10 Strategies to Reduce Medication Errors

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10 Strategies to Reduce Medication Errors

PLUS

COVID-19 Coverage

Technology Digital Marketing 101

Diabetes New Diabetes Products

Pain NSAIDs and Liver Toxicity
CONVENIENT + COMPLIANT + CONSISTENT
CONVENIENT

- Quick and easy - saves time
- Pre-measured components
- Single NDC#/kit for easy claims processing

COMPLIANT

- Helps facilitate compliance with 503A and USP <795> guidelines

CONSISTENT

- Promotes accurate dosing each time
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Drug Topics® (ISSN# 0012-6616) is published monthly and Drug Topics Digital Edition (ISSN# 1937-8157) is issued every week by MultiMedia Healthcare LLC, 2 Clarke Drive, Suite 100 Cranbury, NJ 08512. One-year subscription rates: $61 in the United States & Possessions; $109 in Canada and Mexico; all other countries, $109. Single copies (prepaid only) $10 in the United States; $10 in Canada and Mexico; all other countries, $15. Include $6 per copy for U.S., postage and handling. Periodicals postage paid at Cranbury, NJ and additional mailing offices. POSTMASTER: Please send address changes to Drug Topics®, PO Box 457, Cranbury, NJ 08512-0457. Canadian G.S.T. number: R-124213133RT001. Publications Mail Agreement Number 428132838. Return undeliverable Canadian addresses to: IMEX Global Solutions PO Box 457, London, ON N6C 6B2 CANADA. Printed in the U.S.A. © 2020 MultiMedia Healthcare LLC All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical including by photocopying, or information storage and retrieval without permission is written from the publisher. Authorization to photocopy items for internal/educational or personal use, or the internal/educational or personal use of specific clients is granted by MJH Life Sciences for libraries and other users registered with the Copyright Clearance Center, 222 Rosewood Dr. Danvers, MA 01923, 978-750-8400 or visit http://www.copyright.com online. For uses beyond those listed above, please direct your written request to Permission Dept. email: etemple-morris@mmhgroup.com. Unsolicited manuscripts, photographs, art, and other material will not be returned. Publisher assumes no responsibility for unsolicited manuscripts, photographs, art, and other material.

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Prepare Your Pharmacy During the COVID-19 Pandemic

As the global COVID-19 pandemic and consequent public health crisis continues on, health care providers on the frontlines of this crisis deserve all of the support needed to continue serving their patients. With increasing pressures on the health care system, expanding the pharmacist’s roles and abilities to provide more services is becoming more important than ever.

With new updates on COVID-19 coming fast, we aim to provide you with the most timely, relevant information possible across both our digital and print platforms. Keep an eye on DrugTopics.com for the latest developments, as we will continue to report on how to navigate these unprecedented times in your pharmacy.

In this issue, we provide helpful tips on how pharmacies can keep their businesses thriving even in these difficult times. A smart business strategy for pharmacies to remain competitive in this market include digital marketing and advertising. In this issue, we dive into how to employ digital strategies into your pharmacy’s marketing approaches. As Steve Hoffart, PharmD, owner of Magnolia Pharmacy in Magnolia, Texas, said, “It’s important to meet your customers where they are.” They will appreciate the convenience and immediacy that you provide.

Our cover story on page 14 brings you 10 key strategies for reducing medication errors. Although there are many systemic problems that make it harder for pharmacists to prevent or catch these errors, there is still much that you can do to improve patient safety.

On page 18, Jennifer Gershman, PharmD, CPh provides pharmacists with an update on new diabetes medications and technologies to help you educate your patients about diabetes treatment, monitoring options, and pipeline drugs.

Finally, this issue also includes coverage from the 2020 Pharmacy Development Services Super Conference, which was held from February 27 to 29 in Orlando, Florida. For independent pharmacy owners, the coverage provides helpful tips on how to diversify your revenue opportunities, from the products you stock to the services you provide, as well as how to use budgets to increase cash flow.

Thank you for reading and continue to follow us on DrugTopics.com for the latest news.

Mike Hennessy, Sr.
Chairman and Founder of MJH Life Sciences
BLAZE A NEW TRAIL
TO THEIR LDL-C GOAL

NEXLETOL:
Oral, once-daily, nonstatin

In clinical trials, NEXLETOL delivered:
- 18% mean reduction in LDL-C (compared to placebo) when added to maximally tolerated statin dose (P<0.001)1
- Incidence of skeletal muscle adverse events comparable to placebo2

For more information about NEXLETOL, visit NEXLETOLHCP.com

INDICATION
NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Limitations of Use: The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Dosage Form and Quantity: NEXLETOL is available as an oral tablet containing 180 mg of bempedoic acid, taken once a day with or without food.

Contraindications: None.

Warnings and Precautions: Hyperuricemia: NEXLETOL may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, in patients with a history of gout.

Tendon Rupture: NEXLETOL is associated with an increased risk of tendon rupture, most commonly involving the biceps tendon, rotator cuff, or Achilles tendon. Tendon rupture occurred within weeks to months following NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure and patients with previous tendon disorders.

Adverse Events: In clinical trials, the most commonly reported adverse events were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Events reported less frequently, but still more often than in placebo, included benign prostatic hyperplasia and atrial fibrillation.

Laboratory Tests: NEXLETOL was associated with persistent changes in laboratory tests within the first four weeks of treatment, including increases in creatinine and blood urea nitrogen, decreases in hemoglobin and

IMPORTANT SAFETY INFORMATION (cont.)

leukocytes, increases in platelet counts, increases in liver enzymes (AST and ALT), and increases in creatine kinase. Laboratory abnormalities generally did not require medical intervention. Laboratory test values generally returned to baseline following discontinuation of treatment.

Drug Interactions: Simvastatin and Pravastatin: Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Special Populations: It is not recommended that NEXLETOL be taken during breastfeeding. A pregnant patient should consult with their healthcare provider about whether to continue treatment with NEXLETOL during the pregnancy. The safety and efficacy of NEXLETOL have not been established in patients under the age of 18. Patients over 65 accounted for nearly 60% of patients in clinical trials. No adjustments in dosing are required for age, or for patients with mild or moderate renal or hepatic impairment.

NEXLETOL is available only by prescription. To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or ESPERION at 833-377-7633 (833 ESPERMED).

Please see adjacent Brief Summary.

References:
NEXLETOL® (bempedoic acid) tablets

Professional Brief Summary. Please consult package insert for full prescribing information.

INDICATIONS AND USAGE
NEXLETOL® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

ADVERSE REACTIONS

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20% respectively.

Table 1. Adverse Reactions (≥2% and Greater than placebo) in NEXLETOL-Treated Patients with ASCVD and HbF (Studies 1 and 2)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>NEXLETOL + Statin and/or Lipid-Lowering Therapies (N = 2009)</th>
<th>Placebo (N = 999)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper respiratory tract infection</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>3.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>3.5</td>
<td>1.1</td>
</tr>
<tr>
<td>Back pain</td>
<td>3.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Abdominal pain or discomfort</td>
<td>3.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Anemia</td>
<td>2.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Elevated liver enzymes</td>
<td>2.1</td>
<td>0.8</td>
</tr>
</tbody>
</table>

*Hyperuricemia includes hyperuricemia and blood uric acid increased.

Adverse reactions leading to discontinuation of treatment were more frequent in NEXLETOL-treated patients than in placebo-treated patients. The clinical significance is unknown.

Tendon Rupture: NEXLETOL was associated with an increased risk of tendon rupture, occurring in 0.5% of NEXLETOL-treated patients versus 0.0% of placebo-treated patients. The clinical significance is unknown.

Increase in Creatinine and Blood Urea Nitrogen: Overall, there was a mean increase in serum creatinine of 0.05 mg/dL compared to baseline with NEXLETOL at Week 52. In 0.5% of patients treated with NEXLETOL, had blood urea nitrogen values that doubled (versus 1.5% placebo), and about 2.2% of patients had creatinine values that increased by 0.5 mg/dL (versus 1.1% placebo).

In the Placebo Count, 101% of patients (versus 4.7% placebo) had increases in creatinine levels of 2 or more g/dL and below the lower limit of normal on one or more occasion. Anemia was reported in 2.8% of patients treated with NEXLETOL and 1.9% of patients treated with placebo. Hemoglobin decrease was generally asymptomatic and did not require medical intervention. Decreased leukocyte count was also observed. Approximately 9.0% of NEXLETOL-treated patients with normal baseline leukocyte count had a decrease to less than the lower limit of normal on one or more occasion (versus 6.7% placebo). Leukocyte decrease was generally asymptomatic and did not require medical intervention. In clinical trials, there was no small imbalance in skin or soft tissue infections, including cellulitis (0.4% versus 0.3%), but there was no imbalance in other infections.

In the Placebo Count, 101% of patients (versus 4.7% placebo) had increases in creatinine levels of 2 or more g/dL and below the lower limit of normal on one or more occasion. Anemia was reported in 2.8% of patients treated with NEXLETOL and 1.9% of patients treated with placebo. Hemoglobin decrease was generally asymptomatic and did not require medical intervention. Decreased leukocyte count was also observed. Approximately 9.0% of NEXLETOL-treated patients with normal baseline leukocyte count had a decrease to less than the lower limit of normal on one or more occasion (versus 6.7% placebo). Leukocyte decrease was generally asymptomatic and did not require medical intervention. In clinical trials, there was no small imbalance in skin or soft tissue infections, including cellulitis (0.4% versus 0.3%), but there was no imbalance in other infections.

Increase in Liver Enzymes: Increases in hepatic transaminases (AST and ALT) were observed with NEXLETOL. In most cases, the elevations were transient and received or improved with continued therapy or after discontinuation of therapy. Increases to more than 3× the upper limit of normal (ULN) in AST occurred in 14% of patients treated with NEXLETOL versus 4.4% of placebo patients, and increases to more than 5× ULN occurred in 0.4% of NEXLETOL-treated patients versus 0.2% of placebo-treated patients. Increases in ALT occurred with similar incidence between NEXLETOL- and placebo-treated patients. Elevations in transaminases were generally asymptomatic and did not require discontinuation of therapy. Increases to more than 10× ULN in ALT and AST were observed.

Increase in Creatine Kinase: Approximately 10% of patients (versus 6.6% placebo) had elevations of 50 times or more of the normal value on one or more occasions. Elevations were generally asymptomatic and did not require medical intervention.

DRUG INTERACTIONS
Simvastatin Concomitant use of NEXLETOL with simvastatin causes a decrease in simvastatin concentration and may increase the risk of simvastatin-related myopathy. Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.

Pravastatin Concomitant use of NEXLETOL with pravastatin causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

USE IN SPECIFIC POPULATIONS

Pregnancy: Discontinue NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.

