkinCeuticalsMSLFellowship).

"I'm passionate about opening up this space for pharmacists," Yu said. "Pharmacists can and do work in skincare."

Karen Brown, PharmD, setting up clinical trials

Karen Brown graduated from the University of Montana in 2020 with her PharmD degree. As a student and eventual postdoctoral fellow, she worked in a research lab conducting pharmacogenomics research with rural American Indian and Alaskan Native populations in Montana and the northwest region.

"This was my introduction into clinical research," said Brown, who is founder and CEO of a full-service contract research organization (CRO) called KLEO. "I became fascinated with how to bring clinical research into rural settings and went down a clinical research rabbit hole."

Even though Brown didn't know what a CRO was at that time, she knew she didn't want to pursue a traditional pharmacy role.

Fast forward to today, and her company—what she considers a boutique CRO—supports medical device and diagnostic companies in bringing their product to market. This might involve setting up and managing clinical trials, going

back and forth with FDA and other regulatory bodies, or even working with payers. Currently, KLEO is managing a 30-site clinical trial for a device company.

There were many small steps along the way that led Brown and her company to this point.

"I reached out to my network when I graduated and asked to work on any project," said Brown. She took on many small projects, mainly in data analysis.

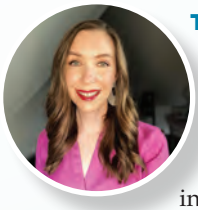
"I got obsessed with how to grow in an entrepreneurial way," Brown said.

Brown used her professional network to get where she is today and advises other pharmacists in pursuit of other opportunities to do the same.

"No one should have taken a chance on me to do data analysis projects, but they did," said Brown.

"Knowing that you have this advanced degree forces you to want to be the expert, but there are so many roles pharmacists can be fantastic in," Brown said. "You might not be the expert, though, and you have to be okay with that at first."

Brown also maintains a research position at the University of Montana where she continues to work toward bringing adequate health care to underserved populations.

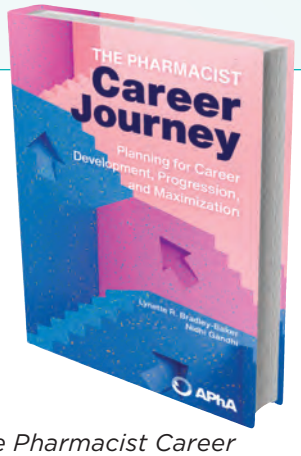


Tara Schneider, PharmD, clinical services for independent pharmacies

Tara Schneider, PharmD, climbed the health system pharmacy administrator ladder until she reached a breaking point in 2020, at the height of the pandemic.

"I was working 20 hours a day," said Schneider. "I was going into work, being on call, but still furloughed and unsure if my job would be around."

Schneider's outlook of pharmacy is inspiring from where she sits today, however. She left her position as a pharmacy administrator and created her own business: The Point of Care Testing Institute (POCTi), where she works with independent pharmacies to help them set up clinical services.



The Pharmacist Career Journey provides resources and actionable planning steps for pharmacists to use throughout their career spectrum. Check out apha.us/CareerJourney for this constructive companion as you enhance, repurpose, or change your career plan.

"It's so rewarding to help like-minded entrepreneurs grow new service lines because you know they will have a big impact on their community," said Schneider.

Schneider herself came from a generation of independent pharmacists, in fact.

Her career change all started with a single webinar about entrepreneurship. "I didn't know anything else outside of health system pharmacy and I definitely didn't know entrepreneurship, but it was so inspiring seeing what [these individuals] did, and I couldn't unsee what I saw."

Sure enough, she took the necessary steps to create a business. First, she created TD Pharmacy Services, a closed-door non-dispensing independent pharmacy that focuses on clinical services like point-of-care testing (POCT).

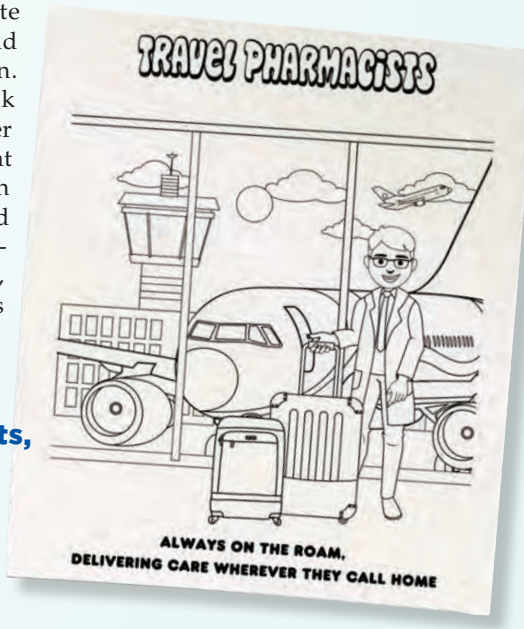
"I wanted to run clinical services on my own," Schneider said. "This is what people really need. I did sick care for so long and what I want to do is prevent people from having to get [sick] care."

TD Pharmacy Services is essentially a concierge pharmacy for patients who have acute and chronic conditions, providing everything from genetic consults and respiratory testing to gut health and supplements.

"In the summer of 2021, I started getting lots of questions about it and others wanted to know how to do this in their pharmacy," said Schneider.

She started doing consultations late that summer and POCTi was born. Through a 5-week program, Schneider helps independent pharmacists launch POCT services and other types of clinical services. Lately, OTC hearing aids

"Pharmacists play a big role in recommending OTC products, and there are many patients who don't have access to a dermatologist or a clinic provider."



have come up as a possible—and viable—service offering.

"Busy pharmacists don't have time to do what it takes to implement clinical services in a short period of time, that is where we come in to do the heavy lifting," said Schneider.

Both of her businesses are cash-based and she still consults with TD Pharmacy Services patients via telehealth appointments. Schneider moved this year from Oklahoma to Kentucky.

Blair Curless, PharmD, PhD, educating pharmacists about cannabis

This summer, purchasing medical cannabis will finally become a reality for patients in Georgia after years of roadblocks to obtaining the drug legally. Certain pharmacists will also be part of this long-awaited moment, creating access to medical cannabis oil for patients in rural parts of the state who don't live near a dispensary.

Georgia's 2019 cannabis law allows independent pharmacists across Georgia to dispense cannabis oil to patients, without association of an approved producer. Georgia's legislature passed a bill in 2019 setting up a licensing process for companies to grow cannabis indoors under close supervision, convert the plant to oil, and sell the product to patients with a doctor's prescription if they are in a registry run by the Georgia Department of Public Health.

Blair Curless, PharmD, PhD, is helping pharmacists get ready to dispense cannabis oil.

"Pharmacists are interested in this, and more are signing up for my classes," said Curless.

Curless is a chemist by training. Before enrolling in pharmacy school, he worked for 7 years helping to research and develop a new revolutionary process in the aluminum industry. He entered pharmacy school in 2011 and earned both a PharmD and PhD through a dual program.

During his last year of graduate training, he got ahold of a CBD product and discovered that it contained harmful contaminants, a schedule I synthetic cannabinoid. Long story short, FDA was notified and they sent out a public warning letter.

"There's so much that's not regulated and there's so much concern—especially these past few years—with cannabis products," said Curless. "I believe pharmacists need to reign this in and be looking more closely at these products."

As a pharmacist and chemist, Curless brings a necessary perspective, especially when it comes to educating other pharmacists about what's out there and what to be aware of.

"If we can get pharmacists educated about this, it'll be much easier for the industry," said Curless.

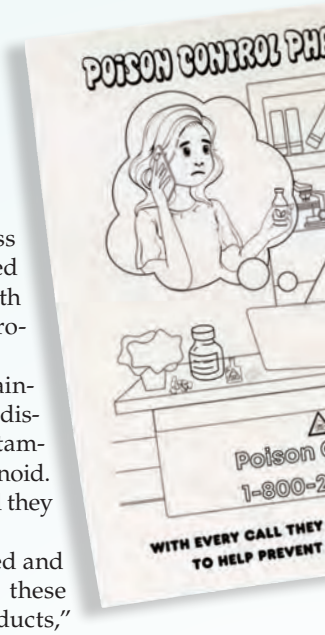
Megan Freeland, PharmD, medical writing and communications

When Megan Freeland, PharmD, was in middle school, she often straddled two different worlds: the life of an honors student at school and a home life that couldn't feel more different. Both were beautiful but had their differences, according to Freeland.

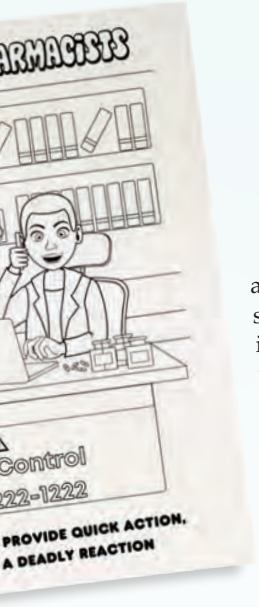
"I was translating information all the time," said Freeland, who is a medical writer. "And now that's what I do in my business. I understand the research and translate that into a format that resonates and makes sense to others."

Her company, StockRose Creative, LLC, is focused on health content for digital health companies, with a special emphasis on improving the health and wellness of Black communities.

"When I started pharmacy school, I knew I didn't want to practice in a traditional role," said Freeland.



"I empower [clinicians] with the tools necessary to use it in practice. It's another tool in their toolbox and essential to know."



"From the beginning my question was always: How do I apply this to a public health setting? There wasn't a clear path, so I was looking for other opportunities, like taking advantage of extracurricular activities related to public health. The common denominator between those two things was always writing."

Freeland also teaches fellow pharmacists how to write through a 6-month coaching program—the Health Professionals to Health Writers Accelerator. She connects her pharmacist clients to both the soft and hard skills they learned in pharmacy school.

"Whether it's the motivational interviewing as a softer skill or the drug information, those are all relevant to health writing because the information needs to be authoritative yet come across as compassionate," said Freeland.

In teaching others, Freeland often has to go back to the place where she was when she was learning to write.

"Writing for me came through doing it, through practice, but it also came easily for me," Freeland said.

Ghada Elnashar, PharmD, MS, medical affairs

Ghada Elnashar, PharmD, MS, has a deep passion for pharmacogenomics. It all started in pharmacy school at the University of Minnesota where she met her mentors and got to network with pioneers in the pharmacy field, including those in the managed care and pharmacogenomics spaces.

"I've always wanted to create a positive change," said Elnashar. After completing her managed care pharmacy residency, she started her career in managed care helping patients on the individual and population scale and worked for a startup before joining OneOme LLC, a precision medicine company co-founded by Mayo Clinic. She is currently associate director of medical affairs at OneOme.

"I think what's unique to me is my master's in biotechnology, which provided me with a scientific foundation of the biotech world, including precision medicine," said Elnashar. She also completed a leadership emphasis in pharmacy school that she said gave her many essential tools and skills she currently uses.

In her role at OneOme, Elnashar helps educate clinicians, payers, health systems, and other thought leaders about pharmacogenomics.

"The ultimate goal is to optimize a medication decision and reduce health care costs," said Elnashar.

In combination with her leadership training, she said she is always using her pharmacist skills in speaking on panels or meeting with clients.

"Pharmacogenomics is here to stay," said Elnashar. "I empower [clinicians] with the tools necessary to use it in practice. It's another tool in their toolbox and essential to know."

Michael Corvino, PharmD, educating PA students

Michael Corvino, PharmD, took a nontraditional route in order to arrive at his current position. Not only is Corvino an adjunct professor at the Charleston Southern University Physician Assistant Program, but he also works for a company called UpStream, which provides chronic care management services in various primary care clinics.

Corvino graduated from the Medical University of South Carolina College of Pharmacy in 2015 and accepted a job with Walgreens, where he had his first taste of spending one-on-one time with patients through MTM.

"Because I didn't do a residency, I knew it would be much harder to transition into a true clinical role later in my career," said Corvino. "To continue my education and gain more clinical knowledge, I used all my days off work and my PTO to spend time learning from various pharmacists."

As time passed, he wanted to move toward earning a board certification. "I was able to accumulate enough time working with MTM patients to become eligible to take the Certified Diabetes Care and Education Specialist [CDCES] exam," said Corvino.

After receiving his CDCES, he went on to earn board certifications in pharmacotherapy and ambulatory care as well.

During this time, Corvino also started creating pharmacotherapy infographics for social media—which would land him his current job with the CSU PA program based on recommendations given by colleagues.

