PHARMACY IN 2021
TRENDS TO TRANSFORM AN EVOLVING PROFESSION

A New Administration... COVID-19

PHARMACY SOFTWARE FOR PHARMACY SUCCESS

ENHANCE PATIENT CARE

IMPROVE PROFITABILITY

INCREASE PATIENT SAFETY

“The system is user friendly and because every pharmacy is different, they will customize it to your needs.”

JUDY HARRIS, Owner, Pharmacist, All-Care Pharmacy

www.libertysoftware.com or call us at 800-480-9603
PHARMACY IN 2021
TRENDS TO TRANSFORM AN
EVOLVING
PROFESSION

A New Administration - COVID-19

PHARMACY SOFTWARE FOR
PHARMACY SUCCESS

- FLEXIBLE PHARMACY WORKFLOW
- PATIENT ADHESION AND PERFORMANCE DASHBOARD
- TEXT, EMAIL AND VOICE PATIENT MESSAGING
- INTEGRATED FACTS AND COMPARISONS
- CLOUD POWERED MULTISTORE MANAGEMENT
- PRESCRIPTION READY BOARD
- EXTENSIVE REPORTING AND DATA MINING
- MODERN PAYMENT PROCESSING INCLUDING EMV
- MEDICATION THERAPY MANAGEMENT
- SIMPLE DRIVE THROUGH SOLUTIONS
- MESSYNC AND REFILL MANAGEMENT
- INVENTORY CONTROL MADE EASY
- PROFIT AND INSURANCE AUDIT PROTECTION
- FRONT END INVENTORY MANAGEMENT
- ADVANCED BIN MANAGEMENT
- DELIVERY AND REMOTE SIGNATURE MANAGEMENT
- COMPOUNDING TOOLSET

Liberty SOFTWARE

2021 Opportunities and Headwinds in Pharmacy

Opioid Education
PHARMACY IN 2021
TRENDS TO TRANSFORM AN EVOLVING PROFESSION

- A New Administration
- COVID-19
- Expanded Roles
- Virtual Health

VACCINES
Understanding the COVID-19 Vaccine

TECHNOLOGY
Using Data to Protect Profits

RESPIRATORY
Updates in Asthma

DIABETES
OTC Basics

PAIN
Community-Based Opioid Education
The High-Quality CBD You Can Trust

Forth™ CBD is third-party lab tested for quality and purity. Our full-spectrum CBD Lotions and Tincture Drops provide all the benefits of the hemp plant without forfeiting quality—helping to relieve unwanted tension, to improve recovery time from physical activities, and to provide a sense of relaxation.

*Tincture Drops available in 10mg and 20mg of CBD per serving

Learn more at Ealternativesolutions.com
Much of our focus over the last year has been on the ongoing battle with the coronavirus disease 2019 (COVID-19) pandemic and its effects on pharmacy. As we head into the new year, this battle will continue. As new vaccines roll out and the first wave of vaccinations begins, pharmacists will be tasked to help with massive immunization efforts over the course of the next year.

A session at the American Society of Health-System Pharmacist’s (ASHP) Midyear 2020 Clinical Meeting and Exhibition, which was held virtually December 6-10, 2020, highlighted the pharmacist’s important role in these COVID-19 vaccination efforts. Read on page 16 to learn more about the COVID-19 vaccines’ development processes and how to address vaccine hesitancy. You’ll also find more coverage from the meeting throughout the issue, including updates on asthma management and top policy priorities for health-system pharmacists as we head into the new year.

Apart from COVID-19, there are several other industry trends taking root that will likely have a transformative effect on the profession in years to come. Between an expanding scope of practice, increasing acceptance of virtual health, and breakthrough advancements in medicine, there is no shortage of topics to discuss. Read our cover story on page 10 to find out more.

On page 26, Jennifer Gershman, PharmD, gives insight into some of the most highly-anticipated FDA approvals expected for 2021. Stay up-to-date on these impending treatments across therapeutic areas including COVID-19, oncology, migraine, and more.

For our career-minded pharmacists, Drug Topics® editorial advisory board member Mohamed Jalloh, PharmD, BCPS, discusses how pharmacists can build career skills for the future of pharmacy. As Jalloh writes in his commentary starting on page 28, “Every pharmacist dreams of a great purpose in their pharmacy career. However, many often feel frustrated with the current employment market.” Read on to learn how pharmacists can adapt their skills to keep up with an evolving profession and take advantage of future employment opportunities.

As we look back at 2020 and ahead to 2021, the Drug Topics® team wishes all of our readers a happy new year.

Thank you for reading,

Mike Hennessy Sr
Chairman and Founder of MJH Life Sciences™
EDITORIAL MISSION: Drug Topics® is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics® for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
Survey: Pharmacists Ready to Receive, Administer COVID-19 Vaccines

A survey of 400 pharmacists nationwide conducted by the American Pharmacists Association (APhA) asked pharmacists if they were ready to receive and administer coronavirus disease 2019 (COVID-19) vaccines.

According to the responses, 37% of pharmacies are ready to receive the vaccines and start vaccinating patients as soon as they are available, whereas 23% are in the final preparation stages. Thirty-four percent of pharmacists said they are not prepared to vaccinate in the first wave of vaccination efforts, but plan to participate in the future. Six percent said they would not participate in vaccination efforts and cited logistical difficulties as the reason.

APhA also asked pharmacists if they would be willing to receive the vaccine themselves. Fifty-two percent said they would be willing as soon as possible, 17% said they would receive it after 6 months, and 9% said they would get it after 1 year. Seventeen percent were undecided and 6% said they would not receive it.

Study: Link Between Social Isolation Amid Pandemic and High Blood Pressure

Recent study results reported a potential link between social isolation as a result of the coronavirus disease 2019 (COVID-19) pandemic and high blood pressure, according to investigators.

Presented virtually at the 46th Argentine Congress of Cardiology, results of the study showed that “admission to the emergency department during the mandatory social isolation period was linked with a 37% increase in the odds of having high blood pressure, even after taking into account age, gender, month, day and time of consultation, and whether or not the patient arrived by ambulance,” said study author Matías Fosco, MD, of Favaloro Foundation University Hospital, Buenos Aires.

Fosco hypothesized that high blood pressure in patients amid COVID-19 may have been due to increased psychological tension in response to travel restrictions, police controls, and apprehension in regard to COVID-19 infection. Not only that, but early COVID-19 warnings, which were later proved false and dismissed, suggested that high blood pressure medications could spur adverse effects on COVID-19 outcomes.
Irving Pharmacy is improving efficiency and profitability.

After partnering with PDS, the pharmacy was able to synchronize 75 patients and increase their average GP/Rx 78% using SmartDispense strategies (in less than 9 months!).

Irving Pharmacy, Paterson, NJ
PDS Member Since 2019

Learn How PDS Can Improve Your Pharmacy’s Performance
800.987.7386 | pharmacyowners.com/medsync
PHARMACY IN 2021

TRENDS TO TRANSFORM AN EVOLVING PROFESSION

By Frieda Wiley, PharmD

Drug Topics® January 2021

DrugTopics.com
How will a change in administration, a vaccine for COVID-19, and other factors change the industry in the year ahead?

By Keith Loria

At the end of 2020, the biggest buzz in pharmacy—and the world—were the Pfizer and Moderna coronavirus disease 2019 (COVID-19) vaccines. At press time, both vaccines have received emergency use authorizations by the FDA and began shipping in the US.

Trends Taking Root

Calvin Knowlton, PhD, MDiv, BScPharm, CEO of Tabula Rasa Healthcare and former president of the American Pharmacists Association believes one of the biggest trends in 2021 will be a focus on the safe use of medications. “We have
been talking about this for more than 5 decades, but it seems that this will become the future of the pharmacy practice,” he said.

Reasons for this shift are many. For one, dispensing margins continue to shrink, which will reduce a pharmacist’s involvement and increase the responsibilities of pharmacy technicians. Additionally, society, via government mandates, is moving the industry to value-based payment versus fee-for-service health care models.

In Kowalton’s opinion, pharmacists are uniquely suited for identifying and mitigating adverse drug effects.

“Pharmacists fully understand and have been educated on the sciences underlying drug disposition,” he said. “If one compares the curriculum of pharmacy school education to medical school education, pharmacy education focuses on pharmacokinetics, pharmacogenomics, pharmacodynamics, etc., and medical education focuses on pathophysiology of organ systems and differential diagnoses.”

Among the trends to keep an eye on for 2021, said George E. MacKinnon III, PhD, MS, RPh, FASHP, FNAP, who is founding dean and professor of the Medical College of Wisconsin School of Pharmacy, are continued adoption of virtual, telehealth, and digital health services and the electronic health record (EHR) becoming more accessible digitally to pharmacies, nontraditional sites, and patients.

“Additionally, the ongoing shortage of primary care physicians and the fact that many patients have not been seen by providers due to COVID-19 for their chronic medical conditions that most often require medications and dosage adjustment to achieve goals, presents a unique opportunity for pharmacists to be reimaged as the ‘Front Door to Health Care,’” he said. “Bidirectional access to the EHR is critical.”

