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In Memoriam: Michael J. Hennessy Sr

Drug Topics® mourns the passing of Michael J. Hennessy Sr, chairman and CEO of MJH Life Sciences™. Hennessy was committed to improving health care and patients’ lives, as is seen throughout his career. Following his graduation from Rider University in 1982, he started his journey in medical publishing as a sales trainee, eventually advancing to the position of chief operating officer. In 1986, Hennessy became chief operating officer of Medical World Business Press. The company prospered and was eventually sold to a Boston-based venture capital firm.

Hennessy launched MultiMedia Healthcare, LLC, in 1993 and built a portfolio of award-winning clinical journals. In 2001, Freedom Communications, Inc., acquired MultiMedia HealthCare, about the time that Hennessy was pioneering a new approach to print and digital publishing with Intellisphere®, LLC (now part of MJH Life Sciences™). Guided by the principles of innovation and entrepreneurial spirit and reflecting its founder’s dedication to improving quality of life through health care research and education, Intellisphere publishes a variety of integrated print and digital products on a range of topics in research and clinical medicine.

Hennessy added other companies and capabilities to the MJH Life Sciences™ portfolio, including health care market research leader HRA®, respected journals like The American Journal of Managed Care®, and the leading accredited continuing medical education company Physicians’ Education Resource®, LLC (PER®).

In 2019, MJH Life Sciences™ made its largest acquisition to date with the Healthcare and Industry Sciences divisions of UBM Medica, nearly doubling the size of the organization, and adding a number of legacy titles to an impressive portfolio. This acquisition made the organization the largest independently owned medical communications company in North America.

In late 2019, Hennessy elevated his role to Chairman while naming his son, Mike Hennessy Jr, to assume the leadership role of the organization and carry on the family legacy. Under Mike Jr’s leadership, the company enhanced its global potential by entering into a long-term partnership with BDT Capital Partners, LLC, in November 2021.

Hennessy’s counsel and insight had been sought out by several organizations, including his alma mater Rider University, where he served on the Board of Trustees and was elected to the executive committee. He also had a long record of service at the local level, where he was a strong advocate for veterans and environmental issues.

Hennessy’s true passion was his relationship with his wife, Patrice “Patti” Hennessy. After meeting her in college, Hennessy devoted his life to Patti and his family, raising 4 children. Hennessy was Patti’s rock as she bravely battled cancer for almost 10 years until her death in January 2020. Hennessy recently honored Patti by making a donation to Rider University to expand the Science and Technology Center at their alma mater. The Mike and Patti Hennessy Science and Technology Center is set to be completed in 2022.

Hennessy’s legacy and “family first” mantra will live on through his children, their spouses, and his 10 grandchildren. He will be greatly missed by his family, friends, and his MJH Life Sciences™ family.
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## Editorial Mission

*Drug Topics®* is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to *Drug Topics®* for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
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A s the second year of the COVID-19 pandemic draws to a close, flu season has begun to ramp up. Although the 2020-2021 season had unusually low rates of influenza—likely due to the infection control measures in place to combat the pandemic—experts are not yet sure what the 2021-2022 season might look like.

Kristen Nichols, PharmD, a board-certified pharmacotherapy, pediatric, and infectious diseases pharmacist and senior content management consultant for clinical effectiveness at Wolters Kluwer, discussed the importance of influenza vaccines in a multipart interview.

The coadministration of COVID-19 vaccines with other vaccines is acceptable in adults, Nichols explained, adding that there is no recommendation regarding the timing of vaccination. Therefore, they can be administered in patients at the same time without issue.

According to Nichols, the recommendations made for previous doses of the COVID-19 vaccine—suggesting that patients wait before receiving any other vaccines—were made from an abundance of caution because not enough data were available.

Now, however, there are data explaining any adverse effects to the COVID-19 vaccine, and there is no longer a need to space out the COVID-19 vaccine from any others. If 2 vaccines need to be administered same time, current guidance is to inject into different sites; if vaccines must be given in the same arm, they should be spaced 1 inch apart.

