Pharmacists Fight HIV
Virtual care takes center stage amid pandemic

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Adapt to a “New Normal” During Uncertain Times

Just a few months ago, the novel coronavirus disease 2019 (COVID-19) hit the United States and rapidly changed lives. As reopening efforts and recovery plans start to take hold, it should be recognized that community pharmacies are ideally positioned to support this national effort.

As social distancing remains encouraged, pharmacies have stepped up to adapt their services in many ways. This includes ensuring that the strain of the global pandemic does not interfere with the care of patients with chronic and complex conditions. Our cover story dives into the important role of the pharmacist in helping patients with HIV manage their disease states, especially during a time when in-person counseling is not always plausible and telemedicine takes center stage.

States are slowly easing barriers to pharmacist-provided COVID-19 testing. In this issue, you’ll find an update on the current state of coronavirus testing in the pharmacy, including the maze of federal, state, and supply chain practicalities. As Christopher Daly, PharmD, MBA, BCACP, said, “Pharmacy is going to be a big part of the testing capabilities, especially when the second wave hits. But you can’t just start testing tomorrow.”

In our May issue, we provided an update on the vaccine development pipeline. In this issue, on page 20, Jennifer Gershman, PharmD, advises how pharmacists can combat the antivaccination movement and promote other recommended vaccines by using logic and data to reassure patients. These tips will also surely help pharmacists when an impending COVID-19 vaccine becomes available in the future.

Additionally, in our technology section, we discuss how pharmacies can protect themselves from cyberattacks and avoid HIPAA violations. Investing in the right tools and training for your business’ technology systems is crucial to preventing a potential data breach.

Education remains key, whether you’re staying up-to-date on the latest products or brushing up on counseling points for your patients. Get educated on diabetes devices on page 18 and learn more about OTC considerations for patients with autoimmune diseases on page 22.

As always, Drug Topics® remains committed to providing pharmacists with the most up-to-date industry information. Continue to follow us on drugtopics.com and stay tuned for a new, updated look coming soon.

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More than 240 patient advocates and health care associations urged Congress to take immediate action to reform pharmacy direct and indirect remuneration (DIR) clawback and performance measure fees, according to a letter sent to congressional leaders. The letter, which was commended in a joint news release from several pharmacy organizations, urged DIR fee reform to make prescription drugs affordable for patients and prevent pharmacies from closing, which would limit access to vulnerable populations.

“Members of Congress should not overlook the clear and present opportunity to address these needed reforms this year,” the groups wrote to Senate Majority Leader Mitch McConnell (R, Kentucky), Senate Minority Leader Charles Schumer (D, New York), Speaker of the House Nancy Pelosi (D, California), and House Minority Leader Kevin McCarthy (R, California).

DIR reform has gained bipartisan support from Congress; the letter asserted that DIR clawback and performance measure fees “threaten a pharmacy’s ability to support patients.”

The joint news release cited data from the Centers for Medicare & Medicaid Services, which found that DIR fees charged by payers to pharmacies have grown by 45,000% since 2010. According to the release, consequences of the fees include inflating patients’ out-of-pocket expenses for their prescription drugs and threatening pharmacies’ financial stability. Approximately 2000 pharmacies have closed since 2018.

“On behalf of Medicare Part D beneficiaries, we urge you to advance legislative efforts to reform pharmacy DIR clawback and performance measure fees. We write to you on behalf of patients, pharmacies, health care organizations, and health care practitioners who are working collaboratively to ensure access to needed prescriptions, particularly during the COVID-19 pandemic. Patient medication access is vital to patient health and well-being and can protect against otherwise avoidable emergency department visits, especially at this time,” the groups wrote.
Officials with the FDA approved dapagliflozin (Farxiga, AstraZeneca) to reduce the risk of cardiovascular (CV) death and hospitalization in adults with heart failure (HF) with reduced ejection fraction, with and without type 2 diabetes. The approval is based on data from the landmark phase 3 DAPA-HF clinical trial (NCT03036124), which included 4744 patients with New York Heart Association class II, III, or IV HF and an ejection fraction of 40% or less. Patients received dapagliflozin at 10 mg once daily or placebo, in addition to recommended therapy. Over the median of 18.2 months, the primary outcome, which was a composite of worsening HF or CV death, occurred in 16.3% of patients treated with dapagliflozin and 21.2% treated with placebo (HR, 0.74; 95% CI, 0.65-0.85; P < 0.001).

Dapagliflozin is the first sodium glucose co-transporter 2 inhibitor proven to significantly reduce the risk of CV death and hospitalization for HF.

Community Pharmacists Eager for Provider Status, Prescriptive Authority

A survey conducted by the Southwestern Oklahoma State University College of Pharmacy found a high level of interest among community pharmacists in obtaining provider status and prescriptive authority, according to a poster published in the American Pharmacists Association 2020 Virtual Poster Hall Gallery.

The study, led by Nika A. Hakim, PharmD; Nancy T. Williams, PharmD; and Lisa A. Appeddu, PhD, used a voluntary survey to evaluate pharmacists’ interest in gaining provider status and prescriptive authority, confidence in their ability to take on these responsibilities, and perceived barriers in pursuing these duties. Data overwhelmingly showed interest in obtaining provider status and prescriptive authority. Overall, 93.5% either agreed or strongly agreed that provider status is important for the future of the profession, and 81.3% agreed or strongly agreed that they are prepared to practice as a provider now. Eighty-six percent reported being “confident” or “very confident” in their ability to prescribe medication under a collaborative practice agreement and autonomously.

Celecoxib Oral Solution Gains Approval for Acute Migraine Treatment

The FDA has approved celecoxib oral solution 25 mg/mL (Elyxyb; Dr. Reddy’s Laboratories) for the acute treatment of migraine with or without aura in adults.

Previously known as DFN-15, the agent is a selective inhibitor of cyclooxygenase 2, available in a ready-made liquid solution. It is not indicated for the preventive treatment of migraine.

Study results on the efficacy, tolerability, and safety of 120 mg celecoxib oral solution versus placebo for the acute treatment of migraine were published in Headache. Trial participants treated a single migraine attack with either the drug or placebo as soon as possible after onset of moderate to severe pain. Investigators randomized 622 patients to receive either 120 mg celecoxib oral solution or placebo, and 567 patients treated a migraine with study drug. At 2 hours post dose, celecoxib oral solution showed significant superiority over placebo for freedom from pain, at 35.6% (98 of 275) vs 21.7% (57 of 263; P < .001), respectively (odds ratio [OR], 2.00; 95% CI, 1.36-2.94). Celecoxib oral solution was also significantly superior for freedom from most bothersome symptom at 2 hours post dose, according to the study.

High Blood Pressure Medications Appear to be Safe With COVID-19

Investigators from New York University (NYU) Grossman School of Medicine found no link between treatment with 4 drug classes—angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, beta-blockers, and calcium channel blockers—and increased risk of infection with severe acute respiratory syndrome coronavirus 2, the virus that causes the novel coronavirus disease 2019 (COVID-19).

The study incorporated 12,594 patients in the NYU Langone electronic health record with COVID-19 test results and compared participants treated with high blood pressure medications with those who are not. The study incorporated 12,594 patients in the NYU Langone electronic health record with COVID-19 test results and compared participants treated with high blood pressure medications with those who are not.
**FDA Grants EUA to Saliva-Based COVID-19 Test for At-Home Use**

The first diagnostic test that will allow at-home collection of saliva samples for coronavirus disease 2019 (COVID-19) testing has received emergency use authorization (EUA) from the FDA.1

Rutgers the State University of New Jersey’s RUCDR Infinite Biologics’ COVID-19 test received the amended EUA, which follows the FDA’s recent decision to grant approval to the saliva-based test for use by health care workers at testing sites. The new at-home self-collection assay was developed by RUCDR in partnership with Spectrum Solutions and Accurate Diagnostic Labs.

Patients will be able to use a designation self-collection kit, sending the saliva sample to the Rutgers clinical genomics laboratory in a sealed package for testing, according to the FDA.1

**HIV PrEP Uptake Remains Low Among Teens**

Preexposure prophylaxis (PrEP) has been an important tool in preventing the further spread of HIV. Although adolescents and young adults are particularly affected by HIV, the uptake of PrEP has remained low among teenagers. A new review in *JAMA Pediatrics* looks at the current status of PrEP uptake among adolescents aged 13 to 19 years who are at risk.

Among the 37,377 diagnoses of HIV made in 2018, 7734 cases were diagnosed in adolescents and young adults aged 12 to 24 years and 1707 diagnoses occurred in adolescents aged 13 to 19 years. Two-thirds of all HIV infections in adolescents and young adults occurred in young African American men who have sex with men. Investigators found that PrEP awareness and engagement was lowest among teenagers who were at the greatest risk of HIV.

Despite CDC recommendations, many clinicians who treat adolescents do not routinely offer HIV testing or do a sexual history taking to assess sexual risk exposures. Prescribing PrEP was found to be often guided by clinicians’ perceptions of the patient’s HIV risk as well as the clinician’s knowledge and acceptance of PrEP guideline.1

**Apremilast Shows Efficacy in Mild to Moderate Plaque Psoriasis**

Apremilast (Otezla; Amgen) significantly improved psoriasis symptoms compared with a placebo in adults with mild to moderate disease, according to top-line results from a phase 3 clinical trial.1

The phase 3 ADVANCE study, a multicenter, double-blind trial, assessed the efficacy and safety of apremilast in adults with mild to moderate plaque psoriasis (NCT03721172). A total of 595 patients were randomized to receive either oral apremilast at 30 mg twice daily or placebo for the first 16 weeks, and all patients received apremilast during an open-label extension phase through week 32.