There are no available data on NEXLETOL use in pregnant women to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

In animal reproduction studies, bempedoic acid was not teratogenic in rats and rabbits when administered at doses resulting in exposures (AUCs) that were 20-30 times human exposures (AUCs) at the maximum recommended human dose (MRHD) of 180 mg to pregnant rats and rabbits, respectively. In an embryofetal development study in rats, bempedoic acid was given orally to pregnant rats at 8, 30, and 120 mg/kg/day during the period of organogenesis (gestation day 6 to 17). There were no increases in the incidence of non-adverse fetal skeletal variations (bent long bones and bent scapulae and incomplete ossification) at doses ≥ 30 mg/kg/day (less than the clinical relevance threshold) or in the absence of maternal toxicity. At maternally toxic doses, bempedoic acid caused decreases in the number of viable fetuses, increases in resorptions at 60 mg/kg/day (11 times MRHD) and reduced fetal body weight at ≥ 30 mg/kg/day (6 times MRHD). No adverse development effects were observed when bempedoic acid was given to pregnant rabbits during the period of organogenesis (gestation day 8 to 18) at doses up to 80 mg/kg/day (12 times MRHD).

In a pre- and postnatal developmental study in pregnant rats given oral doses of bempedoic acid at 5, 10, 30, and 60 mg/kg/day throughout pregnancy and lactation (gestation day 6 to lactation day 20), there were adverse effects on delivery in the presence of maternal toxicity, including: increases in stillborn pups, reductions in numbers of live pups, pup survival, pup weight, pup growth and slight delays in learning and memory at ≥ 10 mg/kg/day (at exposures equivalent to 36 times MRHD). Lactation: There is no information regarding the presence of NEXLETOL in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. NEXLETOL decreases cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol and may cause harm to the breastfed infant. Because of the potential for serious adverse reactions in a breastfeeding infant, based on the mechanism of action, advise patients that breastfeeding is not recommended during treatment with NEXLETOL.

Pediatric Use: The safety and effectiveness of NEXLETOL have not been established in pediatric patients.

Geriatric Use: Of the 3095 patients in clinical trials of NEXLETOL, 753 (24%) were 65 years and older, while 478 (16%) were 75 years and older. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients. However, greater sensitivity of some older individuals cannot be ruled out.

Elevated liver enzymes include hyperuricemia and blood uric acid increased.

*The safety and effectiveness of NEXLETOL have not been established in pediatric patients.

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03/20 US-NXTL-2000177
The Power of Depreciation and Amortization When Buying a Pharmacy

By Scotty W. Sykes, CPA, CGMA

Buying a pharmacy is one of the bigger financial decisions you will make in your lifetime. Whether you are buying assets or the common stock, it is imperative that you understand any opportunities you may have to maximize the post-closing cash flow from the purchase.

Generally, there are 2 ways to purchase a pharmacy. The first option is to purchase the stock of the target pharmacy. If you purchase the common stock of a pharmacy, you purchase the entire entity, which includes all the assets and liabilities. You walk into the pharmacy the next day as the owner. Nothing changes but who owns the business.

The second option is to purchase the assets of an existing pharmacy. The buyer selects the assets to purchase, which typically includes inventory, fixed assets, and goodwill and scripts. There are advantages and disadvantages of each option, but 1 notable difference is depreciation and amortization.

**Depreciation and Amortization Benefits**
Depreciation is the expensing of tangible assets, such as equipment and furniture, over a period of time. Amortization is the expensing of intangible assets, such as goodwill/script value, over a period of time. There is no actual cash outlay for the pharmacy for depreciation and amortization; it’s simply a tax adjustment to help a taxpayer deduct acquisition costs and ultimately lower taxable income.

When buying the stock of a pharmacy, the taxpayer is not allowed any depreciation for the price paid for the stock. Generally, the purchase price of the stock can only be deducted for tax purposes when the stock is eventually sold. However, when buying specific assets, you can depreciate or amortize the assets you purchased.

For example, if you purchased furniture and fixtures for $50,000, and a robot for $100,000, the government generally allows you to expense that over 5 to 7 years. However, there are also special bonus depreciation rules that may allow you to deduct the entire amount in the first year. Goodwill or script value, an intangible asset, is amortized or expensed over 15 years.

**Value of Asset Purchases**
Clearly, being able to deduct the cost of the assets you purchased is a major cash and tax planning opportunity. First, a buyer will want to allocate as much of the purchase price to the furniture, fixtures, and equipment so they can recover their cost more quickly. Keep in mind that a seller will want to allocate as little as possible to those assets because it will most likely cause the seller to report ordinary income, which is taxed at the higher ordinary tax rates.

Secondly, the expensing of furniture, fixtures and equipment can be accelerated by using special tax elections under Section 179 or Section 168(k).

These elections allow taxpayers to potentially expense or depreciate the entire cost of the asset in 1 year instead of 5 or 7 years. As a new pharmacy owner, using depreciation to lower or even eliminate any tax liabilities in your startup years is a major benefit. These elections could then be used as a broader tax plan to create losses, which can be utilized to offset other income. Anyone thinking of buying the stock of a pharmacy should make sure they understand the depreciation benefits they may be giving up.

**Consider Tax Exceptions**
As with most tax laws, there are exceptions. A stock purchase may be eligible to be structured under IRC Section 336(e) or 338(h)(10). With these elections, you can purchase the common stock of a pharmacy but still receive the depreciation benefits of an asset purchase. This is very valuable in areas where licensing and other setup requirements for new pharmacies are onerous. Before you consider these elections, you should work with a competent health care and transactional attorney, as well as a certified public accountant. The requirements of such transactions are specialized, and both parties must agree to them.

Taking time to understand your options in regard to depreciation and amortization when buying a pharmacy can help you increase cash flow, lower your tax liability, and negotiate the right purchase price.
How can you diversify your revenue opportunities to achieve optimal success as an independent pharmacy? At the 2020 Pharmacy Development Services (PDS) Super Conference, which was held February 27 to 29 in Orlando, Florida, Lisa Faast, PharmD, vice president of business development and services at PDS, discussed a few strategies to enhance revenue opportunities outside of the PBM.

1. **Allergy Tests**
   Allergy skin tests are typically conducted by a physician; however, it is not just allergists who can do them. In some states, pharmacists can perform them as well, according to Faast. However, she noted that they do have to be done in a physician’s office.
   “There are a couple of ways that you can participate monetarily in these allergy tests,” Faast explained. For example, you can purchase and resell the allergy tests to the provider. Faast noted you can also work with a collaborative practice agreement to do the test and screening for the physician in the physician’s office and share in that revenue.

2. **Lab Tests and Point-of-care Wellness Tests**
   “If you’re not doing some sort of lab test, I think you’re missing out on a big niche,” Faast said. PDS partners Physician 360 and MyLAB Box offer a menu of laboratory testing that you can make money on. Both are designed to be cash-based models, meaning you don’t have to be able to bill for the tests for it to work.
   “And so that is a great way to take a program that’s already good, already viable on its own, with no PBM, and be able to add on even more service-based pharmacy revenue,” Faast said.

3. **Pharmacogenomic (PGx) Interpretation Tests**
   With RxGenomix’s program, you get paid as a pharmacist to interpret PGx tests with the prescriber, according to Faast. When the patients get the results back, you look at the results and get paid $90 per test to talk to the prescriber and adjust patients’ therapies based on their PGx results. RxGenomix will update patients’ profiles, so as their drugs change or genetic profiles get updated with new information, you have the opportunity to follow up and bill for those services.

4. **Cannabidiol (CBD)**
   Although CBD seems like it’s been around for a while, it’s still the beginning of the market, and there’s a lot of opportunity in that market that isn’t being taken advantage of, according to Faast. “Even if you’re selling it, you probably could be doing more,” Faast said.
   This could include providing more education, marketing support, and working to alleviate the stigma around CBD in the community.
   Faast emphasized that although states have differing laws regarding CBD, it’s still important to become educated to prepare for changes in legislation. “State laws change frequently, and when the change is in your favor, you’ll be ready to pounce on that and you’ll be first to market,” Faast said.

5. **OTC Supplements and Retail Products**
   “OTCs are a fantastic way for you to own the market,” Faast said. Patients are willing to pay for high-quality supplements, if you’re able to give them the education they need. Faast suggested getting your employees involved by training them so they feel confident talking about these products with consumers.
   Knowing what products are trending in the OTC health, beauty, and wellness retail market is important. “You need to know what’s hot right now and what to sell,” Faast said. “People do those impulse buys.” Stocking your pharmacy with the latest products in this space can help drive more revenue that will add up over time.

6. **Weight Loss Coaching**
   Since weight is often at the root of patients’ medical problems, weight loss coaching can be a viable service to offer in your pharmacy. “Doing weight loss coaching is great way to diversify your revenue outside of the PBM,” Faast explained. You can devise a program that includes group-based services or 1-on-1 consultations.
Using Budgets to Increase Cash Flow for Your Pharmacy

For independent pharmacy owners, understanding the fundamentals of your business’s finances and how to manage your budget is essential to making better decisions that improve cash flow. At the 2020 Pharmacy Development Services (PDS) Super Conference, which was held from February 27 to 29 in Orlando, Florida, Dan Benamoz, RPh, founder and executive chairman of PDS, and financial expert Andy Tanner gave a lesson on how to boost your financial IQ.

Pharmacies often focus on their cash flow, but Tanner noted that the ability to understand how your overall business works is important in managing the company finances. “When you have a cash flow problem, it’s really not a cash flow problem. Cash flow is a symptom of some other problem in our business,” he said.

According to Tanner, there’s never been a more important time to understand your budget, especially in the pharmacy industry. “Now that’s more than what we buy and sell, what are our expenses are,” he said. “Our ability to make decisions based on data, not just a whim, not just what we think, is going to be very, very key in the coming years.”

To better understand how to overcome cash flow problems, look at your finances from a fundamental analysis perspective. Of particular importance is diving into the components that make up your financial statement. Benamoz highlighted the 3 reports that make up a statement:

- **Balance sheet**: Benamoz described the balance sheet as a “snapshot of a single moment in time” that contains your assets (“things and stuff”), liabilities (everything you owe), and equity (what you own).
- **Sales**: Sales minus costs of goods sold gives you a gross profit. That, minus expenses, gives you net income.
- **Cash flow**: This includes first cash that comes in through operations (e.g., operational expenses, income, day-to-day expenses), investments, and financial cash flow.

According to Benamoz, if the balance sheet is a snapshot, then the sales and cash flow reports are the “movies” of your business finances. “Profit and cash are not the same thing; they are 2 totally different things that have to have their own movies,” he said. Tanner added that it’s important to distinguish the difference between profit, which is “a theory of what might be,” and cash, which is “real and what’s in the bank.” The ability to read and understand how these financial statements interact with each other will change your whole business, he said.

“Understanding your cash that’s coming from operations, understanding your cash that comes in and out from your investments, and understanding cash you use with debt and finance are the 3 places that you’re going to have cash coming in and out,” Tanner said.

In terms of increasing your cash flow, Benamoz emphasized an important consideration: being busy and being profitable are not the same thing. For example, if you wanted to increase your sales by 40%, you might say that you want to increase orders by 200 prescriptions per day to reach that goal. However, Benamoz suggested looking at it a different way in order to focus on profitability. Instead, cutting expenses by 10% may also help you reach that goal and increase profitability.

According to Tanner, when it comes to managing expenses, the burden of leadership and entrepreneurship is decisiveness and making determinations as to what stays and what goes. “When a person understands that the purpose of an expense is to increase income, that the purpose of an asset is to increase income, and the purpose of a liability is to buy an asset, now they have a lens through which they can make those decisions,” Tanner said.

