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References:

* For vaccine recommendations, please visit www.cdc.gov.
† Among adults for whom vaccination status could be assessed in the 2018 National Health Interview Survey. CDC = Centers for Disease Control and Prevention; Tdap = tetanus, diphtheria, and acellular pertussis.
Here’s what you should know:

- The CDC recommends that **adults 19 years of age and older** receive a dose of Tdap, if they have not previously been vaccinated with Tdap.¹
- In a 2018 survey, it was reported that only **31.2% of adults ≥19 years of age** received Tdap vaccination during the preceding 10 years.²†
  - 46.1% of adults ≥19 years of age received an influenza vaccination in the 2017-2018 season.²†
  - 69.0% of adults ≥65 years of age have ever received a pneumococcal vaccination as of 2018.²†
- Although pertussis infection in adults is usually less severe than in babies and young children, complications can still occur. In one study, 91% of adults with pertussis (N=79) **experienced a cough for an average of 54 days**, and 61% of adults with pertussis (N=203) **missed an average of 10 days of work** in another study.³,⁴
- Depending on the vaccine, 79% to 85% of adult patients indicated they were **likely to get vaccinated if recommended by their healthcare provider.⁵**

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*For vaccine recommendations, please visit www.cdc.gov.

¹Among adults for whom vaccination status could be assessed in the 2018 National Health Interview Survey.

CDC=Centers for Disease Control and Prevention; Tdap=tetanus, diphtheria, and acellular pertussis.

Vaccination: the great debate

N
ever has the topic of immunology been so embroiled in social and political controversy as it is today. In September, President Joseph R. Biden released his COVID-19 Action Plan, titled “Path Out of the Pandemic.” It mandates the following: Companies with 100 or more employees must ensure each individual is vaccinated or tested weekly for those who choose to remain unvaccinated, all workers in health care settings that receive Medicare or Medicaid reimbursement must be vaccinated, and states should require vaccinations for workers in schools.1

In the court of public opinion, the controversy over vaccines becomes even more heated as the discussion moves to requirements for children. Some health care providers oppose any mandate that states eligible children must get one of the COVID-19 vaccines, while others are strongly in favor of such action. As we went to press last month, the FDA Vaccines and Related Biological Products Advisory Committee had just convened and, in a 17-0 vote, recommended the authorization of the Pfizer-BioNTech COVID-19 vaccine for children 5 to 11 years old—the first step in a chain of decisions by federal agencies that may see children eligible for shots by the time this issue is in your hands.2

The Supreme Court has been busy as well, recently declining, without comment, the attempt to block New York City’s requirement that public school teachers had to receive the COVID-19 vaccine to return to work.3

The fight to decide on your own inoculation choices is nothing new in the United States, just as the argument of requiring vaccinations to protect public health is also nothing new. These kinds of public outcries, to stand the science, technology, and development of vaccines has never been so essential. I hope you enjoy this month’s issue.

REFERENCES:

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Nutrition  By Lois Levine

Many new parents have misconceptions about the relationship between introducing foods and developing allergies, according to Vivian Hernandez-Trujillo, MD, FAAP, FAAAAI, FACAAI, director of the Division of Allergy and Immunology at Nicklaus Children’s Hospital in Miami, Florida.

“Food allergy affects approximately 8% of children,” Hernandez-Trujillo said during her session at the 2021 American Academy of Pediatrics National Conference & Exhibition on essential advice to prevent food allergies. “Discussion with parents regarding solid food introduction is essential.”

Hernandez-Trujillo noted a lack of evidence supporting dietary restriction during both pregnancy and lactation. There is also no convincing evidence for use of soy-based formula in allergy prevention, little evidence that hydrolyzed formula prevents atopic disease, and no evidence supporting delayed introduction of solid foods beyond 4 to 6 months to protect against atopic disease, she added.

“The times are changing: The recommendations of avoidance of solids and ‘allergenic’ foods until 3 to 5 years old are no longer advised,” Hernandez-Trujillo said. She cited the Learning Early About Peanut Allergy (LEAP) study: “The take-home message of this study was that the early introduction of peanuts significantly decreased the frequency of the development of peanut allergy among children at high risk.”

Next, Hernandez-Trujillo pointed to the 2016 Enquiring About Tolerance (EAT) study, which was designed to investigate the best time to introduce 6 allergenic foods to the infant diet: cow’s milk, peanut, egg, sesame, fish, and wheat. The findings proved that early introduction resulted in lower food allergy prevalence and was achievable and safe.

Pediatric Pharmacology  By Miranda Hester

Asthma is the most common chronic condition in childhood, affecting 1 of every 12 children, said Heather De Keyser, MD, MS, assistant professor of pediatric pulmonology at the Breathing Institute, University of Colorado School of Medicine and Children’s Hospital Colorado in Aurora, during her presentation at the 2021 American Academy of Pediatrics National Conference & Exhibition. Biologics for asthma and allergic skin disease target certain markers such as IgE, IL-5, and IL-4. The agents can be administered either at home or in a clinician’s office, De Keyser said.

Omalizumab (Xolair) is the oldest available biologic for asthma and is anti-IgE. Mepolizumab, an anti–IL-5 biologic, has been shown to reduce exacerbations and eosinophils and result in improved markers of control. Benralizumab (Fasenra), an anti–IL-5 biologic, significantly reduced exacerbation risk and increased markers of lung function in patients with higher eosinophil levels.

Omalizumab is also approved for the treatment of chronic idiopathic urticaria.

De Keyser recommended health care providers evaluate medication adherence in patients with poorly controlled asthma, atopic dermatitis, or urticaria and become knowledgeable about the adverse effects of biologics.
“Children and adolescents with attention-deficit/hyperactivity disorder (ADHD) have a consistently higher prevalence of sleep disorders as compared to the general pediatric population,” said Grace Wang, MD, FAAP, assistant professor of pediatrics at Penn State Health in Lancaster, Pennsylvania, as she began her presentation on ADHD and sleep disorders at the 2021 American Academy of Pediatrics National Conference & Exhibition.

“There is evidence that shows that resolving the underlying sleep disorders can improve and, in some cases, resolve, a patient’s ADHD diagnosis.”

During “My Child Won’t Sit Still! Is It ADHD, or an Underlying Sleep Disorder?” Wang described a 6-year-old female patient with seasonal allergies and dysfunctional voiding patterns in the context of constipation; who was hyperactive and emotionally labile; had difficulty sustaining attention and was falling behind her classmates. She presented as an alert girl with normal vital signs and intellect, with good eye contact and a cooperative attitude during the interview. Vanderbilt parent/teacher rating scales were implemented and suggested ADHD, combined type. The physician asked about snoring and discovered that the child did indeed snore, was a mouth breather, was restless throughout night, and occasionally sleepwalked. Furthermore, she was exhausted after school, falling asleep on the drive home. This information prompted a polysomnography; results showed sleep-related hyperventilation and a mild/borderline degree of obstructed sleep apnea syndrome.

“Studies have shown [that] 25% to 64% of patients with ADHD have some sort of sleep-disordered breathing,” Wang said. “The million-dollar question then becomes ‘Can you expect improvement of ADHD symptoms after addressing sleep disorders?’”

Ultimately, adenotonsillectomy was recommended for this patient. Not only did her sleep improve after the surgery, but so did her attention span and behavioral issues.

Patients with ADHD can also experience restless legs syndrome (RLS), which can be treated with iron supplements, leg massages, compression devices, and lower body exercises.

In concluding, Wang offered this advice: “Because sleep deprivation and RLS can mimic symptoms of ADHD, have a high index of suspicion when screening a patient for these conditions.”

