Pharmacists Move into Practices
More medical groups see value

Plus
- Adherence: What Really Works
- Industry Consolidation Increases
- Worst Pharmacy Mistakes

New Drug Review
Lucemyra for Opioid Withdrawal
THINK FIRST BEFORE YOU COMPOUND

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SAVES TIME  PRE-FLAVORED  COMPLIANT
The Ballgame Conversation About Pharmacy

It’s time to tell people what we do for a living.

Have you ever been asked to write an elevator speech? In other words, what you would say if you had 30 seconds (about the time it takes for a ride in an elevator) to describe your business or to sell a project to a perfect stranger?

I’ve written an elevator speech a couple times as a brainstorming exercise when I’ve participated in strategic planning processes with organizations that I’ve been involved with. More recently, I did it as part of a marketing seminar that was meant to be specifically for my pharmacy.

It’s not easy to describe an organization’s mission or purpose, or in the more recent case, what makes my pharmacy unique, in about three or four sentences.

I live in a somewhat rural part of Wisconsin, so the idea of riding in an elevator with a stranger is somewhat foreign, due to the fact that (a) there is only one elevator in my town, and (b) everyone knows everyone, so the idea of somehow ending up in an elevator with a stranger just isn’t very likely.

I like to think that instead of an elevator speech, I’m writing a “get to know the other parents at the ballgame a little better conversation.” At this point in my life, my kids’ ballgames are where most of my interactions with others are taking place. I use the word “conversation,” because it’s not likely anyone wants to listen to a prerehearsed 30-second speech anyway.

At the ballgame, when another parent inevitably asks me, “So, what do you do for a living?” I’ve found it helpful to be prepared with more than, “I’m a pharmacist.”

I’ve noticed that very few people have a good idea of what a pharmacist actually does. Maybe it’s because pharmacists do so many different things, or maybe it’s because every time there’s a pharmacy-related story on the news, the one and only video shot is of the counting tray and someone (by assumption, it must be the pharmacist) counting pills by fives and pushing them to the side.

“I’m proud of the many things we, as pharmacists, do every day. And it’s so important for people to know what we do and how it applies to their everyday life.”

So as part of the conversation (again not a speech), I like to point out the services we offer and say things like, “I spend time with patients who take a lot of medications and look for ways to simplify their regimen to make it easier for them” or, “Have you ever picked up an antibiotic for your child and wanted to know for sure it was the right dose? Well I make sure it is.”

I’m proud of the many things we, as pharmacists, do every day. And it’s so important for people to know what we do and how it applies to their everyday life.

The cover story in this issue (see page 27) revolves around even more activities that pharmacists are doing these days, specifically as part of the primary healthcare team in primary care settings like medical clinics and physician’s offices. How great is that! Our profession is continuously evolving and we need to keep finding ways to use our knowledge and skill set to improve patient care.

I’d encourage you to think about how you spend your day and how you describe our profession to others. We need to make sure people outside our profession know how we spend our days so that, someday, the video of the pill-counting pharmacist looks as odd as someone using a pay phone or typewriter.

And just like someday, when we all have jet packs attached to the back of our white coats, the idea of using an elevator will be very odd too.
EDITORIAL ADVISORY BOARD

Drug Topics
Voice of the Pharmacist

EDITORIAL MISSION: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
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USP has tested and verified select dietary supplements for their ingredients, potency and manufacturing process. USP does not verify efficacy claims. See www.USPverified.org.
Two U.S. universities are offering novel pharmacy degree programs.

The University of Rhode Island (URI) in Kingston, RI, and Johnson & Wales University in Providence, RI, are now offering a dual degree in pharmacy and physician assistant studies. This is the first collaboration of its type between public and private universities in the country.

In addition, the University at Buffalo School of Pharmacy and Pharmaceutical Sciences in Buffalo, NY, has launched a new Masters in Pharmacometrics and Personalized Pharmacotherapy program, one of the few classroom-based programs offering this content.

URI PharmD students can apply to Johnson & Wales’ Master of Science in Physician Assistant Studies program after completing their fourth year of URI’s six-year pharmacy program.

“We worked with Johnson & Wales University to design a program in which our students would complete both degrees in a seven-year span. We are one of the only public institutions with the 0-6 PharmD degree,” Celia P MacDonnell PharmD, clinical professor of pharmacy at URI’s College of Pharmacy, tells Drug Topics. “The idea was to complete both degrees in the same timeframe as completing a PGY1 Residency training.”
same timeframe as completing a PGY1 Residency training.”

Christine Berard-Collins, RPh, director of pharmacy for Lifespan, a Rhode Island-based nonprofit health system, says the partnership reflects the everyday healthcare environment. “Medications are an important, but complex, component of care to help many of our patients get healthy and stay healthy,” she said in a URI statement. “In our hospitals and ambulatory practices, pharmacists and physician assistants work together to give our patients the expertise of both.”

The University at Buffalo’s Masters in Pharmacometrics and Personalized Pharmacotherapy program provides advanced training in pharmacokinetics and pharmacodynamics.”

Pharmacometricians play a critical role in drug discovery and development in research institutes, pharmaceutical industry, regulatory agencies, and academia,” says Donald Mager, PharmD, PhD, professor and vice chair of the Department of Pharmaceutical Sciences, in a statement. “Students in this program will master the skills to optimize drug therapy, allowing for the provision of precision medicine and individualized therapies.”

Interest in combined degrees is growing, William Jusko, PhD, director of the new graduate program and distinguished professor with the University at Buffalo School of Pharmacy and Pharmaceutical Sciences, tells Drug Topics. “We have particularly seen an increase in numbers of PharmD students who are interested in a joint PharmD/MS degree. Many of our MS students either choose to continue for the PhD degree or elect to join the pharmaceutical industry,” he says. “The program also offers a unique opportunity for scientists who already have a PhD degree in another field to efficiently gain the credentials for employment in a higher demand area.”

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### How Civica Rx Will Impact Drug Shortages

Civica Rx, the new not-for-profit generic drug company formed by a consortium of health systems, could help alleviate shortages of certain critical drugs in hospitals.

The company will initially manufacture 14 hospital-administered generic drugs that have suffered from supply shortages, and then will expand production to other medications. The organization is not naming the drugs it will manufacture for competitive reasons, according to a statement.

Civica Rx says it expects to save the U.S. healthcare system hundreds of millions of dollars annually. “Research into the actual costs of manufacturing and distributing generic drugs suggests that, in many instances, prices for generic drugs used in hospitals can be reduced to a fraction of their current costs,” the organization says.

The seven initial governing members of Civica Rx—which represent about 500 U.S. hospitals—are: Catholic Health Initiatives, HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence St. Joseph Health, SSM Health, and Trinity Health. More than 120 other health organizations could also become involved.

“The fact that a third of the country’s hospitals have either expressed interest or committed to participate with Civica Rx shows a great need for this initiative. This will improve the situation for patients by bringing much needed competition to the generic drug market,” says Martin VanTrieste, Civica Rx’s CEO and former chief quality officer for Amgen, in a statement.

VanTrieste agreed to lead the new organization without compensation. Civica Rx will be an FDA-approved manufacturer that will manufacture some drugs itself and will subcontract manufacturing for others. It says it expects to have some medications available as early as next year.

### Highest-Rated Retail and Mail Order Pharmacies

Consumers rank Sam’s Club, Good Neighbor Pharmacy, Wegmans, and Humana Pharmacy best within their individual categories in terms of customer satisfaction, according to a new survey.

In the J.D. Power 2018 U.S. Pharmacy Study, Good Neighbor Pharmacy ranks highest overall among chain drug stores, followed by Health Mart and Rite Aid Pharmacy.

Sam’s Club ranks highest overall among mass merchandiser pharmacies, followed by Costco and the CVS/pharmacies inside Target stores.

Among supermarket pharmacies, Wegmans has the highest ranking, followed by H-E-B and Publix.

Among mail order pharmacies, Humana Pharmacy ranks highest overall in mail order, with Kaiser Permanente Pharmacy as second and Express Scripts as third.

“The retail pharmacy business has been in the spotlight ever since Amazon announced in June 2018 that it’s getting into the space,” says Greg Truex, senior director and health-care practice leader at J.D. Power, in a statement. “Amazon, or any other organization looking to disrupt the $100 billion U.S. mail order pharmacy market, will have their work cut out for them. Legacy pharmacy players have invested heavily in delivering superior service, while brick-and-mortar pharmacies are starting to reap significant customer satisfaction gains from retail-style clinics offering health and wellness services.”

Among community pharmacies, health and wellness services are most important to customers, according to J.D. Powers. “Such services are currently present in 86% of chain drug stores, 83% of supermarket pharmacies, and 75% of mass merchandiser pharmacies,” the research firm said.

For mail order pharmacies, delivering prescriptions on time is associated with a significant increase in overall customer satisfaction, according to the survey. Consumers also place high value on receiving prescriptions within five days of completing an order.
High Blood Pressure Twice as Common as Believed

The rate of Americans with high blood pressure is actually double its current reported rate, according to new data.

That’s according to the medical technology company higi, which will present its findings at the American Heart Association Hypertension 2018 Scientific Sessions. The company found a nearly 30% increase in the number of Americans who are now classified into the high blood pressure category, which doubles the national rate of high blood pressure from 33.6% to 62.4%.

This is due to new guidelines from the American Heart Association and American College of Cardiology (AHA/ACC) that have lowered the definition of high blood pressure from 140/90 mmHg to 130/80 mmHg.

In an analysis of nearly 40 million blood pressure tests across higi’s network of more than 11,000 health stations in retail pharmacies, higi examined the national impact of the new blood pressure guidelines.

Surprisingly, higi’s analysis also found a greater increase in high blood pressure in more populous, higher income, and more “healthy” communities, while less populous, lower income, and less “healthy” communities maintained overall greater rates of high blood pressure.

Florida is most impacted by the new AHA/ACC blood pressure guidelines, with a large number of older, Medicare-covered patients now falling into the high blood pressure category, according to higi.

Miami, Tampa, FL, and Washington, DC, had the greatest increases in rates of high blood pressure, while Atlanta, Baltimore, and Philadelphia had the highest total rates of high blood pressure, according to higi.

Immunosuppressant Drug Linked to Skin Cancer

An immunosuppressant used to treat inflammatory bowel disease, rheumatoid arthritis, and other diseases may be a contributor in developing skin cancer, according to a new study.

The research, published in a recent issue of Nature Communications, identified a “strong case” for an association between azathioprine (Azasan) and the mutational signature found in cases of cutaneous squamous cell carcinoma (cSCC), a common form of skin cancer.

It was already known that azathioprine causes increased sensitivity to UVA light, and probably contributes to development of skin cancers, researchers from the University of Dundee in Dundee, UK; Queen Mary University of London; and the Wellcome Sanger Institute in Cambridgeshire, UK, write.

Using mutational signature analysis of cSCC tumors from 37 patients, many of whom had been on azathioprine, they found a new signature, Signature 32. Its incidence correlates with chronic exposure to azathioprine.

“We recommend all physicians give appropriate advice on UVA avoidance—including year-round sun protection for their patients on azathioprine,” says Charlotte Proby, professor of dermatology in the School of Medicine at the University of Dundee, in a statement.

However, Proby and her colleagues are not necessarily advocating withdrawal of azathioprine. “As with all medications, the risks must be balanced against the benefits, particularly with the need to treat potentially life-threatening diseases with an effective drug,” Proby says.

