The Future of Pharmacy Automation

Plus

Hepatitis C
The Vaccine Pipeline
Is My Pharmacy Job Safe?
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.

• Hemorrhagic occlusive retinal vasculitis, including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or intravitreal route have not been established by adequate and well-controlled studies. Vancomycin is not indicated for prophylaxis of endophthalmitis.

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.

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)

**Important Limitations of Use:**

- 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. 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.

- Clinically significant serum concentrations have been reported in some patients 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. These patients may be at risk for the development of adverse reactions associated with higher doses of FIRVANQ™; therefore, 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. Monitor renal function.

- Otoxicity has occurred in patients receiving vancomycin hydrochloride. It may be transient or permanent. Assessment of auditory function may be appropriate in some instances.

- 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.

- Hemorrhagic occlusive retinal vasculitis (HORV), including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or intravitreal route have not been established by adequate and well-controlled studies. Vancomycin is not indicated for prophylaxis of endophthalmitis.

### CONTRAINDICATIONS

- Hypersensitivity to vancomycin

### ADVERSE REACTIONS

#### In addition to the information presented above from clinical trials, the following adverse reactions have been identified during post-approval use of vancomycin hydrochloride:

- **Otoxicity:** Hearing loss, vertigo, dizziness, and tinnitus have been reported.

- **Hematopoietic:** Reversible neutropenia, usually starting 1 week or more after onset of intravenous therapy with vancomycin or after a total dose of more than 25 g, has been reported. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has been reported.

- **Miscellaneous:** Anaphylaxis, drug fever, chills, nausea, eosinophilia, rashes (including exfoliative dermatitis), Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis have been reported with the administration of vancomycin.

A condition has been reported with oral vancomycin that is similar to the IV–induced syndrome with symptoms consistent with anaphylactoid reactions, including hypotension, wheezing, dyspnea, urticaria, pruritus, flushing of the upper body (“Red Man Syndrome”), pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours.

#### 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.

#### Pregnancy:
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 solutions 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 solutions 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 CutsPharma, 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 Cuts Pharma
941 Woburn St. Wilmington, MA 01887 USA
Rev. 2/2018
FDA’s Drug Information Specialists

When you think of drug information (DI) specialists, you may envision pharmacists providing empiric therapy recommendations, writing hospital newsletters, or performing literature searches. Unlike the work of traditional DI specialists, the role of an FDA DI pharmacist is much broader. In addition to the traditional DI role of answering inquiries about drug products, pharmacists at the FDA also provide regulatory guidance for drug development, serve as a conduit for reporting drug problems, and are often the first agency contact for whistleblowers.

The DI specialists in the Center for Drug Evaluation and Research’s (CDER’s) Division of Drug Information (DDI) can be the first to learn of an emerging public health risk or patient safety issue. Nothing illustrates this better than the fungal meningitis outbreak in 2012. What began as one call—a patient reporting serious complications after use of contaminated injection produced by the New England Compounding Center—signaled the beginning of the outbreak.

In July 2018, DDI specialists began fielding an unusually high number of questions about a recall occurring in Europe. The European Medicines Agency had recalled some valsartan medicines due to an impurity in the bulk active ingredient, which came from a Chinese company that supplied several manufacturers. A division pharmacist consulted with CDER’s Office of Compliance and the FDA issued a statement about three voluntary recalls from U.S. manufacturers that had used the affected ingredient. Within the first month of the investigation, 4,000 inquiries informed the FDA’s expanding investigation and communications to the public.

In another incident, a concerned pharmacist alerted FDA to a new sleep aid named Elavil OTC Sleep that was being marketed as an OTC dietary supplement labeled as containing melatonin, valerian root, and vitamins. The DDI pharmacist recognized this product was being marketed in a way that would confuse consumers to think it contained Elavil, a well-known prescription antidepressant. While Elavil is no longer marketed as a brand-name drug, generic amitriptyline products are still often referred to as Elavil. CDER collaborated with the FDA’s Center for Food Safety and Applied Nutrition, which regulates dietary supplements, to address concerns with the company marketing Elavil OTC Sleep. A warning letter was issued to the company within weeks, and it was cited for misbranding and for making multiple drug claims. The product’s website has been taken down and many pharmacy professional associations, including the Institute for Safe Medicine Practice, issued warnings about it.

DDI also receives whistleblower complaints about good manufacturing practice violations. DDI has escalated several whistleblower complaints ranging from drug registration and listing violations to major quality issues in manufacturing sites. Many of these cases have resulted in warning letters and nationwide recalls.

If something looks peculiar with a product you receive, drug you dispense, or the place you work, tell us. Contact FDA’s Division of Drug Information at druginfo@fda.hhs.gov or 855-543-3784. Our staff will work with you to get the information to our experts. Your report may be the index case for an investigation that protects the public and patient safety.
It’s Time to Get the Medications Right

We spent roughly $480 billion for prescription drugs in 2016. We wasted $528 billion on nonoptimized medication use. Why? The reasons are complex.

First, we lack a systematic coordinated approach to medication management that can ensure medications are appropriately and effectively used.

Second, we are in the midst of the greatest evolution in healthcare, a transition from population health-based clinical guidelines to personalized precision medicine. Whole genome sequencing reveals new mutations and is allowing ever greater precision. Advances in pharmacogenomics, diagnostics, targeted therapies, and even microbiome influences are progressively narrowing our understanding of drug and genetic therapy from a shotgun approach to laser certainty.

Third, policy and payments must align with these scientific and delivery system realities if we are to close the gap between scientific discovery and direct patient care.

This is why we launched the Get the Medications Right (GTMRx) Institute with a specific crosscutting—and, I believe, unique—focus: Bring critical stakeholders together, bound by the need to optimize outcomes and reduce costs by getting the medications right.

More than 200 members come from both the practice delivery side—including the underused services of clinical pharmacists and genetic counselors—as well as the IT and analytics/artificial intelligence, advanced diagnostics, and policy and payment spheres, all working with patients to transform care.

Our goal is to attack the issue of nonoptimized medication use. We’re engaging physicians, clinical pharmacists and other providers to transform practice and integrate comprehensive medication management (CMM) as the means by which to focus on this personalized precision approach to medication management. We’re boosting evidence while informing payers and policymakers about CMM’s promise to lower costs and improve lives.

Understanding CMM
What is CMM, and why do we believe it will optimize clinical outcomes? It’s a systematic approach to medications where physicians and pharmacists ensure that medications—prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements—are assessed to determine that each is appropriate for the patient, effective, safe, and able to be taken by the patient as intended.

CMM optimizes medical outcomes by ensuring medications are appropriately and effectively used. This not only boosts cost-effectiveness; it assures that all conditions are effectively managed, building the bridge from trial-and-error population-based medication use to personalized science-and-data-driven medication therapy.

It’s important to distinguish between CMM and other forms of medication therapy management (MTM). CMM is patient-centric, based on optimizing the clinical goals of therapy, and was defined by the Patient-Centered Primary Care Collaborative.

Many organizations have taken to calling what they do “comprehensive medication management.” They may do two or three components, but no more. CMM includes 10 specific elements. An organization must do all 10; otherwise, it isn’t providing comprehensive medication management.

Medical knowledge is said to be doubling every 73 days. With medications representing 80% to 85% of how we prevent and treat disease, we must focus on optimizing medications.

It’s time to get the medications right.
Your Approach to Hiring Is All Wrong!

Neither your gut nor peer advice will get you the caliber people you need

Most pharmacy owners trust their gut to determine how to locate and hire the best possible candidates for any job opening. Others seek advice from more established colleagues. Neither one is a sound basis for hiring future superstars if you want to build an A-team.

And, if you’re looking for a technician or a cashier on the basis of experience, that, too, is the wrong reason to select an individual. You can give anyone the experience they need.

Experience is not the right basis for hiring because it may be the wrong experience. Your culture and how you want things done matter far more than somebody else’s adverse experience, especially if it was in a chain store or big box store.

Certain qualities indicate that a person will succeed no matter what type of job you are hiring her for. Her attitude towards learning and success are most important.

Indeed, drive and determination, plus an attitude towards learning, can be the most important information you can discover about her.

What Now?
The approaches to recruiting candidates that you were using ten years ago no longer succeed very well, especially during this period of peak employment for the general population, when the barrel of labor supply is almost empty.

Here’s what you should be doing:

▶ Advertise online as well as in the local newspaper because this is where the largest number of applicants seek new employment. When properly done, you can even entice individuals who are currently employed but who are seeking a better opportunity.

▶ Describe the benefits of coming to work for you rather than somewhere else. And make certain those benefits are what most people are seeking today (ie, health insurance, child care assistance, etc.).

▶ Give good people reasons to leave their current jobs. Surveys show that as many as 67% of those gainfully employed are unhappy in their current positions and would prefer to move to a better job. Make sure you extol all the benefits and opportunities you offer.

▶ Offer flexibility arrangements (ie, days of week, hours, etc.), as long as they are compatible with your needs.

▶ Show that you are interested in helping applicants make a career of working for you.

Hiring the Smart Way
Once you receive resumes in your email, interview the top three candidates to see which one is most qualified. You can assess qualifications by holding a two-minute phone call with the applicant and using a well-prepared, short questionnaire.

And finally, perform a reference check to determine if the applicant really has the abilities you want in an employee. Sometimes, you may learn something about that individual that you could not discern from any conversation.

By following this proven method for hiring the most qualified people, you can select the future stars of your team.
SPECIALTY MATTERS

By Jason Poquette, RPh

A Case for Health System Specialty Pharmacy

Pending for specialty pharmaceuticals continues to rise, with the front-runners like CVS Specialty and Accredo generating more than $30 billion in annual revenues in 2018 alone. By 2020, industry experts believe specialty drugs will account for 50% of U.S. spending on pharmaceuticals.

Health systems and hospitals have been watching this trend and are entering the specialty drug dispensing industry. According to an analysis by Adam Fein of Drug Channels, "about one-quarter of all accredited specialty pharmacy locations are owned by hospitals, health systems, physician practices, and providers’ group purchasing organizations.

But revenue alone is a rocky road on which to build the case for a health system specialty pharmacy. Margin pressures have forced several significant players to exit the market. Premier Inc. recently announced its decision to move away from the specialty pharmacy business.

Health systems need to think strategically about how they design and implement specialty pharmacy programs. Those with access to 340B pricing may be lured into believing that the profits are virtually guaranteed; however, increasing political pressure and focus on this model, and legislation to reduce 340B reimbursements to hospitals, may require a new approach.

The case for a successful health system specialty pharmacy model is built on the foundations of service and savings. Here is where health systems can offer value that often cannot efficiently be supplied by traditional mail-order specialty pharmacies.

Service

Part of the service advantage of a health system specialty pharmacy is a result of the convenience of being able to dispense directly to patients who are already at the hospital to see their providers, have blood drawn, or are there for outpatient treatment. Well designed specialty pharmacy workflows can provide an efficient way to dispense these medications to patients while they wait for their appointment or procedure.

This service also allows health systems to use their best clinical staff to provide face-to-face counseling with patients about the use of specialty medications either within the individual clinics, during infusions, or in counseling rooms on-site.

Savings

The cost of specialty pharmaceuticals continue to rise, and health systems need to think about ways they can help payers manage costs as well as care. By working closely with hospital providers and patient electronic medical records, health system specialty pharmacies can save money for payers by quickly discontinuing or delaying medications.

There is an opportunity for hospitals to think about partnering with payers around outcomes-based pricing models where margins can be tied to tangible goals for patient success. Readmission prevention services for high-risk patients can also be used to help care for these patients in comprehensive, efficient ways. These and other creative approaches are more efficiently managed by a hospital outpatient specialty pharmacy.

The real winner of a health-system-based specialty pharmacy program are the patients, who will receive end-to-end care of their chronic illness or disease. By putting patient needs first and revenue second, hospitals can create value-based models for specialty pharmacy that are good for patients, payers, and providers.
NACDS’s four new policy recommendations for opioid abuse prevention include increasing access to naloxone and working towards a national prescription drug monitoring program (PDMP).

The organization’s opioid recommendations include state-level legislative and regulatory revisions that would foster the creation of a national PDMP database, Steven C. Anderson, NACDS president and CEO, tells Drug Topics.

Proposed PDMP requirements include daily reporting of controlled substance dispensing information to state PDMPs, data standardization to improve PDMP usefulness, a check to the state PDMP by providers prior to issuing a controlled substance prescription, and enabling interstate access to PDMP data.

In Missouri—the only state without a PDMP—NACDS is continuing to work with its two in-state partners on a statewide PDMP that builds on the current county-based program, which covers nearly 80% of that state’s population, according to Anderson.