Patients with ADHD have some sort of sleep-disordered breathing, which Wang described as “stopping breathing,” or “sleep-related hyperventilation.”

By Lois Levine

Developmental Health

Q Of all the different arguments to persuade adults, and their eligible children, to get the vaccine, what would you say is the most convincing one?

Well, if they are hesitant because they are unsure of safety and efficacy, we have more than enough data on that. It is a tremendous platform to stand on.

There is a difference between these people and vaccine deniers, who are vaccine cynics. If that’s still going to allow for the circulation of the virus, and allow for variants to be created, then what do you do? I think you compel people to be vaccinated.

Q Should pharmacists or pediatricians administer these vaccines?

Pediatricians are used to being the medical home for kids, but I have no problem with pharmacists giving this vaccine. They just need to make sure that people stick around for at least 15 minutes after a dose, and that they have the equipment to give epinephrine or other sorts of supportive measures, should there be an anaphylactic reaction.

For the complete story, visit drugtopics.com.
4 Techniques to Improve Medication Adherence

Help patients (and parents) change their behavior by speaking clearly, using data, and remaining nonjudgmental. By Miranda Hester

This article originally appeared in Contemporary Pediatrics®.

It’s a tale as old as time: A patient receives a prescription for a chronic condition such as asthma, and at later date, the patient reluctantly admits that they have only been taking it 25% of the time.

Medication nonadherence is an issue around which many health care providers can share frustrating anecdotes. During a session at the virtual 2021 American Academy of Pediatrics National Conference & Exhibition, Heather De Keyser, MD, MS, assistant professor of pediatrics—pulmonology medicine at the University of Colorado School of Medicine and Children’s Hospital Colorado in Aurora, discussed the impact and scope of nonadherence, reasons for nonadherence, and ways to improve adherence.

Nonadherence to medication is a frustrating problem, with the worldwide average adherence for chronic diseases at approximately 50%, according to De Keyser. She noted that nonadherence can be costly, citing one study of 43,356 children with asthma on Medicaid that found if adherence to inhaled steroids rose from the 33.35% seen in the participants to just 40%, $8 million per year in cost savings would result; increasing adherence to 80% would save $57 million per year.

Even in patients with serious medical issues, De Keyser said that adherence can be low, with 58% nonadherence in the 6 months following newly diagnosed epilepsy and 30% to 76% nonadherence in patients with solid organ transplant—with the poorest adherence in adolescent patients.

A variety of factors can influence medication adherence, including poor access to care, poor provider knowledge of the formulary, patient/provider relationships, social determinants of health, stigma, medical beliefs that lead to intentional nonadherence, forgetfulness, poor technique, and medication administration responsibility.

De Keyser noted that primary nonadherence—not getting the prescription filled—is only 14% to 20% and 24% to 40% for subsequent fills; secondary nonadherence, or prescription being filled but not used, is 30% to 70%. Whether due to poor device technique, true adherence with asthma medications is likely very low.

Ask a provider why patients don’t take their medications, and many will answer that patients would “if only they knew how important it was.” However, De Keyser emphasized that the reasons behind nonadherence are complex and can range from a prescription not being filled because it requires frequent refills to parents being unsure of the proper dose to the child or parent simply forgetting the dose.

She also shared a study that looked at HIV medication adherence. Barriers related to habit were far more commonly reported by children and parents than barriers tied to education. Habit is indeed a strong driver of an action, thanks to the loop of cue, routine, and reward, said De Keyser. She explained that the habit loop was used to improve oral care when a toothpaste company wanted to sell more product, encouraged people via an ad to run their tongue along their teeth and whether they felt a film to brush their teeth—which resulted in the reward of no more film.

To improve adherence, De Keyser recommended asking all patients on chronic medications about adherence and verifying their understanding with objective data, particularly when the condition is not well controlled. When talking with patients and parents, she advised that providers speak clearly, use data, and be nonjudgmental.

Even health care providers don’t always adhere to habits related to good health, she noted, adding that mentioning your own lack of flossing, for example, can help put patients at ease and let them know they’re not alone.

DE KEYSER NOTED THE FOLLOWING 4 TECHNIQUES TO IMPROVE ADHERENCE:

1. **Place-based cue:** The patient puts the medication in a place where they will regularly see it throughout the day, such as the kitchen table or the bathroom sink.

2. **Time-based cue:** The patient uses the medication at certain times of day, such as right before going to school in the morning and during evening mealtimes.

3. **Habit stacking:** The patient connects using the medication to another established habit, such as right after waking up or right before brushing their teeth.

4. **Technology:** The patient uses timers on their smartphone, other smartphone apps, or electronic health monitors. De Keyser recommended using smartphone times and reminders for medications that require only a short course because notifications can become easy to ignore.

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The Future of Vaccinology

Andrew J. Schuman, MD; and Russell Libby, MD

No aspect of pediatric medicine has been as impactful on the health and well-being of our patients and communities as the vaccines that now routinely prevent 16 diseases that were once commonplace. Current vaccines include those based on live attenuated viruses (eg, varicella, rotavirus), killed whole organism (eg, rabies, hepatitis A), polysaccharide or native proteins (eg, pneumococcal, meningococcal), and recombinant or whole molecular modification (eg, hepatitis B, herpes zoster).

Today nearly 260 vaccines are in development (Figure 1). Many of these are directed at infectious diseases, but many novel vaccines are being developed to treat or prevent allergies, autoimmune disorders, cancers, and even Alzheimer disease. Following the emergence of severe acute respiratory syndrome (SARS) in 2003 and Middle East respiratory syndrome (MERS) in 2012, both deadly coronavirus infections, investigators spent subsequent years developing and perfecting innovative vaccines including adenovirus vector vaccines and messenger RNA (mRNA) vaccines. Both vaccine types were rapidly adapted to combat the SARS-CoV-2 pandemic once the Chinese published the genetic sequence of SARS-CoV-2 in January 2020. These vaccines instruct cells to manufacture specific antigens—ie, the spike proteins in the case of the SARS-CoV-2 virus—so that the immune system manufactures spike protein antibodies. As of this writing, the United States has deployed 2 mRNA vaccines (Pfizer and Moderna), as well as a genetically engineered adenovirus vector vaccine (Johnson & Johnson). Both vaccine technologies can easily be modified to target a litany of other viruses.

To date, several adenovirus vector vaccines for HIV, Ebola virus, influenza virus, Mycobacterium tuberculosis, and Plasmodium falciparum are under human clinical trials, and others are being developed against rabies, dengue virus, and MERS. Currently, mRNA-based vaccines are in development against HIV, rabies, Zika, cytomegalovirus, respiratory syncytial...
As effective as intramuscular or subcutaneous injections, with less pain associated with injection, according to the company.

**Conclusion**

Vaccine technologies in development may facilitate a rapid and effective response to new threats and likely will target not only infectious diseases but also allergies, autoimmune conditions, and cancers. Additionally, new vaccine delivery systems will overcome production and storage obstacles that have slowed the response to the COVID-19 pandemic. Pediatricians and parents, recognizing how much vaccines improve the health and well-being of young patients, have much to look forward to.

For full references, visit drugtopics.com

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**New Ways to Administer Vaccines**

Additionally, there are new vaccine delivery systems under development. The most common method of immunizing children to date has been the direct injection of vaccines either intramuscularly or subcutaneously. Several years ago, a live attenuated influenza intranasal vaccine was developed, which has benefited countless needle-phobic children and adults. Now Altimmune has developed an adenovirus-vectorized intranasal vaccine, now in phase 1 clinical trials, that generates a broad IgG, mucosal IgA, and T-cell response to SARS-CoV-2 and is stable at room temperature. Altimmune is also in clinical trials for intranasal vaccines for anthrax and influenza.