According to Tanner, these are the 3 questions you should use to guide these decisions:

1. **Do you still need it?**
2. **Can you get it somewhere else for less?**
3. **Is this a want or a need?**

When doing your budget, use your previous year’s profit and loss statement as a starting point. Factor in the historical information, such as how sales are trending, and adjust for other considerations, such as DIR remuneration fees and expense changes in payroll.

Being strategic in your budgeting can significantly change your business, Tanner concluded, and understanding how your financial statements work with each other can help you make financially intelligent decisions.

REFERENCES

The novel coronavirus disease 2019 (COVID-19) has become a global pandemic, with confirmed cases surpassing 500,000 worldwide to date. As of press time, the United States alone has more than 75,000 cases. Some of the hardest-hit states, such as California, New York, New Jersey, Washington, and Florida, currently make up over half of the country’s total COVID-19 count.

“Our American society is entering into a new reality when it comes to public health,” Michael Jackson, BPharm, EVP, and CEO of the Florida Pharmacy Association (FPA) told Drug Topics in an email.

Community pharmacies are especially vital during outbreaks such as COVID-19; this is primarily because community pharmacists remain on the frontlines of public health by serving as direct points of access for their patients.

“As patients, their families, and communities work together to ‘flatten the curve’ amidst the COVID-19 pandemic, access medications to treat chronic diseases, behavioral health conditions, and over-the-counter symptom management is vital,” Ken Thai, PharmD, president of the California Pharmacists Association (CPhA), wrote in an email. "Pharmacists in communities across the state are upholding their oath to serve their communities to ensure that patients can live happier, healthier, and safer lives by bringing the care to the patients’ doorsteps whenever possible.”

Dr. Thai added that, as grocery and convenience stores are forced to limit access, many neighborhood independent pharmacies are a solid community resource for basic hygiene and health needs.

“Pharmacists can provide direct clinical consultation on managing symptoms with over-the-counter medications and be a direct line to primary care providers to authorize necessary refills for patients,” he wrote. "As the ability to test for active infections, immunizations, and treatments for COVID-19 become available, having access to a neighborhood pharmacy (usually within 5 miles or less) will increase access significantly thereby affording the state the ability to quickly and successfully beat this pandemic.”

Drug and supply shortages remain a concern. Thai explained the 3-pronged considerations in identifying drug shortages: “There are 3 areas to consider with potential drug shortages in relation to the COVID-19 outbreak: symptomatic treatment, maintenance of chronic health conditions, and disease treatment.”

Thai noted that, considering that the symptomatic presentation of COVID-19 has similar features as the common cold or flu, many OTC medications can be used.

“However, as members of the community preemptively purchase the medications to manage fever, coughs, and body aches, there is a steady demand put on the limited supplies that community pharmacies, chain drug stores, and grocery stores have in stock,” he wrote. "Anecdotally, we are starting to see the cold/flu aisles of stores being cleared out.”

“As for the management of chronic health conditions, the current supply and future supplies need to be considered. Patients and prescribers are requesting early refills and extra days’ supply with local counties requesting all non-essential community members to quarantine themselves. Most pharmacies are prepped with inventory to handle their normal prescription volume for typically 1 to 2 months; however, it will be on a case-by-case basis of certain medications potentially being out of stock in the pharmacy and also from drug suppliers. Another factor to consider is the future production of these medications as most of the active pharmaceutical ingredients (API) that drug manufacturers use comes from single source suppliers that had to halt productions amidst the outbreak.”
“Finally, treatment guidelines of COVID-19 infections have not been finalized, but preliminary studies out of France, suggest that chloroquine and hydroxychloroquine could be potential medications for fighting off the infection,” Thai said.

According to Thai, local independents have reported that the price of these medications from secondary suppliers is already increasing, which will be an emerging concern. Moreover, as vaccinations are developed, community pharmacies will be primed and ready to administer vaccines to the community, he added.

In Florida, Jackson identified several key procedures which allow pharmacists expanded authority.

“Governor DeSantis has issued both a public health emergency order as well as a state of emergency order which provides new authority for pharmacists to assist patients with their refills and removes certain prescription barriers in place by pharmacy benefit manager plan designs,” Jackson said. “There are also additional initiatives under way such as filing for and receiving a request from the Center for Medicare and Medicaid services for a waiver to allow policy changes to help expedite patient care services in the Medicare, Medicaid and CHIP programs.”

Jackson also commented on Florida’s passing of a state bill that allows pharmacists to test and initiate treatment for influenza and Group A streptococcus.

“The Florida House and Senate has taken a position of unprecedented support of the services that Florida’s pharmacists can provide,” he said. “The Florida House and the Governor approved sweeping changes to the way that pharmacy is practiced in this state. It was a clear message and overwhelming strong support by our state that pharmacists can and need to do more for our citizens. We have over 21 million Floridians living in this state with over 1000 a day moving here. The demand for health care services is not going to decline. With the changes to the pharmacy practice act in House bill 389, pharmacists can make a difference.”

Thai also praised California’s state response to COVID-19, citing the importance of a coordinated response between the state and pharmacy professionals. “The California Legislature and the Governor of California worked collaboratively to pass emergency funding measures,” he wrote. “The landmark legislation enabled a coordinated response between health care facilities, local governments, and schools to ensure effective treatment of COVID-19 and strict preventative measures to limit its spread.”

State pharmacy associations are offering plenty of resources for pharmacists to navigate these unprecedented times. The Washington State Pharmacy Association (WSPA) has provided their pharmacists and health care providers with a COVID-19 resource page with links to reputable COVID-19 sources. The WSPA additionally released their own set of guidelines for pharmacy practitioners in maintaining their health in order to continue to provide customers with the help they need, related to COVID-19 or otherwise. The Pharmacists Society of the State of New York (PSSNY) has provided “Resources for Pharmacists” with updated New York state news.

The California Pharmacists Association (CPhA) has been especially proactive by offering residents social media alerts in addition to their resource page. CPhA is also creating a student-pharmacy connection portal to ensure that frontline pharmacy professionals can contact students able to volunteer under their supervision, according to Thai.

As the virus continues to spread, independent pharmacists have prioritized the availability of COVID-19 information, as well as taking precautions to limit the spread of the virus.

Peter A. Kreckel, RPh, manager of Thompson’s Pharmacy, has instilled measures to tackle the pandemic at his independent pharmacy, which is based in Pennsylvania. “My staff, every hour on the hour, have to wash their hands. That’s when I wipe down all the counters and wipe off the door with a bleach rag” he told Drug Topics in an interview. In addition to enacting mitigation efforts in his pharmacy, Kreckel has also assembled a comprehensive educational flyer that he has distributed to his customers, and has encouraged his colleagues to use as well.

“We also have a drive through – this is one case where I welcome the drive-through because it is decreasing contact. When people come into my pharmacy and get in line, I separate them. I say, ‘You need to move apart 6 feet because of the social isolation we’re doing.’ I will enforce that.”

For references, visit DrugTopics.com.
In March, the FDA announced the first drug shortage due to the coronavirus disease 2019 (COVID-19). As of press time, the agency did not name the drug that is in short supply. The FDA has also identified about 20 drugs that solely source their active pharmaceutical ingredients or finished drug products from China.

The agency is unable to disclose the drug without the manufacturer’s permission, because doing so would reveal the location of the active pharmaceutical ingredient source that the manufacturer uses, Michael Ganio, PharmD, FASHP, director of pharmacy practice and quality for American Society of Health-System Pharmacists, told Drug Topics®. “This information is considered proprietary. However, the drug is already on the FDA drug shortages list, and the FDA has noted that alternative therapies can be used by patients.” In late March, ASHP added chloroquine and hydroxychloroquine to its drug shortages list, both of which are being investigated for use in treating COVID-19.

Simultaneously, US Surgeon General Jerome Adams urged Americans to stop buying facemasks, as pharmacies are running out of masks. Hand sanitizers are also becoming increasingly hard to find at drugstore chains and other retailers.

In response, some pharmacies are taking measures to mitigate supply shortages. For example, Kroger is limiting how many cold and flu-related products—along with hand sanitizers—its customers can buy.

President Trump also signed a bill providing more than $8.3 billion to fight the COVID-19 outbreak. The legislation will provide federal and public health agencies money for vaccines, tests, and potential treatments.
FDA OKs OTC Ibuprofen, Acetaminophen Combo Product

Officials with the FDA approved GlaxoSmithKline’s (GSK) Advil Dual Action, the first OTC formulation combining ibuprofen and acetaminophen, for pain relief. Each tablet contains 125 mg of ibuprofen and 250 mg of acetaminophen and is indicated for adults and children 12 years of age and older.

The approval is based on data from 7 clinical studies, 3 of which were pivotal efficacy and safety studies in pain relief. The findings demonstrated that the combination product achieved superior efficacy compared with the individual monocomponents of ibuprofen and acetaminophen alone, as evidenced by appreciable improvements in acute pain symptoms across multiple pre-specified endpoints.

Evidence Supports Universal Hepatitis C Screening Recommendation

A new systematic review shows that new direct-acting antiviral therapies (DAAs) are highly effective at targeting the hepatitis C virus (HCV) with few adverse effects.

The review, published in the *Journal of the American Medical Association*, updates a previous analysis from 2013, which found that interferon-based antiviral therapy was associated with increased likelihood of sustained virologic response (SVR). The new report focused on current DAA regimens and was expanded to include adolescents. Moreover, the current review findings informed a new recommendation by the US Preventive Services Task Force (USPSTF) for universal screening of HCV.

According to the newly pooled data, SVR rates with currently recommended all-oral DAA regimens are substantially higher (>95%) than with interferon-based therapies evaluated in the previous 2013 review (68%-78%). DAA regimens were also linked to fewer harms than older interferon-containing therapies, according to the review.

Evidence on DAA therapies in adolescents was limited, but they consistently reported high (97%-100%) SVR rates, the review found.

Pharmacy Groups Express Concerns About Health Care Megamergers

In new comments to the US government, several pharmacy groups say that mergers of major companies, such as CVS Health and Aetna, have had significant anticompetitive effects, without improving the cost and quality of health care.

The Alliance for Pharmacy Compounding, American Pharmacists Association, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and National Community Pharmacists Association collectively urged for antitrust policy reform, in a joint comment to the Federal Trade Commission and the Department of Justice Antitrust Division.

Citing the CVS Health/Aetna and Cigna/Express Scripts mergers, as well as the OptumRx affiliation with UnitedHealthcare, the pharmacy groups said that vertical consolidation in the pharmacy sector has yielded significant anticompetitive effects, without promised improvements in cost or quality of care.

The agencies should create a regulatory regime that does not allow these transactions to unduly harm health care access, quality, and service, the groups argued.

In the pharmacy sector, the 3 largest pharmacy benefit managers control more than three quarters of all prescriptions filled in America—equalling over 3.3 billion prescriptions, the groups wrote.
10 Strategies to Reduce Medication Errors

Tzipora R. Lieder, RPh

It’s been 20 years since the Institute of Medicine released its landmark *To Err is Human* report, but medication errors remain a serious problem in our health care system. Pharmacists are positioned to play a key role in preventing or catching errors that can occur at the various stages of the drug-use process: prescribing, dispensing, and administration. Here are some strategies that can help.
10 Strategies to Reduce Medication Errors

**1 MINIMIZE CLUTTER AND DISTRACTIONS**

The pharmacy environment is often fast-paced and intense, with high prescription volume, insufficient staffing, and demanding patients. Keeping pharmacy counters clear and clutter free can be challenging, but it is an important part of reducing risk for dispensing errors, said Matthew Grissinger, RPh, director of error reporting programs at the Institute for Safe Medication Practices (ISMP) in Horsham, Pennsylvania. He advises pharmacies to use a basket system to keep different patients’ prescriptions and drugs separate, as well as to clear away the bottles from prescriptions that have been completed. Ideally, he said, pharmacists should take phone calls in a quiet, distraction-free area.