Treatment with apremilast resulted in a statistically significant improvement, compared with placebo, in the primary end point of the static Physician’s Global Assessment response, defined as a score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline, at week 16. The study also met its secondary end points of achieving at least 75% improvement from baseline in the percentage of affected body surface area (BSA), change in BSA total score from baseline, and change in psoriasis Area and Severity Index total score from baseline. Each finding was also statistically significant for the treatment effect of apremilast compared with placebo.1

**Heart Disease Risk Associated With Cognitive Decline**

Results from a recent study found that individuals with a higher risk of developing cardiovascular disease (CVD) showed increased cognitive decline, including an increase in typical markers of Alzheimer disease, and indicated that monitoring for and controlling heart disease may lead to maintaining and improving cognitive health later in life.

The study, published in the *Journal of the American College of Cardiology*, involved 1588 dementia-free participants from the Rush Memory and Aging Project, and followed them for 21 years.2

Results showed that higher cardiovascular risk burden was associated with speedier decline in episodic memory, working memory, and perceptual speed.2

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1. FDA Grants EUA to Saliva-Based COVID-19 Test for At-Home Use

2. Heart Disease Risk Associated With Cognitive Decline

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**Small doses**

For more pharmacy news and references, visit drugtopics.com
States Slowly Ease Barriers to Pharmacist-Provided COVID-19 Testing

By Fred Gebhart

In early April, the US Department of Health & Human Services authorized licensed pharmacists to order and use coronavirus disease 2019 (COVID-19) tests approved by the FDA. By mid-May, about two-thirds of states had adjusted regulations for pharmacist-provided testing, but just a handful of pharmacies had managed to navigate the maze of federal, state, and supply chain practicalities.

In California, pharmacy, medical, and consumer groups lobbied Gov Gavin Newsom and regulators for nearly 6 weeks before the state’s Department of Consumer Affairs eased restrictions that prevented most pharmacies from testing.

“This waiver will allow pharmacists to order COVID-19 tests for their patients and collect specimens to send to a laboratory for processing,” said Richard Dang, PharmD, APh, BCACP, a board member of the Pharmacists Society of the State of New York. “Beyond that, there are questions about [personal protective equipment], where will we procure the tests, billing, and more. Pharmacy is going to be a big part of the testing capabilities, especially when the second wave hits. But you can’t just start testing tomorrow.”

“Testing is coming, but getting there is a step-by-step process, and you need to work out the logistics.”

A key problem involves meeting both state scope of practice and state laboratory requirements. At deadline, the FDA had issued emergency use authorizations for 4 point-of-care COVID-19 tests. The tests require a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver, typically issued by the state health department.

The first step to pharmacy-based COVID-19 testing is the certificate of waiver, said Allie Jo Shipman, PharmD, MBA, director of state policy for the National Alliance of State Pharmacy Associations. Next comes navigating the scope of practice regulations, which can be a frustrating exercise.

A recent poll by National Community Pharmacists Association (NCPA) found that most of its members want to test for COVID-19. “As an association, we have had to temper expectations a bit,” said Hannah Fish, PharmD, CPHA, NCPA’s associate director of strategic initiatives. “Testing is coming, but getting there is a step-by-step process, and you need to work out the logistics.”

Reimbursement remains uncertain. Federal regulators require insurers to cover COVID-19 testing at no cost to patients, but there are no requirements to reimburse test providers. Commercial insurers have mechanisms to cover medical costs but not pharmacy costs.

“Centers for Medicare & Medicaid Services is trying to take advantage of access to pharmacies as providers, but they are hemmed in by existing statutes,” said Tom Kraus, JD, vice president of government relations for the American Society of Health-System Pharmacists. “They are creating workarounds like having pharmacies register as labs to get paid, and there are mechanisms like incident-to payments for pharmacists in health systems or in medical practices. But there are no mechanisms that work for most community pharmacies. That’s something we need legislation to fix.”
Pharmacists Feel Overworked, Face More Discrimination

Survey results reveal improvements and challenges in the workplace. By Christine Blank

Pharmacists, pharmacy technicians, and other pharmacy staff felt overtaxed even before the coronavirus disease 2019 (COVID-19) pandemic hit, according to findings from the 2019 National Pharmacist Workforce Study. The survey results showed that 69% of full-time pharmacists reported that their workload “increased” or “greatly increased” compared with the prior year.1

Although the profession is much more racially and gender diverse than in previous years, pharmacy staff reported age and gender discrimination, according to the findings. The Midwest Pharmacy Workforce Research Consortium has conducted the annual study for the Pharmacy Workforce Center (PWC) since 2000.1

Among full-time, actively practicing pharmacists, 71% rated their workload level at their primary place of employment as “high” or “excessively high” in 2019, compared with 66% and 68% of full-time pharmacists in 2014 and 2009, respectively.1

The highest proportions of full-time pharmacists rating their workload as “excessively high” or “high” or were in chain (91%) and mass merchandiser (88%) settings; the lowest proportions were in independent community (48%) and ambulatory care (57%) pharmacy settings, the PWC said.1

“Employers, such as large pharmacy chains and others, should consider how they can boost fulfillment and lower exhaustion amongst their employees, which will lead to retaining a strong workforce. Perhaps there are lessons to be learned from independent and hospital settings [that] are succeeding at meeting the needs of its personnel,” PWC said in a statement.2

Overall, 44.2% of full-time pharmacists received an increase in base pay in 2019 compared with 31.7% in 2014; 48.4% said their base pay stayed the same.1

Full-time pharmacists in community retail pharmacies (approximately 12%) reported a base pay decrease in the past year compared with full-time pharmacists in hospital settings (2%).1

Nearly a third (31%) of pharmacists reported experiencing incidents of discrimination in 2019. “The most common type of harassment reported by pharmacists was hearing demeaning comments related to race/ethnicity at 15.7%,” PWC said in a statement.2

Just 15.9% of all discrimination incidents and 17.2% of all harassment incidents were reported to an employer.2

In good news, the profession is starting to become more diverse. Women made up nearly two-thirds of the pharmacy workforce in 2019 compared with 40.4% in 2009. “This has positive implications for patients, as these practitioners are trained in new systems of care and will play key roles in the future of pharmacy practice,” PWC said.2

For references, visit drugtopics.com.

2019 National Pharmacy Workforce Study

OTHER IMPORTANT FINDINGS FROM THE PWC STUDY INCLUDE THE FOLLOWING2:

- Patients continue to have access to important pharmacists’ services in a variety of settings. Notably, 72% of pharmacists said they offer naloxone dispensing in a community setting in 2019.
- The percentage of licensed pharmacists that have a PharmD degree increased dramatically, to 53% in 2019 from 37.8% in 2014 and 21.6% in 2009.
- The percentage of licensed pharmacists that have a PharmD degree increased dramatically, to 53% in 2019 from 37.8% in 2014 and 21.6% in 2009.
- Pharmacists who graduated during the latest decade (2011-2019) reported a mean student loan debt at time of graduation of $142,875, higher than the $82,188 reported by pharmacists graduating between 2001 and 2010.
- The profession continues to trend younger, PWC found. In 2019, 48.8% of practicing pharmacists were 40 years or younger, compared with just 24.4% in 2009. “This has positive implications for patients, as these practitioners are trained in new systems of care and will play key roles in the future of pharmacy practice,” PWC said.2
Professional burnout among pharmacists, already a growing concern in the United States, could be exacerbated by the coronavirus disease 2019 (COVID-19) crisis. The current pandemic strains pharmacy capacity and exposes persistent underlying problems, according to 3 experts on pharmacy burnout.

A national survey of more than 4700 pharmacists concluded that, although more than half (54.2%) of respondents reported meaningful work, 32% and 33% also said they felt “a lot” or “totally” emotionally and physically exhausted. Community pharmacists demonstrated higher rates of work exhaustion and interpersonal disengagement, as well as lower levels of professional fulfillment, compared with those practicing in hospitals and other work settings. A poster showing the results was presented in the 2020 American Pharmacists Association (APhA) Virtual Poster Hall Gallery.1

In a video interview with Drug Topics®, study coauthor Matthew Witry, PharmD, PhD, noted the 3 predominant factors of burnout:

1. **Physical and emotional exhaustion**
2. **Depersonalization**
3. **Autonomy/personal accomplishment**

Along with already slumping pharmacist retention rates and closing pharmacies, the pandemic puts immense pressure on the health care profession, as pharmacists work tirelessly to support their patients and communities.

The survey findings also suggest that larger pharmacy chains should emulate independent pharmacy workplaces to improve fulfillment and lower levels of exhaustion.1

“We saw lower scores for a sense of control at work in those corporate settings, which isn’t surprising, since there is more of a corporate structure with a lot of those retail environments, where a lot of those decisions are getting made at higher levels of management,” said Witry, an assistant professor in the Department of Pharmacy Practice and Science/Division of Health Services Research at The University of Iowa College of Pharmacy in Iowa City.

Findings from a separate survey conducted by the National Pharmacy Technician Association showed that most chain and mass retail pharmacy technicians do not feel safe at work during the current pandemic, with just 26.1% reporting feeling safe compared with 63.8% of independent pharmacy technicians.2

Caroline Gaither, PhD, FAPhA, coauthor of the study presented at APhA, senior associate dean of the Professional Education Divisions, and a professor in the Department of Pharmaceutical Care and Health Systems at the University of Minnesota College of Pharmacy, encouraged scrutinizing workplace conditions during the pandemic.

“In addition to burnout, which is something that you would like to avoid, we also do research in the area of what’s called well-being,” he told Drug Topics® in a video interview. “And that’s being able to have constructive conditions at work and beyond, even in your personal life, that enable workers to thrive and achieve their full potential.”

Part of that also is something called resilience: the ability of a person or a group of people or even a system to adapt and rebound and even grow from adverse conditions, stress, or trauma.”