"I was hired to create the content for Pharmacology 1, 2, and 3 as well as teach the content when the school's first cohort started," Corvino said.

His pharmacotherapy infographics for social media also turned into a podcast that he created and cohosts called Cor-Consult RX: Evidence-Based Medicine and Pharmacy.

"I enjoy the variety of different settings and roles in which I work," said Corvino. "The most rewarding aspect of my job is seeing patients grow in their knowledge of the disease state that they are living with. The same can be said about working with students. It's very rewarding to see students start at the beginning of a program and help them get to a place where they are excellent providers." ■

Pharmacists can break down barriers to transgender health care

Lauren Howell, PharmD

A bill signed into law in June 2023 makes Texas the largest state so far to ban gender-affirming care for minors. Once the law takes effect in September, health care providers will be prohibited from prescribing hormones or puberty blockers. They will also be prevented from performing surgeries to help minors with gender transition. For individuals who are currently receiving prescription hormones and puberty blockers, the law requires that they be gradually taken off these medications "in a manner that is safe and medically appropriate."

What does this mean for patients?

The bill in Texas is one of more than 75 anti-LGBTQ+ bills that have been signed into law this year alone. Kelsea Aragon, PharmD, assistant professor at The University of New Mexico College of Pharmacy, explains that "this is creating decreased access in a population that has already had difficulty accessing health care."

While these laws vary from state to state, the barriers that they create for patients include the banning of gender-affirming care, use of appropriate restrooms, and playing sports as well as attacks on using gender-affirming pronouns, forced outing laws, and anti-drag laws. Many of these laws also add criminal consequences such as felony child abuse charges and loss of license for anyone found to be providing gender-affirming care.

Amy Howard, MS, PharmD, pediatric clinical pharmacist at the University of Maryland School of Pharmacy, states that "much of the legislative controversy in recent years focuses on whether gender-affirming care of minors is harming children. Legislation being introduced is often written and promoted as a child protective action." She also expressed that "Setting 'timelines to detransition' patients who are currently receiving care and restricting access to puberty suppression therapy will have a major impact on the physical and mental health of transgender youth." A study published in *PLos One* by Cunningham and colleagues in December 2022 found that there is a link between suicide- and depression-related web searches and states' passing of anti-transgender bills.

The role of pharmacists

As the most accessible health care provider, pharmacists should serve as a resource for patients affected by these laws. A 2019 article by Eckstein and colleagues published in *Currents in Pharmacy Teaching and Learning* reported that 40% of community pharmacists rated themselves as "not at all prepared" to counsel patients on transgender-related care. Pharmacists should be aware of local organizations and resources that will hopefully assist patients with maintaining access to care.

Advocacy, self-education, and allyship are all examples of ways that pharmacists can support patients.

"Those who work in this care space need to continue showing up to provide testimony, educating others whenever possible, and being vocal champions," said Howard. "If we want to ensure that treatment options for transgender youth are as safe as possible, we need to promote funding well-designed research in this field. It's also important to encourage national participation to strengthen the external validity of these studies." Moving forward, Howard believes "the profession should solicit and amplify willing voices who can speak from their lived experiences to better inform future policy and advocacy." ■

Building trust

As the most accessible health care provider, the easiest way for pharmacists to help is by creating a safe and welcoming environment. Specific examples from Amy Howard, MS, PharmD, of how to build trust with patients and their families include

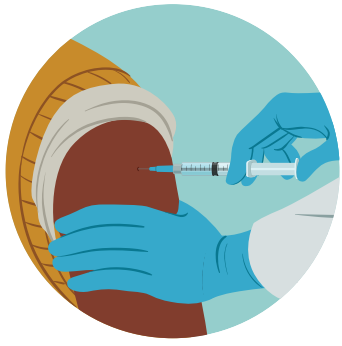
- Start by introducing yourself, including your pronouns. By consistently normalizing use of your pronouns, you can help people feel less singled out. If you are unsure—it is always better to politely solicit their preferences than assume and risk misgendering someone.
- Mirror their language—use words from their lexicon about their body and their care to help your patients feel heard and understood.
- Avoid deadnaming (i.e., referring to someone by a name they no longer use) by saying "You introduced yourself as _____, which is different from what I have in your chart/profile. Is _____ the name you would prefer me to use?"
- Avoid assumptions about what anatomical organs a transgender patient may or may not have. If there is a medically necessary reason for you to inquire, be certain to make the reason you need to know clear to the patient.
- Adopt or advocate for systems that have gender-inclusive language and the ability to enter preferred names. ■

Researchers seek to understand what factors affect vaccine uptake

Jonathan Little, PharmD

Describing the various sociodemographic disparities that may be associated with vaccine uptake can be difficult, but a study published on November 11, 2022, in *JAPhA* characterizes differences in disease burden, and sociodemographic and lifestyle characteristics for cohorts of participants who received certain common vaccines.

"Consistent with previous literature, minority participants had lower vaccination rates for all vaccines included with the exception of pneumococcal vaccination in patients under age 65 [years]," said Keri Hurley-Kim, PharmD, MPH, lead author of the study and clinical professor at the University of California at Irvine School of Pharmacy & Pharmaceutical Sciences.



"There is evidence to suggest that racial and ethnic minority groups receive vaccinations at lower rates overall compared to those of non-Hispanic white backgrounds."

In an effort to describe differences between the entire database cohort and smaller cohorts of recipients for influenza, hepatitis B (HBV), pneumococcal, and HPV vaccines, researchers analyzed data from the NIH All of Us (AoU) database, which contains hundreds of thousands of adult subjects' metrics.

The authors outlined several characteristics of the groups who received these vaccines, such as age, insurance status, employment, annual household income, health status (e.g., comorbidities), and lifestyle behavior.

Setting this one apart from other studies, researchers used a single large database to look at multiple vaccines as opposed to focusing solely on one characteristic related to one vaccine as many other studies do.

"There is evidence to suggest that racial and ethnic minority groups receive vaccinations at lower rates overall compared to those of non-Hispanic white backgrounds," Hurley-Kim said. "However, existing literature was based on surveys or vaccine administration records, both of which lack many demographic, lifestyle, and health-related variables. The AoU database contains all of this information, so it presented a new methodology for examining the interplay between various factors and their impact on vaccination status."

Details

Individuals included in the research cohorts were those who received a flu vaccine in the 2017–2018 flu season and those who received any of the other vaccines (HBV, pneumococcal, HPV) at least once in their lifetime prior to December 1, 2018. The entire research cohort in the AoU at the time of analysis was roughly 315,000 participants, and the size of the vaccine cohorts studied ranged from about 2,000 patients to 15,000 patients.

The researchers found that all vaccine cohorts had higher proportions of white and non-Hispanic/Latino participants than the general AoU cohort. This finding may suggest that nonwhite or Hispanic/Latino individuals may be less likely to receive vaccines than white and non-Hispanic/Latino individuals. This is a key finding that also demonstrates that the AoU database can be useful in studying vaccination rates in minority populations.

Additionally, higher apparent vaccination rates were found in Black participants in the cohort of patients under 65 years who received the pneumococcal vaccine, and this cohort also had the worst self-reported physical health. To be indicated for a pneumococcal vaccine at age 65 years or younger typically means the individual may have diabetes, chronic respiratory illness, or cardiovascular disease.

Going beyond

According to the study findings, all vaccine groups had higher proportions of participants with health insurance compared to the general AoU cohort. This underscores the importance of having insurance to pay for vaccines.

Pharmacists can help individuals without health insurance receive certain vaccines through nontraditional methods such as public health fairs or pharmacy school vaccine initiatives.

As the authors note, the findings from this research are in alignment with the literature on vaccine disparities.

"This study provides further information on racial and ethnic vaccine-related disparities and may help inform interventions to address these," said Hurley-Kim. "It also serves as the basis for ongoing follow-up research looking at disparities in pneumococcal vaccination rates among participants with chronic diseases."

Becoming better educated on these characteristics helps pharmacists know who may be less likely to receive certain vaccines, and who they can engage in discussions about the importance of vaccines. Pharmacists may then implement strategies such as increased outreach, provision of education, motivational interviewing, and more, to help their patients receive needed vaccinations. ■

Pain and inflammation, topicals, and other

Migraine is the second leading cause of disability globally and, worldwide, 50% of the population suffered from headache and 30% have experienced migraine in the past year. Patients will be looking for advice and assistance with their decision-making process as they search for relief of their pain and discomfort. Also, topical treatments can provide relief to affected skin within a week. While overall fungal skin infections can be difficult to treat, symptomatic relief, eradicating the existing infection, and preventing future infections is possible.

Pain and inflammation

Migraine headache products (n = 564)

Excedrin Migraine	53%
Tylenol	7%
Advil Migraine	5%
Motrin IB	2%
Aleve	1%

Headache relief (n = 549)

Excedrin	26%
Tylenol	25%
Advil	16%
Aleve	6%
Motrin	5%

Back pain relief (n = 553)

Aleve	13%
Advil	9%
Salonpas	9%
Tylenol	7%
Motrin IB	6%

Topicals

Scar treatment (n = 548)

Mederma	49%
ScarAway	2%
Bio-Oil	2%
CeraVe	1%
Cicatricure	1%

Lice treatment (n = 498)

Nix	49%
RID	13%
Walgreens	1%
Sklice	1%
Licefree Spray	1%

Topical pain relief (n = 527)

Voltaren	26%
Aspercreme	10%
Icy Hot	7%
BIOFREEZE	6%
Salonpas	6%

Athlete's foot treatment (n = 535)

Lotrimin	30%
Lamisil	19%
Tinactin	10%
Dr. Scholl's	2%
CVS Health	2%

Stretch mark treatment (n = 472)

Mederma	18%
Palmer's	11%
Bio-Oil	7%
Mother's Friend	1%
Equate	1%

Sunscreen (n = 567)

Neutrogena	23%
Coppertone	18%
Banana Boat	10%
Sun Bum	3%
Aveeno	2%

Toe/Foot/Nail antifungal treatment (n = 453)

Lotrimin	16%
Lamisil	14%
Fungi Nail	6%
Tinactin	4%
Kerasal	4%

Eczema relief (n = 504)

Aveeno	14%
Eucerin	14%
CeraVe	9%
Aquaphor	3%
Gold Bond	2%

Other

Incontinence products (n = 516)

Depend	32%
Poise	7%
Always	2%
TENA	2%
Walgreens	1%

Sleep aid (n = 568)

Unisom	23%
Benadryl	11%
Vicks ZzzQuil	7%
Nature Made	2%
Sominex	2%

Smoking cessation (n = 600)

Nicorette	32%
NicoDerm	23%
Nicotrol	3%
CVS Health	2%
Equate	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 APhA's *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.

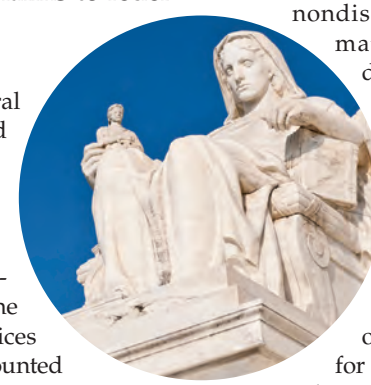
SCOTUS clarifies knowledge requirement for pharmacy violation of "usual and customary" standard

David B. Brushwood, BSPharm, JD

In a recent unanimous opinion, the Supreme Court of the United States recognized a subjective standard for interpreting the "usual and customary" requirement in the submission of pharmacy claims to federally funded programs.

Background

The federal False Claims Act (FCA) imposes liability on anyone who "knowingly" submits a false claim to the government. Some false claims are straightforward. For example, if a pharmacy dispenses 60 dosage units of a medication but submits a claim for 180 dosage units, then this is clearly a false claim. On the other hand, it may be less clear whether a pharmacy's "usual and customary" price should be based on its standard retail price, or instead should reflect a discounted price that the pharmacy routinely extends as a price-match to meet a competitor's lower price.



Following a whistleblower complaint, the federal government sued two pharmacy companies alleging that the discounted prices they adopted were actually their "usual and customary" prices. The government alleged that these discounted prices comprised a majority of sales for many drugs sold to patients who paid cash, yet the pharmacies allegedly submitted false claims to Medicare and Medicaid that reflected the higher nondiscounted prices as their "usual and customary" price.

The pharmacies moved for dismissal of the government's case. The district court granted the motion, reasoning that although the claims may have been false, they had not been submitted "knowingly." Applying an objective standard, a federal appeals court affirmed the district court's dismissal, noting that the phrase "usual and customary" could reasonably be understood as applying to the defendants' retail prices and not to their discounted prices.