"Patients should be getting both, especially people who have not received any doses yet of the COVID-19 vaccine. Both viruses can certainly cause mild illness but can also cause more severe illness, resulting in hospitalization. And so, from a general pandemic management perspective, the last thing we need is many people hospitalized with the flu right in the middle of our COVID-19 problems," Nichols explained. According to CDC surveillance data, as of press time on December 20, 2021, 1057 patients had been admitted to hospitals with influenza—and both COVID-19 and influenza activity is on the rise.

Patients who are apprehensive about receiving the vaccines at the same time should still get both—even if that means waiting between them. "Even a week is [a] reasonable [time to wait]," she said. "Almost all of your adverse reactions to vaccines happen within a week...so that will give you time to tell—if you had a reaction—whether it was from the COVID-19 vaccine before getting the flu vaccine."

Coadministering vaccines can benefit pharmacists in other ways, Nichols added. For example, due to the current staffing shortage, an increase in vaccination rate can decrease the illnesses and hospitalizations and lessen the burden on the health care system overall.

"Actively listening to patients' concerns and reserving judgment can be really important for building that trust and building that relationship," she said. "There are a lot of people that will let you share information and correct some misperceptions if you take that time to listen and hear what their real concerns are."

For references, visit drugtopics.com.
As an industry, virtual reality (VR) has moved far beyond a tool for gaming and entertainment: Over the last decade, VR—a market with a global value of $17.25 billion in 2020 and an anticipated growth to $184.66 billion by 2026—has gained a foothold within the larger health care industry.

VR simulation is being used for everything from medical education to pain management to rehabilitation. Pharmacists—and the pharmaceutical industry—are also learning just how VR can make a difference, as well as the significant role it can play in patient care.

The History of VR in Health Care

Mary Youssef, PharmD, RPh, a mobile IV infusion therapist for HealthIV, noted that pharmacies and pharmacists have been exploring the possibility of better workplace accuracy and efficiency for years. This has slowly led to the study of VR in the burgeoning pharmacy field.

VR technology in health care grew from the desire to create immersive sensory experiences in virtual environments. This sensory delivery produces different stimuli in several ways to replicate the physical world. The experience is almost indistinguishable to that provided by natural stimuli and affects all 5 senses.

"With regards to pharmacy, VR can potentially be applied as follows: added to or as a replacement for some drug therapies; in patient counseling and behavior modification; in drug design and discovery; and in pharmacist education," Youssef said. "There is still ongoing research with VR systems in these fields."

In a 2019 study published in Pharmacy and Therapeutics, investigators explored many of these applications.

"The majority of studies conducted during the past decade have found VR to be safe and effective, and to promote a high degree of user satisfaction," the authors wrote, adding that "VR technology has become increasingly affordable, flexible, and portable, enabling its use for therapeutic purposes in both inpatient and outpatient environments."

Ani Rostomyan, PharmD, has been practicing as a clinical pharmacist in Los Angeles for 7 years. An avid user of and educator about VR, she recently founded SheAni, Inc, a concierge consulting company that teaches patients and health care practitioners about drug metabolism, drug mechanisms of action, and pharmacogenomics utilizing VR.

She explained how VR provides a multisensory experience, which enhances therapy and elicits true emotional and physiological responses that are nearly identical to the responses in real-life situations.

"As VR has advanced in pharmacy, I have noticed the storytelling format playing a bigger role," Rostomyan said. "By making these complex and highly intricate biochemical processes more accessible and easier to understand, it helps patients get a better grasp of the information [that is] given to them, creating a much better environment for patient medication adherence, disease state understanding, and patient outcomes."

Kimberly Garza, PharmD, PhD, MBA, an associate professor and graduate program officer at Auburn University Harrison School of Pharmacy in Alabama, has been working with VR for some time.

"I first came to VR in the context of entertainment. It’s such a powerful experience and embodies the avatar that you are taking a perspective of, and it can really change people’s perception," she said. "Once I started looking into how VR was being used in health care, I wanted to...learn how it could help with treatments."

Using Auburn University’s dedicated VR space in their Innovation & Research Commons facility, Garza discovered how she could help patients with rheumatoid arthritis, utilizing VR to show them what disease progression would look like across different treatment options.

Her pharmacy students are combining VR and haptic devices—mechanical devices that mediate communication between a user and computer—to learn about various physical limitations that patients
may experience. Garza noted that the empathy-building learning activities are critical to the successful development of professional identity among her pharmacy students.