By Gabrielle Ientile, Assistant Editor

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he continued. “When you think of this COVID-19 situation, we’re all also keeping an eye on work conditions that will support resilience. Can you actually grow and take advantage of very stressful and difficult situations?”

Gaither discussed the National Academies of Science, Engineering, and Medicine’s explanation of clinician burnout, which includes 2-pronged influences. On 1 side are the frontline workers and health care providers working for a particular health care organization that has varying policies and procedures, whereas the other side determines work system factors, including job demand, workload, and the number of work hours.

“If there’s a good balance there, then the health providers are able to really thrive and do the work, but when the job demands become too high, that’s where you can get into some of the more negative consequences,” Gaither said.

“Now, the other piece of that is, they say that these work system factors are also influenced by the individual—so, how much resilience that person has, their ability to cope with adversity, and also how much their work interferes with their personal life,” Gaither continued. “I really like the model, because they’ve started to talk about the system factors that are beyond what the individual provider is able to contribute and that the burnout is not necessarily related to some kind of individual failure, but it’s really related to kind of the way the work environment is structured.”

A contributing factor to burnout, according to Schommer: Community pharmacy practice is increasingly pressuring pharmacists to conveniently and quickly distribute medications.

“We’re finding that in community pharmacy practice, the distribution of pharmaceuticals is so vital, and you have to have that pressure on you all day long to be as efficient as possible. At the same time, community pharmacies are being recognized by the public by government agencies, such as CDC [the Centers for Disease Control and Prevention]...as health care access points, that you can get vaccinations, immunizations, screenings, and point of care testing,” he said. “There are a lot of patient care and public health services that are being provided.”

The experts put forth the idea of moral injury, in which health providers pursue their responsibilities but face constraints within their organization that affect their well-being and ability practice at their best.

Pharmacists remain eager to take on more responsibilities, according to Witry. “Pharmacists are probably feeling really appreciated. They’re making a difference—getting that care to people, being that access point, answering important questions, being a source of care,” he said. “When people aren’t going to their primary care physician appointments, they can still call their pharmacist or they can still talk to the pharmacist across the plexiglass.”

However, issues within the health care systems must be addressed so that pharmacists can do their job and avoid burnout.

“Do the pharmacists feel that their employers kind of have their backs? Do they feel supported? Are employers really stepping up to take care of their health providers? I think [that] is something that also probably needs to change,” Gaither said. “And then this idea of the profit motive in health care—there’s a lot of things that we could do better with if we had more resources and more reimbursements...to really provide patient care.”

For references, visit drugtopics.com.
The uptick in dietary supplement use and integrative health and medicine practices in the United States creates both opportunities and concerns for pharmacists and health providers, who need to stay well informed to help patients avoid harmful effects. Some patients may seek vitamin or herbal supplements for health and wellness, often believing that these are safer than conventional OTC and prescription pharmaceutical products. However, so-called natural remedies come with their own set of health risks.

“Dietary supplements are very helpful and really needed when they are chosen correctly and properly,” said Farzana Kennedy, RPh, FACA, owner and president of Dalitso, an integrative pharmacy in Alexandria, Virginia. “Often, they can be harmful if not properly monitored or checked for interactions or contraindications in a patient who has preexisting conditions.”

**Acting as Educators**

Dietary supplement use has reached an all-time high, with 77% of Americans reportedly using these products, according to a 2019 survey conducted by the Council for Responsible Nutrition. The increased patient demand for non-pharmacologic health options has created unprecedented opportunities for pharmacists to expand their interactions with patients.

Many patients consider community pharmacies the ideal place to purchase vitamins and other dietary health supplements. Pharmacists can positively affect the patient experience by:

- Providing supplement education
- Making supplement recommendations
- Assessing for interactions, contraindications, and toxicities
- Collecting a patient’s complete medication history, including supplements
- Assessing for drug-drug, drug-micronutrient, and drug-supplement interactions
- Helping patients evaluate natural products for quality-related issues

Pharmacists can also educate patients about the potential effects of taking dietary supplements on laboratory test validity and results.

“In general, validating and interpreting laboratory test results can be key tools in helping health care professionals optimize clinical decisions related to their patients’ health,” said Cathy Rosenbaum, PharmD, RPh, MBA, CHC, CDP, a holistic clinical pharmacist and founder and CEO of Rx Integrative Solutions in Blue Ash, Ohio. “Pharmacists are uniquely poised to prospectively educate the public on any laboratory test interferences with medications, supplements, or micronutrients to minimize safety risks.”

**Biotin: A Lesson in Disclosing Supplement Use**

Through their frequent interactions, patients and pharmacists often build a strong rapport and a trusting relationship. To assist patients who take biotin, pharmacists can follow these tips from Cathy Rosenbaum, PharmD, RPh, MBA, CHC, CDP, a holistic clinical pharmacist and founder and CEO of Rx Integrative Solutions in Blue Ash, Ohio. These steps also can be customized to fit the nuances of other dietary supplements and natural products.

1. Talk with the laboratory technician who will run the patient’s blood assays to find out if biotin interference will be an issue.
2. Counsel the patient to discontinue biotin use for 48 hours prior to thyroid testing, according to American Thyroid Association recommendations.
3. Factor in biotin-drug interactions with the interpretation of laboratory assays that use biotin technology, such as cardiovascular diagnostics and hormone blood tests, and may be affected by high-dose biotin consumption.
relationship in which patients feel comfortable discussing supplements. Pharmacists should advise their patients to also report all dietary supplement and natural product use to physicians prior to any blood testing, Rosenbaum said.

A laboratory-testing interaction involving biotin illustrates several important ways pharmacists can help keep patients safe through counseling. Many patients who pick up a bottle of biotin, a water-soluble B vitamin, view it as a harmless supplement to enhance physical appearance (eg, skin, hair, nails). Rosenbaum warns that this assumption can be problematic because of the lack of clinical research with standardized biotin dosing to support these claims.

The scientific community has long known that biotin functions in the body as a cofactor for enzymes involved in carboxylation reactions, and it plays a role in fatty acid and carbohydrate oxidation. Daily amounts of biotin needed for general health is defined in different ways because there is no standardized recommended dietary allowance for this nutrient. A generally suggested intake for adults is between 30 mcg and 100 mcg a day.

OTC biotin products come in many doses that are significantly higher than the amount provided in adequate nutrition, some as much as 10,000 mcg per dose for therapeutic indications.

Several reports link high-dose biotin supplementation to falsely elevated levels of the thyroid hormones triiodothyronine and levorotatory thyroxine and falsely low thyroid-stimulating hormone levels, all used to diagnose and monitor thyroid disease. Taking supplemental biotin at 20 mg or more on a daily basis may interfere with thyroid biosays that use streptavidin— or avidin—biotin systems.

Excessive biotin intake can lead to misdiagnosis, inappropriate treatment, or even death. For example, biotin supplementation can produce altered levels of troponin, one of the biomarkers elevated during acute myocardial infarctions. According to a November 28, 2017, FDA statement on biotin concerns, a patient who took high doses of biotin died because of complications related to falsely low troponin levels found in a test that relied on biotin technology. Because patients may be unaware of biotin interference, they may not report taking biotin supplements, and may even be unaware they are taking the supplement at all, according to the FDA.

**CBD and Medical Cannabis: Countering Ads That Overpromise**

The challenges of providing patient guidance in integrative medicine are not exclusive to biotin. The recent explosion of cannabis and cannabidiol (CBD) products presents more issues because these products are routinely promoted as completely safe, with no risks. Buying into this hype could have deleterious consequences for patients.

“Pharmacists are uniquely poised to prospectively educate the public on any laboratory test interferences with medications, supplements, or micronutrients to minimize safety risks.”

CATHY ROSENBAUM, PHARMD, RPH, MBA, CHC, CDP

“Pharmacists providing direct patient care by providing medical cannabis or hemp-based CBD products must know and understand patient diagnoses, treatment plans, and how to monitor patients for interactions,” Kennedy told Drug Topics. “One big problem is that cannabis dosing is not standardized, and therefore, pharmacists should educate themselves to help patients receive optimal care regarding the product and dose that will sit well with them without [adverse] effects or other undesired feelings.”

Kennedy also stated that the ubiquitous deluge of CBD products from companies draws increasing concern about quality. He urges pharmacists to practice due diligence, vetting ingredients and confirming that there has been third-party testing for impurities, heavy metals, and other substances.

CBD products are often erroneously advertised as devoid of drug interactions. Evidence shows that CBD is well tolerated sans psychotic effects, provided doses do not exceed 600 mg. However, CBD potently inhibits CYP3A4 and CYP2D6 enzymes, which could cause higher-than-normal increases in serum concentrations of calcium channel blockers, benzodiazepines, antihistamines, antiretrovirals, statins, cyclosporine, and other drugs cleared through these enzymes.

For more information and to stay up-to-date on issues in dietary supplements and integrative health, visit FDA.gov, PubMed.gov, or ClinicalTrials.gov.
In the wake of the novel coronavirus 2019 (COVID-19) pandemic, pharmacists face an ongoing challenge with helping patients optimally manage chronic conditions.

In HIV care, for example, pharmacists play a key role in monitoring treatments, counseling patients, and assisting with adherence challenges, all of which current social distancing measures can make more difficult. Furthermore, the potential effects of the COVID-19 virus on patients with HIV remain uncertain, even as reports indicate that other chronic conditions such as diabetes and hypertension may put affected individuals at higher risk. “So far, there is no major report to suggest that HIV patients are more or less susceptible to COVID-19 than individuals who do not have HIV or are otherwise healthy,” Rodney Ho, PhD, professor of pharmaceutics at the University of Washington School of Pharmacy in Seattle, told Drug Topics. “We don’t know why.”