So noted a key priority for pharmacists will include helping patients with medication adherence. Because comorbidities are risk factors for COVID-19, it is important that patients be adherent to their medications, especially for chronic conditions such as heart disease, diabetes, and COPD.

Other priorities will include pharmacists taking on more responsibilities such as ordering and administering COVID-19 vaccines, making medication therapy recommendations to optimize patients’ drug regimens, and making drug substitutions when drug shortages occur.

Giuseppe Aragona, MD, general practitioner and medical advisor at Prescription Doctor, sees more pharmacies turning over to a more digital health services with prescription drugs is a lot more difficult, will be a more common move towards delivery. Dealing with prescription drugs is a lot more sensitive than delivering somebody’s meal, so whether this could feasibly be done on a larger scale, with privacy and safety front and center, will be a big part of whether we see this happen more commonly.

“Previously viewed with skepticism by regulators and payers alike, telemedicine prescribing has become a central aspect of care delivery, and will remain in 2021.”

JESSE C. DRESSLER, ESQ

advanced click and collect system in 2021, where patients will book in to collect medicine at specific time slots, rather than just show up.

“This is likely to stop masses of people arriving at the same time, helping to keep a more controlled environment for prescription pick-ups,” he said. “Secondly, and slightly more difficult, will be a common move towards delivery. Dealing with prescription drugs is a lot more sensitive than delivering somebody’s meal, so whether this could feasibly be done on a larger scale, with privacy and safety front and center, will be a big part of whether we see this happen more commonly.”

COVID-19 Brings About Change
The COVID-19 pandemic of 2020 has brought forward the challenges of an overwhelmed health care system and a need to embrace all essential health care providers, and that embrace needs to include pharmacists.

The pandemic has changed society and the way that individuals go about their daily lives.

“For the major pharmacy retailers and even independent pharmacies, making home delivery an option may cut down on in-store purchases, but it could retain existing business and bring in new sales by alleviating concerns from patients who are seeking ways to limit their potential exposure to the virus through similar options such as grocery deliveries,” So said.

With the pandemic, many patients were directed to stay at home or shelter-in-place, severely disrupting the previous paradigm of in-person receipt of care.

“Perhaps the greatest fundamental shift was the acceleration in the acceptance of telemedicine,” said Jesse C. Dresser, Esq, a partner and head of the pharmacy group at law firm Frier Levitt. “Previously viewed with skepticism by regulators and payers alike, telemedicine prescribing has become a central aspect of care delivery, and will remain in 2021.”

A New Administration
With President-Elect Joe Biden set to take office on January 20, 2021, pharmacists should see some impact going forward.

“We may see legislation that could result in pharmacists being granted widespread provider status that may enable them to gain reimbursement for specific services such as pharmacogenomic testing evaluation and
“Community pharmacists must position themselves as the medication regimen quarterback or coach, and charge for it as a concierge pharmacist.”

CALVIN KNOWLTON, PHD, MDIV, BSCPHARM

drug therapy recommendations,” So said. “However, gridlock on Capitol Hill could stall these changes.”

Although the Trump Administration has long been pushing to remove manufacturer rebates in the Medicare Part D space, this does not appear to be a high priority on President-Elect Biden’s agenda.

“Instead, Biden has emphasized that his administration will reduce drug prices through various avenues including, without limitation, repealing laws that prevent Medicare from negotiating lower drug prices with drug companies, setting reasonable prices for new drugs that don’t face competition, prohibiting companies with ‘abusively priced generic drugs’ from raising their prices and imposing tax penalties on these companies, allowing people to buy safe prescription drugs from other countries, improving generic drug supplies, and eliminating tax breaks for drug company ads,” Dresser said.

Biden has hinted at revoking the non-interference clause, the Medicare Part D provision that has long prevented the government from taking a direct role in negotiating drug prices.

Final Thoughts

Kok-Hong Tan, BSPharm, a pharmacist at EHR Pharmacy, an independent community pharmacy in Fort Worth, Texas, said the pharmacist profession and practice will continue to evolve in 2021, driven by the changing needs of society, pharmaceutical markets, advancements in treatment, government regulations, and so on.

As the pharmacy landscape evolves, health care technology standardization and advancement will also need to progress.

“When one of these factors above creates a ripple, the pharmacy practice landscape will be affected in a different magnitude,” Tan said.

“Pharmacist-provided patient care will be the future of pharmacy services, as the pharmacist profession slowly gains full provider status in the health care world.”

So noted that Amazon’s entry into the pharmacy services space will have a potentially big impact on the market in 2021.

“They will offer direct competition to major pharmacy retail chains,” he said. “People are so used to using their Amazon app to purchase other essentials, whether it is household products, face masks, clothing, or electronics—it will be interesting to see if they will also use the service to order prescription drugs.”

And although there’s no question that COVID-19 has altered pharmacy, Knowlton argues that Amazon and its subsidiary, Pillpack, will have larger lasting effects on the pharmacy landscape in the future.

“This is all the more reason that community pharmacists must position themselves as the medication regimen quarterback or coach, and charge for it as a concierge pharmacist,” he said. “To move from the 50-year-old, 1-drug to 1-drug interaction construct that is based on what has been reported in the literature, to a multidrug simultaneous drug interaction system based on pharmacotherapy science, with COVID-19 drugs or without, is the future for the profession.”

In 2021, Knowlton encourages fellow pharmacists to use their pharmacokinetics, pharmacogenomics, and pharmacodynamics background and put it to use.

“This is our real value proposition as pharmacists,” he said.

Pharmacists assist in management of chronic conditions through comprehensive medication management services in community pharmacies. Yet, reimbursement models from many commercial insurers and government (Medicaid and Medicare) have not caught on to fairly compensating pharmacists.

MacKinnon feels the pharmacy profession in conjunction with medicine, needs to step forward to accept this challenge and make changes for patient and provider benefits alike.

“Keeping a patient on their medication and out of the ER/hospital saves money,” he said.

Looking ahead, MacKinnon would like to see more emphasis on pharmacy partnering with medicine.

“The explosion of high-cost specialty pharmaceuticals and growing use of biomarkers with the soon-to-be future of precision medicine at our doorstep, as deployed via pharmacogenomics, it only makes sense that pharmacists emerge with a more appreciated and expanded role,” he said. “Frankly, the addition of a pharmacist to most physician group practices will be clinically and financially prudent if not essential in time.”
There are an estimated 34.1 million adults with diabetes, accounting for 13% of all US adults and a staggering 26.8% of US adults aged 65 or older. Every day, patients with diabetes are in the aisles of local pharmacies in search of OTC products to help them with various symptoms, whether diabetes-related or not. What should pharmacists consider when helping these patients choose appropriate OTC products?

Topical Products for Tingling Pain

Patients with diabetes frequently come to the pharmacy in search of relief for peripheral neuropathy—but experts say pharmacists shouldn’t rush to recommend OTCs.

“[If I were] a community pharmacist, if somebody told me that they’re having pin and needles or tingling in their fingers or their toes, I’d actually recommend that they go back to their doctor; because usually, that’s a sign that their diabetes is not under control,” said Candis M. Morello, PharmD, CDCES, FCSHP, FASHP, professor of clinical pharmacy at UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences in La Jolla, California. Morello is director of the diabetes intense medical management clinic at the Veterans Affairs San Diego Healthcare System, where her team creates unique treatment protocols for very complex patients with type 2 diabetes.

According to Morello, when glycemic control is improved, diabetes complications, including peripheral neuropathy, are “absolutely reversible,” Morello said. She has found that this usually takes about 3 months using a multiprong approach, including diet, exercise, and drug therapy.

In the interim, there is a place for OTC treatment for peripheral neuropathy.

Although the supplement α-lipoic acid has demonstrated positive effects on peripheral neuropathy, Morello is hesitant to recommend it to patients who are already taking a slew of oral prescription drugs. She prefers topical options, including capsaicin cream (0.075% 4 times daily, according to the American Academy of Neurology) and lidocaine patches.

Morello said patients should be cautioned to wash hands well—including under their nails—after using capsaicin cream to avoid accidentally getting it in their eyes. Lidocaine patches can be cut to fit the affected area and may be worn for up to 12 hours per day.

In considering the root cause of peripheral neuropathy, pharmacists should determine whether the patient is a smoker; as smoking can decrease blood flow to extremities and lead to nerve pain, noted Danielle Hambrick, PharmD, manager of a Walgreens pharmacy in downtown Chicago, Illinois.

According to her, this symptom might be the impetus for patients with diabetes to quit smoking, she said. Pharmacists can assist such patients in selecting smoking cessation aids, such as nicotine patches for long-term control and nicotine gum for breakthrough cravings.

Foot Care Pharmaceuticals

“Ulcers, amputations, all of that is...
“Any patient that comes up with an over-the-counter question, there’s always a chance they could [have] diabetes.”

Danielle Hambrick, PharmD

preventable,” Morello said, as long as patients look at their feet every single day and visit their physician at the first sign of a problem. Hambrick added that any sign of infection on the feet, such as an open wound, swelling, or fever, is a huge red flag and should be referred to the patient’s physician.