**2 VERIFY ORDERS**

For prescriptions called in by phone, it’s important to write down and then repeat the order to verify that it was heard correctly; ISMP recommends spelling drug names during read back.¹

E-prescribing comes with its own pitfalls, according to Dixie Leikach, RPh, vice president of Catonsville and Paradise Professional Pharmacies in Catonsville, Maryland. Her pharmacy often deals with problems caused by improper use of the technology. For example, sometimes prescribers can’t find the correct drug strength or dosage form on the e-prescribing drop-down menu, so they select a similar drug from the list and then write the intended product in notes in other areas of the prescription, which can be missed during order entry. “We’ve learned over time that we have to read all the information and clarify if something really doesn’t make sense,” Leikach said.

**3 USE BARCODES**

Scanning barcodes plays an important role in checking that the correct drug, dosage form, and strength has been selected. Grissinger said, ensuring that the most common dispensing errors are avoided. But he cautions that in the retail environment, this will only work if orders are entered in the system before selecting the drug bottle; if pharmacists pull the wrong drug off the shelf and enter its NDC number, barcoding will not catch that error because the incorrect barcode will appear on the prescription label.

At Boulder Community Health (BCH) in Boulder, Colorado, where Christopher Zielenski, PharmD, is pharmacy clinical coordinator, the use of barcoding throughout the system, from dispensing through administration, has resulted in a huge reduction in errors. Since they began requiring barcode scanning for medications being placed in automatic dispensing cabinets, the rate of mistakes in filling medications has been reduced to nearly zero, he reported.

**4 BE AWARE OF LOOK-ALIKE SOUND-ALIKE (LASA) DRUGS**

ISMP maintains a long list of drugs with similar names that may be confused, which it recommends printing in bolded tall man (uppercase) letters (eg buPROPion/busPIRone).² It is imperative for pharmacists to stay informed about what those drugs are, experts said. Grissinger advised that every pharmacy choose 5 common LASA pairs and develop strategies to avoid errors with them, such as separating them. If drugs are separated, he cautioned, pharmacists and techs need to know where they are located.

Leikach said that LASA lists grow as more drugs become available in generic formulations. She gave risper-idone and ropinirole as an example. “When those were brand names they weren’t a problem, but once they both went generic and they’re both available in the same strength... and they’re sitting next to each other on the shelf, all of a sudden you’ve got a huge potential for pretty severe med errors and adverse drug effects.”

**5 HAVE A SECOND PAIR OF EYES CHECK PRESCRIPTIONS**

One way to prevent human error is by involving a second human—a pharmacist or technician (as permitted by state law)—in the dispensing process. “If I’m the one taking the prescription and entering it, then I’m not pulling the drug and counting it, because I know I have to final check it,” Leikach said. “Someone else, a tech or another pharmacist, will look at it.... We check each other.” When she worked in environments where there was no one else there to check, she would walk away from prescriptions once she’d reached a certain point in the dispensing process, so that she could come back with “a fresh set of eyes.”

Grissinger cautioned that final checks should always include verification of the original order entry, whether by keeping the paper
prescription with the label and medicine bottle until completion or by pulling up the scanned prescription on the computer screen.

6 DESIGN EFFECTIVE WARNING SYSTEMS Various alert strategies can be helpful, but human nature is to overlook the familiar. That’s why Leikach moves around shelf talkers alerting staff about LASA drugs so they continue to catch the attention of staff members. She has also requested that the pharmacy software system change some alerts to hard stops, so that the pharmacist or technician is required to stop, read the alert, and type a response—thus ensuring that they pay attention.

Reporting safety events allows a big picture to develop so we can identify trends at the system level and then address those issues. CHRISTOPHER ZIELENSKI, PHARMD

7 INVOLVE THE PATIENT Patients are their own last line of defense when it comes to medication errors, and investing a minute or 2 in speaking to them can reap huge dividends in catching medication errors. Grissinger advises asking the patient when they pick up the prescription: “Open the bag; is this what you were expecting? Look at the label, look at the name of the drug, look inside the bottle if it’s a refill to make sure it’s what you got last time.”

Basic counseling can help ensure that patients understand what their prescription is for and how to take it properly; it sometimes helps catch errors as well. Leikach recalled situations where she could tell that her explanation did not make sense to the patients. “They said, ‘That’s not why I went to the doctor, that’s not what he told me!’” This enabled her to catch medication errors made by the prescriber or the dispensing pharmacist, she said.

Speaking to patients is also valuable in obtaining an accurate medication reconciliation, Zielenski noted, which is why BCH has instituted training in active listening for staff involved in medication reconciliation.

8 TRUST YOUR GUT “Pharmacists need to recognize their role to the patient,” Leikach said. “When you receive a prescription—especially if you get to know your patients—then if something doesn’t make sense don’t just let it go.” Question the patient and call prescribers to verify, she advised, and if necessary, dig deeper to obtain clarification on why something was prescribed as it was and whether it was a mistake. After enough occasions of being thanked by prescribers for catching their errors, Leikach realized that “you really do need to push when you feel that something isn’t right,” she said.

9 BE PROACTIVE “Let’s not keep waiting for things to go wrong and fix them,” Grissinger said. Experienced pharmacists can sense when things are not going right and should address those concerns, he said. “Otherwise something’s going to go wrong and the pharmacist is going to get blamed for that when we saw it coming a mile away.”

ISMP has free self-assessment tools that pharmacists in different practice settings can use to evaluate how well they are maintaining patient safety. Its Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy includes over 200 items in 10 elements important for safe medication use.

Sometimes, Zielenski said, simple changes can have a big impact. For example, BCH started stocking batteries on the floors after pharmacists realized that barcode medication administration rates were dropping due to scanner batteries running out. Similarly, BCH includes dosing and administration instructions with emergency kits.

“Those types of tools can be implemented anywhere,” he noted. “Front-line staff can develop them; it doesn’t have to come from a manager.”

10 TRACK MEDICATION ERRORS “I believe in reporting safety events—which are classified as near-misses and errors—even if they are your own, to allow a big picture to develop so we can identify trends at the system level and then address those issues and encourage peer-to-peer feedback,” said Zielenski. He recently published an article describing how BCH developed several interdisciplinary committees that used medication safety event reports through its voluntary electronic safety event reporting system to perform continuous quality improvement throughout the hospital. Over the course of 3 years, there was a significant drop in rates of medication errors and concomitant increase in the rate of near misses, while reporting rates remained the same.

Open discussion of medication errors is most helpful when an institution has a just culture perspective, Zielenski added. “As soon as it becomes part of a normal conversation, I think that’s where you really start to gain traction on reducing medication errors,” he said.

For references, visit DrugTopics.com.
Pharmacies that haven’t added digital marketing and advertising to their mix are missing the target. Digital isn’t a trend, it is where most Americans spend their time. “It’s important to meet your customers where they are,” said Steve Hoftart, PharmD, owner of Magnolia Pharmacy in Magnolia, Texas. “Where you market depends on what resonates with the majority of customers. Our patient population responds well to the interactivity of our digital and social media efforts, so we’ve been leaning heavily on that approach.”

Brittany Sanders, PharmD, owns The Pharmacy at Wellington in Little Rock, Arkansas. She opened the pharmacy with newspaper ads, billboards, flyers, and other conventional approaches in 2015. Today, she focuses on digital channels. “Digital lets us hyper target,” she explained. “If somebody is searching for something as simple as ‘Band-Aids’ or anything related to pharmacy within 3 miles of our store, they get us. We can be so specific that if somebody is in the Walgreen’s parking lot across the street, we serve an ad to bring them over. You can’t do that with conventional channels.”

Conventional marketing is based largely on a combination of geographical coverage, newspaper circulation, television or radio broadcast range, and best guesses about which demographics are most likely to read a specific paper or tune to a particular channel. Digital marketing is customer centric. And the cost per impression is far lower than conventional channels.

Sanders spends about $500 for 9000 impressions on over-the-top (OTT) ads on streaming media, such as Sling and YouTubeTV. OTT advertising targets specific demographics, including age, sex, income, health status, education, and specific geographical areas. Anyone in her target demographic within 5 miles of the store sees her ads no matter what they are streaming. And she knows which ad spots in each demographic is most successful.

“Sam Walton, the founder of Walmart, used to say that half of marketing dollars are wasted, you just don’t know which half,” said Blair Thielemier, PharmD, founder of BT Pharmacy Consulting in Jonesboro, Arkansas. “Digital tells me what is working and what isn’t. So if I want to target people with diabetes who live within 10 miles of my store, I can see precisely what works [and] what doesn’t.”

As smartphone use grows, a mobile app becomes a key marketing tool, added Kurt Proctor, PhD, RPh, senior vice president of strategic initiatives for the National Community Pharmacists Association (NCPA) and president of the NCPA Innovation Center. “With a mobile app, your store is effectively open 24/7,” he said. “You connect with patients on their time, not yours. Convenience is vital now that we have all come to expect immediate response.”

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<th>2019 Smartphone Use by Age Group</th>
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<td>54% of Americans age 65 and older</td>
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<td>79% of 50- to 60-year-olds</td>
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<td>92% of 30- to 49-year-olds</td>
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Do Digital Right

1. **Highlight what makes your pharmacy special.** Whether it’s free delivery, compounding, diabetes care, or something else, promote services patients may not get at chain stores.
2. **Keep it personal.** Patients want to see faces they recognize, not stock photos.
3. **Emphasize special promotions and sales.** Nothing brings customers in like a great deal. Promote specials on all your digital channels.
4. **Keep it fresh.** Show content that is fresh and new, not the same old, same old.
5. **Make it convenient.** Let patients refill online or on your app.
New Diabetes Medications, Technologies You Should Know

Pharmacists can play an integral role in managing patients with diabetes

By Jennifer Gershman, PharmD, CPh

According to the National Diabetes Statistics Report, 34.2 million Americans are living with diabetes. With new drugs and technologies available, pharmacists are at the forefront of the effort to educate patients and health care professionals about diabetes treatments, monitoring options, and pipeline drugs (see Table). Pharmacists can assist with individualizing technology based on patients’ needs.

**New Diabetes Medications**

**Semaglutide**

Semaglutide (Rybelsus) was approved on September 20, 2019, as the first oral medication in the drug class glucagon-like peptide receptor agonist (GLP-1 RA), which is unique in its format—the other drugs in the class are injections. It is indicated for the treatment of type 2 diabetes, in combination with diet and exercise. Semaglutide injectable (Ozempic) was approved in 2017 for patients with type 2 diabetes. Rybelsus is not recommended as first-line therapy for patients with type 2 diabetes; rather, metformin is considered the preferred drug for initial treatment. Novo Nordisk, the manufacturer of Rybelsus, provides a savings support card to eligible patients with private or commercial insurance; individuals can use the card to pay $10 for a 30-day prescription of the medication. The American Diabetes Association (ADA) guidelines recommend the use of a GLP-1 RA, such as semaglutide, to achieve greater blood glucose lowering over initiating insulin for patients whose oral therapy treatments have failed.