“Virtual reality creates a feeling of actually being there, a feeling that events are actually happening and… that you are actually inhabiting the virtual body,” Garza said.

**VR and Patient Care**

The availability of VR systems in pharmacies can promote medication adherence and medication therapy management, as well as facilitate the development of a therapeutic action plan, according to Youssef.

“This can be done by providing short visual and auditory instructions regarding [the] medication and demonstrating techniques or administration practices,” she said. “Patients could then use the system to perform these behaviors virtually allowing them to practice without harming themselves or wasting medication. Most patients are too shy or too anxious in the pharmacy to ask for advice or help, therefore with the introduction of self-serve VR patients can step to the side and immerse themselves at ease.”

Study findings have also shown that a combination of VR and medical pain management can reduce severe pain experienced by people receiving wound care for burn injuries. VR helps control pain as it captures the mind’s attention and blocks pain signals from reaching the brain. It is akin to active hypnosis as it provides tactile and sensory feedback and enables the rallying of the neurotransmitter mechanisms that decrease pain. It can also be used to make injections and other painful or potentially frightening procedures less distressing to children.

VR has also proved effective for acute or chronic pain caused by injuries, and by cancer, neuropathy, migraine headaches, fibromyalgia, and pruritus, among other conditions.

“Perhaps the most highlighted implication regarding its efficacy is its potential to reduce the use of opioids, presenting a beacon of light in the current opioid crisis,” Youssef said.

VR has also been studied as a treatment for anxiety and other mental health disorders.

“The current drug remedies available for such disease states work to influence physiological systems, easing the mind,” Youssef said, “whereas VR treats cognitive systems, immersing all senses in real-time use. This may be used to target treatment options not addressed by current drug models.”

Findings from another study on VR, whose results were published in *JMIR Mental Health* in 2017, described how patients who used VR programs were able to dramatically decrease pain scores without any adverse effects or abnormal vital signs.

“VR is not meant to be a sole treatment or modality for pain management,” Rostomyan said. “However, VR amplifies the effectiveness of other traditional approaches such as medica-tions, physical therapy, and exercise.”

**Recent FDA Approvals**

In a landmark decision, the FDA recently approved the first VR system for chronic lower back pain, providing an opioid-free alternative to many current pain management regimens.

AppliedVR is behind the EaseVRx device, which utilizes cognitive behav-ioral therapy and other therapeutic techniques to guide patients through games, lessons, and exercises to reduce their chronic back pain. The immersive software experience comes about through a VR headset.

Patients are required to use the device for 2 to 16 minutes every day for 8 weeks. Through this treatment, the VR therapeutic offerings stand in for traditional treatment options.

“We worked tirelessly over the past few years to build an unmatched body of clinical evidence that demonstrates the power of VR for the treatment of pain and couldn’t be more thrilled to achieve this important milestone,” Josh Sackman, cofounder and president of AppliedVR, said in a company statement. “But our mission does not stop with this one approval. We’re committed to continuing research that validates our efficacy and cost-effectiveness for treating chronic pain and other indications.”

**The Future of VR in Pharmacy**

Most pharmacists advocating for VR believe it offers several advantages due to its creating an artificial environment so similar to the real world.

“This implementation can even [be applied in] the educational sector to better understand drug binding and efficacy in the body with future pharma-cokinetic use,” Youssef said. “The enveloping effect of the virtual world has significant potential. With further research, more data will become available regarding its efficacy, and as the technology improves, costs and other obstacles will be reduced. Having another world in the pharmacy may begin to bridge the dissonance we see with patients and medication.”

For references, visit drugtopics.com.

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Patient Education Is Key to Reducing Adverse Effects of OTC Analgesics

Acetaminophen and ibuprofen are accessible over the counter, but do patients know all the risks associated with these medications? By Aine Cryts

OTC medications are more accessible than ever before: according to the Consumer Healthcare Products Association, OTC analgesic products accounted for $4.5 million worth of retail health care product sales in 2020.¹

But these easily accessible remedies come with their own set of potential problems. OTC pain relievers such as aspirin and ibuprofen can lead to gastrointestinal issues including nausea, diarrhea, and flatulence. Additionally, adverse effects of naproxen, for example, can include upset stomach, nausea, heartburn, headache, or drowsiness.