OTC moisturizers are important in the prevention of foot problems. “If you have dry skin, you can get fissures, and bacteria and fungi love to invade and cause infection,” Morello explained. There are a variety of diabetic foot creams on the market; she recommends those containing urea or ammonium lactate. Hambrick pointed out that moisturizers should only be used on the tops and soles of feet, not between the toes, which could lead to fungal growth.

According to Hambrick, patients with diabetes should be educated about proper foot care. This includes always drying feet entirely after bathing and protecting feet by wearing socks in the house and shoes outside. Nail files are preferred for cutting toenails, but if clippers must be used, they should only be straight-edged, not curved, to avoid cutting the skin.

**Vitamins and Supplements**

Although various vitamins and supplements are promoted for diabetes, there is limited data on their efficacy. In fact, supplements such as St. John’s wort, prickly pear cactus, aloe, and ginseng may interact with conventional diabetes drugs. Certainly, patients should not take dietary supplements in place of medications they have been prescribed for diabetes.4

Studies have found that various vitamins play a role in glucose metabolism and the risk for diabetes and its complications, but there is not enough data to recommend routine supplementation in the general population with diabetes. An exception is vitamin B12 supplementation in patients with type 2 diabetes taking metformin. Patients should be encouraged to eat a varied diet to ensure sufficient vitamin intake.5

Although the American Diabetes Association does not recommend routine multivitamins for patients with diabetes, Morello said that she and the dieticians she works with still recommend multivitamins because it can be difficult for patients to get all their nutrients solely from food sources.

Morello noted that patients who decide to take dietary supplements should be urged to choose only products that have been validated by a third party, such as the USP Dietary Supplement Verification Program or ConsumerLabs.com. “You just want to make sure that it was manufactured properly, that the amount and concentration that it says is in the bottle is actually in the bottle,” she said. “They’re spending valuable money, and we want to make sure they’re getting a product that actually contains what it says it does.”

**Other Illnesses**

Pharmacists should be mindful that patients seeking relief from cold and flu symptoms might also have diabetes. “Any patient that comes up with an over-the-counter question, there’s always a chance they could [have] diabetes, so part of our counseling is making sure that we understand their pre-existing conditions,” said Hambrick. These patients should be counseled to steer clear of products containing sugar, including cold syrups and throat lozenges. Fortunately, there are still many options labeled sugar-free. They should also avoid products containing pseudoephedrine and other nasal decongestants, as they have been shown to increase blood glucose.

Hambrick noted that pharmacists should make sure patients with diabetes who have respiratory infections have an adequate supply of test strips. “Any time that a diabetic patient is ill, even if they’re well controlled outside of that illness…they may have fluctuations with their blood glucose control, so they may need to test a little bit more often,” she said. These patients should also stock up on glucose tablets, she added, in case their blood sugar drops as a result of reduced appetite during illness.

According to Morello, for patients with diabetes complaining of constipation, psyllium is an excellent choice because it increases fiber intake and has been shown to decrease postprandial glucose concentrations.

Hambrick also stressed the importance of making sure patients with diabetes are adequately vaccinated. “With diabetes, your immune system is a little bit more compromised, and so those things like flu and pneumonia can be more severe,” she explained.

For references, visit drugtopics.com.
Understanding the COVID-19 Vaccine

Pharmacists can prepare themselves to address patients’ questions and concerns about the COVID-19 vaccines. By Jennifer Barrett

The coronavirus disease 2019 (COVID-19) vaccine landscape is rapidly changing. As pharmacists prepare to eventually immunize the public, they should equip themselves with the knowledge necessary to accurately address patients’ questions and concerns.

In a virtual session at the American Society of Health-System Pharmacists 2020 Midyear Clinical Meeting and Exhibition, Litjen Tan, PhD, MS, chief strategy officer at Immunization Action Coalition in Saint Paul, Minnesota, and Mary S. Hayney, PharmD, MPH, FCCP, BCPS, professor of pharmacy at the University of Wisconsin–Madison School of Pharmacy, discussed the clinical considerations for ensuring the safety and efficacy of a COVID-19 vaccine, as well as opportunities to address vaccine hesitancy.

Clinical Trial Designs

With COVID-19 vaccines moving through the development process at a much faster pace than other vaccines might, patients may be concerned about compromised safety and efficacy. However, there is no reason for worry, Tan explained in his overview of the clinical trial design process for COVID-19 vaccines. Although the process differs from that of traditional vaccine development, Tan reiterated that no steps are eliminated in the evaluation of safety and efficacy.

According to Tan, the process for traditional vaccines from the time of development to actual vaccine manufacturing and dissemination takes anywhere from 10 to 20 years. For COVID-19 vaccines, all the same development steps still apply; however, the phase 2 and phase 3 trials are instead conducted simultaneously to ensure an “exquisite balance of speed, safety, and efficacy,” for a target timeline of up to 12 months, Tan said.

“That is the reason why the development process of normally 8 years can be very very quickly compressed to a rapid development process without sacrificing safety and efficacy,” Tan said.

According to Tan, this involves ensuring the safety and effectiveness in healthy human participants are studied in parallel while maintaining the trial size, quality approval of regulatory trials, and ability to scale up. Additionally, incoming data can be used to modify the trial as it moves forward.

Regulatory Review and Approval

Although COVID-19 vaccines may come out of the [EUA], is that all federal agencies that are involved in the process, along with private partners, will monitor safety after the public begins using that vaccine.” Litjen Tan, PhD, MS

Tan used the Pfizer/BioNTech vaccine trials as an example of “how the clinical trials have been compressed so [manufacturers] can adapt as the data come,” he said.

Pfizer began with 4 vaccine candidates, Tan explained. In the phase 1 study, for each of those candidates, Pfizer started with a younger age group and multiple doses, conducting an internal safety review for each dose. Each dose that passed the safety review was then moved up to testing in older age groups. Pfizer used these data to select its best vaccine candidates to study in phase 2 and phase 3 trials.

“It was during phase 2 and phase 3 that they eventually whittled it down based on the first 360 participants of the [simultaneously conducted] phase 2/phase 3 trials,” Tan said. After the first 360 participants, Pfizer was able to unblind those to see which of the vaccine candidates was the best option to advance into the final, larger phase 3 trials.

“What is true for all vaccines, including vaccines that
Additionally, vaccinators are not required to collect signatures attesting that the recipient understands the information provided, Hayney added.

**Addressing Vaccine Hesitancy**

Tan discussed some of the foreseeable barriers to individuals accepting administration of a COVID-19 vaccine in the United States. “We do know that we are going to have challenges in getting people to take up the vaccine,” he said, noting that vaccinating adults in particular will be a road block. “We have a lot of data that show that we don’t vaccinate our adults well,” he added. For adults, vaccination tends to be a convenience factor, and individuals who do not have a regular health care provider may not receive recommendations.

However, according to Tan, lack of confidence in a vaccine is the biggest barrier to COVID-19 immunization uptake. In a poll conducted by The Associated Press-NORC Center of Public Affairs Research, only half of Americans reported a willingness to get vaccinated with a COVID-19 vaccine.3

“There has been a considerable decline in COVID-19 vaccine acceptability in the past 4 months,” Tan said. Factors weighing on acceptance include concerns about adverse effects (AEs), efficacy, risk perception/need for vaccine, and associated costs. However, health care providers play an important role in fostering vaccine acceptance. “The provider recommendation to get vaccinated is one of the top reasons why a patient ends up getting vaccinated,” he added.

Seventy percent of individuals who said they would not get the COVID-19 vaccine cited concern about potential AEs as the reason.1 However, FDA released its detailed analysis of the Pfizer/BioNTech clinical data for their COVID-19 vaccine candidate, in which the agency reported no serious safety concerns. Minor AEs are common with the vaccine, with the majority of study participants experiencing injection site reactions, short-term fatigue, and headaches.3

“Your recommendation is the reason why people get vaccinated….The CDC wants to promote confidence in health care personnel.”

For references, visit drugtopics.com.
P

harmacists can play a substantial role in the education and management of therapies for asthma. In a virtual session during the American Society of Health-System Pharmacists 2020 Midyear Clinical Meeting and Exhibition on December 6, 2020, experts discussed updates in asthma management, including new data and upcoming guideline changes that will impact pharmacy practice.1

**Guideline Updates**

Nathan A. Pinner, PharmD, BCPS, an associate clinical professor at Auburn University Harrison School of Pharmacy, and Brooke L. Gildon, PharmD, a professor at Southwestern Oklahoma State University College of Pharmacy, provided an overview of recent updates to recommendations for the management of asthma with inhaled corticosteroids (ICS) and long-acting beta-agonists (LABAs), as well as impending guideline changes.

**ICS/LABA Therapy**

Major changes were added to the Global Initiative for Asthma (GINA) 2020 recommendations, particularly regarding mild asthma.