The Supreme Court reversed the dismissal.

Rationale

The Supreme Court acknowledged that the phrase "usual and customary" is, on its face, "less than perfectly clear."

The court reasoned that the "knowingly" requirement in the FCA refers to the defendants' "knowledge and subjective beliefs—not to what an objectively reasonable person may have known and believed." The government claimed that the defendant pharmacies had "received notice that the phrase 'usual and customary' referred to their discounted prices," and that they "comprehended those notices and then tried to hide their discounted prices."

The Supreme Court concluded that if the pharmacies actually knew what the phrase meant when the claims were submitted, then they may have known that their claims were false. The ambiguity of the phrase does not preclude the possibility that the defendants knowingly submitted a false claim if the defendants actually understood the meaning of the phrase despite its ambiguity.

It does not matter whether some other objectively reasonable interpretation of "usual and customary" could apply to pharmacy claims based on nondiscounted prices. What matters is whether the defendants actually knew that their claims were false.

The case has been sent back to the lower courts for further proceedings. Legal liability will be determined based on a subjective standard for interpreting the knowledge requirement related to the phrase "usual and customary."

What matters is whether the defendants actually knew that their claims were false.

Takeaways

The pharmacy professional can play a significant role in promoting the economic efficiency of drug therapy while maintaining or improving the quality of therapeutic outcomes. Yet public policy concerns related to rising pharmaceutical costs cannot be effectively addressed through marketing gimmicks that may violate federal law.

Discount pharmacy pricing can convey the inaccurate message that pharmacies control drug prices and that pharmacies are responsible for escalating drug costs.

Pharmacy discount programs may shift the price of medications from drugs that are being discounted to drugs that do not qualify for the discount, creating an illusion of significant savings when the broader reality is otherwise.

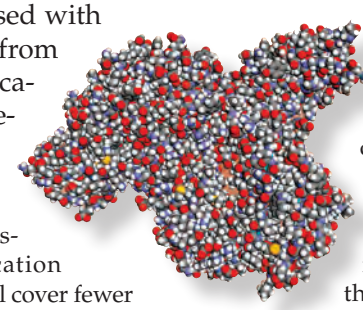
Pharmacy discounts can trivialize the value of pharmaceutical products and pharmacy services.

The recent Supreme Court case serves as a reminder that pharmacy pricing strategies must be developed equitably, so that rational choices can be made by patients based on straightforward information. ■

Dispensing the correct quantity of somatropin can be complicated

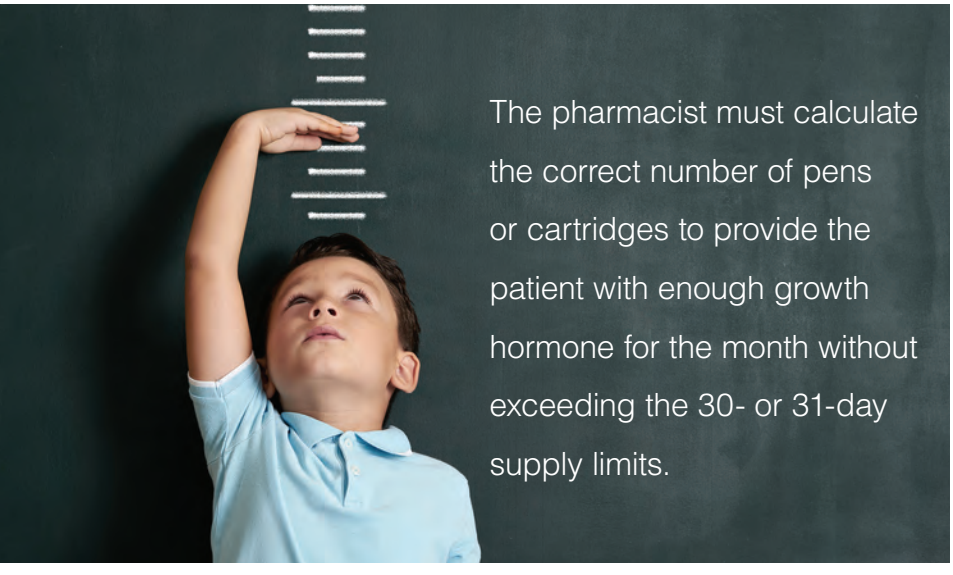
Institute for Safe Medication Practices, Horsham, PA

Somatropin human growth hormone is available from multiple manufacturers using various brand names (e.g., Genotropin–Pfizer, Humatrope–Eli Lilly, FlexPro–Norditropin, Omnitrope–Novartis, Saizen–EMD Serono, Inc., Zorbtive–EMD Serono, Inc.) and in multiple dosage forms (e.g., pen devices, cartridges to be used with pen devices, vials). The indications for use vary from product to product. This variety of products, indications, and dosage forms can present challenges to specialty pharmacies.



However, these pharmacies face several other challenges related to dispensing these products. They must have a process to calculate and verify the appropriate dose and dosing frequency as well as ensure the correct quantity and days' supply are dispensed.

Sometimes this requires dispensing medication amounts that will cover fewer than 30 or 31 days (e.g., a 23-day supply) since the pharmacy cannot dispense partial volumes from the medication containers and may not be able to split cartons containing multiple cartridges or pen devices.



Challenges

Most PBMs limit the quantity of medication that a pharmacy can dispense to a maximum of a 30- or 31-day supply. Depending on the patient's daily dose, this may require dispensing more than one somatropin pen or cartridge. However, the pharmacist must calculate the correct number of pens or cartridges to provide the patient with enough growth hormone for the month without exceeding the 30- or 31-day supply limits.

Another factor pharmacies must manage is whether the patient is receiving six or seven doses per week. For example, if a patient is prescribed FlexPro 10 mg/1.5 mL pens with a dose of 1 mg per day, three pens will last 30 days. If the patient's dose is 1 mg per day for six days per week, three pens will last 35 days. If the pharmacy cannot bill for a 35-day supply, they may dispense two pens (a 23-day supply). Or the pharmacy could recommend to the provider that the prescription be changed to FlexPro 5 mg/1.5 mL pens, as five pens will last 29 days.

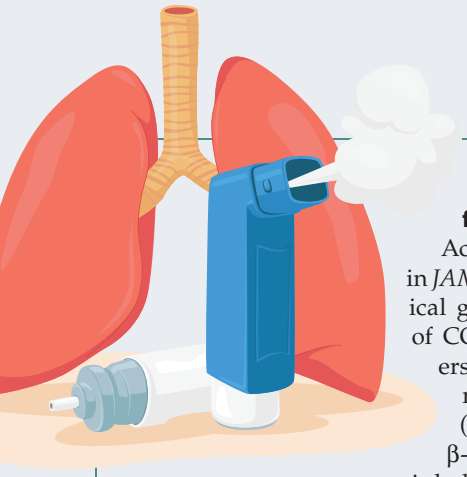
These situations result in additional workload for pharmacists and pharmacy technicians or liaisons as they must contact the provider to suggest different products to maximize the days supply, and then they have to contact the patient more frequently to coordinate refills. And, given the variable quantity often required for these medications, there is an increased risk that the refill call with the patient or actual refill dates will be set incorrectly, potentially leaving patients without medication for days. There is also the potential for increased costs for the patient if they must pay their regular monthly copay but only receive a 23-day supply. Also, if a patient is enrolled with a copay card that has a limited number of charges per year (e.g., 12 charges for 12 months), they will expend all charges before the end of the year if they need more medicine before 30 days. So, at the end of the year, they may need to pay higher out-of-pocket copays.

Takeaways

Evaluate your pharmacy workflow and the potential for errors when dispensing growth hormone products. Leverage technology to help standardize work and calculations. This may be possible within your pharmacy dispensing and/or clinical patient management software platforms. As drug names may be truncated and carton contents difficult to decipher when selecting products during order entry, work with the pharmacy's dispensing software vendor to provide a hyperlink to images of the product cartons on data entry and verification screens.

Investigate requiring a pharmacist to double check and document all growth hormone dosing calculations. Finally, educate staff on growth hormone challenges and risks. ■

Inpatient*Insights*



LAMA–LABA therapy may be preferred to ICS–LABA for patients with COPD

According to a recent paper in *JAMA Internal Medicine*, clinical guidelines for treatment of COPD recommend inhalers containing long-acting muscarinic antagonists (LAMAs) and long-acting β-agonists (LABAs) over inhalers containing inhaled corticosteroids (ICSs) and LABAs. However, data from randomized clinical trials comparing these combination inhalers have been conflicting,

Feldman and colleagues from Brigham and Women's Hospital and Harvard Medical School (Boston) conducted a propensity score–matched cohort study to determine which inhalers are associated with the least incidence of exacerbations and pneumonia hospitalizations.

The study, published online on May 22, 2023, included over 137,000 patients from Optum's Clinformatics Data Mart, a large commercial insurance–claims database, who had a diagnosis of COPD and filled a new prescription for a combination LAMA–LABA (aclidinium/formoterol, glycopyrronium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol) or ICS–LABA inhaler (budesonide/formoterol, fluticasone/salmeterol, fluticasone/vilanterol, or mometasone/formoterol) between January 1, 2014, and December 31, 2019. Patients younger than 40 years were excluded, as were those with a prior diagnosis of asthma.

Over 30,000 matched pairs were identified for the primary analysis, which indicated that LAMA–LABA use was associated with an 8% reduction in the rate of first moderate or severe COPD exacerbation and a 20% reduction in the rate of first pneumonia hospitalization, compared with ICS–LABA use.

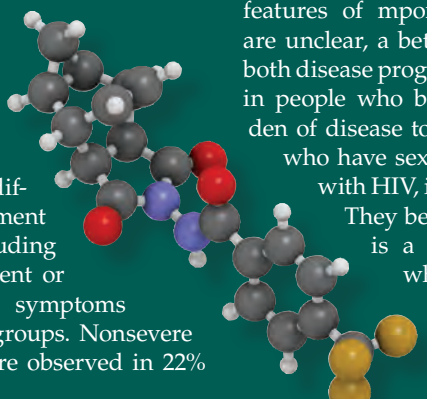
The authors indicated that these findings were robust across a range of prespecified subgroup and sensitivity analyses. ■

Tecovirimat effective in treating patients with both HIV and mpox

Preliminary data have shown that tecovirimat, a novel antiviral approved for the treatment of human smallpox, can be effective in patients with mpox. Although it has not been approved by FDA for treatment of mpox, CDC recommends that it be considered for use in patients with comorbid diseases and those with severely compromised immunity, such as patients with HIV.

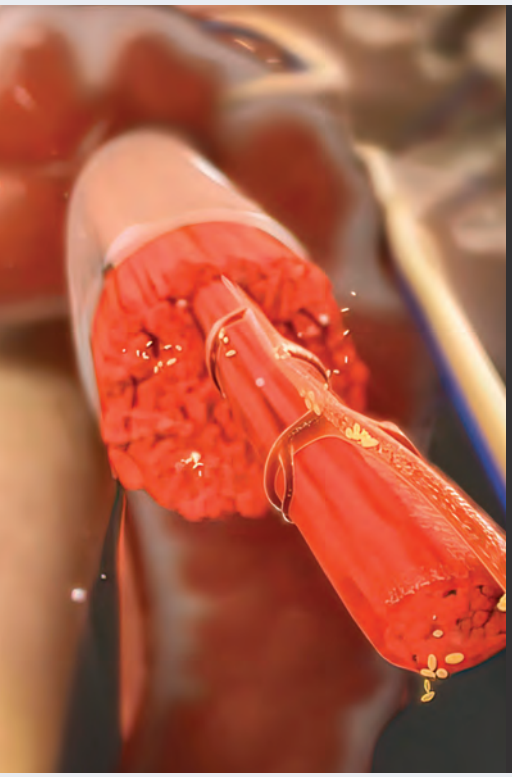
In a recent study published in the May 2023 issue of *Annals of Internal Medicine*, researchers from Columbia University Medical Center, NewYork-Presbyterian Hospital, and Weill Cornell Medicine, compared mpox treatment outcomes in patients with HIV and those who are HIV negative.

The retrospective cohort study included 196 patients treated with tecovirimat from June 20, 2022, to August 29, 2022, at two academic medical centers in New York City. Of the 154 patients who tested positive for mpox, 72 also tested positive for HIV.