Around 700,000 cases of cSCC are diagnosed in the United States annually, and more than 40,000 new cases diagnosed annually in the United Kingdom.

The study was funded by a grant from Cancer Research UK.

Christine Blank is a contributing editor.
Work hours can be long for pharmacists working in a retail or hospital setting. As an employee, a pharmacist may feel that he or she is stuck with whatever hours or shifts that management gives them. But it doesn’t need to be that way.

Pharmacists need to realize that they hold the power when negotiating for better hours, says Alex Barker, PharmD, founder of The Happy PharmD, which provides motivational career counseling to pharmacists in all practice settings. “The more indispensable you are, the more likely you are to have a major bargaining chip when negotiating,” says Barker.

Whether a pharmacist is looking to reduce long days and overtime, or to realign their current hours to meet personal needs, they must justify their request by providing information that will demonstrate how the requested revision will benefit the organization, he says. “Simply going to a manager or director and asking for a change in hours is a poor approach.”

Take for example, a pharmacist who works five days a week, and on three of those days he spends an extra two hours earning overtime, says Barker. That pharmacist can ask to officially be assigned those extra working hours on those three days, and in return, eliminate one day from his workweek.

One argument should be: The pharmacist would be saving the retail store—or hospital—a significant amount of money by absorbing those extra hours at the overtime rate into their regular pay scale.

Another argument that can be made: “In some cases, the extra hours could be a justification for letting a store or a clinic remain open later in the evening,” says Barker.

Barker describes a pharmacy client who wanted to work more days, but fewer hours each day. “She positioned the negotiation in such a way that if she worked more days, she could provide coverage during the busy hours of the store.” In the end, she didn’t get the exact arrangement she wanted, but it was close enough to satisfy both parties, he says.

Beyond the benefits of reduced overtime pay or better hours, pharmacists should look for a correlation between patient safety and the requested work schedule, as that is always an issue that weighs on managers’ minds, Barker says.

For example, the pharmacist in the previous scenario could have argued that having more pharmacists on hand during busy hours would reduce the likelihood of dispensing errors.

Anna Legreid Dopp, PharmD, director of clinical guidelines and quality improvement at ASHP, agrees that pointing to patient safety and patient care is important when discussing work hours. She suggests providing data that validates the positive effects on patient care and patient safety that such a change would provide.

But, where pharmacy hours are concerned, she noted that some pharmacists thrive on the extra hours and aren’t necessarily looking for a reduction.

Look Outside Your Pharmacy
Barker notes that unions representing pharmacists can be a resource for pharmacists in negotiating hours. In dealing through a union, pharmacists should remember that unions generally want things to be fair, so if you’re part of a large organization, look around and see what other pharmacists may have that you don’t. “For example, how are other hospitals handling pharmacists’ schedules?” he offers.

But it’s important to consider that “every union rep is going to be different and some may fight harder than others,” Barker added.

Safety is an issue among the 700 pharmacists.
CAREER

Kathleen Gannon Longo

CONTINUED FROM PAGE 9

The worst thing that could happen is a manager will say ‘No.’ There is little or no consequence that comes from asking, and if you’re rejected, it doesn’t mean you’ll be rejected the next time.”

TWO RULES:

1. Don’t be afraid to ask for what you want.
2. Justify your request by showing management why giving you the hours you want will benefit them.

Lauren Vallone is involved in collective bargaining negotiations with the more than 2,000 hospital and retail pharmacists represented in the union. Vallone agrees with Barker in that negotiating may often involve reducing a workweek or, in some cases, adding days to a workweek.

“It can be an issue of age,” Vallone says. Longer 12-hour days may be more difficult for the older worker, whereas a younger member of the pharmacy workforce may find such a schedule to be good.

Vallone has found that in most of the collective bargaining sessions in which she has participated, “the members get what they need.” In addition to negotiating hours, the union has negotiated issues such as how many flu shots a pharmacist can administer and still be expected to safely fill the required number of prescriptions.

Nationwide Initiative Is Promising

ASHP has recently made a commitment to supporting the well-being of the pharmacy workforce and reducing burnout, which can stem from working long hours. The organization is leading the pharmacy effort associated with the National Academy of Medicine’s Action Collaborative on Clinician Well-Being and Resilience, which addresses the serious consequences of burnout among healthcare providers.

“We feel it can benefit both pharmacists and patients and can help pharmacists to feel their best and do their best,” says Aretha Hankinson, director of advocacy communications at ASHP.

For hospital pharmacists, stress and burnout on the job can be caused by internal and external factors, says Christina Martin, PharmD, MS, director of membership forums at ASHP. External factors can include personal elements such as family issues or personal financial situations. Internal factors can include long hours leading to stress, onerous rules and regulations, increased oversight, inspections, audits, high employee turnover, and drug shortages.

“The goal of the initiative is to raise awareness of these issues, provide the education, and get the discussion going on the organizational level,” says Dopp. Overall, pharmacists should never be afraid to ask for different work hours, says Barker. “The worst thing that could happen is a manager will say ‘No’. There is little or no consequence that comes from asking, and if you’re rejected, it doesn’t mean you’ll be rejected the next time.”

Kathleen Gannon Longo is a contributing editor.

Find Power in Numbers

At 1199SEIU United Healthcare Workers East, which represents healthcare workers in Florida, New Jersey, New York, Massachusetts, and Washington, DC, representative Lauren Vallone is involved in collective bargaining negotiations with the more than 2,000 hospital and retail pharmacists represented in the union. Vallone agrees with Barker in that negotiating may often involve reducing a workweek or, in some cases, adding days to a workweek.

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Nationwide Initiative Is Promising

ASHP has recently made a commitment to support-
Of the estimated 1.7 million new cases of cancer that will be diagnosed in the United States this year, the most fortunate patients will have a board certified oncology pharmacist (BCOP) on their care team to help them. In addition to being cancer medication experts, BCOPs deliver a broad range of expertise and unique levels of practice, skills, and responsibilities to their patients. The pharmacist’s critical role in the care of oncology patients was underscored in a recent retrospective review of transitional care management (TCM) conducted at Boston Medical Center. The study concluded that pharmacist intervention reduced the average 30-day unplanned readmission rate among patients who had an inpatient oncology service. The readmission rate was 18.7% among patients who completed the TCM process; it was 37% for patients who did not. Pharmacists in the study were credited with identifying errors in more than half the discharge medication reconciliations completed by physicians. The authors concluded that pharmacists’ subsequent intervention with patients helped to reduce harm and optimize patient care.

“The oncology pharmacist is often one of the few team members who fully understands the safety, efficacy, pharmacologic, and financial components of patient care,” says Michael Bourisaw, executive director of the Hematology/Oncology Pharmacy Association. “The changing landscape of healthcare and evolving approach to cancer care—including oral therapies, targeted therapies, and personalized medicine—emphasizes the need for the oncology healthcare team to include an oncology pharmacist.”

Resource for Staff and Patients
The Cancer Care Center at Baptist Health Lexington in Kentucky sees about 100 patients each day. On-staff clinical oncology pharmacy specialists Megan May and Jeannie Patrick—who are both PharmD and BCOP—consider education to be one of their primary roles there. They provide in-services and up-to-date information to their fellow interdisciplinary team members in addition to counseling every new oral chemotherapy patient. They also facilitate drug acquisition and patient management, working off treatment plans to help streamline the way products are ordered and treatment plans are entered.

May and Patrick are the only two clinical specialists in the Baptist Health Lexington Cancer Care Center; two to three other pharmacists compound IV chemotherapies, and two pharmacists are responsible for oral chemotherapy dispensing. May says her work begins before a new patient starts chemotherapy. Once the oncologist has made a diagnosis and recommended treatment with her assistance, she sits down with the patient...
to do a medication reconciliation. She reviews their list of at-home medications and double checks it for accuracy with their local pharmacy to ensure there will be no interactions with the patient’s chemotherapy.

“Then we go over with the patient what we’re prescribing, what it’s for, how to take it, how long they’re going to take it, any side effects they might have from that, and we also touch on adherence,” says Megan May, PharmD, BCOP.

**Insurance Navigator**

Almost all of the oral chemotherapy medications prescribed at the cancer center are considered specialty drugs, and most are available from the in-house pharmacy. When medications are in limited distribution, or when drug manufacturers require the use of a specific specialty pharmacy, they are ordered from outside. May and Patrick help the cancer center’s financial navigator find ways to reduce high out-of-pocket costs for the specialty medications. One recent case involved a 71-year-old with prostate cancer whose oncologist wanted to start on abiraterone (Zytiga). The insurance company approved the prescription, but the copay was $2,106 per month. “Obviously, there was some sticker shock,” recalls Patrick.

The financial navigator started a search, and two days later found a

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**Four Tips for Counseling Cancer Patients**

Community pharmacists pride themselves on the high level of professional counsel they provide to all their patients. Here’s how to go above and beyond for cancer patients:

**Talk to patients about their medication schedule.**

Many oral chemotherapy medications are taken on a three-weeks-on, one-week-off schedule, which can be counterintuitive for many patients, says Rychalsky. “They think they have to take it every day,” she explains, adding that this is probably the number one mistake that patients make. To avoid potentially serious consequences, Rychalsky advises pharmacists to review each medication with patients to make sure they understand how and when to take them.

**Research the drugs to understand when patients should call their clinic for help.**

“When I’m counseling patients on IV chemotherapy, I try to make sure that they know what is an expected side effect, and what is something that is expected but rare that they should call us about right away,” says Darren Luon. Since patients can retain only so much information every time they’re counseled about their medications, Luon says added reinforcement from their local pharmacist can be very helpful.

**Stay current on the literature.**

This can be challenging with all new oncology medications in the pipeline and new studies in the works, says May. “One thing I always tell students and residents that we’re training is to make sure they know the references that are available, and to stay up to date on when they’re approved. This will help all pharmacists.”

**Reinforce that most medications will come from specialty pharmacies.**

Pharmacists need to be aware of the process required for specialty medications, so they can direct and reassure their patients accordingly, says Patrick. Patients may also need to be told that they’ll have high out-of-pocket costs for the initial fill until they get financial assistance through a grant or copay card.
“We have the most experience in being able to guide our patients in terms of how to manage side effects and supportive care in general,” he says.

Luon’s colleague, Kristen Rychalsky, PharmD, BCOP, BCPS, oncology clinical pharmacist II, also relishes the role of counselor, which she first experienced while working at a VA hospital. She recalls one patient who was suffering from a medication-related rash on his hands and feet. His physician hadn’t talked to him yet about side effects, so Rychalsky addressed the issue by holding the medication until the rash resolved and reducing the dose.

“The next time I was able to talk to him, the patient simply expressed his gratitude in such a touching way,” she recalls. “I was not only working to the top of my ability, but I knew the appreciation that the patient felt for me and my role. It was an amazing experience to have as any type of healthcare professional.”

Luon admits that a cancer clinic is not the easiest or happiest place to work. With many patients moving towards the end of life, conversations often center on difficult topics. Still, he appreciates all the hard work and experience that got him to this point. That, and a large dose of compassion, keeps him going day to day.

“We’re basically fighting an uphill battle a lot of times. We want to make patients get better, but there’s only so much you can do sometimes,” he says. “In order to keep doing this, you need to have that drive and love this field.”

$6,500 grant that the patient was qualified for and received. After the patient’s first copay, Patrick estimates that his monthly cost dropped to about $500.