NACDS now recommends that naloxone be coprescribed with some opioid prescriptions. Because certain patient populations are at increased risk of overdose due to the nature of their condition or to the combination of medications they take, coprescribing ensures immediate access to naloxone that could prove life-saving in emergencies, Anderson says.

“NACDS will pursue state legislation that ensures all patients taking potentially dangerous combinations have access to naloxone when the initial opioid prescription is filled. NACDS urges the authorization of pharmacists to prescribe and dispense naloxone immediately upon identifying patients at potential risk of overdose, or an individual that presents with possible abuse of heroin,” Anderson says.

NACDS is also urging for reforms in the design of health plans to help identify and treat patients with substance use disorders (SUDs) and is urging improved coverage for pain management treatments other than opioids.

“Opportunities exist to leverage the role of the pharmacist in services that improve access to medications for SUDs and addiction, incentivize screenings for SUDs, and improve access to medication assisted treatment at the physician- and community-pharmacy levels,” says Anderson.

NACDS proposes to pursue federal and state policies that require coverage of alternative non-opioid drug therapies for chronic pain management at the same formulary and cost-sharing tier. NACDS also proposes to require coverage of complementary or integrated health pain management services, according to Anderson.

Pharmacists’ role in opioid abuse prevention is warranted and welcome—70% of Americans support leveraging pharmacy’s role to help solve issues related to opioid abuse, says Anderson.

In addition, a national survey conducted in January by Morning Consult and commissioned by NACDS found that, by a 2-to-1 margin, pharmacies and pharmacists are considered to be a solution, not a contributor, to the problem of opioid abuse. ■

— By Christine Blank
More than 29 million U.S. adults have type 2 diabetes mellitus; its prevalence worldwide has increased by 30% in the last 10 years, according to a new report from the American Heart Association (AHA). There are 6.5 million people in the United States in heart failure.

Recent clinical trials have demonstrated the shared pathophysiology between diabetes mellitus and heart failure, the synergistic effect of managing both conditions, and the potential for diabetes mellitus therapies to modulate the risk of heart failure outcomes.

AHA is calling for a team-based approach to caring for and managing patients with heart failure and diabetes. This integrated approach should include:

- Primary clinicians practicing in primary care, cardiology, and endocrinology
- Other clinicians: pharmacists, dieticians, and physical therapists
- Specialists (when needed): palliative care, nephrology, and hospitalists
- Community resources: social workers, community health workers

“Central to team-based care is the recognition that approaches to chronic disease management require the development of individualized plans of care that consider patient preferences and effective coordination of care across all members of the healthcare team,” the paper states.

Other topics addressed in the paper include: the epidemiology of type 2 diabetes and heart failure, pathophysiology, medical management including glycemic goals, considerations of glucose-lowering medications (metformin, sulfonylureas, thiazolidinediones, insulins, GLP-1 receptor agonists, DPP-4 inhibitors, SGLT-2 inhibitors), considerations relating to heart failure therapies (angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, angiotensin receptor neprilysin inhibitor, beta blockers, ivabradine, mineralocorticoid receptor antagonists, and ICD/CRT), clinical considerations with patients with chronic kidney disease.

Download the report here: https://bit.ly/2MSmxk1

— By Daniel Verdon

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**Type 2 Diabetes: A Risk Factor for Heart Failure**

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**Massachusetts Commission Calls for More Transparency on PBM Spread Pricing**

The Massachusetts Health Policy Commission (HPC) is calling for more oversight in spread pricing by pharmacy benefit managers (PBMs).

In a new report, HPC examined spread pricing and its impact on the state’s commercial health plans and Medicaid. The findings were presented recently at an HPC’s Market Oversight and Transparency committee meeting.

A 2020 state budget proposal would limit PBM margins under contracts with MCOs and accountable care organizations (ACOs), HPC says.

To examine the potential impact of these different pricing practices, the HPC compared generic drug prices in the MassHealth MCO program and in the commercial market to the pharmacy acquisition cost for the drug, based on the National Average Drug Acquisition Cost (NADAC).

“The difference between the payer price and NADAC is largely comprised of the dispensing fee to pharmacies and the potential profit retained by PBMs. The HPC also compared the MCO/PBM prices to Massachusetts Commission Calls for More Transparency on PBM Spread Pricing

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**New Certificates for Pharmacists**

ASHP has launched the Emergency Medicine Certificate and the Nutritional Support Certificate.

The emergency medicine course comprises 11 online modules, offering 27 hours of CE credits.

The Nutritional Support Certificate from ASHP and the American Society for Parenteral and Enteral Nutrition consists of 11 online modules and offers 19.25 hours of CE.


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**CVS to Offer HealthHUBs at 1,500 Stores**

CVS Health has announced that it will expand its HealthHUBs to 1,500 locations by the end of 2021. Fifty CVS locations in the Houston, Atlanta, Philadelphia/Southern New Jersey, and Tampa, FL, areas will be the first to offer expanded services. This is about 15% of the CVS Pharmacy locations in those markets.

The stores offer personalized pharmacy support programs and expanded MinuteClinic services, as well as one-on-one and group counseling on topics such as nutrition and weight loss.

— Valerie DeBenedette

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**CVS to Offer HealthHUBs at 1,500 Stores**

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FFS, using FFS prices as a benchmark for the pass-through pricing model that includes the set dispensing fee of $10.02 per prescription."

PBMs assert that spread pricing models provide more predictability for health plans than pass-through models, in which drug prices for plans fluctuate directly with changes in drug acquisition cost. However, with greater transparency, payers can make informed choices about allocation of state spending or premium dollars, including appropriate compensation for both pharmacies and PBMs.

Key findings:

- In 2017, drug spending in Massachusetts increased by 4.1%.
- MassHealth drug spending nearly doubled in five years from $1.1 billion in 2012 to $1.9 billion in 2017.
- Spread pricing covered 22% of PBM salaries in 2014 and about 54% in 2016.
- "PBM payments to pharmacies are sometimes even below the pharmacy’s acquisition costs of the drugs, which can affect the financial viability of pharmacies and potentially impact access to care."
- In the fourth quarter last year, MCOs paid an average $159.24 per prescription buprenorphine-naloxone 8-2 mg, which was 111% higher than the average Medicaid fee for service price of $75.53.


Hospital Drug Diversion: An Underreported Threat

Results from a survey of 651 healthcare professionals indicate that many believe drug diversion within healthcare settings is a significantly growing problem and an underlying contributor to the ongoing opioid epidemic. But for the same group, identifying and combatting the problem remains a challenge. Only one in five respondents thought diversion was a problem at their facility.

According to the survey, "Health Care’s Hidden Epidemic: A Call to Action on Hospital Drug Diversion," jointly conducted by Becton, Dickinson and Company (BD) and global publishing opinion research consultancy KRC Research, much of the current information on drug diversion within healthcare settings stems from isolated cases and anecdotal evidence. The authors conclude that there are only inaccurate glimpses into the realities of drug diversion within hospitals.

Healthcare Providers

- 85% of healthcare respondents are concerned about healthcare and provider-based drug diversion.
- 20% of healthcare provider respondents reported they believe diversion is a problem in their facility.

C-Suite Executives

- 89% believe drug diversion to be a significant problem.
- 53% believe drug diversion is a problem within hospital settings.
- 17% believe drug diversion is a problem in their facility.
- 67% of executive respondents believe employees are comfortable discussing drug diversion at work.
- 89% of provider respondents said they were at least somewhat or very comfortable discussing diversion with colleagues.

Reasons cited for discomfort discussing drug diversion among colleagues

- 67% believe it sounds accusatory.
- 51% fear it raises suspicion.
- 40% believe it engenders mistrust between peers.
Insights for Implementing Enhanced Community Pharmacy Services

By Brittany Hoffmann-Eubanks, PharmD, MBA

Introduction

The U.S. population is expanding at an estimated 8% every ten-years.1 As the population ages, both the number of people with chronic conditions and the burden on primary care will increase as well.2 As a result, primary care physicians (PCPs) are tasked with managing all of a patient’s health conditions and coordinating care with other providers. Compounding the problem is the expected shortage of PCPs of from 15,000 to 50,000 by 2030, according to the Association of Medical Colleges.3 To address these concerns, new innovative care models such as patient-centered medical homes and accountable care organizations—where PCPs collaborate with other healthcare providers to improve outcomes for patients—have been developed.2

Pharmacists have traditionally been integrated into team-based care (TBC) models in health systems. Now, TBC programs are being expanded to the community pharmacy setting.2

Pharmacists have traditionally been integrated into team-based care (TBC) models in health systems. Now, TBC programs are being expanded to the community pharmacy setting.2

What Is Implementation Science?

Implementation science (IS) is “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice to improve the quality and effectiveness of health services.”6 The ultimate goal of IS is the improvement of the quality of healthcare, usually beginning with an evidence-based practice (EBP) that is under-used.7 The EBP is then evaluated, and quality gaps at the provider, clinic, or healthcare system level are identified and addressed. It is important to note that IS is not the same as clinical research, since IS studies generally focus on the rates and quality of use of EBPs rather than their effects.7 For example, an IS outcome would measure the number of pharmacists providing hypertension management in a community pharmacy as opposed to the impact of pharmacist-led hypertension management on health status. IS focuses on evaluating the process of implementation and its effect on the EBP.7 A comprehensive discussion of implementation science is beyond the scope of this article, but has been reviewed elsewhere.6,7

CPF Study Grant Synopsis

The study, “Removing Barriers to Organizational Change in Community Pharmacies: An Analysis of the Successes and Challenges of Implementing Enhanced Services,” was completed in 2018.8 It was a cross-sectional mixed-methods study that surveyed 268 North Carolina community pharmacies, and interviewed 40 community pharmacists responsible for implementing CPESN in their pharmacy.
among high-performing and low-performing pharmacies were compared using performance metrics for payment identified by the NC-CPESN. Implementation effectiveness was measured by the number of comprehensive medication reviews conducted and the reach of comprehensive medication reviews via the number of eligible patients who received the intervention. Turner and colleagues then evaluated organizational factors that contributed to or hindered the successful implementation of enhanced services in community pharmacies. Study results showed that community pharmacies that had a clinical pharmacist on staff were significantly more likely to be effective at implementing the CPESN program. Further, community pharmacies with a strong climate for implementation were significantly more likely to be effective at implementing the program. Those that had previous relationships with physicians, care managers, and public health agencies were more successful with implementation, as well. The study team has taken the research findings and developed an online learning module to provide guidance on how to implement enhanced pharmacy services within community pharmacies.

Integrating Community Pharmacies into Team-Based Care

There are several major implications for integrating community pharmacists into team-based care from this study. According to Turner and Renfro, it is very important to create a strong climate for implementation within the community pharmacy organization. For example, pharmacies that had sufficient support for carrying out enhanced patient care services were more successful. Pharmacies that provided resources such as adequate staffing and in-depth CPESN training were also more successful. In contrast, putting all of the CPESN workload on one staff member hindered success. Similarly, pharmacies that built their implementation plan as they were going along were less successful than those that had a process in place for managing change. For example, assessing pharmacy workflow for efficiency and having continuous quality improvement measures can be helpful in implementation.

Furthermore, pharmacies that involved the entire staff and had established mechanisms for rewarding or recognizing their staff were also more successful. Communication from leadership about the expectations for staff participation and the importance of the CPESN program were also crucial to successful implementation.

Another major finding from the study was that pharmacies varied in the strength of relationships with healthcare organizations and patients. Pharmacies that had previously partnered with physicians or had relationships with other healthcare providers were more successful with CPESN implementation. As a result, the study showed that having resources available for pharmacies who did not have previously established relationships would be beneficial to the implementation of CPESN.

The authors conclude that further research is required to better understand the variation in implementation success that was observed between the high- and low-performing pharmacies by documenting a small set of implementation strategies and comparing them.

Conclusion

The demand for primary care services is increasing as the U.S. population expands and ages. Pharmacists can help bridge this gap. New care delivery models that include pharmacists have already been implemented in primary care settings and are expanding to community pharmacies. As such, payers are looking to involve community pharmacists for their expert drug knowledge and accessibility. One approach is through pharmacy expanded services programs, but little is known about how to implement these programs in the community setting. Results of a Community Pharmacy Grant implementation science study found that having adequate resources, training, and relationships with local healthcare providers were important to the successful implementation of CPESN programs in North Carolina community pharmacies. Further research is required to better understand implementation strategies between low- and high-performing CPESN pharmacies.
Pharmacists have come a long way since the days when their only responsibility was dispensing drugs.

Starting in the 1980s, pharmacists were urged to take on a vital role by providing medication expertise to ensure patients properly and safely use their medications. The 2003 Medicare Prescription Drug Improvement and Modernization Act fueled the change.