Results of the study showed no difference in treatment outcomes, including days to improvement or rate of persistent symptoms between the two groups. Nonsevere adverse effects were observed in 22% of the participants and the two groups had similar rates of hospitalization, indications for treatment, and co-occurring infections.

The authors concluded that although the future incidence and demographic features of mpox infection outbreak are unclear, a better understanding of both disease progression and treatment in people who bear the greatest burden of disease to date, primarily men who have sex with men and those with HIV, is critically important. They believe that tecovirimat is a promising treatment whose efficacy will hopefully be borne out in future rigorous studies. ■



Standardized procedure for periprocedural DOAC use in patients with AFib

Discrepancies remain in periprocedural DOAC recommendations for patients with AFib undergoing elective surgery. In an effort to develop a standard procedure, Alan N. Barkun, MD, and colleagues at several international institutions conducted a cohort study among adult patients receiving a DOAC (apixaban, rivaroxaban, or dabigatran) for AFib who were scheduled for an elective procedure or surgery.

The study, published in the May 2023 issue of the *American Journal of Gastroenterology*, included 556 patients undergoing digestive endoscopy. Most of the patients underwent colonoscopies (63.3%) or gastroscopies (14.0%), with 18.9% having both on the same procedural day. Standardized periprocedural management consisted of DOAC interruption 1 day pre-endoscopy with resumption 1 day after procedure at low-moderate risk of bleeding or 2 days after procedure in patients with a high bleeding risk. Thirty-day outcomes included GI bleeding, thromboembolic events, and mortality.

Results of the study showed that patients with AFib undergoing DOAC therapy interruption for elective digestive endoscopy experienced low rates of arterial thromboembolism and major bleeding. Four patients (0.7%) experienced an arterial thromboembolic event within 30 days, GI bleeding events occurred in 2.5% of patients with major GI bleeding in 0.9% of patients. Three patients (0.5%) died after the endoscopy.

The authors concluded that this strategy should be considered for most patients with AFib who undergo elective endoscopic procedures. ■

Tirofiban shown to be effective for treatment of stroke

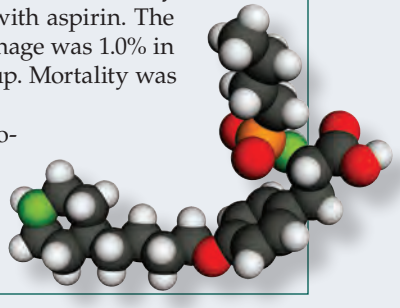
Recent observational studies have suggested that the glycoprotein IIb/IIIa receptor inhibitor tirofiban may be effective in selected patients with acute ischemic stroke. However, the use of tirofiban in patients with no evidence of complete occlusion of large- or medium-sized vessels has not been extensively studied.

The RESCUE BT2 investigators conducted a multicenter trial in China that evaluated the efficacy of tirofiban versus aspirin in patients with ischemic stroke without occlusion of large- or medium-sized vessels and with an NIH Health Stroke Scale score of 5 or more and at least one moderately to severely weak limb. The study was published in the June 1, 2023, issue of *NEJM*.

Patients were assigned to receive I.V. tirofiban (plus an oral placebo) or 100 mg oral aspirin (plus I.V. placebo) for 2 days; all patients then received oral aspirin until day 90. The primary efficacy end point was an excellent outcome, defined as a score of 0 or 1 on the modified Rankin scale at 90 days. The primary safety end points were death and symptomatic intracranial hemorrhage.

Results of the trial showed that 29.1% of the patients treated with tirofiban had a score of 0 or 1 on the modified Rankin scale at 90 days compared with 22.2% of the patients treated with aspirin. The incidence of symptomatic intracranial hemorrhage was 1.0% in the tirofiban group and 0% in the aspirin group. Mortality was similar in the two groups.

The authors concluded that the use of I.V. tirofiban was associated with a greater likelihood of an excellent outcome than low-dose aspirin. Incidences of intracranial hemorrhages were low but slightly higher with tirofiban. ■



Experts issue updates for managing lower GI bleeds

Ariel L. Clark, PharmD

Lower gastrointestinal bleeds (LGIBs) account for approximately 250,000 emergency department (ED) visits annually and occur more often than upper gastrointestinal bleeds (UGIBs), according to the latest figures.

Patients with an LGIB are at risk for major complications, which can lead to lengthy hospital stays, concurrent infections, and added treatment costs. In their recent clinical practice guideline on the management of LGIBs, published in the February 2023 issue of the *American Journal of Gastroenterology*, the American College of Gastroenterology (ACG) provides clinicians with updates on the management of LGIBs, including helpful key concepts and recommendations.

Risk factors for lower GI bleeds

As with other types of bleeds, medications put patients at a higher risk. The most risky ones include antiplatelets, like aspirin, as well as anticoagulants, like vitamin K antagonists and DOACs. Patients who have experienced a cardiovascular episode, such as a heart attack, are most often given dual antiplatelet therapy. Aspirin, even at a low dose when used with another antiplatelet medication, significantly increases a patient's bleed risk, according to the American Heart Association.

Management and risk assessment

Signs of a GI bleed, including vomiting blood and hypovolemic shock, will be present upon a patient's admission to the ED. Clinicians should carefully review patient presentations upon admission and pay particular attention to these symptoms as well as gather a thorough patient history.

There are also several predictive tools that can be used to determine bleed severity. The 2023 guideline update includes information on new predictive tools, including the Oakland score and SHA2PE score, to help clinicians determine if a patient can be safely discharged.

Key guideline concepts and recommendations

Excessive bleeding causes hemodynamic instability due to lack of appropriate blood flow through the body. The ACG guideline update recommends crystalloid I.V. fluid replacement to optimize blood pressure.

Hematochezia. Bleeding from the rectum can be a sign of both a UGIB or an LGIB. Loren and Abbid noted in a 2020 *American Journal of Gastroenterology* article that 15% of hematochezia cases were due to UGIB. Providers should rule out a proximal source with an upper endoscopy.

Coagulopathy and antithrombotics reversal. Clinicians should always review medication lists for patients presenting with bleeds.

For the majority of patients, reversing an agent shouldn't be necessary unless the INR is greater than 2.5, according to the update. Platelet replacement can also be considered in patients with severe LGIB. Experts suggest replacement to a level of 30–50 x109/L if needed.

Diagnostics. Along with upper endoscopy to rule out other bleeds, colonoscopy remains a key diagnostic indicator for LGIBs.

Hemodynamic instability. Treatment of hemodynamic instability can include the use of packed red blood cells. ACG recommends withholding this strategy unless the patient's hemoglobin level reaches a threshold of 7 g/dL.

Coagulopathy and antithrombotics reversal. When the patient has a life-threatening LGIB or an INR that is "substantially exceeding the therapeutic range," reversal should still be considered. For patients with nonvalvular AFib taking warfarin for stroke prevention or a DOAC who require reversal, ACG has specific recommendations as to which reversal agent should be used.

In almost all cases, oral anticoagulants should be held on admission if reversal isn't needed.

Diagnostics. The 2023 ACG update strongly recommends a colonoscopy for patients who are hospitalized with an LGIB, unless bleeding has subsided. Prep for the colonoscopy should be with 4–6 L of polyethylene glycol and clinicians should avoid emergent procedures.

Clinicians can also consider computed tomography angiography in cases when patients continue to have severe rectal bleeding.

Resuming antithrombotics. Due to the risk of thromboembolism after an acute LGIB resolves, antithrombotics and/or antiplatelets should be resumed, according to the update, except in the case of diverticular hemorrhage. ■

New stem cell product answers unmet need for cancer patients without bone marrow match

Corey Diamond, PharmD

In April 2023, FDA approved Omisirge (omidubicel-onlv–Gamida Cell Ltd.), a cell therapy derived from modified donor umbilical cord blood. Omisirge is the first FDA approval for an "expanded" umbilical cord blood product (i.e., umbilical cord blood products that have been cultured in a laboratory to artificially enhance natant stem cell production).

The market niche for Omisirge is to give stem cell transplant candidates—often patients suffering from blood cancers—an alternative option if they are unable to find a suitable donor.

Oncology experts now have more treatment avenues available for patients who are unable to secure a fully matched bone marrow donor.

Omisirge versus standard of care

The FDA approval of Omisirge is based on results of a Phase 3, randomized, multicenter study conducted by the manufacturer, Gamida Cell, Ltd. Results were published in the journal *Blood* in October of 2021. Researchers compared Omisirge transplantation to standard transplantation of umbilical cord blood. The trial consisted of 125 patients with confirmed blood cancers, including hematological malignancies, acute lymphoblastic leukemia, acute myelogenous leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, lymphoma, and acute leukemia.

The primary outcome was the median time to engraftment, defined as an absolute neutrophil count of >500/µL. The research team found that patients treated with Omisirge had a statistically significant reduction in the time to engraftment versus patients treated with a standard umbilical cord blood transplant. In fact, patients in the Omisirge treatment arm had their median time to engraftment reduced by roughly half compared to the active comparator (10 days vs. 20.5 days, respectively).

Furthermore, the trial results were significant in three secondary outcomes, with Omisirge reducing the median time to platelet engraftment by 13 days as well as rates of infection and hospitalization. While the trial was not powered to detect differences in long term outcomes, the two treatment arms did not differ significantly in overall incidence of chronic graft versus host disease (GvHD), severity of GvHD, relapse rate within 15 months, non-relapse mortality, cumulative neutrophil engraftment by day 42, and overall survival.

Advantages

Omisirge's theoretical advantage as an "expanded" blood-cell therapy product allows it to combine the ideal properties of both bone marrow and umbilical cord blood as a graft source. Like a bone marrow sourced graft—with an average engraft time of 10 days—Omisirge engrafts extremely quickly, reducing the risk of infection. However, unlike a bone marrow graft source, and similar to an umbilical cord graft, Omisirge may yield long term advantages, such as better survival and GvHD rates.

With the approval of Omisirge, oncology experts now have more treatment avenues available for patients who are unable to secure a fully matched bone marrow donor. Along with that, clinical algorithms for selecting a graft source may need to be re-evaluated.

"Today's approval is an important advance in cell therapy treatment in patients with blood cancers," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, in a news release. "Hastening the return of the body's white blood cells can reduce the possibility of serious or overwhelming infection associated with stem cell transplantation. This approval reflects FDA's continued commitment to supporting development of innovative therapies for life-threatening cancers."

Safety and warnings

Omisirge carries similar risks to other approved umbilical cord products, such as a boxed warning for infusion reactions, GvHD, engraftment syndrome, and graft failure.

Additionally, patients may require monitoring for signs and symptoms of possible transmission of serious infections, as well as life-long monitoring for secondary malignancies or rare genetic diseases transmitted from donor cells. ■

Pharmacists provide revenue, quality of care through AWV and CCM services

Loren Bonner

As physician practices try to meet outcomes required by new value-based payment models, pharmacists are being brought in to help them meet certain quality metrics.

Results of these arrangements appear to be positive, according to a new study published March 1, 2023, in the *American Journal of Health-System Pharmacy*.

Pharmacists in these arrangements are mostly spending their time performing chronic care management services (CCM) and transitional care management, which are generally non–face-to-face visits reimbursed by Medicare. Pharmacists can also see patients in person for evaluation and management (E/M) services and annual wellness visits (AWV), also reimbursed by Medicare.

Researchers of the new study found that pharmacist provision of AWVs and CCM in a privately owned family medicine clinic grew the number of patients who received these services while also increasing reimbursement for the clinic.

"This information provides additional evidence that pharmacists can positively contribute to clinical practice, by improving both revenue and quality of care via AWVs and CCM," said study author Keri Mack, PharmD, from Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy in Florida.

While the total number of AWVs completed remained about the same, Mack said the reimbursement from those visits increased. The boosted revenue was likely driven by improvements in advanced care planning, annual depression and alcohol misuse screenings, and counseling for CVD and obesity. Several of these counseling codes and screenings are also tied to current Merit-based Incentive Payment System (MIPS) quality measures, she noted.

"AWVs represent an important opportunity for preventative care and to ensure clinicians are meeting and reporting quality metrics, which are now tied to reimbursement," said Mack.

Increases

The research team only examined reimbursement for CCMs and AWVs. They reviewed claims data for Current Procedural Terminology codes and reimbursement applicable to AWVs and CCM and found that reimbursement from AWVs increased by $25,807.21 in 2018 and $26,410.01 in 2019 compared to 2017 for the small family practice where the study took place. Additionally, reimbursement from CCM increased by $16,664.29 in 2018 and $5,698.85 in 2019.