“We keep a running log, and as that grant money starts to trickle down and run out we start the same process all over, looking at grants to see if anything has opened up that we can apply for. If not, we’ll reach out to the manufacturer for assistance,” Patrick explains.

**Patient Counselor**

At Smilow Cancer Hospital at Yale New Haven in Connecticut, Darren Luon, PharmD, BCOP, clinical pharmacy specialist in medical oncology, still recalls a case he handled as a P4 student that led to his decision to specialize in oncology. It involved a young patient who only spoke Cambodian, which Luon had learned as a child.

“She and her family had no idea what was going on because there was such a language and cultural barrier,” he says. “The team let me sit down with [the patient’s family] and talk about everything to see how they were doing. It really affected me greatly, and after that I wanted to go into oncology 100%.”

Today, counseling patients is a major part of Luon’s role at Smilow. While the oncologist talks to patients about their cancer diagnosis, prognosis, and the treatments that are available, his role is to explain the drugs. “We have the most experience in being able to guide our patients in terms of how to manage side effects and supportive care in general,” he says.

**Case Study: Covering the Cost of Cancer Meds**

Oncology patients face many challenges, not the least of which is getting the treatment they need in a timely manner. So what happens when the prescribed medication is denied by the insurance carrier?

That was the case early last February at Baptist Health Lexington with one of Patrick’s patients—a 59-year-old male with Stage 4 lung cancer who tested positive for the EGFR mutation. A new trial reported in the New England Journal of Medicine had concluded that osimertinib (Tagrisso) could be an effective treatment. His provider prescribed it for him on February 6.

However, the FDA had not yet been updated package labeling, and wouldn’t until mid-April. The insurance company denied the request on February 7. Patrick filed an appeal the same day.

“In this particular instance, we reached out after we received the denial letter, composed an appeal, attached the New England Journal of Medicine article, and submitted that to the insurance company in order to get approval for that patient,” Patrick recalls. “Usually there’d be a delay if you were waiting on that type of thing, but as pharmacists we can step into that role and help ensure that our patients are receiving the most cutting-edge treatment.”

The appeal was successful, and the insurer approved the prescription on February 12. The patient ended up with no copay.

Patrick says taking this sort of action to support a patient is an important part of her job. “Anybody with this type of diagnosis is emotionally dealing with other things as well. You throw insurance into the realm of things and it just totally convolutes all that a patient knows,” she says. “Taking that off of them and owning it really helps our patients in the long run from an emotional standpoint, as well as from a treatment standpoint.”

Beth Longware Duff is a contributing editor.
IMPORTANT SAFETY INFORMATION AND INDICATIONS

Indications
FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:
- *Clostridium difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Contraindications
- FIRVANQ™ is contraindicated in patients with known hypersensitivity to vancomycin.

Important Limitations of Use
- Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.
- Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Warnings and Precautions
- FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.
- Significant systemic absorption has been reported in some patients (e.g., patients with renal insufficiency and/or colitis) who have taken multiple oral doses of vancomycin hydrochloride for *C. difficile*-associated diarrhea. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. Monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
- Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. In patients over 65 years of age, including those with normal renal function prior to treatment, renal
function should be monitored during and following treatment with FIRVANQ™ to detect potential vancomycin induced nephrotoxicity.

- Ototoxicity has occurred in patients receiving vancomycin. It may be transient or permanent. It has been reported mostly in patients who have been given high intravenous doses, who have an underlying hearing loss, or who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

- Use of FIRVANQ™ may result in the overgrowth of non-susceptible bacteria. If superinfection occurs during therapy, appropriate measures should be taken.

- Prescribing FIRVANQ™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.

Adverse Reactions

- The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use FIRVANQ™ safely and effectively. See Brief Summary of Full Prescribing Information for FIRVANQ™ on the next page.

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To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**WARNINGS AND PRECAUTIONS**

- **Hypersensitivity to vancomycin**: May occur. Use only if clearly necessary.

**CONTRAINDICATIONS**

- **FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis.** Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. Parenteral administration of vancomycin is not effective for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. If parenteral vancomycin therapy is desired, use an intravenous preparation of vancomycin and consult the package insert accompanying that preparation.

**ADVERSE REACTIONS**

The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

**Table 1: Common (≥5%) Adverse Reactions for Vancomycin Hydrochloride Reported in Clinical Trials for Treatment of *C. difficile*-Associated Diarrhea**

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>Adverse Reaction</th>
<th>Vancomycin Hydrochloride (%) (N=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Flatulence</td>
<td>8</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Edema peripheral</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>5</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Urinary tract infection</td>
<td>8</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Hypokalemia</td>
<td>13</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Back pain</td>
<td>6</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>7</td>
</tr>
</tbody>
</table>

* Adverse reaction rates were derived from the incidence of treatment-emergent adverse events.

**USE IN SPECIFIC POPULATIONS**

**Geriatrics:** In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with vancomycin hydrochloride to detect potential vancomycin induced nephrotoxicity. Patients over 65 years of age may take longer to respond to therapy compared to patients 65 years of age and younger.

**Pregnant women:** There are no available data on FIRVANQ™ use in pregnant women to inform a drug associated risk of major birth defects or miscarriage.

**Nursing mothers:** There are insufficient data to inform the levels of vancomycin in human milk.

**OVERDOSAGE**

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

**PATIENT COUNSELING INFORMATION**

**Antibacterial Resistance:**

Patients should be counseled that antibacterial drugs including FIRVANQ™ should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When FIRVANQ™ is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by FIRVANQ™ or other antibacterial drugs in the future.

**Important Administration Instructions:**

Instruct the patient or caregiver to:

- Shake the reconstituted solution of FIRVANQ™ well before each use and to use an oral dosing device that measures the appropriate volume of the oral solution in milliliters.
- Store the reconstituted solution of FIRVANQ™ in the refrigerator when not in use.
- Discard reconstituted solutions of FIRVANQ™ after 14 days, or if it appears hazy or contains particulates.

This is a brief summary of information from the prescribing information and does not include all of the information from the full PI. See the complete PI at www.FIRVANQ.com.

To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Initial U.S. Approval: 1964

Manufactured for Cutis Pharma

841 Woburn St. Wilmington, MA 01887 USA

Rev. 2/2018
FDA Approves Lofexidine for Opioid Withdrawal Symptoms

The FDA approved lofexidine (Lucemyra, Catalent Pharma Solutions) in May for treatment of opioid withdrawal symptoms in adults. Lofexidine is a selective alpha-2 adrenergic agonist that reduces the release of norepinephrine, which decreases sympathetic tone. Reduction in norepinephrine is believed to be key in mitigating symptoms of opioid withdrawal.

**Efficacy**

The efficacy of lofexidine was evaluated in two phase 3 randomized double-blind placebo-controlled trials of patients meeting DSM-IV criteria for opioid dependence. In the first phase 3 trial, 602 patients received either lofexidine 2.88 mg total daily dose, 2.16 mg total daily dose, or matching placebo. The coprimary efficacy endpoints were the mean Short Opiate Withdrawal Scale of Gossop (SOWS-Gossop) on days 1 through 7 on treatment and the proportion of patients who completed seven days of therapy. Mean difference in scores between both lofexidine groups and placebo was found to be statistically in favor of lofexidine, indicating lessened withdrawal symptoms. Patients on lofexidine were also more likely to complete seven days of therapy than those on placebo. Those discontinuing treatment cited lack of efficacy.

In the second trial, 264 patients received either lofexidine 2.88 mg total daily dose or matching placebo. The coprimary efficacy endpoints were the mean SOWS-Gossop score on days 1 through 5 on treatment and the proportion of patients who completed five days of therapy. As with the first study, patients on lofexidine were found to have statistical reductions in SOWS-Gossop on days 1 through 5 and a statistically higher proportion of patients retained on therapy at day 5.

A study comparing lofexidine/methadone versus buprenorphine/naloxone in detoxification demonstrated noninferiority of buprenorphine compared to lofexidine.

**Safety**

The safety of lofexidine was assessed across three randomized double-blind placebo-controlled trials. The trials enrolled 935 patients on short-acting opioids experiencing withdrawal. The combined dataset presented a similar safety profile and the drug was well tolerated. Adverse reactions that were reported in more than 10% of patients on lofexidine included orthostatic hypotension, bradycardia, dizziness, somnolence, sedation, and dry mouth.

Geriatric use of lofexidine has not been determined; caution is advised. Safety in pregnant and/or lactating women has not been established.

**Dosing**

Lofexidine is dosed 0.54 mg orally four times daily with 6 hours between each dose. Subsequent dosing should be guided by symptom presentation and tolerability of side effects. The maximum total daily dosage is 2.88 mg. Lofexidine is administered for the first 5 to 7 days after last use of opioids, and can be continued for up to 14 days.

Dose adjustments are recommended in renal insufficiency. Patients with an eGFR between 30 ml/min/1.73m2 to 89.9 ml/min/1.73m2 should receive 0.54 mg four times daily, a maximum total daily dose of 2.16 mg. Patients with an eGFR <30 ml/min/1.73m2, ESRD, or on dialysis should receive 0.18 mg four times daily, a maximum total daily dose of 0.72 mg.

Dose adjustments are recommended in hepatic insufficiency and are dependent on the Child-Pugh score: Mild (score 5 to 6), give a maximum total daily dose of 2.16 mg; Moderate (score 7 to 9), give a maximum total daily dose of 1.44 mg; Severe (score >9), give a maximum total daily dose of 0.72 mg.

It’s never a fun topic to talk about, but mistakes in the pharmacy do happen. Whether it is a mistake made by a new pharmacist overwhelmed with the scope of the job or a mistake made by a veteran at the end of a long shift, no pharmacist can be perfect all the time.

The good news is that often, making mistakes makes for better pharmacists, allowing them to set up better systems. The bad news is that mistakes are hard to admit. As one pharmacist told us, “Until we create a culture that encourages improvement of the system that fosters the errors that are committed, we cannot expect candor and transparency in error reporting.”

In an effort to provide more transparency, and help you learn from the mistakes of others, we asked Drug Topics readers to share their experiences in this difficult area. Here are excerpts from some of their replies.

**Pharmacy Mistakes**

These pharmacists made serious errors, but more importantly, they took the time to prevent them from happening again.

**Knowing When to Say No**

“When I was two years out of pharmacy school, I allowed myself to be convinced by a local MD to dispense an adult dose of Compazine (prochlorperazine) suppository for a 13-year old-girl. I questioned the dose, but acceded to his argument that she was ‘adult sized.’

I prepared the prescription, but cautioned the parent not to exceed the dose and, perhaps try a half of a suppository. They exceeded the dose based on verbal instructions from the MD and came back for a refill on a Sunday morning.

I phoned the doctor and, once more, he instructed me to fill that prescription. The child suffered a seizure which is a characteristic adverse reaction to that drug, was hospitalized but fully recovered. The parents sued the doctor and me.

After a week in court, I was found not liable. The doctor was liable, as were the parents. I learned that it’s OK to refuse to fill a prescription when you know that the dose is excessive, despite the protests of the doctor and the patient.

**Checking the Refill Request**

“A patient left a message and asked us to refill the last HIV medication they had on file. We refilled it the next day and sent it to the patient, not knowing that the last refilled medication was discontinued, and a new medication was called in.

By the time I tried to contact the patient, she had already taken the medication and was having adverse reactions to it. I finally got in contact with her, letting her know she had to discontinue the medication that was sent and start on the new medication.