Pharmacists and pharmacy technicians have a role to play in educating and supporting patients seeking out OTC pain relief products, said Erin Pauling, PharmD, assistant dean for academic affairs at New York’s Binghamton University School of Pharmacy and Pharmaceutical Sciences. Her advice: “Come out from behind the counter,” and approach patients who are lingering in the pain relief aisles at retail pharmacies. A good warm-up question, Pauling noted, is “Have you talked to your doctor about [the pain you’re experiencing]?”

The most important thing, Pauling said, is to get as much information as you can about the patient’s pain symptoms, current medications, and allergies. But the bigger picture is this: “You have to follow where the patient is.”

Jenna Mills, PharmD, an assistant professor of pharmacy practice at the University of Findlay College of Pharmacy in Ohio, said it’s also important to ask about the other medications a patient is taking; these products may also include acetaminophen, and adding an additional acetaminophen product could put the patient over the maximum daily dose. Exceeding the maximum daily dose can result in liver toxicity, she added.

Acetaminophen can also be found in cough, cold, and allergy products, in addition to medications that address difficulty in falling asleep, said Mills. “If the patient doesn’t realize that acetaminophen is in a pain reliever and their cough medicine and the medication they take to sleep at night, there’s a real risk for overdose.”

Equally important is reading the back of the medication box, Mills added. Pharmacists should pay attention to the amount of acetaminophen in the specific product. For example, she said, the regular dose could be 350 mg, whereas the extra strength and extended-release versions could be 500-mg or 650-mg doses, respectively.

Although the generally recommended maximum daily dose is 4000 mg of acetaminophen, even doses close to that daily limit can be toxic to the liver, according to a 2020 article posted by Harvard Health Publishing.²

Pauling further recommended asking patients who are interested in acetaminophen products about their alcohol intake, the combination of which can also result in liver damage. According to Cleveland Clinic,³ consistent, heavy alcohol use—more than 1 drink each day for women and more than 2 drinks each day for men—combined with ongoing daily acetaminophen dosing can predispose the liver to acetaminophen-associated toxicity.

Three good follow-up questions to ask patients in the pharmacy:

1. Did your doctor direct you to take this medication?
2. Have you taken this medication before?
3. How long has this pain been going on?

Because OTC pain relievers are intended for short-term pain relief, it’s important to ask patients about their follow-up plan and to ensure they receive routine monitoring by their physician, said Mills. Pharmacists and pharmacy technicians can tell patients to take these medications along with food or milk to avoid an upset stomach. Pauling, who is also a clinical assistant professor of pharmacy practice at Binghamton University, added that patients shouldn’t fall asleep right after taking the pain relievers. “Staying upright—not supine—allows the body to digest the medication, which can prevent gastrointestinal issues.”

For references, visit drugtopics.com.
Parents around the country breathed a sigh of relief late last October when the FDA issued an emergency use authorization for the Pfizer-BioNTech mRNA vaccine for children aged 5 to 11 years. 

Pharmacies, along with pediatricians’ offices and schools, have been identified as a major distribution point to administer the vaccines in children. A Plan for Widespread Distribution

Prior to the FDA ruling, the White House announced that “tens of thousands of pharmacies across the country will offer the vaccine to their local communities.”

“Pharmacists are a trusted source of information for parents, and local pharmacies will be a convenient, accessible option for many families. Pharmacies will offer family-friendly in-store clinics to best meet the needs of local communities,” according to a statement from the White House.

“Pharmacy partners will launch comprehensive campaigns to reach parents and families, including texts, calls, and outreach to meet local communities where they are.”

The US government has purchased 50 million more doses of the Pfizer-BioNTech COVID-19 vaccine to prepare for the pediatric vaccine rollout, the companies said in a news release.

“These important planning actions by the federal government will help ensure that pharmacies—the most accessible health care destinations in the country—are ready to continue to meet the needs of the American public when the time comes and when the science confirms that COVID vaccines for that age group are safe and effective,” said National Association of Chain Drug Stores (NACDS) President and CEO Steven C. Anderson in a statement.

“Pharmacies remain critical access points in the ongoing vaccination effort and, as the 2021-2022 flu season persists, pharmacies continue to meet the nation’s preventive care vaccination needs, all in one visit,” he added.