Researchers also found that with pharmacists' services in place, the number of CCM encounters increased to 362 in 2018 and 152 in 2019 and the number of AWVs totaled 236 and 267, respectively.

Completed Healthcare Effectiveness Data and Information Set (HEDIS) measures and star ratings also increased during the study period.

"The major strength of this study was that improvements in both quality metrics and reimbursement were shown even with a single pharmacist in a small private practice," said Mack.

However, in 2019, there were issues with the third-party billing vendor for the practice. Delayed billing of office visits led to many claims being denied as a penalty for untimeliness, according to Mack. Reimbursement for pharmacist-led AWVs and CCM may not be representative of the true reimbursement potential had these billing issues not been present, Mack added.

Additionally, since this practice was not required to report MIPS measures until 2020, those measures could not be analyzed during the timeframe of the study.

"The published evidence on reimbursement for pharmacist-led AWVs and CCM is relatively limited, but our study adds to that body of literature without contradicting results of other publications on this topic," Mack said.

Getting started

Mack believes that data on this topic not only allow the profession of pharmacy to move forward, but help fill an important need in primary care.

"In the world of primary care, we not only have a shortage of physicians, but increased demands on those remaining physicians," Mack said. "Our payment systems are shifting from a fee-for-service to a quality-based payment system. Reporting these quality metrics for a practice, or even for individual providers can be hefty, which further increases demands on those providers and allows less time for patient care."

However, using pharmacists in this capacity remains slow to catch on, particularly in certain regions of the United States.

"If pharmacists are looking to embed themselves within a clinic, choosing a progressive physician who is pro-pharmacy is a great place to start," said Mack.

"As word gets around as to the value of this pharmacist in one clinic, more physicians may be ready to embed a pharmacist within their own practice," she said. "If pharmacists are already within a clinic and experiencing barriers, starting with a simpler clinical service, such as AWVs, can be beneficial to build trust prior to expanding to other services, like diabetes management via a collaborative practice agreement." ■

Visit pharmacist.com/Practice/Practice-Resources/Billing-Payment-Center to access APhA's billing and payment resources designed to help you understand existing and emerging opportunities for compensation from providing certain patient care services.

ASHP releases latest workforce survey results

Esther Boadi, PharmD

In April 2023, the American Society of Health-System Pharmacists (ASHP) released survey results about pharmacy workforce well-being in the hospital setting. Pharmacy directors at 1,498 general and children's medical/surgical hospitals in the United States were surveyed using a mixed-mode method of contact by email and mail. IQVIA supplied data on hospital characteristics and the survey sample was drawn from IQVIA's hospital database. The response rate was 23.7%.

Pharmacist prescribing

The survey showed that inpatient pharmacists independently prescribed medications, including the selection, initiation, monitoring, and adjustment of medication therapy pursuant to a diagnosis in 27.1% of hospitals in 2022, compared to 30.9% of hospitals in 2021 and 21.1% of hospitals in 2020.

Data analytics

The survey results indicated that advanced analytics such as artificial intelligence, machine learning, and predictive analytics, are used in 8.7% of hospitals, an increase from 4.0% in 2021 and 2.6% in 2020.

While basic analytics, such as data from smart pumps, clinical decision support or automation in dispensing, and compound technology, are used in 84.7% of hospitals, the survey found that 6.6% of hospitals do not use any form of analytics.

Pharmacy service-level integration

Survey results show that 53.6% of hospitals report some integration of pharmacy services at all transitions of care, while 27.9% report that they are not at all integrated. However, 16.6% of hospitals consider themselves mostly integrated, an increase from 8.6% in 2021.

Advanced pharmacy technician activities

While traditional pharmacy technician activities such as purchasing, billing, and controlled substance management still predominate, more advanced roles are emerging. These advanced roles include regulatory compliance, 340B Drug Pricing Program management, responsibility for USP chapter <797> compliance, and initiation of medication reconciliation. Technicians have taken on many of these advanced roles since 2021.

Workforce well-being and shortages

Since the beginning of the pandemic, the entire workforce has been struggling with staff shortages, job training, job turnover, burnout, and overall employee well-being.

Survey results showed that various aspects of burnout are being seen in 34.0% of hospitals, while 83.7% of the hospitals surveyed are attempting to prevent and mitigate burnout.

Health-system pharmacies are experiencing workforce shortages; however, the survey results showed that these shortages have had limited impact on budgeted positions, with 62.8% of hospital pharmacy directors reporting that their budgeted pharmacist full-time employees (FTEs) remained the same.

The survey results indicate that 12.3% of pharmacy technician FTE positions are vacant. Additionally, 74.6% of hospitals reported inpatient pharmacy technician turnover, with a rate of 26.9%—an increase of 13.2% since 2014.

For pharmacists, 4.7% of FTE positions are vacant, with the overall rate of pharmacist turnover at 11%. In 2014, by contrast, the overall turnover rate was 6.8%.

The average number of full-time equivalents per 100 occupied beds is 16.9 for pharmacists and 16.1 for pharmacy technicians.

The survey authors concluded that adoption of practice advancement initiatives has continued the positive trend from past years despite workforce issues. The full survey results were published online on April 6, 2023, in the *American Journal of Health-System Pharmacy*. ■

A minute with ...

Meagan A. Brown, PharmD, BCACP

Clinical Associate Professor, Dept of Pharmacy Practice, and PGY-1 Community-Based Pharmacy Residency Director, University of Mississippi School of Pharmacy, Jackson, MS; Clinical Pharmacist, G.A. Carmichael Family Health Center, Yazoo City, MS

Member since 2006

"I have truly enjoyed being engaged in APhA. I feel that APhA has opportunities for all who want to be involved—through special interest group work, subcommittees, leadership, you name it! It is truly an organization that makes you feel 'at home' when you come to conferences, and one that leaves you feeling invigorated as you return home."

How has APhA helped you establish meaningful connections?
As a residency program director, it's been really fantastic to find commonality but also celebrate the uniqueness of community residency, and APhA has facilitated a lot of my connections in this space. I have had the opportunity to work with individuals on committees who I otherwise may not have met.

How does APhA help you thrive in your everyday practice?
As a member, I rely on trusted information from APhA on everything, from vaccines to the latest on pandemic-related issues, to provide me with resources for my students and patients.

What excites you about the profession of pharmacy?
I am excited most to see how some of the creative things we learned during the pandemic can really transform how we view our profession, by highlighting all the amazing ways pharmacists continue to provide care for patients and how we can turn this into a sustainable model that emphasizes the value of having a pharmacist on your team.

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?
I have the privilege of running a cardiometabolic consult service in a federally qualified health center, serving the underserved, under a collaborative practice agreement in rural Mississippi.

I was working diligently with a patient who went from nonchalantly telling me she "had to die from something" to jumping out of her chair and hugging me when we were finally able to get her A1C from double digits almost to her goal.

She had never seen an A1C near 7 in her 15 years of dealing with diabetes, which I'm sure made her believe it was unachievable. It took us about 3 years to convince this patient that she was worth it—making the changes we asked and adhering to her regimen, while asking questions that helped us understand why she may have been hesitant to accept our suggestions at times. We are still seeing her today, she is still making great choices for her health, and we have empowered her in a way that no one had before. ■

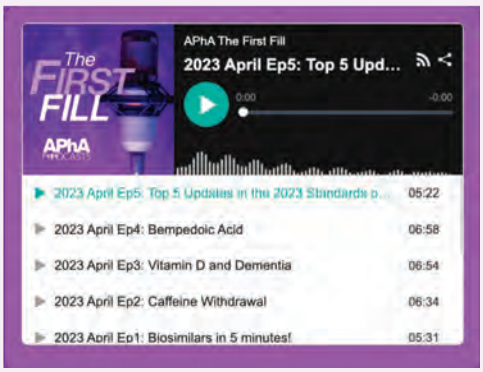
Get involved

Looking to join a professional community dedicated to caring for underserved patient populations? Look no further than the Care of Underserved Patients (CUP) Special Interest Group (SIG)! As a member of this community, you'll network with practitioners, administrators, and educators who share your passion for providing patient-centered care to underserved patients. Whether you're currently practicing in a clinical setting or looking to get involved with federally qualified health centers, free and charitable health clinics, or other community-based pharmacy settings, this community is for you.

"The CUP SIG is passionate about improving health equity by finding ways to address social determinants of health," said Anna Staudt, SIG coordinator. "The SIG offers many invaluable resources and networking opportunities related to improving medication access as well as linkage to other services because medication use is only one part in a holistic approach to care."

Don't miss out on this opportunity to connect with like-minded professionals and make a real difference in the lives of underserved patients. Join the CUP SIG today by visiting apha.us/UnderservedSIG to learn more! ■

Did you hear?



APhA's new podcast, The First Fill, allows pharmacists to grab bite-sized CPE credits on the go! Get your 5-minute doses now on Spotify, Google Podcasts, Apple Podcasts, or APhA's website.

Each month, APhA releases five, 5-minute podcast episodes offering a fresh dose of education highlights, practice pearls, and insights to inform your pharmacy practice and advance patient care.

Listen to brand-new episodes at your convenience! The First Fill allows you to earn CPE on the go and is available at www.pharmacist.com/Podcasts/TheFirstFill. The first six months are free. ■

Get published

APhA's Books and Digital Publishing department is looking for new authors to contribute to an Open Access resource on PharmacyLibrary, Cultural Aspects of Health Care: A Toolkit for Pharmacy Education. This resource is designed to equip pharmacy educators with practical tools for learners to better serve individuals from diverse cultures, communities, and populations. The current collection of 33 active learning strategies and reflection activities enables educators to integrate cultural aspects into existing health care courses and educational seminars within pharmacy and other related disciplines.

The overarching purpose of the toolkit is to provide educators with a resource to guide learners to

- Evaluate and challenge attitudes and values about diverse cultures, communities, and populations.
- Develop a knowledge framework for serving diverse cultures, communities, and populations.
- Develop skills to work with diverse cultures, communities, and populations.

If you are interested in contributing, please send your CV to aphabooks@aphanet.org. ■

What's on tap: 2023 Beers Criteria update

Katie Meyer, PharmD, BCPS, BCGP, Director of Content Creation; and Hailey Mook, PharmD, Senior Manager, Custom Education, APhA, Washington, DC

In 1991, Mark Beers, MD, and colleagues at University of California Los Angeles developed the Beers Criteria to identify potentially inappropriate medication (PIM) for nursing home residents.[1] Since their initial release, the Beers Criteria has been updated six times and expanded the criteria to apply to all adults 65 years and older.[2,3] In 2011, the American Geriatrics Society (AGS) took ownership of updating the Beers Criteria, which was then updated in 2019.[4] In May 2023, AGS 2023 updated the AGS Beers Criteria for PIM use in older adults.[5]

The number of medications that older adults take continues to grow, with more than 40% of this age group taking five or more prescriptions a day, also known as polypharmacy.[6] The high medication burden associated with polypharmacy has shown to increase odds of developing an adverse drug event (ADE), which is harm experienced by a patient because of exposure to a medication.[7] An additional factor that leads to older adults experiencing ADEs include pharmacokinetic and pharmacodynamic changes that result from aging.[8] A reduction in renal and hepatic clearance and an increase in volume of distribution for lipid-soluble drugs prolong the elimination half-life of medications and increased sensitivity to medications demonstrates these changes.[9]

According to CDC, older adults visit emergency departments (EDs) more than 450,000 times a year for an ADE, creating an additional $3.5 billion in health care costs.[10,11] Knowledge of the PIMs and potential risks of using the medications can decrease further ADEs in your patients.

Updates to 2023 Beers Criteria

Structural updates

The updated 2023 Beers Criteria is structured similarly to the prior publication, with a few exceptions.[5] One notable exception is the removal of medications with low or absent use in the United States. Medications that were previously included in tables within the publication that were used by less than 4,000 Medicare beneficiaries based on the 2020 data that are no longer on the U.S. market were removed from their prior table and included in a separate table within the publication. Some examples of medications that were removed include the benzodiazepines flurazepam and quazepam as well as the NSAIDs fenoprofen, ketoprofen, meclofenamate, and mefenamic acid—all of which were removed due to low use. Ranitidine was also removed due to its removal from the U.S. market in 2020.[12]

Another structural element added to the 2023 Beers Criteria is the addition of a table that summarizes companion articles that were written to accompany the 2015 and 2019 iterations of the Beers Criteria to provide recommendations for patients, providers, and health systems for how to use the Beers Criteria.[5,13,14] This table reinforces the principle that the Beers Criteria help clinicians identify PIM use in older adults, but that clinicians should make decisions based on individual patient characteristics and goals.