According to the updated guidelines, GINA no longer recommends short-acting beta-agonists (SABA) without ICS. Instead, GINA now recommends that all adults and adolescents with asthma should receive an ICS-containing controller for either symptom-driven (in mild asthma, GINA steps 1-2) or daily (GINA steps 2-5) treatment to reduce the risk of serious exacerbation and to control symptoms.2

According to Pinner, the most notable change is the addition of as-needed ICS-formoterol in step 2 and as-needed ICS-formoterol as a controller option in step 1. He noted that in step 1, there had previously been no controller option.

This change was based on evidence that as-needed ICS-formoterol provided benefit compared with as-needed SABA or maintenance ICS and evidence that overuse of SABA is associated with an increased risk of severe exacerbations. The updated guidelines also provide more consistent messaging for patients with mild asthma, Pinner explained.

He noted that step 1 for the GINA guidelines is very similar to the Expert Panel Report (EPR)-3 for intermittent asthma; however, step 1 in the GINA guidelines is advised for patients who experience symptoms less than twice monthly. As-needed low dose ICS-formoterol is the preferred approach for such patients, which is supported by indirect evidence, Pinner said.

In step 2 for mild asthma, 2 preferred controller options were recommended: daily ICS or as-needed budesonide-formoterol.

“If you have patients who are on [ICS] daily for therapy, there’s no reason to change if they’re doing well,” Pinner said. “But if there [are] some people who could benefit from using an as-needed ICS-LABA, that’s also an acceptable therapy here.”

**Short-Term ICS Dose Increases**

Gildon discussed short-term increases in ICS dose for worsening symptoms in patients with asthma.

According to her, GINA 2020 recommends early increases in controller therapy, specifically with early or mild asthma symptoms. These increases are based on the patient’s usual medication regimen.

However, EPR-4 draft guidelines conditionally recommend against such short-term increases for increased symptoms or decrease peak flow in patients aged 4 years and older with mild-to-moderate persistent asthma who are likely to adhere to daily ICS treatment. They classify this increase as either doubling, quadrupling, or quintupling ICS.3

“The rationale for this recommendation is due to a lack of consistent efficacy data and then possibly some concerns regarding safety…with growth suppression as an example,” Gildon said. However, she noted that it’s important to keep in mind that the EPR-4 draft says there is a potential role for ICS increase in patients with poor adherence.

Gildon pointed to several studies looking at ICS increases. In 1 study, which looked at ICS increases in adults and adolescents, the results demonstrated that a temporary quadrupling of ICS with deteriorating asthma symptom control resulted...
in fewer severe exacerbations. On the other side, a different study that examined 7-day quintupling of ICS with asthma control in the yellow zone in children showed that the rate of severe asthma exacerbations did not differ significantly between high-dose and low-dose groups. However, the findings did suggest that increasing ICS may affect linear growth in children.

“Something that was not found to be statistically significant, but something that we do want to follow is this decrease in linear growth between the high-dose and low-dose group,” Gildon said. “And that’s something I think we need to continue following when it comes to evaluating this option if we were to use it in pediatric patients.”

Furthermore, a systematic review and meta-analysis published in 2019 of 8 trials indicated that temporary increased ICS was associated with reduced risk of treatment failure. The analysis looked at increased doses compared with stable doses in adults and children. According to Gildon, the analysis demonstrated a benefit observed in adults compared with children and also identified that quadrupling the dose had a greater impact than doubling.

“This review did have moderate, quality evidence that supports the increase of ICS dose in certain patient populations and a self-initiated action plan to reduce risk of exposure to systemic corticosteroids,” she explained.

According to Gildon, pharmacists should consider how these data might affect the care of patients with asthma.

Short-Course ICS/SABA in Young Children
Gildon also discussed current data around short-course ICS plus as-needed SABA at the onset of a respiratory illness in pediatric patients aged 0 to 4 years old with recurrent wheezing.

According to the EPR-4 draft recommendations, a short-course (7-10 days) of ICS and SABA for quick-relief therapy starting at the onset of a respiratory illness is recommended in such patients. Recurrent wheezing was defined as 3 or more wheezing episodes triggered by respiratory tract infection in their lifetime or 2 in the past year and are symptomatic between episodes. However, Gildon noted there are still conflicting data on the impact on height and weight gains in the literature.

Gildon emphasized the importance of caregiver education if this draft recommendation is put into place in the pediatric population.

“There is a potential for overuse in this situation, so we want to make sure parents know exactly when this short-course ICS would be recommended,” Gildon said. Intermittent ICS can be initiated at home based on a written action plan. Importantly, the plan must be initiated at the first sign of symptoms associated with respiratory tract infections.

FDA Boxed Warning for Montelukast
Gildon touched on the more recent addition of the boxed warning to montelukast.

In March 2020, the FDA officially added a boxed warning to montelukast for serious mental health adverse effects (AEs), including agitation, attention problems, vivid dreams, depression, anxiety, irritability, memory problems, suicidal actions, and tremors.

“I’ve seen this in my practice a number of times in our pediatric patients,” Gildon said. According to her, parents whose children are affected typically present with concerns about their child’s irritability and agitation, or indicate that the child is behaving differently.

“This not something new,” Gildon said. “We’ve heard about this for a while.” Back in 2008 and 2009, there was earlier communication about the risk with montelukast regarding mental health AEs, but there was no boxed warning placed at that time.

However, she noted that the boxed warning does help increase the awareness for risk and can help pharmacists discuss the risks and benefits of this medication with patients.
Pharmacists Tackle Opioid Crisis With Innovative Projects

Two pharmacists discuss projects integrating opioid education and management into community pharmacy settings.

By Karen Berger, PharmD

Two pharmacists recently worked with the Community Pharmacy Foundation (CPF) on unique projects focused on addressing the opioid crisis.

Community Pharmacist Integration Into Opioid Management

Elizabeth Dragatsi, RPh, BCPS, knows that pharmacists are in an ideal position to assist patients taking opioid therapy. Throughout her experience in hospital pharmacy and clinical practice, Dragatsi became acutely aware of the unaddressed needs relating to adverse drug effects (ADEs) or interactions that undermined treatment goals. Knowing she wanted to help patients in these situations, Dragatsi went on to earn her BCPS and formed her own company, Dragatsi & Co.

As a consultant pharmacist, Dragatsi studied the most complex patient medication lists from all over Maine. She soon identified almost $50,000 worth of preventable ADEs in 11 patients. This discovery led Dragatsi to form new relationships with practice sites and federally funded health care centers.

“I saw an opportunity to perform innovative pharmacy practice...but needed to figure out how to do this in a financially viable way,” she said.

Dragatsi submitted a grant proposal to CPF on integrating pharmacists into the medication review process and addressing ADEs. The grant was approved.

Within just 1 week of beginning the project, Dragatsi became keenly aware of the opioid crisis’s effects on her community. New legislation forced patients to taper off opioids, but the patients needed help. Dragatsi incorporated this into her project.

“I accumulated a treasure trove of new clinical information centering around effective OTC medication use in patients as part of self-care when tapering off opioids,” Dragatsi said.

In the polypharmacy patients, Dragatsi was able to identify $280,890 worth of preventable AEs and reduce some of the concurrent medication use. In patients with chronic pain, there was a 43.3% reduction in morphine milligram equivalents due to patient self-care education.

Dragatsi applied for a second CPF grant to further tackle the opioid problem. “I knew that there was a need for pharmacists to be educated and integrated into the medication-assisted therapy process meaningfully, and to know how to reduce stigma using new terminology,” she said.

Dragatsi had many goals as part of this project, including:

- creating a 17-month calendar of self-care clinical pearls, such as the beneficial impact of smoking cessation and OTC self-care tips on opioid tapering;
- surveying pharmacists for baseline knowledge about 17 clinical pearls;
- producing patient leaflets (with project support by Frank McGrady, PharmD, BCPS and Kris Ravin, PharmD); and,
- educating pharmacists based on survey data, using written and live continuing medical education courses.

Dragatsi observed that all of the materials provided to patients “really contributed to patient resilience,” she said. She also emphasized that pharmacists tend to focus on prescription drugs, often overlooking the benefits of OTC medications. “In the OTC realm, there is a lot of patient benefit to be realized,” she added.

In this project, Dragatsi was able to personally help 22 patients taper down and off of opioids by working closely with providers and using OTC products. Overall, Dragatsi & Co. assisted over 100 patients in tapering opioids.

So what can pharmacists do in practice to help patients as Dragatsi
Opioid Education and Safety Consultations
To better leverage pharmacist-patient communication, Tanvee Thakur, PhD, BPharm, recently completed her project with CPF focused on enhancing transparent opioid education.

Although currently a scientist at RTI Health Solutions, Thakur was pursuing her PhD at the University of Wisconsin–Madison School of Pharmacy at the time of the project. During this time, she recalled talking to pharmacists about the opioid crisis and the importance of patient education, but observed that very few providers were truly engaging with patients about the risks of opioids.

Through more discussion, Thakur realized that “both patients and doctors wanted pharmacists to educate patients about opioids, but pharmacists were sometimes unsure how to discuss this sensitive topic without sounding accusing,” she said. Thakur thought that a patient handout would help both pharmacists and patients discuss opioids.