In order to fix the mistake, I needed to call her doctor and inform him that she had taken the discontinued medication.

I had to notify the Board of Pharmacy of the error. I also used this as a teaching tool for the technicians when they retrieve a voice mail request to verify with the patient to see exactly what they need refilled.”
Being Firm with the Patient

“The gravest mistake I made as a pharmacist, I think, was when I had prior knowledge that a patient/coworker had undergone chemotherapy not long before she came to pick up an as-needed prescription for a Z-Pak, and I wasn’t as firm enough as I could have been about checking with her physician despite her description of ongoing upper respiratory symptoms.

Her sister was with her, and I think that I didn’t want to alarm her, despite my private concerns about how long the patient, my coworker—a nurse—might have left. For many years, I felt that I contributed to her demise.

Now, after the deaths of my own parents, and other friends and acquaintances, I realize that a simple sentence such as ‘I care about you, and you need to check with your doctor about picking up this prescription for a Z-pak’ would’ve alleviated my feeling of guilt of inadequacy.

Since, then, I have tried to be more honest about patient questions of their therapies.

Another coworker patient had a new prescription for lithium, and despite a lack of knowledge about what it meant (ie, possible bipolar disorder, mania, schizophrenia, etc.), I tried to emphasize that she keep contact with the physician because there were many monitoring considerations with this medication to result in favorable response.”

Standing Up to a Bullying Doctor

“When I worked in a surgery pharmacy, I let the anesthesiologist convince me not to question a patient’s allergy to Demerol, and to dispense fentanyl. According to him, he never had a patient be cross-sensitive.

The patient made it through surgery, but on the way to recovery broke out in hives, starting on the patient’s back, where the initial injection of fentanyl was given. The patient recovered after being given Benadryl.

Since then, I always check hive reactions when dispensing any med in a similar or possible cross-reactive category.

My most important lesson was to not be bullied by any physician when any important ‘flag’ occurs while verifying orders.”

Nicholas Hamm is associate editor of Drug Topics.
Medication nonadherence is a recurring challenge in the healthcare industry, and the consequences are alarming: Approximately 50% of all patients who have chronic illnesses do not take their medications as instructed, according to the World Health Organization. Nonadherence costs the U.S. healthcare system between $100 billion and $300 billion annually.

Many pharmacists and pharmacies routinely engage in adherence-improving practices such as medication synchronization, processing early refills, changing prescriptions to 90-day supplies, activating refill reminders, and deprescribing when appropriate.

While these tactics often prove helpful, they do not guarantee success. Norman Tomaka, BSPharm, MS, FAPhA, spokesperson for the APhA and clinical consultant pharmacist in ambulatory care, says getting a patient to successfully adhere to a medication program is not the result of any single tried-and-true strategy but rather a combination of “multifaceted solutions that fit the patient’s lifestyle as most productive.”

Here are some strategies to consider.

### Practical, Adherent-Friendly Regimens

Pharmacists who focus on patient engagement are able to collect pertinent information that might positively alter the patient’s experience and medication regimen. Communication increases patient understanding, and improves the clinician’s ability to customize treatment in a way the patient finds more reasonable and therefore doable.

For Donney John, PharmD, executive director of NOVA ScriptsCentral in West Falls, VA, engagement starts with empathy.

“If I as an educated pharmacist cannot do it, how can I expect my severely ill patient to take multiple medications every day?”

“With medication adherence, people are overburdened with the number of medications they are taking, so don’t ask your patient to do anything you wouldn’t do. If I as an educated pharmacist cannot do it, how can I expect my severely ill patient to take multiple medications every day?” he says.

Tomaka is a huge proponent of face-to-face communication whenever possible. More personal interactions have been proven to optimize adherence, he says.

### Cultural and Regional Considerations

Cultural habits and practices also enhance
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Two transformational multibillion-dollar deals in the healthcare and pharmacy industries have been in the works for months—the $69 billion CVS-Aetna merger and the $52 billion Cigna-Express Scripts merger—despite concerns that more consolidation will mean higher costs and fewer choices for patients. Pharmacists, particularly independents, could also be affected, experts say.

The Cigna-Express Scripts merger has gotten a go-ahead from the Department of Justice, but DOJ has not ruled on the CVS-Aetna merger at press time. However, Reg Blackburn, managing director of The Braff Group, a leading mergers and acquisitions firm specializing in healthcare services, expects the CVS-Aetna merger to go through.

“[Pharmacists] are the experts regarding medication choice and side effects. They trained eight years for their PharmD, and now they are counting, pouring, and typing due to mergers,” says Mayer, adding that pharmacists in larger settings don’t have time for patient counseling. “Over the past 10 years, mergers have resulted in poorer choices of medication for consumers and patients.”

“Independent pharmacies are getting less and less, and going out of business,” says Mayer. There used to be 59 independent pharmacies in Marin County, CA, where he ran his pharmacy before retiring. “Today there are three independent pharmacies. The chains are buying up all the pharmacies.”

Stephen Schondelmeyer, PharmD, PhD, a professor of pharmaceutical economics and head of the Department of Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy, agrees. “Chains that are in one of these vertically integrated systems have guaranteed volume without competition on price,” he says. “The independents in those systems may have seen an even faster loss of volume out there. They could be shut out.”

Marketplace Shifts
Perry Cohen, CEO of The Pharmacy Group, says the mergers are examples of a growing trend: Companies responding to the need for new care models for healthcare services. “The marketplace needs new care models and wants to embrace these companies that get ahead of the curve,” says Cohen.

“Over the past 10 years mergers have resulted in poorer choices of medication for consumers and patients.”
Cohen says current care models are “healthcare professional driven, expensive, and inefficient,” adding they are “not a sustainable model going forward.” That’s why some of the biggest players are changing their strategies, and he gave the added examples of United Healthcare buying DaVita Medical Group and Amazon acquiring PillPack.

New care models will leverage technology to allow most care to happen in the patient’s home with the aid of telehealth, mail, Amazon deliveries of dose packages, or small in-home dispensing kiosks that combine the medication with patient engagement through a WiFi connection to the pharmacy, Cohen predicts.

More Mergers Coming
Blackburn expects to see more vertical mergers and acquisitions, like the CVS-Aetna and Cigna-Express Scripts deals, and horizontal mergers and acquisitions, like the failed attempt by supermarket chain Albertsons to buy Rite Aid and its EnvisionRX PBM business. That proposed $24 billion deal collapsed in August.

“The horizontal is being driven a lot by the reimbursement pressure,” Blackburn said. “The vertical is much more strategic around the control of the overall person’s healthcare.”

While the Rite Aid and Albertsons deal may have fallen apart, Blackburn expects that what is left of Rite Aid may eventually be absorbed by another chain. After attempts to sell its stores to Walgreens were stopped in June 2017 by federal antitrust issues, Rite Aid later transferred 1,932 stores and three distribution centers to Walgreens in March for about $4.4 billion.

Other companies are making deals as well, like Fred’s Inc., which operates about 600 general merchandise and pharmacies, including 13 franchised locations. The company scrambled after its plan to buy 865 Rite-Aid stores, as part of the original Walgreens-Rite Aid deal, was scrapped.

Since then, Fred’s has been selling off pieces of the company. In June, it closed on a $40 million deal to sell assets from its specialty pharmacy unit to Advanced Care Scripts Inc. an affiliate of CVS Health. On September 10, Fred’s agreed to sell patient prescription files and pharmacy inventory of 185 stores in 10 Southeastern states to Walgreens for $165 million plus an amount equal to the value of the related pharmacy inventory.

Fred’s will continue to operate 162 pharmacies, but the company announced 80 layoffs and it’s unclear how many pharmacy jobs Walgreens will pick up.

Mayer, Cohen, and Schondelmeyer are members of the Drug Topics Editorial Advisory Board.

Gail Kalinoski is a contributing editor.
the patient experience. These may reach beyond race and ethnicity to include geographic trends or even the patient’s work environment.

Teresa Burks, PharmD, BCACP, pharmacist-in-charge at St. George Medical Center Pharmacy, part of Family Health Centers in St. George, SC, encourages pharmacists to familiarize themselves with their patient populations.

“Every area may be different and have their own uniqueness that you may want to emphasize as it relates to the patient experience and [action plan],” she says.

“In St. George, the patients are very personable, so in addition to healthcare, they want to talk about things going on in their lives—almost like a family environment.”

Some diseases present differently among races and cultures, but clinicians should also consider how perceptions of those illnesses vary among different groups. “In most African American and Latino cultures, getting an insulin prescription equals death because they don’t connect the dots between when the medication is started and the progression of the disease,” John points out.

John also feels gathering information about the patient’s employment and work schedule provides critical clues that help tailor the patient’s medication regimen. “Knowing what the person does for a living gives you an idea of how the medication fits into the patient’s life. If a person is a postman or a mail carrier, it would be easier for him to use an insulin pen than an insulin vial because it’s portable and the insulin can be delivered discretely.”

**Technology’s Role**

Alarm reminders help keep regimens front-of-mind, but experts caution that technologies such as software and apps are only appropriate for patients who are most likely to use them. John cautions against using most health apps, stating that the majority carry a three-month shelf life and are not designed with the end-user in mind.

**BEDS-TO-MEDS ADHERENCE PROGRAM**

Community pharmacists are experiencing a growing role as hospitals look to them as a resource to improve adherence and reduce readmissions, a key metric in many value-based payment arrangements.

One example is the “Meds to Beds” program at the University of California at San Francisco. Pharmacists from two retail pharmacies on the hospital campus meet with patients before they leave the hospital. The pharmacists explain their discharge medications and then follow up with patients to ensure they are compliant.

**Education: A Delicate Balancing Act**

Offering clear, concise, and actionable communication regardless of additional strategies enacted is the most important element to help patients better manage their medication regimen. “Communication is a two-way street—a dialogue,” Burks says.

While technology improves adherence in patients who are already avid users, he says it is a poor substitution for the nuances of human communication. “If you don’t communicate with your patient, the basic robotic functions will be replaced by technology, but I don’t know of a single robotic function that can connect with a patient and give them information that makes sense for their lifestyle,” says Tomaka.

Frieda Wiley, PharmD, BCGP, is a writer in the Cincinnati, OH, area.
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Pharmacists play an important role during flu season through vaccine administration and education about vaccines. Available vaccines include standard dose, high-dose for those aged 65 and older, adjuvant for those aged 65 and older, cell-based, recombinant, and live-attenuated (nasal spray).

The last flu season was a bad one and this one may be bad as well. However, for this season, the vaccines are predicted to be a better match to the circulating strains.

While many pharmacists worry about the time constraints caused by vaccinations—yet another thing to do!—there are many ways to simplify vaccine administration and still make a positive impact for your patients this flu season.

Here are five tips for making flu season easier in the pharmacy:

1. **Have Talking Points Ready**
The CDC recommends that everyone get vaccinated early, before flu season begins—preferably by the end of October. Remind patients that it takes about two weeks after vaccination to develop protective antibodies.

I tell vaccine-hesitant parents that there were 180 pediatric deaths last season, according to the CDC’s summary of the 2017–2018 flu season. Of those deaths, about 80% occurred in children who had not received a flu shot.

And don’t just rely on yourself to give out this info—pharmacy interns can provide patient education and answer drug information questions, which can enhance their clinical skills and ease your work flow.