Additional time will be spent on how pharmacists should use the Beers Criteria later in this article.

Lastly, one subtle but important update to the 2023 Beers Criteria was the addition of language around exceptions noted within the criteria to ensure the criteria are more individualized to clinical practice and more diverse and relevant across multiple settings of care. The panel recognizes the limitations caused by a lack of diversity in clinical study populations and includes exceptions within the criteria in hopes of ensuring that the recommendations are not oversimplified and that the full clinical scenario is taken into consideration during decision-making.[5]

Clinical updates

The 2023 Beers Criteria had several relevant clinical updates for pharmacists.

It should be noted that only a selection of clinically important updates is reviewed in this article.

Learning objectives

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

- Discuss the prevalence, mechanism, and impact of adverse drug reactions in older adults.
- Recall updates to the 2023 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults.
- Review evidence to support updates to the 2023 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults.
- Identify how pharmacists should apply the 2023 Beers Criteria in practice.

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. **According to CDC, older adults visit emergency departments more than ____ times a year due to an ADE?**
   a. 350,000
   b. 450,000
   c. 550,000
   d. 650,000

2. **What additional adverse outcomes were added to the 2023 Beers Criteria rationale to avoid the use of proton pump inhibitors in older adults?**
   a. *Clostridioides difficile* infection and pneumonia
   b. GI malignancies and pneumonia
   c. Bone loss and fractures
   d. Blood clots and bone loss

3. **In which of the following patients should baclofen be avoided based on updates to the 2023 Beers Criteria?**
   a. A 74-year-old man with an eGFR of 65 mL/min/1.73 m^2 taking baclofen for chronic low back pain
   b. A 66-year-old woman with an eGFR of 35 mL/min/1.73 m^2 taking baclofen for spasticity related to multiple sclerosis
   c. A 55-year-old man with an eGFR of 90 mL/min/1.73 m^2 taking baclofen for chronic low-back pain
   d. A 75-year-old woman with an eGFR of 70 mL/min/1.73 m^2 taking baclofen for spasticity related to multiple sclerosis

Updates related to cardiovascular disease, diabetes, fall, fracture and delirium prevention, estrogens, and proton pump inhibitors (PPIs) will be reviewed. Table 1 provides a summary of selected changes and recommendations for pharmacists.

Relevant updates in cardiovascular disease

A large focus of the 2023 Beers Criteria was the use of anticoagulants in older adults. Because anticoagulants are a mainstay of therapy for conditions such as prevention of thromboembolic stroke in patients with chronic atrial fibrillation (AFib) and prevention and treatment of venous thromboembolism (VTE), it is unsurprising that the number of patients using these medications has increased as the population in the United States continues to age.[15]

Over 11% of Medicare Part D beneficiaries use an oral anticoagulant.[16] Bleeding is the primary ADE associated with the use of anticoagulants, with intracranial hemorrhage and GI bleeding among the more severe bleeding events associated with use.[15] The vitamin K antagonist (VKA) warfarin and the direct oral anticoagulants (DOACs) apixaban and rivaroxaban are among the most used anticoagulants in older adults that pose a potential risk of an ADE.

The 2023 Beers Criteria recommends that the anticoagulants warfarin and rivaroxaban should be avoided in older adults.[5] Warfarin was added to this list based on emerging evidence that, compared with DOACs, warfarin has higher risk of major bleeding and similar or lower effectiveness for initial treatment of nonvalvular AFib and VTE, leaving DOACs to be the preferred choice. This recommendation is consistent with the 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation, which stated that non–vitamin K oral anticoagulants (NOACs) are recommended over warfarin in NOAC-eligible patients with AFib.[17] The evidence supporting this recommendation comes from four randomized controlled trials (RCTs) that demonstrate at least noninferiority of NOACs compared with warfarin.

A similar statement comes from the American Society of Hematology 2020 Guidelines for Management of Venous Thromboembolism, which suggests using DOACs over VKAs for treatment of VTE.[18]

It should be noted that patients whose symptoms are well-controlled (i.e., >70% time in range [TIR] INR and no adverse effects) with warfarin could remain on warfarin therapy.[5]

The recommendation of rivaroxaban for the treatment of long-term nonvalvular AFib and VTE was previously to use with caution in older adults, but the 2023 Beers Criteria now recommends to avoid its use in older adults. New evidence surrounding the bleeding risk associated with rivaroxaban use compared to apixaban or dabigatran found that rivaroxaban had a higher risk of major bleeding.[19] Bonde and colleagues found that rivaroxaban was associated with 1.89 RR of major bleeding compared to apixaban.[19]

A 2017 systematic review and meta-analysis found that rivaroxaban was associated with significantly higher major bleeding risk compared with dabigatran.[20] With these recommendations in mind, there may be situations in which warfarin and rivaroxaban are the better choice for a patient; for example, when finances are a barrier to use or medication adherence is a concern (and thus once-daily dosing is preferred).

Table 1. Summary of select changes to the 2023 Beers Criteria

Drug or drug class	Recommendation	Recommendation for pharmacists
Cardiovascular disease		
Warfarin	Avoid use due to increased risk of major bleeding for initial treatment of nonvalvular atrial fibrillation or VTE.	Recommend alterative options for treatment (i.e., DOACs) as appropriate if not contraindicated or limited by cost.
Warfarin	Avoid use with SSRIs due to increased risk of bleeding.	Review for drug–drug interactions, if an alternative anticoagulant or antidepressant can't be identified, moniter INR closely.
Rivaroxaban	Avoid use due to increased risk of major bleeding for long-term treatment of nonvalvular atrial fibrillation or VTE.	Recommend alterative options for treatment (i.e., apixaban) as appropriate if not contraindicated or limited by once-daily dosing.
Rivaroxaban	Reduce dose when CrCl <50 mL/min based on package insert.	Refer to package insert for dose reduction in patients with reduced kidney function. Recommend dose reduction based on indication.
Apixaban	Use is safe in CrCl <25 mL/min.	Closely monitor patient for adverse drug events such as bleeding.
Aspirin	Avoid initiating aspirin for primary prevention of cardiovascular disease in older adults.	Use shared clinical decision-making to determine if benefits outweigh risks of initiating/deprescribing aspirin for primary prevention of cardiovascular disease based on age, level of cardiovascular disease risk, and bleeding risk.
Diabetes		
Sulfonylureas	Avoid as first- or second-line monotherapy or add-on therapy unless there are substantial barriers to use of other agents.	Look for opportunities to recommend deprescribing or offer more appropriate alternatives (e.g., new start prescription; titration; or if patient presents with dizziness, shakiness, or low blood sugar; patient purchases glucose tablets).
SGLT-2 inhibitors	Use with caution in older adults due to increased risk of urogenital infections and euglycemic diabetic ketoacidosis.	Educate patient on signs and symptoms of euglycemic diabetic ketoacidosis such as mailaise, nausea, and vomiting and of urogenital infections.
Fall, fracture, and delirium prevention		
Anticholinergic agents	Cummulative exposure is associated with increased risk of falls, delirium, and dementia.	Review full medication profile for total anticholinergic burden. Make recommendations to reduce anticholinergic burden whenever possible.
CNS active agents	Avoid any combination of >3 CNS-active drugs. The guidelines now include gabapentinoids and skeletal muscle relaxants due to risk of falls and fractures.	Review full medication profile for use of multiple CNS-active agents. Make recommendations to reduce use of medications with sedative properties whenever possible.
Opioids	Opioids may increase risk of developing delirium.	Recommend a multimodal approach to pain management in older adults. Optimize nonpharmacologic and nonopioid pharmacologic options prior to using opioids in most circumstances.
Antidepressants	Mixed evidence for risk of falls and fractures; emerging evidence that SNRI use may increase risk of falls.	Re-evaluate effectiveness of antidepressants in older adults often; taper if continued use is not beneficial.

Table 1. Summary of select changes to the 2023 Beers Criteria cont'd

Other		
Baclofen	Avoid use when eGFR <60 mL/min/1.73 m^2.	Confirm eGFR; if <60 mL/min/1.73 m^2, suggest tapering to discontinuation or safer alternative.
Estrogens	Do not initiate systemic estrogen (e.g., oral tablets or transdermal patch). Consider deprescribing among older women already using estrogens.	Use shared clinical decision-making to determine if benefits outweigh risks of initiating/deprescribing systemic estrogen therapy.
Proton pump inhibitors	Avoid use due to increased evidence for risk of developing pneumonia and GI malignancies.	Look for opportunities to recommend deprescribing if more than 8 weeks of scheduled use unless for high-risk patients or failure of H2RAs.

Abbreviations used: CNS, central nervous system; CrCL, creatine clearance; DOACs, direct oral anticoagulants; eGFR, estimated glomerular filtration rate; INR, international normalized ratio; SSRI, selective serotonin reuptake inhibitor; VTE, venous thromboembolism.

Source: Adapted from Reference 5.

The drug–drug interaction between warfarin and selective serotonin reuptake inhibitors (SSRIs) is now included in 2023 Beers Criteria as part of drug–drug interactions that should be avoided in older adults.[5]

The mechanism behind the interaction is thought to be due to serotonin's ability to inhibit platelet aggregation coupled with inhibition of warfarin metabolism via the cytochrome P450 pathway.[21] SSRIs are found to have a favorable safety profile in older adults and therefore are commonly used in an estimated 20% of older adults.[22]

In addition to overall safety concerns, DOACs have also been updated to reflect dose adjustment guidelines based on kidney function. The recommendation to avoid use of apixaban at CrCl of <25 mL/min was removed based on increased evidence of safe use at lower CrCl. Only 25% of apixaban is eliminated by the kidneys, making it the DOAC least reliant on kidney function for clearance.[23] Based on the package insert, emerging evidence continues to become available for the safe use with careful monitoring of apixaban in patients with reduced CrCl.[24] The modification to rivaroxaban directs clinicians to refer to the package insert based on the indication for patients with a CrCl <50 mL/min.[25] The various indications for rivaroxaban use and the action points for dose reduction are numerous and are best reflected in the package insert.

To better align with the U.S. Preventive Services Task Force Recommendation (USPSTF) on the use of aspirin for primary prevention of cardiovascular disease (CVD), the 2023 Beers Criteria also recommends avoiding use of aspirin for primary prevention of CVD in older adults.[26] Based on the evidence from 14 RCTs provided in the USPSTF's recommendation, the increased risk of GI bleeding, intracranial bleeding, and hemorrhagic stroke do not outweigh the benefit of low-dose aspirin to reduce risk of cardiovascular events.[26]

The discontinuation of aspirin in older adults should be based on shared decision-making and take into account a person's age, level of CVD risk and bleeding risk, preferences, and reasons for taking aspirin. It is important to note that aspirin is generally still indicated in this population for secondary prevention of CVD.

Ticagrelor, an oral P2Y12 inhibitor, should be used with caution in older adults due to an increased risk of major bleeding compared with clopidogrel, especially in adults 75 years and older. A 2021 systematic review and meta-analysis found a 20% increased risk of a bleeding event in older adults using ticagrelor compared to clopidogrel.[27] It is still possible that the benefit of using ticagrelor may outweigh the risk for certain patients.

Dextromethorphan/quinidine, which is used for the treatment of pseudobulbar affect, experienced a slight modification in the 2023 Beers Criteria. As seen in its package insert, dextromethorphan/quinidine is contraindicated in heart failure due to concerns of QT prolongation.[28] Phase 2 clinical trials of the medication found in a randomized, double-blind (except for moxifloxacin) placebo- and positive-controlled (400 mg moxifloxacin) crossover thorough study found mean changes in corrected QT interval were 6.8 ms for dextromethorphan/quinidine alone and 9.1 ms for dextromethorphan/quinidine plus 400 mg moxifloxacin. Dextromethorphan/quinidine may exacerbate heart failure and should not be used in this patient population.

Relevant updates in diabetes

An update to the recommendation for the use of sulfonylureas in older adults has been added to the 2023 Beers Criteria. In the previous edition of the criteria, only long-acting sulfonylureas (e.g., glyburide, and glimepiride) were recommended to avoid in older adults due to risk of prolonged hypoglycemia.[4] The updated recommendation states that both short- (e.g., glipizide) and long-acting sulfonylureas should be avoided in older adults due to the increased risk of cardiovascular events, all-cause mortality, and hypoglycemia

compared to other agents.[5] The recommendation states to avoid use of these agents as first- or second-line monotherapy or add-on therapy unless there are substantial barriers to use of other options, such as cost of medication.