According to a statement on Aidsinfo,
Pharmacists Fight HIV

“The pharmacist’s role is to serve as an expert when the physicians are caring for patients by looking for data to provide the best evidence available and being able to develop appropriate time-sensitive information.”

RODNEY HO, PhD

HIV Training Paths for Pharmacists

Optimally managing a complex disease state such as HIV demands a level of clinical skill that transcends the infectious disease training given in pharmacy school. Although formal training in pharmacology helps, Rodney Ho, PhD, professor of pharmaceutics at the University of Washington School of Pharmacy in Seattle, and Dan Scales, PharmD, AAhivp, director of pharmacy collaborative care at Vivent Health and owner and founder of Scales Pharmacy in Denver, Colorado, agreed that many pharmacists may not be adequately prepared to provide HIV care. They may not have intimate understanding of the social complexities stemming from long-term effects of treatment or possess the skills to train patients on pre-exposure prophylaxis.

The problem is compounded by the lack of set standards exist for HIV-specific training, so organizations must take the initiative to ensure their pharmacists receive adequate training. “There are a lot of programs out there attempting to incorporate all the necessary elements of HIV training, but it’s hard to find a single program that covers all the things you need,” Scales said.

Pharmacists at his institution must become certified through the American Academy of HIV Medicine (AAHIVM). Vivent Health also collaborates with other agencies to ensure its pharmacists receive proper training to conduct HIV testing and counseling. Kelly Cantwell-McNelis, PharmD, AAhivp, a clinical pharmacy specialist at Christiana Care’s William J. Holloway, MD, Community Program in Wilmington, Delaware, and an anonymous pharmacist from another organization reported that most of their pharmacists have received similar training.

Not every pharmacist pursues the same educational path. Sometimes a pharmacist has to research training opportunities in HIV medicine, which is what a clinician at the University of Florida College of Pharmacy in Gainesville did. After completing a PG-Y2 residency in critical care medicine, earning dual board certifications in critical care and pharmacotherapy, and working in a variety of settings, John M. Allen, PharmD, BCPS, BCCCP, FCCM felt the need to seek additional training to manage patients with HIV at his local Veterans Affairs Medical Center.

A clinical assistant professor in the Department of Pharmacotherapy and Translational Research, Allen often refers to CDC and AAHIVM guidelines for information. “In addition to their general HIV guidelines, the AAHIVM also provides guidelines for a number of different situations for HIV patients, as well as pharmacist-specific accreditation,” he said.

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a US Department of Health & Human Services website, the “limited data currently available do not indicate that the disease course of COVID-19 in persons with HIV differs from that of persons without HIV.” However, the website subsequently states that the use of effective antiretroviral therapy (ART) in the HIV population might be responsible for the current trend. Before the introduction of ART, a CD4 cell count below 200/mm3 was considered a risk factor for complications resulting from other respiratory infections. At press time, the website stated that whether HIV increases COVID-19 risk is still unknown. Until experts know for sure, the scientific consensus is that proactive measures to limit risk and exposure to COVID-19 should bear little difference to the measures taken by individuals who are generally healthy.

Preventive Measures During Pandemic

Health care systems have taken precautions to mitigate exposure and risk for patients with HIV. Perhaps the most significant change involves encouraging patients to stay home unless clinicians feel an office visit is medically necessary.

Clinicians are also taking proactive measures to prevent drug shortages and limit onsite visits. As a result, mail order use has surged. “We reach out to patients via phone around 5 to 10 days ahead of their next refill, so we can mail out their prescriptions to enhance adherence,” said a Houston, Texas–area HIV pharmacist who practices at an outpatient pharmacy located in a health center and wants to remain anonymous.

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multiple trips to the pharmacy. Patients who pick up their prescriptions must maintain a 6-foot distance from other patients. The clinic also requires these patients to fill out a COVID-19 screening form that helps pharmacists determine who needs additional assistance or medical attention.

**Telemedicine Takes Center Stage**

Physical distancing in the HIV community has driven a massive uptick in telemedicine services. Many patient interactions, such as follow-up visits and education, now occur remotely. Although the industry trend indicates that most services for this patient population have gone remote, exceptions may apply with at-risk populations.

For example, providers at Christiana Care’s William J. Holloway, MD, Community Program in Wilmington, Delaware, might require a site visit for patients who are older than 60 years or have certain disease states, such as lung disease and hypertension. “We are using virtual and telephonic visits, as well as preset algorithms for COVID,” said Kelly Cantwell-McNelis, PharmD, AAHIVP, a clinical pharmacy specialist with the community program.

In the outpatient pharmacy based in Houston, Texas, pharmacists make adherence calls to patients to monitor refills while screening them for signs and symptoms of the virus. “Since HIV patients are immunocompromised, we ask them if they are experiencing dry cough, fever, or chills currently, and document them in our pharmacy software,” the HIV pharmacist at the clinic said.

Phone calls and tracking prove critical because the clinic has a high number of patients with CD4 counts falling below 200 mm3, a sign of full-blown AIDS. These patients receive regular phone calls to monitor and address adherence, as well as to screen patients for opportunistic infections. Because of the pandemic, patients are now given the COVID-19 screening questionnaire over the phone.

Although telemedicine interventions have made operations more efficient, there have been hurdles. For instance, helping patients understand why they should call the pharmacy before making a trip has become a teaching opportunity that requires vigilance. “It took us a couple of weeks to get patients to understand that they should call us first and let us triage their symptoms,” said Cantwell-McNelis.

On the virtual front, Dan Scales, PharmD, AA-HIVP, director of collaborative care pharmacy at Vivent Health and owner and founder of Scales Pharmacy in Denver, Colorado, and his colleagues have worked diligently to get set up to speed on a new technological platform. He said that he thinks the process has gone generally well but recognizes that success also depends on the patient’s resources.

Scales noted major obstacles with a patient living in a rural area. “We have to use video relay because the patient’s internet connection is not stable enough to hold a conversation in real time,” Scales said. Because the patient is deaf, interaction also requires a sign language interpreter.

Historically, the health care industry has wrestled with telemedicine navigating the nebulous web of integration and reimbursement. If there is any benefit from the pandemic, it is the swift action to establish and bill for telemedicine services, according to Cantwell-McNelis. She cited a recent *New England Journal of Medicine* article highlighting the near-overnight transition. “The speed of the transition has been dizzying. Changes that would typically encompass months of planning, pilot testing, and education have been compressed into days,” the authors wrote.

**Post-pandemic Shifts in HIV Medicine**

With no viable cure or treatment for COVID-19 yet, investigators are exploring the potential benefit of antiviral protease inhibitors (PIs) routinely used in HIV medicine. The findings’ effects on the HIV population continue to unfold with emerging data and research.

At press time, 15 studies exploring the effects of PIs on COVID-19 were found on ClinicalTrials.gov. Results from a randomized, controlled, open-label clinical trial on lopinavir-ritonavir (Kaletra) following 199 patients in China showed that the drug did not speed recovery or reduce the viral load in patients with COVID-19.

“Until we know more about how PIs affect COVID-19, people with HIV should not switch their HIV medicine in attempt to prevent or treat COVID-19,” Scales warned.

Sources predict lasting changes in the post-COVID era of pharmacy. Scales and Cantwell-McNelis foresee telemedicine becoming a mainstay of treatment. He believes that the dynamics of the virus will further elevate the demand and profile of pharmacists’ contributions to the health care system by serving as a resource to the physician.

“Many physicians are emergency room doctors or heart specialists who are not trained in infectious diseases or to think about DDIs [drug-drug interactions] and how to monitor for heart conditions,” Ho said. “The pharmacist’s role is to serve as an expert when the physicians are caring for patients by looking for data to provide the best evidence available and being able to develop appropriate time-sensitive information.”

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Get Educated on Diabetes Devices

Pharmacists must be tuned in to the latest technology for patients who monitor blood glucose. By Tzipora R. Lieder, RPh

In the ever-changing world of diabetes devices, pharmacists need to stay on top of developments so that they can answer patients’ questions about what is available.

CGM Overview
Continuous glucose monitors (CGMs) are used increasingly to help patients with diabetes monitor and treat blood sugar levels, said Panteha Kelly, RPh, BCACP, APh, CDE, a clinical pharmacist specialist and clinic coordinator at the University of California, San Diego, Health Diabetes Self-Management Clinic in La Jolla, California.

Continuous scanning, or real-time, CGMs provide a constant reading of interstitial glucose to a receiver or smart device, and alarms alert the wearer when glucose is approaching patient thresholds for hyper- or hypoglycemia. In contrast, intermittently scanning, or flash, CGMs require the user to swipe the transmitter over the sensor to display data from the previous 15 minutes, including trend arrows showing whether blood sugar is rising or dropping and how quickly; they do not have alarms or alerts.

The most popular CGM on the market is the Dexcom G6 system. Unlike earlier Dexcom models and the other real-time CGMs, Guardian Connect and Eversense, Dexcom G6 does not require finger sticks for calibration. Eversense requires implant and removal every 3 months in office by a provider.

Jennifer Trujillo, PharmD, FCCP, BCPS, CDE, BC-ADM, believes that once it has been on the market for a while longer and gets approval for longer wear (6 or 12 months), it will likely be used more. Trujillo is an ambulatory care pharmacist and certified diabetes care and education specialist at the University of Colorado Anschutz Medical Campus Center for Adult Diabetes Care and Research in Aurora.

Freestyle Libre is the only flash CGM; it costs less than the Dexcom G6 and is easier to use, Trujillo said. Kelly cautioned that it must be scanned at least once every 8 hours to save the data for review later.

Real-time CGMs are usually preferred.