2. **Know What’s New This Season**
The CDC is recommending the nasal spray as an option for nonpregnant healthy individuals 2 through 49 years of age. However, the American Academy of Pediatrics recommends the inactivated flu vaccine due to efficacy concerns with the nasal spray.

Pharmacists practicing in states where they can vaccinate children should first offer the inactivated vaccine and only provide the nasal spray to those whose parents would otherwise refuse the flu shot.

3. **Establish Work Flow Strategies with Your Staff**
When the pharmacy is busy, technicians and pharmacy interns can be a lifesaver. If patients stop by to let you know they want to come in the next day for a flu vaccine, then give them the forms to complete at home so that their wait time is shortened.

Technicians can do all of the insurance processing so that you can focus on giving the flu vaccine. Pharmacy interns can administer vaccines in many states, so you can supervise them during the process and provide patient counseling on the most common adverse effects, which include pain or swelling at the injection site and low-grade fever. Pharmacy technicians in Idaho can now administer vaccines, which can ease work flow and enable pharmacists to focus on patient counseling.

4. **Be Honest with Patients and Prioritize**
Encourage patients to come during a pharmacist overlap if you have one. Some pharmacies with lower prescription volumes have one pharmacist per day and limited technician hours.

A long line of patients can be overwhelming, but it is important to focus on the task you are completing first, to prevent an error. If a patient is waiting for an antibiotic, then prioritize and get that ready first before administering a flu vaccine.

Be honest and let your patients know the time frame that works best for you and have them complete the paperwork and do any shopping while they wait.

5. **Establish a Connection with Your Patients**
Giving flu vaccines is a great way to get to know your patients. They can also see firsthand how pharmacists play an important role in direct patient care. This will make the season more enjoyable to both patients and pharmacists.

Good luck this flu season, and know you are making a difference.

Jennifer Gershman, PharmD, CPh is a pharmacist and freelance writer from South Florida.
Pharmacists Move Into Practices

More medical groups see value.

Fred Gebhart

Just as hospital pharmacists moved out of the basement and into direct patient care in the 1980s and 1990s, outpatient pharmacists are moving out from behind the counter and into medical practices.

“There is a demand for pharmacists from the physician side in ambulatory care,” says Elizabeth Cuevas, MD, director of the Primary Care Transformation for Residency Clinics at Allegheny Health Network, a nonprofit eight-hospital academic medical system with facilities in Western Pennsylvania and Western New York. Allegheny is putting pharmacists into about 250 different practices that are part of its accountable care organization (ACO), a payment model in which the health system receives higher reimbursement if it improves quality and reduces costs.

“We’ve used our pharmacists for improved medication management, medication reconciliation, patient education and outreach, symptom management, disease management, and making sure patients are actually taking their meds,” says Cuevas. “Pharmacists have a natural role in practices.”

Allegheny isn’t alone in placing pharmacists in physician practices and ambulatory care clinics. Integrated health systems and larger group practices nationwide are moving in the same direction.

In the ideal arrangement, pharmacists are embedded in practices with 5 to 10 physician and nonphysician practitioners, explains John Kennedy, MD, chief medical officer of AMGA, formerly the American Medical Group Association. “For smaller practices or areas that may be more remote, you can use telemedicine or share remote [pharmacist] support as long as you have a shared electronic health record.”

Allegheny is using embedded pharmacists and shared services, depending on the size and location of the practices. Practices with one or two providers usually can’t support a full-time pharmacist, but they can benefit by sharing the services of a pharmacist, according to the health system.

A group of small practices that are relatively close to each other might share a pharmacist who rotates through the different offices, for example. More distant locations might do better with video and data links to a central pharmacist. Either way, pharmacists are part of the

CONTINUED ON PAGE 28>
cover story

Starting in the Hospital

Allegheny’s decision to put pharmacists on patient care teams can be traced back 30 years, to when inpatient physicians began working with clinical pharmacists. Then, Michael Korczynski, PharmD, BCAP, came on board as manager for Clinical Services, Pharmacy – Ambulatory Care.

“I had come from Kaiser Permanente and the VA, so I was familiar with an autonomous role for pharmacists,” Korczynski says. “But it was a foreign concept here.”

Even so, in the years before Korczynski started at Allegheny, its physicians and pharmacists had built up a strong relationship working together on the inpatient side, he says. “I started an anticoagulation service and working with a primary care practice. Physicians quickly latched onto the new-to-them services.”

Changes in physician education also helped foster physician acceptance of pharmacists on care teams, says Kennedy. Most younger physicians train with pharmacists on inpatient care teams. Once they join a practice, they expect the same access to a medication specialist, he says. Practices and health systems that can offer a pharmacist in the office have a hiring advantage as the physician shortage grows.

What Pharmacists Offer

Putting a pharmacist in the office brings quality and financial advantages, which is critical in value-based reimbursement models, such as Allegheny Health’s ACO.

“Like all things in healthcare, it is about the dollar,” says Paul Lebovitz, MD, vice chair of the Allegheny Health Network Medicine Institute. “The present model, which is physician-centric, is not getting us to that quadruple aim of better outcomes, lower costs, better patient satisfaction, and improving the work life of our healthcare providers. We are moving to a patient-focused model using team-based care. Pharmacists are an important part of the team and the model.”

Eric Maroyka, PharmD, BCPS, director of the Center on Pharmacy Practice Advancement at ASHP, says placing pharmacists in the primary-care setting ensures care is provided in the most cost-effective location. “We are seeing care moving toward a more preventative model and not just episodic acute care,” he says. “The sickest of the sick will be in hospitals. Anything that can be done on an ambulatory care basis will be done that way and that is where the maximum payment will be.”

A single physician cannot provide the same quality of care as a team that incorporates a pharmacist, says Lebovitz. “I have made a significant impact with patients, but I recognize that there is so much more I could have done with help,” he says. “That’s what this transformation of care is all about.” Patients have better outcomes in team models, he says, because there are more eyes on the patient from the entire team.

Pharmacists also can lower costs of administering services, improve physician efficiency, and curb physician burnout, says Lebovitz. Anything pharmacists and other team members can take off the physician’s plate saves money and gives physicians more time to spend with patients.

“It doesn’t take physicians long to rec-

Source: Managed Healthcare Executive’s Managed Care Pharmacy Survey 2018. The survey received more than 100 responses from executives at medical practices, hospitals, large healthcare systems, benefit management organizations, health plans, long-term care organizations, group purchasing organizations, consulting firms, and more.

**FIGURE**

Most Healthcare Leaders Support Pharmacist Reimbursement

<table>
<thead>
<tr>
<th>Should pharmacists be compensated under Medicare Part B for prescribing medications and helping assess patient conditions?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td><strong>NO</strong></td>
</tr>
</tbody>
</table>

I have made a significant impact with patients, but I recognize that there is so much more I could have done with help. That’s what this transformation of care is all about.”

Paul Lebovitz, MD

[images of Paul Lebovitz]
Study: Embedded Pharmacists Improve Quality

Jill Sederstrom

Embedding a clinical pharmacist in established primary care medical home practices can yield big benefits, according to a study in the Journal of International Medical Research. The study found that diabetes and hypertension patients who participated in Intermountain Healthcare’s Collaborative Pharmacist Support Services (CPSS) program were more likely to achieve their disease management goals, improve their time to achievement, and increase their ambulatory encounters, compared to those not in the program.

Under the CPSS program, ambulatory care clinical pharmacists worked alongside physicians in Intermountain Healthcare’s Medical Group primary care clinics to treat adult patients with diabetes or hypertension. The pharmacists initiated and adjusted medications, and ensured medications were being used safely and effectively.

Pharmacists also reviewed medication lists after hospitalizations, lowered drug costs by switching to generic or lower tier medications, worked with providers to determine the optimal therapy for a given patient, and deprescribed potentially dangerous medications, according to a statement from Intermountain Healthcare, located in Salt Lake City.

When pharmacists worked collaboratively with physicians to provide patient care, the study found that patients were:

- 57% more likely to achieve an A1C level less than 8%,
- 93% more likely to achieve their blood pressure goal,
- 87% more likely to achieve both disease management goals than those patients who did not participate in the CPSS program.

The study included data from 359 patients who were enrolled into the CPSS program between July 2012 and April 2015. This data was compared to data from 999 patients who were not enrolled in the program.

Physician practice and clinic leaders may not know what pharmacists can do for them. For example, they may know that up to half of new scripts for chronic care meds are never filled; they may not know that pharmacists can help patients start to use their meds.

The key is talking with physicians about practice problems, then showing how pharmacists can address them. The whole discussion is about improving outcomes, reducing costs, and boosting satisfaction, Korczynski says.

Pharmacists looking to start these discussions can consult ASHP’s sections for ambulatory care practitioners and pharmacy managers, which can provide hands-on information for pharmacists interested in working with practices.

There is literature showing that when pharmacists are allowed to bill at higher levels, they can generate revenue to cover their salaries.”

CONTINUED ON PAGE 30

MICHAEL KORCZYŃSKI, PHARMD, BCAP
Another resource is the American Medical Association’s physician practice improvement strategies: STEPS Forward. For information on how and why to embed pharmacists in practices, visit www.stepsforward.org/modules/embedded-pharmacists.

AIMM, the Alliance for Integrated Medication Management, is another resource. AIMM, Apexus (the HRSA-designated Prime Vendor for the 340B drug pricing program), and ASHP sponsor the A3 Collaborative. The year-long program helps provider organizations such as Allegheny create value-defined initiatives to build population management strategies by implementing clinical pathways that integrate medical care and comprehensive medication management services.

“Practices are seeing more and more pressure to account for outcomes,” says Todd Sorensen, AIMM executive director. “That changes the whole focus from quantity care to quality care.”

**Reimbursement Challenges**

The lack of provider status isn’t keeping pharmacists out of ambulatory care clinics and medical practices. But more pharmacists would be in more practices if they were recognized as providers and could bill directly.

“Not having provider status has an impact at the executive decision-making level on whether or not to hire a pharmacist for the practice,” says Kennedy. When the pharmacist cannot directly bill for services and generate revenue, the practice must find other ways to support the role. That usually means looking at cost savings, which may not appear until the second or third year. That lag can slow adoption.

“Right now, the system is paying for pharmacists in practices,” says Cuevas. The need to demonstrate a return on the pharmacist investment is slowing pharmacist hiring.

Though Allegheny Health is in the process of adding pharmacists to 250 practices, they currently only have them in a handful of clinics, Cuevas says. “The pharmacist is not able to bring in direct revenue, but you can see a decrease in 30-day readmissions, a decrease in morbidity, a decrease in ER admissions because you have a pharmacist doing medication management and reconciliation. It is a matter of recognizing that the costs you are saving are different from direct billing.”

Pharmacy organizations are pushing for provider status at the federal and state levels, but that alone isn’t enough. Legislation must also allow pharmacists to bill at realistic rates.

“There is literature showing that when pharmacists are allowed to bill at higher levels, they can generate revenue to cover their salaries,” says Korczynski. “If the rules say pharmacists are providers, but they can’t bill at higher levels, provider status won’t help.”

Commercial payers are part of the picture as well. Change is coming, but slowly.

“Direct billing for pharmacy care out of medical practices is still in its earliest stages,” says Keith T. Kanel, MD, MHCM, clinical associate professor of medicine at the University of Pittsburgh School of Medicine. He was principal investigator for the Primary Care Resource Center Project. The CMS Innovation center project put pharmacists in primary care practices in parts of Pennsylvania and West Virginia. The project, which began in 2012, showed a 25% reduction in 30-day hospital readmissions and reduced 90-day costs of care by more than $1,000 per patient.