Several companies are developing a microneedle patch to administer vaccines. The microneedles are impregnated with vaccine that targets immune cells in the dermis. Best of all, these are pain free and stable at room temperature. The patch is applied via a preloaded applicator and removed after a few minutes, leaving the vaccine-impregnated tips embedded in the dermis, releasing vaccine over time. These patches are being investigated as a potential alternative to intramuscular vaccines for influenza and COVID-19.

Two more vaccine delivery systems may change the way patients are immunized. An oral vaccine mechanism, Vector-Adjuvant-Antigen Standardized Technology (VAAST), which targets mucosal IgA, is being perfected by Vaxart. VAAST has shown promising results for H5N1 influenza, H1N1 influenza, influenza B, norovirus, and RSV. The second is a vaccine capsule filled with nanoparticles, injected subcutaneously, that would slowly release the vaccine over time, potentially eliminating the need for immunization booster doses. Enesi Pharma is developing a universal vaccine implant (UVI) using their ImplaVax needle-free delivery device to inject each UVI up to 7 mm into the dermis (Figure 2). Preclinical studies have shown this method to be...
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THE COST OF ANTIBIOTIC RESISTANCE

By Christine Blank
espite technological advances, new antibiotics, and pharmacists’ involvement, antibiotic resistance is still a major health care challenge in the United States.

The Scope of the Problem

Although data on antibiotic resistance are hard to pin down and underreported, experts estimate the problem has increased in recent years.

“The number of [antibiotic] prescriptions that are going out [to patients] and the number of [antibiotic] prescriptions that are inappropriate in the ambulatory care setting are increasing,” said Lucas T. Schulz, PharmD, BCIDP, clinical coordinator for infectious diseases at University of Wisconsin Health clinical associate professor at University of Wisconsin-Madison School of Pharmacy.

“Antibiotic resistance is the next COVID-19,” Schulz said, “if we ignore it or we choose not to focus on it. We know it’s here. If we don’t make more people and more legislators aware—and if we don’t do something about it now—there are going to be bad outcomes,” Schulz added.

The prevalence of some antibiotic resistant organisms, like extended-spectrum β-lactamases (ESBLs), is increasing, according to Athena Hobbs, PharmD, BCIDP, infectious diseases clinical pharmacy coordinator at Methodist Le Bonheur Healthcare in Memphis, Tennessee.

The spike in ESBLs is “a huge concern because this means that patients may not receive the correct antibiotic initially before we know what organism is causing the infection,” Hobbs explained. “This will also force clinicians to use more broad-spectrum antibiotics up front, which will lead to worse antimicrobial resistance down the road.

“We need to continue to be vigilant in the health care field as well in the community to only prescribe or take antibiotics when they are needed,” Hobbs said.

In a large study published in JAMA Network Open, investigators found that antimicrobial use deviated from recommended practices for 55.9% of patients who received antimicrobials for community-acquired pneumonia or urinary tract infection present at admission or who received fluoroquinolone or intravenous vancomycin treatment. In addition, infections caused by bacteria resistant to multiple antibiotics led to $1.9 billion in health care costs and more than 10,000 deaths among older adults across the US in 2017, according to a recent study published in Clinical Infectious Diseases.

These findings are a “stark reminder of the incredible and costly burden of antibiotic-resistant infections on our patients and our nation’s health care system,” said Daniel McQuillen, MD, president of the Infectious Diseases Society of America (IDSA), in a news release.

“We must respond to this growing public health threat with strong federal investments in key areas,” he said, “to ensure that safe and effective antibiotics, upon which modern medicine relies, are available when patients need them.”

IDSA is calling for government investment in antibiotic stewardship, antibiotic innovation, surveillance, research, diagnostics, infection prevention, the infectious diseases workforce, and global coordination.

In particular, the bipartisan Pioneering Antimicrobial Subscriptions to End Upsurging Resistance Act (PAIR), “which would change the way the federal government pays for novel antibiotics to revitalize the pipeline and promote stewardship,” is a critical piece of the solution, the organization said.

The CDC’s 2019 antibiotic resistance threats report found that nearly 3 million people in the United States each year experience an infection due to an antimicrobial-resistant pathogen, said Monique Bidell, PharmD, BCPS, a medical science liaison for Ferring Pharmaceuticals and former clinical pharmacy specialist at Massachusetts General Hospital in Boston.

“However, this number is likely even higher due to underreporting,” she said.

At the same time, antibiotic prescribing practices have improved during the past 2 years due to COVID-19. Between April 2020 and February 2021, there was a marked decrease in respiratory virus detections, which resulted in a 79% decline in ambulatory antibiotic prescribing rates for respiratory infections.

“This is probably because physicians and patients knew that their respiratory symptoms were due to COVID-19, and we could do rapid diagnostics [to determine whether patients were positive for it],” Schulz said, adding that patients also understand that COVID-19 is a virus and that antibiotics are not typically prescribed to treat a virus.

Advances and Best Practices

Pharmacists have been making great headway in the antibiotic resistance conundrum for several years by serving as valuable leaders and members of antibiotic stewardship teams and through educating patients and other health care providers on appropriate prescribing.

“We have certainly increased awareness of antimicrobial resistance and [it being] a driver of negative patient outcomes,” said Ronak G. Gandhi, PharmD,
BCPS, senior attending clinical pharmacist of infectious diseases at Massachusetts General Hospital. The advances made by the infectious disease community during the past 10 to 15 years in terms of diagnostics, software, and other resistance mechanisms are invaluable, Gandhi said.

Several newer tests detect genes that code for specific antibiotic-resistant determinants, Bidell explained. “While great in theory, there are challenges with many of these platforms in that most methodologies do not provide actual antibiotic susceptibility data at the time of identification, so there is not always an opportunity to guide therapeutic decisions,” she said.

One best practice for implementation is to have dedicated personnel, such as antibiotic stewardship team members, respond to the results “so that if therapeutic changes need to be made, they can be done so in a timely manner,” Bidell advised. “Stewardship programs need to decide at the program level if they have both the patient volume and personnel to support effective implementation of these technologies.”

Rapid tests identifying whether the infection is viral or bacterial are increasing in clinics, emergency departments, and other point-of-care sites, Schulz said. “We know that viral infections are not going to respond to antibiotics. That is a very simple way to slow or stop antibiotic resistance.”

There are a few providers of the rapid viral versus bacterial tests, but additional research is needed to confirm the tests are “correct enough times,” Schulz noted.

In addition to diagnostics, the integration of stewardship platforms into the electronic medical records that allow easier reporting to the CDC’s National Healthcare Safety Network Antimicrobial Use and Resistance Module can help track antibiotic utilization and compare a health system to similar institutions in terms of antibiotic use, said Gandhi. “This can lead to collaborations between institutions to share best practices to reduce antibiotic use.”

It is “critically important” that pharmacists participate in those platforms, Schulz added.

**Pharmacists’ Crucial Role in Antibiotic Stewardship Programs**

One of the biggest steps that pharmacists can take to address antibiotic resistance is to participate in and promote antimicrobial stewardship programs within health care teams, Bidell noted.

Schulz agreed, adding that to combat antibiotic resistance, everyone must first think of themselves as an antibiotic steward. “A steward is just being a good pharmacist: right patient, right dose, right time, and right duration,” he said. “It is something we should be doing for every patient.”