“Pharmacists should counsel patients to take Rybelsus at least 30 minutes before the first food, beverage, or other oral medication for the day, with no more than 4 ounces of plain water. This counseling point is imperative to ensure that patients get the most benefit they can from this medication,” said Andrea Levin, PharmD, BCACP, assistant professor, Department of Pharmacy Practice, Nova Southeastern University College of Pharmacy. The most common adverse effects (AEs) include nausea, diarrhea, vomiting, decreased appetite, indigestion, and constipation. Rybelsus carries a boxed warning regarding the increased risk of thyroid c-cell tumors, and patients who have had medullary thyroid carcinoma (MTC) or a family history of MTC should not take the medication.

The starting dose of Rybelsus is 3 mg orally once daily for 30 days. After 30 days, the dose should be increased to 7 mg once daily, which may be increased to a maximum of 14 mg once daily if additional blood glucose lowering is needed after at least 30 days on the 7-mg dose. The PIONEER 3 randomized clinical trial evaluated the safety and efficacy of oral semaglutide with a dose of 7 mg/day and 14 mg/day, compared with sitagliptin added on to metformin with or without a sulfonylurea, in patients with type 2 diabetes. There were 1864 patients included in the study conducted at 206 sites in 14 countries. The study revealed that both doses of semaglutide compared with sitagliptin resulted in statistically significant greater reductions in A1C levels over 26 weeks ($P < 0.001$).

**Glucagon**

Glucagon (Baqsimi) nasal powder was approved July 24, 2019 as the first glucagon therapy for the emergency treatment of severe hypoglycemia that can be administered without an injection. It is indicated for the treatment of type 2 diabetes, in combination with diet and exercise. Semaglutide injectable (Ozempic) was approved in 2017 for patients with type 2 diabetes. Rybelsus is not recommended as first-line therapy for patients with type 2 diabetes; rather, metformin is considered the preferred drug for initial treatment. Novo Nordisk, the manufacturer of Rybelsus, provides a savings support card to eligible patients with private or commercial insurance; individuals can use the card to pay $10 for a 30-day prescription of the medication. The American Diabetes Association (ADA) guidelines recommend the use of a GLP-1 RA, such as semaglutide, to achieve greater blood glucose lowering over initiating insulin for patients whose oral therapy treatments have failed.

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Glucagon

Glucagon (Baqsimi) nasal powder was approved July 24, 2019 as the first glucagon therapy for the emergency treatment of severe hypoglycemia that can be administered without an injection. The glucagon injection must be mixed through a several step process. Glucagon nasal powder is approved for patients 4 years and older, and the product comes ready to use in a precise premeasured dose. Eli Lilly also provides a coupon for patients with commercial drug coverage to pay $25 for up to 2 devices. The recommended dose is 3 mg administered as 1 actuation of the intranasal device into 1 nostril. If there is no response after 15
minutes, an additional 3 mg dose from a new device may be administered while waiting for emergency assistance. The most common AEs associated with glucagon nasal powder are nausea, vomiting, headache, upper respiratory tract irritation, watery eyes, eye redness, and itching of the throat.8

Pharmacists can play an important role in counseling patients about the appropriate use of glucagon nasal powder. Patients should be educated to ensure that caregivers, family, and friends know where the product is kept and how to use it. The shrink-wrap or tube should not be opened until it is ready to be used or the product may not be fully effective.8 To prepare the dose, the shrink-wrap should be removed by pulling on the red stripe, and the lid can be opened and the device should be removed from the tube. The plunger should not be pressed until the dose is ready to be given. The device should be held between the fingers and thumb, and the tip should be inserted gently into 1 nostril until finger(s) touch the outside of the nose. Then, the plunger should be pushed firmly all the way in. The dose is complete when the green line disappears. After administering the dose, someone should call 911 emergency services immediately, and the device and tube should be discarded. The patient should be encouraged to have a fast-acting source of sugar (eg juice) and a snack as soon as possible. If the patient is unconscious, then the individual should be turned onto his or her side. Glucagon nasal powder should be stored in the shrink-wrapped tube at temperatures up to 86°F.8 Patients should replace the used product right away so it is readily available.

Liraglutide
Victoza (liraglutide) was approved June 17, 2019, for pediatric patients 10 years of age and older for the treatment of type 2 diabetes.9 This is the first non-insulin drug approved to treat type 2 diabetes in children since metformin was approved for pediatric patients in 2000.9 The starting dose of liraglutide for pediatric patients is 0.6 mg daily, and after at least 1 week, it may be increased to 1.2 mg daily if additional blood glucose lowering is needed.10 The maximum dose is 1.8 mg daily after at least 1 week of treatment with 1.2 mg daily. Liraglutide includes a boxed warning about the increased risk of thyroid C-cell tumors. Patients who have a medical or family history of MTC, or an endocrine system condition called multiple endocrine neoplasia syndrome type 2, should not use liraglutide. The most common AEs are nausea, diarrhea, vomiting, decreased appetite, indigestion, and constipation.10

Innovative Technologies
Diabetes technology includes hardware, devices, and software that patients can use to help manage their condition.11 Levin discussed some of the advances in diabetes technology, such as continuous glucose monitoring (CGM), and emphasized that insurance coverage varies by plan. The 2020 ADA guidelines provide more evidence-based information about available technologies and emphasize an individualized approach to selecting the best one, depending on the patient’s needs.11

“One of the great benefits of CGM is that patients are alerted when blood glucose levels are low or high,” said Levin. Additionally, CGM is a useful tool for lowering A1C levels. Most patients using intensive insulin regimens (multiple daily injections or insulin pump therapy) should assess blood glucose levels using self-monitoring of blood glucose or CGM prior to meals and snacks, at bedtime, prior to exercise, when blood glucose is expected to be low, after treating low blood glucose until it is normal, and prior to and while performing critical tasks, such as driving.11 DiabetesWise.org is a nonprofit resource that pharmacists and patients can use to help decide on the best device.12 The CGM options include Dexcom G6, Medtronic Guardian, Abbott Freestyle Libre, and Eversense.12

**Table: Diabetes Pipeline Drugs**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Description</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imeglimin</td>
<td>Oral first-in-class drug that improves mitochondrial function</td>
<td>Poxel Pharma</td>
</tr>
<tr>
<td>Dasiglucagon</td>
<td>Treatment of severe hypoglycemia, new drug application submission expected early 2020</td>
<td>Zealand Pharma</td>
</tr>
<tr>
<td>HypoPal rescue pen</td>
<td></td>
<td></td>
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<tr>
<td>Dulaglutide (Trulicity)</td>
<td>Evaluating higher doses for type 2 diabetes</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Tirzepatide</td>
<td>Dual GIP and GLP-1 RA</td>
<td>Eli Lilly and Company</td>
</tr>
</tbody>
</table>

NDA: New Drug Application; GIP: glucose-dependent insulinotropic polypeptide
NSAID-Induced Hepatotoxicity Rare, but Still Important to Note

By Frieda Wiley, PharmD

When many think of non-steroidal anti-inflammatory drugs (NSAIDs), adverse effects (AEs) such as gastrointestinal bleeding, nephrotoxicity, and cardiovascular challenges frequently come to mind. These drugs fall among the world’s most commonly used medications, but 1 AE, hepatotoxicity, gets little fanfare.

In 2010, nearly 43 million of adults living in the United States, or approximately 20%, took aspirin a minimum of 3 times per week for 3 months or more. Additionally, 29.1% used NSAIDs on a regular basis.

Jason Varin, PharmD, assistant professor and director of alumni relations at the University of Minnesota College of Pharmacy, shed some light on the state of affairs. “Based on a number of issues, people think of acetaminophen causing liver damage and NSAIDs causing kidney damage,” he said. “This can be true, but they are not mutually exclusive.”

NSAID-induced hepatotoxicity is relatively uncommon, occurring in approximately 4 of every 100,000 patients per year. Individuals who have certain chronic illnesses, including existing compromised liver function, have a higher incidence of additional liver injury. Genetics can also contribute to a person’s risk. Rather than pronounced liver failure, NSAID-induced hepatotoxicity is more likely to manifest through elevated liver enzymes, such as alanine transferase. Patients who have NSAID-induced liver failure are also less likely to face the invasive consequences frequently associated with acetaminophen-induced hepatotoxicity. Varin said that acetaminophen is responsible for upwards of 20% of liver transplants and is the leading cause of liver failure in the United States.

A review article published in Hepatology International found that only 18 of 698 studies conducted through July 30, 2016, on 9 different NSAIDs were randomized controlled trials. Of those 18 studies, 8 contained data supporting the hepatotoxic potential of diclofenac, etoricoxib, and celecoxib, based on criteria for hepatotoxicity.

Of those 3 NSAIDs linked to hepatotoxicity in the randomized control trials, diclofenac was found to have the higher number of liver-damaging incidents (0.015 to 4.3x10^-2). Celecoxib trailed behind with 0.13 to 0.38x10^-2, followed by etoricoxib, which ranged from 0.005 to 0.930 x10^-2.

Although these studies help shed some light on the potential dangers associated with NSAID use, more data is needed to paint a clearer picture.

“We definitely need more studies, since post-marketing results are very important to determine if long-term use or dosages higher than recommended would lead to more dangerous or unwanted toxicities,” explained Farzana Kennedy, RPh, FACA, owner and president of Alexandria Compounding Company in Alexandria, Virginia.

Until additional studies are conducted, Kennedy and Varin offer the following tips for pharmacists to help them lessen the burden of NSAID-induced hepatotoxicity for their patients.

- Take NSAIDs with food, as some can cause stomach upset, even with a single dose.
- Educate patients to take only the minimum amount necessary and to never exceed recommended dosage.
- Always read the ingredient list, as NSAIDs and acetaminophen may be present in other medicines. Ibuprofen is available as a single ingredient in Advil, Motrin, and as a generic, but you will also find it in other medicines, such as several cold and influenza preparations.
- Encourage patients to check with their pharmacists or physicians prior to taking any OTC medications.
- Educate patients when dispensing NSAIDs or any medications that may have liver- or alcohol-induced toxicity. When NSAIDs are used in long-term treatment, make sure the patient’s liver enzymes are checked periodically.

For references, visit DrugTopics.com
Many US Children Not Following Recommended Vaccine Schedule

By Jill Sederstrom

More than 1-third of all children in the United States are not following the recommended vaccine schedule, according to a new study. The study, published in Pediatrics, found that only 63% of children were adhering to the early childhood immunization schedule recommended by the Advisory Committee on Immunization Practices (ACIP).1

Approximately 1 quarter, or 23%, were vaccinating their children on what researchers designated as an “alternate” schedule that either limited the number of shots per visit or skipped at least 1 vaccination series. Another 14% of children were using an “unknown or unclassifiable” pattern, indicating that the child’s parents had either limited the shots per visit or vaccine series received or were not in line with the ACIP recommendations.