The Pharmacist’s Role

“The expectation is that pharmacists will play a major role in the administration of [children’s COVID-19] vaccines,” said Mitchel C. Rothholz, RPh, chief of governance and state affiliates at the American Pharmacists Association (APhA). Both chain and independent pharmacies are vital players within the national plan, he noted.

“Pharmacies within the federal COVID vaccination network (about 40,000 sites), as well as pharmacies that are part of their state/local jurisdiction plan, will have access to the Pfizer-BioNTech pediatric vaccine,” Rothholz said. “Many of these pharmacies have been reviewing their operations and preparing for receipt and administration of the pediatric vaccines.”

Pharmacists are also collaborating with their local school districts, Rothholz added.

The vaccine is a 2-dose primary series, administered 3 weeks apart, at one-third of the dose—10 mcg—compared with the dose of 30 mcg for individuals 12 years and older.

How to Handle Children’s COVID-19 Vaccinations

“There is a lot being asked of vaccine providers across the health care system,” Rothholz said. Pharmacies are managing COVID-19 vaccines—including booster shots—along with seasonal influenza vaccines and numerous other immunizations.

Some organizations are also providing staff to volunteer at COVID-19 vaccination clinics. As a result, Rothholz noted, it is “critical that both the
As of December 13, more than 239 million Americans have received at least 1 dose of the COVID-19 vaccine, representing 72.6% of the population. More than 200 million Americans are fully vaccinated (60.9%), and just over 54 million have received a booster (16.5%). Globally, more than 8.51 billion COVID-19 vaccine doses have been administered—but there's still more work to be done. 

There are 112 vaccines currently being tested in clinical trials around the globe, with more than 75 vaccines still in the preclinical stage. 

Below, find some of the latest approval data from the United States and around the world.

### Global approvals

- **Ocugen**
  - This vaccine is not yet available in the United States, but has been authorized in 17 countries and has been given emergency use status by the World Health Organization (WHO).
  - The Ocugen vaccine, known as Covaxin, is administered as 2 shots 28 days apart.

- **Oxford/AstraZeneca**
  - The Oxford/AstraZeneca vaccine (Vaxzevria) has an efficacy of 76% and has been widely distributed around the world thanks to its low-cost production.
  - Although the US financially supported the initial development of this vaccine, challenges with clinical trial execution and the data that came out of these trials—as well as safety concerns—the vaccine has only been approved via EUA in the United Kingdom and Argentina.
  - India approved a version of this vaccine (Covishield) in January 2021.
  - Brazil was the first country to give full approval to this vaccine, in March 2021.
  - The WHO recommended the Oxford/AstraZeneca vaccine for emergency use in adults 18 or older on February 16, 2021.

- **Bharat Biotech**
  - The vaccine developed by Bharat Biotech (COVAXIN) was added to the WHO emergency use listing in November 2021.
  - This was the first COVID-19 vaccine developed in India that was granted this authorization.
  - Countries across Asia, Africa, and South America have also authorized this vaccine, although recent corruption-related controversies led to a suspension of this authorization in Brazil over the summer.
  - Bharat Biotech created a partnership with Ocugen in order to develop their vaccine for the US market. By October, a request to the FDA to run a phase 3 trial of the vaccine had been submitted.
  - After expanding manufacturing capacity, Bharat Biotech anticipates producing up to 1 billion vaccine doses per year.

- **Sinovac**
  - This vaccine (CoronaVac) is one of the leading vaccines in China.
  - More than 1 billion doses of the Sinovac vaccine have been distributed globally.
  - Despite this widespread reach, there are now concerns about how long the protection from this vaccine lasts.
  - Clinical Trial results out of Turkey and Brazil drew wildly different conclusions: the Brazilian trial found 100% efficacy against severe disease, while the Turkish trial found an efficacy of 83.5% against COVID-19 infection with at least 1 symptom.
  - The Sinovac Vaccine has received conditional approval in China and emergency authorization by the WHO. The European Medicines Agency launched a rolling review of the vaccine in May 2021.