“The changing healthcare environment has required pharmacists to assume advanced roles. They now must focus not only on how to improve healthcare quality, but also on driving down healthcare costs,” says Bernice Man, PharmD, practice coordinator at Northwestern Specialty Pharmacy in Chicago.

“The increase in the number of specialty therapies has . . . promoted integration of pharmacists into clinics to ensure appropriate initial and continued education, as well as timely follow-up and medication management,” she adds.

As a practice coordinator and clinical pharmacist, Man supervises clinical pharmacists within specialty pharmacy, assumes administrative/management-oriented decision-making responsibilities, serves as the point person for electronic medical record issues, handles human resources-related activities and time cards, precepts pharmacy residents and students, and helps patients navigate their insurance benefits.

Pharmacists at Northwestern Specialty Pharmacy also recommend adjunct medications as necessary, perform interventions such as dose adjustments, clinically monitor patients after starting therapy, and counsel patients.

Laura Happe, PharmD, MPH, wears a lot of hats as a pharmacist. She is not only editor-in-chief of the Journal of Managed Care and Specialty Pharmacy, but is also an associate professor in population health at Wingate University, Charlotte, NC; an adjunct associate professor at the University of Florida at Gainesville; and an author.

Happe warns, however, that multiple gigs like hers should be complementary and not in conflict. “In a gig economy, it is necessary to establish synergy between what I do, making logistics easier, and creating a better product,” she says.

As the journal’s editor-in-chief for the past six years, she sets the publication’s strategic agenda, makes final decisions about which articles to print, and oversees the peer review process.

In her role at Wingate, Happe teaches population and public health across interdisciplinary departments, providing an interprofessional educational experience for pharmacy students.

At the University of Florida, she is director of the managed care pharmacy track in a master of science pharmacy outcomes program designed for working professionals and post-PharmDs.

Happe’s book, If you give an Ox an Oxy (Morgan James Publishing), is due out in November and is geared toward teenagers to use in conversation with their parents and teachers about opioids. She wrote it after she saw some disappointing statistics about the low rate of discussions between parents and their children on the subject of prescription drug abuse.

“I’ve never served in a retail setting because I have always been interested in nontraditional pharmacist roles,” Happe says. She notes an oversupply of pharmacists and insufficient roles in traditional retail and hospital settings, leading to shorter hours and less pay.

“But there are a plethora of opportunities—research, consulting, analytics, technology, and writing—for specialized pharmacists with a secondary degree or additional experience,” she adds.

“I don’t let walls or silos become a constraint,” she says. Physicians recognize that pharmacists can help with diagnoses and medication therapy, and with quality measures tied to medication in value-based programs, and contribute to the financial success of a team.

“I also have an opportunity to practice at the top of my license, pursue things about which I am passionate, and make a difference,” she says.

On the other hand, Happe faces a few challenges as a pharmacist with many roles:
Difficulty being reimbursed for service.
- Not being identified as a provider.
- Lack of collaborative practice agreements in many states.
- The logistics of management, accounts, and calendars.

The Multifunctional Pharmacy
Randy McDonough, PharmD, co-owner of Towncrest Pharmacy in Iowa City, IA, says his pharmacy has been evolving since its inception and is integrated into healthcare teams with which it works.

Towncrest encompasses five areas, McDonough says:

1. Traditional dispensing. McDonough says Towncrest has become more efficient in dispensing drugs by using automation—the pharmacy has three robots and an automatic pill counter—and by optimizing the use of technicians who conduct medication verification.

2. Clinical responsibilities. Medication therapy management, transitions of care, and medication optimization and synchronization—enabling consumers to fill all of their prescriptions on the same day and receive compliance packaging to spur adherence—are key clinical roles. McDonough says that the pharmacy makes recommendations to physicians, 50% of whom accept them.

3. Durable medical equipment. Pharmacists fit customers for CPAP masks, diabetic shoes, and compression stockings, and assist with ostomy bags and wound care.

4. Compounding. Pharmacists work with prescribers to establish proper dosage and products for patients with special needs.

5. Long-term care. Pharmacists provide medication management, make home visits, evaluate and optimize medications, and share information with prescribers. Between 500 and 600 of Towncrest’s patients are in a nursing facility.

McDonough says the changing roles of pharmacists align with the dynamic healthcare industry and could also be attributed to pharmacists gaining additional education and training.

“You can no longer make money just from dispensing, but have to be diversified, so we work closely with accountable care organizations (ACOs), payers and physicians to develop new reimbursement models,” he says.

Towncrest has conducted a variety of pilot programs, including one that indicated a $300 per member per month savings due to medication management.

Added Education
Nidhi Saraiya, PharmD, clinical pharmacy manager, infectious diseases, at Montefiore Health System in New York City, agrees with Happe that more education and training are no longer uncommon. “However, that’s not the public perception. We need to change that; the public is not aware of our training and background,” she says.

But physicians are clamoring for assistance with medication and appreciate pharmacists’ new roles. Shaw agrees that physicians have offered little resistance. “Although economics has played an important role over the last few decades to reshape healthcare, the exponential advancement in medicine has created a necessity to work as a team to provide seamless care,” he says.

“I’ve never served in a retail setting because I have always been interested in non-traditional pharmacist roles.”

LAURA HAPPE, PHARMD

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LAURA HAPPE, PHARMD

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Gottlieb: Creating Space for Opportunities and Innovation

At the 2019 Asembia Specialty Pharmacy Summit, former FDA Commissioner Scott Gottlieb discussed advances within the agency during his tenure. By Kayt Sukel, contributing writer

In April, Scott Gottlieb, MD, stepped down after two years of service as commissioner of the Food and Drug Administration (FDA). Gottlieb was the keynote speaker at this year’s Asembia Specialty Pharmacy Summit in Las Vegas. During his speech, he discussed how the agency wrote “modern rules for new technological paradigms,” in order to create a regulatory framework to help govern drug development and approval opportunities in the future.

Gottlieb discussed those changes and how they will help implement sound regulations and policy moving forward.

**On gene therapy:**
“We had to rewrite the rules for how we were going to approach these new technologies and really lay the foundation for what the regulatory architecture would look like moving forward. In respect to gene therapy, a lot of the issues are not on the clinical portion of the review. These gene therapy products are so effective, you can often determine clinical effectiveness on a very small series of patients.

“But there are safety issues: how durable will the treatment effect be? Will there be off-target effects? Those issues relate less to the clinical performance that is assessed in any premarket study and more to the product features and the vector itself that is delivering the gene. That is, how the gene gets set and sorted, and any manufacturing issues related to that.

“It’s exactly inverted from traditional drug development where approximately 80% of the complexity and challenge for the FDA is the clinical portion of the review and 20% is the CMC, or the chemistry, manufacturing, and controls portion of the review. When it comes to these gene therapy paradigms, 80% of the complexity for the agency is the product portion and only 20% is on the clinical portion.

“This lends itself to a whole new paradigm where you can use the framework of accelerated approval to allow these products to come to market more quickly based on small amounts of clinical data, recognizing that you aren’t going to answer all the longer-term questions in any reasonably-sized premarket setting. But, you have much more robust authority to require postmarket follow-up of these products, closely monitoring the patients under that legal framework.”

**On cell-based regenerative medicine:**
“With cell-based regenerative medicine, we promulgated a policy to establish a right mind about when a cell, taken out of your body and manipulated, could become a drug. That existed in law and regulation, but it never existed in practice if the agency hadn’t drawn a bright line and started to vigorously enforce around that line. We were seeing rapid growth in clinics, all marketing different stem cell products—some with really tragic outcomes. So we put out that guidance and started taking enforcement actions establishing that bright line.

At the same time, we recognized that a lot of innovations happen in small academic medical centers where individual investigators were trying to develop these products. They didn’t have the resources or the sophistication to file individual license applications to become drug developers so, for the first time, we developed a framework, where as long as individual investigators were following...”

“When it came to targeted medicine, we faced the idea that disease was no longer defined by phenotype but by genotype.”

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Dr. Gottlieb
the same manufacturing protocols for products, they could pull their clinical data and file a common application in order to get an individual license to each academic institution to market their own products. It was a highly novel approach to how we go about giving biological license applications to sponsors for the first time—and a paradigm we could replicate in other settings.”

**On targeted medicine:**

“When it came to targeted medicine, we faced the idea that disease was no longer defined by phenotype but by genotype. This was really the holy grail of what came out of mapping the human genome. But the regulatory paradigm didn’t give us readily available tools to take advantage of this. So we started things like basket trials or tissue-agnostic trials where you’d get approval for a drug in multiple tissue types as long as they targeted the same molecular signature of disease. You’d also see master protocols where you could study multiple drugs within the context of the same registration trail or the same patient cohort. These were all designed to try to change the paradigm to allow for more easy and efficient development of targeted medicine.”

**On next-generation analytical tools:**

“Things like next-generation sequencing (NGS) and artificial intelligence (AI) [are arriving], where you don’t have tools that lend themselves to premarket approval: An AI device is a self-learning device that learns from its own mistakes. How do you regulate that through a premarket approval process where you are testing the ability of the device not only to make mistakes but to learn from them and get better? Rather than set up a paradigm where we require premarket approval for these devices or premarket testing with NGS platforms, we said instead that we would certify certain publicly available databases of information maintained by the National Institutes of Health and if you test your device against that publicly available database and get a certain result, a certain performance characteristic against that publicly available data, that would suffice for FDA approval. That demonstrates the clinical utility, validity, and reliability of the device.”

**On digital health tools:**

“Let’s talk about things like medical apps on your phone. How do we regulate that as a medical device? Do we require premarket approval any time a company makes a modification to such an app, which quite literally could happen overnight? We can’t ask monitors to come in every day with a supplement to a medical device application. Instead of regulating the product itself, we decided to take a firm-based approach. We’re going to regulate the firm and say as long as the firm that promulgated the digital health tool has good standard operating procedure in place to test the underlying architecture of the software, we will allow them to not only go to market with new modifications but go to market with new products without having to come in every time and ask for premarket approval from the FDA and be subject to postmarket testing and post-market monitoring.”

**On electronic health records (EHRs) and practical data:**

“For the very first time, the agency has the ability to use data from EHRs to conduct postmarket surveillance and, eventually, practical clinical trials in real-world settings.”

“The idea is to see if the agency can develop a new paradigm for replicating clinical studies using real-world evidence. You’ve seen a recent approval... for a drug treating men’s breast cancer where the effects were established using practical clinical data. There are multiple other examples, both public and private, where this same thing is happening.

“This is really a paradigm change for the FDA. It’s going to change the culture of the agency’s prospective clinical data. And, I think, it will really change the opportunities for manufacturers in a very significant way because, if the agency builds its capabilities and builds confidence in these new data paradigms, it will open up more changes to sponsor and move forward these new kinds of clinical development approaches.”

“For the first time, the agency has the ability to use data from EHRs to conduct postmarket surveillance and, eventually, practical clinical trials in real-world settings.”

**Scott Gottlieb, MD**
Pharmacy has a problem: One of the traditional core tasks for most pharmacists is getting medications to patients. Getting the right medication to the right patient at the right time carries the potential for direct interventions that improve patient outcomes. But the mechanics of medication dispensing are mind-numbingly tedious, repetitive, and nearly impossible to perform without error.

Pharmacy also has a solution: Automation. Dispensing robots never get bored, never get distracted, and make far fewer mistakes than their human counterparts. And in this era of ever-shrinking prescription margins, dispensing robots free up pharmacists and technicians for more profitable clinical services that require human judgment. In 2016, Tom Gierwatoski, RPh, installed a ScriptPro dispensing robot in his Platte Valley Pharmacy in Brighton,
CO. Automation allowed him to boost prescription volume by 50%, freeing up time to expand compounding and grow nonprescription services such as durable medical equipment and diabetic shoe fitting while halving his dispensing staff.

“We were able to reallocate staff to things that require more human attention,” Gierwatoski says. “And because the robot cut our average wait time to five minutes, I have more time to talk with patients because I’m not backlogged waiting for prescriptions to get to me.”

Automation has long been a fixture in central fill facilities, large health systems, and other settings that count their daily prescription volume by the thousands. Newer generations of community pharmacy automation have made dispensing robots cost-effective for pharmacies with prescription volumes as low as 150 per day, says Bill Lockwood, executive director of the American Society for Automation in Pharmacy.

“Automation is making pharmacies more efficient, no question about it,” he says. “Increased efficiency is giving pharmacies the opportunity to offer more services and to provide more drug safety.”

“Our robots normally cover at least 45% of pharmacy scripts. But we have seen it go as high as 80% or 90%. It depends on the mix of business.”