Working with Betty Chewning, PhD, FAPhA, as a co-principal investigator, Thakur developed a handout for pharmacists to assist in counseling on opioid prescriptions. Pharmacists could use the handout during counseling to highlight important information, guide essential talking points, and distribute to the patient with a reminder to call with any questions.

After using the handout during patient counseling, the pharmacist would fill out a survey to answer questions such as:

- What is your comfort level?
- Do patients ask more questions?

The research was done at 3 pharmacies: Hayat Pharmacy in Milwaukee, Wisconsin, and 2 Reedsburg Medical Center community pharmacies in Reedsburg, Wisconsin.

Thakur and Chewning analyzed 57 real-time surveys of pharmacists who used the opioid handouts. Pharmacists reported that using handouts in conjunction with counseling was the most helpful method, but the most important thing was just making an effort to talk about opioids. “It is up to the individual comfort of the pharmacist on which way to use the handout, but pharmacists felt more satisfied when they addressed opioid risks and safety rather than avoiding the topic,” Thakur said.

“On the patient side, it was like a normal counseling session,” Thakur explained. “The hardest part was finding pharmacists to participate, as many were too busy. Still, we had a few amazing pharmacists who participated and made sure the surveys were completed.”

Although Thakur was not sure what to expect in terms of results, she noted that she was pleasantly surprised. Along the lines of adding more time, she mentioned how busy community pharmacists can easily incorporate opioid counseling. Pharmacists can access the handout from the CPF website. “Even though there is limited time to counsel, pharmacists can take 40 to 50 seconds and make a brief statement. We can show patients that we care about their safety by saying, ‘I care about you and your loved ones being safe. That’s why I’m telling you this medication is an opioid and has overdose and dependency risks.’

We can explain that opioids should only be used as prescribed, then disposed of safely to keep the patient and the patient’s family safe. Then remind the patient to read the handout at home and call if questions arise. This takes less than a minute and is a wholesome approach to patient education,” Thakur explained.

The handouts developed by Thakur and Chewning were shared with the team at Flip the Pharmacy, a 5-year pharmacy transformation program aiming to re-work community-based pharmacy practice beyond filling prescriptions, as they created their opioid progression change packages for June to October 2020.

“Even though pharmacists are busy, we can use this resource and take a few seconds to talk to patients openly,” Thakur said. “As a researcher and a pharmacist, I see that using our expertise can help make a big difference in fighting the opioid crisis.”
You can’t fix what you don’t track. Technology will help you identify potential reimbursement problems before they trigger reduced payments or claims audits.

Understanding pharmacy reimbursement is a tall order, even for owners who’ve been in business for decades. Pharmacy benefit managers (PBMs) structure their contracts with broad rights to initiate claims audits, which can lead to recoupment of entire reimbursement amounts plus potential audit fees. What’s worse, an audit uncovering systemic errors could void profits on hundreds of claims.

Any approach to maximizing community pharmacy reimbursement should include an active triage component, supplemented by ongoing use of pre-and post-edit and pharmacy claims reconciliation software.

Pharmacy Claims Processing
Let’s say, in the normal course of business, your pharmacy receives a prescription for an existing patient. Your counter technician enters the script into the pharmacy system based on patient name and other identifiers. The script goes into a queue, then makes its way to the filling tech. Once filled, the pharmacist verifies that everything on the written prescription matches up with what’s in the medication bottle.

When your pharmacy deems the script ready to submit for adjudication, you transmit it over a digital bridge to the PBM. In turn, the PBM examines the patient’s insurance coverage, the specific drug dispensed and the contract payment rate compared to the actual claim amount submitted. If everything lines up correctly, the PBM processes the claim for payment, which can take anywhere from a week to 90 days (depending on whether insurance is government-sponsored or commercial). Simultaneously, claims submitted at prices less than contracted amounts would be reimbursed at the lower level.

As you can see, the process involves a lot of variables. Realistically, you can’t expect to handle pharmacy claims data analysis for all your transactions manually. Many independent pharmacies use pre-and post-edit software from a third-party company to follow claims through adjudication. A pre-and post-edit platform automatically tracks, for example, prescription fill dates, drugs dispensed, and prices charged. Primarily, this type of software ensures claims are submitted correctly. In addition, many pharmacies run a reconciliation platform in tandem to make sure claims are also paid correctly. Reconciliation allows you to concisely see which claims have been paid and if the amount the store submitted for payment was the amount actually paid. Reconciliation software also provides a breakdown of claims aged up to 30 days, 60 days, 90 days, or 90 days plus.

Appoint a trusted team member to take charge of reviewing the reconciliation reports. This individual should run the reports at regular intervals, ideally weekly. Any claims that haven’t been paid as anticipated should prompt a call from your captain to the corresponding insurance company asking why proper reimbursement hasn’t been issued.

Additional Challenges
Independent pharmacy revenue leakage can also happen outside the parameters of reconciliation.
For instance, a pharmacy’s computer system typically uses an algorithm to set prices for dispensed drugs. The algorithm generates a measure of cost multiplied by a markup plus a dispensing fee. When you fill a prescription, it’s tied to the pricing formula—or it’s overridden to establish a discretionary price. Overrides cause inconsistency in pricing, which can raise audit flags with PBMs. Be sure your store has protocols and clear guidance for technicians and pharmacists regarding when an override may be used.

Another area to watch is the National Drug Code (NDC) number—the universal product identifier tied to every prescription. The NDC submitted on a claim must be an exact match to the NDC on the product dispensed to the patient. In the case of generic drugs with multiple manufacturers, NDCs differ for each strength and bottle count. It’s not uncommon to have old inventory on the shelf, along with bottles of the same drug in new sizes or strengths. To avoid NDC mix-ups, consider software that monitors NDCs and will issue a hard stop at the pickup window when attempting to adjudicate an outdated NDC.

Similarly, dispense as written (DAW) codes can cause problems if not properly triaged. This comes into play when a brand-name drug isn’t covered by the PBM, but the prescriber specifies a branded product. The DAW code on the claim must match the instructions on the prescription. If the script doesn’t include a DAW tag for a particular brand and you sell the branded product while having the generic equivalent on your shelf, an insurance audit would dictate that you only receive payment at the generic rate. Again, claims editing software would catch such an instance before it becomes a financial liability.

Finally, it’s essential to have a current average wholesale price (AWP) file incorporated into your claims processing system. Drug manufacturers publish AWPs, which establish the basis for wholesale drug prices and PBM reimbursements. Be sure your AWPs are updated at least weekly; even better, run those updates daily, if available. An outdated AWP file could fail to translate drug price increases, that would result in a loss of income. When investigating claims editing software, ask if it automatically corrects for the latest AWP information.

The overarching theme in maximizing community pharmacy reimbursement is that you can’t remedy what you don’t measure. In other words, if you don’t have the optics to understand potential problems, you won’t be able to solve them. Appoint a trusted staff member to oversee pharmacy claims data analyses and continually monitor the claims process. When your pharmacy gets to the root of any problems, metrics will verify over time whether they’ve been permanently fixed.

### Stopping the Threat

Fully understanding pharmacy reimbursement is hard enough as it is, but, for even the most seasoned independent pharmacy, revenue leakage is an ever-present threat that requires constant attention. A Good Neighbor Pharmacy business coach can serve as a second set of eyes on your business, performing pharmacy claims data analysis and identifying anything that results in reimbursement that’s less than it should be. Your coach will help you optimize the way you reconcile claims and plug leaks along the way to make sure you’re maximizing your reimbursement at every turn.

Jeff Puetz is director of Field Business Coaching at Good Neighbor Pharmacy.

---

**Common Prescription Discrepancies**

Any prescription discrepancies must be resolved by either the prescribing physician or patient’s insurance company. Some common problems that typically occur:

- Lack of legally required information, such as prescriber’s signature, drug quantity, date, or proper patient identifiers;
- Incorrect calculation of days’ supply;
- Refill submitted sooner than allowed;
- Wrong quantity;
- Invalid DEA/NPI/prescriber identification number.
Visit drugtopics.com for an enhanced website experience.

- Get easy access to news, information, practical solutions, trusted perspectives through peer-based forums and opinions.
- View in-depth interviews with industry experts.
- Find therapeutic and condition-specific information for optimal patient care.
- Medical World News® Discover the 24-hour news channel for healthcare professionals, by health care professionals.

**Website Enhancements**
- Streamlined navigation, so it is more user-friendly
- Improved mobile compatibility, so it is easier to read on your phone
- Increased responsiveness, so you can find what you are looking for
Enhanced Website Experience

Use our improved navigation and search.

Sign up to receive e-newsletters and the print publication.

Read keynote highlights, industry trends and policy updates.