### US approvals

- **Pfizer-BioNTech**
  - The Pfizer-BioNTech COVID-19 vaccine was fully approved by the FDA on August 23, 2021, under the name Comirnaty.
  - The emergency use authorization (EUA) is still in effect for vaccination of certain populations, including as a 2-dose series for children aged 5 and older, and a third primary series dose for immunocompromised individuals aged 12 and older.
  - The EUA also authorizes the vaccine as a single booster dose for individuals aged 16 and older.
  - The Pfizer-BioNTech vaccine is authorized for use as a heterologous single booster dose for adults aged 18 and older who have completed an initial vaccination series.

- **Moderna**
  - The Moderna mRNA COVID-19 vaccine is available under an EUA as a 2-dose primary series for adults aged 18 or older and as a third primary series dose for adults who are immunocompromised.
  - The vaccine is also approved for use as a heterologous single booster dose for adults aged 18 and older who have completed an initial vaccination series.

- **Janssen**
  - The Johnson & Johnson COVID-19 vaccine is available under an EUA as a single-dose primary vaccine for adults aged 18 and older.
  - It is also available as a heterologous single booster dose for adults aged 18 and older at least 2 months after completing their primary vaccine series.

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public and private sectors devote the resources necessary to adequately and safely staff this enhanced campaign. The health of America depends on it.”

In addition, those who manage the pharmacy enterprise need to talk with their staff about how best to manage the workflow. “We are really encouraging that dialogue to happen so that workload can be talked through and supported where needed,” Rothholz pointed out.

Managing the workflow will also help prevent pharmacist and pharmacy technician errors and reduce workplace stress. It will also reduce the likelihood of pharmacists and pharmacy technicians leaving the job or profession, Rothholz noted.

“Across the whole system—medicine, nursing, nursing assistants, [and] pharmacy team members—people are moving out of their professions and jobs. That is putting a strain on the system,” Rothholz said. “We are really trying to encourage discussions between management and their teams to talk through solutions.”

Many pharmacies are also utilizing appointment-based software systems to help manage the COVID-19 vaccine workload, according to Rothholz.

The administration of the COVID-19 vaccine to children ages 5 through 11 is a collaborative effort between the pharmacist and the parent or caregiver, who must work together to make the vaccine experience as non-traumatic as possible, Rothholz said. Engaging the support of parents and caregivers in the process can help with managing the child’s concerns, Rothholz added. When possible, pharmacists should avoid showing the needle on iPads or other electronic devices to help with distraction. As always, pharmacists should confirm the vaccine the child is receiving with the parent or caregiver, Rothholz advised.

For references, visit drugtopics.com.
An emerging body of evidence is changing perceptions and approaches to rheumatic diseases in children. Pharmacists can expect more demand for biologic agents for children with lupus, polyarticular juvenile idiopathic arthritis (pJIA), and other pediatric autoimmune conditions and less reliance on conventional disease-modifying antirheumatic drugs (DMARDs).

Early Biologics, Better Outcomes
Growing recognition that similar exposure to biologics in children and adults produces similar results could bolster the use of pharmacokinetic matching to extrapolate efficacy from adult to pediatric populations. Pharmacokinetic-based approvals could ease the path to more pediatric approvals and broader off-label pediatric use of agents approved for adults.

“Pediatric rheumatologists are well aware that children with JIA do respond well to biologics and that biologics have dramatically changed outcomes for children with JIA,” said Yukiko Kimura, MD, professor of pediatrics at Hackensack Meridian School of Medicine and chief of the Division of Pediatric Rheumatology at Hackensack Meridian Health in New Jersey.

But, Kimura said, “clinical inertia and insurers requiring step therapy—failing DMARDs before you can use biologics—are common barriers to starting biologics early in children.” For these, patients, the question becomes, “How can we personalize treatments to get the best outcomes?”

Kimura was the principal investigator for the STOP-JIA trial (NCT02593006), an observational cohort study comparing 3 initial therapeutic approaches to pJIA: DMARDs only, biologics only, and a combination of DMARDs plus biologics. Data came from the Childhood Arthritis and Rheumatology Research Alliance (CARRA), a nationwide registry of more than 12,000 children with lupus, JIA, and other rheumatic diseases.

Although all 3 patient groups showed improvement, 59.4% of the combination therapy group had clinically inactive disease after 24 months compared with 48% of the biologics-only group and 40.1% of the DMARDs-only group.