“Forward thinking commercial plans are beginning to develop ways to pay for an office-based pharmacist,” Kanel says. “That is going to become a game changer when it becomes more common.”

Fred Gebhart is a contributing editor.
Optimizing Workflow and Synchronization

When Moundsville Pharmacy owner Jason Turner decided to improve adherence and pharmacy workflow, he turned to his QS/1® support team for guidance on implementing QS/1’s Workflow tools. By leveraging the power of the NRx® Pharmacy Management System, Turner increased efficiency and expanded his synchronization program to over 1,000 patients. In addition, he reduced operating costs, transformed his pharmacy into a model for performance-driven workflow and was able to handle increased prescription volume. That’s the power of a QS/1 partnership.

“Expanding our prescription synchronization program and utilizing QS/1’s built-in tools led to a 22% increase in monthly volume and the acquisition of a second location.”

Jason Turner, PharmD - QS/1 customer since 2003
Lower Drug Prices Aren’t Worth Higher Health Risks

HHS efforts to increase competition could hurt patients.

Everyone on the “buy side” wants lower cost medicines. But at what cost? As HHS tries to make medications more affordable, patient safety must not be sacrificed.

Directed by HHS, FDA convened a Working Group in August to examine potential prescription drug importation policies. Its recommendations would likely promote competition for certain off-patent sole-source drugs that cost more in the United States than elsewhere. Yet, foreign sellers can already increase competition by working with authorities to export FDA-approved products to the United States via the legitimate supply chain. While FDA is considering allowing foreign sellers to export to the United States to increase competition, they are doing so without directly addressing the core issue of domestic price spikes.

Pharmacists are willing to consider novel approaches to lower the cost of medications, but are concerned the Working Group’s potential recommendations will incentivize foreign sellers by relaxing importation requirements. These requirements protect patients and ensure safe and effective medications.

Demand for convenient lower-cost medications has created a new economic incentive for criminals to manufacture and sell dangerous counterfeit drugs. Counterfeits are often made in unsafe conditions; contain too much, too little, or no active ingredients; and/or may contain dangerous or deadly substances.

Drug counterfeiters regularly trade in the highest-cost, hardest-to-get, and most sought-after products in America. Whenever there is a drug shortage, public health crisis, or price spike, counterfeiters and criminals swoop in, and target patients by offering access, “deals,” and even “cures.” Should HHS authorize importation of high-cost and/or high-demand off-patent medicines, we should expect criminals to similarly flock to that new market.

Expanding mechanisms available to import foreign-sourced medicines to the United States would exacerbate an already unmanageable safety situation. Officials already struggle to stop dangerous fakes from entering the country. Counterfeit pills laced with fentanyl and other synthetic opioids that kill Americans are shipped into the United States in mass quantities from foreign sources. The FDA estimates that it is able to inspect 0.06% of all packages thought to contain drug products that enter international mail facilities.

HHS’s actions could also have the unintended consequence of suggesting to Americans that it’s safe to buy any medicine from foreign sources. This messaging matters. U.S. consumers buying medications from Canadian online pharmacies rarely, if ever, receive the same regulator-approved products provided to Canadian consumers. The FDA has found that 85% of drugs promoted as Canadian came from 27 other countries. Just as criminals now pass themselves off as Canadian, allowing even a limited legal means of importation would cause criminals to pass themselves off as meeting the requirements of a new restricted importation policy.

Pharmacists can play an important role in educating patients about their buying options, including ways to identify and coordinate cost-effective regimens that consider treatment plans, payer policies, and other members of the care team. Pharmacists can help optimize the impact of patients’ medications, but cannot do this effectively when patients’ medications may not be safe or effective.
After learning that some generic versions of the drug valsartan were contaminated with a potentially carcinogenic chemical called N-nitrosodimethylamine (NDMA), the FDA has issued a recall to 13 manufacturers and some repackaging companies. Valsartan is an angiotensin II receptor blocker used to treat hypertension and heart failure.

In late August, FDA said it might recall more drugs in the angiotensin II receptor blocker class depending on its lab test results. “The active ingredient is made at a factory in China or India; it is then repackaged and sold under other manufacturer’s names,” says Guy L. Mintz, MD, FACP, FACC, director of cardiovascular health and lipidology at Sandra Atlas Bass Heart Hospital and North Shore University Hospital, and associate professor of medicine at Zucker School of Medicine, all in Manhasset, NY.

In September, the FDA announced that another contaminant—N-nitrosodiethylamine (NDEA), also a suspected human carcinogen—was found in batches of valsartan drug products. In addition to valsartan, recalled products include a valsartan–hydrochlorothiazide combination, a valsartan-amlodipine combination, and a valsartan-amlodipine-hydrochlorothiazide combination. Twenty-two countries have recalled more than 2,400 batches of valsartan products.

Here are four things to know about the recall:

1. **The Severity of Risk Is Unknown.** The Environmental Protection Agency classifies NDMA as a carcinogen. “The increased risk of cancer was found in animal studies, however the level of NDMA was much higher than the levels of NDMA found in the affected valsartan products,” says Michael Ganio, PharmD, MS, BCPS, FASHP, director of Pharmacy Practice and Quality at American Society of Health-System Pharmacists in Bethesda, Maryland. Acceptable levels of NDMA are found in foods such as meats, dairy products, and vegetables, and in some water supplies. For example, there is an estimated 0.304 to 0.354 mcg of NDMA in one pound of bacon. “The levels of NDMA in the affected valsartan products were above acceptable levels, and FDA determined that they posed an unnecessary risk to patients,” Ganio says.

2. **Not All Valsartan Was Recalled.** Only products made with the valsartan that contained NDMA are affected. Products from some manufacturers are not affected by the recall, Ganio says. Patients may be able to switch to the same strength pills from a manufacturer that is unaffected by the recall, Ganio says. Patients may be able to switch to the same strength pills from a manufacturer that is unaffected by the recall. FDA keeps a comprehensive and up-to-date list of recalled drugs on its website.

3. **Patients Must Not Stop Their Meds.** Abruptly stopping valsartan could result in a dangerous rise in blood pressure, which may place patients at risk for stroke or other types of organ damage, says Brent Reed, PharmD, associate professor at University of Maryland School of Pharmacy in Baltimore. The FDA has advised patients to continue taking their medication and to call their pharmacist to ask if they need to switch to a version made by an unaffected manufacturer or to contact their prescriber.

4. **Good Alternatives Exist.** There are seven other drugs in the angiotensin II receptor blocker class that patients might be able to take, Mintz says. Patients might also be able to use other families of drugs to treat high blood pressure such as diuretics, calcium channel blockers, beta blockers, and angiotensin converting enzyme (ACE) inhibitors. These families of medications have been used for decades to treat high blood pressure.

Alternatives include: irbesartan, losartan, candesartan, olmesartan, telmisartan, eprosartan, and azilsartan. Pharmacists can identify which products are available based on each drug’s unique 10-digit National Drug Code and work with a health insurer’s network of prescribers and dispensing pharmacists to steer patients toward those drugs, says Susan A. Cantrell, RPh, CAE, chief executive officer of Academy of Managed Care Pharmacy in Alexandria, VA.

Karen Appold is a medical writer in Lehigh Valley, PA.
Over the last several years, pharmacists have embraced information technology, software, automation, and hardware to support their daily work load and help them better manage an increasing number of patients. But more innovations are coming. Advances in predictive modeling, robotics, mobile apps, and diagnostics are opening new horizons for pharmacists, which can vastly improve their ability to dispense medication, minimize errors, and monitor patient adherence.

**Pharmacy Information Systems**

Improving patient engagement and encouraging medication adherence after discharge is a top priority for pharmacists, especially as more focus on supporting value-based care, says Ken Perez, vice president of healthcare policy at Omnicell, a supplier of medication management solutions based in Mountain View, CA. He says pharmacy information systems can help by offering medication synchronization and medication therapy management, for instance.

They can also help pharmacists flag patients who are abusing or selling opioid medications, if those systems are integrated with prescription drug monitoring programs (PDMPs), says Perez. PDMP databases are maintained by almost every state, and pharmacy information systems are beginning to integrate with them.

Rebecca Chater, RPh, MPH, FAPhA, director of clinical healthcare strategy at Omnicell, adds that more systems are also integrating with electronic health records (EHR). Newer systems will access actionable data, such as lab values and diagnoses codes. This will help pharmacists efficiently document their tasks and share data with the broader healthcare team, Chater says. “These emerging information systems will help break down silos. These new age systems are all about supporting patient care as it relates to medication usage.”

Mark Neuenschwander, president, the Neuenschwander Company, a medication automation consultancy based in Bellevue, WA, says pharmacy information systems and automated dispensing systems are already helping pharmacists more efficiently view patient medication histories, fill subscriptions, and avoid medication errors. “These systems are pretty sophisticated and are helping pharmacists do a better job of monitoring because of the vast amounts of data they contain,” he says. Neuenschwander is a member of the Drug Topics editorial board.

**Automated Dispensing**

Perez considers automated drug dispensing an essential standard of care in hospitals. These systems facilitate patient safety and also cut down theft. “The information that is flowing through these dispensing systems has to be mined more extensively to gain insights,” he says. “For example, artificial intelligence, predictive modeling, and algorithms could be used to predict drug shortages, price increases, waste, and theft based on dispensing patterns.”

In the community pharmacy setting, Neuenschwander thinks most dispensing systems will remain semi-automated, depending on whether the pharmacy wants to invest in more expensive sophisticated automation. But Amazon’s purchase of PillPack will influence pharmacies to check out more automated dispensing options, he says. “To stay competitive, the smart retail pharmacy might consider establishing a competing dispensing system that combines smartphone apps and barcode scanning to prompt patients to take their medications,” he says.

Chater agrees there is room for growth for automated dispensing in community pharmacies. “They are not ubiquitous in community pharmacies, although they’ve gained significant traction,” she says.

One way to improve patient adherence...
ence and produce better health outcomes is to provide medications in multimedication packaging. But this is arduous when it’s done manually, says Chater. “Having automation in place helps pharmacists provide this service to patients without consuming too much time.”

This is where medication synchronization in the pharmacy comes into play, she says, noting that the software and algorithms needed to make it work is generally available, but not widely used. Such is also the case for the robotic automation needed for multimedication packaging. These systems will appear in the future as more pharmacies become more patient-centric, she says.

Mobile Apps
The number of mobile apps that can be used in pharmacy practice is growing, and helping pharmacists better care for patients and their business, says Timothy Aungst, PharmD, an assistant professor of pharmacy practice at Massachusetts College of Pharmacy and Health Sciences in Worcester, MA.

“Mobile apps are finding greater use for reference purposes,” he says. “Drug information contained in the apps is an important practical resource in pharmacy practice.”

There also has been a push in communication apps, trying to make more concise platforms for patient-pharmacist communications, he says. “Pharmacists would be able to communicate better with patients and their providers.”

Aungst predicts that apps will soon be integrated with EHRs, and patients will be able to share lab information with their pharmacists, who will then work with physicians to determine the best medication for them. He expects HIPAA-compliant secure texting communication platforms to grow.

Apps are already helping patients access their medical information. They send reminders for appointments, laboratory tests, and test results, Aungst says. They also improve remind patients to take their medications as prescribed.