Bidell echoed that pharmacists can play a key role in facilitating use of the “right” antibiotic—one that is active against the pathogen without introducing unnecessary collateral damage—at the right dose at the right time for the right duration. “In some cases, the best stewardship approach is antibiotic cessation or taking a watch-and-wait approach (in order) to minimize unnecessary antibiotic exposure that can place patients at risk for adverse effects and/or Clostridioides difficile infection,” she said.

One untapped area still contributing significantly to antimicrobial resistance is outpatient stewardship, Gandhi noted. “Antibiotics can be prescribed by so many health care professionals. Controlling what we do [in inpatient settings] is important, but it’s a small slice of the cake compared to managing outpatient antibiotic use,” he said.

Advancements in outpatient stewardship can dramatically improve antimicrobial resistance locally and globally.

Although governmental pushes have promoted outpatient stewardship, the execution of these efforts is still in its infancy, Gandhi added.

Another avenue to combat antibiotic resistance, said Ghandi, would be granting more pharmacists provider status and allowing pharmacists trained in infectious diseases to be more involved in care at the community level as midlevel practitioners.

Pharmacists can also encourage the use of newer antibiotics such as meropenem/vaborbactam (Vabomere) and ceftolozan (Fetroza) that target highly resistant pathogens, Schulz advised.

However, because of the higher cost of some newer medications—on average, $1000 per day vs $10 to $15 for older medications—there is a “friction point between pharmacy and providers,” Schulz said. “Too often, pharmacists are viewed as a hurdle to clear.”

The typical hospital billing system, as well as the Centers for Medicare & Medicaid Services reimbursement guidelines, are preventing newer drugs from being utilized more often, Schulz added. “We need to look beyond their initial price tag,” he said. “If you identify the handful of patients who need that drug, they are going to have better patient outcomes.”

At this year’s upcoming American Society of Health-System Pharmacists’ Midyear Clinical Meeting—being held virtually from December 5 through December 9—Bidell, Gandhi, and Thomas Lodise, PharmD, PhD, professor of infectious disease at Albany College of Pharmacy and Health Sciences in New York, will discuss roles for newer broad-spectrum therapies against resistant gram-negative pathogens.

They will also outline more nuanced clinical scenarios in which clinicians can appropriately take a “novel agent-sparing” approach, Bidell said.

“The reason the latter stance is important is that not all institutions have the same resources with respect to access to these broad-spectrum agents— for example, due to formulary restrictions—or with respect to susceptibility testing capabilities.”

“We also know that use of any antibiotic brings the risk of subsequent development of resistance,” she added. “So if there is an opportunity to use a more conventional agent in place of a broader and newer agent, there are certain specific clinical scenarios where that may be a perfectly reasonable approach.”

For references, visit drugtopics.com.
The flooding tide of individuals with elevated blood glucose levels is a daunting challenge and an alluring opportunity. The CDC estimates that 83 million Americans, more than 1 in 3, have prediabetes and that 84% of them don’t know it.

The CDC also knows that community pharmacy can play a major role in preventing and delaying progression to diabetes. The concept grew from The Asheville Project, a pharmacy-based, chronic-disease treatment and prevention program launched by the city of Asheville in North Carolina in 1997.

The numbers are compelling. For individuals with prediabetes, losing 5% to 7% of initial body weight and increasing physical activity to 150 minutes per week can reduce the risk of developing type 2 diabetes by 58% (71% for people older than 60 years).

“We were doing diabetes prevention through lifestyle modification. We just didn’t know to call it that 25 years ago,” said Barry Bunting, PharmD, who helped launch and manage The Asheville Project. He now manages the American Pharmacists Association (APhA) Diabetes Prevention Program (DPP) funded by the CDC.

“We were educating people on their risk of progressing to diabetes, giving a lot of personal coaching on eating a little better, moving a little more, and losing a few pounds,” Bunting said. “That is the same script the CDC uses in its lifestyle-change DPP.”

DPP Elements

The CDC has partnered with APhA, the National Community Pharmacists Association (NCPA), and other pharmacy groups to extend the reach of its DPP to the local level. The CDC is also working with state and local health departments, Medicaid, and advocacy groups such as the Association of Diabetes Care & Education Specialists (ADCES) to involve pharmacists in expanding access to diabetes prevention services through early intervention.

“I am a huge pharmacy fan,” said Angela Forfia, ADCES senior manager of prevention. “And not just because pharmacies have been in diabetes prevention since the very beginning. It’s all about access to pharmacies, pharmacists’ training, and the reality that people with prediabetes are overrepresented in pharmacy patient populations. Pharmacists know that lifestyle intervention is twice as effective as off-label metformin at reducing the risk of progressing from prediabetes to type 2 diabetes.”

Dozens of pharmacies, primarily independents and some grocery store outlets, have launched DPPs.

“This is the direction we are headed,” said Benjamin McNabb, PharmD, owner of Love Oak Pharmacy in Eastland, Texas. “I call it the community wellness model. The approach is managing diseases in the community before they get to the point where you need medication and other interventions. It’s about providing information, providing care at the personal level to keep potential problems from escalating. And it’s one more service you can eventually get paid for.”

A DPP has 3 tiers. Tier 1 is promoting awareness of prediabetes. Pharmacy engagement can be as simple as bag stuffers and countertop displays, quick conversations with patients who could...
be at risk, and social media messages. "Social media, patient emails, and flyers in the store have been fantastic for us," said Amber Suthers, MSAH, CPhT, clinical services coordinator at Surgoinsville Pharmacy in Tennessee. The pharmacy was part of NCPA’s first DPP cohort.

"And prediabetes is an obvious conversation when a patient comes in to pick up meds for blood pressure and cholesterol," Suthers added, "especially if they seem on the heavy side, like so many are. People don’t always recognize their potential for diabetes."


Tier 2 is screening, testing, and referring. Moving from awareness of prediabetes to screening is an easy step. The CDC and the American Diabetes Association have a 7-question screening test that can be completed online (www.cdc.gov/prediabetes/takethest/section6) or printed out.

Pharmacies in some states can also provide onsite glycated hemoglobin (HbA1c) testing to determine blood glucose levels. Patients with prediabetes (HbA1c level, 5.7%-6.4%) can be referred to a CDC-recognized program, including the pharmacy’s own program if available.

Medicare and some Medicaid programs cover DPPs. So do some state and local public health programs, commercial insurers, and employers. DPP providers can charge a flat fee or offer a sliding scale to boost access.

Tier 3 is offering your own DPP. "When we find prediabetes, we tell them that their medications or other risk facts may qualify them for our education classes," Suthers said. "People are doing DPPs even with the challenges of [COVID-19]. We have participants who have met their weight loss and exercise goals through the pandemic. Based on our first 6 months of data that we submitted to the CDC earlier this year, we will meet the requirements for reimbursement."

**Launching a DPP**

Starting a DPP begins with an application to become a CDC-recognized delivery organization. Pharmacies agree to use a CDC-approved curriculum in a 12-month lifestyle-change program that includes at least 16 weekly 1-hour sessions for the first 6 months and 6 monthly sessions for the next 6 months.

"You’re asking for 24 hours of participants’ lives over the next year," Bunting said. 

"[A] DPP is all about lifestyle changes, small changes over time, nothing dramatic or extraordinary. They get a coach, someone to help along the way and to hold them accountable. And the group dynamic, either in person or online, makes a huge difference in results."

Classes are conducted by a trained lifestyle coach. That person can be a pharmacist or, more often, a pharmacy technician.

"From an economic perspective, it makes more sense to involve a technician to lead the program," said John Beckner, RPh, senior director for strategic initiatives at NCPA. "The pharmacist needs to be visibly involved, but the more successful pharmacies have trained multiple lifestyle coaches, not just the pharmacist, to share the task and provide more flexibility in scheduling."