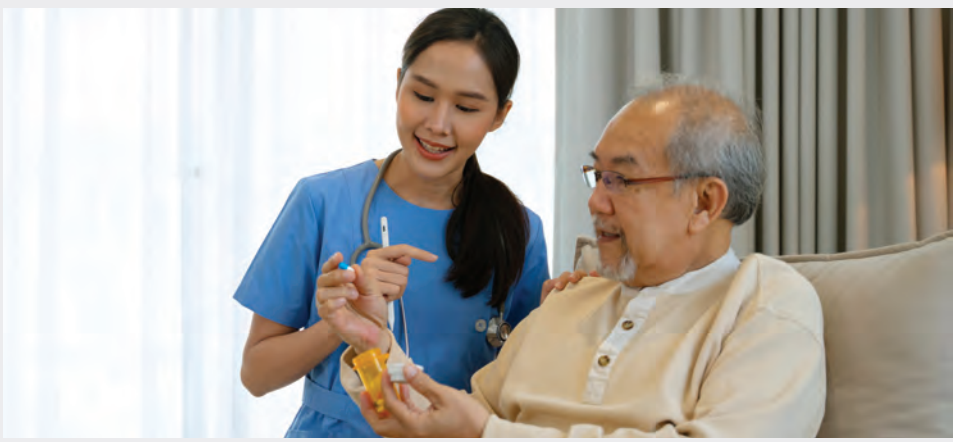
If sulfonylureas must absolutely be used, the 2023 Beers Criteria recommends that short-acting agents are chosen instead of long-acting ones because it is hypothesized that the likelihood of developing hypoglycemia increases with age due to a reduction in glucagon secretion and decreased ability to recognize warning signs of hypoglycemia.[29] The natural increase in hypoglycemia coupled with the role of sulfonylureas in an increasing chance of hypoglycemia leads to a great cause for concern in this population. A 2022 population-based cohort study demonstrated how sulfonylurea use compared to metformin was associated with an increased risk of cardiovascular death and ventricular arrythmia.[30] Sulfonylureas are thought to lead to a prolonged QTc interval via the blocking of potassium channels at the cellular level.

A popular alternative to sulfonylureas are sodium-glucose cotransporter-2 (SGLT-2) inhibitors due to their additional benefits to cardiovascular and kidney outcome that coincide with their effectiveness for treating patients with diabetes. According to the 2023 Standards of Care in Diabetes, "among individuals with type 2 diabetes who have established atherosclerotic cardiovascular disease or indicators of high cardiovascular risk, established kidney disease, or heart failure, sodium-glucose cotransporter 2 inhibitor and/or glucagon-like peptide 1 receptor agonist with demonstrated cardiovascular disease benefit is recommended as part of the glucose-lowering regimen and comprehensive cardiovascular risk reduction, independent of A1C and in consideration of person-specific factors."[31]

While these medications do provide an increased benefit to many patients with diabetes, they should be used in caution in older adults with careful monitoring. The 2023 Beers Criteria notes that the SGLT-2 inhibitors canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin should be used with caution due to the risk of developing urogenital infections (especially in women) in the first month of treatment and the risk of developing euglycemic diabetic ketoacidosis (DKA). The panel recognizes the value of these medications but strongly urges the recommendation to closely monitor these medications for ADEs.[5] Providers should screen patients regularly for signs and symptoms of urogenital infections and UTIs early on. Euglycemic DKA (i.e., blood glucose <250 mg/dL) may be more difficult to identify compared to DKA with hyperglycemia.[32] Signs of euglycemic DKA include malaise, nausea, and/or vomiting.

Reducing the risk of falls, fractures, and delirium in older adults

Delirium is common among hospitalized older adults and associated with adverse outcomes from increased risk of falls to prolonged hospitalization, institutionalism, and death. It has been estimated that delirium costs the U.S. health care system $38 billion to $152 billion annually.[33]



One recent systematic review identified potential predisposing factors associated with delirium and listed multiple medications, psychoactive medications, narcotic analgesics, and anticholinergic medication use as predisposing factors, among others that are not medication related.[33] Falls are a leading cause of injury among older adults, with an estimated 36 million falls reported each year.[34] Approximately 20% of falls lead to injury, including fractures, which is estimated to cost the U.S. health care system $5.96 billion annually.[35] The 2023 Beers Criteria continues to acknowledge the importance of reducing medication-related risk of delirium, falls, and fractures, and updates associated with use of medications with anticholinergic and sedative properties, opioids, and antidepressants will be discussed here.

Risks related to the use of medications with anticholinergic properties have been well-documented in the literature. ADEs related to anticholinergic medication use range from dry mouth, constipation, urinary retention, tachycardia, and blurred vision to cognitive impairment, delirium, and increased risk of falls and fractures.[36] Studies have also found correlation with use of medications with anticholinergic properties and increased risk of development of pulmonary infections, brain atrophy leading to dementia, and all-cause mortality.[36]

While risks related to medications with anticholinergic properties have been included in the Beers Criteria for some time, the 2023 update now includes the increased risk of delirium and falls or fractures within the risk rationale for the use of more than one medication with anticholinergic properties, acknowledging the cumulative effect of using multiple medications with anticholinergic properties.[5]

While medication classes like

Table 2. Medications in the top 200 with anticholinergic and sedative properties

Activity	Medications with anticholinergic properties
Low	Metoprolol, sertraline, escitalopram, bupropion, furosemide, trazodone, fluoxetine, prednisone, citalopram, alprazolam, venlafaxine, clonazepam, lorazepam, famotidine, acetaminophen/oxycodone, loratadine, diltiazem, aripiprazole, celecoxib, hydralazine, mirtazapine, valproate, sumatriptan, isosorbide, clindamycin, methocarbamol, diazepam, chlorthalidone, nifedipine, risperidone, morphine, hydrocortisone, prednisolone, methylprednisolone, levocetirizine, carbamazepine, buprenorphine, acetaminophen/codeine, lansoprazole, pramipexole, lithium
Moderate	Tramadol, cyclobenzaprine, quetiapine, pregabalin, paroxetine, baclofen, oxcarbazepine, olanzapine, desvenlafaxine
High	Meclizine, dicyclomine, nortriptyline, diphenhydramine, hydroxyzine, amitriptyline, tizanidine, oxybutynin
Activity	**Medications with sedative properties**
Low	Oxybutynin, metoprolol, furosemide, famotidine, loratadine, diltiazem, celecoxib, nifedipine, levocetirizine, lansoprazole, pramipexole, atorvastatin, lisinopril, amlodipine, omeprazole, losartan, hydrochlorothiazide, simvastatin, montelukast, rosuvastatin, pantoprazole, carvedilol, meloxicam, pravastatin, ibuprofen, estradiol, diclofenac, clonidine, glimepiride, propranolol, naproxen, hydrochlorothiazide/losartan, fenofibrate, lovastatin, cephalexin, donepezil, methotrexate, esomeprazole, valsartan, hydroxychloroquine, olmesartan, benazapril, timolol, irbesartan, verapamil, memantine, ropinirole, progesterone, mirabegron, amlodipine/benazepril, testosterone, gemfibrozil, prazosin, ramipril, glyburide
Moderate	Meclizine, dicyclomine, hydroxyzine, tizanidine, sertraline, escitalopram, bupropion, trazodone, fluoxetine, citalopram, venlafaxine, acetaminophen/oxycodone, aripiprazole, mirtazapine, valproate, sumatriptan, methocarbamol, diazepam, risperidone, morphine, carbamazepine, buprenorphine, acetaminophen/codeine, tramadol, cyclobenzaprine, quetiapine, pregabalin, paroxetine, baclofen, oxcarbazepine, olanzapine, desvenlafaxine, gabapentin, acetaminophen/hydrocodone, duloxetine, lamotrigine, levetiracetam, benzonatate
High	Nortriptyline, diphenhydramine, amitriptyline, alprazolam, clonazepam, lorazepam, lithium

first-generation antihistamines, antiparkinsonian agents, antidepressants and antipsychotics with strong anticholinergic activity, urinary antimuscarinics, and antispasmodics are considered common culprits, it is important to acknowledge that other medications with low or moderate anticholinergic properties may also contribute to a cumulative anticholinergic risk and lead to ADEs. For example, combining loratadine (low) with citalopram (low) and cyclobenzaprine (moderate) may cumulatively lead to anticholinergic ADEs. Fifty-eight of the top 200 medications prescribed in 2020 have anticholinergic properties ranging from low to high.[36,37] Table 2 includes a list of the top 200 medications with their respective anticholinergic and sedative activity.

Similar to medications with anticholinergic properties, medications with sedative properties are well-documented for causing ADEs in older adults. ADEs associated with the use of medication with sedative properties include drowsiness, lethargy, respiratory depression, poorer cognitive and physical functioning, falls, and fractures. The risks of ADEs associated with medications with sedative properties are also additive and cumulative.[36,38,39] AGS has previously acknowledged the additive sedative potential and includes three or more CNS-active agents as a point at which clinicians should intervene.[4] In the 2023 Beers Criteria, gabapentinoids and skeletal muscle relaxants were added to the list of CNS-active agents that should be avoided in combination due to increased risk of falls and fracture.[5]

Gabapentinoids are frequently used in older adults for management of neuropathic and other pain and nonpain syndromes. In light of the opioid epidemic, clinicians have increased use of gabapentinoids to decrease opioid prescribing in many settings.[40] One study assessed the prevalence of prolonged use of gabapentin in a postsurgical setting and found that among 17,970 patients who were post total knee (45%) or total hip (21%) replacement, 22% who were initiated a new prescription for gabapentin as part of their post operative plan continued use of the medication at >90 days following discharge.[41]

While gabapentoids are considered to have moderate sedative potential, use of the medications are not without risk. Researchers in Ontario, Canada, conducted a retrospective population-based study to assess the 30-day risk of hospitalization in older adults initiated on gabapentin.[42] The study analyzed records from 34,159 patients initiated on doses >600 mg/day and 76,025 records from patients initiated on doses <600 mg/day. Patients initiated on higher doses were more likely to present to the hospital with altered mental status (1.27% vs. 1.06%).[42]

It is important to remember that, when gabapentinoids are used, to "start low and go slow" to avoid ADEs.

Skeletal muscle relaxants also are generally considered to have a moderate sedative potential but have been found to cause ADEs in older adults. A retrospective cohort study analyzed a cohort of 1,807,404 patients from Veteran Affairs hospitals and found that patients prescribed skeletal muscle relaxants were more likely to seek emergency care and be hospitalized compared to patients taking antihistamines.[43]

Skeletal muscle relaxants do not modify underlying properties of disease and are only useful for short-term symptomatic improvement in older adults.[44]

On top of the addition of skeletal muscle relaxants to the list of CNS-active agents that should be avoided, baclofen is now listed as one to avoid in patients with an eGFR <60 mL/min/1.73 m^2 due to the risk for encephalopathy.[45]

Baclofen is one of the most commonly prescribed medications and is used for various conditions including spasticity related to multiple sclerosis or spinal cord injury (a labeled use) and chronic low back pain (an off-label use).[37,46]

Baclofen is primarily eliminated via the kidneys unchanged, and its elimination half-life increases as kidney function declines. A retrospective population-based cohort study conducted in 15,942 older adults with chronic kidney disease who were newly prescribed baclofen found a dose- and renal function–dependent increased risk of hospitalization with encephalopathy in patients with an eGFR <60 mL/min/1.73 m^2 within 30 days of initiation.[45] Patients with the highest risk were those taking doses of >20 mg per day or those with a progressively lower eGFR.

As medication experts, pharmacists are uniquely positioned to prevent and reduce the incidence of ADEs in older adults.

Additionally, opioids have now been added to the list of medications that may exacerbate delirium in older adults based on emerging data, as recent studies have evaluated the association of opioids with delirium in various practice settings ranging from critical care to outpatient presentation to the ED.[47,48] While data are mixed within the outpatient/ED setting, studies have found a correlation between opioid use and development of delirium in the inpatient setting.[47] Pharmacists working in inpatient settings should be cognizant of emerging data related to opioid use and offer appropriate nonpharmacologic or nonopioid pharmacologic treatment options when possible in older adults.