Noninvasive Glucose Monitoring
Testing blood sugar several times daily is burdensome for diabetic patients. Many don’t test as frequently as they should, which can result in poor control of blood glucose levels.

Several technology companies are working to create noninvasive glucose monitoring technologies. For instance, Know Labs, in Seattle, WA, is developing a noninvasive arm band-like device that would use radio spectroscopy, machine learning, and complex algorithms to monitor glucose levels. Joshua Welborn, PharmD, who has consulted with Know Labs, says hospital pharmacists may have limited data from only a few blood tests. “The longer a patient is in the hospital the more data we have which, usually, leads to better glucose control. A noninvasive device that scans in real time would be extremely helpful.”

Welborn says that a device that measures glucose levels noninvasively at 15-minute intervals without bothering the patient would be ideal. “The entire healthcare team needs to know when glucose levels might be high or low as soon as possible so that the physician and pharmacist can adjust the treatment plan,” he says. “To stay competitive, the smart retail pharmacy might consider establishing a competing dispensing system that combines smartphone apps and barcode scanning to prompt patients to take their medications.”

Joseph Constance is a writer living in Wyckoff, NJ.
Nonmedical exemptions to vaccines are on the rise in many of the states that allow them. This is creating pockets of vulnerability across the United States, according to new research.

Researchers examined the rate of philosophical belief nonmedical exemptions (NMEs) in 18 states that allow these types of exemptions in a study published in *PLOS Medicine.* They found that the rates of NMEs had increased in 12 of these states since 2009.

“There are pockets in the United States where vaccine NMEs are widespread and there is risk of breakthrough infections,” coauthor Peter Hotez, MD, PhD, FAAP, dean of the National School of Tropical Medicine at Baylor College of Medicine, Houston, tells *Drug Topics.*

The study also identified what they called “hotspot” areas where there are large numbers of NMEs. These areas were identified as: Seattle; Spokane, WA; Portland, OR; Phoenix; Salt Lake City; Provo, UT; Houston; Fort Worth; Plano, TX; Austin, TX; Troy, MI; Warren, MI; Detroit; Kansas City, MO; and Pittsburgh.

“Especially in some of the western state counties there are large numbers of children not receiving their routine vaccinations,” Hotez says. As the rate of NMEs increases, he says, it can create risks for breakthrough childhood infectious diseases. The risk for measles is particularly significant because it’s so highly transmissible.

Researchers don’t know why the rates have been rising in recent years in those dozen states. While researchers found that, in some of the states identified, the rates appear to have plateaued, rates in at least a third of the 18 states that allow exemptions continue to be on the rise.

“We’re concerned that in several states, it’s the result of organized antivaccine activities,” Hotez says, adding that more research is needed to better understand why this is happening, and whether there are common social or demographic factors in areas with high NMEs.

The authors of the study also examined whether the rate of NMEs corresponded with actual vaccination coverage. They reported there was an inverse association between the NME rate and number of kindergarten students who were vaccinated for measles, mumps, and rubella.

Researchers believe the findings could also have implications for other countries that either allow NMEs or are considering them. “Our concern is that the rising NMEs linked to the antivaccine movement in the United States will stimulate other countries to follow a similar path,” they wrote in the study.

**FIGURE 1**

Nonmedical Exemption ‘Hotspots’

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**REFERENCE**


Jill Sederstrom is a contributing editor.
Introduction

Hepatitis C is caused by the hepatitis C virus (HCV). HCV causes an acute infection which may lead to chronic infection in an estimated 55% to 85% of patients. Chronic infection is defined as at least 6 months of detectable viral HCV RNA in the blood. There are no commercially available vaccines for HCV, but there are many highly successful curative treatment options.

Chronic HCV infection carries many life-threatening sequelae including both end-stage liver disease (ESLD) and hepatocellular carcinoma (HCC). An estimated 185 million worldwide have chronic HCV, with 3.5 million cases in the United States. More than half of those infected are unaware of their infection.

HCV is blood-borne, with the leading route of transmission for acute infection being intravenous drug use (IDU). Other potential risk factors include mother-to-child transmission, intranasal drug use, and long-term hemodialysis.

There are currently seven identified genotypes of HCV that are further subdivided into 67 subtypes. Genotypes 1, 2, and 3 are most common in the United States, accounting for 75.8%, 12.0%, and 10.4% of cases, respectively. The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) released HCV treatment guidelines that are organized by genotype. Guideline-directed therapy for HCV involves several levels of subgrouping to further optimize the probability of treatment success. Figure 1 illustrates this classification process. Recommendations for patients outside the groups listed (e.g., patients with decompensated cirrhosis) are made in the following sections.

The goal of treatment is to reduce all-cause mortality and liver-related morbidity, including ESLD and HCC. Successful treatment involves curing the infection. Clinically, this is done by achieving a sustained virologic response (SVR12), defined as an undetectable HCV RNA count (viral load) at least 12 weeks after completion of therapy.

Treatment is accomplished with the use of combinations of direct-acting antivirals (DAAs) for 8, 12, or 24 weeks. DAAs target one of three key proteins of the HCV viral replication cycle: NS3/4A protease enzyme, NS5A replication complex, or NS5B polymerase enzyme. Inhibition of NS5A or NS5B prevents RNA replication, while NS3/4A inhibition alters protein modification. Current guideline-recommended regimens...
are designed to inhibit at least two of these proteins. Generally speaking, the cure rate for all DAA regimens is above 90% for any given regimen and population, and, in most cases is above 95%.7

DAA treatment regimens in the current guidelines include: glecaprevir/pibrentasvir (GLE/PIB), elbasvir/grazoprevir (EBR/GZR), ledipasvir/sofosbuvir (LDV/SOF), sofosbuvir/velpatasvir (SOF/VEL), sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX), sofosbuvir/daclatasvir (SOF + DAC), simeprevir/sofosbuvir (SIM + SOF), and ombitasvir/paritaprevir/ritonavir with dasabuvir (PrOD) or ombitasvir/paritaprevir/ritonavir without dasabuvir (PrO).4 Ribavirin (RBV) is an RNA antimetabolite that is commonly used to augment regimens in patients with compensated cirrhosis or who have failed prior HCV therapy.4 Pegylated interferon alpha (PEG-IFN) together with RBV was the mainstay of all hepatitis C therapy until introduction of the first DAAs in 2011.4 The recent introduction of GLE/PIB has replaced the final guideline recommendations for PEG-IFN-based regimens (end-stage renal disease [ESRD] patients with genotype 2, 3, 5, or 6).

The list of drugs for hepatitis C has been changing in recent months. Olysio (simeprevir), Technivie (ombitasvir/paritaprevir/ritonavir), and Viekira XR (an extended release form of ombitasvir/paritaprevir/ritonavir with dasabuvir) have been discontinued by their manufacturers. We include information about these drugs here for the sake of completeness and in case their availability resumes.

**Screening, Diagnosis, and Monitoring**

Diagnosis of HCV is made in two steps. Screening is done by testing for HCV antibodies. If positive, confirmation of active infection is done by testing for viral load. Patients may test positive for HCV antibodies and negative for viral load under two circumstances: spontaneous clearance of the virus, or successful treatment with antiviral therapy.4 For those who initially test negative for HCV antibodies and are suspected of having liver disease, the guidelines recommend testing for viral load or retesting for HCV antibodies if exposure to HCV occurred within 6 months.4 If the viral load is negative there is no active infection, but the patient is not immune to reinfection.2

AASLD-IDSA guidelines recommend a one-time HCV test for the following at-risk groups.4

- All persons born between 1945 and 1965 regardless of country of origin
- Injection-drug users, including one-time users
- Intranasal illicit-drug users
- Long-term hemodialysis
- Persons with percutaneous exposures in an unregulated setting (especially tattoo and piercing parlors)
- Healthcare workers who have become exposed to infected blood
- Children born to infected mothers
- Persons who were ever incarcerated
- Recipients of blood components before July 1992 or clotting factor recipients before 1987
- HIV infection
- Sexually active persons about to start pre-exposure prophylaxis for HIV
- Unexplained chronic liver disease and/or cirrhosis hepatitis including elevated alanine aminotransferase (ALT)
- Solid organ donors

Patients who have tested negative for viral load but who continue to engage in high-risk behaviors, such as IDU and HIV-positive men having unprotected sex with other men, should be tested annually.4

The viral load is also used to track therapeutic success during and after treatment. It is repeated 4 weeks after start of therapy to track virologic response and 12 weeks after treatment to assess for SVR12. Other tests done prior to treatment are HCV genotype testing, liver fibrosis/cirrhosis assessment, screening for HIV and hepatitis B, and resistance-associated substitution (RAS) testing when required, usually before initiation of elbasvir/grazoprevir as described below.

Safety assessments at baseline should include the following4:

CONTINUED ON PAGE 38
Complete blood count (CBC)
International normalized ratio (INR)
Hepatic function panel (albumin, total + direct bilirubin, ALT, aspartate aminotransferase [AST], and alkaline phosphatase)
Glomerular filtration rate (GFR)

Testing for these parameters should be repeated at least at 4 weeks into treatment and then as clinically indicated.4

**Treatment Summary**

HCV therapy consists of once or twice-daily oral regimens of the DAA combinations listed below. Table 1 summarizes the guideline recommendations by genotype in treatment-naïve patients with compensated liver disease.

DAA metabolism and transportation involves at least one of five major components: CYP3A, CYP2C8, P-glycoprotein (P-gp), breast cancer resistance protein (BRCP), and organic anion transporter 1B1/1B3 (OAT1B1/3).10 Concomitant medications that inhibit or induce these enzymes or transporters may increase or decrease DAA exposure, respectively. Additionally, many DAs are themselves inhibitors of these enzymes and transporters and may contribute to elevated levels and associated toxicities of coadministered medications. Table 2 depicts the involvement of each DAA related to these metabolic enzymes and transporters.

In most cases, medications interacting with DAs do not represent an absolute contraindication, but may warrant additional monitoring, dose adjustment, or temporary discontinuation during DAA treatment. For example, acid-suppressing drugs may impair absorption of the NS5A inhibitors ledipasvir and velpatasvir. Current rec-

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**TABLE 1**

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**Abbreviations:** NC, no cirrhosis; CC, compensated cirrhosis
- Numbers in chart body represent recommended weeks of therapy
- Green cells represent first-line recommendations; yellow cells represent alternative recommendations
- Recommended if NS5A RAS mutations for elbasvir are detected
- 8-week regimen for LDV/SOF when recommended are optional for non-Black, HIV-uninfected patients whose baseline viral load is < 6 million units/mL
- When Y93H NS5A - resistance-associated substitution (RAS) for velpatasvir is detected

Source: AASLD-IDSA (http://www.hcvguidelines.org)
Advances in Hepatitis C Treatment: The Era of Direct-Acting Antivirals

Recommendations for coadministration of DAAs with proton-pump inhibitors (PPIs) includes either separating DAA administration by at least 4 hours with velpatasvir or administering the PPI simultaneously with ledipasvir. Histamine receptor antagonists (H2RAs) should be given 12 hours apart from DAAs. Antacids and DAA administration should be separated by at least 4 hours. Additionally, there are maximum allowable doses of PPIs and H2RAs. Many statins are substrates of OATP1B1, P-gp, and BCRP, and tend to incur significant increases in exposure when given with DAAs. Typical management of statin-based and DAA interactions involves careful monitoring for myopathy and statin dose-reduction accordingly. Rosuvastatin particularly is contraindicated with LDV/SOF. A 10-mg daily maximum is recommended with the regimens SOF/VEL and OBV/PTV/r, and a 5-mg daily maximum is recommended with PrOD.