Customize content specific to your needs.
There are a variety of promising and unique medications in different therapeutic areas expected for approval in 2021. By Jennifer Gershman, PharmD, CPh

According to the FDA, 53 new drugs received approval in 2020. 1 As the coronavirus disease 2019 (COVID-19) pandemic persists throughout the United States, the FDA is focusing on treatment options for COVID-19. The FDA also issued guidance for the industry regarding conducting clinical trials for investigational drugs during the pandemic to ensure the safety of study participants and the integrity of the data. 2 According to a Vizient Drug Price Forecast report, health systems can expect a 3.29% increase for pharmaceutical purchases made from January 1 to December 31, 2021.3 Additionally, a variety of specialty drugs are expected to be approved in 2021. 3 Pharmacists should stay up-to-date with the latest drug information so that they are well versed about pipeline drugs for 2021 (Table).4-22

Top Pipeline Drugs for 2021

COVID-19 Treatments
On November 21, 2020, the FDA issued an emergency use authorization (EUA) for the monoclonal antibodies casirivimab and imdevimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older weighing at least 40 kg who are at risk of progressing to severe COVID-19 and/or hospitalization.4 This therapy should not be used in patients hospitalized due to COVID-19 or who require oxygen therapy due to COVID-19.4 The dose is 1200 mg of casirivimab and 1200 mg of imdevimab administered together as a single intravenous (IV) infusion over at least 60 minutes.5 Casirivimab and imdevimab are currently being investigated in the phase 3 RECOVERY trial (NCT04381936).5,7 The investigational monoclonal antibody bamlanivimab received an EUA on November 9, 2020, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older weighing at least 40 kilograms who are at high risk of severe COVID-19 and/or hospitalization.8 Bamlanivimab is administered as a 700 mg IV infusion over at least 60 minutes, and should not be used in patients hospitalized due to COVID-19 or who require oxygen therapy due to COVID-19.8 Additionally, bamlanivimab is currently being investigated in the phase 2/3 ACTIV-2 trial (NCT04518410) in patients with mild-to-moderate COVID-19 who do not require hospitalization and the BLAZE-2 study (NCT04497987) for the prevention of COVID-19 in residents and staff at long-term care facilities.9,10 The ACTIV-3 clinical trial (NCT04501978) revealed that bamlanivimab was unlikely to help hospitalized COVID-19 patients.11

HIV Prevention
Cabotegravir is an investigational, long-acting medication that was recently granted breakthrough therapy designation by the FDA for HIV pre-exposure prophylaxis (PrEP).12 This designation was based on the efficacy and safety results from HPTN 083 (NCT02720094). HPTN 083 was a phase 2b/3 randomized, multicenter, double-blind trial that compared long-acting, injectable cabotegravir with daily oral emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg (Truvada) for HIV prevention.13 The results showed that cabotegravir was 66% more effective than emtricitabine/tenofovir at preventing HIV.13 Cabotegravir is given as an intramuscular injection every 8 weeks, which could offer another option that may enhance adherence.13 Trial safety results showed that cabotegravir was well tolerated, and the most common adverse effects (AEs) were injection site reactions.13

Duchenne Muscular Dystrophy
Casimersen is an investigational drug known that uses a proprietary phosphorodiamidate morpholino oligomer chemistry for the rare disease Duchenne muscular dystrophy in patients who have a genetic mutation that is amenable to skipping exon 45 of the dystrophin gene.14 An interim analysis of the double-blind, placebo-controlled phase 3 ESSENCE trial (NCT02500381) demonstrated a statistically significant increase in dystrophin production with casimersen.14,15 This ongoing clinical trial is collecting additional safety and efficacy data.15

Multiple Myeloma
Idecabtagene vicleucel (ide-cel; bb2121) is an investigational drug for the treatment of multiple myeloma in adult patients, and it is the first anti-BCMA chimeric antigen receptor T-cell therapy.16 The biologics license application (BLA) is based on positive safety and efficacy results from the phase 2 KarMMa study (NCT03361748), which
Hypercholesterolemia
Evinacumab is an investigational monoclonal antibody for the treatment of patients with a rare inherited form of high cholesterol known as homozygous familial hypercholesterolemia (HoFH). VeloImmune technology was used to develop evinacumab, and it works by binding to and blocking the function of angiopoietin-like 3 in patients with HoFH. Positive efficacy and safety results from the phase 3 ELIPSE trial (NCT03399786) were presented at the American College of Cardiology's Annual Scientific Session. These data supported the BLA submission to the FDA. In the ELIPSE trial, 65 patients were randomized to receive either evinacumab 15 mg/kg intravenously every 4 weeks plus other lipid-lowering therapies versus lipid-lowering therapies alone. Patients in the evinacumab group had reduced their low-density lipoprotein cholesterol from baseline by 49% compared with placebo at week 24 (P < .0001). Evinacumab was well tolerated, and the most common AEs were flu-like illness and rhinorrhea.

Migraine
The novel drug dihydroergotamine mesylate (INP104) or DHE is for the treatment of migraine headaches in adults with or without aura. This medication is administered via Precision Olfactory Delivery technology, which is the first and only delivery system to use the vascular-rich upper nasal space for fast and lasting migraine relief at a lower dose than previous FDA-approved products. The phase 3 STOP 301 trial (NCT033557333) evaluated the safety and efficacy of INP104 in 360 patients, and over 5650 migraine attacks were treated. AEs were mild, and the most common ones reported were nasal congestion, nausea, nasal discomfort, and abnormal taste. Overall, 66.3% of patients reported pain relief, 38% had pain freedom, and 52% reported freedom from their most bothersome migraine symptoms 2 hours following their first dose of INP104.

Biosimilars
Biosimilars are expected to lower drug costs by $100 billion over the next 5 years. The biosimilar AVT02 is highly similar to adalimumab (Humira), demonstrated by the pharmacokinetics study following subcutaneous administration. Additionally, SB11 is a proposed biosimilar referencing ranibizumab (Lucentis) for retinal vascular disorders.

For references, visit drugtopics.com.

<table>
<thead>
<tr>
<th>DRUG NAME/COMPANY</th>
<th>INDICATION</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casirivimab and imdevimab/ Regeneron</td>
<td>Treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years and older</td>
<td>FDA issued EUA with possible approval in 2021; currently in phase 3 RECOVERY trial</td>
</tr>
<tr>
<td>Bamlanivimab/Eli Lilly</td>
<td>Treatment of mild-to-moderate COVID-19 in adult and pediatric patients 12 years and older</td>
<td>FDA issued EUA with possible approval in 2021; currently in phase 2/3 ACTIV-2 and phase 3 BLAZE-2 trials</td>
</tr>
<tr>
<td>Cabotegravir/ ViiV Healthcare, GlaxoSmithKline</td>
<td>HIV PrEP</td>
<td>FDA granted breakthrough therapy designation; planned NDA submission first half of 2021</td>
</tr>
<tr>
<td>Casimersen/Sarepta Therapeutics</td>
<td>Treatment of Duchenne muscular dystrophy amenable to skipping exon 45</td>
<td>NDA submitted with priority review granted; expected decision date February 25, 2021</td>
</tr>
<tr>
<td>Idecabtagene vicleucel/ Bristol Myers Squibb and bluebird bio, Inc.</td>
<td>Treatment of multiple myeloma in patients who have received at least 3 prior therapies including an immunomodulatory agent, proteasome inhibitor and anti-CD38 antibody</td>
<td>BLA submitted and granted priority review; decision date March 27, 2021</td>
</tr>
<tr>
<td>Evinacumab/Regeneron</td>
<td>Adjunct to other lipid-lowering therapies in patients with HoFH</td>
<td>Granted breakthrough therapy designation; BLA submitted and decision date February 11, 2021</td>
</tr>
<tr>
<td>DHE (INP104)/Impel NeuroPharma</td>
<td>Acute treatment of migraine headaches in adults with or without aura</td>
<td>NDA submitted</td>
</tr>
<tr>
<td>AVT02/Alvogen</td>
<td>Biosimilar to adalimumab, various conditions including RA, psoriatic arthritis, CD, UC</td>
<td>BLA submitted and decision date September 2021</td>
</tr>
<tr>
<td>SB11/Samsung Bioepis and Biogen</td>
<td>Biosimilar to ranibizumab for retinal vascular disorders</td>
<td>BLA submitted and decision date fourth quarter of 2021</td>
</tr>
</tbody>
</table>

TABLE.
TOP PIPELINE DRUGS OF 2021*22

**Note:** BLA, biologics license application; CD, Crohn disease; DHE, dihydroergotamine mesylate; EUA, emergency use authorization; HoFH, homozygous familial hypercholesterolemia; NDA, new drug application; PrEP, pre-exposure prophylaxis; RA, rheumatoid arthritis; UC, ulcerative colitis
Every pharmacist dreams of a great purpose in their pharmacy career. However, many often feel frustrated with the current employment market. According to a 2019 US Bureau of Labor Statistics report, the projected employment of a pharmacist is purported to decrease by 3% within the next 10 years. Unfortunately, the days of receiving a generous starting bonus, working at the same pharmacy job for the next 25 years, or starting at $120,000 are gone. Therefore, to remain competitive in the future employment environment, experts recommend gaining career skills that would likely complement the upcoming trends in the pharmacy profession.

Below are some key trends that could impact future employment opportunities.