NCPA works with ADCES to train pharmacists and technicians. Pharmacies enrolling in a DPP through NCPA can get more than $5000 in financial support, including coach training, technology to document patient encounters, and financial incentives. Other industry organizations offer similar support, largely funded by the CDC.

Finding patients can be challenging. Social media, bag stuffers, store displays, and even newspaper ads can work, depending on local demographics and the patient population. Patients in existing diabetes self-management education and other diabetes-related services can be good referral sources.

"They aren’t a lot of people actively looking to change their lifestyle," Bunting said. "Getting the message out about prediabetes through as many channels as possible is vital, even if people aren’t motivated to change right now. We need to plant that seed so that when they have a wake-up moment, they know their pharmacy can help."

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There are multiple paths to reimbursement for diabetes prevention programs (DPPs). Medicare covers these programs for CDC-recognized providers, but accreditation requires 12 months of DPP data. Programs must have at least 5 participants, and at least 60% of participants must attend at least 9 of the first 16 sessions and 3 of the final 10 sessions. Participants must also lose at least 5% of starting body weight and document physical activity minutes. The CDC’s action guide for community pharmacists (www.cdc.gov/diabetes/prevention/pdf/pharmacists-guide.pdf) has more details.

Some state Medicaid programs also cover DPPs, but eligibility varies by state and local requirements. Medicaid programs and state pharmacy associations can provide details. In addition, some health departments partner with pharmacies to support diabetes self-management education programs as well as pharmacy-based DPPs. Health departments and other public entities may also have funding to help pharmacies launch a DPP.

Existing DPPs run by community, faith-based, and other local organizations can also partner with pharmacies to provide DPP screening and referral services. Increased foot traffic, customer referrals, and customer loyalty also boost the bottom line.

"When I started my own diabetes practice, the biggest return was actually from people telling their family, friends, and physicians," said Sandra Leal, PharmD, MPH, CDCES, president of the American Pharmacists Association. "[A] DPP gives you more opportunities for patient engagement and trust."
When we found out my daughter had type 1 diabetes, I felt as though my world had turned upside down. When you have a crying newborn, a teething baby, or a child with an ear infection, you know you will have a few rough days and sleepless nights. However, a diagnosis of type 1 diabetes means many years of sleepless nights and worrisome days.

You would think that as a pharmacist I would be well equipped to take care of my child with this condition. In some ways I felt confident, and in others, clueless. For example, take insulin. In type 1 diabetes, the immune system attacks the pancreas. The body now needs injected insulin to live. Not enough insulin can kill a person, but too much insulin can also kill a person.

What other medications have dosing that is not clearly outlined and can change multiple times a day? As a medical professional, this is the most challenging part of the situation. Now imagine you have no medical background and your child receives this diagnosis. You spend several days at the hospital and then are left to your own devices to take care of someone who depends on you to regulate their pancreas and ensure their blood glucose level doesn’t go too high or too low.

And your child, whose normal and carefree life is stripped away in 1 terrifying hospital stay, now has a life of counting carbohydrates, injections, and managing the day-to-day challenges of diabetes.
and finger sticks. (Thanks to technology, the sticks soon change to pumps and continuous glucose monitors for many patients, making life just a little easier.)

I joined as many Facebook groups as I could find for parents of children with type 1 diabetes. One common thread that stuck out was that sometimes these parents have trouble at the pharmacy. As a pharmacist, writer, and parent of a child with type 1 diabetes, I thought I might try to bridge the gap and offer some tips on how pharmacists can help.

Here are some common issues, and suggestions on how to address them:

**Why do patients need a blood glucose meter if they have a continuous glucose meter (CGM)?**
You would think that when a child uses a CGM, they would have no need for a blood glucose meter. One parent mentioned that their pharmacist didn’t know a blood glucose meter was necessary because their child had a Dexcom CGM. However, a blood glucose meter is needed for a couple of reasons: to calibrate the Dexcom while the sensor is warming up (2 hours every time it is changed, which is every 10 days, or sometimes less, as it can fall off before then) or in case of a Dexcom signal loss or failure.

Our pediatric endocrinologist also suggests that when treating a low blood sugar level, we should finger stick our daughter because the number “catches up” faster than the Dexcom. This method also helps prevent overcorrecting the low number, ending up with a high number, and therefore requiring more insulin (see the cycle?).

**How can we help patients afford their insulin?**
It has been all over the news for years: Insulin costs a fortune and is unaffordable for many people. Patients often resort to skipping doses or using lower doses to conserve insulin. For those with a high co-pay, high deductible, or other affordability issues, pharmacists can help by familiarizing themselves with manufacturer assistance programs. For example:

- Patients who use Humalog can visit the manufacturer’s website and choose a coupon that works with their insurance. They can pay $25 per 30-day supply or select the My$99Insulin program to pay $99 for a 1-month supply of up to 3 vials or 2 packs of pens.

**Why do patients need multiple types of the same insulin?**
When my daughter received her diagnosis, we used Humalog at the hospital. Our insurance only paid for Novolog, so we went home with the Novolog cartridge pen. The pen had the ability to dose in half units, so we filled the prescription for cartridge vials. However, changing the vials would sometimes interfere with the pen’s spring mechanism, so a few months in we switched to the traditional NovoLog FlexPen and would round up or down rather than using half units. Then we decided to use the InPen, a “smart pen,” and go back to using the cartridge vials with it. But before we could even start the InPen, my daughter finally decided she was ready to try the pump, so we needed the Novolog vials. Although it’s always best practice to check, a simple conversation with the parent (who becomes very knowledgeable very quickly) may save you the time and effort of trying to reach a prescriber, and get them on their way quicker with the insulin they need.

Sometimes, just a simple phone call or words of encouragement can help. Asking parents whether they need assistance with the injection technique or whether they have any questions may open up a conversation and provide an opportunity for you to help.

Remember, when parents are faced with a diagnosis of type 1 diabetes in their child, they are completely shocked and overwhelmed in most cases. Pharmacists can take steps to help parents in these difficult situations. After a few months, parents will be well equipped to deal with the ins and outs of type 1 diabetes, but they would fare even better with a pharmacist as part of their support team.

**Other Helpful Tips**

1. Do not attempt to help with dosing unless you are a certified diabetes educator (CDE) or have clinical experience doing so. Insulin dosing is highly individualized. The same goes for diet. Refer the parent to the CDE or a pediatric endocrinologist.

2. If parents ask for reading material, suggest some commonly recommended books such as *Think Like a Pancreas* by Gary Scheiner, MS, CDE, and *Sugar Surfing* by Stephen W. Ponder, MD, FAAP, CDE, and Kevin L. McMahon. You can also suggest they listen to the Juicebox Podcast, a top-rated podcast for patients with type 1 diabetes.

3. Ask parents what you can do to help. Maybe you can try to sync their insulin with supplies so they can make fewer trips to the pharmacy or remind them of your free delivery service. When parents are picking up a prescription for their child with type 1 diabetes, ask whether they need alcohol swabs, ketone strips, or glucose tablets.

4. Advise parents to pick 1 or 2 days per month to check all supplies so that they never run low. Additionally, recommend that they request any refills several days early to account for any issues, including refill authorization by the physician or out-of-stock products.
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At the 2021 Total Pharmacy® Solutions Summit, which was held virtually on September 25 in partnership with Drug Topics®, Sneha Baxi Srivastava, PharmD, BCACP, CDCES, DipACLM, provided tips for pharmacists to prioritize and successfully implement patient-centered communication strategies during a session that offered continuing education credits to attendees.