**TABLE. Answers to Commonly Asked Questions About CGMs**

<table>
<thead>
<tr>
<th>Query</th>
<th>Dexcom G6</th>
<th>Freestyle Libre</th>
</tr>
</thead>
<tbody>
<tr>
<td>For what age is it approved?</td>
<td>2 years and up</td>
<td>18 years and up</td>
</tr>
<tr>
<td>Where is it placed?</td>
<td>Abdomen or (in patients aged 2-17) buttocks</td>
<td>Upper arm</td>
</tr>
<tr>
<td>How long can the sensor be worn?</td>
<td>10 days</td>
<td>14 days</td>
</tr>
<tr>
<td>Is finger-stick calibration required?</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Can it be worn in water?</td>
<td>Yes, when bathing and swimming</td>
<td>Yes, when bathing</td>
</tr>
<tr>
<td>What is the warm-up time?</td>
<td>2 hours after inserting sensor</td>
<td>1 hour after inserting sensor and scanning it</td>
</tr>
<tr>
<td>Must the sensor be removed for MRI/CT scanning?</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>What substances interfere with use?</td>
<td>Acetaminophen at doses &gt;1000 mg every 6 hours may increase glucose readings.</td>
<td>Vitamin C doses &gt;1000 mg may increase glucose readings; salicylic acid (aspirin) doses &gt;650 mg may lower readings.</td>
</tr>
</tbody>
</table>
for patients with type 1 diabetes, who need close monitoring of their blood glucose and alerts, whereas flash CGMs are appropriate for patients with type 2 diabetes. The alarms on a real-time CGM can be lifesaving by, for example, alerting patients with hypoglycemic unawareness when their blood sugar is dropping, so they know not to drive, Kelly said.

“Real-time CGMs also allow data sharing, so it’s a great option for kids so that their parents can have the CGM data on their phones, as well,” Trujillo said.

**Insulin Pumps and Close-loop Systems**

About half of Trujillo’s patients with type 1 diabetes use insulin pumps. “The evidence at this point indicates that patients can achieve good glucose control in a variety of different ways, either through injection therapy or through insulin pump therapy, so I think it requires a thoughtful conversation between the patient and the provider,” she said.

Hybrid closed-loop systems combine the functionality of a CGM with a pump to automate insulin delivery based on real-time glucose values. The first hybrid closed-loop system, Medtronic’s MiniMed 670G, was approved in 2016. This CGM communicates with an insulin pump designed to decrease or stop insulin when glucose is low and increase insulin delivery when glucose is high, without input from the user.

Tandem’s t:slim X2 Insulin Pump with Basal-IQ technology was approved in 2018 as an insulin pump and CGM. The pump suspends insulin delivery if the CGM detects glucose falling below a predefined threshold.

Tandem’s next advance, approved in December 2019, is Control-IQ technology, which automatically increases, decreases, or suspends delivery of basal insulin based on insulin delivery history, CGM data, and predicted glucose values. Control-IQ uses the Dexcom G6 CGM with the t:slim pump.

For patients who have traditional insulin pumps, Trujillo said, providers track glucose trends over 3 or 6 months and work with the patients to adjust basal insulin rates for different times of day. “[This is as] opposed to the hybrid closed-loop insulin pumps, where the basal rates are constantly changing based on the glucose readings from the CGM,” she explained. “There is encouraging evidence that the hybrid closed-loop systems can improve glucose variability, particularly overnight.”

Patients are slowly transitioning to newer models but still represent a small percentage of patients with type 1 diabetes, Trujillo said.

Patients should be carefully selected, according to Kelly. “I can’t give a closed-loop system to just anybody at this time, because if it malfunctions [or] if someone has a low health literacy, it can be dangerous.”

**CGM Counseling Considerations**

Medicare typically covers CGMs for patients with diabetes who test their blood sugar at least 4 times a day and take multiple daily doses of insulin. Trujillo said. She believes that almost all patients with type 2 diabetes can benefit from a flash CGM. “Knowledge is very powerful,” she said, “and when you’re able to see your glucose values all day long without sticking your finger, that information can create important behavioral changes and can create more understanding of how medications are working and how different behaviors are influencing glucose.”

Patients can observe how stress, lack of sleep, and lack of exercise negatively affect their blood glucose control, whereas exercise and healthy eating improve glucose control, she said: “Seeing that over time can certainly improve glucose management overall.”

The 2 most popular CGMs can be dispensed in pharmacies, which places pharmacists in an ideal position to counsel patients about these devices, especially because most patients with type 2 diabetes are managed by primary care providers who may be less familiar with diabetes technology advances, Trujillo said. (See the Table for answers to commonly asked questions about CGMs.)

Kelly emphasized that patients need to understand that when starting to use a CGM, they cannot draw conclusions regarding diabetes management until they have collected 10 to 14 days of data. To capture nighttime data, she noted that patients starting to use the Freestyle Libre should scan their device both right before going to bed at night and upon waking up in the morning.

Trujillo encourages pharmacists to learn more about CGMs by taking continuing education courses and watching tutorials on the manufacturers’ websites. “It’s challenging to keep up on the latest and greatest but certainly important for a frontline health care provider like a pharmacist to do so,” she said.
Vaccines are crucial to protect public health globally, and pharmacists can play an important role in educating patients on the importance of immunizations. The World Health Organization named vaccine hesitancy as one of the 10 global threats of 2019. The measles outbreak was largely fueled by the antivaccination movement, and between January 1, 2019, and December 31, 2019, there were 1282 confirmed measles cases across 31 states. This was the greatest number of cases reported in the United States since 1992, a majority of which occurred in patients who were not vaccinated against measles. The cases included 128 patients requiring hospitalization, with 61 patients experiencing complications such as pneumonia and encephalitis. As of May 7, 2020, there have been 12 confirmed measles cases in 7 jurisdictions. Adults and children should be encouraged to stay up-to-date on their immunizations to combat vaccine-preventable diseases. Children can be protected against 14 diseases by 2 years of age when they are up-to-date with their vaccines.

Measles and Combating the Anti-Vaccination Movement

Pharmacists should educate families and debunk the myth that the measles, mumps, and rubella (MMR) vaccine causes autism. The CDC recommends that all children receive 2 doses of the MMR vaccine: the first at 12 to 15 months of age and the second at 4 to 6 years of age. The Wakefield study published in The Lancet in 1998 ignited fear among the public that the MMR vaccine caused autism, but it was fraudulent. The study was retracted, and author Andrew Wakefield lost his medical license. However, those opposed to vaccination continue to cite the false claim that links the MMR vaccine with autism, which has contributed to a decline in vaccination and increased the spread of measles globally. One recent large-scale study involving 657,461 Danish children over a 10-year period demonstrated that there is no link between the MMR vaccine and autism. Pharmacists should educate families about the negative health consequences of vaccine refusal for children and adults, especially regarding the MMR vaccine. Measles can result in serious complications: pneumonia, encephalitis, permanent hearing loss, hospitalization, and death. Refusing the vaccine also puts those who are too young to receive it or immunocompromised at risk. Many social media platforms, such as Facebook, Twitter, Pinterest, and YouTube, have taken steps to counter vaccine misinformation, but inaccurate information is still spreading globally. One study based on surveys of almost 2500 US adults found that up to 20% of participants were somewhat misinformed about vaccines. Survey participants who reported increased exposure to information about measles and the MMR vaccine on social media were more likely to grow more misinformed about immunizations. However, those who reported increased exposure to these health topics in traditional media were less likely to support antivaccination claims. Some noteworthy study findings include the fact that 18% of participants mistakenly believe it is very or somewhat accurate that vaccines cause autism. Also, 20% incorrectly report that it makes no difference if parents choose to delay or spread out childhood vaccines instead of adhering to the CDC-recommended immunization schedule.

According to a study by Health Testing Centers, between 2009 and 2018, 27
US states experienced a decline in the percentage of vaccinated kindergarten-age children. Data from the CDC were used to analyze vaccine rates for kindergartners for the most common immunizations, including MMR; diphtheria, tetanus, and pertussis (DTaP); polio; hepatitis B; and varicella. The results found that MMR vaccination rates fell below the 95% target aimed at providing the best protection against measles in 26 states.

The benefits usually outweigh any risks when it comes to vaccines, said Mary Malek, PharmD, AAHIVP, a pharmacist specializing in HIV who practices in New York. “As pharmacists, we must continue to recommend vaccinations to all our patients,” Malek said. “In order to combat the antivaccination movement, we have to use logic and numbers that tell the story.”

Measles was declared eliminated in the United States in 2000, but in the past 5 years especially, there has been an increase in cases. “Reassuring parents is needed, and using data to support that, I believe, is key. If we do not learn from our past, we will never be able to have a better future,” Malek said. Pharmacists can use social media platforms to educate the public and champion vaccines. Community outreach programs and health fairs are also great ways to spread the word about being up-to-date on vaccines. Additionally, pharmacists can advocate for stricter state vaccine laws regarding religious or philosophical exemptions.

**Encourage Influenza Vaccination**

During the 2019-2020 influenza season, 174 influenza-associated pediatric deaths were reported to the CDC as of May 9, 2020. This past season, influenza-associated hospitalizations in the United States were higher overall than in most recent seasons, and rates for children aged 0 to 4 years and adults 18 to 49 years were the highest the CDC has on record for these age groups, exceeding the rates reported during the 2009 H1N1 pandemic. The CDC’s interim report revealed that the influenza vaccine was 45% effective overall against any influenza virus. Additionally, the vaccine offered a substantial protection of 55% efficacy against the illness among children and adolescents aged 6 months to 17 years. These results are consistent with those from previous influenza seasons, which ranged from 40% to 60%. Children should receive the vaccine as soon as it becomes available, especially those receiving it for the first time as they need 2 doses. The American Academy of Pediatrics has no preference for using flu shots over nasal sprays for the 2020-2021 season. The CDC’s Advisory Committee on Immunization Practices plans to meet this summer but is not expected to make major changes for the upcoming influenza season.