“The findings in this study reaffirm that deviations from the recommended immunization schedule, whether as the result of parents following an alternate schedule or other factors, result in many children remaining out-of-date for an extended period of time,” the study authors wrote.1

Children were more likely to follow an alternate schedule if they had moved across state lines, were not the first-born, lived in the Northeast, were black or multi-race, or were living below the poverty line, according to the study. Researchers used provider-verified vaccination data from the 2014 National Immunization Survey to determine the vaccination patterns of those included in the study.

Shaliz Pourkaviani, MD, a neonatologist, told ABC News that families often work to create a modified immunization schedule that will split up the number of vaccines a child receives at 1 time, which can be a “disservice” to the child.2

“Delaying vaccines delays the body’s ability to develop an immune response, relying on immunity from the rest of the community,” Pourkaviani said.

Dr Ofer Levy, the director of the Precision Vaccines Program at Boston Children’s Hospital in Massachusetts, told Healthline that the results of the study mirror a troubling trajectory on hesitancy that has emerged.3

Health care providers can play an important role in combating misinformation by providing reliable and accurate information to parents.

“It is important to speak with moms and try to dissect each individual family’s concerns regarding vaccines,” Pourkaviani said. “Often time’s parents don’t have a good understanding of why they are refusing, and seem to want to be a part of the anti-vaccine movement promoted by social media influencers/blogs and concepts that are not backed by reliable data.”

REFERENCES

Barriers Coming Down for Complex Generic Drug Products

This year may mark a dramatic difference in the development and approval of complex generic drug products. On February 24, 2020, the FDA approved the first generic of albuterol sulfate (ProAir HFA), an inhalation aerosol for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease, and the prevention of exercise-induced bronchospasm in patients 4 years of age and older. This approval marked a milestone by allowing a new generic for one of the most commonly used rescue inhalers in the country.

A complex generic drug product such as this one historically has been difficult to get approved because of the complex formulation or mode of delivery. Today, many complex drugs lack generic competition, even though exclusivities no longer block their approval. However, the FDA now is taking new steps to further facilitate complex generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing complex drug products.

The FDA regularly posts and revises Product-Specific Guidances (PSG) and is prioritizing complex generic products. It has started new initiatives to ensure the regulatory requirements for complex generic drugs are streamlined, predictable, and science based. The goals of the initiatives are to help reduce the time, uncertainty, and cost of complex generic drug product development.

Developing More Generic Topical Dermatological Drug Products

The FDA is collaborating with international researchers to evaluate a new method for monitoring the amount of a topical drug in the dermis. This new method for measuring the concentration of drugs in the skin may help drug developers determine whether proposed generic versions of drugs applied to the skin perform as well as their brand name equivalents.

Currently under study are a generic acyclovir (Zovirax) cream, complex injectables, implants, formulations and nanomaterials complex mixtures, and nasal locally acting products. Another area under investigation is abuse-deterrent opioid drug products. Markham C. Luke, MD, PhD, who is the director of Division of Therapeutic Performance in the Office of Research and Standards at the FDA, said his office is looking at developing new generic, abuse-deterrent opioid drug products and has recently issued a guidance paper on it. “We are actually doing some of those trials ourselves to see how feasible they are,” Luke told Drug Topics. “The opioid epidemic is a big public health issue, and so we are very mindful that there is a need for not just abuse deterrent opioids, but generic formulations for treatments for opioid abuse as well.”

In 2019, there were 1014 approved or tentatively approved Abbreviated New Drug Applications and 107 first generic drugs approved, according to the 2019 Office of Generic Drugs Annual Report. It shows that 110 complex generic drugs were approved, which was 11% of the generic drug product approvals in 2019.

Bob Lobo, PharmD, who is director of clinical programs at Vanderbilt University Medical Center, Nashville, Tennessee, said there is a great unmet need for less expensive, generic versions of complex medications. “Significant savings to payers and the federal government from approving more generic versions of complex medications could be realized,” said Lobo. He cited a recent study on the economic burden associated with extended-release (ER) versus immediate-release (IR) formulations among Medicare and Medicaid beneficiaries. The study identified a potential annual cost savings of $2.6 billion by switching certain ER drugs to comparable generic IR formulations. This study only looked at 20 ER oral medications, but it suggests that the annual savings from greater access to generic medications are quite significant.

“I applaud the ongoing efforts by the FDA to help to create innovative new pathways for generic versions of complex branded products, as this will serve to improve access to a large number of important medications. These efforts will likely benefit our patients and reduce the cost to the patient and the health care systems providing these medications,” Lobo told Drug Topics.
Pharmacists: Never Miss an Opportunity to Counsel

Thirty-five years ago, I was working outside in my yard when a local physician came to pay me a visit. He started out telling me that I was young and new to the health care system, and that he realized that pharmacists were getting into patient counseling. He told me he was irritated that I was counseling his patients about the adverse effects of medications. He told me about a 60-year-old patient who had who was on long-term prednisone therapy for allergies. I had the “audacity to scare” this patient by telling him that prednisone could “cause stomach ulcers and possibly type 2 diabetes.” I confirmed that I did inform the patient of my concerns about long-term prednisone therapy for allergies.

About 2 months later, I filled a prescription for ranitidine (Zantac) for this same patient; less than 6 months after my warning, the patient was started on NPH insulin. I had been practicing for 4 years at that time and longed for the day that pharmacists would have input in patients’ pharmacotherapy. /That day is here! Now, I have physicians not only taking my advice, but seeking out my advice. Physicians and physician assistants frequently call me to ask for alternative therapies.

Recently, we had a prescription rejected for rifaximin (Xifaxan) for a patient who was discharged from the hospital on thiamine 100 mg, folic acid, and a multiple vitamin. I went out to talk with the patient’s husband and discussed his wife’s serious condition. I told him that rifaximin was approximately $2500 per month and would need a prior authorization.

I printed out a flyer from a presentation I created on hepatic encephalopathy. I told him that lactulose syrup would be the next best option. About an hour later, I received an electronic prescription for lactulose 15 mL twice daily from the patient’s physician. I spent at least 10 minutes that I didn’t have educating this patient’s husband about the use and adverse effects of this medication. He left grateful that I took so much time and provided him with measuring devices needed for accurate dosing.

Forty years ago, when I was in pharmacy school, a friend of mine told me that his dad, who was a pharmacist, was told by a physician in the 1970s “you sell the toothpaste and [leave] the prescribing to me!” When I see how far this profession has come, I never lose sight of where I want this profession to go. It only makes sense to me that getting paid for our knowledge and patient counseling skills is most appropriate. That is something I never would have envisioned back in 1985.

I always offer this advice to students I precept: “When a physician asks you a question, don’t pull out your phone.” Physicians have already checked the most common databases. Know the drugs needed for patients with alcoholism and post-bariatric surgery. Consult the prescriber to remove those dipeptidyl peptidase 4 inhibitors from patients using glucagon-like peptide-1 drugs. Make sure the lisinopril has been stopped for 36 hours before starting sacubitril/valsartan (Entresto). Don’t play “gotcha” when advising a prescriber; we all have our knowledge base and should be respected for the breadth and depth of what we know.

This 61-year-old pharmacist wants this profession to continue its direction in being a major decision-maker on the health care team. Oh, and I’ll sell the toothpaste too—and make sure it is free of pyrophosphates, which can cause gingival irritation; I’ll never miss an opportunity to counsel a patient!

“I had been practicing for 4 years at that time and longed for the day that pharmacists would have input in patient’s pharmacotherapy. That day is here!”

By Pete Kreckel, RPh

Pete Kreckel, RPh, practices community pharmacy in Altoona, PA.
Pharmacist-led home infusion centers are making it easier for patients to access long-term therapy without enduring protracted hospital stays. Not only does it enable patients to more quickly resume their normal activities, but home infusion can be more cost effective than a long hospital stay and reduce the risk of hospital-acquired infections.

“The push is to get patients home and not be in the hospital so someone has to provide a service for them when they are home,” said Ryan McFerrin, PharmD and co-owner of Druid City Vital Care, Northport, Alabama. “What happens on the other days that you used to be in the hospital? Keeping people out of the hospital is our main goal. We want you to get therapy, but if you ask me, I’d rather get therapy at home on my couch than in a hospital bed.”

The National Home Infusion Association (NHIA) estimates that there are currently 1500 US pharmacies offering infusion therapies. “The industry has experienced rapid growth in the last decade,” said Connie Sullivan, RPh, NHIA president and chief executive officer. “We think that the growth is going to continue.”

According to the Department of Health and Human Services, home infusion is one of the fastest growing sectors of home health care. One reason for projecting growth is that the number of patients estimated to need such therapy is expected to increase. The American Hospital Association estimates that approximately 133 million Americans currently have at least 1 chronic illness. That figure is forecasted to reach 170 million by 2030, with many of those patients requiring medication that needs to be infused or injected, including the growing number of biologics.

Unlike retail or independent pharmacies, infusion centers are basically closed-door pharmacies that not only compound prescriptions for patients but can administer therapy—via needle or catheter—and monitor a patient’s treatment.

“We don’t have customers walking in to fill a prescription,” said Sullivan. “An infusion center operates essentially in collaboration with home health care agencies and companies, such as durable medical equipment companies, to provide acute and chronic clinical oversight and sterile products to patients who need extended infusion therapy. They’re facilities that offer sterile compounding services, primarily to make IV solutions, and provide the clinical oversight of these patients, which can be quite acute.”

Infusion centers provide ongoing therapy for conditions such as congestive heart failure, cancer, multiple sclerosis, rheumatoid arthritis, inflammatory bowel disease, psoriasis, and pain treatment, as well as nutrition and hydration problems.

“Anti-infectives are the most common therapies for home infusion, such as vancomycin, cefazolin, ceftriaxone, ertapenem, [and] micafungin,” said Binh Ngo, PharmD, pharmacy manager at University of California San Diego Pharmacy Infusion Services. “Other therapies that are often provided in the home are total parenteral nutrition, inotrope for CHF, chemotherapy, hydration, and factor replacement for hemophilia.”

Although very few retail pharmacies currently offer infusion therapy, Sullivan said it’s possible for a retail pharmacy to expand and diversify into home infusion if they understand the care model and the facility requirements for the sterile compounding component.

“We are creating a hospital level environment in a home setting for those patients [who] want to or need to continue their IV treatments after they are discharged from the hospital,” said Sullivan.

A home infusion center setup requires an office area for staff and patient care management, as well as sufficient space for equipment and inventory. Some centers have an on-site, ambulatory infusion suite for specialty infusion therapy. An essential requirement of any home infusion center is a sterile compounding facility.

“A sterile compounding facility that is compliant with USP 797 and 800 is a must for home infusion services,” said Ngo. “There must be training and competencies on aseptic technique, process validation for the pharmacists and technicians, hand hygiene, and garbing. Equipment for sterile compounding such as automated compounding devices will be needed for TPN and compounding.”

A home infusion center generally
dispenses a 7-to-14 day supply of compounded sterile medication to the patient with laboratory tests typically done at least weekly. Pharmacists need to coordinate the blood draw and track laboratory test results before the next shipment is due, so the results can be reviewed before the drug is shipped out. This can be challenging if a patient does not keep appointments.

“Certain drugs require more clinical oversight, such as those that require PK monitoring, TPN, inotrope, or chemotherapy,” said Ngo.