Effective communication is an undervalued strategy for improving patient outcomes and empowering patients on their wellness journey. Srivastava, associate director of pharmacy skills education and associate professor at Rosalind Franklin University Medicine and Science in North Chicago, Illinois, emphasized the importance of seeing patients as complex individuals to achieve patient-centered care.

When communicating with patients, pharmacists should do the following:

- understand the patient’s complete illness experience, including social, psychological, and biomedical factors;
- promote an equitable relationship with all patients;
- foster a therapeutic alliance; and
- develop self-awareness of the effects on patients.

Pharmacists are already one of the most trusted and accessible health care providers in their communities. When patients can express their questions and concerns to a supportive pharmacist who is equipped with effective patient-centered care strategies, their health and well-being can significantly improve.

Successful communication starts with a welcoming environment, Srivastava explained. Having dedicated spaces for wellness services and pharmacist consultations is one way to accomplish this. She noted that in

CONTINUED ON PAGE 22 >

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one study, investigators found that “a
person in the pharmacy wants the
availability of health and wellness
services. And so, this might be some-
thing that you consider and that could
be a great…starting point to then
have these conversations with your
patients,” she said.

The consequences of ineffective
patient communication can be serious,
including decreased use of preventiv-
es services such as mammograms,
Papanicolaou tests, digital rectal exams,
and vaccinations; increased risk of
mislmanaging chronic conditions and
treatments; increased preventable hos-
pitalizations; higher health care costs;
reduced quality of life; and increased
morbidity and mortality.

In the absence of research-based
knowledge and empathetic counsel,
patients can be making decisions
based on incorrect information and
experience worse health outcomes as
a result. Srivastava pointed to a health
care quality survey to show the conse-
quences of ineffective communication.

The survey respondents
reported the following:

- Thirty-nine percent disa-
geried with what the clinician
wanted to do (in terms of rec-
ommended treatment).
- Twenty-seven percent were
concerned about cost.
- Twenty-five percent found the
instructions difficult to follow.
- Twenty percent felt the recom-
mended treatment as against
their personal beliefs.
- Seven percent did not under-
stand what they were supposed
to do.

“It’s data like this that brings me
to talk about the skills and those little
things we can change in our day-to-day
encounters to hopefully affect these
numbers,” Srivastava said.

She added that effective communi-
cation can also significantly improve
medication adherence, noting that of
100 prescriptions written, an estimated
50 to 75 are filled by the pharmacy, 48
to 66 are picked up from the pharmacy,
25 to 30 are appropriately taken, and
a mere 15 to 20 of those initial 100
prescriptions are refilled. Although
communication is not the only factor
affecting these refill rates, Srivastava
explained that patient-centered care is
a strategy all pharmacists can imple-
ment in their store to make a differ-
ce.

Patient satisfaction is directly
linked to having effective commu-
nication between patient and phar-
macist. She said that core elements
of patient satisfaction include:

- expectations,
- communication,
- decision-making,
- time spent,
- clinical team,
- referrals,
- continuity of care, and
- dignity.

A common theme underlying many
of these elements is patient empow-
erment. According to Srivastava, by
listening intently to patient experi-
ences with other health care providers,
pharmacists can teach patients how to
take control of their wellness journey
through health literacy.

“Low health literacy means that
the patient is not able to use or
understand the information that’s pre-
sented to them in a way that can opti-
mize health care,” she said. Low health
literacy is not necessarily determined
by a patient’s literacy in general but is
more closely related to their past and
present relationships with health care
providers and the health and wellness
resources they have access to.

Pharmacists can improve health
literacy by confirming that they’re
understanding the information being
presented to them and involving them
in the decision-making process in
consultations. Pharmacists can use the
teach-back method, during which they
ask the patient to repeat what was dis-
cussed during the consultation.

“When you teach a patient how to
use that glucometer, or that insulin
pen, or that inhaler for asthma, take
a step back and say ‘OK, now show me
how you’re going to use it.’ I cannot tell
you how many times that [I find] they
need more help,” Srivastava said, add-
ing that pharmacists should not feel
the need to hide the fact that they’re

Health behaviors are largely determined by
patient perceptions, including the following:

- Perceived susceptibility. What is the risk of acquiring an illness or vulnerability to an illness/disease?
- Perceived severity. How serious is it to get the illness/disease and/or leave it untreated or undertreated?
- Perceived benefit. How effective are the treatments or actions to prevent the illness/disease?
- Perceived barriers. What are the obstacles present in applying the health behavior actions?
- Cues to action. What is the stimulus to trigger the decision to take the recommended action?
- Perceived self-efficacy. What is the level of confidence in ability to successfully perform the recommended action?
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“One thing that helps me is taking a step back and thinking about each person and [asking], ‘All right, what is guiding them to make their decisions?’”

Sneha Baxi Srivastava, PharmD, BCACP, CDCES, DipACLM

making sure the patient understands the information. Effective patient communication also means building trust and rapport, and creating an atmosphere where the patient is engaged.

Srivastava also underscored the idea that patients are individuals and that implementing effective communication is not easy. She pointed to the health belief model as a valuable resource for understanding health behaviors. “One thing that helps me is taking a step back and thinking about each person and [asking], ‘All right, what is guiding them to make their decisions?’” Srivastava said.

Moreover, taking the time to genuinely understand the perceptions and motivations behind a patient’s health behavior and outlook can be vital to enhancing communication. In addition, what drives the patient to act is an equally important factor for pharmacists and thinking about each person and [asking], ‘All right, what is guiding them to make their decisions?’” Srivastava said.

In addition to enhanced patient outcomes, effective patient communication strategies can also lead to a more successful pharmacy business. Customers are increasingly demanding patient-friendly wellness and consultation spaces, and the pharmacy is the ideal location for these services. “When we think about...how we can improve patient satisfaction, that increases patient outcomes,” Srivastava said. “And we become a pharmacy practice...that people talk about.”

For references, visit drugtopics.com.
New Advances in Breast Cancer Therapy

By Shams Alrubaie, PharmD Candidate; Michele Kozubal, PharmD Candidate; and Jonathan Ogurchak, PharmD, CSP

Breast cancer continues to affect women globally, with approximately 13% developing invasive disease. New treatment regimens and options are on the horizon for breast cancer therapy. The following therapies highlight the current progression in clinical trials.

HER2-targeted Therapy
Breast cancer, specifically HER2-positive cancer, is typically considered an aggressive cancer, and is associated with poor outcomes. Trastuzumab has been the standard of care for HER2-positive breast cancer and has undoubtedly increased overall survival among patients with this type of disease. Due to resistance to HER2-targeted therapies in some patients, research has been directed to this area. There are 7 FDA-approved targeted therapies that are frequently used in combination with endocrine and chemotherapy. Investigators are studying new compounds: HER2-targeted tyrosine kinase inhibitors (TKIs), antibody-drug conjugates (ADCs), and monoclonal antibodies, among others. These compounds may be more efficient at inhibiting HER2 signaling. In the meantime, combination therapy with HER2-targeted therapy and CD4 and CD6 kinase inhibitors, PI3K inhibitors, or immunotherapy may be the way of overcoming resistance.

Endocrine Therapy
Adjuvant hormone therapy is still favored for up to 10 years in most patients with estrogen receptor (ER)-positive breast cancer. Endocrine therapy aids in preventing recurrence, metastatic disease, and contralateral tumors. Menopausal status aside, tamoxifen is the conventional standard of care. Benefits from hormone treatment are dependent on the extent of ER expression. Recently, aromatase inhibitors have been the new therapy of choice, as they can greatly reduce recurrence risk compared with that of 5 years of tamoxifen therapy. However, these agents are contraindicated in premenopausal women. The length of endocrine therapy remains patient specific, but a duration of 5 to 10 years with either an aromatase inhibitor or tamoxifen has shown benefit compared with just 5 years of tamoxifen.

