Dementia & Alzheimer's
WHAT YOU NEED TO KNOW

IN MY VIEW > DeAnn Mullins, PharmD
You either shrink from challenges or work to overcome them.

NEW DRUG REVIEW
OXYCODONE/NALTREXONE
Extended release for severe pain

LIPID MANAGEMENT
NEW OPTIONS WHEN STATINS ARE NOT ENOUGH

UPFRONT
Why Consumers Trust Pharmacists

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CARDIAC MATTERS
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IN MY VIEW
Hey, can I help you?

JOSEPH CRUZ, PharmD

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LISA HOLLE, PharmD

NEW DRUG REVIEW
Oxycodone/naltrexone ER
Chains step up efforts against drug abuse

KATHLEEN GANNON LONGO

As 2016 drew to a close, Walgreens stepped up its efforts to combat drug abuse in the community. The national pharmacy chain announced late in December that it had expanded the availability of naloxone, without a prescription, to Mississippi, Missouri, and Washington, D.C. According to Walgreens, this brings the total to 33 states, plus the District of Columbia, where the livesaving opioid antagonist can be dispensed without a prescription. Naloxone can now be furnished without a prescription in about 5,800 Walgreens pharmacies nationwide, said Walgreens in a written release.

CVS Health has also stepped up its efforts to “prevent and address prescription drug abuse in the communities we serve.” With efforts recently expanded to Nevada, “naloxone is available without a prescription at CVS pharmacy locations in 37 states,” a CVS spokesperson told Drug Topics.

“By making naloxone available without a prescription, we are making it easier for families and caregivers to help their loved ones by having it on hand in case it’s needed,” said Rick Gates, BSPharm, Walgreens Group Vice President of Pharmacy.

“CVS Health has worked to increase access to naloxone, a safe and effective antidote to opioid overdose, because we believe that by expanding the availability of this medication, we can save more lives and give people a chance to get the help they need for recovery,” said the CVS spokesperson.

The chains’ expansion of their naloxone programs comes on the heels of a meeting in early December between NACDS and the Department of Health and Human Services where naloxone was discussed. According to National Association of Chain Drug Stores spokesman Chris Krese, the chain pharmacy organization

FOR MORE ABOUT PREVENTING OPIOID ABUSE.

CONTINUED ON PAGE 31
How you can help prevent opioid abuse

CHRISTINE BLANK

Pharmacists are on the front lines of helping to curb abuse and misuse in the opioid epidemic, according to two pharmacy educators who believe better communication with other health care providers and patients is one of the keys to success.

Dan Hartung, MPH, Associate Professor at Oregon State University’s College of Pharmacy, and Nicole O’Kane, PharmD, Clinical Director for HealthInsight Oregon, shared techniques pharmacists can use to help prevent opioid abuse during a recent Pharmacy Quality Alliance webinar.

And pharmacists’ intervention is certainly needed, since 250 million opioid prescriptions were dispensed in 2013 and opioids comprise two-thirds of all drug-related poisonings. The CDC and the FDA issued new guidelines for prescribing opioids in 2016, after injuries and deaths from opioids jumped in 2014. There was a 14% increase in opioid-related deaths in 2014 to 29,467.

Recognizing the need for pharmacist involvement, the Agency for Healthcare Research and Quality gave on the pharmacist. Because pharmacists are on the frontlines, we advocate for expanded roles for pharmacists to advocate for safer use of opioids,” Hartung said.

As they develop the curriculum and toolkit, the researchers have held several focus groups with patients, pharmacists, and prescribers around the state.

“Pharmacists really perceive that their role in monitoring safe prescriptions should extend to opioids. They also felt their role should be to identify patients at high risk of opioid misuse who would benefit from early interventions and to act as a member of the care team, with opportunities to collaborate with prescribers,” Hartung said.

But pharmacists also expressed significant concerns about the challenges of querying patients about opioid scripts and working with other health care providers on this massive problem.

“I view my role as being highly responsible for abuse/misuse, but with very little resources/strategies to make this determination,” one pharmacist said during focus groups.

O’Kane shared several ways pharmacists can better communicate with other providers and patients when they have concerns. In focus groups, many pharmacists said they “didn’t want to be the bad guy or they were uncomfortable” talking about potential opioid abuse with patients.

“Make sure you are coming from a place of caring,” O’Kane said. “Before contacting their prescriber [after seeing a potential problem on the PDMP], inform the patient that you are concerned about his safety, first and foremost, and that you have concerns. Use nonjudgmental, supportive language.”

Ask patients open-ended questions and communicate about what is being done on their behalf, O’Kane suggested. “Inform them about the PDMP and why it’s being used as a safety tool for them. When approached from a...”

WAYS THAT PHARMACISTS CAN HELP PREVENT OPIOID ABUSE

1. Review patients’ opioid scripts thoroughly. Check their concurrent use of opioids with other medications as well as dosages.

2. Use the PDMP to confirm history of scheduled medications.

3. Practice effective communication with providers.

4. Prescribe and dispense naloxone.

5. Support safe medication disposal systems.

SAFETY TRIGGERS CHECKLIST

1. The opioid dose seems inappropriate
2. When it’s a new patient not previously taking opioids
3. When the opioid dose is significantly increased in patients taking these medications long-term
4. When a combination of medications poses a safety concern (eg opioids, with benzodiazepines and/or muscle relaxants)
5. Filling opioid prescriptions too frequently
6. When the combination of medications does not make therapeutic sense
7. When patients are seeing multiple prescribers and/or pharmacies

(continued on page 28)
Get ready for the new USP hazardous medications standards

VALERIE DEBENEDETTE

In February 2016, the U.S. Pharmacopeial Convention published Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, which sets standards for handling these drugs. Although those standards will not be implemented until July 1, 2018, the countdown is on — and health-system pharmacists and others who deal with hazardous drugs need to start getting ready now, if they have not started already.

The standards will be enforceable by the FDA, state pharmacy boards, and the Joint Commission. This makes understanding what they entail of vital importance to pharmacists and anyone who uses these drugs.

A symposium about ensuring readiness for USP Chapter <800> was held at the 51st Midyear Clinical Meeting and Exhibition of the American Society of Health-System Pharmacists in Las Vegas. A poll of those in attendance or listening to the symposium via webinar found that 12% said that their organization was already in full compliance with Chapter <800> standards. However, 20% clicked yes to “We are in trouble.”

Chapter <800> applies to all health care personnel who handle hazardous drugs and all entities that store, prepare, transport, or administer these drugs, with no exceptions based on size or type of facility or on the amount of drugs used, said Martha Polovich, PhD, RN, Director of the PhD Program at Byrdine F. Lewis School of Nursing and Health Professions Georgia State University in Atlanta. There is a three-fold purpose to the standards: patient safety, worker safety, and environmental safety, she noted. Environmental safety refers to safety within the workplace. “There is plenty of time to be in compliance, but it is not too early to start,” she said.

The first step in compliance is to compile a list of hazardous drugs being used or stored, which will determine which parts of Chapter <800> apply, Polovich said. The second step is to create an interdisciplinary team because the effort must be organization-wide since it runs from pharmacy practice to nursing and every part of an organization where hazardous drugs might be handled or used, she added.

The National Institute of Occupational Safety and Health (NIOSH) created a list of hazardous drugs in 2014 and categorized them into three groups. (See box) said Ryan A. Forrey, PharmD, MS, FASHP, Director of Pharmaceutical Services at Emory University Hospital Midtown in Atlanta. The three groups are antineoplastic drugs, all of which have reproductive hazards; non-antineoplastic drugs, some of which have reproductive hazards; and drugs that have reproductive hazards only, he said. These groupings do not indicate a level of risk, he added.

Each organization or entity needs to create an assessment of risk based on which hazardous drugs they handle, Forrey said. “Anyone who would come in contact with a hazardous drug has to be involved in the assessment of risk process.” He noted that a hazardous drug in tablet form might not pose much risk, but if a nurse crushes the tablet to put in applesauce for a patient, there is a greater risk. If the patient then vomits after receiving the drug, there is a risk to the personnel who clean the mess up.

Engineering controls must meet the Chapter <800> standards, Forrey said. There are several types of primary and secondary engineering controls that may be required based on the hazardous drugs used in a facility. A primary control is a device such as a biological safety cabinet that minimizes worker exposure to a hazardous drug, he explained. A secondary control is the room in which the primary is placed, one that might need negative air pressure and several changes of air per hour.

These types of safety equipment, along with personal protective equipment, are intended to protect nurses and other employees, said Polovich. Training must be done across the organization. Forrey added that the nursing staff needs to understand what the risks are and why the protective equipment needs to be used consistently and correctly.

In each facility or entity, someone must be assigned to oversee compliance, training, and review certifications for Chapter <800>, said Jeannell Mansur, PharmD, FASHP, FSMSO, "HAZARDOUS CONTINUED ON PAGE 31"
Pharmacists were rated as one of the most trusted professionals in the United States again in 2016. For the second year, pharmacists were rated second only to nurses in Gallup’s annual survey about the professions that Americans deem the most honest and that maintain the highest ethical standards.

The rating that pharmacists earned in this annual Gallup survey is built on established pharmacist-patient relationships in neighborhoods throughout the nation, said Steven C. Anderson, President and CEO of the National Association of Chain Drug Stores (NACDS). “The takeaway for policymakers is that the pharmacist-patient relationship has tremendous potential to do even more to improve patient health and well-being, along with the overall quality and affordability of health care, Anderson said.”

In a November survey of likely voters who are highly aware and engaged in current events – commissioned by NACDS and conducted by Public Opinion Strategies – pharmacies also achieved a 63% favorability rating. Respondents gave their own pharmacy a 75% favorability rating and their own pharmacist a 77% favorability rating. “Those who are more frequent users of pharmacist-provided services rate pharmacies and pharmacists even more highly,” Anderson said.

“The Gallup survey and NACDS’ own research – as well as a host of other sources – validate the NACDS members’ role as the face of neighborhood health care,” Anderson said.

Pharmacists’ high rating is due to the fact that they are “clinically trained medication experts who can answer patients’ questions and offer advice about their medications,” said B. Douglas Hoey, RPh, CEO of the National Community Pharmacists Association (NCPA).

Pharmacists are also known for their accessibility to patients, “who can go down to their local pharmacy to get their prescription drug services at a moment’s notice,” Hoey said. “The wait pales in comparison to the wait many patients experience in a doctor’s office after scheduling appointments.”

The level of trust consumers have with pharmacists can only grow as pharmacists continue to adapt to the changing nature of health care delivery, according to Hoey. “That includes more coordinated care with other health care providers that drive better health outcomes and also involves offering niche health services that patients come to rely upon like immunizations, transitions to care, health screens, diabetes education classes, etc.,” Hoey said. “With the doctor shortage in America projected to grow over the next decade, it is pharmacists who can help fill the gap.”

Plus, pharmacists are perfectly positioned to drive greater medication adherence through services such as medication synchronization programs like Simplify My Meds and medication therapy management, according to Hoey. In fact, a study conducted by Langer Associated on behalf of NCPA found that a patients’ personal connection with a pharmacist or pharmacy staff is the biggest predictor of medication adherence.

“It is time for payers and policymakers to better utilize the accessibility, expertise and public trust in pharmacists. NCPA will carry that message into 2017 as health care reform efforts accelerate and the shift toward a value-based care system continues,” Hoey said.

In 2017, NACDS will advocate for improving patient access to pharmacists’ services by designating pharmacists as providers in Medicare, optimizing patient care through enhanced scope of practice for pharmacists and pharmacy technicians, and working for reasonable reimbursement levels and other policies that are essential for the viability of pharmacy patient care, according to Anderson.

Anderson also noted the importance of keeping pharmacy top-of-mind amid efforts to alter or repeal the Affordable Care Act. “As the incoming Administration and Congress consider potential changes to the Medicare and Medicaid programs, we ask that you ensure that beneficiary access to pharmacies is protected. Policies that reduce local pharmacy access lead to poorer health outcomes, ultimately resulting in increased future health care costs,” NACDS, NCPA and other pharmacy groups wrote in a recent letter to President-Elect Donald Trump and Congressional leaders. 

Christine Blank is a Contributing Editor.
CHRISTINE BLANK

Two organizations opposed to tobacco sales at pharmacy chains are turning their attention to the Walgreens annual shareholder meeting scheduled for late January.

Starting January 6, Truth Initiative and DoSomething.org are asking young people to sign a petition telling Walgreens that tobacco doesn’t belong on its shelves. “The Walgreens Board of Directors went to great lengths – twice – to block a vote from their agenda that would have been a step toward taking tobacco off Walgreens’ shelves,” Truth Initiative said in a statement provided to Drug Topics.

Walgreens is under other pressure on this issue. Shareholders of Walgreens Boots Alliance and members of the Interfaith Center on Corporate Responsibility also want Walgreens to discuss taking tobacco products off their shelves at the annual meeting.

However, the proposal “was not included in this year’s proxy,” Phil Caruso, a spokesperson for Walgreens, told Drug Topics. “We firmly believe that the most effective step retail pharmacies can take to help smokers quit is to address the root causes of smoking, which go far beyond the small percentage of smokers who access this product at pharmacies.”

Walgreens offers smokers a number of solutions to “help them change behavior and quit smoking,” Caruso said. “A year ago, we began offering telemedicine consultations for smoking cessation with board-certified physicians through our program with MDLive, and we also began a pilot program to offer personal, face-to-face smoking cessation consultations with nurse practitioners.”