**Direct-to-consumer (DTC) Health Care and Specialty Pharmacies**

The DTC model is one of the fastest-growing health care models and represents a $700 billion industry. Averill Gordon, PharmD, the group vice president for hims & hers, a telemedicine company, said that many health start-up companies are investing in creating their own pharmacies and will likely recruit pharmacists to help launch them internally. In addition, many of such pharmacies are adopting the mail-order model for servicing such DTC patients, said Kathleen Wong PharmD, a former Alto Pharmacy manager and current Modern consultant.

However, she suspects that many such pharmacies will use courier-like medication delivery services to prevent patients from being limited to delays due to UPS or FedEx logistical issues.

**What can a pharmacist do now?**

Many community pharmacists can volunteer under their current pharmacy managers to the skills and process in obtaining the proper legal and operational requirements to open or manage a pharmacy. Such pharmacists can master the processes ranging from how to purchase medication-related inventory to how to facilitate home delivery services legally.

**Digital Therapeutics (Dtx) Interventions**

Dtx are defined as software therapeutic interventions that are able to directly prevent, manage, or treat a medical disorder. The Dtx market is purported to grow 21% annually, with over 300,000 new digital health start-ups in the current market.

Julie Fishman, MPA, RPh, a digital health executive, said pharmacists need to know how such Dtx interventions could affect medication therapy. For example, she claims that there are digital therapeutics used for pain, and providers may need to adjust pain medications for patients to effectively correspond with the “dose” of the Dtx interventions. Pharmacists can lead the adjustments of such pain medication regimens to provide truly personalized pain medication recommendations.

In addition to providing treatment recommendations, pharmacists may help pharmacy benefit managers (PBMs) integrate Dtx onto formularies like what Express Scripts has already done. Many managed care pharmacists already have the experience of evaluating interventions to clarify whether they should or shouldn’t be included in a formulary. Therefore, many Dtx companies would value the input of a pharmacist to learn how to demonstrate the efficacy, safety, and financial viability of their Dtx to managed care organizations.

**What can a pharmacist do now?**

Many pharmacists can visit websites such as the Digital Therapeutics Alliance to learn more about digital health and Dtx. Pharmacists should also practice helping to make formulary decisions by volunteering.
to work with PBMs or working with local physicians to help develop their in-clinic injection or immunization formularies.

**Pharmacogenomics and Personalized Care**
Pharmacogenomics is the study about how DNA may significantly affect how patients might respond to medications. Experts suspect that the pharmacogenomics market will grow 8.6% by 2024 and generate $10.2 billion in market value. With the advent of companies such as 23andme, patients have become motivated to learn how their genetic code and habits can significantly affect their health.

According to Gordon, pharmacists may need to learn how to evaluate a patient's genomic profile, in context with their pharmacogenomic profile, to provide a truly personalized medication review. “Imagine if you can now aggregate everything about yourself, go to a doctor's office with a report that says what will probably what will work for me from a personalized medication perspective,” he said. “A pharmacist should learn to be able to account for all of those data points to help guide pharmacotherapy therapy.”

**What can a pharmacist do now?**
The University of Florida has an entire online curriculum of certificate programs in topics ranging from “implementing pharmacogenomics into clinical practice” to learning about “pharmacogenomic implementation, testing, and reimbursement.” Pharmacists may want to consider getting a sufficient amount of continued education to gain the skills of providing pharmacogenomic recommendations.

**Value of Health Informatics and Data Science**
Health informatics is considered the use of computer sciences and health care information sciences to help in the management of information. Data science is considered the use of scientific methods to gain further insight from organized or disorganized data.

Both market areas are projected to grow over 20% over the next 5 years as health organizations have seen greater value in using machine learning and artificial intelligence. Kim (Frey) Jacoby, PharmD, MSHI, a senior clinical expert for the digital health start-up Komodo Health, claims that any data science skill is important. According to her, pharmacists will make a greater impact of querying and evaluating data due to understanding the context of the health data versus data science professionals without any health care knowledge.

**What can a pharmacist do now?**
Jacoby says that pharmacists can learn different areas of data science such as using engineering model development, creating different types of machine learning algorithms, or even learning a programming language like “R” or “Python.” However, before jumping into data science, pharmacists can learn basic terminology by reviewing websites such as practice RxNorm. Pharmacists can also take any online data science courses from Coursera from Johns Hopkins University and use public health datasets to practice what they learn. Finally, pharmacists can visit the RxNav, RxMix, SNOMED websites to learn to codify medication information and large aggregate datasets to analyze and practice using the knowledge to apply in your current setting.

Due to the ever-changing health care landscape, pharmacists have greater opportunities to integrate or create new roles by continuing to adapt their skills.

For references, visit drugtopics.com.

**Mohamed Jalloh, PharmD, BCPS, is an assistant professor of pharmacy practice at Touro University California and a clinical pharmacist at OLE Health. He is also a member of the Drug Topics® Editorial Advisory Board.**
During the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition in 2020, several ASHP officials provided an update on key policy issues in the industry.

**Pharmacist Recognition and Scope of Practice**

“Pharmacist recognition has been a huge priority for us at ASHP,” Doug Huynh, JD, director of federal legislative affairs, said during the virtual session. The recent federal designation allowing licensed pharmacists to order and administer vaccines to any patients 3 years and older, as well as the ability to administer coronavirus disease 2019 (COVID-19) vaccines, represents a big win for the profession. “In broad strokes, this is really dramatic recognition by the [US Department of Health & Human Services] of the role pharmacists play in COVID-19 response,” Tom Kraus, JD, MHS, vice president of government relations, added. He noted that gaps around reimbursement remain, because the current requirements allow reimbursement only for the vaccine but not necessarily for related services, such as medication management services, do not need the same level of supervision required for in-person services. According to CMS, pharmacists can provide these services under virtual supervision until at least 2021. “One of the things we’ve been pushing them on is the idea of simplifying incident-to billing and making sure that the billing that is being done for pharmacists’ services is actually reflective of the value that is provided,” she said. Wall noted that ASHP hopes to push CMS to make this change permanent and ensure that pharmacists can be reimbursed appropriately.

**CMS Reimbursement Changes**

Jillanne Schulte Wall, JD, senior director of health and regulatory policy, discussed some of the payment changes made by the Centers for Medicare & Medicaid Services (CMS). During the pandemic, CMS clarified that pharmacists providing telehealth or incident-to services, such as medication management services, do not need the same level of supervision required for in-person services. According to CMS, pharmacists can provide these services under virtual supervision until at least 2021. “One of the things we’ve been pushing them on is the idea of simplifying incident-to billing and making sure that the billing that is being done for pharmacists’ services is actually reflective of the value that is provided,” she said. Wall noted that ASHP hopes to push CMS to make this change permanent and ensure that pharmacists can be reimbursed appropriately.

**340B Drug Pricing Program**

In continuation of the 340B Drug Pricing Program reimbursement cuts, CMS proposes 2 options: the payment of average sales price (ASP) minus 22.5%, the cut initially proposed, or an even steeper cut of ASP minus 34.7% plus an overhead-handling payment of 6%, which equals ASP minus 28.7%. According to Wall, CMS based the new proposals on hospital surveys sent out earlier in 2020. “We asked them not to do this during a pandemic…. This was really the wrong time if they wanted a lot of information from hospitals,” Wall said. “I don’t think they got a very good cross section at all of how hospitals are using this program.” Wall noted that ASHP continues to push for protecting the 340B program.

**Drug Shortages**

According to Huynh, the Coronavirus Aid, Relief, and Economic Security Act, passed in March 2020 featured many of ASHP’s key policy priorities related to drug shortages. These included requirements for manufacturers to provide the FDA with more information about the causes of shortages and expected duration, requirements to establish contingency plans, and incentives to encourage manufacturers to produce drugs in shortage.

In response to COVID-19, the FDA initiated a number of regulatory flexibilities around compounding. Notably, the agency announced that it will not enforce the 1-mile radius requirement from the hospital and health-system draft guidance. The FDA also allowed flexibility around compounding products in short supply and revising beyond-use dates for certain products compounded for patients with COVID-19. However, many of these policies are temporary. “We’re a long way from resolving drug shortages; that’s a perennial issue,” Kraus said. However, ASHP hopes to continue working with these agencies to address impending drug shortages.

By Jennifer Barrett
IN MY VIEW / DISPENSED AS WRITTEN

By Peter A. Kreckel, RPh

Pharmacists Must Unify to Overcome Challenges in Profession

“We have met the enemy, and they are ours!”

Oliver Hazard Perry in a dispatch to Major General William Henry Harrison.

M y opening lecture for the summer semester at Saint Francis University starts out with me introducing myself to the class of future pharmacists.

Then, I open the classroom door and look up and down the hallway. I close the door, and the students look at me with an inquisitive stare. I tell them there is no one sitting in the hallway waiting to take their place and they have earned their seat in the classroom. I tell them for the next 11 months, their job is to work together as a team so they all can make it through this rigorous didactic curriculum. I give them my slogan for the year: “We are no longer competitors, we are colleagues.”

It appears as a headline on page 1 of my Intro to Pharm notes. It also has made it to several of their class t-shirts.