Immunotherapy
Pembrolizumab (Keytruda) has been very promising against tumor activity with an added plus of a respectable safety profile. Findings from a recent study of patients with a triple-negative breast cancer diagnosis showed a significant difference in complete pathological response in patients who received neoadjuvant chemotherapy with pembrolizumab compared with those who received chemotherapy and placebo.

CDK4/CDK6 Inhibitors
CDK4 and CDK6 are enzymes that play an essential role in cell division. They partake in the transition from the G1 phase to the S phase in cell division. Blocking this step may be beneficial in treating breast cancer and stopping the growth of cancer cells. The inhibition of CDK4 and CDK6 is considered to be broad spectrum because it inhibits the division of healthy cells as well as tumor cells. This drug class is used in patients with HER2-negative metastatic breast cancer specifically as an adjuvant to hormonal therapies. But CDK4/CDK6 inhibitors have some major adverse effects, including bone marrow suppression and an increased risk of infection, because of their effect on immune cells.

Agents that belong to this class include ribociclib (Kisqali), abemaciclib (Verzenio), and palbociclib (Ibrance). All of these were FDA approved between 2015 and 2017.

PI3K Inhibitors
PI3K is an enzyme that plays an important role in the signaling pathways of cells and cancer cells. Many studies are examining how each class plays a specific role in certain types of cancers. However, there is a specific isoform of PI3K found in breast tissues (PI3K-C2γ). Investigators have found that some females may have this mutation in the PIK3CA gene, a breast cancer mutation gene, which affects PI3K function and cancer cell growth.

Alpelisib (Piqray) is an FDA-approved PI3K inhibitor for the treatment of patients with advanced or metastatic breast cancer. It can be used for both HER2-positive and HER2-negative breast cancers, but patients must have 1 or more PIK3CA mutations in the tumor tissues.

Shams Alrubaie and Michele Kozubal are PharmD Candidates at Duquesne University in Pittsburgh, Pennsylvania, anticipated to graduate in spring 2022.

Jonathan Ogurchak, PharmD, CSP, is CEO and cofounder of STACK, a professional information management platform. He also serves as a preceptor at over 15 schools of pharmacy for a virtual advanced pharmacy practice experiential rotation for specialty pharmacy, technology, and entrepreneurship.
**WHEN YOU POKE THEM, PROD THEM.**

When giving a COVID-19 or flu vaccine to patients 50 years and older, *urge them to schedule a shingles vaccination, too.*

*Routine vaccination is an essential preventive care service that should not be delayed because of the COVID-19 pandemic. Because of COVID-19-related reductions in people accessing vaccination services, it is important to assess vaccination status at each patient visit. Please visit CDC’s COVID-19 webpage for more information.*

**Indication**

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

**Important Safety Information**

- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX.

- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX.

- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.
If they’re 50 years and older, it’s time to start the conversation

Patients may be coming in for their COVID-19 or annual flu vaccination. But for patients 50 years and older, there’s another risk to watch out for—shingles.2,3 That’s why it’s also the perfect opportunity to discuss vaccination with SHINGRIX.

99.5% of people aged 50 years and older are infected with varicella zoster virus2,3

In 1 out of 3 people the virus reactivates and causes shingles3

There are a lot of things that patients can’t prevent as they age—but you can help them prevent shingles. Don’t wait another day to schedule a SHINGRIX vaccination with your appropriate patients.

Download our Shingles Discussion Guide at talkshingles.com

• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.


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SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE
SHINGRIX is a vaccine indicated for prevention of herpes zoster (HZ) (shingles) in adults aged 50 years and older.

2 DOSAGE AND ADMINISTRATION
2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule:

- A first dose at Month 0 followed by a second dose administered 2 to 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Adults Aged 50 Years and Older

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,531 (60%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were White (74%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (6%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

The reported frequencies of specific solicited local adverse reactions and general adverse reactions (overall per subject), by age group, from the 2 studies are presented in Table 1.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
<td>Placebo</td>
</tr>
<tr>
<td>Pain</td>
<td>1315</td>
<td>1312</td>
<td>1311</td>
</tr>
<tr>
<td>Myalgia</td>
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<td>20</td>
<td>1</td>
</tr>
<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Shivering</td>
<td>36</td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>GI</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

* 7 days included day of vaccination and the subsequent 6 days.

a Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

b Placebo was a saline solution.
c Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
d Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.
e Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.

GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The local and general adverse reactions seen with SHINGRIX had a median duration of 2 to 3 days.

(continued on next page)
There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited local reactions (headache, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, and 4%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

**Unsolicited Adverse Events:** Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 51% and 32% of subjects who received SHINGRIX (n = 14,645) or placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (4% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX or placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

**Serious Adverse Events (SAEs):** In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) or placebo (2.2%) from the first administered dose up to 30 days post-vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post vaccination. One subject vaccinated with SHINGRIX and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

**Deaths:** From the first administered dose up to 30 days post-last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

**Potential Immune-Mediated Diseases:** In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

**Dosing Schedule:** In an open-label clinical study, 238 subjects 50 years of age and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

### 6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

**General Disorders and Administration Site Conditions**

Decreased mobility of the injected arm which may persist for 1 or more weeks.

**Immune System Disorders**

Hypersensitivity reactions, including angioedema, rash, and urticaria.

**Nervous System Disorders**

Guillain-Barré syndrome.

**Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX**

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

#### 8.2 Lactation

**Risk Summary**

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

#### 8.5 Geriatric Use

**Adults Aged 60 Years and Older**

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years). [See Adverse Reactions (6.1).]

#### 17 PATIENT COUNSELING INFORMATION

- Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.
- Inform patients about the potential for adverse reactions that have been reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

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Produced in USA.
Patient Education Key as Biosimilar Approvals Increase

Women make up to 80% of health care decisions in the United States, but for some, biosimilar knowledge is lacking. By Marissa Fox

Biosimilars are biological products that, according to the FDA, are “highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product.” Biosimilars are near copies—though not exactly the same—as their reference biologics, and both biologics and biosimilars are made from living organisms or natural sources.

Biosimilars are particularly important for women’s health because many biosimilars treat conditions that disproportionately affect women, such as breast cancer, rheumatoid arthritis, and irritable bowel syndrome, and can reduce treatment costs by 21%.

It is estimated that 67% of the recipients of biosimilars are women. However, a HealthyWomen survey showed that 70% of female patients did not understand biosimilars or biologics.

Because biosimilars are relatively new in the United States, education gaps persist among patients and even health care providers.

Between March 4, 2021, and March 18, 2021, HealthyWomen, a nonprofit organization that aims to empower women to take a proactive role in their health and the health of their families, conducted a series of 3 roundtable forums titled the “Value of Biosimilars in Women’s Health.” The series brought together a wide range of health care experts, from patients and advocates to physicians, researchers, and drug company leaders, who shed light on key topics and painted an inspiring picture of the potential for biosimilars to improve women’s access to affordable care.

Across the series, several key themes emerged:

• Education on biosimilars is needed.
• We’re still in the early days of biosimilars in the United States, and more biosimilars are coming.
• Biosimilars show promise for lowering costs and improving access to care, especially for women.
• Communication about treatment options that include biosimilars is key.

According to HealthyWomen, as prescribers have become more comfortable with biosimilars, some of these treatments have become the go-to drug in their category. For example, a biosimilar that promotes white blood cell production after cancer treatment has a 72% utilization rate. However, another biosimilar—this one for autoimmune disorders—represented just 17% of the market.