WALGREENS CONTINUED ON PAGE 28

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*PharmCAP – Web-based solution for pharmacy regulatory and compliance management
The United States and other countries will continue to spend more on specialty medications, and less will be spent on brand-name drugs, according to a new forecast. In addition, spending on drugs in the U.S. will grow at a much slower rate, according to the Quintiles IMS Institute report, “Outlook for Global Medicines Through 2021: Balancing Cost and Value.”

1. **THE GROWTH RATE** for U.S. spending on medicines will decline by half, from **12% in 2015 to between 6% and 7% in 2017**. Plus, prescription drug spending is forecast to grow between **6% and 9% through 2021**, the report found. “The decline reflects the end of hepatitis C treatment-driven growth and greater impact of patent expiries—including the introduction of biosimilars—following a period in which fewer brands faced new generic competition,” said QuintilesIMSInstitute in a press statement. Plus, U.S. growth in 2014 and 2015 was driven by historically high price increases for both brand drugs and generics.

2. **U.S. BRAND DRUG PRICES** will increase at a slower rate, due both to competition from generics and Congressional backlash over soaring brand prices. “Brand prices will increase at 8% to 11% — more slowly than the 12% to 15% in the past three years, and with fewer outlier major price increases, as these have become unsustainable in light of high-profile media and political attention.”

3. **SPECIALTY MEDICINES** will lift the share of global healthcare spending from **30% in 2016 to 35% in 2021**, driven by the adoption of new breakthrough medicines. While specialty medicines will continue to increase in share in developed markets, and approach half of medicine spending in the U.S. and five major countries in the European Union, specialty drugs will continue with a lower share (between 5% and 20%) of total medicines spending.

4. **PATIENT OUT-OF-POCKET COSTS** are forecast to decline, despite rising brand prescription costs, as patients shift to newly available generics and receive co-pay assistance for brands, the report found. Notably, more than one-third of prescriptions will have no out-of-pocket costs. “Free prescriptions are a growing trend, as some patients receive preventive services under the Affordable Care Act, under expanded eligibility for Medicaid and through some insurance plans.”

5. **SEVERAL NEW THERAPIES** are moving through the registration process around the world and are expected to come to market soon. In the anti-infectives and antivirals category, new treatments for HIV, bacterial disease, anthrax, hepatitis C, and malaria will be launched. In the arthritis and pain category, there will be new drugs for osteoarthritis and migraine headaches. In the genito-urinary and hormones segment, there will be new launches for osteoporosis, hypogonadism, contraception, and infertility. In addition, breakthrough therapy designations for cancer treatments and shorter development cycles have led over a quarter of the entire late-stage drug pipeline to be focused on developing oncologics. “Therapies for CNS disorders follow, making up almost one-eighth of the total pipeline,” the report said.
Pharmacies within community mental health centers improve adherence

VALERIE D’BENEDETTE

Pharmacies that are integrated into community mental health clinics (CMHCs) improve patients’ adherence to medication regimens and reduce the rate of hospitalizations and emergency department (ED) visits compared to the use of community pharmacies. These reductions were associated with significant cost savings.1

A new study shows the adherence rate for patients who filled their prescriptions at integrated pharmacies was 96% vs 82% among those who used community pharmacies. The risk ratio for hospitalization was 0.88 and for ED visits was 0.95. This translates to savings of $57 per member month for behavioral hospitalizations and to an approximate savings of $226,084 from the reduction in rate of hospitalizations over the the study period.

The approximate savings from fewer ED visits for behavioral health issues was $1.23 per member month, or $4,900 over the course of the study. The use of pharmacies integrated into the CMHCs generated a total savings of $230,984 or approximately $700,000 per 1,000 patients annually.

“It really underscores the importance of the pharmacist on the interdisciplinary team and being able to provide an integrated solution to a big problem and a very complex group of individuals,” said Melissa Odorzynski, PharmD, MPH, Vice President for Marketing and Strategy at Genoa, a QoL Healthcare Company, in Egan, MN. She is a co-author of the study.

The goal of the study was to determine if there were benefits to having a pharmacy within a mental health center and, if so, what those benefits were. The researchers involved were with Care Management Technologies in Morrisville, NC, and Genoa. They retrospectively analyzed data from Medicaid claims paid by Southwest Michigan Behavioral Health for all inpatient and outpatient services and prescriptions filled between April 1, 2014 and April 30, 2015 at two CMHCs.

The study group was composed of an adult patient dataset representing people from one of the two centers who had filled at least two prescriptions at the in-house pharmacy during the study period. Each dataset was matched to a control group patient dataset that included patients who filled their prescriptions for the same medications at an outside pharmacy during that time.

Diagnoses included ADHD, anxiety, bipolar disorder, depression, and mood disorders. Medications included atypical antipsychotics, benzodiazepines, antidepressants, and mood stabilizers. Improved adherence to medications was seen not only for all medications, but also for specific classes of psychotropic drugs.

There were 496 patients in the study and 1,378 patient-medication matches were evaluated in the two groups. Adherence rates were based on comparisons of medication possession ratios (the total days’ supply divided by the number of days from the first fill date to the last). This ratio was calculated for each medication an individual patient was taking. Cost savings were calculated based on estimated costs for hospitalizations and ED visits, whether they were for behavioral issues or nonbehavioral issues.

Although a difference in the rates of medication adherence was expected, the significant differences in the rates of hospitalizations, ED visits, and costs were not expected, said Odorzynski. The baseline medication adherence rates were high for patients using either integrated pharmacies or community pharmacies, she noted. “That was a bit interesting and I think it is a testament to the services the community mental health center is providing.”

There are about 4,000 CMHCs in the United States dealing with mental health issues and addictions, Odorzynski said. Genoa has more than 330 pharmacies integrated into CMHCs around the country and is the largest national pharmacy provider to such centers. The company is opening pharmacies at CMHCs at a rate of one each week, she said. These pharmacies are full-service and can fill all prescriptions for patients at the clinics, but they are not open to the general public, she added. Pharmacists at the clinics work with the physicians and other health care providers, and offer counseling with the patients.

Having the pharmacy within the CMHC may have increased the adherence rates because patients do
Dementia & Alzheimer’s

The Growing Prevalence of Alzheimer’s Disease Could Suggest an Untapped Potential For Pharmacy

Jill Sederstrom

Community pharmacists can help patients with Alzheimer’s be more compliant, simplify drug regimens, and identify medications that cause additional confusion.

Many pharmacies across the country are searching for new ways to demonstrate their value as a health care partner in a way that is manageable and cost effective. One solution could be to focus on a population that’s growing rapidly: Patients with Alzheimer’s disease. By employing just a few resources and tapping into a pharmacist’s existing knowledge and skills, pharmacists can become the perfect partner in the battle against Alzheimer’s disease.

“Helping Alzheimer’s patients makes use of the compliance and adherence information that we’ve already learned...
for all of our patients. So this is a patient population that we can very easily serve with very few resources, just a little time, and we can really make a significant difference in their care and their outcomes,” says Lori Syed, PharmD, Director of Advanced Pharmacy Practice Experiences in the Department of Pharmacy Practice at Mercer University, in Atlanta, GA.

Community pharmacists can help by simplifying drug regimens, identifying medications that may be causing additional confusion, or using innovative packaging strategies, but their role doesn’t end there. Pharmacists can also aid in the identification of possible Alzheimer’s symptoms.

Across the country, a growing number of pharmacies are offering simple cognitive memory screenings as part of their regular counseling services.

Community pharmacies are also reaching out to form partnerships with local chapters of the Alzheimer’s Association or developing stronger relationships with the physicians who treat these patients to better serve this population.

**A Growing Problem**

As the baby boomers enter their golden years, the number of patients diagnosed with Alzheimer’s is on the rise. According to the Alzheimer’s Association, approximately 5.4 million Americans were living with Alzheimer’s disease in 2016. By 2050, the number of people over age 65 who have the disease is projected to be 13.8 million—nearly three times current levels if no significant clinical breakthroughs are made.

There will be a great need in the medical community to care for these patients. Many pharmacists in both community and clinic settings are already armed with the tools and skills necessary to be a valuable member of the healthcare team.

According to Syed, pharmacists already have the ability to speak two languages: They can have a simplified conversation with a layperson and a more technical, detailed, medical discussion with physicians and other healthcare providers.

This “bilingual” ability—combined with their accessibility, extensive drug knowledge and established trust with patients—positions pharmacists to be a powerful resource to both patients and physicians.

“We have that ability to liaison between patient and physician,” Syed says. “Often times patients may tell us things or we may elicit more information about how they are taking medications than they’ve shared with other caregivers. We may know that they are only taking their medication every other day because they really can’t afford it.”

**Identification of Memory Concerns**

Community pharmacists may also be among the first health care practitioners to notice early symptoms of Alzheimer’s disease in their regular patients.

Everyone is occasionally confused, particularly older adults who are often managing multiple medications. However, Syed says if pharmacists have tried giving patients tools to help manage their medications and confusion still persists it may be time for concern.

Geriatric neurologist Rita A. Shapiro, DO, FACP, FAAN, says pharmacists should look for changes in adherence, confusion at the cash register, a customer wearing clothing that doesn’t match the season, or trouble communicating as possible early signs of dementia.

“Many times dementia is uncovered when a person begins to fail functionally in their own life,” Shapiro says, who serves as a Clinical Associate Professor in the Department of Neurology and Rehabilitation at the University of Illinois College of Medicine at Chicago.

“Pharmacists will probably notice first that this person who used to be very reliable about refilling their meds has run out of one or is filling one and not the other.”

Syed recommends that pharmacists who are concerned either talk with the patient’s caregiver or contact the prescribing physician to discuss any changes in behavior or habits they’ve observed.

“In Alzheimer’s we don’t have a lot of medication choices for treating. The medications don’t cure at this point, they may just slow the on-going effects of disease. Because we’ve been there...
to recognize changes early, we have a chance of getting a patient on a medication sooner, “she says. “That’s a benefit to the patient.”

Shapiro, who has more than three decades of affiliation with VA care, says there’s a spectrum of opinions when it comes to whether medications should be used in all patients. She recommends adhering to guidelines such as those developed by the VA or the Alzheimer’s Association to guide prescriber decisions.

Medications may not be the best choice for everyone, particularly patients who are very frail or have other issues such as cardiac or GI contraindications with the patient and their family. At Acquaviva’s Pharmacy in Palm Bay, Florida, Carl Acquaviva, RPh, says

“it really became a full-on health event, but memory screenings were sort of the primary focus of what we were trying to do.”

According to the Alzheimer’s Association, there are currently 24 drug candidates for Alzheimer’s in phase 3 trials and many more potential drugs in earlier stages of development. Research is continually underway to explore new treatment options as well as drugs targeted at preventing the disease.

FACT BOX:

According to the Alzheimer’s Association, there are currently 24 drug candidates for Alzheimer’s in phase 3 trials and many more potential drugs in earlier stages of development. Research is continually underway to explore new treatment options as well as drugs targeted at preventing the disease.

SOME OF THE RESEARCH INCLUDES:

> The Phase 3 trial of the anti-amyloid antibody Aducanumab (Biogen): Earlier phase I studies of the drug found that those patients who took the medication had a statistically significant reduction on amyloid plaque and a slowing of clinical impairment in patients with prodromal or mild stages of the disease. This was the first time an investigational drug for Alzheimer’s was able to produce these types of results. Researchers are currently examining whether the results can be replicated in larger patient populations.

> The Alzheimer’s Prevention Initiative’s (API) Autosomal Dominant Alzheimer’s Disease (ADAD) Treatment Trial: This trial is testing to see whether an investigational drug can prevent the onset of Alzheimer’s symptoms in people who are cognitively healthy but possess a rare genetic mutation that puts them at increased risk for the disease.

> The API Generation Study: This study is studying the impact therapies that target amyloid proteins in the brain can have in preventing or delaying the emergence of Alzheimer’s symptoms in high genetic risk individuals.

> The Dominantly Inherited Alzheimer’s Network Trials Unit (DIAN-TU) and DIAN-TU Next Generation (NexGen) studies: These studies are exploring the effect of modifying therapies for individuals at risk of having a gene mutation that causes dominantly inherited Alzheimer’s disease.

> Alzheimer’s Association’s “Part of the Cloud Initiative”: This initiative includes research that examines the role and timing that neuro-inflammation and immune responses play in brain changes that have been linked to Alzheimer’s.

**LINKS TO STUDIES:**

Phase 3 trial of the anti-amyloid antibody Aducanumab (Biogen)  

Autosomal Dominant Alzheimer’s Disease (ADAD) Treatment Trial  

The API Generation Study  

The Dominantly Inherited Alzheimer’s Network Trials Unit (DIAN-TU) and DIAN-TU Next Generation (NexGen) studies  

“Part the Cloud Initiative”  
> www.alz.org/partthecloud
toms of Alzheimer’s for patients and their caregivers. The materials were provided through the Good Neighbor Pharmacy network, in which his pharmacy participates.

Some pharmacies are going one step further by performing memory screenings in house. For instance, Kmart Pharmacy recently partnered with the Alzheimer’s Foundation of America (AFA) to offer free-confidential memory screenings at all of its pharmacy locations for the month of November.