When the investigators observed disease activity over time, patients in the trial fell into 1 of 3 groups: slow, moderate, or rapid improvers. The trajectory analysis of treatment response showed that the 3 groups began to diverge within 3 months, Kimura noted. The single most important predictor of rapid improvement was early initiation of biologic therapy after pJIA symptoms appeared.

“Regardless of which treatment plan a child was started on, if they started a biologic within 3 months of symptoms appearing, their chances of being in the best response group increased by 3.5 times, supporting the idea that starting biologics is superior,” she said.

However, she added, there were a few children in the rapid improver group who received only conventional, nonbiologic DMARDs. For this small group of children, early initiation of DMARDs was the significant predictor of rapid improvement.

“Understanding how to distinguish patients who aren’t going to respond to methotrexate versus the patients who will do very well on methotrexate is critical,” Kimura said. “We need to be able to tell which patients need to start biologics early and which patients may not need to be exposed to biologics at all.”

Pharmacokinetic Approvals
One of the enduring barriers to treating children is the paucity of pediatric clinical trials compared with adult trials. Adjusting adult dosing to child-sized bodies doesn’t always work.

“Children aren’t just little adults,” said Aimee O. Hersh, MD, an associate professor and chief of the Division of Pediatric Rheumatology at the University of Utah in Salt Lake City.

Kimura

Update on Childhood Rheumatic Disorders
Emerging evidence is changing health care providers’ approach to treating pediatric rheumatic diseases. By Fred Gebhart
“Children aren’t just little adults. Pediatric patients are still growing and developing their bodies and their immune systems, so their reactions to treatment aren’t always the same as adults. And their disease isn’t the same.”

AIMEE O. HERSH, MD, ASSOCIATE PROFESSOR AND CHIEF, DIVISION OF PEDIATRIC RHEUMATOLOGY, UNIVERSITY OF UTAH

Pediatric patients are still growing and developing their bodies and their immune systems, so their reactions to treatment aren’t always the same as adults. And their disease isn’t the same.”

Up to 20% of all patients with lupus have childhood onset, Hersh said. This is a total of approximately 10,000 children and adolescents in North America alone. Children with lupus have higher rates of organ disease, including lupus nephritis; premature atherosclerosis with increased risk of myocardial infarction; multiple skeletal deficits; and multiple psychosocial impairments that extend into adulthood.

“Most of the treatment approvals in childhood lupus have been extrapolated from adult studies,” she continued. “Patient-reported outcomes could be very different for pediatric patients versus adult patients, as well as medication, disease, and (adverse) effects. Seeing more trials and outcomes through the lens of the child, and the adult managing their long-term development, is crucial.”

One way to learn more is to follow children over time. Hersh is the current chair of CARRA, which follows children for at least 10 years to glean longer-term data on the natural history and treatment outcomes of pediatric rheumatic diseases. CARRA and other pediatric rheumatology groups are also pushing the FDA to require pediatric arms of adult studies for new and extended approvals.

An FDA comparison of treatment response between those with pJIA and adults with rheumatoid arthritis (RA) suggests another approach to pediatric approvals.

Pharmacy investigator and study author Renu Singh, PhD, reported on a response-and-exposure comparison of registration trial data for infliximab, tocilizumab, golimumab, and adalimumab in pJIA and adult RA. Results of the exposure comparison showed that exposure in pJIA trials was similar to or higher than exposure in adult RA trials across all 4 biologics. The sole exception was lower pediatric exposures to infliximab in patients weighing 70 kg or less.

The pJIA response was similar to or higher than responses in adult RA trials, suggesting that children may be more like little adults than we currently believe—at least when assessed by exposure to different biologics.

“These analyses provide support for the use of pharmacokinetic exposure matching for extrapolation of efficacy from adults with RA to children with JIA for products with an established mechanism of action,” said Mara L. Becker, MD, MSCE, a professor of pediatrics at Duke University School of Medicine in Durham, North Carolina. “This bridges a huge gap in clinical pharmacology and may allow for therapeutic approvals with an adequate pharmacokinetic study that matches a pediatric dose with an exposure associated with efficacy in adults. This is a big step forward in therapeutic approvals.”