Lockwood

The Pros and Cons of Pharmacy Automation

Dispensing robots began rolling out to retail and ambulatory care pharmacies in the 1990s. The idea was to automate dispensing to save time and reduce human-caused errors. Robots generally meet those goals.

The Upside

**Speed:** Robots are faster than humans. Different robots offer different technologies and different fill rates, but a typical community pharmacy robot from ScriptPro can fill up to 125 prescriptions per hour.

**Safety:** To the human eye, one white pill looks a lot like any other white pill and it is all too easy to count four pills or six pills, instead of five. Robots don’t mix up different formulations or make counting errors.

**Security:** Medications are locked inside the robot and access is limited to specific staff with positive identification. Thus, opportunities for diversion or human error are reduced.

**Service:** Robots typically reduce fill times and wait times, which can improve service levels and customer satisfaction. Reducing human time in dispensing also frees up pharmacists and technicians to spend more time with patients, provide additional non-Rx services, and expand areas such as immunizations, health screening, and diagnostic testing.

The Downside

Automation also introduces new opportunities for error.

**GIGO:** Garbage in, garbage out. Robots are computers. If a human inputs the wrong information, fills a cell with the wrong medication, or makes some other mistake, safety is compromised.

**Variety:** There is little standardization across automation systems, which can create confusion if the pharmacy switches vendors or brings in a staffer familiar with a different system.

**Downtime:** All mechanical devices can break down, including dispensing robots. It doesn’t happen often if units are maintained and serviced regularly, but the pharmacy needs a backup plan to work with if there is an equipment failure.

**Glitches:** Software failures happen with any computer-based technology. Updates should be tested locally before they are installed into the whole system.

**Refills:** Robots can’t refill themselves. Inventory management is crucial. An authorized user must always be available to refill robots if medication stock runs low.
One thing robotics isn’t doing is reducing pharmacy employment. Robots are more efficient, more reliable, and less expensive than technicians or pharmacists. Pharmacy owners typically reemploy staff who are no longer needed in dispensing rather than letting them go.

“Dispensing medications will eventually become fully automated using various types of robotics,” predicted Al Babington, CEO of PrescribeWellness, a Tabula Rasa HealthCare company. “Clinical work—the education, motivations, and support that pharmacists provide to patients to enact behavioral change—will be the new foundational service.”

In his prerobot days, Gierwatoski filled about 200 scripts per day at Platte Valley pharmacy. The operation is located in a hospital, handling hospital outpatient needs and discharge prescriptions as well as serving patients from two dozen physician offices in an attached medical building. About 70% of his prescription volume was, and is, new scripts.

“The volume of new prescriptions meant I had to have two technicians all the time inputting, handling insurance, and everything else associated with new scripts,” he says. “With the robot we are averaging 300 scripts per day and just one technician doing all the inputting. There are plenty of more rewarding and more profitable things we can do versus counting pills on a tray.”

**Robotic Numbers**

Dispensing automation comes in a variety of sizes, shapes, capacities, and capabilities, from simple pill counters to robots that spit out a stream of filled, labeled, and capped vials. But robots can’t fill every script.

“Our robots normally cover at least 45% of pharmacy scripts,” says Mike Coughlin, president of ScriptPro. “But we have seen it go as high as 80% or 90%. It depends on the mix of business.”

Gierwatoski says his robot fills about half of his daily prescription volume.

Most of the rest are filled using pill counters.

“We might have five scripts a day that we count out by hand” he says.

The key to maximizing robot use is selecting the right drugs for robotic dispensing. The most common method is to track the top 100 to 200 products dispensed at the pharmacy and load the most common into the robot.

Local regulation may play a role, too. Gierwatoski points out that Colorado prohibits controlled substances in dispensing robots. So, all of his controlled substance scripts must be filled manually or using pill counters.

Coughlin says the largest ScriptPro robot has 225 cells, which means 225 different drugs or drug dosages can be stored in the system and dispensed. Some customers use multiple robots to keep up with their prescription volume, but the top 200 drugs cover the bulk of products dispensed in most community pharmacies.

Comparing the cost of technician labor to robotic labor is easy. Robots cost about $12 per hour, Coughlin says. Technician salaries average a bit over $18 per hour nationwide. Add in the costs of benefits, hiring, training, and absences and robots look even more financially attractive.

**Right Business, Right Robot**

Unfortunately, there is no one-size-fits-all automation system. Every manufacturer approaches automation from a different perspective with different types and sizes of practices in mind. Gierwatoski settled on ScriptPro after talking with other pharmacists and spending hours with different automation makers at pharmacy conferences.

It can be tough to choose the right system for a specific pharmacy, says Kurt Proctor, PhD, RPh, senior vice president of strategic initiatives for the NCPA and President of the NCPA Innovation Center. The good news is there are appropriate systems for most pharmacies.

“You can overextend on automation technology and bring in more robotics than your business warrants,” Proctor cautioned. “That’s just a purchasing mistake. But assuming you bring the right automation into your pharmacy, there is no real downside.”

Script volume is only part of the picture when it comes to selecting a dispensing robot. The local labor situation is just as important.

“The robot is doing something that a person would have to do otherwise,” Coughlin says. “If labor is tight, a robot may be the best alternative. We have sites that might not need a robot based on other factors, but have a hard time getting reliable technicians. There is a lot of financial modeling involved in deciding whether or not a robot could be cost-effective and then choosing the
Because he’s putting his trust in you

As a pharmacist, you are trusted to guide optimal drug treatment. But the sheer volume of drugs, new therapies and complex patient conditions raise challenging questions as you make vital decisions. Where can you go for reliable, quick answers backed by deep evidence when you need it?

With continuous content updates from PharmD experts, Clinical Pharmacology powered by ClinicalKey will support you in making swift, confident drug decisions for every patient. Start with a free trial or demo at elsevier.com/cpck
Some automation systems can be customizable with plug-in modules. Surescripts automation offers an electronic prior authorization plug-in that integrates with electronic health records and helps eliminate phone calls to healthcare providers. It also offers a price transparency plug-in that delivers patient-specific drug benefit and cost information at the point of care. Combined with electronic prior authorization, prescribers and pharmacists can make medication decisions with price transparency and complete the prescribing process within the electronic health record, according to the company.

**Support for Automation**

NCPA clearly supports pharmacy automation. So does APhA and the Academy of Managed Care Pharmacy. Chain pharmacies and health system pharmacies were early adopters of pharmacy robots.

“We are seeing an increase in the uptake of automation in a lot of areas. A lot of hospitals are looking into a shared service center, mirroring central fill for a mail order or chain pharmacy. Independents with more than one location are looking at their own central fill operations as well as robots in individual stores.”

Support for Automation

NCPA clearly supports pharmacy automation. So does APhA and the Academy of Managed Care Pharmacy. Chain pharmacies and health system pharmacies were early adopters of pharmacy robots.

“We are seeing an increase in the uptake of automation in a lot of areas,” says Samm Anderegg, PharmD, MS, BCPS, a spokesperson for ASHP. “A lot of hospitals are looking into a shared service center, mirroring central fill for a mail order or chain pharmacy. Independents with more than one location are looking at their own central fill operations as well as robots in individual stores.”

Automation is increasing efficiency in all of these settings, Anderegg continued. And despite long standing fears that automation will lead to job losses, pharmacies are using the increased efficiency to redeploy personnel, not cut employment.

When automation moves into the pharmacy, technicians spend less time counting and pouring and more time managing technology. They are also moving into more patient-centered, non-distribution roles that compliment pharmacists in their growing clinical roles.

“Pharmacists want to create and grow new revenue streams to support a clinical business,” Anderegg says. “Automation can support that transition away from fee-for-service distribution models to practice models with the pharmacist as a primary provider or resource for both patients and other providers. The pharmacist sees patients on average of 35 times a year where their primary care doc is seeing them four times a year. That’s a clinical business opportunity.”

New Business Models

Proctor sees pharmacy business models evolving along two parallel tracks. And both rely on automation.

One model is focused on dispensing. The goal is to dispense prescriptions to patients as quickly, accurately, and cheaply as possible. Dispensing robots meet all three goals at the same time.

The other model is focused on care management, more complex patients, and preventive services to keep people out of hospitals, physician offices, emergency rooms, and other higher-cost sites. That means focusing on a full line of immunizations and vaccines, clinical testing, and other services as allowed by state practice acts. And it means jumping into clinical programs such as the enhanced medication therapy management pilot from CMS management and the CMS chronic care management pilot that brings patients into the pharmacy for scheduled monthly visits.

Washington and other states are including pharmacists in both public and private payer networks, Anderegg noted. That opens more opportunities to expand clinical services for direct reimbursement, which requires more time to document and bill for services.

Anderegg’s company, DocStation, provides some of those back office solutions, but pharmacies still need more staff hours freed up from counting pills, answering insurance questions, working through PBM logjams, managing inventory, and other dispensing duties to track interventions, outcomes, and reimbursement claims.

“There is plenty of dispensing as part of the care management model, and automation gives you the time to focus on care instead of product,” Proctor says. “The rest of healthcare is spending a ton of money, mostly in nurse call centers, trying to reach people on the phone. The community pharmacist already has that relationship with patients, physicians, social services and already sees patients 35 times a year. That’s when you start to develop a business model that is not solely focused on the dispensing silo, PBM-controlled world.”
Is My Pharmacy Job Safe?

By Joan Vos MacDonald, contributing writer

Predicting which pharmacy jobs will still be around in five or fifteen years isn’t easy because the future is not what it used to be. The accelerating pace of change in the healthcare industry would have been difficult to imagine even a decade ago.

From mergers and acquisitions potentially reshaping pharmacy concepts, to expanded prescribing possibilities and the increasing presence of telepharmacy, some jobs may indeed disappear, while others evolve or prompt pharmacists to seek further training.

Lowell Anderson, DSc, FAPhA, adjunct professor in the Department of Pharmaceutical Care and Health Systems, University of Minnesota College of Pharmacy, sees a continuing movement away from dispensing prescriptions as the centerpiece of the practice of pharmacy.

“Existing technologies such as central-fill and robotics will replace the active involvement of the pharmacist with each prescription,” says Anderson. “There will be an increasing use of technicians to be responsible for the dispensing and inventory functions—this includes checking the final product. We may see the concept of the assistant pharmacist reappear—phased out in the 1950s—as exists in many European countries.”

Many pharmacists will be challenged to redefine their careers in the absence of traditional dispensing responsibilities. “That means determining and augmenting one’s particular skills and identifying a customer for those skills,” says Anderson.

Healthcare Team Members
One role that is projected to increase is for pharmacists to become members of a healthcare team. For years, pharmacists have been employed to increase the efficiency of healthcare in hospital settings, and similar care models are being developed that may use pharmacists to coordinate medication in other care environments.

“At the moment, community pharmacists may not be practicing at the top of their profession,” says Joseph B. Guglielmo, PharmD and dean of the UC San Francisco School of Pharmacy. “They may be able to counsel a patient on the prescription they’re dispensing, but that’s not filling the real gap in health care. No one reviews all the medication you’re on, whether you’re taking the wrong hypertensive drug or whether the herbal supplement you’re taking interacts with your cholesterol medication or your antidepressant.”

By managing medication use, as part of a team, pharmacists can help increase safety, efficiency, and cost. Pharmacists are well-positioned to identify gaps in medication adherence and are knowledgeable about cost-effective medication solutions.

One development that is making it easier for pharmacists to participate in healthcare teams is networks of community pharmacies that provide enhanced clinical services, like CPESN, which coordinates patient care with broader care teams. Networks have formed in 32 states, and are inviting independent pharmacists to offer pharmacy services as part of a team.

“That’s a change that’s a great opportunity for pharmacists to get involved with patients,” says Angela Dominelli, MBA, PhD, adjunct professor of pharmacy administration at Albany College of Pharmacy and Health Sciences. “If a graduate pharmacy student wants to do something different and wants to really engage with patients, they could take a cue from IT professionals. A lot of IT people provide services full time or on a part-time basis, working for several places and crafting a whole full-time career from this. New graduates coming out can get to use their critical skill sets to help with CPESN services, one or two days a week, and can go to multiple stores and create a full-time opportunity for themselves.”

More Services
Both chain and independent pharmacies are evolving to offer more services, which may include a wider range of immunizations and/or long-term management for conditions such as diabetes. All 50 states now let pharmacists provide immunizations, and in some states,
pharmacists can also prescribe naloxone, contraceptives, epinephrine, and some travel medications.