According to Jennifer Speares, RPh, Director of Compliance and Administration for Kmart Pharmacy, the pharmacy conducted about 5,000 memory screenings across its approximately 500 locations during the month-long event.

The event took place at the same time as the Medicare re-enrollment period, allowing the pharmacists to offer comprehensive patient counseling sessions that included memory screenings, assistance with re-enrollment, and immunizations.

“It really became a full-on health event, but memory screenings were sort of the primary focus of what we were trying to do,” Speares says.

Syed says clinic or retail pharmacies anywhere can very easily add a quick mental status assessment into their regular counseling process. She recommends visiting the Alzheimer’s Association’s website, alz.org, to see their free assessment tools.

“You can download those tools and use them as part of your practice,” she says.

While the Kmart initiative was initially a one month-event, Speares says the pharmacy quickly realized it wanted to form a long-standing partnership with the AFA and continue the memory screenings. Kmart is also exploring other ways to expand its services geared toward Alzheimer’s patients.

“As a pharmacist who is responsible for training thousands of other pharmacists, I would love to see this become a part of normal training, like an immunization,” she says.

Pharmacists may be poised to aid in early identification, but their efforts shouldn’t end there. Pharmacists can be important allies in the care and management of Alzheimer’s disease.

As a drug expert, pharmacists can conduct a thorough drug utilization review of a patient’s medication list to identify other medications, such as anti-histamines or muscle relaxants, that are known to cause or amplify existing memory issues.

“We want to at least take a look and make sure that none of the offending agents are involved in their care,” Syed says.

Shapiro recommends pharmacists familiarize themselves with the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults guidelines, produced by the American Geriatrics Society. She says these guidelines can help pharmacists identify medications that could be problematic for those with dementia.

There are also several strategies pharmacies can use to try to improve medication adherence.

For instance, Syed says pharmacists may be able to help patients and their caregivers simplify drug regimens by creating a schedule that limits the number of times a day a patient needs to take medication by aligning medicines to morning or evening doses.

Acquaviva’s Pharmacy offers free compliance packaging for its patients. Although the service is open to everyone, Acquaviva says the pharmacists try to highlight the services to Alzheimer’s patients and their caregivers.

On Hawaii’s Big Island, KTA Super Store pharmacy isn’t able to offer compliance packaging, but they do fill some of their patient’s pill boxes each month to ensure their patients are getting the correct medications at the right times.

Kerri Okamura, RPh, the store’s Director of Pharmacy, says they also offer a medication synchronization program for patients and their families.

“We try to synchronize so they can get everything at once, so trips to the pharmacy are less frequent,” she says.

Creating visual cues for patients, such as making a colored chart or incorporating pictures of the medications into a drug schedule, can also be useful.

In addition to adopting medication adherence strategies or policies, pharmacists can also serve as a liaison between physicians and their patients. Experts agree that patients may be more likely to want to please their physicians and may not provide accurate accounts of their adherence or medication habits.

Patients may be more candid with pharmacists, giving them a more realistic picture of their habits. Syed says communicating with physicians is important so that all members of the care team can have an accurate sense of the patient’s actual dose, particularly for patients with dementia.

“"You spark interest and conversation and it makes people aware and maybe it’s enough to get people over the hump to pursue it with their doctor.”

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if a patient is trying to stretch his or her medication by taking it less often than prescribed.

“If the physician thinks that he’s not getting the full effect of the medication that he wants, he may be increasing the dose and this would not be good,” she says.

As a physician, Shapiro also advocates for open communication between the physician and pharmacist.

“When pharmacists call physicians I think one thing that might be helpful for both, is to give an alternative, like this comes in a long-acting form, a generic form, may I substitute this?” Shapiro says, who also serves as an Attending Physician at the Jesse Brown VA Medical center.

Suggesting alternate delivery methods of medications, such as patches or sprinkle forms, once a patient begins having difficulty eating or swallowing is another way pharmacists can offer value.

Shapiro says pharmacists should also review prescription labels to make sure the information is accurate and in the patient’s native language. Dos ing for all approved medications for Alzheimer’s disease should start low and go high, so refill directions may be different than the initial fill. Shapiro says it’s important to make sure any refills aren’t still left with the original directions.

Providing Caregiver Support
Alzheimer’s strips patients of their independence and basic functioning, creating a greater reliance on caregivers.

Community pharmacists can serve caregivers too, by providing those caring for Alzheimer’s patients with information about local resources, adult day care centers, or a list of support groups and services in the community.

Okamura says the pharmacy in Hawaii has even partnered with its local Alzheimer’s Association chapter to try to increase awareness about the services that exist in the community. For example, the Alzheimer’s Association chapter is always included in the pharmacy’s wellness fairs.

“We try to support each other when we can,” she says.

Acquaviva’s Pharmacy held a fundraiser this summer to raise money for its local Alzheimer’s Association chapter. The event raised about $1,300 and increased awareness about the disease and the resources that exist in the community.

“You spark interest and conversation and it makes people aware and maybe it’s enough to get people over the hump to pursue it with their doctor,” Acquaviva says.

A Team Approach
Shapiro believes that when a pharmacist is part of the healthcare team it can result in better patient and family satisfaction, reduced emergency room visits, reduced adverse effects, and fewer hospitalizations.

“Ideally, the number of medicines go down, there’s de-prescribing, and there’s more appropriate dosing,” she says.  

Jill Sederstrom is a Contributing Editor.
The occasion: The Institute for Safe Medication Practices’ (ISMP) Cheers Awards, which honored Ascension for its comprehensive implementation of ISMP’s six 2014-2015 Targeted Medication Safety Best Practices for Hospitals. Ascension achieved compliance levels that exceeded the national average, according to ISMP.

Ascension, which is based in St. Louis and has 141 facilities in six states, provided outcomes data to ISMP that supported its implementation of the best practices, said Allen Vaida, PharmD, FASHP, Executive Vice President of ISMP. To ensure that its efforts were on target, Ascension hired an outside consulting firm to monitor the progress of the initiative. Facilities across the health care system were 93% compliant with ISMP’s Best Practices, said Roy Guharoy, PharmD, MBA, and Chief Pharmacy Officer at Ascension.

“We felt that implementation was critical to improvement in patient safety, Guharoy told Drug Topics. “Medication errors can be catastrophic, so within Ascension, we issued a call for action among multi-disciplinary teams to incorporate these Targeted Best Practices into patient care.”

The “call to action” began with representatives from the pharmacy department, as well as from the quality and safety areas. The initiative then moved to the hospital level where doctors, nurses, risk managers, IT experts, and other disciplines were included.

Critical to success, explained Guharoy, was communicating with each facility within the health system about why these changes were so important. With facilities ranging from 25 beds to 500 beds, the challenge was to reach each one and ensure that each facility was on board. “We had a conversation with each hospital,” Guharoy said. According to an ISMP Medication Safety Alert, the six Targeted Medication Safety Best Practices for Hospitals were:

1. Dispense vincristine (and other vinka alkaloids) in a minibag, not a syringe.
2. Use a weekly dosage regimen default for oral methotrexate; if overridden to daily, a hard stop verification of use for a cancer indication is required. Also provide education to patients being discharged on weekly dosing.
3. Measure and express patient weights in metric units only.
4. Dispense oral liquids not commercially available as unit dose products in oral syringes.
5. Use oral liquid dosing devices that display only the metric scale.
6. Eliminate glacial acetic acid from all areas of the hospital and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).

Using the second Best Practice as an example, Vaida stressed that the support of executive leadership within Ascension helped steer the health system in the right direction. Since daily doses of methotrexate when indicated for arthritis or another autoimmune disease can be fatal, an electronic alert can reduce the potential for this error. But an IT department may not view this as a priority. “Senior management, however, can step in and ask them to make it a priority,” Vaida said.

Vaida also noted that while each facility within Ascension did not achieve compliance with every standard, a facility may have exhibited the intent to do so in the future. For example, while some facilities still used scales that measured in pounds, they planned to request metric scales with their next order.

Guharoy stressed that the implementation of the Best Practices is an ongoing effort. In fact, ISMP has revised two of its existing practices and added additional ones, said Vaida. Ascension leadership is committed to engage in the same process for the new standards, according to ISMP.

Kathleen Gannon Longo is a Contributing Editor.
Sixty-two percent of forecast panelists (FPs) – 148 pharmacists nominated by report leaders – predicted that President Donald Trump is unlikely to support federal provider status for pharmacists. “The best hope for gaining passage of this legislation has been to insert the bill into another health-related measure. Provider-status legislation certainly will be reintroduced in the new Congress, and pharmacy forces will continue to work hard for its passage,” according to the forecast. Fifty-four percent of FPs believe the new president will try to allow Medicare to negotiate lower drug prices. However, “it seems unlikely that the Trump administration will move in this direction, given the biopharmaceutical industry’s opposition,” according to the report, published in the November, 2016 issue of the American Journal of Health-System Pharmacy. In addition, two-thirds of FPs indicated that President Trump is unlikely to seek involvement of the federal government in influencing pricing of new drugs. Sixty-two percent of FPs also said that it is unlikely that the new admn...
In a rapidly changing technology environment, features such as touch screen, a variety of cabinet configurations, innovative drawer design, and increased responsiveness, are essential to facing those challenges.

Duke University Hospital in Durham, NC, turned to Omnicell’s XT series automated dispensing system when it needed to deploy cabinets in five areas of the hospital.

“We have deployed various cabinet types into five different places that are very different in terms of patient population. We will have an additional series of cabinets coming in the early part of 2017,” said Matt Kelm, PharmD, MHA, Manager Unit Dose Distribution, Department of Pharmacy.

The hospital has Omnicell XT automated dispensing cabinets located in the pulmonary and radiology units, endoscopy procedural area, cardiac stress test unit, and in the lab.

“We have one cabinet inside our IV clean room where we use automated dispensing cabinets provide greater capacity/touch screen

Health system pharmacies that require large-scale deployment of automated dispensing cabinets are faced with multiple challenges.
dispensing cabinets to manage high-risk or high-cost medications as well as controlled substances,” said Kelm.

Kelm said that a key feature of the redesigned system is an increased capacity that allows for 30% more medications in the same footprint as the old design.

Another plus is the new drawer configuration. “[Omnicell] developed innovative drawer designs that has made it much more effective for us as a customer in terms of right-sizing the pockets that are available, and we found the new locking bins to be superior to the prior product,” said Kelm. The new cabinet is more responsive and faster, he added.

According to Omnicell, the XT series includes automated medication and supply dispensing cabinets, Anesthesia Workstation, and Controlled Substance Manager. The system is fully integrated with Connect-Rx from Aesynt, allowing customers who use AccuDose-Rx cabinets to use the new hardware without changing their software and server infrastructure. Connect-Rx is a common technology platform that integrates automation and information technology across systems.

**KEY FEATURES OMNICELL XT SERIES:**
- Single-dose dispensing
- Smart drawer design
- Improved guiding lights
- Flexible cabinet changes
- User-friendly/IT-friendly features

**Touch screen technology**

Kelm noted that he is impressed by the responsiveness of the touch screen, which is a change from the older pressure-style system, and is similar to working on a smart phone.

“That’s been a noticeable improvement for us, along with the lighting of the cabinet that is much better, brighter and easy to see.”

The upgraded XT series has had a positive impact on patient care and staff efficiency, according to Kelm.

“From a patient-care perspective, our role is to support the care nurse. The easier we can make a medication pass for the care nurse, the better for the patient. With this increased capacity, we have the ability to have more diversity of line items stocked in the cabinet – that means more meds on the unit at the nurse’s finger tips,” said Kelm.

Kelm said that the new system also makes it easier for the care nurse when medications are stored in a single location because if the nurse is getting the drug out of an automated dispensing cabinet he is not looking across multiple places to find the drug that has come from pharmacy; it’s in one place now.

That’s something that the pharmacy staff has been actively studying from a pharmacy efficiency standpoint, he said.

“We have a study we’re doing right now to see whether these new configurations are improving the time it takes the pharmacy technician to restock the cabinet.”

Kelm said that the fundamental redesign of the Omnicell XT cabinet will also make maintenance easier.

Kim Howland, Vice President of Global Product Development for Omnicell, said customers want to spend less time managing their medications and their supplies and want to cut costs.

“For us, we started thinking about our old hardware. You were very connected to the cabinet and most of the work had to be done at the cabinet. Today people are used to using handheld smartphones so we started thinking about ways we could get some of the labor away from the cabinet,” said Howland.

**Automated dispensing marketplace**

The market, according to Howland, is being driven more by the requests of customers to make a product easier to use and less by vendor consolidation.

“We’re starting to see care move outside the four walls of the hospital and to alternative sites. The consolidation of health care systems and the sites of care, is really driving more of our change. We have to have our solutions be more flexible and adaptive.”

Anthony Vecchione is the Executive Editor of Drug Topics.
When Chris Nadeau, PharmD, a fourth-generation pharmacist from Maine, was looking for a way to increase compliance among his geriatric patients he discovered that there was also a pattern of non-compliance among two groups of his patients.

“We saw a trend with lack of compliance in the behavioral/mental health and non-English speaking community due to misunderstanding or misinterpreting directions. Many of these patients, particularly mental health patients, are unable to access transportation services to pick up their medications, further decreasing compliance,” said Nadeau.

The challenge for Nadeau was to get patients to not only take their medications on time but also to make sure that the medications got to them.