Angus Worthing, MD, FACP, FACR, of Arthritis and Rheumatism Associates and a clinical assistant professor of medicine (rheumatology) at George-town University Medical Center, has seen his patients on biologic or biosimilar therapy finally find relief after months or years of disabling pain.

“Getting on these drugs not only helps pain but prevents disability from joint damage and improves people’s health and lifespan,” he said.

The Biologics Price Competition and Innovation Act of 2009, part of the Affordable Care Act, created an abbreviated approval path for biosimilars. So far, the FDA has approved 31 biosimilars, 20 of which are currently available to patients.

More biosimilars are coming, but for them to achieve their potential, patients and health care providers alike need to better understand these agents.

For references, visit drugtopics.com.
The #PizzaIsNotWorking: It’s Time to Rethink Pay for Pharmacy Technicians

This occasional “reward” hardly makes up for the belligerent customers, insurance issues, and—yes—stressed-out pharmacists.

As a kid, growing up, my mom always baked bread, usually on Mondays. The smell wafted through the house as we enjoyed her handiwork fresh out of the oven. The only way we could be more excited was when she took the leftover dough and made us pizza with Velveeta cheese and pepperoni. We had pizza at home, long before the first pizza shop opened in our town in the late 1960s.

One of my clerks—an Italian woman—had another view of pizza. Antonia hated pizza because it reminded her of her childhood in the 1930s. Antonia said that when they had pizza at her house, it meant things were bad. Her mom would roll out the leftover bread dough and top it with tomatoes and leftover cheese, or maybe some pepperoni, salami, or soppressata—anything she could scrounge up in the refrigerator. Not a good day at Antonia’s home when pizza was served.

Somewhere between my childhood and adulthood, pizza became not only a treat but also a reward. Little League teams had a pizza party if they won a big game. Kids who won fundraisers at their schools had a pizza party. Cab Scout’s celebrated a successful Pinewood Derby with a pizza. Even an occasional drug sales rep might drop off a box of pizza to his pharmacies for hustling his vaccines. So what’s a 100% German guy doing writing about pizza?

All over social media, we are seeing the hashtag #PizzaIsNotWorking. It’s a catchphrase to show that pharmacy staff is not motivated by an occasional pizza. At one time in my career, pharmacy technicians were just a step up from a clerk. Most pharmacy techs did the mundane jobs: counting pills or filling out the occasional third-party triplicate claim form. After a couple months of training, a pharmacy tech in the early 1980s was fully trained and capable.

“Somewhere along the line, pizza became not only a treat but also a reward.

In the 40 years since I kicked off my career, the pharmacy technician profession has changed—possibly even more than the pharmacist profession. Today, technicians may do the data entry for the pharmacist, as well as the preparation of the prescription. Today, the pharmacy technician might do everything from receiving the prescription (either on paper or electronically) to bagging the completed prescription. The pharmacist needs to be onsite to do the verification, but other tasks fall on the technicians. Today, it takes at least a year of intensive training to create a proficient technician.

For all these tasks and duties assigned to technicians, their pay has in no way kept up with their workload.

Pharmacy technicians, especially in retail, have the most stressful job in the service industry. I’ve seen local convenience stores offering salaries $3 to $5 more than our techs are offered to operate a cash register, make sandwiches, and stock shelves—with significantly less stress and significantly more pay. Is it any wonder that our community pharmacy techs are leaving in droves? Handing them a pizza once a year on Pharmacy Technician Day hardly makes up for the belligerent customers, insurance issues, and—yes—stressed-out pharmacists.

There is not one topic I have addressed more often than staffing issues in the pharmacy. I’ve been called a staffing guru by a hospital pharmacist who read my comments as he was researching how to staff his hospital’s outpatient pharmacy. I’ve always said that the difference between a good day on the bench and a miserable day is the quality and quantity of staffing.

The big chains have made massive amounts of money with vaccinations. They got almost $40 for each COVID-19 shot given, along with all the other vaccines we administer. All this money has been made on the backs of the pharmacist and their technicians. The chains need to give at least a $5 per hour increase to everyone in their pharmacies. The money is there—we’ll be glad to order our own pizzas.

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.
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FINERENONE FOR HEART FAILURE IN ADULTS WITH CHRONIC KIDNEY DISEASE ASSOCIATED WITH TYPE 2 DIABETES

Megan M. Pantos, PharmD; and Kevin W. Chamberlin, PharmD, FASCP

The FDA has approved finerenone (Kerendia, Bayer) for the treatment of adults with chronic kidney disease (CKD) associated with type 2 diabetes.1 Finerenone is a non-steroidal selective mineralocorticoid receptor (MR) antagonist used to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure.1,2 Finerenone is activated by aldosterone and cortisol, and it also regulates gene transcription. Finerenone works by blocking MR-mediated sodium reabsorption and MR overactivation in epithelial and nonepithelial tissues. Finerenone has high potency and selectivity for the MR.

Efficacy

The FIDELIO-DKD trial (NCT02540993) established the efficacy of finerenone via a randomized, double-blind, placebo-controlled multicenter study of adult patients with CKD and type 2 diabetes.3,4 The study randomized 5734 patients, of whom 2827 received treatment with finerenone and 2831 received placebo (60 were dismissed and 16 did not take treatment). Finerenone reduced the incidence of a sustained decline in eGFR of greater than or equal to 40%, kidney failure, or renal death (HR, 0.82; 95% CI, 0.73-0.93; \( P = .001 \)). The reduction in urinary albumin to creatinine ratio in patients being treated with finerenone was 31% after 4 months and remained stable thereafter. Patients being treated with finerenone had a decrease in systolic mean blood pressure of 3 mm Hg and mean diastolic blood pressure of 1 to 2 mm Hg after 1 month and remained stable after. Finerenone was also found to reduce the incidence of the composite end point of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke or hospitalization for heart failure (HR, 0.86; 95% CI, 0.75-0.99; \( P = .034 \)).

Safety

Finenone is contraindicated in patients receiving treatment with concomitant strong cytochrome P450 3A4 inhibitors.3 Patients should avoid grapefruit and grapefruit juice while taking finerenone. It is also contraindicated in those with adrenal insufficiency or severe hepatic impairment. Adverse reactions include hyperkalemia.

Dosing & Administration

Finenone is available in 10- and 20-mg tablets. The recommended starting dose of finerenone is based on the patient’s eGFR. If the eGFR is greater than 60 mL/min/1.73m², the starting dose is 20 mg by mouth once daily. For patients with eGFRs between 25 and 60 mL/min/1.73m², the starting dose is 10 mg once daily. Finerenone is not recommended for an eGFR less than 25 mL/min/1.73m². Prior to starting finerenone, the patient’s serum potassium level and eGFR should be measured. The target daily dose of finerenone is 20 mg. Serum potassium should be monitored every 4 weeks after initiation or an increase in dose. If the serum potassium is less than 4.8 mEq/L, the patient may remain on 20 mg daily or be increased from 10 to 20 mg once daily. If the serum potassium is 4.8 to 5.5 mEq/L, the current dose or initiation dose of finerenone should be maintained. If the serum potassium goes above 5.5 mEq/L, finerenone should be held and the clinician may consider restarting at 10 mg once daily when the serum potassium goes below 5 mEq/L. Finerenone should not be initiated if the serum potassium is greater than 5 mEq/L. No dose adjustment is required for patients 75 years or older or those patients with mild or moderate hepatic impairment. Finerenone may be crushed and mixed with water or soft foods such applesauce immediately prior to use and administered orally. Finerenone has not been studied in patients younger than 18 years, those who are pregnant, or those who are breastfeeding.