“Pharmacists are already giving vaccines,” says Dominelli. “Some take the next step. Some pharmacists set up a whole business dispensing long-acting antipsychotic injectables, so folks don’t have to receive their medication from a doctor. That’s a whole new opportunity that will only expand as more and more specialty drugs come out,” she says.

“There’s also more of a need for prior authorization and there are some really savvy pharmacists who set up their own prior-authorization business. They hired pharmacists and pharmacist technicians and are going to doctors, saying, ‘We know this paperwork is cumbersome, so why not contract with us? We’ll take care of this for you,’” she says. These pharmacists saw an opportunity and were on it.

Regularly assessing a community’s needs and envisioning new ways to fulfill those needs is an essential business model for independent pharmacies. That means keeping up on new medical trends to potentially incorporate and capitalize on.

“Changes will have an impact on pharmacy practice, but if you’re sharp, you can see wonderful opportunities in that change.”

ANGELA DOMINELLI, MBA, PHD

“There’s a mental health first aid [course], a day-long program, that some pharmacy owners are sending staff members to, so they can better assist patients already identified with mental health issues, but also help identify patients who haven’t yet been diagnosed,” said B. Douglas Hoey, RPh, MBA, and CEO of NCPA. “Mental health is such a growing concern in our country with a higher incidence of depression and anxiety among teenagers. It’s important to let the community know these issues matter to you and that you are trained to help them.”

Recent mergers and acquisitions may also lead to new roles for pharmacists in managing long-term medical conditions. The merger of CVS Health and Aetna may create new healthcare models requiring a pharmacist’s involvement, says Dominelli.

“They are piloting designs that provide patients with new services to help manage long-term conditions,” she says. “Some of those services may be provided by pharmacists and some by nurse practitioners. There will be an opportunity there for pharmacists to work in an interdisciplinary mode, to work in ways they haven’t done before. They are piloting certain care programs for people with cardiac conditions and people with diabetes that provide an opportunity for pharmacists to get out from behind the counter and closer to patients.”

Proposed legislation in Congress may increase the ways to reimburse pharmacists for more services. If passed, the Pharmacy and Medically Underserved Areas Enhancement Act (S 109 and HR 592) means that beneficiaries in medically underserved communities could get Medicaid and Medicare Part B services from a pharmacist who would be paid for providing the services. Such reimbursement would not only protect existing pharmacy jobs but potentially create some, as well as filling a need for healthcare in many communities.

According to Hoey, one way to ensure that pharmacy remains a profitable profession is to not accept the status quo and to look for opportunities to fill healthcare gaps in society.

“Whether it’s in consulting in the pediatric ICU or in a long-term convalescence home, there is always a role for someone who is a problem solver, a critical thinker, and a great communicator,” said Hoey. “The same is true for community pharmacists. You have to go into it not assuming that role is necessarily going to be there in fifteen years. You have to be willing to be among the people pushing a law forward to proactively come up with a model where pharmacists get paid for active review of medications.”

Drug Research

Research will continue to require pharmacists. “There’s plenty of opportunity,” says Dominelli. “New drugs coming out are more complex than earlier modalities and need more pharmacological vigilance. We need more people to look into drug safety, so pharmacist-involved clinical trials will still go on. Pharmacists are well positioned to evolve along with the changes, as long as they stay on top of swiftly changing trends. Changes will have an impact on pharmacy practice, but if you’re sharp, you can see wonderful opportunities in that change.”

Anderson advises pharmacy school students to look outside of contemporary pharmacy practice, to discover which industries may benefit from their expertise.

“Direct patient care is important and rewarding, but there are so many opportunities that build on experiences in patient care,” says Anderson. “The experience of caring for is the foundation for any health-care provider and should be incorporated into one’s personal brand.”
Hepatitis C

Resurgence of a Silent Epidemic

Diagnosis and treatment advancements are not enough

By Beth Longware Duff, contributing editor

World Hepatitis Day 2019 is this month, and the campaign to identify the estimated 300 million people who are living with viral hepatitis, but who have not been diagnosed, is gearing up. In the United States, much of that effort is now focused on diagnosing and treating hepatitis C (HCV), which the CDC has called “a silent epidemic.”

The statistics are sobering: about 3.5 million Americans are believed to be living with chronic HCV infection, and it is estimated that at least half of them don’t know that they are infected. The number of acute hep C cases reported to the CDC more than tripled between 2010 and 2016.

Hep C is the most common chronic blood-borne infection in the United States. It is ten times more infectious than HIV, and is the leading cause of liver disease and liver cancer. More deaths are attributed to hep C than from all 60 other reported infectious diseases combined.

The CDC says that 320,000 deaths can be prevented by testing and referring infected persons to care and treatment. Experts agree that community pharmacists can make a major contribution to this effort.

While there is no vaccine for HCV, there is reason for optimism because there are more new medications available to treat the disease than ever before. These medications are dramatically changing treatment regimens and providing new hope for eradicating the disease, but this will happen only if patients are identified, diagnosed, and treated.

The Recent History of Hep C

Prior to 1989, hepatitis C was the virus with no name. In the preceding decade, large numbers of patients apparently suffering from a viral disease had been identified, but tested negative for both hepatitis A and B. The disease became known as non-A non-B hepatitis until it was sensibly renamed hepatitis C.

In 1990, a test was developed to identify patients infected with HCV, but that created a new treatment challenge. Typically mild in its early stages, hep C is often not diagnosed until it is advanced, taking as long as 20 years to get to that point. Consequently, up to 85% of HCV infections become chronic, with increased risk of severe liver disease, including cirrhosis and liver cancer, and death. Hep C, in combination with hep B, now accounts for 75% of all cases of liver disease worldwide.

“Hepatitis C is predominantly spread by blood contact, so people who have
used intravenous drugs or received a blood transfusion before 1991 when hepatitis C testing became available for the blood supply, are the main group of people who get hepatitis C,” says Coleman Smith, MD, a transplant hepatologist at Medstar Georgetown Transplant Institute and member of the National Medical Advisory Committee of the American Liver Foundation.

Up until quite recently, hepatitis C occurred most frequently in people born between 1945 and 1965 — the so-called baby boomers. Today, however, the opioid epidemic is changing the epidemiology of the disease in the United States. “There’s now a second peak of hepatitis C occurring in much younger people, and that’s theoretically quite problematic,” Smith continues. While many older hep C patients have been or are being treated, many of the younger patients are not so fortunate. Additionally, Smith notes that there are still many people who don’t have access to medical care, are unaware of hepatitis C, continue to use drugs, or are incarcerated or homeless who are at increased risk.

**The Hep C Treatment Landscape**

Up to 25% of people infected with hep C clear the virus from their bodies without treatment. The remainder will develop an acute infection that, left untreated, becomes chronic. The game changer for treating them has been the introduction of direct-acting antivirals (DAAs) that have replaced the traditional regimens of the past. “With the new medications that have clearance in the high 90th percentile, and the pangenotypic medications that are coming out, there’s more of a focus to treat these people so they don’t progress into decompensation and severe liver disease,” says Julie Akers, PharmD, a clinical assistant professor in the Department of Pharmacotherapy at Washington State University College of Pharmacy and Pharmaceutical Sciences. “The difficulty with that in the clinician’s world is that they didn’t already have that focus to be looking for the risk factors for hep C,” which meant that patients were not being routinely screened.

DAA medications are less toxic and offer treatment regimens of eight to 12 weeks, depending on the patient’s degree of liver function or genotype. They target specific steps in the HCV life cycle...
to stop the virus from self-replicating. There are four major categories of DAA: NS3/4A protease inhibitors (PIs), nucleoside and nucleotide NS5B polymerase inhibitors, NS5A inhibitors, and non-nucleoside NS5B polymerase inhibitors.

Smith says DAAs have made identifying people who need treatment even more critical. “If you have someone who has hepatitis C who has access to medical care and insurance, or the wherewithal to pay for these still-expensive drugs, you have a 95% to 99% chance of curing them—and when I say ‘cure’, I mean completely eradicating hepatitis C,” he declares.

Point-of-Care Testing

Now that effective treatment is in place, the challenge remains to get screening and diagnostic services to the people who need it the most. One of the most logical places to start is the local community pharmacy and point-of-care (POC) testing.

According to John Beckner, RPh, senior director of strategic initiatives at NCPA, many customers are already being screened by pharmacists for illnesses like influenza, strep, diabetes, cholesterol, and HIV. Expanding POC testing to include hepatitis C is a logical next step.

“In a lot of cases, local pharmacists are the first line of defense. We have a lot of members in rural areas, and those members are really the face of neighborhood healthcare in the community that they serve,” says Beckner. “They have relationships with their patients, so they can certainly drill down and glean information from patients that might alert them to the fact that they’re a candidate to be screened for hep C.”

The initial antibody test involves a finger stick. It costs $50 to $75, and yields results in under an hour. As simple as that seems, Beckner acknowledges that there are some stumbling blocks, including reimbursement and individual state regulations governing POC testing. While most insurance companies do not reimburse for the test, the patient can pay out of pocket and submit for their own reimbursement.

“Certainly we can have a role in helping choose the appropriate therapies, discussing adherence and adherence strategies, monitoring for toxicity, and the acquisition of the medications,” says Bernadette Jakeman, PharmD, and associate professor at the University of New Mexico College of Pharmacy.

She notes that hep C medications are often provided through specialty mail order pharmacies and require an extensive prior authorization process and high copays. “We oftentimes help with the prior authorization process as well as the patient assistance programs,

Testing Recommendations for Hepatitis C

The CDC advises that testing for hep C should be initiated with anti-HCV. Individuals with reactive test results should be followed up with an HCV RNA.

People who should be tested for HCV include:

- Adults born between 1945 and 1965 inclusive, with no prior ascertainment of HCV risk needed.
- Anyone who currently injects drugs or who has ever injected drugs, even once or many years ago.
- Anyone who:
  - received clotting factor concentrates produced before 1987, when less advanced methods for manufacturing those products were used
  - was ever on long-term hemodialysis
  - has persistently abnormal alanine aminotransferase (ALT) levels
  - is infected with HIV
- Anyone who received a transfusion of blood, blood components, or an organ transplant before July 1992, when better testing of blood donors became available, or people who were notified that they received blood from a donor who later tested positive for HCV infection
- People with recognized exposure to the Hep C virus, including:
  - healthcare workers, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-positive blood
  - recipients of blood or organs from a donor who tested positive for the Hep C virus
- Children born to HCV-positive women.
- People who are incarcerated.
- People who use intranasal drugs.
- People who received body piercing or tattoos done with nonsterile instruments.

For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

which all the medications have. We can help make sure that patients can get and pay for their meds."

Affording the drugs can be a major hurdle for many patients. According to an analysis by the Blue Cross and Blue Shield Association, hep C antivirals costs increased by 19% between 2010 and 2016. Many patients find they cannot rely on coverage from their insurance companies. One study reveals that absolute denials of DAA regimens by insurers have remained high—averaging 35%—and increased over time, regardless of insurance type.

At least one pharmaceutical company has acted to help resolve the situation. In January, Gilead Sciences launched, through its subsidiary Asegua Therapeutics, authorized generic versions of its top-selling Harvoni (ledipasvir/sofosbuvir) and Epclusa (sofosbuvir/velpatasvir). The $24,000 list price for the most common course of therapy is significantly discounted from the branded versions, which can cost nearly $100,000 for a full course of treatment.

“We made this unusual decision because we believe that it is the fastest way to lower list prices for our HCV cures without significant disruption to the healthcare system and our business, as a bridge to longer term solutions aimed at reducing patients’ out-of-pocket medication costs, improving access for Medicaid patients and providing greater pricing transparency,” explained Gilead’s CEO John Milligan in a prepared statement.

“We have amazing treatments now for patients, so it’s a matter of us mobilizing to get people tested, into care, and treated.”

BERNADETTE JAKEMAN, PHARMD

The Final Word

One of the biggest challenges facing healthcare providers today is to spread the word that hep C treatment is far more effective, with fewer side effects and a shorter course than medications that were previously prescribed. Jake- man says it’s a message that’s important to impart to the general public as well to help get the disease under control.

“We have amazing treatments now for patients, so it’s a matter of us mobilizing to get people tested, into care, and treated,” she says. “A lot of people don’t have symptoms because they’re not cirrhotic, but there are a lot of non-liver type of symptoms that we’re seeing. There are definitely reasons to screen and treat early to prevent transmission and future cases.”

Baby Boomers and Hep C

Baby boomers (those born between 1945 and 1965) are encouraged to be screened for Hep C because they are five times more likely to have it than other adults, according to the CDC. In fact, they account for 75% of people with HCV. The reason for this is not well understood.