After searching the marketplace for a better packaging system, Nadeau selected OmniCell’s SureMed multidose blister cards.

The way it works is that when patients sign up for the program, the pharmacy contacts their doctor to get a full medication list and confirm that their meds are current. Patients receive their meds in multidose blister cards that includes directions on the package - how many to take and when along with a photo of what the pill looks like. The blister cards have perforated tear off doses with a medication list printed on the cover.

Currently Nadeau has 200 patients using the cards.

“We pack their meds and we put people into different groups depending on the location within our delivery area,” said Nadeau.

The delivery service, noted Nadeau, is provided free-of-charge and so far, feedback has been overwhelmingly positive.

Nadeau added that doctors have been pleased with the program and are telling their patients about it, especially those who are unable to understand how to take their medications.

“When it comes to this packaging, they know how to take their medication – they punch out a certain blister a certain time a day – they don’t have to worry about dose changes or splitting tablets - so whatever pills are in the pack. They know they are going to take them appropriately.”

Outcomes medication compliance

Nadeau asserted that compliance has been by far the biggest advantage of the system

“We noticed that our patients take their meds on a more regular basis, making them more effective. With this system, patients can track if they actually took their doses because the blister is visibly broken if they took it and the med isn’t there anymore.”

Nadeau said that he has also incorporated medication synchronization into the system.

Nadeau said that his philosophy as an independent pharmacist is to always look for ways to improve patient care.

“Because people are taking their meds on a more regular basis and are more compliant, we have had several dose decreases with some of the oral antidiabetic meds.”

Anthony Vecchione is Executive Editor of Drug Topics.
Chronic lower respiratory disease
How You Can Help Improve Patients’ Quality of Life

Chronic lower respiratory disease (CRD) is third leading cause of death in the US according to the CDC. Although incurable, with appropriate therapeutic regimens under the guidance of pharmacists, COPD progression can be slowed, asthma can be controlled, and the quality of life of our patients can be significantly improved.

Health problems associated with CRD often result from inadequate access to care. Pharmacists are generally readily accessible and can attend to respiratory concerns with appropriate medication usage, and guidance about lifestyle modifications and environmental controls. Most pharmacies now have translation hotlines when language is a barrier.

Patients often face multiple challenges (eg, environmental triggers such as allergens, ozone, indoor and outdoor pollution, tobacco, smoke, and mold) and complicated medication regimens that complicate control of their disease. Counseling patients to avoid and prevent triggers, and to maintain continuum of care with medication refills will help maintain adequate asthma and COPD control.

Appropriate regimens for asthma and COPD are based on disease severity and utilize a stepwise approach that takes into account patient-specific factors.1 In a collaborative effort with the attending physician, pharmacists can ensure that patients understand the various indications of their CRD medications to minimize adverse effects, toxicities, and misuse of their prescriptions.

Drug delivery formulations such as meter dose and dry powder inhalers, nebulizers, and Respimat (Spiriva) pose significant obstacles, as they require hand strength and dexterity. Patients often do not know how to use spacers correctly, so it is important that pharmacists thoroughly explain how to use them.

As a consequence of inadequate training, patients may not get the full benefit of the medications and experience side effects (eg, oral Candida due to inappropriate drug hygiene that requires rinsing after use of oral corticosteroids). Patient understanding of the appropriate use of each medication, sequence of the medication, and manipulation of the devices will increase adherence by providing better control.

Pharmacist-physician collaboration is key to controlling chronic respiratory disease.”

Pharmacist-physician collaboration is key to controlling CRDs. In more than half of the states in the country, pharmacists have some sort of authorization(s) to provide drug therapy management as specified in a written provider protocol. Studies have shown that drug monitoring, counseling and educational services provided by community pharmacists contribute to improved health outcomes. Collaborations are also important because there are many drug classes and drug devices to consider for CRD therapy.

In addition to collaborative care, many states are now creating grounds for pharmacist reimbursement with CRD counseling. Lack of reimbursement is a major challenge contributing to pharmacists’ inability to deliver direct health care services on a widespread basis. Fortunately, in California, Assembly Bill 11114 expands health care services covered under Medicare. This is a move in the right direction considering 30% of Californians are Medicaid recipients, and 11% are Medicare recipients.

Despite effective therapeutic regimens for CRDs, uncontrolled asthma and COPD are still major public health concerns that accounted for approximately 2 million ED visits and cost the US $36 billion in 2014. By providing patient education, pharmacists can help reduce these healthcare expenditures and optimize health outcomes.

Ericka McNeal is a PPSI Intern and a 2018 PharmD/MPH candidate at Touro University, in Vallejo, California. She would like to thank Aglaia Panos, PharmD, for her assistance in the preparation of this article. Contact Ericka at ericka.mcneal@touro.edu
Networking Eric

“Hey, if there is ever anything I can do to help you, let me know.” How many times have we heard this and how many times have we said this? We say it at the drug store, we say it at pharmacy meetings. Heck, we even say it at the funeral parlor! Does anyone ever take you up on your offer?

Back a few years ago, my boss Bill Thompson called me and said that Greg Drew, the President of Value Drug, our wholesaler, was at the University of Pittsburgh for a function. Greg said to the students “If you ever need anything, or want to come to Value Drug, let me know.” Imagine Greg’s surprise when Eric Abanquah, called him and took him up on his offer. Eric came to Value Drug for a few days of meetings with Greg and his staff, but by Wednesday Greg felt he showed Eric all there was to show him! He called Bill, and asked about any ideas to continue Eric’s experience in Altoona.

I told Bill I’d be glad to meet this student, and Eric came to the store to shadow me for a couple of days. We hung out at the store and talked about independent pharmacy and the pharmacist’s role in community health care. Eric’s commute from Pittsburgh to Altoona for this daily adventure, was more than two hours. I told him next day to meet me at St. Francis in Loretto where I teach and he’d get to observe my Pharm class. I also told him to pack his clothes because he’d be a “temporary Kreckel” and stay at our house Thursday night. Eric spent Friday at the store, and he told me that he’d love to do the Rural Pharmacy rotation his P-4 year and be a “Kreckel” for five weeks.

Eric came in the summer for his rotation, and we focused on pharmacotherapeutics at the store and even at home on the back deck. He loved the mechanisms of action and how all that he learned in pharmacy school came into clinical practice. We exposed him to a lot of Central Pennsylvania. He’s a city kid from Philadelphia and enjoyed our excursions to the state parks where we hiked and kayaked. He was apprehensive at first with the idea of kayaking, but after a couple of minutes, I was pushing hard just to keep up with him! He laid aside his apprehensions, tried something new, and enjoyed it to the maximum.

When Eric graduated in 2013, Denise and I went to his graduation to meet his family. His Mom and older brother were born in Philadelphia. His Dad passed away a few years ago. How excited we were to meet this truly amazing American success story, featuring two pharmacists, a chemical engineer, and a student in a master of public health program. Eric focused on his boards and easily passed them. He asked me if I created the NAPLEX questions, as our time spent together was so productive, on the back deck and in the store.

Eric accepted a job at Highmark in Pittsburgh where he works in the Clinical Pharmacy Strategies department. He is busy developing formularies, cost-effective treatments, and evidence-based medicine literature documents. Of the forty students we’ve precepted he is one of the most memorable and often quoted. I’ve been told by current student pharmacists that our kayaking picture sits on his desk at Highmark in Pittsburgh.

So, the next time someone offers their expertise to you in your career path take them up on it. These seasoned pharmacists have a lot to offer, and connecting with them can be very positive networking. Find a mentor and learn from their highly successful habits. Reach out to those people who offer to assist you in following your ambitions and dreams—“Hey, if there is ever anything I can do to help you, let me know.”

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The Low Down on PCSK9 Inhibitors

These human monoclonal antibodies both exert their lipid-lowering effect by binding to PCSK9 and preventing LDL receptors from being degraded in the liver. By inhibiting the destruction of LDL receptors, PCSK9 inhibitors promote the removal of LDL cholesterol (LDL-C) from the circulation, thus lowering levels of LDL-C in the blood.

The labeling for both PCSK9 inhibitors includes indications for patients with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD) who need further LDL-C reductions despite concomitant diet control and statin pharmacotherapy. Evolocumab also has an indication as an adjunct therapy for patients with homozygous familial hypercholesterolemia.

The LDL-C lowering effects observed in clinical trials for both drugs were significant, especially considering these studies evaluated patients on high-dose statin therapy. In a large open-label follow-up of the phase 3 clinical trials evaluating evolocumab, patients treated with the PCSK9 inhibitor in addition to standard lipid-lowering therapy saw a 61% reduction in LDL-C as compared to those treated with standard therapy alone. The combined OSLER-1 and OSLER-2 trials demonstrated the significant LDL-C lowering effect of evolocumab: patients with a median baseline LDL-C level of 120 mg/dL achieved an LDL-C of 48 mg/dL after 12 weeks of therapy.1 Likewise, alirocumab was evaluated against placebo in a large phase 3 trial in which all patients were given statins +/- other lipid lowering therapy. In the ODYSSEY LONG TERM trial, patients treated with alirocumab experienced a 61% reduction in LDL-C by week 24—reduction in mean LDL-C from 122.7 mg/dL to 48 mg/dL.2

Evolocumab and alirocumab are both administered via subcutaneous injection. Evolocumab is available as a 140 mg injection given every 2 weeks, or a 420 mg injection given monthly. Patients with homozygous familial hypercholesterolemia should only receive the 420 mg monthly dose. Alirocumab is available as 75 mg or 150 mg injections, which are given every 2 weeks. The 75 mg dose should be used initially, but can be increased to 150 mg if there is an inadequate response after 4 to 6 weeks. Contraindications include history of hypersensitivity reactions to the respective drugs. Adverse effects of both drugs can include nasopharyngitis, injection site reactions, infection, and musculoskeletal pain.

Because these drugs are biologics, cost is definitely a concern and recent publications have called into question the cost-effectiveness of PCSK9 therapy at current market prices.3 Additionally, the most recent hyperlipidemia treatment guidelines from the American College of Cardiology and American Heart Association do not include specific recommendations about the use of PCSK9 inhibitors since these drugs were not FDA approved at the time of publication. The guidelines advise against routine use of non-statin therapies due to a lack of strong clinical trial evidence of their effects on cardiovascular outcomes.4 Note though that studies of both PCSK-9 inhibitors have seemingly addressed this issue by focusing on clinically meaningful outcomes rather than simply lowering LDL-C.5,6 Once published, these studies will help to determine the place of PCSK9 inhibitors in therapy moving forward.6

Joseph E. Cruz, PharmD, BCPS is Clinical Assistant Professor at Ernest Mario School of Pharmacy at Rutgers University, and The State University of New Jersey Clinical Coordinator—Internal Medicine Englewood Hospital and Medical Center.

REFERENCES
Albert Einstein once said, “In the middle of difficulty lies opportunity.” You either shrink from challenges or work to overcome them. For well over a century, independent community pharmacies have delivered vital services to patients in spite of a marketplace littered with economic landmines.

Value-based care brings unique opportunities to redesign our current health care ecosystem. I believe in a world where prescribers, pharmacists, nurses, and payers stop competing and start collaborating to design an improved system of care that benefits everyone and cares for our clinicians in the process. Caring for our caregivers is just good medicine.

As President of the National Community Pharmacists Association (NCPA), my primary goal this year is to work on connections and relationships with everyone who shares similar values and beliefs and who believes in fixing our broken health care system. We must also create greater accountability for pharmacy benefit managers (PBMs), who continue to add cost, not value, to the health care system and who threaten our very existence.

On average, independent community pharmacies derive more than 90% of their revenue from prescription drug sales, leaving us at the mercy of dominant PBMs that dictate the terms of the vast majority of our revenue for the lifesaving products and services we provide. These drug middlemen do not disclose their methodologies for determining reimbursements in pharmacy contracts, leaving small business health care providers working blind when it comes to proper planning and business management.

The list of egregious PBM tactics is long. Independent community pharmacies now cite direct and indirect remuneration (DIR) fees in the Medicare Part D program at the top of that list. Retroactive DIR fees are imposed by PBMs after the medication has been dispensed. These fees are unpredictable in their amount and timing, making it increasingly difficult for independent community pharmacists to manage their businesses.

NCPA helped generate and support companion bills S. 3308 / H.R. 5951, The Improving Transparency and Accuracy in Medicare Part D Spending Act, (bit.ly/2016dirbills), which are likely to be reintroduced this year Congress, and will eliminate retroactive DIR fees in the Part D program.

Pharmacies across the country are working together to form local networks focused on delivering care above the norm for more complex patients. NCPA is working with Community Care of North Carolina to support the formation of the Community Pharmacy Enhanced Services Network (CPESN) (www.cpesn.com) and to stitch multiple local CPESNs together to serve payers in larger geographical areas.

The new NCPA Innovation Center is supporting this effort by providing community pharmacies with the learning opportunities, tools, and resources they need to re-engineer their practices for the new marketplace. While we are excited about these efforts, there are other examples of the health care status quo being shaken up for the greater good. A broad-based grassroots movement is being unleashed to promote a new health ecosystem called “Health 3.0.” There is a template for wise health care spending called the Health Rosetta available online at healthrosetta.org. I want independent community pharmacists to be a part of this aggregation of health care providers who want to unbreak health care (bit.ly/unbreak-healthcare).