Environmental monitoring of the sterile room is mandatory, including temperature and humidity monitoring. The room needs to receive clean room certification every 6 months. The frequency of end-product testing may differ from state to state, depending on what the board of pharmacy requires.

Not only should staff be knowledgeable about how to use home infusion equipment, but the office will require a staff member who knows how to bill such services since insurance considerations can differ from those encountered by a retail pharmacy. Infusion pharmacies must comply with licensing and other regulatory requirements imposed by state pharmacy boards, as well as accreditation standards required by third-party payers.

Some pharmacists, such as McFerrin, opt to franchise their home infusion center, because the company provides contracts and deals with billing.

“They provide a lot of clinical support and billing support, but mainly it’s the access,” said McFerrin. “If I don’t have access to insurance contracts or products, it’s very difficult for me to be successful.”

Staffing requirements at infusion centers differ from those of a retail pharmacy. An infusion center requires a team of health care professionals that is likely to include a pharmacist who is well-rounded in managing various disease states and therapies; a care transition nurse; an infusion nurse; and, for patients receiving clinical nutrition, a dietitian.

“The home-infusion practice is a multidisciplinary practice and requires someone [who] is team oriented and enjoys speaking to internal and external customers,” said Ngo. “The pharmacist would be working with an RN [registered nurse], RD [registered dietitian], intake [department representative], billing [department representative], pharmacy technicians, [and] physicians. There is quite a bit of coordination of care that takes place when a patient is on board to be discharged. Once a referral is confirmed for the start of care, the intake specialist will inform the pharmacist. Nursing may be staffed by your own nurses, or it can be outsourced to a home health agency, depending on the insurance and whether there are other needs required, such as PT [physical therapy], OT [occupational therapy], ST [speech therapy], or wound care.”

At a home infusion center, the pharmacist reviews and processes the order, including infusion supplies, then consults with the patient and arranges a delivery time. As part of the consultation, the pharmacist determines how the drug is going to be administered—IV push, elastomeric device, gravity, or mechanical pump—and assesses whether the patient or caregiver is able to learn to self-administer, the type of IV access, and home environment before deciding on the setup.

The nurse or home health agency should be informed when the medication and supplies will be delivered, as well as when the first set of laboratory tests should be done.

“The pharmacist speaks with the patient periodically to assess [adverse] effects of the medication and to make recommendations for changing the therapy, should a patient need the change,” said Sullivan. “If the patient is not responding or developing some sort of adverse effect, that needs to be assessed.”

One important consideration before starting any home infusion center is that it will not be a Monday to Friday workweek.

“It’s a very demanding profession in the sense that when a patient needs a drug, they need a drug, and you need to do what’s required to make sure the patient doesn’t miss a dose, so there’s no interruption in therapy,” said Sullivan.

McFerrin agrees that the schedule can be demanding; however, he enjoys visiting patients at home and getting to know them. Interacting with patients was what he liked most about his previous retail pharmacy job, but offering infusion services provides new challenges and a chance to deliver an essential service to his community.

“You’re basically on call 24/7, 365 days a year. That’s the biggest word of caution I would offer to someone considering this. But at the same time, the biggest reward I get is seeing sick people get better.

RYAN MCFERRIN, PHARMD AND CO-OWNER OF DRUID CITY VITAL CARE, NORTHPORT, ALABAMA

You’re basically on call 24/7, 365 days a year, that’s the biggest word of caution I would offer to someone considering this. But at the same time, the biggest reward I get is seeing sick people get better.
Health System Pharmacy Collaboration

What does it mean for patients?

Health system pharmacies collaborate with a variety of groups and other health professionals, depending on the topic or area with which they want input and collaboration. For patient care, they collaborate with other health professionals (ie physicians, physician extenders, nurses, case managers, social workers, laboratory and radiology technicians, or other pharmacists). They will also review current literature and reference articles—and may even contact the drug manufacturer—when determining the appropriateness of drug therapy for a patient’s condition.

Pharmacies collaborate with professional associations, regulatory agencies, drug wholesalers, and peers when they are seeking information related to regulatory requirements, best practices, and drug shortages. Pharmacies will also seek out consultants and other subject matter experts to do the best job possible. Although pharmacists are known as the drug experts, they aren’t afraid to seek out others for guidance and to make sure they are following the appropriate rules and guidelines.

“While medications are based in science, there is also patient variability, so collaborating is important when a patient does not fit the standard indications for a drug therapy or is experiencing a side effect,” said Barbara Giacomelli, PharmD, FASHP, vice president, advisory services for McKesson RxO. “Pharmacy as a profession is highly regulated, and like other aspects of health care, changing rapidly, whether related to medication therapy advancement, insurance coverage, technology advancement, drug shortages, or new regulations.”

Cathy Kuhn, PharmD, director of strategy consulting at Updox and the APhA-APPM president and board trustee with the American Pharmacists Association, said it’s also important for health-system pharmacies to collaborate with pharmacies outside of the health system, which may include a patient’s community pharmacy. “Collaboration is critical to ensuring patient safety and optimal clinical outcomes, ultimately enhancing high-value care,” she said. “When pharmacists and prescribers work together as one cohesive unit, they can effectively impact health care by minimizing prescription confusion, reducing health care costs, and transforming the patient experience.”

Charles Lee, MD, senior director of clinical knowledge for First Databank, a provider of integrated drug and medical device databases that supports health care professionals, said the health system pharmacist is in a unique position as the coordinator of the team’s medication therapy plan and education for the patient. “In many organizations, the health system pharmacist has been evolving from just dispensing medications into being a member of a coordinated clinical care team in collaboration with prescribers, nurses, caregivers, and other pharmacists,” he said. “They often make clinical rounds with other team members. They participate in developing medication therapy plans, dispensing [including compounding] [medications], monitoring patients’ responses to treatments, and providing patient education.”

Effect on Patients

These collaborations all come back to patient safety. Kuhn noted that, although providers are tasked with consulting patients, diagnosing illnesses, and prescribing medication, pharmacists work every day to ensure patients are properly taking their medications as prescribed and avoiding any harmful effects—acting as a vital component in the patient care cycle. “And since patients expect the care they receive to be seamless, both parties must communicate and collaborate accordingly to ensure patient needs are being met, thus resulting in improved health outcomes,” she said.

Giacomelli noted that advances in medication therapies mean disease states that were once difficult to manage now have drugs that can benefit patients, but these therapies tend to be higher in cost and out-of-pocket expenses for patients. “Drug shortages also are a challenge for patients, and pharmacists collaborate to determine best alternative therapies so patient care isn’t compromised,” she said. “The patient comes first, and pharmacists collaborate to make sure they receive the best care possible.”

Quality patient care requires health care professionals to work as a team. With the complexities of medical care, PBMs, drug shortages, new therapies versus traditional therapies, etc, it is important for pharmacists to collaborate with the entire health care team. “As drug treatment becomes more personalized—such as genomic treatments—therapy team models with health system pharmacists in a central coordinator role will becoming increasingly more important to improve cost efficiencies and to optimize medication therapy outcomes among the health systems population,” Lee said.
The Apothecary Shoppe: An Inner-City Success Story

The Salt Lake City, Utah, metropolitan area is home to nearly 1.25 million people. The Apothecary Shoppe, a community pharmacy, is located in the densely populated northeastern section of the city. It is not far from the famous Salt Lake Temple of the Church of Jesus Christ of Latter-Day Saints, the state Capitol, and the campus of the University of Utah. The area is home to students, well-to-do business owners and professionals, and a large percentage of the city’s population of individuals experiencing poverty, chronic illness, and homelessness.

The pharmacy itself is housed in the Salt Lake Regional Medical Center. Kevin DeMass, RPh, is the owner and leader of a talented team of professionals that encounters a wide variety of patients, ailments, and medications. DeMass is a pleasant, outgoing, and charismatic individual who accepts the challenges of running an inner-city pharmacy with a big smile and the tenacity to find ways to provide patients with the medications they need while still generating the revenue necessary to stay open.

For example, due to its location and the public-service mission of the hospital, The Apothecary Shoppe treats many patients with mental and behavioral health conditions, as well as social, emotional, and economic challenges. To help care for these patients, DeMass was part of a team of health care professionals, social workers, and religious leaders that established the Valley Mental Health Clinic 20 years ago. The clinic provided professional services to patients, and then as part of their treatment, health care providers wrote prescriptions for the patients. The Apothecary Shoppe filled the prescriptions and kept in close contact with the providers, while working diligently to counsel, coach, and help patients stay on therapy. This process led The Apothecary Shoppe to become an early adopter of compliance packaging. Unfortunately, a few years ago the clinic established a 340B program and DeMass no longer services the clinic.

When DeMass attended a medical symposium sponsored by the Utah Pharmacy Association, he heard a pharmacist talking about the benefits of naloxone in preventing deaths from the misuse of opioids. The idea that such a simple treatment could save so many lives captured his attention. After the presentation, he struck up a relationship with the presenter and agreed to participate in an effort to obtain grants to purchase naloxone kits. According to DeMass, he has dispensed nearly 1000 kits to patients or their caregivers. While the kits are paid for by a grant, DeMass said each kit is dispensed with a 20-to-30 minute private training session. As part of the program, he donates his time to foster care program. This even includes providing all the necessary documentation the families may need.

The pharmacy is supported by a variety of technologies, including an Rx 30 pharmacy system that interacts with a VoIP telephone/IVR system, an AutoMed robot, and an EyeCon & Kirby Lester pill counter. DeMass uses The Digital Pharmacist to support his website and mobile app and improves patient compliance by using several PrescribeWellness patient care modules.

With its wide variety of services and capabilities, The Apothecary Shoppe is able to cater to the needs of the community while still maintaining a successful business model.
Preparing Pharmacies for Performance-Based Reimbursement

In 2019, pharmacies experienced increased downward pressure on reimbursement rates as narrow networks continued to form and grow in relevance. However, in 2020 we expect the industry to continue moving toward value-based care and performance-based payment models.

**Performance-based opportunities increasing**

Although pharmacies would like to live in a world without direct and indirect remuneration (DIR) fees, that will not happen in 2020. In fact, the amount of DIR fees collected will likely continue to grow on average next year. This requires pharmacies to actively understand their contracts, manage their cash flow, and focus on lowering their DIR fees by improving clinical services that impact performance by optimizing outcomes. Now more than ever, community pharmacies need a pharmacy services administrative organization (PSAO) partner that can leverage scale, and influence in-contract negotiations with pharmacy benefit managers (PBMs) and other third-party payers.

This year, Health Mart Atlas is partnering with a large national payer to evaluate its 2 chain codes separately. This means pharmacies who illustrate top performance will be evaluated separately, better positioning the high-performing pharmacies for increased rebates.

**alternative reimbursement plans**

The health care industry is beginning to see a spectrum of new payment methods ranging from traditional fee for service to shared savings and risk-bearing models based on patient outcomes. However, if DIR fees dissolve, it is critical that the plans and the networks are structured to incentivize the top performing pharmacies and ensure they are still being reimbursed based on driving better patient outcomes.