“Most baby boomers are believed to have become infected in the 1960s through the 1980s when transmission of hepatitis C was highest,” states the CDC. “Baby boomers could have gotten infected from medical equipment or procedures before universal precautions and infection control procedures were adopted. Others could have gotten infected from contaminated blood and blood products before widespread screening virtually eliminated the virus from the blood supply by 1992.”

Source: “Hepatitis C: Why People Born from 1945-1965 Should Get Tested”, CDC Publication No. 220401
Hospital health systems benefit greatly from pharmacists in terms of quality, safety, and value. The value of the pharmacist is further demonstrated by linking clinical activities with patient and financial outcomes.

Value-based programs encourage paying providers based on the quality, rather than the quantity, of care they provide to patients. These programs reward healthcare providers with incentive payments for the quality of care provided to individuals with Medicare. The goals of these value-based programs include better care, enhanced health, and lower costs.

Payment Based on Value
Value-based programs were first established through the Medicare Access and Children’s Health Insurance Program Reauthorization Act of 2015 (MACRA). Under this act, value is emphasized over quantity. CMS established five value-based programs with goals to link provider performance of quality measures to provider payment (See Figure).

The end-stage renal disease (ESRD) program is considered a first-of-its-kind in Medicare: the goal is to promote high-quality services to outpatient dialysis facilities treating patients with ESRD through pay-for-performance or value-based purchasing (VBP) programs. The hospital VBP program rewards acute care hospitals with incentive payments.
How Baptist Health South Florida Does It

Madeline Camejo, PharmD, is the vice president and chief pharmacy officer at Baptist Health South Florida (BHSF), Miami. BHSF currently participates in the shared savings and risk contracts in both the commercial and Medicare Advantage insurance plans, she says. BHSF is part of an administrative services only (ASO) agreement, which is an arrangement by which an organization funds its own employee benefit plan such as a health plan. With ASO arrangements, an outside firm is hired to perform specific administrative services, and the employer takes full responsibility for claims made to the plan. The ASO plans usually cover short-term disability, health, and dental care benefits.

The value-based programs at BHSF are interdisciplinary and include physicians, nurses, pharmacists, social workers, and care coaches. “Pharmacy supports chronic care management, TOC, disease management (chronic heart failure and diabetes), and data analytics,” says Camejo. Population health plays an important role, and the Baptist Health Quality Network (BHQN) staff is part of this team. Hospitals must find the format that works for them and their population of patients to ensure that the program is manageable and feasible. You take a team approach to overseeing the care of the patient. One pharmacist leads the value-based team and eventually a pharmacy technician can assist with medication management. There is limited information available regarding the ratio of pharmacists-to-patients that should be established for population management. “In order to expand pharmacy impact with regard to value-based/population management, I think any clinic we develop should evaluate metrics from the contracts and bundle programs and ensure we include measures to show return on investment. Also, there may be opportunities to have pharmacy informatics collaborate with BHQN data analytics to further explore things we can be doing with value-based programs and data,” says Camejo.

for the quality of care they provide to Medicare patients. The program’s goals include eliminating or reducing adverse events, establishing evidence-based care standards and protocols to improve patient outcomes, improving patient care experiences by enhancing hospital processes, increasing care transparency for consumers, and identifying hospitals that provide high-quality care at a lower cost to Medicare. It’s estimated that the total amount available for value-based incentive payments for 2019 is approximately $1.9 billion.

The Patient Protection and Affordable Care Act of 2010, also known as the ACA or Obamacare, includes many payment reforms to promote hospital efforts to address and prevent adverse events after discharge.

One example is the hospital readmissions reduction program (HRRP) that gives hospitals a strong financial incentive to enhance their communication and care coordination, and collaborate with patients and caregivers on postdischarge planning. The HRRP uses the excess readmission ratio to help estimate hospital performance, and it is the ratio of predicted-to-expected readmissions. The following conditions and procedures are included in the HRRP: acute myocardial infarction, chronic obstructive pulmonary disease, heart failure, pneumonia, coronary artery bypass graft surgery, and elective primary total hip arthroplasty and/or total knee arthroplasty.

The 30-day risk readmission measures include all-cause unplanned readmissions that occur within 30 days of discharge from the initial admission and patients who are readmitted to the same hospital or another acute care hospital for any reason. Unfortunately, about 20% of patients are rehospitalized within 30 days after hospital discharge, with adverse drug events (ADEs) being the most common complication.

Transitions-of-care (TOC) has been trending throughout the pharmacy
profession and is an important process in the prevention of medication errors and ADEs. It is characterized as the movement of a patient from one set of providers or level of care to another and can involve patients moving to a different area of the hospital or being discharged into the community.

Systematic problems involving TOC are often considered a primary cause of ADEs. Pharmacists can play an important role in TOC in the hospital setting. Medication reconciliation, structured discharge communication, and patient education can prevent adverse events after discharge. Inpatient TOC opportunities include daily medication education, prescriber order clarifications, renal dose adjustment, medication monitoring, and streamlining drug therapy.

Hospitals have also created TOC pharmacist positions as a new emerging opportunity. This may include collaborating as part of an interdisciplinary team and establishing TOC clinics or directing TOC programs.

The emergency department is a crucial part of TOC for pharmacists and can include adding drug therapies, removal of medications, dosage and strength corrections, and determining when the last dose was taken.

Other advantages of a pharmacist-directed TOC program include standardized medication reviews, consistent clinicians, access to all hospital providers, contact with outpatient pharmacies, and collaboration with case management. Patients taking multiple medications are at an increased risk of ADEs, and approximately 45% of ADEs that lead to hospitalization are preventable.

One randomized multicenter study found that a comprehensive pharmacist intervention that included medication reviews, patient interviews, and follow-up care reduced the number of readmissions and emergency department visits. Pharmacists can play an extremely important role in the continuity of patient care at the time of discharge through counseling patients on their medications, assessing for duplication of therapy, providing educational materials, and addressing any concerns.

HRRP appears to be effective in reducing hospital readmission rates of Medicare patients and is associated with effective TOC outcomes; however, the program has been criticized because it penalizes hospitals caring for more vulnerable patient populations. Therefore, hospitals now receive bundled payments for targeted illnesses that cover all costs associated with patient care for a 30-day period.

The value modifier (VM) program measures the quality and cost of care provided to individuals with Medicare and determines the amount of payments to physicians based on their performance. The hospital-acquired condition (HAC) reduction program saves Medicare approximately $350 million annually and encourages hospitals to enhance patient safety and reduce the number of hospital-acquired conditions after surgery.

Alternative Payment Models (APMs) have become popular within value-based programs. Here the payment is linked to effective management of a population or episode of care. Bundled payments involve payments for an episode of care, and medical home models are characterized by a team-based approach to comprehensive primary care coordinated by a primary care provider.

**Population Health**

Population health has become an important aspect of value-based programs. It is an intensive focus on the overall health of a population to improve care, reduce costs, and promote wellness. Comprehensive services include specialty care, hospital care, post-acute care, patient education, and self-care resources; the focus should be on the highest-risk patients to help manage costs. Pharmacists can be key leaders in interdisciplinary patient care teams that include medication therapy management, disease state management, wellness promotion, medication management during TOC, population health research, and pharmacoeconomics.

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**REFERENCES**


Compounding Industry Weighs in on Newest MOU Draft

By Mari Edlin, contributing writer

The 2012 nationwide fungal meningitis outbreak resulting from contaminated steroid injections from the New England Compounding Center in Framingham, MA, is still reverberating throughout the industry. The FDA and compounding pharmacy stakeholders are still wrestling with many unresolved issues from the tragedy, but there are ongoing discussions and a proposed piece of legislation to reach a resolution.

After the tragedy, Congress passed the Drug Quality and Security Act (DQSA) in 2013, which authorized FDA to create a memorandum of understanding (MOU) with states to address some interstate distribution of compounded drugs by traditional compounders—called 503A facilities in the law, after the section of the Federal Food, Drug, and Cosmetic Act (FD&C).

The agency plans to finalize the MOU in 2019.

Distribution Levels of Drugs Sold Interstate

FDA issued a draft MOU in 2015, but withdrew it after strong pushback from pharmacist, physician, and patient groups. The agency released a revised draft in September 2018 that outlines the allowable level of out-of-state distribution of compounded drugs in states that enter into the MOU. The revised version also allows for a greater percentage of total prescriptions for compounded drugs—50%—before becoming what the FDA considers an “inordinate amount,” which would require additional reporting by and inspection of compounding pharmacies.

If state pharmacy boards choose not to sign the MOU, only 5% of total prescription orders dispensed or distributed by a 503A compounder in that state can be shipped out of state.

Reed Smith LLP, a law firm based in Pittsburgh, directed a letter to the FDA last December, targeting the threshold change and other issues. Although the threshold has increased, Rachael Pontikes, a partner with Reed Smith, says the firm believes the boost does not solve the concerns raised by the 2015 draft. The new threshold “has also narrowed what is included in that threshold to compounded products,” she says.

Shawn Hodges, PharmD, president and CEO of Innovation Compounding, a 503A pharmacy in Kennesaw, GA, is concerned about the potential 5% cap if Georgia’s pharmacy board decides not to sign the MOU. His pharmacy, like others, compounds products in a specific therapeutic area—in his case, compounded products for allergy immunotherapy—which might not be available from pharmacies in other states.

“We are concerned about patient access. It’s difficult to tell a doctor ‘no’ when a drug is allowed clinically, but not by federal law,” Hodges says.

“The proposed 5% cap creates the potential that patients won’t be able to access compounded medications,” says Scott Brunner, executive vice president, International Academy of Compounding Pharmacists (IACP). Hodges says the MOU puts pressure on state boards, which may be hesitant to sign the MOU in its present form. “It’s an unfunded mandate for states,” Brunner adds. “The FDA is, in effect, commandeering a state agency to take enforcement actions that the state legislature hasn’t necessarily funded. That creates ambiguity over whether state boards even have the legal authority to sign the MOU.”

“There is no incentive to sign,” says Peter Koshland, PharmD, of Koshland Pharm: Custom Compounding Pharmacy, a 503A pharmacy in San Francisco. “Signing the MOU will present even more work even if it increases the percentage of products sold across state lines.”

Brunner adds another caveat to the MOU—stakeholders do not have enough time to respond to the terms.

‘Dispense’ and ‘Distribute’

The 2018 draft MOU also revisits the definitions of “dispense” and “distribute”
that had traditionally been distinct. Currently, they are the same in the MOU draft. Public comment swayed the agency to make more of a distinction, says Ilisa Bernstein, PharmD, JD, deputy director of the Office of Compliance, Center for Drug Evaluation and Research at FDA.

The definitions are consistent with previous law she says. “We are getting closer, but because the MOU is not yet operational, no one has signed it yet. We have spent many years trying to make the MOU acceptable.”

No other organizations consider “dispense” and “distribute” to be the same thing. “The difference is not clear,” says Erik Tosh, RPh, chairman of the IACP Board.

Brunner says the FDA conflates the definitions in a way that runs contrary to how they are defined in state and national laws, and even in the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act.

“The FDA’s proposed MOU redefines the two terms in a way that Congress did not intend and which stands to limit patient access to compounded medications,” Brunner says.

Office Use Compounding

Another disputed issue is the FDA’s refusal to allow 503A pharmacies to compound for office use, that is, supplying a small quantity for physicians to keep on hand in their offices to use when needed by their patients.

“Compounders provide access to medications that are not commercially available, but that prescribers believe are necessary for adequate treatment. Doctors should be able to order them. We want to do the right thing but need guidance on what is expected,” Koshland says.

“Some state laws allow 503A pharmacies to compound for office use, but FDA’s interpretation is that office use is not allowed due to the requirement that there be a prescription,” Brunner says. “Pharmacists can compound a 30-day

Bipartisan Legislative Action on Compounding in Congress

The good news for the industry is a new bill—HR 1959, Preserving Access to Compounded Medications Act of 2019 by Congressmen H. Morgan Griffith (R-VA) and Henry Cueller (D-TX).

An IACP statement emphasizes the need for clarification of the MOU and for new legislation: “The FDA has misinterpreted congressional intent, overstepped its regulatory authority, and is jeopardizing patient access to compounded medications as a result,” IACP’s Scott Brunner says. “This legislation, which has broad support both in Congress and from an impressive coalition of groups representing pharmacists, physicians, and patients, seeks to assure that FDA’s role and actions in regulating compounding pharmacies are in line with Congress’ stated aims when it passed DQSA in 2013.”