As pharmacists, we are deeply connected to our patients and we have a core desire to help people be well.

DEANN MULLINS, BPHARM
The author is the National Community Pharmacists Association President and owner of Mullins Pharmacy, WeCare Wellness, and the WeCare Diabetes Education Program, Lynn Haven, Fla.
FDA announced approval of oxycodone/naltrexone extended-release capsules (Troxycya ER; Pfizer) for the treatment of pain severe enough to warrant daily around-the-clock, long-term opioid treatment for which alternative treatment opioids are inadequate.

On March 18, 2016 the CDC published new guidelines for the prescribing of opioids for chronic pain. Of patients presenting to physician offices with non-cancer pain symptoms or a pain-related diagnosis, an estimated 20% received an opioid prescription. Opioid medications resulted in an estimated 165,000 deaths between 1999 and 2014. Each Troxycya ER capsule contains pellets of oxycodone hydrochloride surrounding sequestered naltrexone hydrochloride. When taken as directed, the naltrexone remains sequestered. When the capsule is crushed, the naltrexone acts to counteract the effects of the oxycodone to reduce abuse by the oral and intranasal routes.

**Efficacy**
The efficacy of oxycodone/naltrexone was established in one randomized 12-week, double-blind, placebo-controlled clinical trial. Eligible study patients consisted of adults 18 years or older with documented diagnosis of nonspecific moderate to severe chronic low back pain for a minimum of 3 months. Those who entered the screening period with management of their chronic pain using 1) a non-opioid analgesic; 2) an as-needed opioid; or 3) daily opioid regimen, and who scored had a daily average pain score between 5 and 9 on an 11-point numeric pain rating scale (ranging from 0 = no pain to 10 = worst possible pain) for at least 4 of the last 7 days of screening were eligible to enter the open-label, conversion phase. After 4 weeks of open-label conversion phase, patients meeting the protocol-based treatment response criteria were randomized into the double-blind treatment period to receive either placebo or oxycodone/naltrexone. Those randomized to placebo received a gradual blinded taper. Patients who either completed the 12-week double-blind treatment period or discontinued before the end of week 12 entered a 2-week post-treatment follow-up consisting of a gradual taper of either the oxycodone/naltrexone or placebo.

A total of 410 patients received oxycodone/naltrexone in the open-label phase: 281 patients were randomized to the double-blind treatment period (134 to placebo and 147 to the oxycodone/naltrexone). Efficacy was evaluated by patients’ self-recorded daily average low back pain rating using the 11-point numeric pain rating scale. The mean difference in pain scores from randomization to the final 2 weeks of the treatment period was statistically significant for oxycodone/naltrexone compared with placebo (mean pain score [range], 1.2 [−4.1 to 6.7] and 0.6 [−4.4 to 7.3] for placebo and oxycodone/naltrexone, respectively, p=0.0114). From screening to the final 2 weeks of the treatment, 44% of placebo patients and 57.5% oxycodone/naltrexone patients reported ≥30% decrease in weekly average pain score (p=0.0248). In this same period, 29.9% placebo patients and 39.7% oxycodone/naltrexone patients demonstrated ≥50% reduction in weekly average pain scores (p=0.0874).

**Safety**
Oxycodone/naltrexone contains warnings for addiction, abuse and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; and cytochrome P450 3A4 interaction (concomitant use with CYP3A4 inhibitors or discontinuation of CYP3A4 inducers).

The most common side effects (>10%) reported with oxycodone/naltrexone are constipation (21.3%), nausea (25.3%), vomiting (13.9%), and headache (11.6%). Oxycodone/naltrexone is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastro-
intestinal obstruction including paralytic ileus, and hypersensitivity to oxycodone or naltrexone.

Clinically significant drug interactions with oxycodone/naltrexone include the following. (See Table).

Dosing
Oxycodone/naltrexone is supplied in the following dosages: 10/1.2 mg, 20/2.4 mg, 30/3.6 mg, 40/4.8 mg, 60/7.2 mg, and 80/9.6 mg. In opioid-naïve or opioid-non-tolerant patients, oxycodone/naltrexone should be initiated at 10/1.2 mg orally every 12 hours. Conversion factors for other opioid preparations are available in the package insert.

The capsules should be swallowed whole and may not be manipulated, crushed, dissolved, or chewed. The capsules may be opened, the contents sprinkled over applesauce, swallowed without chewing, and mouth rinsed to ensure all capsule contents swallowed. The pellets should not be administered through a nasogastric or gastric tube.

ASHLEY JOHNSON, a 2017 PharmD Candidate, is a 4th-year honors pharmacy student at the University of Connecticut School of Pharmacy, Storrs, CT, where Lisa M. Holle, PharmD, BCOP, FHOPA is Associate Clinical Professor.

REFERENCES

NEW DRUG REVIEW
Ashley Johnson and Lisa M. Holle, PharmD, BCOP, FHOPA

**TABLE 1**

| DRUG INTERACTIONS | \(|\) |
|--------------------|-----|
| **Anticholinergics** | Opioid use may increase risk of urinary retention or constipation |
| **Benzodiazepines, CNS depressants, muscle relaxants** | May cause additive pharmacologic effects including increased risk of sedation, respiratory depression, and death |
| **CYP3A4 AND CYP2D6 INHIBITORS** | May cause increased plasma concentrations of oxycodone and prolonged opioid effects |
| **CYP3A4 inducers** | May cause decreased plasma concentrations of oxycodone resulting in decreased efficacy and/or withdrawal |
| **Diuretics** | Opioids may inhibit antidiuretic hormone release Monitor patient blood pressure and signs of decreased diuresis |
| **Mixed agonist/antagonist or partial agonist opioid analgesic** | May cause reduced efficacy and/or withdrawal |
| **MAOIs** | May cause additive pharmacologic effects including increased risk of sedation, respiratory depression, and death or cause serotonin syndrome. Use not recommended during or within 14 days of stopping MAOIs |
| **Serotonergic agents** | May cause serotonin syndrome Monitor patient during initiation and dose changes |

**Special Populations**

| **Hepatic impairment** | May cause elevated levels of oxycodone and naltrexone Dose conservatively and monitor patient for signs of respiratory depression or withdrawal |
| **Pediatric patients (18 years of age)** | No studies currently available |
| **Pregnant or lactating women** | No studies currently available; however, opioids can cross the placenta and into the breast milk |
| **Renal Impairment** | May cause elevated levels of oxycodone and naltrexone Dose conservatively and monitor patient for signs of respiratory depression or withdrawal |

*Indicates a demographic advertisement.
Opioid Abuse
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safety standpoint, people have a hard time staying hostile, one pharmacist told us."

Pharmacists should also practice motivational interviewing techniques so they are more comfortable when faced with a potentially difficult conversation with patients. “Ask questions like, ‘What’s working for you?’ Always ask permission, rather than telling the patient. For example, ‘I have some concerns. Do you think that this information would be helpful to you?’,” O’Kane said.

Make sure you are coming from a place of caring.

NICOLE O’KANE, PharmD

In addition, inform patients when you have reviewed their prescription history using the PDMP. “They have a legal right to know that you have reviewed their report and to see a copy of the printed report,” O’Kane said. Then, inform them of next steps and be sure to include an expected timeline, such as 24 hours. 

Mental Health
CONTINUED FROM PAGE 11

not have to make an extra trip to an outside pharmacy. But there may be additional reasons for the improved rates. What causes these differences?” Odorzsynski asked. The pharmacists in the clinics are experts in psychiatric illness and addiction and understand the medications, their side effects, and the barriers that patients may face in staying on their medication, she pointed out. “Our entire focus is around how we address those barriers and rip them down.”

REFERENCE

Christine Blank is a Contributing Editor.

Walgreens
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at select Healthcare Clinics located inside Walgreens stores.”

In addition, the retailer’s Balance Rewards for healthy choices program offers smoking cessation content and tools on Walgreens.com, individual support through the Walgreens online Pharmacy Chat, and tools to enable participants to track their progress toward smoking cessation. Participants in the program earn Balance Rewards points as an incentive.

Meanwhile, Truth Initiative and DoSomething.org’s new effort comes on the heels of another successful campaign by DoSomething, Take Back the Shelves, which asked young people to use social media creatively to demand that pharmacies remove tobacco from their shelves during December. More than 69,000 youths joined that effort, according to Truth Initiative.

“Tobacco and pharmacies just don’t mix,” said Aria Finger, CEO at DoSomething.org. “In 2014, CVS Health stopped selling tobacco products and we hope that other pharmacies will follow their lead and listen to young people.”

“Pharmacies are a trusted source of health information and services. Yet in 2016, more than 50,000 pharmacies still sell tobacco—

the number one preventable cause of death in the U.S., killing more than 1,300 people each day,” Truth Initiative said.

After CVS banned the sale of tobacco products in its stores nationwide, the chain reported that cigarette purchases dropped a percentage point in states where the company has a large presence. During that time, 95 million fewer packs of cigarettes were sold in those states, according to Truth Initiative.

Youth who signed up for the Take Back the Shelves campaign learned “how tobacco companies attract young consumers by displaying their products at point-of-sale, behind checkout counters and on eye-level shelves,” according to Truth. They could download a template and create artwork with items they want to see behind pharmacy checkout counters instead of tobacco products.

Then, they shared their drawings on social media with #TakeBacktheShelves, tagging a pharmacy to ask them to remove tobacco products from their shelves.

The campaign got celebrity endorsement. Kira Kosarin, a 19-year-old star of Nickelodeon’s The Thundermans, recorded a public service announcement to encourage fans to join the effort.

Christine Blank is a Contributing Editor.
T he Federal Food, Drug, and Cosmetic Act (Act) defines a dietary supplement as a product intended for ingestion that contains a “dietary ingredient” intended to add further nutritional value to supplement the diet. A dietary ingredient is a vitamin, mineral, herb, or other botanical, amino acid, or a dietary substance for use by humans to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances.

Supplements are typically marketed to consumers in forms such as tablets, capsules, soft gels, gel caps, powders, or liquids and do not require a prescription written by a health care practitioner. These products are sold in most pharmacies, grocery stores, and nutritional supplement centers.

Unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. This means supplements should not make claims, such as “reduces pain” or “treats heart disease.” Claims like these can only legitimately be made for drugs that have been approved by the FDA for a particular indication.

Under existing law, including the Dietary Supplement Health and Education Act passed by Congress in 1994 (DSHEA), the FDA can take action to remove products from the market, but the agency must first establish that such products are adulterated (e.g., that the product is unsafe) or misbranded (e.g., that the labeling is false or misleading).

FDA regulates both finished dietary supplement products as well as dietary ingredients. It also regulates dietary supplements under a different set of regulations than those covering “conventional” foods and drug products. Under the DSHEA:

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. These firms are responsible for evaluating the safety and labeling of their products before marketing to ensure that requirements are met.
- FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.
- Because dietary supplements are under the “umbrella” of foods, FDA’s Center for Food Safety and Applied Nutrition oversees these products. The DSHEA, which amended the Act, created a new regulatory framework for the safety and labeling of dietary supplements. FDA is not authorized to review dietary supplement products for safety and effectiveness before they are placed on the market.

FDA provides a safety reporting portal for the public. This lets FDA know when consumers, health professionals, or industry members find a problem with a particular dietary supplement. It is an electronic version of the existing MedWatch 3500, 3500A, and 3500B forms used by industry and consumers to report problems with FDA-regulated products. The electronic version is tailored exclusively for dietary supplements.

Stakeholders of the dietary supplement industry, which includes individual consumers and pharmacists, may use the reporting form on the safety reporting portal to meet the reporting requirements established under the Act.

This article is not intended as legal advice and should not be used as such. When legal questions arise, pharmacists should consult with attorneys familiar with the relevant drug and pharmacy laws.
What is the best way for busy pharmacists to ensure they give each patient the time and attention needed for them to learn about their medications?

The key is to make counseling the patient your number one priority while they are there in front of you, said Stacey D. Curtis, PharmD, Clinical Assistant Professor at the University of Florida College of Pharmacy, Gainesville.

“The person standing in front of you who needs to be educated becomes your number one priority throughout your day,” Dr. Curtis said. “The person the phone or the prescription that needs to be typed or reviewed then takes the second seat.”

Patient care must be the number one priority, and education is patient care, Curtis added. Education translates to better patient compliance and adherence to medication regimens, she added. “If patients are educated, we reduce healthcare costs and improve their quality of life.”

The key to ensuring that the person being counseled gets the undivided attention of the pharmacist is a properly managed workflow in the pharmacy, Dr. Curtis said. Managing time can be difficult when there are 300 or more prescriptions in the queue and the pharmacy is short staffed, she added. “I get it. I’ve been doing that for a long time.”

In addition to her position at the University of Florida, Dr. Curtis has been a community pharmacist for 19 years. She currently works at a big-box store in Gainesville that deals with a varied community that includes many with low health literacy. “You must greet them, acknowledge them, and observe their understanding,” she said. And it is not a matter of spending a set number of minutes with each patient, she stressed, because it depends on making sure they understand what they need to know before they leave.

In a well-managed workflow, everything needs to be taken care of in a timely manner “You don’t walk into a pharmacy knowing that your first day,” Dr. Curtis said. But if the prescriptions waiting to be checked have all been input correctly and only need verification, “then I am in good standing,” she said. “It is not about adding time to your day. It is more about really using your time to the best of your ability.”