We, as pharmacists, need to form a cohesive unit like so many other health professions do. We are often competitors, working for different chains and pulling business away from other pharmacies. I get frustrated when I call a competitor pharmacy for a patient transfer and get the 5-minute hold routine. When we call most doctors' offices, there is an option to press a button if you are a health care facility, and you get immediate attention. Why can’t we pharmacists have the same options?

A former state representative summed it up well. He said, “Pete, when the lobbyists come to my office to speak on behalf of pharmacy, I never see a unified message. The independent pharmacists have 1 message; the chain pharmacists might have a different message, and hospital pharmacists might have another message! Your profession needs to unify like physicians, nurses, and physician assistants!”

Who speaks for the physicians? We all know it is the American Medical Association. Who speaks for the nurses? It is the American Nurses Association. Who speaks for the physician assistants? It is the American Academy of Physician Assistants. Who speaks for pharmacists? It is the National Community Pharmacists Association, American Pharmacists Association, National Association of Chain Drug Stores, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Association of Boards of Pharmacy, and many others.

The Latin phrase “divide et impera”, meaning divide and rule, credited to Julius Caesar, is what has happened to our amazing profession. Pharmacy benefit managers have divided us on all fronts with predatory pricing, reimbursements, and the latest, sending our patients to different pharmacies.

At the same time, our profession is seeing wage stagnation or decreases, lack of adequate staffing, and the scarcity of employment opportunities.

So of all the pharmacy organizations, which one can save us? I doubt it’s just one of them. Our profession must band together in unity to push forward and relay 1 consistent message. It will all start as a grassroots effort, where we begin to treat each other as health care professionals the minute the phone rings and another pharmacist is requesting a transfer. Remember, we can no longer be competitors, we need to become colleagues. 

Peter A. Kreckel, RPh, practices community pharmacy in Pennsylvania.
Remdesivir in the Treatment of COVID-19

Ryan Nolan, PharmD candidate 2021, and Lisa Holle, PharmD, BCOP, FHOPA, FISOPP

On October 22, 2020, the FDA approved remdesivir (Veklury; Gilead) as the first treatment for coronavirus disease 2019 (COVID-19). Remdesivir is now indicated for adult or children 12 years of age and older weighing at least 40 kg for the treatment of COVID-19 requiring hospitalization. Remdesivir is an inhibitor of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) RNA-dependent RNA polymerase, an essential component of viral replication. Remdesivir, an adenosine nucleotide prodrug, is metabolized into its active form after being distributed into cells, resulting in delayed chain termination during viral RNA replication.

The double-blind, randomized, placebo-controlled ACTT study (NCT04280705) enrolled 1062 hospitalized adult patients who met certain criteria suggestive of lower respiratory tract infection. Participants also had to have a laboratory-confirmed SARS-CoV-2 infection. Five hundred and forty-one participants received remdesivir 200 mg intravenously (IV) on day 1 and then 100 mg IV on days 2 through 10, and 521 participants received placebo.

The primary outcome was the time to recovery based on the first day within the 28 days after treatment initiation. Patients who received remdesivir had a median time to recovery of 10 days (95% CI, 9-11) compared with 15 days (95% CI, 13-18) in the placebo group (rate ratio for recovery, 1.29; 95% CI, 1.12 to 1.49; P < .001, by a log-rank test). The Kaplan-Meier estimates of mortality by day 15 were 6.7% with remdesivir and 11.9% with placebo and 11.4% with remdesivir and 15.2% with placebo by day 29 (HR, 0.73; 95% CI, 0.52-1.03).

The second double-blind, randomized control trial GS-5734 (NCT04292730), standard of care was compared with a 5- and 10-day course of remdesivir in evaluating clinical status of hospitalized patients. Only the 5-day course was shown to be statistically significant at improving COVID-19 symptoms compared with standard of care when assessed on day 11. The third trial (NCT04292899) compared a 5-day course with a 10-day course of remdesivir in hospitalized patients with severe COVID-19. On day 14, no significant difference in recovery and mortality rates between the 2 groups was reported.

In the ACTT trial, the placebo group experienced more adverse effects than the remdesivir group (31.6% vs 24.6%). The most common adverse reactions observed with remdesivir are nausea (5%), increased aspartate aminotransferase (3%), and increased alanine transaminase (ALT) (2%). Hepatic lab testing should be performed in all patients before and while receiving remdesivir. Consider discontinuation if ALT levels increase greater than 10 times the upper limit of normal and discontinue if ALT elevation is accompanied by signs or symptoms of liver inflammation. Avoid coadministration with chloroquine phosphate or hydroxychloroquine sulfate as cellular data has shown reduced antiviral activity.

The current dosage recommendation of remdesivir is a 200 mg IV infusion over 30 to 120 minutes on day 1 followed by a daily 100 mg IV infusion on days thereafter. For patients only on supplemental oxygen, the recommended duration is 5 days compared with patients on mechanical ventilation or extracorporeal membrane oxygenation where the recommended duration is 10 days.

For references, visit drugtopics.com
<h2>Selling Your Pharmacy?</h2>

Maximize Your Value  
Minimize Your Worry

HAYSLIP & ZOST  
Pharmacy Sales Experts Ready to Help You!  
www.RxBrokerage.com

Tony Hayslip, ABR/AREP  
713-829-7570  
Tony@RxBrokerage.com

Ernie Zost, RPH  
727-415-3659  
Ernie@RxBrokerage.com

Call Hayslip & Zost Pharmacy Brokers LLC for a free consultation. We have helped hundreds of independent pharmacy owners nationwide get the maximum value for their pharmacies. For more information about us, please visit our website.
Help Repatha® patients address continuity of care questions with Repatha® Ready® resources

Injection support
Repatha® Ready® nurses are available for supplemental injection support over the phone, 7 days a week. To connect with a Repatha® Ready® nurse, watch a self-injection video demonstration, or find additional resources, have patients visit Repathainjection.com

Refill options
Talk to your patients about the availability of 90-day refills and home delivery options for Repatha®

Patients may pay $5 per month
Eligible commercially insured patients may pay $5 per month with the Repatha® Copay Card.* To learn more or for patient enrollment, visit Repatha.com/copaycard. If your mail-order pharmacy does not accept the Repatha® Copay Card, you may be eligible to receive reimbursement directly from Repatha® Ready®. Contact 1-844-REPATHA (1-844-737-2842)

*Eligibility requirements for the Repatha® Copay Card: Open to patients with commercial prescription insurance and who are not enrolled in any government-funded program that pays for prescription drugs. This program is not open to uninsured patients or patients enrolled in any federal, state, or government-funded healthcare program such as Medicare, Medicare Advantage, Medicare Part D, the Retiree Drug Subsidy Program, Medicaid, Veterans Affairs (VA), the Department of Defense (DoD), or TRICARE®, or where prohibited by law. Cash Discount Cards and other noninsurance plans are not valid as primary under this offer. Other restrictions, including annual copay maximum limits may apply. This offer is subject to change or discontinuation without notice. Please visit https://www.repatha.com/patient-services-and-copay-registration/#atandc for full terms and conditions.

Learn more about patient resources and support at RepathaHCP.com or call 1-844-REPATHA (1-844-737-2842)

© 2020 Amgen Inc. All rights reserved. USA-145-82508 11/20
Need Expert Help Selling your Pharmacy?

Approached by a Chain To Sell?  
Looking for an Independent Buyer?

Need a Valuation for Your Pharmacy?  
Need Financing for a Pharmacy Purchase?

Contact Hayslip & Zost Pharmacy Brokers LLC for all your answers!

www.RxBroker.com

“Your knowledge of the business climate allowed me to get top dollar for my pharmacy.”

-Jim Angell, Kerrville TX

“My experience with Tony Hayslip and Ernie Zost was very positive. I appreciate their honesty, fairness, integrity and professionalism.”

-Robert Guy, Super “D” Drugs, Greenville MS

“Hayslip & Zost’s knowledgeable staff and expertise allowed us to get a great price for our pharmacy. I strongly recommend their company to represent you throughout the selling process.”

-Helen T., RPH, CEO Yuba City CA

“Tony and Ernie did an outstanding job representing our pharmacy. I received top dollar thanks to them!”

-D. Cox, CEO- Boise ID

Endorsed by State Pharmacy Associations

HAYSZIP & ZOST
PHARMACY BROKERS, LLC

Looking for an independent buyer?

Contact Hayslip & Zost for All Your Answers
RxBrokerage.com
1.800.530.5650
Hayslip & Zost Pharmacy Brokers LLC

“Pharmacies selling to large corporations leave as much as $500,000 on the table.”

Tony Hayslip

MAXIMIZE your value... MINIMIZE your worry

Hayslip & Zost Pharmacy Brokers LLC — RxBrokerage.com

We have helped hundreds of independent pharmacy owners to get confidential answers and maximize the value of their businesses. With over 50 years experience, we specialize exclusively in buying and selling pharmacies. Our only job is to represent you throughout the whole process.

Ernie Zost, RPH
727-415-3659
Ernie@RxBrokerage.com

Tony Hayslip, ABR/AREP
713-829-7570
Tony@RxBrokerage.com