**Industry consolidation: challenges and opportunities**

Two recent megadeals—CVS Health’s acquisition of Aetna and Cigna’s agreement to buy Express Scripts—both closed in 2019. These deals could generate a hypercompetitive marketplace for PBMs, PSAOs, and for pharmacies, in general. As these vertical integrations, strategic alliances, and partnerships continue to form across the industry, there is also an opportunity to create new ways of delivering and paying for care. For pharmacies, it’s all about accessing new pharmacies from an access perspective, but it might also be an opportunity. A PSAO can be an important partner for community pharmacies to help minimize their DIR fees and maximize reimbursement to succeed in this new model. It is critical to be part of a top-performing pharmacy network that is invited to the negotiation table and is aligned with the payers that recognize the value of pharmacy. The right PSAO will partner with payers willing to incentivize pharmacies through contracts or through pay-for-performance opportunities.

**Building transparency into performance**

Health Mart Atlas is working with industry organizations like NCPA and NACDS, which are focusing their efforts on driving transparency, as well as expanding non-DIR performance-based bonus and activity fee opportunities. If DIR fees continue, pharmacies need more transparency and standardization in how they’re being measured. There is an opportunity for the Centers for Medicare & Medicaid Services (CMS) to help drive guidance around how these fees are implemented. If DIR fees fade away, CMS can help ensure that true performance-based payment models are in place so that top performing pharmacies continue to benefit from better reimbursement due to their hard work.

Fortunately, health experts see more reimbursement tied to performance, and most Medicare Part D claims now have some type of performance-related payments. This is expected to continue in 2020 and beyond, meaning that community pharmacies must prepare for value-based care. Not only is it the right thing for patients, but it is also critical for community pharmacies to maintain their financial success.

This article was originally published by Managed HealthCare Executive.

Eyad Farah is vice president and general manager of Health Mart Atlas.
On December 20, 2019, the FDA approved lumateperone tosylate (Caplyta™, Intra-Cellular Therapies) for treatment of schizophrenia in adult patients. Lumateperone is an atypical antipsychotic. The exact mechanism of action is unknown. However, lumateperone demonstrates binding affinity and antagonistic activity at central serotonin 5-HT2A receptors and postsynaptic central dopamine D2 receptors.

**Efficacy**

The efficacy of lumateperone was studied in 2 randomized, double-blind placebo-controlled multicenter trials (study 1 and study 2). The primary efficacy measure in both studies is the Positive and Negative Syndrome Scale (PANSS) total score. This scale scores patients’ symptoms associated with schizophrenia on a scale of 1 (absent) to 7 (severe).

In study 1, a total of 335 patients participated, with an age range of 20 to 55 years old. All participants met diagnosis criteria of schizophrenia, according to the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV). Patients were randomized to receive lumateperone 42 mg, lumateperone 84 mg (double the recommended dose), an active comparator, or a placebo. Compared with the placebo group, participants randomly assigned lumateperone 42 mg demonstrated a statistically significant reduction from baseline to day 28 in the PANSS total score, compared with participants who were administered the placebo.

Participants administered lumateperone 84 mg did not demonstrate a statistically significant difference in PANSS total score compared with those taking the placebo. A total of 450 participants, ranging from 19 to 60 years old, are included in study 2. All participants met diagnosis criteria of schizophrenia, according to the DSM-IV. Participants were randomized to receive lumateperone 28 mg, lumateperone 42 mg, or a placebo. Participants randomized to lumateperone 42 mg demonstrated a statistically significant reduction from baseline to day 28 in total PANSS score, compared with participants administered the placebo. The group receiving treatment with lumateperone 28 mg was not statistically significant compared with those receiving the placebo.

**Safety**

In studies, the most common adverse reactions occurring with greater frequency than placebo are: somnolence/sedation (24%), nausea (9%), dry mouth (6%), dizziness (5%), an increase in creatinine phosphokinase (4%), fatigue (3%), vomiting (3%), decreased appetite (2%), and an increase in hepatic transaminases (2%). In studies, extrapyramidal symptoms occurred at rates of 6.7% for lumateperone and 6.3% for placebo. Metabolic changes, such as hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain, have been associated with antipsychotic drugs. A patient’s fasting plasma glucose, weight, and fasting lipid profile should be monitored before or soon after starting therapy and throughout treatment. Leukopenia, neutropenia, and agranulocytosis have been associated with antipsychotic medications. Patients demonstrating clinically significant neutropenia must be monitored for signs of infection. Discontinue lumateperone in patients with an absolute neutrophil count <1000/mm3 and monitor the patient’s white blood cell count until recovery. Patients with hypotension, with cardiovascular disease, or with cerebrovascular disease should be monitored for orthostatic hypotension.

The use of lumateperone is not recommended in patients with moderate (Child-Pugh class B) to severe hepatic impairment (Child-Pugh class C). No dose adjustment is recommended in patients with mild hepatic impairment (Child-Pugh A). Concomitant use of lumateperone with a moderate or strong CYP3A4 inhibitor or a UGT inhibitor increases lumateperone exposure, which may increase the risk of adverse effects. Concomitant use of lumateperone with a CYP3A4 inducer should be avoided.

**Dosage**

In adult patients with schizophrenia, lumateperone should be administered 42 mg orally once daily. Lumateperone does not require any dose titration. Lumateperone should be given with food. Lumateperone is available only in 42-mg strength capsules.

**References**

How to Attract Millennial Customers

Pharmacists weigh in on how to bring this generation to the pharmacy

Millennials are often classified as being born between 1981 and 1996, which means the older end of the cohort are nearing 40 years old and are more likely to be regular visitors to a pharmacy. But even those on the younger end of the generational range still have plenty of reasons for coming in, which is why pharmacists should find ways to attract millennials of all ages to their locations.

Aaron Gilbert, PharmD, a pharmacist in Louisville, Kentucky, said millennials live “in the now,” so you have to sell to them “in the now.” Gilbert said, “These customers have 1 primary shopping platform: their cell phone. The era of waiting in lines and dealing with [salespeople] is over. It’s archaic, and to most millennials, undesirable. In almost every industry you can see the shift from traditional, retail experiences to digital, convenient experiences. Pharmacy is no different and must evolve along with the rest of the American market.”

That means providing patients with a robust digital solution and using digital marketing strategies to keep your brand top of mind. “Millennials don’t leave their doctor’s office with a prescription and walk into their neighborhood pharmacy...they Google” to find a pharmacy where they can fill their prescription, Gilbert said. “Millennials learn about brands through AdWords [Google Ads], shopping, display, social, and more.”

The millennial generation is also more likely to become loyal to brands through Facebook, Instagram, blogs, and podcasts. “The millennial consumer is also a very intelligent consumer, with a world of knowledge at their fingertips, so online reputation and social proofing are critical in the acquisition funnel,” Gilbert said.

Shelley Roberts, PharmD, owner of Grassroots Pharmacy in Lexington, Kentucky, said millennial customers appear to care a lot more about the experience than simply the products pharmacies carry. “We focus on a welcoming environment that is clean and inviting, with interesting displays and decor,” she said. “Social media is also a big focus for us. Many times, a customer will get to know us on social media before ever coming into the store. They come in for the first time and say, ‘I feel like I already know you!’ from watching my videos online.”

Roberts added that this is a population that pharmacies can still make an impression on. “They are not only here for prescriptions, they have an interest in alternative therapies and supplements as well,” she said. “They are an age group [for which] we can truly change health care outcomes by catching them earlier in life. While they may not have a lot of prescriptions themselves right now, they will have aging parents that we could help in the long term.”

THE POWER OF DIGITAL

With access to information more available than ever, consumers have more ways to research and educate themselves before they buy. In fact, 23% of millennials say they like to research before they buy something. Approximately 80% of millennials use their phones to research prices, whereas 68.9% use their phones to read reviews. That’s why it’s important to encourage customers to post reviews on Yelp and other sites.

Of course, no matter how much millennials value online resources, face-to-face medical consultation remains irreplaceable, which is why there’s still an important need to speak with the licensed technicians and pharmacists who oversee and help manage a patient’s prescription needs. Ross Goetz, PharmD, a pharmacist in Cincinnati, Ohio, said pharmacists must still offer the level of compassionate care that all patients deserve. This can come in digital forms, such as HIPAA compliant live chat, app messaging, push notifications, and SMS.

“Pharmacies were built on high traffic roads to meet the needs of patients. Millennials still drive those roads, but they also navigate and explore the internet, and if you want to attract them then you need to have your store on the digital highway,” he said. “A digital solution isn’t exclusive to millennials though. All patients, regardless of [their] generation, can benefit from having more options in their health care experience. With options, they can use the solution...”
that best meets their needs.”

Alex Evans, PharmD, founder of Pharmacy Compliance Specialists, LLC, in Jacksonville, Florida, said pharmacists must maximize the use of their software systems in the store. Creating apps for the pharmacy is another important step. Some important questions to ask about pharmacy technology: Do you have an app to order refills? Do you have a website to not only order, but check your available medications? Do you have text or call alerts when the medications are ready? Do you accept Apple Pay and similar payment systems?

CONVENIENCE IS IMPORTANT

Many millennials are accustomed to making online purchases on their computers and smartphones, so convenience is key for attracting this generation of shoppers. Evans explained that a pharmacy looking to boost its business should offer home delivery or mail order options to cater to their needs. “You’re going to need to do this to attract a generation accustomed to 1-click ordering on Amazon,” he said. “Mail order might be regulated by state law, but most states should at least allow home delivery. This is a great way to attract millennials and baby boomers at the same time.”

A pharmacy is more than just the prescriptions it fills, which is why pharmacy owners should think about what else is in the store and carry the front-end items that millennials are looking for. “Get feedback from customers, such as what cosmetic brands they like or food products they want to buy,” Evans said. “This is a great time to target the so-called LOHAS [Lifestyle Of Health And Sustainability] market, focused on healthy living and sustainability, that is so popular with this generation. Offering organic, non-GMO, vegan, etc, products, and a wide array of nutraceuticals, will give you a boost to your front-end sales and keep this generation of customers.”

Other convenient services at the pharmacy include compliance packaging, which generally comes at the request of the children of aging parents, and extended days supplies at discount pricing for reducing trips to the pharmacy.

Hussein El Khatib, PharmD, with Toledo Family Pharmacy in Ohio, said to attract the “cyber” generation, pharmacies need to offer delivery services, as well as programs like medication synchronization and compliance packaging in any sort of form, especially blister pouch packaging that is becoming more common with stores preferring automation in single and multi-dose packaging. “I think offering products like that, coupled with accepting coupons and programs that save the patient money, is key in all of this,” he said. “Never forget, superb customer service is a must.”

DON’T DISMISS CONCERNS

Getting on the bad side of a customer will usually mean they are going to go somewhere else. Goetz noted that ignoring their concerns or dismissing a problem is a sure way to lose business. “If someone has a problem, deal with it, and don’t make excuses or place blame, even if the customer is wrong,” he said. “You should immediately fix the issue.”

THINK GREEN

Keeping sustainability practices in mind will not only boost your millennial customer base, but also can potentially reduce a pharmacy’s operating costs. A store that offers reusable bags rather than plastic or doesn’t print out pages of receipts will be appreciated by those thinking green. “If you can demonstrate you are helping the environment, you will draw them in and possibly reduce your costs,” Evans said.

Retailers can also demonstrate their interest in making a difference by partnering with organizations or other brands that are known for their social consciences. Many places work with brands to help drive charitable donations, environmental awareness, and community impact in authentic ways.
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