“You also need the proper support to manage workflow,” she stated. Everyone in the pharmacy needs to be cross-trained so that they can fill in when someone calls in sick or if the pharmacy is swamped. Pharmacy staff must also be trained to understand that a pharmacist who is counseling a patient should only be interrupted when absolutely necessary, she added.

Few things hinder a pharmacist’s ability to function at their highest level of care as much as not having enough trained staff or pharmacy technicians, Dr. Curtis said. “That is the biggest impediment that we face today.”

At the University of Florida, Curtis teaches a professional practice skills lab with two other professors. It is a yearlong class teaching what a pharmacist needs to know in the day-to-day operations of a community pharmacy. It is a required course for all first-year pharmacy students. She also teaches a course on advanced topics in community pharmacy that in part how to manage workflow. “There is no book on managing workflow in a pharmacy,” she said. “We actually made up our own curricula.”

Valerie DeBenedette is the Managing Editor of Drug Topics.
Drug Abuse
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conveyed the message that “chain pharmacy supports the adoption of laws and policies that authorize pharmacists to dispense naloxone without a patient-specific prescription from a prescriber, such as via statewide protocols. This approach serves to make naloxone more accessible for overdose prevention purposes.”

In a 2015 letter to the National Alliance for Model State Drug Laws, NACDS urged the alliance to “promote state laws and policies that eliminate administrative barriers to pharmacist-provided naloxone. Pharmacists are recognized medication experts who are well-situated in communities to improve access to naloxone…. community pharmacists are the most readily accessible healthcare providers for some individuals.”

The chain pharmacy organization also urged the Alliance to “pursue liability protections for all health care providers, including pharmacists, who prescribe and dispense naloxone in good faith. Such liability protections can help to eliminate the fears of health care providers who may otherwise be wary of providing naloxone because of liability concerns.” In the letter, NACDS noted that recent laws have addressed this issue.

CVS explained that in each state where naloxone is available without a prescription, the chain “has entered into a collaborative practice agreement or standing order agreement with a prescriber to dispense naloxone, for patients. As such, the patient does not need to present an individual prescription for naloxone, but it remains a prescription medication that is dispensed at the pharmacy counter. These are similar to the agreements we have in place that allow pharmacists to provide flu shots to patients without an individual prescription.” In some states, according to information provided by NACDS, the collaborative agreement is through the Board of Pharmacy.

In addition to complying with state protocols, individual training is important for pharmacists who are involved in dispensing naloxone without a prescription. At both Walgreens and CVS, such pharmacists undergo a training program, as well as completing any training an individual state may require. CVS has developed training in coordination with the Boston University School of Medicine. “Following the training, CVS pharmacists who dispense naloxone are able to counsel patients and caregivers on a number of important points, including identifying an overdose, calling 911, giving rescue breaths, administering naloxone, and remaining with patients until help arrives,” said the CVS spokesperson. “When naloxone is dispensed, training is provided [to patients] on how to use the medication, including steps to contact 911, as naloxone is not a substitute for medical care, and anyone who is administered the drug should seek immediate medical attention,” said Phil Caruso, a spokesman for Walgreens.

In early 2017, Walgreens plans to further expand the naloxone program to Arkansas, California, Connecticut, Iowa, Kentucky, Nevada, and Tennessee. “We’re committed to making the medication easier to obtain and will continue to make the medication available state-by-state where regulations allow,” Caruso said. CVS Health agrees. “We support the expanded availability of naloxone and are exploring opportunities in other states.”

Kathleen Gannon Longo is a Contributing Editor.

Hazardous
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CJCP, a principal consultant with the Medication Management and Safety Joint Commission Resources Joint Commission International in Oak Brook, IL. This person must understand the chapter and the risks of hazardous drug exposures. There will be a lot of documents that will need to be developed and standard operating procedures that must be created. “It is a considerable assignment,” she said.

However, there are resources to help. “There are tools that have been created for you to see where you are in compliance with <800>,” Mansur said. The Joint Commission has created a self-assessment tool that is available online at http://www.hazmedsafety.com. There is also a book, Safe Handling Practices for Hazardous Drugs, that contains information, checklists, and training materials, and which is also available at the same website, she added.

In addition, USP has a list of frequently asked questions about Chapter <800> at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.

The symposium was to have been led by Thomas H. Connor, PhD, Research Biologist with NIOSH and the CDC in Cincinnati. Connor could not attend.

Valerie DeBenedette is Managing Editor of Drug Topics.
EDUCATIONAL OBJECTIVES

GOAL: Prepare pharmacists with the knowledge they need to have to provide contemporary pharmacologic therapy to patients with hyperlipidemia.

After participating in this activity, pharmacists will be able to:

> List the benefits and limitations of cholesterol-lowering therapies approved before 2014
> Describe PCSK9 genetic polymorphisms and their contributions to LDL and cardiovascular risk
> Describe PCSK9 inhibitors’ mechanism of action, and their specific actions that address previously unaddressed needs
> Review clinical trial evidence and assimilate finding to understand PCSK9 inhibitors’ safety and efficacy
> Discuss PCSK9 inhibitors’ place in therapy
> Describe the administration technique for available injectable PCSK9 inhibitors

After participating in this activity, pharmacy technicians will be able to:

> Recall traditional approaches to cholesterol management
> Identify newer cholesterol-lowering agents, and know their unique uses and dispensing storage requirements
> Recognize when to refer patients to the pharmacist for cholesterol counseling

Introduction

Over the past several years, experts in cardiology and endocrinology have made a major shift in the way that they approach the management of their patients’ lipids. Although statins still rule the initial management of patients with elevated low-density lipoprotein (LDL), the importance of adjunctive therapy is emerging. This article explores the evolution of major clinical guidelines and the literature base that prompted those changes; identifies the most promising adjunctive antihyperlipidemic agents; delineates the pharmacologic and pharmacokinetic advantages and disadvantages of antihyperlipidemic agents; focuses on PCSK9 inhibitors; and defines the role of the pharmacist in the contemporary care of patients with hyperlipidemia.

National guidelines for lipid management

Lipoproteins are defined as very-low-density lipoproteins (VLDL), calculated as 20% of triglyceride concentrations), LDL, and high-density lipoprotein (HDL).1,2 High native HDL concentrations provide some level of cardioprotection. Total cholesterol (LDL + VLDL

Abstract

Many recent advances in the understanding of lipid management greatly impact the profession of pharmacy and individual pharmacists. Clinical trial evidence has re-established the need to achieve aggressive lipid lowering, including the use of adjunctive therapy when statins are insufficient. Ezetimibe and the PCSK9 inhibitors are some of the most promising agents for adjunctive therapy, although many drugs used for lipid management have their advantages and disadvantages. Pharmacists need to understand why guidelines are evolving and how we can assure that patients reach optimal outcomes.
Major national lipid guidelines

National Cholesterol Education Program (NCEP) adult treatment panel guidelines were published in 2002 and remained in effect through 2013. They recommended achieving an LDL cholesterol level commensurate with the patient’s baseline risk of cardiovascular disease. Those with cardiovascular disease or the highest risk of cardiovascular disease had to achieve an LDL less than 100 mg/dL, although a level less than 70 mg/dL was acceptable when those with moderate or low cardiovascular disease risk had to achieve LDL levels less than 130 mg/dL or less than 160 mg/dL, respectively. The non-HDL cholesterol goals were 30 mg/dL above the LDL goals for each category of cardiovascular risk. The guidelines did not specify a preferred agent for cholesterol management and advocated for aggressive multidrug therapy if needed to achieve LDL and non-HDL goals. The authors of the guidelines initially designed the document using epidemiologic data and then assessed clinical trial data to see if it supported their epidemiologic orientation.

In 2013, the American College of Cardiology and the American Heart Association (ACC/AHA) took over the role of hypercholesterolemia guideline creation from NCEP. ACC/AHA guidelines stress the pre-eminence of statin therapy with a dosing intensity dictated by a patient’s cardiovascular risk. Patients younger than age 75 years with atherosclerotic cardiovascular disease (ASCVD; history of acute coronary syndromes [unstable angina, myocardial infarction (MI)], stable angina, stroke or transient ischemic attack, peripheral arterial disease of atherosclerotic origin, or arterial revascularization [coronary, cerebrovascular, leg artery]), LDL concentration above 190 mg/dL (which includes most patients with heterozygous and homozygous familial hypercholesterolemia [FH]), and those with a 10-year ASCVD risk more than 7.5% (based on ACC/AHA risk calculator; www.cvriskcalculator.com) should utilize high-intensity statin therapy. Atorvastatin 40–80 mg or rosuvastatin 20–40 mg are considered high-intensity statin therapy because both reduce an average patient’s LDL more than 50%.

Patients with diabetes mellitus who do not meet the criteria for high-intensity therapy, patients with a 10-year risk of ASCVD between 5% and 7.4%, and those not tolerating higher-intensity statin therapy can consider a moderate-intensity statin therapy. Atorvastatin 10–20 mg, rosuvastatin 5–10 mg, simvastatin 20–40 mg, pravastatin 40–80 mg, lovastatin 40 mg, fluvasstatin 80 mg, or pitavastatin 2–4 mg are moderate-intensity statins because these reduce LDL by 30% to 49%. If patients do not tolerate or are likely to not tolerate high-intensity statin therapy, moderate-intensity statin therapy should be employed. In persons older than age 75 years, the guideline does not insist on treating it with pharmacotherapy or on any intensity of statin therapy. For all patients, once the maximum tolerated statin dose is achieved, the ACC/AHA 2013 guidelines state that a nonstatin drug may be considered to further reduce LDL, but the benefits and risks, drug interactions, and patient preference should be considered, and the ACC/AHA had no preference about whether or not it should be used.

In August 2016, the European Society of Cardiology (ESC) along with the European Atherosclerosis Society (EAS) developed their guideline. Its recommendations are a hybrid of the NCEP and the ACC/AHA 2013 approaches. Patients with ASCVD, diabetes mellitus, or chronic kidney disease are considered high or very high risk. For all other patients, they recommend using the Systematic Coronary Risk Evaluation (SCORE) system, which estimates the 10-year cumulative risk of a first fatal ASCVD event (scoring criteria given in ESC/EAS 2016 guidelines), unlike the ACC/AHA CV risk calculator, which estimates fatal and nonfatal event risk. Low and moderate ASCVD death risk have a 10-year risk of less than 1% and 1% to 5%, while those with risks of 5% to less than 10% and 10% or greater are classified as high or very high risk, respectively. All patients with ASCVD are considered very high risk, as are those with diabetes mellitus who have target organ damage such as retinopathy or nephropathy. Patients with a marked elevation in total cholesterol (>310 mg/dL) or blood pressure (>180/110 mm Hg) would be considered high risk even if the SCORE risk was less than 5%, as would all other patients with diabetes mellitus. In patients at very high ASCVD risk, an LDL goal of less than 70 mg/dL or a 50% or greater reduction from baseline if the LDL is 70 to 135 mg/dL is recommended. In patients at high ASCVD risk, an LDL goal of less than 100 mg/dL or a 50% or greater reduction from baseline if the LDL is 100 to 200 mg/dL is recommended. In subjects at low or moderate risk, a target LDL of less than 115 mg/dL is recommended. Statins are considered the preferred baseline therapy in all patients not achieving their goal, and the dose should be maximized to achieve the LDL goal or to the maximum tolerated dose. Unlike
### Table 1: Pharmacologic and safety comparison of different lipid-lowering medications