Patients are sometimes hesitant to get an influenza shot because the efficacy can vary each season, so it is important for pharmacists to tell patients that an annual vaccine for everyone 6 months and older is the best way to protect against the illness. Evidence demonstrates that the vaccine protects against influenza-related complications such as hospitalization and death. One study examined the impact of pharmacy-based immunization services on the likelihood of patients receiving the adult influenza and pneumococcal vaccines. The study found that patients were more likely to be vaccinated against influenza and pneumonia after receiving the immunization services. As some of the most accessible health care professionals, pharmacists can play an important role in increasing influenza immunization rates.

Pregnant women are at higher risk of influenza-related complications, so it is especially important for this population to be vaccinated. Influenza vaccination during pregnancy also provides passive immunity to the baby during the first few months of life. One CDC report revealed that only 53.7% of pregnant women received the influenza vaccine; therefore, pharmacists can play a vital role in educating pregnant patients about the importance of the vaccine.

**Vaccine Resources For Pharmacists**

Pharmacists can stay up-to-date with the latest vaccine information through the CDC website. The Immunization Action Coalition also includes information on all immunizations as well as frequently asked questions. Further, the CDC has a free Vaccine Schedules app that includes all recommended immunizations for children and adults. The agency also created a free app called the PneumoRecs VaxAdvisor to help determine which pneumococcal vaccines patients need based on their age and medical history.

“For references, visit drugtopics.com.”
Over 80 autoimmune diseases affect an estimated 14.7 million to 23.5 million people in the United States. The mainstays of therapy consist of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, disease-modifying antirheumatic drugs (DMARDs), and anti–tumor necrosis factor (TNF)–α biologics, but various products over the counter also help relieve symptoms. Pharmacists can help patients select the appropriate OTC medications in light of special considerations related to their conditions.

NSAIDs: An Important Part of Therapy

For rheumatoid arthritis (RA) and other autoimmune diseases, NSAIDs can be a good starting point for relieving pain and inflammation, said Wendy Ramey, BSPharm, RPh, CSP, clinical pharmacist with a specialty in inflammatory conditions at University of Kentucky’s specialty pharmacy and infusion services in Lexington. For some conditions, such as ankylosing spondylitis, most insurance companies require that patients try OTC or prescription NSAIDs before being approved to move on to biologics, she said.

Ramey recommends that patients limit OTC NSAID use to short periods. “If they need to go beyond 2 or 3 weeks of everyday use, then they’re going to need to talk to us about some other kind of treatment to take care of their pain,” she said.

Community pharmacists who notice patients with autoimmune diseases consistently buying these OTC products should initiate a discussion regarding use, said Jessica Farrell, PharmD, clinical pharmacist at the Center for Rheumatology at the Albany College of Pharmacy and Health Sciences in New York. “If [patients are] using lots of NSAIDs consistently with a DMARD—methotrexate, hydroxychloroquine, sulfasalazine—or a TNF inhibitor...then maybe that DMARD or biologic is not adequate,” Farrell said. Patients should be advised to speak with their provider about trying a different therapy. Patients also should take a histamine-2 receptor blocker or proton pump inhibitor (PPI) because of gastrointestinal toxicities related to NSAIDs, she advised.

Other Helpful OTCs

Pharmacists can recommend other OTC products to manage symptoms. For patients with inflammatory arthritis, Farrell encourages use of OTC topical pain-relief products such as lidocaine patches and diclofenac gel. “These are great options for patients who have more mild disease or in smaller joints or for small flares that don’t require systemic therapy,” she said.

Pharmacists also can guide patients toward OTC products to treat the dry mouth and eyes associated with Sjögren syndrome. “Many of our patients [with] other autoimmune diseases have overlap Sjögren syndrome,” Farrell reported. Various products treat dry mouth, including mouthwashes, gums, and toothpastes, and it often takes trial and error to find what works best for each patient, she said. Patients with Sjögren may need help finding the right eye drops, whether they need a preservative-free product or one for sensitive eyes. Gel-like drops can be particularly helpful for patients with severe nighttime dryness that interferes with sleep, Farrell said.

Mild injection site reactions in patients on injectable therapies can be
treated with OTC topical steroids or antihistamines, according to Farrell.

For patients who complain of insomnia, which can be caused by an autoimmune disease or its treatment, Ramey recommends melatonin products rather than antihistamines, which can have other unwanted effects.

Supplementary Sources
Various nutritional supplements also play a role in managing autoimmune diseases. Folic acid supplementation is crucial to reduce the gastrointestinal and liver toxicities of methotrexate therapy in patients with RA. Although most patients take prescription folic acid, Farrell said, some use the OTC version. Recommendations on amounts vary, but common regimens consist of 1 mg daily or 5 mg once weekly.

Some data suggest that cherries and cherry extract products have antioxidant properties and reduce inflammation in patients with gout. Farrell commonly adds those products as an adjunct for patients taking uric acid-lowering therapies, such as allopurinol and febuxostat, who need additional lowering therapies, such as allopurinol.

Avoid Interactions
An important drug interaction in this population occurs between immunosuppressant mycophenolate mofetil and PPIs. Farrell noted. PPIs can reduce absorption of mycophenolate mofetil, which requires an acidic environment for optimal absorption, so patients should take mycophenolate mofetil at least 90 minutes before the PPI. Pharmacists are in an ideal position to alert patients about this interaction, she said, because physicians might not be aware that their patients are taking OTC PPIs.

To avoid toxicity, acetaminophen use should be limited to 2 g per day in patients taking drugs that are metabolized by the liver. Ramey said. Farrell noted that in patients taking hydroxychloroquine, any OTC product potentially associated with increased risk of QTc prolongation, such as pseudoephedrine, could be problematic.

"For the most part, we [in the field of rheumatology] are very lucky to have drugs that don’t cause us very many [drug interaction] problems," Ramey said.

Pharmacy software might flag an interaction between methotrexate and NSAIDs, but that is not clinically relevant in this patient population, Farrell said. NSAIDs can prevent excretion of methotrexate, which is used in high doses in oncology, and result in toxicity, but that is not an issue at the doses used in autoimmune diseases, she said.

Infection Control
Because so many patients with autoimmune disease take immunosuppressants, pharmacists counseling them should be on the lookout for infections. "If a patient with an autoimmune disease is coming in looking for something to treat a possible infection, that would be the first clue that something needs to be addressed with their doctor," Ramey said. "Because so many of our medications increase the risk of infection, we always want to know if a patient has a cut or a bug bite that is starting to look infected; that is our biggest concern."

Patients on immunosuppressants who want to buy OTC cough or cold products should be reminded that their current treatments prevent them from fighting infections. "If they’re on methotrexate, sometimes, if it’s a very mild infection, we might not have to hold it, but if they’re on biologics, they definitely should hold during an infection."
Pharmacies Can Take Steps to Protect Against Cyberattacks

By John Schieszer

When it comes to cybersecurity threats related to the Health Insurance Portability and Accountability Act (HIPAA), pharmacists are in a unique and rather unenviable position.

Joey Mattingly, PharmD, PhD, MBA, an associate professor and vice chair of academic affairs of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy in Baltimore, teaches a pharmacy management course that examines practical implications of HIPAA. Like all businesses, pharmacies are susceptible to cyberattacks, he said, so it is important to have an information security plan that covers everything from training to what to do if a breach occurs.

“Many large chain pharmacies have well-established policies and procedures, but a start-up pharmacy or smaller organization may not have as large of an infrastructure in place,” Mattingly told Drug Topics.

Recent data breaches with large companies and potential interference in major political elections have heightened attention to cybersecurity concerns, and it is paramount that pharmacists understand their existing company policies, Mattingly said. Pharmacists starting their own businesses should consider hiring information technology experts to establish detailed standard operation procedures specific to security.

“Err on the side of caution. One large data breach could [affect all] your patients, your employees, and yourself. The fallout from a data breach could be devastating and potentially ruin your business, particularly since it involves our patients’ personal health information,” he said.

Investing in proper training is key. Mattingly advocates taking the time to teach, review best practices, and make sure all employees practice what they learned. “Test your processes and systems for security gaps,” he said. “Many retail stores use secret shoppers to test customer service, [and] a pharmacy can use this technique to see if any of your employees would fall for a basic hacking ploy [such as a phishing email].” Mattingly advises focusing on best practices rather than failures: “You should provide incentives for your pharmacists and technicians who do things right.”

Better Equipped to Combat Threats

Pharmacists now have more tools and technologies to protect their data, but cyber criminals have also developed new strategies, and the risk continues to evolve, according to Mattingly. Protecting against a cyberattack should be viewed as a business expense or operating cost, he noted. “Pharmacies are already pressured with decreasing margins on pharmacy sales, so it is important that pharmacists advocate for either increased revenues for pharmacies or other financial support [such as low-interest loans and tax incentives] for technology and training investments,” he said.

Neil Edillo, PharmD, assistant director of pharmacy services and information management and medication safety at Oregon Health & Science University (OHSU) in Portland, said that as far as he knows, no cyberattacks have targeted only the pharmacy community.

“The primary threat to obtain user login credentials is phishing. As great as our email servers are, some of these email attempts are able to find their way...
through to our end users. Our health system has provided education about what phishing attempts look like and what to do with them,” Edillo said. OHSU has instituted test programs in which they internally generate a phishing-like email that is distributed to all users across the university and health system from an outside mail server. “If the user clicks on the links contained in the email, they are immediately provided instruction on phishing attempts and to maintain their vigilance against cybersecurity threats,” Edillo told Drug Topics’

A Potential Leak
Pharmacists interested in protecting themselves and their customers from cyberattacks need to invest in vendors that handle their data, according to investigators at American University in Washington, DC. They conducted a study and found that a data breach due to a third-party supplier was more likely to lead to an underinvestment in cybersecurity measures. The study authors wrote that all companies need to look at every entity that handles their data—just 1 weak link and the system is compromised. Study coauthor Jay Simon, PhD, an associate professor of information technology and analytics at American University’s Kogod School of Business, said there is a huge range of cybersecurity threats, depending on the systems, data involved, and the attackers’ goals. ‘A computer needs to have adequate security settings and software, but the user also needs to understand how to avoid installing malware or falling for phishing scams. Pharmacists face the added legal and ethical ramifications of having sensitive personal data compromised, which makes all these measures even more crucial,” Simon told Drug Topics”.