Specifically, the HR 1959 would:

- Authorize “office-use” compounding by 503A pharmacies where permitted by state law.
- Define the terms “distribute” and “dispense” consistent with the NABP model pharmacy act and other state and federal law definitions.
- Clarify that compounding pharmacies are retail pharmacies for purposes of FDA inspection authority.
- Require FDA to go through the formal rulemaking process for establishing DQSA policies rather than issuing “guidance documents” that circumvent requirements for public notice and input.
- Formally recognize state boards of pharmacy as the primary regulators of pharmacy compounding.
supply prior to receipt of prescription, but the FDA says it can’t leave the pharmacy until the prescription is received. It can’t be stored by the physician without a patient-specific prescription, so it’s largely a dispute about which highly trained, highly regulated healthcare professional’s shelf it sits on.

Tosh is concerned, however, that the cGMP standards often require testing and are not always cost efficient.

For many 503A pharmacies, the requirement that only 503B pharmacies can compound without a patient-specific prescription stands in the way of patient access. The physician’s only option is to write a prescription for the compounded substance, send a patient to the pharmacy to pick it up, and then return to the physician’s office for a subsequent visit—for which the patient will be charged—to have the medication applied, Tosh says.

Jennifer Burch, PharmD, president of IACP and owner of Central Compounding Center South, a 503A pharmacy in Durham, NC, knows the burden this places on a patient who might not have immediate access to a medication.

Although only 503B pharmacies may compound for office use, Burch says it is usually too small a quantity to make it economically viable for them. During a public hearing on drugs compounded for office use, Burch says it is usually too small a quantity to make it economically viable for them.

Outsourcing facilities, or 503B compounding pharmacies, created under DQSA that do not require a patient-specific prescription under Section 503B of FD&C. These facilities are subject to increased quality standards, such as compliance with Current Good Manufacturing Practice (cGMP), and enhanced reporting.

The FDA says its new draft is based on feedback from stakeholders and comments received on the initial draft guidance and is being revised, in part, to reflect further consideration of how cGMP requirements should be applied.

Bernstein says that due to the stricter requirements for these pharmacies, they “provide a higher level of patient protection.”

Tosh says that due to the stricter requirements for these pharmacies, they “provide a higher level of patient protection.”

Rulemaking versus Guidance Documents

Another concern is FDA’s reliance on guidance documents to regulate compounding, says Tosh. “There is a statutory process by which agencies must issue regulations, he notes. “When it is announced—having followed that proper statutory process—stakeholders must abide by it in their operations.

"Unfortunately, FDA has been skirting the proper rule-making process, issuing Guidance for Industry (GFI) documents. Those GFI’s do not have the force of formal regulation, but the FDA is holding compounding pharmacies accountable to GFI as if they were proper rules,” he says. “They do not create or confer any rights for or on any person and do not operate to bind FDA or the public for enforcement purposes.”

But CDER’s Bernstein says the FDA uses guidance to interpret the law and that it enables stakeholders—not just compounders—to provide input that is reflected in guidance documents.

“We need to exercise oversight to prevent another 2012 outbreak that wasn’t an isolated incident and ensure regulatory oversight as Congress had intended,” Bernstein says. "Compounding can be an important component of care, but products aren’t reviewed for quality and safety which can cause health risks. Promoting access to quality compounded drugs requires that compounders follow the law.”

It’s an unfunded mandate for states. The FDA is in effect commandeering a state agency to take enforcement actions that the state legislature hasn’t necessarily funded. That creates ambiguity over whether state boards even have the legal authority to sign the MOU.”

Scott Brunner
10 Ways to Reduce Administrative Costs

By Keith Loria, contributing writer

Operating an independent pharmacy comes with lots of costs, chief among them being inventory and labor. But it’s the smaller, administrative costs that can accumulate and really impact a pharmacy’s bottom line and determine if it is successful or not.

“Every nickel counts,” Jason Montgomery says. “It’s really about defining those other expenses and managing correctly. Sometimes it’s just a matter of awareness and having someone with an outside perspective taking the time to review.” Montgomery is vice president of business coaching at AmerisourceBergen and works with independent community pharmacists across the country to help them optimize their business performance.

While some administrative costs like legal, accounting, and other professional services are often considered, Montgomery says it’s the non-service related expenses where pharmacies can really save, such as snow removal, security, pest control, office equipment, and insurance. For most of these vendors, these expenses can be reviewed on a quarterly or annual basis.

“Even though pharmacy falls under a fixed-cost category, there are still things that fluctuate and need to be reviewed,” he says. “Rent, for instance. If you don’t own your property and are leasing, that can change as market conditions change. This can always be revisited with a landlord. It doesn’t need to be an expected fixed cost year after year.”

Nimesh Jhaveri, president of Health Mart and senior vice president of McKesson Corp., which works with its franchise stores to help them identify best practices that will increase their capacity to meet all requirements, calls it a challenge akin to a moving target, and that changes as the industry changes.

“It is okay to reach out to peers and to your franchise and ask for assistance,” he says. “Leverage your support systems to educate, understand market and industry trends, set goals for key performance indicators, and—most importantly—take action utilizing all resources available to you.”

Avoiding Mistakes

Scott Jensen, MBA, is director of program development at Arete Pharmacy Network, which offers a portfolio of technology-based solutions designed to centralize and reduce the administrative burden of independent pharmacies. With more than 10 years’ experience developing programs and value-added services that reduce administrative burdens for independent pharmacies, he’s observed many things that ultimately help them compete in an increasingly competitive landscape.

“One of the biggest mistakes is holding on to the mindset that administrative costs are fixed, or that more costs will be incurred with the addition of the services of a third-party vendor,” he says. “If there is no opportunity for savings on staff overhead costs as a result of engaging a third-party vendor, the intent should be to repurpose the previous administrative effort to activities that generate revenue for the pharmacy.”

Jensen says that pharmacies should be thinking about ways in which time can be converted into revenue. He suggests creating an opportunity to retrain staff otherwise dedicated to administrative functions.

Jhaveri says another big mistake pharmacies make is not knowing where they stand and where the market is set. Pharmacists are often focused on the patient in front of them and giving exceptional care. “Pharmacists shouldn’t get so busy working ‘in’ the business that they don’t spend time working ‘on’ the business,” he says.

“Independent pharmacies also typically invest heavily in staffing and customer service. This investment can be a differentiator and important for patient outcomes if all employees are being maximized. Heavy staffing can also be a cash flow killer in a low margin business if not optimized,” he says. One of the benefits of being a franchisee is that you can call on the franchise company to identify how a pharmacy can prepare to take advantage of the changing healthcare landscape. “A pharmacy owner can’t ignore key indicators and expect optimal results,” he says.

Here are some top tips for reducing administrative costs.

1. Understand Administrative Costs

Many pharmacy owners do not know how much they pay in administrative costs for daily, monthly, and annual activities. That’s why it’s important to dig into data on these activities to understand that it may be less expensive to pay a third party to provide administrative services, like reconciliation, on their behalf.
Jensen says when a pharmacy owner or operator seeks to partner with a Pharmacy Services Administration Organization (PSAO), the owner should gain a thorough understanding of all services provided. “Some administrative functions, like appealing underpaid maximum allowable costs (MAC), quality/adherence functions, or reconciliation, which may be dragging the pharmacy down, may be provided by a PSAO either at no extra cost or at a cost less than current staff overhead costs,” he says.

**Leverage Technology**

Whether it’s patient engagement, cash-flow management, or script fulfillment, chances are that there are technology solutions you can leverage for increased efficiency.

“If you are affiliated with a PSAO or buying group, reach out to see if they can make recommendations on specific technology solutions. Typically, a PSAO will have existing relationships with third-party vendors that offer discounted rates to participating pharmacies,” Jensen says.

Susan Maze, COO and CFO of the American Pharmacy Cooperative, Inc., says the organization helps independent pharmacies by bringing in technology affordably. “We offer [a full-time equivalent] predictor that all pharmacies can use to manage staff hours and not overstaff,” she says. “It looks at a pharmacy’s history and forecasts what the needs would be on any given day.”

Technology is responsible for many advancements in healthcare and allows stakeholders to work more efficiently.

“A major challenge facing many pharmacies is the lack of time to invest in new services and focus on patient outcomes,” Jhaveri says. “Technology plays a large role in freeing up the necessary resources, as well as providing the platform to further integrate pharmacies into the larger healthcare system.”

**Network**

When pharmacy owners and operators engage with peers who share similar administrative pressure-points, they are more likely to discover solutions that work. That’s why Jensen recommends building and expanding a peer network.

Vendor contracts and external partner relationships are a huge part of success and can help with keeping costs down, Jhaveri notes. “It is also important to scrutinize expenses, eliminate any nonessential costs, and ensure there are no overlaps in services provided,” he says. “Don’t pay for things that aren’t being utilized. Pharmacists need to complete a yearly review of partnerships and select the ones most advantageous to their practice operations.”

**Diversify Services**

In an industry of declining profit margins, independent pharmacies need to differentiate themselves amongst the competition by offering services such as immunization, delivery, point-of-care testing, nutrient depletion therapy, and diabetic programs.

“Diversifying product offerings can increase the top line and help mitigate reimbursement pressures,” Jhaveri says.

**Be Flexible**

Don’t ever answer the question “Why are we doing this?” with “Because that’s how we’ve always done it.” When evaluating the “why” be prepared and be willing to make productive change. Change can be a good thing if done the right way.

**Look at the Small Things**

Some of the easiest ways to save on administrative costs is to look at simple things, like supplies. For example,
pharmacies produce a lot of paper and print material, so use the most cost-effective toner and ink cartridges.

Use the right size boxes for packaging to reduce postage for shipping and even look at bags, Montgomery says.

Many pharmacists are also members of lots of pharmacy organizations and pay membership fees to each. While they may get good information and perks from such associations, they should still make sure they are necessary and useful, and the fees aren’t going to waste.

**Emphasize Education**

Independent pharmacists must leverage available resources to continually educate themselves as well as to train their technicians to handle all tasks that do not require a pharmacist.

“For instance, through the Health Mart franchise, we provide tools to help support the technician so the pharmacists can focus on activities at the ‘top of their license.’” Jhaveri says. “Additionally, training and continuing education courses are offered through Health Mart University. Business planning and coaching tools are also offered. All of these resources keep independent pharmacies well-informed.”

**Employees Matter**

Sometimes the solution lies in employing the right people. Jensen says when critically analyzing processes, it’s important to include a performance review of the people performing the administrative processes. “You may find that an employee with the right set of skills makes the most impact,” he says.

“It’s really about defining those other expenses and managing correctly. Sometimes it’s just a matter of awareness.”

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A Look at the Vaccine Pipeline

The upcoming products you need to keep an eye on  By Nicholas Hamm

The drug approval process is infamous for its complexity and the length of time it takes. But as complicated as standard drugs are to develop, biologics—such as vaccines—are more complicated.

On average, vaccines take about 10 to 15 years to develop, compared to the average six to seven years for a standard drug. In addition to the longer development period, vaccines also have a lower success rate—fewer than 10% of vaccine candidates ever reach the market, compared to about a 12% success rate for drug candidates overall.

That long lead time and high failure rate means that a large number of needed vaccines are still missing from healthcare's armamentarium.

One study from the Duke Global Health Institute’s Center for Policy Impact in Global Health forecasts a bleak future for vaccines. Analyzing more than 500 vaccine candidates for 35 neglected diseases in the pipeline, the study found the chances of efficacious vaccines gaining approval over the next five years is “unlikely.” The study concluded that there is a significant gap in funding.

However, not all the pipeline news is bleak. From improved flu vaccines to the first C. diff (Clostridioides difficile—until recently called Clostridium difficile) vaccines, there are many exciting recent and upcoming developments in vaccines.

C. difficile

C. diff infects close to half a million Americans every year, according to the CDC. A large reason for the spread of C. diff is inappropriate antibiotic prescribing. While measures have been made to reduce overprescribing, C. diff still directly leads to around 15,000 deaths annually and is still a “major health threat,” according to the CDC.

There are C. diff vaccines in the pipeline, but that pipeline took a hit when Sanofi ended trials of its promising vaccine in late 2017. However, there are still two good candidates in the works.

The current frontrunner is Pfizer’s PF-06425090. After favorable phase 2 trials, Pfizer is hopeful that phase 3 trials, set to conclude late next year, will allow the vaccine to be the first C. diff drug to grant long-term protection.

VLA84, from Valneva, is another candidate, but ran into money problems. While the company says its vaccine is ready for phase 3 trials, it has put those trials on hold due to lack of a partner to help shoulder the cost of trials. Valneva says that it will only continue trials if there is another vaccine approved and it can perform a head-to-head trial.

That gamble could pay off though—Valneva says that it will only continue trials if there is another vaccine approved and it can perform a head-to-head trial.