<table>
<thead>
<tr>
<th>MECHANISM OF ACTION</th>
<th>USE IN UNSTABLE ELEVATED LIPS</th>
<th>MUSCLE TOXICITY POTENTIAL</th>
<th>PREGNANCY/ BREASTFEEDING</th>
<th>DRUG INTERACTIONS</th>
<th>GI ADR POTENTIAL</th>
<th>NOTES</th>
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</thead>
<tbody>
<tr>
<td>PCSK9 inhibitors</td>
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</tbody>
</table>
| Blocks PCSK9, extends life of LDL receptors that take LDL out of the circulation | Yes | +/− | Yes | Pregnancy: No human data, animal data show no risk | Pregnancy: No known interactions, eliminated by saturable binding to PCSK9 and nonsaturable proteolysis | * | Skin ADRs Injection pain, bruising, rash, eczema, erythema, urticaria
|                     |                               |                            |                         |                   |                  |       |
| Statins             |                               |                            |                         |                   |                  |       |
| Block HMG CoA, a critical step in cholesterol synthesis | No |‡ | Yes | Pregnancy: Category C | Pregnancy: Category X | All statins: avoid use/caution with cyclopiazonic acid | * | Best initial therapy for high cholesterol, most evidence for benefit
|                     |                               |                            |                         |                   |                  |       |
| Fibrates            |                               |                            |                         |                   |                  |       |
| Activates lipoprotein lipase | No |‡ | ** | Gem: Yes, but monitor | Fibrates: Contra-indicated in severe renal dysfunction, dose altered in impaired renal function | Fibrates: Increased INR | Gem | No use in gallbladder ducts
|                     |                               |                            |                         |                   |                  |       |
| Niacin              |                               |                            |                         |                   |                  |       |
| Hepatocyte diacylglycerol acyltransferase-2 inhibitor, leads to breakdown of VLDL and LDL particles | No |‡ | Use with caution | Pregnancy: Category C | Pregnancy: Category C | Niacin increases risk of myopathy with statins | **+ | Dyspepsia, nausea (take with food), diarrhea (only 1 dose 10 mg)
|                     |                               |                            |                         |                   |                  |       |
| Ezetimibe           |                               |                            |                         |                   |                  |       |
| NPC1L1 protein inhibitor, leads to less dietary and biliary cholesterol absorption | No |‡ | Use with caution | Pregnancy: Category C | Pregnancy: Category C | Ezet + Feno = Increased gallbladder risk | * | Only 1 dose (10 mg)
|                     |                               |                            |                         |                   |                  |       |
| Lomitapide          |                               |                            |                         |                   |                  |       |
| Microosomal triglyceride transfer protein inhibition, necessary for VLDL assembly and secretion in the liver | No |† | Yes | Pregnancy: Category X | Pregnancy: Category X | Contraindicated with CYP3A4 inhibitors | +++ | Diarrhea, nausea, dyspepsia, flatulence
|                     |                               |                            |                         |                   |                  |       |
| Mipomersen          |                               |                            |                         |                   |                  |       |
| Antisense oligonucleotide to apo B-100 mRNA, needed to create LDL and VLDL | No |† | Not recommended with severe renal impairment, proteinuria, or dialysis | Pregnancy: Category B | Pregnancy: Category B | No kinetic interactions with statins, ezetimibe, warfarin (can be used safely together) | ° | SQ dosing only
|                     |                               |                            |                         |                   |                  |       |
| BAS                 |                               |                            |                         |                   |                  |       |
| Binds cholesterol-rich bile acids, prevents enteropathic recycling of cholesterol | Yes | − | Yes | Pregnancy: Category B | Pregnancy: Category B | Attenuates absorption of lipid and diabetes medications, levothyroxine, oral contraceptives, omeprazole, digoxin, warfarin, fat-soluble vitamins | °° | Constipation bloating

*Little to no effect; ‡‡ Major effect; ‡ No effect; ?? Unknown effect. Note: Pregnancy category A is safest, followed by B, C, and D, with X being the worst of all. Abbreviations: ADRs, adverse drug reactions; ASA, aspirin; Atorva, atorvastatin; BAS, bile acid sequestrant; Conc, concentration; Ezet, ezetimibe; Feno, fenofibrate; Gem, gemfibrozil; Gl, glucose intolerance; INR, international normalized ratio; LDL, low-density lipoprotein; LFTs, liver function tests; Loa, lovastatin; NPC1L1, Niemann-Pick C1 like 1; Pitava, pitavastatin; Prava, pravastatin; Rosuva, rosuvastatin; Simva, simvastatin; SQ, subcutaneous; VLDL, very-low-density lipoprotein.

Source: Refs 5,7,10,11
Clinical trials driving differences in the guidelines

Although the NCEP guidelines were driven by epidemiologic associations, the ACC/AHA and the ESC/EAS 2016 guidelines are driven primarily by randomized, controlled trials. The results of major placebo-controlled trials in patients with ASCVD (CARE, LIPID, HPS, GREACE) show that set doses of statins reduce the occurrence of subsequent coronary events and mortality versus placebo. In patients with elevated LDL levels but no ASCVD, major placebo-controlled trials (WOSCOPS, AFCAPS/TexCAPS, ASCOT-LLA) show that set doses of statins reduce ASCVD events and may also reduce mortality versus placebo. In 2 clinical trials of patients with ASCVD and 1 trial of patients without ASCVD, using higher-intensity statin therapy (secondary prevention: PROVE-IT, TNT; primary prevention: JUPITER) was associated with better outcomes than those seen with the use of moderate-intensity statin therapy. At the time that the ACC/AHA 2013 guidelines were being constructed, however, major clinical trials demonstrated no additional benefits when fenofibrate, niacin, or the experimental cholesteryl ester transfer protein inhibitors were used with statins versus statins alone (AIM-HIGH, HPS2-THRIVE, ACCORD, ILLUMINATE). This lack of literature support for achieving better results when such adjunctive therapy was added to a statin was the reason the ACC/AHA guidelines abandoned the specific target LDL goals of the NCEP, which had advocated for multidrug therapy if needed to achieve them.

Until June 2015, we lacked data from randomized, controlled trials suggesting that adding a drug to a statin for further lowering of LDL reduced the occurrence of ASCVD events more than using a statin alone. This changed with the publication of the Improved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT). Patients (n=18,144; median follow-up, 6 years) within 10 days of a recent MI or unstable angina event were randomized to receive ezetimibe 10 mg daily plus simvastatin 40 mg or simvastatin 40 mg alone. The primary endpoint was a composite of cardiovascular death, nonfatal MI, unstable angina requiring hospitalization, coronary revascularization, or nonfatal stroke. Those receiving ezetimibe plus simvastatin had a lower on-treatment LDL (53.7 mg/dL vs 69.5 mg/dL, \( P<.001 \)) and fewer ASCVD events (32.7% vs 34.7%, \( P=.016 \)) than those receiving simvastatin alone. Rates of muscle, gallbladder, and hepatic adverse effects and cancer were similar between the groups, making the balance of benefit to harm very favorable.

Although this is the first and most compelling data that lowering LDL levels with adjunctive therapy is better than using a statin alone, there are some limitations. First, the group was very high risk for recurrent ASCVD events, having just experienced one within the past 10 days, and they compared adjunctive therapy with ezetimibe on top of moderate-rather than high-intensity statin therapy.

None of the PCSK9 inhibitor trials completed to date assessed mortality or cardiovascular events as a prespecified primary outcome. In a meta-analysis, however, PCSK9 monoclonal antibodies reduced the odds of experiencing all-cause mortality by 55% (\( P=.015 \)) and MI by 51% (\( P=.03 \)). It should be noted that the researchers used a fixed-effect model to pool these studies, while a random-effects model might have been more prudent given the clinical and methodologic heterogeneity in the constituent studies. The ODYSSEY LONG TERM trial had 49% and 84% of the weight for the all-cause mortality and MI outcomes, respectively, and warrants separate discussion. Patients (n=2341) at high risk for cardiovascular events with LDL concentrations 70 mg/dL or higher despite maximum tolerated statins received alirocumab 150 mg or placebo subcutaneously injection every other week. The patient’s LDL was reduced from 123 mg/dL to 48 mg/dL in the alirocumab group. In a post-hoc analysis, the alirocumab group had a lower occurrence of major adverse cardiac events (MACE; death from coronary disease, nonfatal MI, nonfatal ischemic stroke, or unstable angina requiring hospitalization) than placebo (1.7% vs 3.3%; \( P=.02 \)) but was driven primarily by reductions in nonfatal MI (0.9% vs 2.3%; \( P=.01 \)).

When the data from adjunctive ezetimibe and PCSK9 inhibitor therapy versus statin alone trials are viewed along with the higher-versus lower-intensity statin therapy trials, the most likely assumption is that lowering LDL to a greater extent further reduces ASCVD events, a conclusion built into the ESC/EAS 2016 guidelines but not able to be incorporated in the ACC/AHA 2013 guidelines.

Comparing pharmacologic agents that lower LDL

Table 1 compares and contrasts the pharmacologic and safety features of the main antihyperlipidemic agents being used in the United States. Some agents have advantages in patients with liver or renal disease, in pregnancy or lactation, and in terms of gastrointestinal tolerability, muscle symptomatology, and drug interactions. The agents also differ in terms of the expected range of LDL reductions that can be expected as denoted in Figure 1. Lipid apheresis (in which a dialysis-like machine is used to extract lipoproteins from the bloodstream), PCSK9 inhibitors, and high-intensity statin therapy have the greatest ability to reduce LDL, with the first 2 options being markedly expensive. Lipid apheresis is also inconvenient, however, because a patient has to go to a health system and be hooked up to the machine. Lomitapide and mipomersen are options in patients with homozygous FH, but are...
Spotlight on PCSK9 inhibitors

LDL receptors are expressed on the surface of hepatocytes. The receptor binds LDL and is internalized, the LDL detaches, and the LDL receptor re-emerges on the cell surface while the LDL is broken down. The normal LDL receptor is recycled approximately 150 times before being broken down itself. PCSK9, however, binds to the LDL receptor and prevents it from releasing its bound LDL once internalized. This leads to premature LDL degradation and increases circulating LDL concentrations. PCSK9 inhibitors are monoclonal antibodies that prevent PCSK9 from binding LDL receptors and therefore prolong the receptors’ effective life. People with dysfunctional PCSK9 have lower circulating LDL and lower risk of ASCVD events.

Evolocumab and alirocumab are both indicated as adjunctive to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous FH or clinical ASCVD who require additional lowering of LDL. Evolocumab is also indicated for patients with homozygous FH receiving other LDL-lowering therapies such as statins, ezetimibe, or LDL apheresis who require additional lowering of LDL.

The impact of these agents on efficacy, safety, and tolerability endpoints in patients without homozygous FH is displayed in Table 1 and Figure 1. This data was derived from numerous well-conducted trials in patients with heterozygous FH or a high risk of cardiovascular disease. In patients with homozygous FH, only evolocumab has been assessed. In the TESLA-B trial, the use of adjunctive injectable evolocumab reduced LDL by 31% (P<.001) versus placebo, which is in line with that seen with other drugs approved for homozygous FH such as lomitapide and mipomersen.

At the European Atherosclerosis Society meeting in June 2016, researchers presented the results of the open-label and single-blinded TAUSSIG trial. In patients with homozygous FH, adjunctive evolocumab reduced LDL by 23%, and over 1.7 years of follow-up, there were no deaths and the annualized cardiac event rate was 2.1%. This is less than the 3.5% estimated annual event rate in other trials conducted in homozygous FH patients receiving statin plus ezetimibe.

Role of pharmacists in contemporary practice

Changing back from a statin-driven guideline to an LDL goal-derived guideline is very important for the practicing pharmacist. Technicians could refer patients with known genetic predilection to hypercholesterolemia, those complaining of a family history of premature MI or ischemic strokes, or patients with cardiac disease currently to the pharmacist for a more in-depth assessment of the adequacy of their lipid-lowering therapy. Pharmacists should start with statins and try to maximize the dose before seeking adjunctive therapy. Ezetimibe has stronger outcome data than the PCSK9 inhibitors, with a lower drug acquisition cost and more-convenient oral dosing making it the first adjunctive treatment of choice. Data show that niacin and fibric acid derivatives lack additional final health outcome benefits when added to statins and have a less favorable safety profile than the PCSK9 inhibitors. This makes the PCSK9 inhibitors the preferable second-line adjunctive therapy. This is also true in patients with homozygous FH who are on statins and ezetimibe where PCSK9 inhibitors have distinct liver safety advantages over mipomersen and lomitapide with similar lipid benefits.

Although these are evidence-based standard recommendations for the average patient, many patients have coexisting diseases and disorders, drug intolerances, and adverse events and by using combinatorial drugs, making standard recommendations implausible. For example, patients resisting self-injection or the high
Drug counseling on signs and symptoms of adverse effects, expected benefits when the patients are compliant, and proper administration times and approaches are critical. Spacing bile acid sequestrants from drugs like statins (giving the bile acid sequestrant 3–4 hours apart from statins, lovastatin, warfarin, and digoxin), using pravastatin and fluvastatin at bedtime, and taking niacin with food to avoid stomach upset are all useful tips. Some patients starting on PCSK9 inhibitors will need to understand how to administer a subcutaneous injection, and pharmacists, with their certifications for immunizations, are increasingly prepared to counsel them on safe use. 

PCSK9 inhibitors are refrigerated and must be warmed to room temperature for 30 to 40 minutes before use, but discarded if at room temperature for 24 hours or longer. The drug product should be inspected visually and if the solution is discolored or contains visible particulate matter, it should not be used. Standard aseptic injection technique is required for every injection. Subcutaneous injections into the thigh, abdomen, or upper arm area are advisable but not if those areas are burned, inflamed, infected, or if a rash is noted. Patients should rotate injection sites, and PCSK9 inhibitors should not be injected into the same site as other injectable medication. Some fine tuning of this counseling based on whether the injections come in a syringe, pen, or autoinjector will be needed.

**Conclusion**

There is a new shift in the paradigm of lipid management. The resumption of LDL goals provides great opportunities for pharmacists to have an important impact on the healthcare team and in patients’ lives, but it requires knowledge of the guidelines themselves, the clinical trials that underlie them, and unique pharmacologic and pharmacokinetic properties of the drugs that are available for use.

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**REFERENCES**


NEW OPTIONS WHEN STATINS ARE NOT ENOUGH

TEST QUESTIONS

FOR PHARMACISTS

1. What type of data did NCEP guidelines primarily use when defining the LDL goals of individual patients?
   a. Randomized controlled trials
   b. Uncontrolled clinical trials
   c. Epidemiologic studies
   d. Case reports

2. Why did ACC/AHA 2013 guidelines not recommend LDL goals like the NCEP guidelines and instead strongly advocate for different intensities of statin therapy with no position on use of adjunctive therapy?
   a. Because clinical trials conducted to that point assessed set doses of statins of different intensities to reduce ASCVD risk, not statin therapy linked to specific target LDL goals, and found no additional benefits from using adjunctive therapy
   b. Because no studies were conducted adding another lipid-altering drug to statins versus a statin alone
   c. Because the ACC/AHA as a rule does not publish guidelines with target goals for diseases
   d. Because statins were so widely used it would make it easier for clinicians to adopt their guidelines

3. According to ACC/AHA 2013 guidelines, what type of statin therapy is recommended for use in those >75 years with or without ASCVD?
   a. High intensity
   b. Low intensity
   c. Moderate intensity
   d. They do not insist on the use of statins or a statin dose intensity.