One additional update related to the risk of falls and fractures was the change of the level of evidence supporting the recommendation to avoid the use of antidepressants in patients with a history of falls and fractures from "high-quality" to "moderate-quality" due to mixed evidence related to causality. The rationale behind the recommendation acknowledges that evidence is increasing related to the risk of using SNRIs. In early 2021, CDC published a report that identified a 30% increased risk of falling in older adults taking SSRIs and SNRIs.[49]

Additionally, a systematic review and meta-analysis published by AGS noted duloxetine as a causative agent for falls as compared to placebo.[50] The change in level of evidence related to this class reinforces that each patient and their unique clinical scenario should be considered when making recommendations based on the 2023 Beers Criteria.

Additional relevant updates

The recommendation to avoid estrogens with or without progestins is not new in the 2023 Beers Criteria. The updated wording to the recommendation includes the statement to avoid initiating systemic estrogens (e.g., oral tablets or transdermal patches) and to consider deprescribing estrogens among older women already using these medications.[5]

Evidence supporting additional recommendations remains a hot topic for debate among geriatricians and gynecologists. The American College of Obstetricians and Gynecologists and the North American Menopause Society do not recommend the routine discontinuation of systemic estrogens in women based on age due to the paucity of evidence in this population.[51] The 2022 hormone therapy position statement of The North American Menopause Society states that extended duration of hormone therapy "remains an individual decision in select, well-counseled women aged older than 60 years to continue therapy."[52]

Shared decision-making should be used to evaluate benefits and risk of initiation or discontinuation of systemic estrogens in women older than 60 years.

It is also important to note that the gender-specific language is consistent with recommendations in publications but does not accurately represent individuals with differing identities.

PPIs are one of the most-prescribed medications and over 25% of Medicare Part D beneficiaries use them.[53] PPIs have been part of the Beers Criteria list PIMs since 2015 due to risk of *Clostridioides difficile* infection, bone loss, and fractures with use for greater than 8 weeks.[54] New supporting data for the 2023 Beers Criteria led to the addition of pneumonia and GI malignancies as possible risks with the use of the PPIs dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole.[5]

The mechanism of pneumonia development with prolonged PPI use relates back to the H+/K+–ATPase enzymes on which PPIs exert their effect. The reduction in acid secretion leads to a decreased innate immune response to bacterial infection and an increased risk of bacterial

micro-aspiration and pulmonary aspiration.[55] A 2018 longitudinal analysis of electronic medical records of adults 60 years and older found that long-term use of PPIs was associated with greater hazard of incident pneumonia.[56] The inhibition of gastric acid leading to hypergastrinemia, gastric atrophy, and bacterial overgrowth are also the potential source of GI malignancy with prolonged PPI use.[56] A recent systematic review with meta-analysis found an increased gastric cancer risk among PPI users.[57]

The 2023 Beers Criteria continues to recommend the avoidance of scheduled use of PPIs for longer than 8 weeks unless for high-risk patients (e.g., those who use oral corticosteroids or chronic NSAIDs), erosive esophagitis, Barret's esophagitis, pathologic hypersecretory condition, or demonstrated need for maintenance treatment (e.g., because of failure of drug discontinuation trial or H2-receptor antagonists.)[5] Like many medications on the 2023 Beers Criteria, to counteract the overprescription of PPIs, deprescribing guidelines specific to PPIs have been developed. The PPI Deprescribing Algorithm developed by the Canadian Medication Appropriateness and Deprescribing Network can serve as a tool when deprescribing PPIs.[58]

Applying Beers Criteria updates in practice

As medication experts, pharmacists are uniquely positioned to prevent and reduce the incidence of ADEs in older adults.

Several studies have demonstrated the pharmacist's impact. One meta-analysis involving 13 studies and 6,198 patients conducted in Europe, North America, and Australia across a variety of clinical settings evaluated the impact of interventions to optimize medication use on ADEs in older adults.[59] Of the 13 studies included, eight included pharmacist-led intervention to identify medication-related problems. Pharmacists made recommendations to prescribers through various modes of communication, including in-person and electronic. Pharmacists also provided education directly to patients in some studies. The study found that patients randomized to the intervention group were 21% less likely to experience an ADE overall, and when restricted to only the 8 studies that included pharmacist-led intervention, patients were 35% less likely to experience an ADE.[59]

Six of the studies also evaluated the rate of serious ADEs, which was defined as those associated with hospitalization, prolonged hospitalization, permanent disability, need for intervention to prevent permanent impairment, or death. In those studies, patients who received intervention were 36% less likely to experience a serious ADE compared to the control group.[59]

This study is just one example of how pharmacists can be successful in preventing ADEs in older adults through a variety of mechanisms, whether it be providing recommendations directly to prescribers as part of the interdisciplinary team or speaking with patients and suggesting they follow up with their prescriber.

AGS provides some general criteria for how clinicians should interpret the recommendations included within the publication.[5] First, the term "avoid" is used throughout the Beers Criteria and has been since its inception. The expert panel acknowledges that medications listed as avoid "the medication should be avoided except under unusual circumstances."[5] It is important for pharmacists to remember that each patient has their own unique needs and goals.

When pharmacists see an older adult taking a medication included in the Beers Criteria, it is important to have a conversation with that patient or provider about the potential risks and considerations specific to that patient.

For example, consider the scenario of a presenting patient who has been taking and tolerating glipizide for years. As the patient's pharmacist, you engage in a conversation with the patient with the purpose of convincing them to change to a different agent that does not carry the same risk for hypoglycemia or cardiovascular mortality. In speaking with the patient, you learn

that they have had similar conversations with their prescriber, but they did not tolerate metformin in the past and are unable to afford the newer agents that are only available under a brand name. In this scenario, it is perfectly acceptable to educate the patient about signs and symptoms of hypoglycemia that they should be looking for.

In addition to the term "avoid," the Beers Criteria also includes a list of medications identified as "use with caution."[5] These medications may be lacking consistent evidence regarding potential harms of use. When a pharmacist sees one of these medications, additional education or monitoring can often be beneficial. For example, an older adult recently initiated on an SGLT-2 inhibitor should be educated about signs and symptoms of urogenital infections; however, the benefits of using the SGLT-2 inhibitor likely outweigh the risk of experiencing this ADE.

Lastly, within each section of the criteria, it is important for pharmacists to thoroughly read the recommendation and rationale. AGS has different recommendations that are specific to each medication and scenario that should be considered. For example, while use of benzodiazepines should generally be avoided due to numerous risks related in older adults, AGS

acknowledges indications in which the class may be appropriate, including seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine or ethanol withdrawal, severe generalized anxiety disorder and periprocedural anesthesia. This is just one of many examples in which a pharmacist's recommendation may change based on the rationale included.

In 2015 and 2019, AGS published companion articles that provided additional guiding principles for how to use the Beers Criteria. The purpose of these articles was to ensure proper interpretation of the criteria, and pharmacists should consider these principles when interpreting the Beers Criteria.[13,14] General principles for pharmacists to consider when using the Beers Criteria include

- Consider each patient's unique clinical scenario and circumstance. Medications included in the Beers Criteria serve as guidance for potentially inappropriate use.
- Thoroughly review and understand the rationale and recommendations for each medication included in order to communicate the most accurate information possible to providers.
- When you identify a potentially inappropriate medication, consider recommending deprescribing or offering appropriate alternatives depending on what is best for the patient.

As the most accessible and informed medication expert, pharmacists are key in ensuring safe use of medications in older adults. Multiple studies have shown that when a pharmacist performs a medication review in older adults, ADEs are prevented.[59]

The 2023 Beers Criteria serves as a resource to support medication safety and should be considered in clinical practice often. Take the few minutes to send a message, fax, or make a phone call—your action may improve the quality of or save a patient's life.

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CPE credit: 1 hour (0.1 CEU)
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Advisory board: Katie Meyer, PharmD, Director, Content Creation, APhA, Washington, DC; Hailey Mook, PharmD, Senior Manager, Custom Education, APhA, Washington, DC.

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CPE information

To obtain 1 hour of CPE credit for this activity, complete the CPE exam and submit it online at www.pharmacist.com/education. A Statement of Credit will be awarded for a passing grade of 70% or better. You have two opportunities to successfully complete the CPE exam. Pharmacists and technicians who successfully complete this activity before July 1, 2026, can receive credit. Your Statement of Credit will be available online immediately upon successful completion of the CPE exam.

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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. Which of the following increases the odds of an older adult experiencing an adverse drug event?
a. Polypharmacy
b. Age-related pharmacokinetic changes
c. Age-related pharmacodynamic changes
d. All of the above

2. According to CDC, older adults visit emergency departments more than ____ times a year due to an ADE?
a. 350,000
b. 450,000
c. 550,000
d. 650,000

3. What additional adverse outcomes were added to the 2023 Beers Criteria rationale to avoid the use of proton pump inhibitors in older adults?
a. *Clostridioides difficile* infection and pneumonia
b. GI malignancies and pneumonia
c. Bone loss and fractures
d. Blood clots and bone loss

4. What is the rationale for SGLT-2 inhibitors being listed as PIMs to be used with caution in older adults in the 2023 Beers Criteria?
a. Increased risk of hypoglycemia and cardiovascular death
b. Dehydration and hyperglycemic diabetic ketoacidosis
c. Euglycemic diabetic ketoacidosis and urogenital infections
d. Increased risk of bleeding and intracranial hemorrhage

5. In which of the following patients should baclofen be avoided based on updates to the 2023 Beers Criteria?
a. A 74-year-old man with an eGFR of 65 mL/min/1.73 m^2 taking baclofen for chronic low back pain
b. A 66-year-old woman with an eGFR of 35 mL/min/1.73 m^2 taking baclofen for spasticity related to multiple sclerosis
c. A 55-year-old man with an eGFR of 90 mL/min/1.73 m^2 taking baclofen for chronic low-back pain
d. A 75-year-old woman with an eGFR of 70 mL/min/1.73 m^2 taking baclofen for spasticity related to multiple sclerosis

6. Which of the following DOACs has the highest risk of major bleeding and GI bleeding in older adults?
a. Apixaban
b. Dabigatran
c. Warfarin
d. Rivaroxaban

7. According to the study by Fleet and colleagues, which of the following is true about the correlation between gabapentin use and altered mental status?
a. Older adults taking gabapentin are more likely to experience altered mental status than those taking opioids.
b. Older adults taking gabapentin are more likely to die within 30 days than those taking opioids.
c. Older adults taking gabapentin at doses of >600 mg per day upon initiation are more likely to die within 30 days than those taking doses of <600 mg per day.
d. Older adults taking gabapentin at doses of >600 mg per day upon initiation are more likely to be hospitalized with altered mental status than those taking doses <600 mg per day.

8. Based on a meta-analysis published by the *Journal of American Geriatrics Society*, which antidepressant may cause an increased risk of falls compared to placebo?
a. Sertraline
b. Vilazodone
c. Escitalopram
d. Duloxetine

9. How should pharmacists apply the updated 2023 Beers Criteria in practice?
a. Restrict use of all medications listed as "avoid."
b. Recommend deprescribing anticoagulants when used long-term for VTE in older adults.
c. Make recommendations based on each patient's unique clinical scenario and goals.
d. Recommend alternative agents to reduce use of all medications with anticholinergic properties.

10. Match the correct interpretation of terminology included within the 2023 Beers Criteria.
a. Avoid: Avoid use of medications under all circumstances.
b. Use with caution: Avoid use of medications except under unusual circumstances.
c. Avoid: Avoid use of medications except under unusual circumstances.
d. Use with caution: Avoid use of medications unless the risk outweighs the potential benefit.

Across

9 Luxurious
10 In an unstructured way
11 Pharmacists are using entrepreneurial skills to change these
12 Once sold under the brand name “Obecalp”
13 Its alpha form is a type of omega-3 fatty acid
15 Regret
17 Bean that is the basis of chocolate
19 This form of 13-across is a type of omega-3 fatty acid
20 Pharmacists can now sell aids to use in this organ
21 _____ drip may benefit from antihistamines
25 Supplements often touted to grow hair and nails
26 Enterobius vermicularis
28 Deductive (e.g., reasoning)
29 Handy item to reduce swelling

Down

1 Of the cheek
2 Estrane steroid with minimal activity
3 Healthy salad green
4 Stomach enzyme that aids in digestion
5 Certain types may be treated with minoxidil
6 Recombinant human growth hormone
7 Opposite of mild, as in pain
8 A reduced ability to smell and detect odors
14 May require stitches
16 Eight-day Jewish celebration
18 Small fingerlike pouch attached to the large intestine
20 Pharmacists help prevent these
22 Serious reaction to infection
23 Powerful judicial group in brief
24 Agile and flexible, like a gymnast
27 Requirement

Solution is available online at pharmacytoday.org.