A few years ago, Merck was hit with a serious ransomware attack, which is a common issue for health care providers, according to Simon. Last June, 5 US health care organizations reported ransomware attacks, with some having to pay to regain access to files. “Keep your security software up-to-date, and understand the common techniques that attackers use. Good password management and not clicking on anything suspicious goes a long way. Be restrictive about who’s allowed access to your computers and network, both physically and electronically,” he said.

Lisa Schwartz, PharmD, senior director of professional affairs at the National Community Pharmacists Association in Alexandria, Virginia, said that like any business, pharmacies face the threat of having digital records hacked. However, these vulnerable data include not just personnel and financial records of the business, but also patient health information, which opens pharmacies up to scrutiny by the US Department of Health & Human Services Office for Civil Rights, which enforces HIPAA.

“It makes sense for pharmacists and pharmacy owners to use many of the tools that are available to HIPAA-covered entities and organizations trying to improve cybersecurity. These include virtual private networks, firewalls, and antivirus software,” Schwartz said. “[Although] those tools help protect the pharmacy management system from cyberattacks, inappropriate access by employees of the pharmacy is another concern.” Pharmacy owners should seek advice from software vendors about the access controls and the best method of monitoring, according to Schwartz. “For example, the pharmacy’s privacy officer could have an alert in place anytime a high-profile patient’s record is accessed to prevent unauthorized use or disclosure,” Schwartz said.

Today’s tactics are more subtle than those of the past, Schwartz said. Cyber criminals often try to collect bits of personal data to trick individuals into replying to an email or clicking a link they would normally discard if it snuck though a spam filter. “Pharmacists and pharmacy staff can do their part to minimize cybersecurity threats by only using pharmacy computers to access trusted websites and to be careful about opening attachments or clicking links in email,” Schwartz said. “For example, if a technician receives an email that appears to be from a familiar vendor but contains an unexpected invoice, call the sender and ask if it is legitimate.” Fred H. Cate, JD, vice president for research and a professor of law at Indiana University, said pharmacists are seeing more desperate requests for help to provide a drug without a prescription or help a patient with shipping or supply chain delays related to the pandemic. “Most of these requests are almost certainly legitimate, but that is just how a criminal would approach a pharmacy, as well, whether in a classic fraud attack or in an effort to find access information [or] an unlocked machine or other ways to infiltrate the system,” Cate said. In recent years, he said, many attacks originated from people sitting in cars in parking lots using wireless access through the payment or other systems. Cate added that because of the pandemic, pharmacists need to be vigilant. “These types of attacks are more likely to succeed and less likely to be noticed when there are other stresses on the system,” Cate said.

For references, visit drugtopics.com.
Hospital Pharmacists Face Challenges in Reducing Antibiotic Overuse

Antibiotics pose a conundrum: These drugs are crucial for destroying or slowing certain types of bacteria, but concern about overuse in hospitals and inappropriate prescribing practices fuels debate about the complex relationship between antibiotic use and antimicrobial resistance.

"Pharmacists play a pivotal role in antimicrobial stewardship in an organization, and it’s really around a multidisciplinary approach and a coordinated effort, with the goal to improve and measure appropriate use of antibiotics,” said Onisis Stefas, PharmD, MBA, vice president and chief pharmacy officer at Northwell Health in New York. “We look to promote high-quality care and positive clinical outcomes, we look to decrease length of stay where possible, and we also look to decrease microbial resistance.”

He explained that patients tend to first receive broad-spectrum antibiotics, which may then be replaced with a more appropriate narrow-spectrum antibiotic based on the subsequent lab results identifying the specific bacteria involved.

“We work hand in hand with providers,” Stefas said. “It is an interdisciplinary action to get the patient on the right drug at the right time.”

Antibiotics are generally overused, especially in patients in the emergency department, according to Michael J. Brown, RPh, BCPS, BCPP, a hospital pharmacist in Lake Oswego, Oregon, who specializes in psychiatry.

“There seems to be a tendency to use Zosyn [piperacillin and tazobactam] and vancomycin initially in patients who present with infectious symptoms,” he said. “This is what we call the shotgun approach and is effective in killing most bacteria. The downside is, this combination is hard on the kidneys, and overuse can lead to bacterial resistance.”

Sarah Jones, PharmD, BCPS-AQ ID, a clinical pharmacist in infectious diseases at Boston Children’s Hospital in Massachusetts, said the hospital is “a very antibiotic-using institution compared to many of its peers.”

“There is a lot of empiric antibiotic use in pediatrics still in all facets, though we have been trying over the last 2 to 3 years to chisel away antibiotic use,” she said. “There is a lot of movement in most centers to have antimicrobial stewardship programs up and running and trying to get to more of an appropriate antibiotic use.”

Surgeons are quick to add antibiotic therapy for patients looking unwell and then later question the drugs’ necessity, according to Jones.

“We are not a proactive stewardship program, but we look back retrospectively a day or 2 into therapy,” Jones said. “We try to explain why an antibiotic is not necessary in the setting that [it was started] for.”

Scaling Down Use

The good news: Many hospital pharmacists have become much more involved in antibiotic de-escalation. Hospital pharmacies have developed protocols for not only narrowing antibiotic therapy but also reducing costs by altering the route of the antibiotics used when appropriate. For instance, changing from an intravenous to an oral form can save a lot of money. Steps to reduce use involve
Most progressive hospitals have better screening and lab testing, according to Brown. “Broad-spectrum antibiotics should only be used initially if the infection is severe or life-threatening,” he said. “Clinical judgment is important, as well. Many antibiotics are used for urinary tract infections in elderly patients. This is often unnecessary unless the patient has symptoms such as altered mental status, pain with urination, or an increased urge to urinate.”

Pharmacists often act as gatekeepers to avoid misuse of antibiotics, Stefas noted, and are charged with reviewing antibiotics, providing recommendations on antimicrobial regimens, and reducing inappropriate or unnecessary use. Boston Children’s Hospital practices “handshake stewardship,” in which pharmacists intervene with prescribing physicians and have a direct line of communication to residents, asking them to question their attending in a decision made by the team. According to Jones, the program has had lingering effects on future cases, with durations of antimicrobial therapy being more regularly followed.

J. Russell May, PharmD, FASHP, a clinical professor at the University of Georgia College of Pharmacy in Athens, practices at Augusta University Medical Center, where his students do antimicrobial stewardship activities. He said that 53% of the antibiotics used in the hospital require a dose adjustment if the patient has decreased kidney function.

“Pharmacists can reduce the dosage of those antibiotics by protocol based on the level of kidney impairment,” he said. “That decreases the chance of a patient having an adverse reaction (and) prevents any toxicity from the drugs. And conversely, if the kidney function improves, we can go the other direction and increase dose to proper dosage.”

**Becoming More Effective**

Most progressive hospitals have pharmacy protocols regarding antibiotic therapy. For example, where Brown practices, staff follow all patients on antibiotics and monitor for appropriate agents, duration of therapy, and drug-drug interactions. “We also switch patients from intravenous therapy to oral as soon as possible,” he said.

“We may also suggest an infectious disease consult in certain circumstances,” Brown added. “We read progress notes from the physicians daily and review lab results. Our aim is to reduce cost, improve outcomes, and decrease drug resistance.”

An important part of the hospital pharmacist’s job involves looking at orders and ensuring that there are no duplicates, Stefas said. It’s also important to avoid dangerous drug-drug interactions, such as with warfarin and ciprofloxacin, which could increase bleeds. “We look at food and drug allergies, as well, making sure a medication is used with food or without food and making sure the timing of that medication is not when patients are receiving their meals,” he added. “We’re also looking to make sure the right drug is used based on indication and the lab results.”

When a patient is discharged, a pharmacist on the floor should provide instructions, Stefas said. “We let people know how important it is for a patient to continue that antibiotic, if necessary, out in the community,” he said. “We stress the importance to the patient and family because [otherwise] it can cause additional issues.”

According to Stefas, early discontinuation of the regimen may contribute to the development of resistance to the antibiotic. This could result in the drug becoming less effective against that bacteria in the future.

A hospital pharmacist also does a lot of data analysis on prescribers and prescriptions and then passes that information to providers to share what’s working, best practices with certain bacteria, and lab result trends.

**Recent and in the Pipeline**

The CDC reported that every year, Americans fight more than 2.8 million serious infections caused by antibiotic-resistant bacteria, with approximately 35,000 deaths. A sustained and robust pipeline of antibacterial drugs and novel therapies is critical to ensure that new interventions keep pace with evolving pathogens.

Brown noted that newer options include meropenem-vaborbactam (Vabomere), a newer agent to fight carbapenem-resistant Enterobacteriaceae (CRE).

“It is the first carbapenem β-lactamase inhibitor combination with activity against broad-spectrum β-lactamases,” he said. “We often use meropenem for patients who are sensitive to penicillin.”

In November 2019, the FDA approved cefiderocol, an antibacterial drug for patients aged 18 years or older with complicated urinary tract infections (cUTIs), including kidney infections caused by susceptible gram-negative microorganisms, who have limited or no treatment options. Another newer addition: plazomicin (Zemdri), an aminoglycoside that received FDA approval in June 2018. Brown warns that this agent should be used only in patients with cUTIs, including pyelonephritis, who have limited or no options.