4. What is the major difference between the ACC/AHA 2013 CV risk calculator and the ESC/EAS 2016 SCORE risk system?
   a. ACC/AHA 2013 calculator uses risk over 20 years instead of 10 years.
   b. ACC/AHA 2013 calculator uses risk over 10 years instead of 20 years.
   c. ACC/AHA 2013 calculator determines risk of all ASCVD events, while ESC/EAS 2016 SCORE only determines fatal ASCVD events.
   d. There is no difference, they calculate the same type of risk over the same time period.

5. What LDL goals are recommended by ESC/EAS 2016 guidelines?
   a. Very high risk = LDL <90 mg/dL; high risk = LDL <110 mg/dL; low-to-moderate risk = LDL <130 mg/dL
   b. Very high risk = LDL <70 mg/dL; high risk = LDL <100 mg/dL; low-to-moderate risk = LDL <115 mg/dL
   c. Very high risk = LDL <40 mg/dL; high risk = LDL <70 mg/dL; low-to-moderate risk = LDL <100 mg/dL
   d. Very high risk = LDL <100 mg/dL; high risk = LDL <130 mg/dL; low-to-moderate risk = LDL <160 mg/dL

6. According to ESC/EAS 2016 guidelines, which adjunctive agent is preferred when statins are insufficient to achieve LDL goals?
   a. Ezetimibe
   b. Niacin
   c. Fenofibrate
   d. Evolocumab

7. What did the PROVE-IT, TNT, and JUPITER trials show?
   a. That higher-intensity statin therapy was not better than moderate-intensity statin therapy at reducing ASCVD events
   b. That higher-intensity statin therapy was the same as moderate-intensity statin therapy at reducing ASCVD events
   c. That higher-intensity statin therapy was better than moderate-intensity statin therapy at reducing ASCVD events
   d. That statins were better than other lipid-lowering drugs at reducing ASCVD events

8. Why was the IMPROVE-IT trial so impactful on the ESC/EAS 2016 guidelines and clinical care?
   a. It showed for the first time that bile acid sequestrants provided the same ASCVD event reductions as statins.
   b. It showed for the first time that bile acid sequestrants provided better ASCVD event reductions than statins.
   c. It showed for the first time that bile acid sequestrants provided inferior ASCVD event reductions than statins.
   d. It showed for the first time that adding ezetimibe to a statin was better at reducing ASCVD events than using a statin alone.

9. Which of the following drugs are known to be harmful to the developing fetus as designated by a Category X status?
   a. Statins, lomitapide
   b. Lomitapide, mipomersen
   c. Fibrates, ezetimibe
   d. Statins, fibrates

10. Which of the following statins would have the lowest risk of drug interactions when combined with CYP3A4 inhibitors?
    a. Simvastatin
    b. Lovastatin
    c. Rosuvastatin
    d. Atorvastatin

11. Which of the following drugs do not have a high risk of GI effects such as nausea or diarrhea?
    a. PCSK9 inhibitors
    b. Niacin
    c. Lomitapide
    d. Fibrates

12. Which of the following drugs can raise serum uric acid concentrations making it riskier in patients with gout?
    a. Fibates
    b. Bile acid sequestrants
    c. Mipomersen
    d. Niacin

13. Which of the following can decrease absorption of fat-soluble vitamins?
    a. Bile acid sequestrants, lomitapide
    b. Ezetimibe, statins
    c. Statins, mipomersen
    d. Mipomersen, lomitapide

14. Which of the following drugs have the greatest ability to reduce LDL cholesterol?
    a. Low-intensity statins
    b. PCSK9 inhibitors
    c. Niacin
    d. Fibrates

15. How does blocking PCSK9 help reduce LDL cholesterol from the circulation?
    a. It reduces LDL receptor manufacture.
    b. It enhances LDL receptor manufacture.
    c. It reduces LDL receptor destruction.
    d. It enhances LDL receptor destruction.
16. Which of the following drugs is linked appropriately with an important potential drawback?
   a. Ezetimibe = subcutaneous dosing only
   b. Fibrates = contraindicated in gallbladder disease
   c. PCSK9 inhibitors = serious drug interactions
   d. Mipomersen = contraindicated with active peptic ulcer disease

17. If there is a patient who cannot use a statin, what is a limitation of ezetimibe monotherapy?
   a. It only reduces LDL by an average of 18% and patients are unlikely to achieve their ESC/EAS 2016 LDL goal.
   b. It reduces LDL by an average of 60% and patients are likely to have an LDL that is too low and require discontinuation of therapy.

18. When counseling a patient on alirocumab administration, what are the following points should be stressed?
   a. Swallow the tablet and stay upright for 30 minutes.
   b. Premedicate with aspirin to prevent the flushing response.
   c. Inject into the thigh, abdomen, or upper arm and rotate the site.
   d. Inject into the buttocks or thigh and rotate the site.

19. Why should a patient look at their PCSK9 injection before injecting it?
   a. To be sure it contains the right volume
   b. To be sure it is free of particulate matter
   c. To be sure it is not discolored
   d. B and C are both correct

20. How long should evolocumab be left out of the refrigerator before injecting?
   a. 10 min  b. 30 min  c. 20 min  d. 24 hr

FOR PHARMACY TECHNICIANS

1. Which of the following drugs is a PCSK9 inhibitor?
   a. Evolocumab
   b. Ezetimibe
   c. Niacin
   d. Lovastatin

2. If you see someone buying over-the-counter niacin, which of the following is a reason to have the patient consult the pharmacist before letting them purchase it?
   a. It can raise uric acid levels.
   b. Should not be used in people with active peptic ulcer disease
   c. It can have drug interactions with other medications like statins and bile acid sequestrants.
   d. All of the above

3. PCSK9 inhibitors can only be injected into the following type of skin:
   a. Inflamed
   b. Freckled
   c. Skin with a rash
   d. Burned

4. Which of the following 2 lipoproteins are both associated with ASCVD when their concentrations are too high?
   a. HDL, LDL
   b. VLDL, HDL
   c. LDL, VLDL
   d. PBL, HDL

5. Why should statins be avoided in patients receiving colchicine or dapptomycin?
   a. Increased risk of liver disease
   b. Increased risk of kidney disease
   c. Increased risk of myopathy
   d. Decreased ability to lower LDL

6. What drug should be used first for most patients with elevated LDL cholesterol?
   a. Fibrates
   b. Statins
   c. Bile acid sequestrants
   d. Lomitapide

7. Which of the following drugs is the least expensive?
   a. Lomitapide
   b. Mipomersen
   c. PCSK9 inhibitor
   d. Ezetimibe

8. How many times is an LDL receptor usually recycled before it is broken down by the body?
   a. 10
   b. 15
   c. 100
   d. 150

9. According to the ESC/EAS 2016 guidelines, what is the LDL goal for someone with the highest risk of ASCVD?
   a. <30 mg/dL
   b. <70 mg/dL
   c. <90 mg/dL
   d. <120 mg/dL

10. Which statin can increase the risk of spilling a protein in the urine?
    a. Lovastatin
    b. Simvastatin
    c. Pitavastatin
    d. Rosuvastatin
nistration will allow importation of drug products as a means of increasing price competition.

Meanwhile, health-system pharmacists’ jobs will continue to move from dispensing and distribution tasks to clinical activities that include prescribing, according to the FPs.

“As part of this transition, pharmacists in many states have been granted authority to modify medication therapy and order medication-related laboratory tests,” the forecast said. “These changes, coupled with a shortage of primary care physicians, will result in pharmacists routinely having prescribing authority in health systems.”

In fact, 35% of FPs agreed that it is very likely that pharmacists in at least 75% of health systems will have prescribing authority within the next five years.

In addition, as pharmacy departments become more complex and operational budgets grow, “there will likely be more management positions held by non-pharmacists who have training in business, accounting, logistics, and other areas,” the forecast said. Fifty-eight percent of FPs felt that it is very likely or somewhat likely over the next five years that at least 10% of health systems will hire a non-pharmacist professional manager to assist the chief pharmacist in high-stakes management functions.

There is good news in the forecast for pharmacy technicians as well. While many techs view their work as an interim position—they do not invest in training and often do not stay in the role for long—some health systems have developed tech career ladders and similar structures that provide advancement opportunities. Thirty percent of FPs predicted that it is very likely that at least half of health systems will have formal career ladders for pharmacy technicians within the next five years; nearly 40% considered this somewhat likely.

The surplus of new pharmacy graduates—nearly doubling between 2001 and 2015 with 13,994 graduates—should decline in the future. “Reflecting growing concern about future job prospects for pharmacists, the number of applicants for admission to pharmacy schools appears to have plateaued,” the report said. And 61% of FPs agreed that it is very likely or somewhat likely that there will be a reduction of at least 10% in overall enrollment in PharmD programs over the next five years.

Christine Blank is a Contributing Editor.

Walgreens and Florida Hospital plan retail health clinic and pharmacy collaboration

Florida Hospital in Tampa, and Walgreens announced a retail health clinic and pharmacy alliance designed to deliver coordinated care and provide greater access to patients across the Tampa area.

Under terms of the agreement, Florida Hospital will operate and provide all clinical services at 15 retail health clinics located within Walgreens stores in the Tampa region.

The retail health clinics will be called Florida Hospital Express Care at Walgreens.

Later in the year, Walgreens plans to open a pharmacy at Florida Hospital Tampa.

In a press release, Pat Carroll, MD, Chief Medical Officer for Walgreens Healthcare Clinics, said the announcement is an example of how Walgreens is developing new and innovative relationships with community health systems. “These are collaborations that offer our patients a true continuum of care and provide more convenient access to a trusted healthcare provider in the community,” said Dr. Carroll.

According to Walgreens, the retail chain and Florida Hospital will also form a collaborative council to share best practices and experiences that aim to improve patient care, quality and satisfaction while reducing health care costs.

Florida Hospital Express Care at Walgreens will operate seven days a week, including evenings.

Anthony Vecchione is Executive Editor of Drug Topics.
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It is said the foremost ethical duty of any healthcare professional is “First, Do No Harm.” Most pharmacists interpret that to mean fill the prescription correctly—with the right drug in the right strength and with a label that correctly states the dose as prescribed. First do no harm seems so simple. It is simple—but it is not easy.

Research by Auburn University College of Pharmacy found a “significant” error rate in community pharmacies was about one error in every one thousand (1/1,000) prescriptions filled.1 Compare that with a community pharmacy in Iowa City, Iowa, which had a significant error rate of one in ten thousand (1/10,000).2

Within the last few years almost every hospital and community pharmacy has installed some form of continuous quality improvement (CQI) program in their workflow. Today almost every pharmacy owner, manager, and administrator realizes the dangers of errors in pharmacy dispensing. To combat this risk of injury to a patient, the people in charge have invested the money and time into CQI. As Dr. Edwards Deming, the father of virtually all quality programming in United States pharmacies, taught, the job of the boss is to provide for the workers the tools needed to increase quality.3 Pharmacy has done that.

The tools for improving quality are available to almost every pharmacist and pharmacy technician in the pharmacies where they work. The bosses have completed the first two steps in any CQI program—they have provided the tools to identify the risks where a mechanical error could occur and they have provided the tools to reduce the risks of an error reaching a patient.

The job now rests on the pharmacists and pharmacy technicians who work on the front line of dispensing. Their job is to make the system work. This may be the weakness in pharmacy’s march to quality. Pharmacists and technicians must study each safety step built into the CQI program in their pharmacy and educate everyone working in the workflow to use each step on every prescription. This is the third step in CQI and quality. This way every pharmacist and pharmacy technician can truly say they are living up to their ethical duty to “First Do No Harm.”

In a future column, I will look at the fourth step in CQI and quality—monitoring the results and answering the twin questions “Did we get better? Is our quality higher that last month?”

REFERENCES
1. Flynn EA, Barker, KN, Carnahan, BJ, National observational study of prescription dispensing accuracy and safety in 50 pharmacies, J Am Pharm Assoc. 2003;43:191-200. Vol. 43, No. 2, March/April 2003. The authors indicated that most mistakes (1.8% error rate) were not likely to cause harm, but some (about one in one thousand) had the potential of causing death or serious injury (~ 0.1%). These can be labeled as significant.

2. The Iowa City pharmacy was testing an implemented CQI system named Pharmacy Quality Commitment (PQC). The test was less scientific than the Auburn study. PQC was developed by Professor David Brushwood and Ken Baker, author of this article and was later sold to Pharmacists Mutual Insurance Company, and is today owned by the National Alliance of State Pharmacy Associations. It is may available through all 51 state pharmacy associations through the Alliance for Patient Medication (APMS). See https://medicationsafety.org/ Last accessed 1/4/2017.

3. See biography of Edwards Deming, https://deming.org/deming-the-man/ last accessed January 5, 2017. Dr. Deming developed Total Quality Management, which is the hallmark of quality for most manufacturers in the United States and world wide. TQC is the template for virtually all CQI programs used in pharmacy today.
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