Influenza

Every year, according to a 2018 article in Vaccine, influenza results in $3.2 billion in direct costs, along with $8 billion in indirect costs. The last flu season resulted in 959,000 hospitalizations and 79,400 deaths, according to the CDC.

Despite this, flu vaccination rates remain low. The CDC estimates that only 37.1% of eligible adults received a flu vaccine over the 2017-2018 flu season. While initial reports those numbers may be slightly higher over this most recent flu season, those numbers are much lower than the CDC desires.

While the general population gives a wide variety of reasons for not getting a vaccine—including unfounded fears of getting flu from the vaccine or not having access—many people (particularly younger people) cite the fact that the flu vaccine doesn’t work. This notion isn’t without weight: The 2017-2018 flu vaccines had such a low efficacy rate (36%) that former FDA Commissioner Scott Gottlieb, MD, made multiple announcements on why the vaccine was not effective and what the FDA was doing to increase that effectiveness.

But recently approved and as-yet-unapproved products could make that dream of a more effective vaccine a reality.

Flucelvax, from Seqirus, is the only cell culture-based flu vaccine available in the United States, first approved in 2016. This formulation, based on preliminary studies, seems to perform much more favorably than traditional egg-based flu vaccines.

What’s most exciting about cell culture-based vaccines though, according to the FDA, is their ability to be quickly manufactured—making them an ideal candidate for dealing with possible pandemics.

Another exciting prospect also relies on something other than an egg base. Medicago’s VLP quadrivalent plant-based flu vaccine, currently in phase 3 efficacy trials in seven countries including the United States, could present another option for faster-produced, more effective vaccines.

Medicago says that it’s plant-based process requires only five to six weeks to produce a clinical-grade vaccine, compared to the five to six months it
generally takes for egg-based vaccines. This speed, the company says, could allow for it to more easily keep up with the constantly-mutating flu virus.

Because viruses only grow in living cells, viruses for vaccines must be propagated in cells. For flu vaccines, this is often done in chicken eggs. This process can lead to egg-adapted changes in viruses, which create viruses that are different than those found in the wild. While some research suggests that these egg-adapted changes are not always responsible for poor-performing flu vaccines, it may be a factor.

Another pipeline candidate is Seqirus’ Fluad QIV, an upgraded, quadrivalent formulation of its already-approved trivalent Fluad. If approved, Fluad QIV would be the first adjuvanted quadrivalent flu vaccine. According to Datamonitor Healthcare, it performs better than other traditional inactivated flu vaccines, meaning that in its expected launch for the 2020-2021 flu season it could capture a large part of the elderly population.

While perhaps more tenuous, new so-called universal flu vaccines are designed to cover all strains for several seasons. They could help increase protection over multiple years and avoid problems with shifting virus strains—if they receive approval and demonstrate those claims. Datamonitor Healthcare says that if approved, these vaccines could hold great promise, as they could boost confidence in vaccination and increase coverage rates.

One of the best candidates, BiondVax’s M-001 is currently only in phase 2 in the United States. However, it has been a part of multiple successful Phase 2 studies in Europe and Israel, and is currently in Phase 3 in Europe. FLU-v from hVIVO is another phase 2 universal vaccine candidate, and it too is set to begin phase 3 trials in Europe.

One potential problem for universal vaccines, according to Datamonitor Healthcare, is that payers are looking for low-cost vaccines—indicating that these could be priced higher than traditional vaccines.

Pneumococcal Disease
According to the CDC, around 900,000 Americans get pneumococcal pneumonia (the most common form of pneumococcal disease in adults) every year—resulting in over 400,000 hospitalizations. While vaccines exist, the CDC says that about 80% of adults with conditions that put them at increased risk and 40% of adult aged 65 or older are unvaccinated.

Currently, the best-selling vaccine is Pfizer’s Prevnar 13, with about $3.5 billion in U.S. sales forecasted for 2019. The pneumococcal vaccine is the 2010 update to the previously-approved Prevnar 7. First approved in 2000, Prevnar 7 was the first pneumococcal conjugate vaccine. The update added an additional five serotypes to the original, due to the possibility of shifting strains of the disease (known as serotype drift). The CDC recommended in 2014 that all adults over the age of 65 receive Prevnar 13, leading to its massive spike in sales.

However, other pneumococcal vaccines with additional serotypes could threaten Pfizer’s market dominance. Merck currently has a 15-serotype vaccine—V114—in phase 3 trials. According to Datamonitor Healthcare, it could replace Prevnar 13 on its expected approval in 2022—if it proves superior to Pfizer’s drug and if serotype drift occurs. GlaxoSmithKline also has a 10-serotype drug in phase 2 trials that is formulated in such a way that it could provide more coverage than Prevnar 13.

One of the biggest threats to Prevnar 13 could be an upgrade to Prevnar: Pfizer is currently working on a 20-serotype vaccine. That vaccine just began its Phase 3 trials earlier this year, so it likely won’t see a release for years.

Meningococcal Disease
Current meningococcal vaccine schedules can be confusing for everyone. All preteens and teens should receive the meningococcal conjugate vaccine, with a booster given at 16, while only some are recommended the serogroup B meningococcal vaccine. That schedule can be affected by a host of other risk factors, potentially adding to the confusion. GSK’s MenABCW-135Y is trying to clear up that confusion. According to Datamonitor Healthcare, it could achieve this due to its broad serotype coverage—it would be the first vaccine cover serotypes A, B, C, W, and Y, which could allow it to cover a wide range of patient populations. It would then replace GSK’s current Bexsero and Menveo vaccines. This would have the added benefit of reducing the number of physician visits required for vaccination. If approved, it is expected on the market in late 2021.

Another possible ripple in the meningococcal market is Sanofi’s Men Quad TT, a likely replacement to the well-established Menactra. According to Datamonitor Healthcare, it could then charge a premium price if it shows superior immunogenicity to Menactra and Menveo.

However, that premium price may be short lived. While its expected launch date is a full year ahead of MenACW-135Y (Q1 2020), GSK’s vaccine is likely to overtake it. This would give the vaccine a short window of use.
Balversa: First Oral Drug for Treating Bladder Cancer

By Lisa M. Holle, PharmD, BCOP, FHOPA

INTRODUCTION

In April, the FDA approved erdafitinib (Balversa, Janssen). It is the first fibroblast growth factor receptor (FGFR) kinase inhibitor for the second- or later-line treatment of patients with locally advanced or metastatic bladder cancer with FGFR3 or FGFR2 genetic alterations. The FDA simultaneously approved a companion diagnostic for use with erdafitinib, the Qiagen therascreen FGFR RGQ reverse transcription (RT) polymerase chain reaction (PCR) kit. FGFR is a family of tyrosine kinases which is activated by genetic alterations found in tumors. It is estimated that up to 3000 patients with bladder cancer have these FGFR genetic alterations.

Efficacy

Approval of erdafitinib was based on the results of a phase 2 multicenter open-label single-arm study that enrolled 87 patients with metastatic or surgically unresectable bladder cancer with FGFR3 mutations or FGFR gene fusions that had progressed on or after at least one prior chemotherapy regimen. Patients received 8 mg of erdafitinib by mouth daily. The primary outcome measure was an objective response rate (ORR) assessed by a blinded independent review committee.

Enrollment into the trial required patients to also have an Eastern Cooperative Oncology Group performance status score of 0 or 1. The results demonstrated a 32.2% ORR (95% confidence interval [CI], 22.4-42%), with a median duration of response of 5.4 months (95% CI, 4.2-6.9). ORR in patients with FGFR3 mutations, FGFR3 gene fusions, and FGFR2 gene fusions were 40.6%, 11.1% and 0%, respectively. Responses were observed in patients previously treated with chemotherapy and those who had previously responded to antiprogrammed cell death (PD)-1 or PD ligand-1 therapy.

Safety

The most common adverse reactions included hyperphosphatemia (76%), stomatitis (56%), fatigue (54%), increased serum creatinine (52%), diarrhea (47%), dry mouth (45%), onycholysis (41%), increased alanine aminotransferase (41%), increased alkaline phosphatase (41%), and hyponatremia (40%). Ocular disorders such as central serous retinopathy or retinal pigment epithelial detachment resulting in visual field defects can occur in up to 25% of patients. The median onset is 50 days. This adverse reaction can lead to dose interruptions, reductions, and discontinuations. Additionally, dry eye symptoms can occur in 28% of patients. All patients should receive ocular lubricants as needed, and monthly ophthalmological examinations should be performed during the first 4 months, and every 3 months thereafter. Hyperphosphatemia occurs about 20 days after therapy initiation (range, 8 to 116 days) and may require dose adjustments and/or phosphate binder therapy.

Erdafitinib exhibits drug-drug interactions with medications that are cytochrome P450 (CYP)2C9 and CYP3A4 inhibitors or inducers, serum phosphate level-altering agents, and substrates of OCT2 and P-glycoprotein. Women of childbearing potential and men with female partners of childbearing potential should be advised to use effective contraception while taking and for at least 30 days after discontinuing erdafitinib.

Dosing

In patients with confirmed FGFR genetic alterations using the FDA-approved companion diagnostic, the recommended dosing for erdafitinib is 8 mg (two 4-mg tablets) daily by mouth with or without food. A dose increase to 9 mg (three 3-mg tablets) daily based on serum phosphate levels and tolerability 14 to 21 days after initiation is recommended. If a dose is missed, or vomiting occurs shortly after taking, another dose should not be taken. Patients should resume with the next scheduled dose of the medication. This medication is available in 3-mg, 4-mg, and 5-mg tablets. Average medication cost is not yet available, but this drug will only be available through a single-source specialty pharmacy, US Bioservices.
Canoes and Aircraft Carriers: Staying Afloat

After a long winter in Central Pennsylvania, spring and early summer have arrived in full bloom and my thoughts turn to one of Denise and my favorite activities, canoeing the beautiful waters of our area. Even my e-mail address confirms my passions. Pharmcanoe@aol.com has been my e-mail since I first signed on back in the 1990s. Some things never change: my home address, my spouse and my e-mail address! Like those constants, my employment situation is consistent too. I’ve worked for independent pharmacists for my entire career, less six months.

Let’s be realistic, independent pharmacists are tough competition. They provide amazing services, outstanding patient care, and can navigate the troubled waters as nimble as a canoe. The big three chains, however, are aircraft carriers. These chains are massive and hulking, slow to move, but stable in the troubled waters. Like an aircraft carrier they have a lot of stuff going on, and many parts that need resources for the entire ship to function. Like an aircraft carrier, chains require lots of overhead and lots of management, which requires a lot of resources. These chains are so top-heavy in management they need to be equally cautious about the contracts they sign because of the sheer amount of profit needed to pay executives, district managers, and pharmacists to work in less-than-ideal conditions.

When patients come to a local independent, they often pick up their prescription within 15 minutes. Most chains today are pushing patients to return the next day. Most independents have same day and often free delivery service. They—like our canoeists—can adapt quickly to market conditions, and take care of the patients. Chains can’t possibly compete with these services and personalized touch. Preferred networks are the tool most often used to drive out the competition or to swamp the canoe. They can’t possibly compete based on service and patient care, so the best they can do is keeping people out of the competition with preferred networks.

One of the big chains is down 20% year-to-date after the recently announced Q2/2019 results. They’re starting to feel on a more massive level the pain that the independents feel every day. Their aircraft carrier is taking on water.

Another major chain had stock trading nearly $50.00 per share in the late 1990s. When the stock plummeted to $10.00 a share, I was in! I bought 100 shares of this chain’s stock for $10.00 a share. Today a share of that stock is worth 54 cents! When aircraft carriers take on water and start to sink, it takes a massive effort to pump out the water and get the ship on course. This chain has been pumping water for more than 22 years, and their stock is still sinking. When the canoe takes on water, you bail the water out, get back in and start paddling.

Whether we are in a nimble canoe, or on a massive aircraft carrier, keeping our watercraft afloat seems to be the focus today. Not a lot of pharmacies, whether independent or chain are focused on moving through the water, as much as on staying afloat. Pharmacy benefit managers with their absurd payment formulas and preferred networks are the gale force winds that are making it nearly impossible to navigate the waters of healthcare. Both chains and independents can sink given the magnitude of the storm.

Whether pharmacies are owned by a massive chain or are a single store entity, a pharmacist is the one whose livelihood is impacted. We as brothers and sisters of pharmacy need to unite and look out for each other. If the PBMs are not soon brought under control, we will all be donning our life jackets, and hoping that the sharks aren’t too bloodthirsty.

Peter Kreckel works in an independent pharmacy in Pennsylvania. You can reach him at editors@drugtopics.com.

“Whether we are in a nimble canoe, or on a massive aircraft carrier, keeping our watercraft afloat seems to be the focus today.”
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