Eravacycline (Xerava), which is a tetracycline-class compound, was approved by the FDA in August 2018 to treat complicated intra-abdominal infections. Omadacycline (Nuzyra), another tetracycline, received approval in October 2018 and is indicated for community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections.
Pharmacists Play Valuable Role in Addressing Social Determinants of Health

Through screening and interventions that target medication adherence and reduce medical spend, pharmacists can help influence outcomes associated with social determinants of health (SDOH), according to a live broadcast session from the 2020 Pharmacy Quality Alliance Annual Meeting.

Dani Markus, PharmD, MBA, vice president of quality at OutcomesMTM, and Sarah Dean, PharmD, MPH, clinical program lead, quality network, at Humana, presented results from a study conducted by Humana, which evaluated SDOH services by collecting data through assessments distributed to pharmacies. The investigators aimed to determine whether pharmacists were able to have effective conversations with patients about SDOH and if intervention spurred changes in the patients’ health-related behavior.

Assessment questions focused on factors that often inform an individual’s health, such as housing, food, transportation, physical/emotional well-being, and school/work life and included the following:

- What is your housing situation?
- Are you worried about your housing?
- Have you worried about running out of food in the last 12 months?
- Has a lack of transportation kept you from going to medical appointments?
- How often do you feel lonely or isolated?
- Do you want help finding or keeping work?

The investigators amassed 9802 (56%) successful assessments from 2162 pharmacies from November 15 to December 31, 2019, which included patients with chronic conditions including atrial fibrillation, chronic obstructive pulmonary disease (COPD), depression, diabetes, hyperlipidemia, hypertension, and osteoporosis.

The most prevalent SDOH reported were food insecurity, social isolation, and transportation, with 12.5% of participants reporting challenges in making food last and affording a sufficient supply and 11.2% reporting challenges in finding transportation in the past 12 months. In addition, 18% reported sometimes, often, or always feeling lonely or socially isolated.

In evaluating data according to the chronic conditions present in the study, those with COPD or depression demonstrated higher reports of SDOH than other demographics did. Although 13% overall said they worried about running out of food, 16.5% of those with COPD and 16.2% with depression reported this concern. According to the investigators, individuals who completed the assessment also showed statistically significant decreases in medical spend.

The investigators identified limitations related to the short study period and follow-up frame and suggested important revisions, such as working toward offering a follow-up service that facilitates action and provides resources based on the conversation between an individual and a pharmacist.

Future recommendations involved offering best practices to facilitate productive conversations. Some pharmacists in the study were successful in engaging individuals and finding helpful resources. Through the assessment, 1 pharmacist determined that an individual was struggling to afford food but not on food stamps; as a result, he put his patient in touch with an agency to help.

Other participants made it a priority to follow up with individuals who expressed SDOH: “We...educated the patient on the available local sources of social assistance, such as Red Cross, Salvation Army, Haven of Mercy, etc. We flagged the patient’s chart to follow up with her when she comes to the pharmacy,” a participating pharmacist told the investigators.

In evaluating data according to the chronic conditions present in the study, those with COPD or depression demonstrated higher reports of social determinants of health than other demographics did.
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No Good Deed Goes Unpunished

We all know that Friday afternoons are hectic in the community pharmacy, especially the first of the month. One Friday, after finishing my typical lunch (yes, I take 10 minutes to do that), I called a pharmacy for a transfer for one of our patients. As I was on the phone, I overheard my technicians, Amber and Katie, looking for trifluridine eye drops. I reminded them to check the refrigerator. None there. After I was done with my call, I asked who wanted the trifluridine drops, assuming it was another Thompson Pharmacy. They said it was some eye doctor’s office but could not recall which.

About 7 years ago, my niece Rachel Fritz, who is now an optometrist, stayed at our home while interning at a local eye clinic. I came home after work one day and told her that a Medicaid managed care organization (MCO) denied a claim for trifluridine because the patient used their 6 prescriptions for that month. I called the ophthalmologist and got the medication changed to valacyclovir, knowing Medicaid would pay to treat genital herpes but not herpes keratitis.

“Uncle Pete, herpes keratitis is sight threatening, and you probably saved that patient’s vision,” Rachel said. Herpes keratitis needs to be treated within hours of diagnosis, and waiting 2 days for prior authorization is not appropriate. My techs called all the ophthalmology practices in Altoona, Pennsylvania, and tracked down the nurse who made the request. I spoke with her, and she said no one in the city had the eye drops in stock. I told the nurse to give me the prescription over the phone and my driver would go to the warehouse to pick up this sight-saving eye drop. I called “Rich,” the representative at Value Drug, around 1:15 PM, and he set the wheels in motion. Less than 2 hours later, my driver, Don, appeared, drops in hand.

When the patient’s daughter came in at that day, she was most appreciative of our efforts. Her 90-year-old mother was a customer of a big-box store, where little effort was made to help this patient. The woman handed me her mother’s Medicare Part D card, and Amber ran the prescription through our pharmacy filling software. When Amber got the approval, her bright smile was absent from her face as she called me over.

Amber informed me that Medicare Part D had paid us $123.02 for this sight-saving eye drop that cost us $189.93, for a loss of $66.91. That’s not counting all the time my techs spent, the mileage and time my driver spent, and time I invested to help this 90-year-old woman get the medication because the big box had no interest in doing so. What should we do? I assured Amber that over the weekend, I would fill out the paperwork to challenge this gross injustice of payment.

My only wish is that the pharmacy team at this MCO could hear my niece say that herpes keratitis is sight threatening and needs to be treated immediately. There was no time to scour other warehouses to find a cheaper generic. This small, 1200-square-foot drugstore will take care of the patients and their problems that the big-box guys could care less about.

Clare Boothe Luce is attributed with saying “No good deed goes unpunished.” This independent pharmacist hopes that this is not the case for the herculean efforts made to help this most needy patient.

IN MY VIEW

By Peter A. Kreckel, RPh

This small, 1200-square-foot drugstore will take care of the patients and their problems that the big-box guys could care less about.
On February 27, 2020, the FDA approved an intravenous solution of amisulpride (Barhemsys; Acacia Pharma) to treat and prevent postoperative nausea and vomiting (PONV). For prevention, amisulpride can be used alone or with another antiemetic. For PONV treatment, it may be administered to patients who received no prophylactic therapy or received a different drug during prophylaxis. Amisulpride, a selective D2/D3 dopamine receptor antagonist, is the first of Acacia Pharma’s pipeline medications to be approved after showing positive results in 4 phase 3 clinical trials.

**Efficacy**

Data from 4 randomized double-blind, placebo-controlled, multicenter trials supported the approval of amisulpride for prevention and treatment of PONV.

Two studies evaluated the agent’s use for prevention of PONV in patients undergoing general anesthesia and elective surgery. In both studies, treatment groups were matched for PONV risk factors. In study 1, participants (n = 342) received 5 mg of amisulpride (n = 176) or placebo (n = 166). In study 2, participants (n = 1147) received amisulpride plus standard therapy of ondansetron, betamethasone, or dexamethasone (n = 572) or placebo plus a standard antiemetic (n = 575). The primary outcome in both studies was complete response (CR), defined as no emesis and no use of rescue medication in the 24-hour postoperative period. In both studies, groups receiving amisulpride demonstrated increased rates of CR: study 1, 44% in the amisulpride treatment group vs 33% in the placebo group (difference, 11%; 95% CI, 5%-17%); study 2, 58% in the amisulpride plus standard antiemetic group vs 47% in the placebo plus standard antiemetic group (difference, 11%; 95% CI, 5%-17%).

Amisulpride’s effectiveness for treating PONV was demonstrated in 2 studies using the agent as a 10-mg single dose. In study 3 (n = 369), participants did not receive prior prophylaxis. Participants in study 4 (n = 465) received prior prophylaxis therapy with a nondopaminergic antiemetic (77%, 5-HT3 receptor antagonist; 65%, dexamethasone; 10%, other medication). Both studies evaluated the CR rates within 24 hours after administration with amisulpride excluding emesis within the first 30 minutes. Groups receiving amisulpride demonstrated increased rates of CR: study 3, 31% in the amisulpride treatment group vs 22% in the placebo group (difference, 10%; 95% CI, 1%-19%); study 4, 42% in the amisulpride treatment group vs 29% in the placebo group (difference, 13%; 95% CI, 5%-22%).

Overall, participants given amisulpride experienced significantly lower incidence of emesis, nausea, and rescue medication use compared with placebo, as monotherapy, and combined with other antiemetics.

**Safety**

Among all the studies of amisulpride, the adverse event (AE) profile was similar to that of the placebo groups. The most common AEs include infusion-site pain (6%), increased serum prolactin (5%), hypokalemia (4%), chills (4%), procedural hypotension (3%), and abdominal distention (2%). QT prolongation is a dose- and concentration-dependent AE associated with amisulpride use. It is unlikely to contribute to a meaningful QT prolongation at approved doses, but monitoring is recommended in patients who are at higher risk; have preexisting arrhythmia or cardiac conduction disorders, congestive heart failure, hypokalemia, hypomagnesemia; or receive concurrent medications that can prolong the QT interval (such as ondansetron). Amisulpride is extensively renally eliminated; its use should be avoided in patients who have severe renal dysfunction, with an estimated glomerular filtration rate less than 30 mL/min/1.73m², because these patients may be at increased risk of AEs.

**Dosing**

For prevention of PONV, amisulpride is given as a 5-mg, single-dose infusion over 1 to 2 minutes at the induction of anesthesia. This may be administered as monotherapy or with another antiemetic medication. For treatment of PONV, amisulpride is infused as a 10-mg dose over 1 to 2 minutes in the event of nausea or vomiting after surgery.
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