Here are summaries of DAA regimens.

Glecaprevir/Pibrentasvir (GLE/PIB)
GLE/PIB is a three-tablet once-daily combination of 300 mg glecaprevir and 120 mg pibrentasvir (total daily dose). Both drugs are more than 92% fecally excreted, highlighting the favorable use of this combination in renally impaired patients. GLE/PIB is a recommended pangenotypic combination used in 8- to 16-week regimens regardless of renal function. Use in decompensated cirrhosis has not been sufficiently studied and remains contraindicated.

Elbasvir/Grazoprevir (EBR/GZR)
EBR/GZR is a single-tablet once-daily combination containing 50 mg elbasvir and 100 mg grazoprevir. EBR/GZR is currently a first-line regimen for genotypes 1 or 4, including patients with severe renal impairment in genotypes 1a, 1b, and 4. Testing for NS5A RASs for elbasvir is required before starting EBR/GZR in genotype 1a patients as it was shown in patients with any documented polymorphisms that SVR12 may be lowered as much as 28%. If baseline RASs are detected, weight-based ribavirin should be added and the treatment duration extended to 16 weeks. EBR/GZR is contraindicated in moderate to severe hepatic impairment.

Ledipasvir/Sofosbuvir (LDV/SOF)
LDV/SOF is a single-tablet once-daily combination containing 90 mg ledipasvir and 400 mg sofosbuvir. Sofosbuvir is a nucleotide analog and important backbone to many other regimens due to its high barrier to resistance and low propensity for drug interactions. It is a direct inhibitor of the viral NS5B polymerase enzyme. One important interaction between SOF and amiodarone involves the development of potentially fatal bradyarrhythmias. Current labeling warns against concomitant use of amiodarone with SOF; if amiodarone use is required, cardiac telemetry for at least 48 hours prior to starting SOF should be performed in an inpatient setting. SOF-containing regimens are not indicated in patients with severe renal impairment (CrCl <

<table>
<thead>
<tr>
<th>Major Enzymes and Transporters Involved in DAA Metabolism/Transport</th>
<th>CYP-3A</th>
<th>CYP2C8</th>
<th>P-GP</th>
<th>BCRP</th>
<th>OATP1B1/3</th>
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<tbody>
<tr>
<td>Daclatasvir</td>
<td>S</td>
<td>S/I</td>
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<tr>
<td>Dasabuvir</td>
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<tr>
<td>Elbasvir</td>
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<tr>
<td>Glecaprevir</td>
<td>S/I (weak)</td>
<td>S/I</td>
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<td>Grazoprevir</td>
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<tr>
<td>Ledipasvir</td>
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<tr>
<td>Ombitasvir</td>
<td>S (minimal)</td>
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<tr>
<td>Paritaprevir</td>
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<tr>
<td>Pibrentasvir</td>
<td>I (weak)</td>
<td>S/I</td>
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<tr>
<td>Ribavirin</td>
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<tr>
<td>Ritonavir</td>
<td>S/I</td>
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<tr>
<td>Sofosbuvir</td>
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<td>Velpatasvir</td>
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<tr>
<td>Voxilaprevir</td>
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Abbreviations: S, substrate; I, inhibitor
Sources: References 10-12, 14, 16, and 19-23

Continued on page 40 >
30 mL/min or ESRD requiring hemodialysis). SOF-containing regimens are currently a mainstay of treatment in patients with decompensated cirrhosis.4

LDV/SOF is currently indicated for genotypes 1, 4, 5, and 6 in both treatment-naive and experienced patients with or without compensated cirrhosis. Note that data from phase III clinical trials support an 8-week (versus 12-week) regimen of LDV/SOF in non-Black treatment-naive patients without cirrhosis whose baseline viral load was < 6 million IU/mL. In patients with decompensated cirrhosis and genotype 1, 4, 5, and 6, weight-based ribavirin is added to the 12-week regimen.

**Sofosbuvir/Velpatasvir (SOF/VEL)**

SOF/VEL is a single-tablet once-daily formulation of 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir (an NS3/4A protease inhibitor). SOF/VEL/VOX is approved to treat genotypes 1 through 6 in patients with compensated liver disease who have failed prior NS5A inhibitor-containing regimen. It may also be used in patients who have failed a SOF-containing regimen without an NS5A inhibitor in genotypes 1a or 3 only. A 12-week regimen is recommended in patients who have failed any prior therapy.5

**Simeprevir plus Sofosbuvir (SIM + SOF)**

SIM + SOF is a two-pill (separately sold) once-daily regimen of one 150-mg capsule of simeprevir (an NS3/4A protease inhibitor) and one 400-mg capsule of sofosbuvir. Simeprevir is no longer available. For information on SOF, refer to the LDV/SOF section. SIM + SOF is an alternative regimen for genotype 1 without cirrhosis for 12 weeks.4 Simeprevir is not recommended in patients with severe renal impairment (CrCl < 30mL/min) and is contraindicated in patients with moderate to severe hepatic impairment.4,21

**Ombitasvir/Paritaprevir/ritonavir +/- Dasabuvir (PrO/PrOD)**

PrOD is a fixed-dose tablet containing 12.5 mg ombitasvir (NS5A inhibitor), 75 mg paritaprevir (NS3/4A inhibitor), and 50 mg ritonavir (pharmacokinetic booster) taken as two tablets once daily. It is no longer on the market, but again, we include information on its use here. The fixed-dose combination of 8.33 mg ombitasvir, 50 mg paritaprevir, 33.33 mg ritonavir, and 200 mg dasabuvir (nonnu-
cleoside NS5B inhibitor) is taken as three tablets once daily. PrOD is an alternative in genotype 1a without compensated cirrhosis or in 1b with either no cirrhosis or compensated cirrhosis. PrO is recommended with weight-based ribavirin in genotype 4 with or without compensated cirrhosis. In patients with severe renal impairment, PrOD may be used for 12 weeks. Use is contraindicated in decompensated cirrhosis.

Ribavirin
Ribavirin (RBV) is a guanosine analog used to combat many types of RNA viruses. It’s proposed mechanism against HCV virus involves introduction of mutations leading to error catastrophe. RBV is contraindicated in pregnant females and/or male partners of pregnant females during treatment and for 6 months following treatment due to teratogenicity risks. RBV is used adjunctively to improve SVR12 rates in special populations including severe renal impairment, decompensated cirrhosis, prior failed treatment, or for regimens used in patients with mutations known to lower efficacy (e.g., NS5A RASs). It is dosed as 1,000 mg or 1,200 mg daily in two divided doses for patients weighing < 75 kg or > 75, respectively.

Special Population: HCV/HIV Coinfection
Patients infected with both HCV and HIV represent a sizeable portion of each respective treatment population (an estimated 80% to 90% of the IV drug-using population with HIV are coinfected with HCV). AASLD-IDSA recommends not interrupting HIV medications when treating HCV and that any changes in the HIV regimen during HCV treatment be made in conjunction with the patient’s HIV healthcare provider. Furthermore, patients coinfected with HIV should be treated as if they were not infected with HIV, but drug-drug interactions between antiretrovirals and DAAs must be anticipated and managed. Antiretrovirals that commonly interact with DAAs include nonnucleoside reverse transcriptase inhibitors (e.g., efavirenz, etravirine, and nevirapine), and protease inhibitors (e.g., darunavir, and atazanavir).

Adverse Events
Overall, DAA-containing regimens are very well tolerated. The most commonly reported adverse events for DAAs include headache and fatigue. These adverse events are usually mild in nature and do not require discontinuation of therapy.

Cost
Figure 2 lists the wholesale acquisition cost (WAC) of each regimen to give insight into drug costs from manufacturer to wholesaler. However, in reality, a wide variance exists in practice due to buying power and rebates negotiated by pharmacy benefits managers and/or insurance carriers. The figure compares the monthly wholesale acquisition costs (WAC) of the DAA regimens. DAC, SIM, and SOF are listed individually; however, their costs should be added together for an estimated total cost. Due to the high costs of DAAs, manufacturers offer programs to help patients with payment and delivery of medications. Each manufacturer has its own qualifying criteria. The following list can help pharmacists guide patients toward more information about these programs.

References are available online at http://bit.ly/HepCAdvances.
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I’ve been precepting students for the past 10 years, and #61 and #62 are currently staying with my wife Denise and me in our home, about two hours from the University of Pittsburgh. This Rural Pharmacy Rotation is sought after by the serious community pharmacy students because of our involvement in working in physicians’ clinics, where we provide pharmacy consultation to the providers.

Denise works at the Centre Volunteers in Medicine (CVIM) in State College, PA, which provides care to the neediest of all patients, the uninsured. Denise does a stellar job getting medications from all kinds of resources such as AmeriCares, Direct Relief, pharmaceutical reps, and MAP programs. She cares for people released from prison and many other patients who have no insurance. Her situation is unique: her patients get brand name drugs that are usually not covered by most insurance plans, thanks to the generosity of the manufacturers. She works with numerous volunteers from an assortment of healthcare careers—physicians, CRNPs, and nurses. State College, home to Pennsylvania State University, is one of the more affluent communities, and their fundraising efforts are most successful in supporting this clinic.

The clinic I work in is a direct-pay family practice clinic. Zane Gates, MD, founder of the Empower-3 clinic, works tirelessly on this model to remove the insurance companies from the examination room. Gates’ clinic is a modern family practice office that caters to the underserved, the Medicaid population, and business groups who buy “memberships” for their employees at a nominal monthly cost. Gates uses his pharmacists and his physician assistants, to provide excellent care at a reasonable cost. The pharmacist sees the patient first, cleans up the med list, verifies adherence, pends refills that are needed, and discusses smoking cessation with the patient, before the provider even walks into the room.

The question every student asks either Denise or me is, “So how did you get a position like this?” The answer can be distilled down to one word: Connections. I met Gates at a mutual friend’s party about six years ago. He asked me to develop a formulary to help him care for his working poor. Working with my wife, daughter, and son-in law, we developed a usable formulary where the drugs cost less than $10 a month. He was pleased, and when he got funding from the State Health Department for a pharmacist for four hours a week, I came to mind. After the grant expired, he was able to keep me on. Four days a week, he has a pharmacist staffing his clinic. I cover two of those days.

Denise got her position at CVIM when the manager came to her and asked if she knew of a pharmacist who would be interested in covering 12 hours a week. Denise offered two names, who were not interested, so she decided this was an opportunity to practice clinical pharmacy. She works directly with the volunteer physicians and residents from Hershey Medical Center. The position is a dream job for her. She has never been happier in her career.

Nothing pleases me more when I get to share in the success of my past student pharmacists. Student #15, Mike Geishauser, a resident of Altoona who graduated from Duquesne University five years ago, called me and asked if he could shadow me at Gates’ clinic, because he landed a position at Altoona Family Physicians as a full-time clinical pharmacist. How did Mike get his dream job? He was persistent in showing the supervising physician articles, information, and proof of the value of a pharmacist in a family practice clinic. We had an awesome day together, and I shared my protocols and my experience in the clinic.

I tell every student that you won’t find a job like I have, you have to create a job like I have. Mike is proof of that.

PETE KRECKEL, BSPharm, practices independent community pharmacy in Altoona, PA. He welcomes your e-mails at pharmcanoe@aol.com.