Improving Adherence

Treatment adherence is a problem in most diseases and most patient populations—pediatric, adolescent, or adult. Community pharmacists have long shown that refill reminders can boost adherence for a variety of medications and on the hardware side, multiple companies have developed pill vials and other devices to remind patients when a dose is due. The iPersonal trial (NCT04358302) is bringing automated reminders to a home-based adherence and exposure response trial of hydroxychloroquine in children and teenagers with lupus.

The trial uses an automated pill vial cap, Pillby, that provides audio, visual, and electronic medication reminders. If the vial is not opened within 10 minutes of a scheduled dose, it flashes visual and audible signals. The patient or caregiver can also opt in to receive additional text and telephone reminders. The vials record all openings, including scheduled pill counts, erroneous openings, or refills, which allows the study team to reconcile pill counts and doses dispensed as reported by the electronic pill vial. Patients were recruited from the CARRA registry.

“If you have any doubts about the design of this trial, they met their enrollment goal within 10 days, during COVID-19,” Becker said. “And they have a waiting list of people who are interested in participating.”

The trial was completed in mid-2021 and final results are pending.

For references, visit drugtopics.com.
Managing T1D in Adults: How Can Pharmacists Help?

Type 1 diabetes requires patients to have knowledge and skill to manage medication and potential complications. By Karen Berger, PharmD

Type 1 diabetes (T1D) is caused when the immune system destroys the insulin-producing β cells of the pancreas. T1D accounts for up to 10% of all cases of diabetes. Because new-onset T1D can occur in any age group and people with the disease live for decades after diagnosis, the overall prevalence of T1D is higher in adults than children.

In November 2021, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) published a joint consensus report in the journal Diabetes Care. The report authors addressed a wide range of topics, from initial diagnosis and management goals to psychosocial care, adjunctive therapies, and future perspectives.

According to Stephanie Ostling Mason, PharmD, CDCES, a diabetes clinical pharmacist at Glytec, continued medical, educational, and psychosocial support is key for patients with T1D. “The management of T1D requires the individual to have a significant level of knowledge and skill to manage complex medication regimens, adopt behavioral changes, and navigate hypoglycemia and hyperglycemia,” she said.

Diagnosis

According to the consensus report, “the clinical presentation may differ, but the classical triad of thirst and polydipsia, polyuria, and weight loss are common symptoms of T1D.” However, Mason noted that the clinical onset and presentation of T1D can vary widely, and a thorough assessment and workup of the patient are needed to make an accurate diagnosis. “Accurate (and timely) diagnosis of T1D is critical and informs decisions regarding insulin therapy, adjunctive therapies, technology, education, and other disease screenings,” she said.

Goals of therapy

In all patients, the goals of T1D management include:

1. Effectively using exogenous insulin to maintain blood glucose (BG) levels as close to the patient’s target range as safely possible, while minimizing episodes of hypoglycemia

2. Managing cardiovascular risk factors

3. Minimizing the psychosocial burden of the disease on the patient

“The key elements of an effective management approach include Diabetes Self-Management Education and Support, BG monitoring, insulin therapy, and the management of potential complications.”

Counseling Tips for Pharmacists

- Ask open-ended questions to start a discussion. Ask how the patient uses their insulin and how they handle hyperglycemia and hypoglycemia and any barriers they encounter.
- Use language that empowers and encourages patients with T1D.
- Use the teach-back method to ensure the patient understands key topics such as injection technique and hypoglycemia treatment.
- Review when and how to use glucagon. Tailor the discussion to the patient’s specific prescription (ie, injection or nasal spray). Make sure the patient can teach their family and friends how to administer glucagon in an emergency.
- Remind patients about the importance of rotating injection sites. Ensure patients know how to store opened or unopened pens or vials of insulin.
and prevention of hyperglycemia and hypoglycemia,” Mason added.

**Monitoring**

For most adults with T1D, the preprandial BG target is 80 to 130 mg/dL whereas the postprandial target is less than 180 mg/dL (or < 140 mg/dL in some patients). The hemoglobin A1c target for most adults is less than 7%.

Hemoglobin A1c, it does not take into account variability in levels and hypoglycemic episodes.

“Continuous glucose monitoring, or CGM, is the standard for glucose monitoring for most adults with T1D,” Mason explained. The monitors measure interstitial glucose or BG levels. Monitors such as the Dexcom G6 display BG levels every 5 minutes and can alert the patient to high or low levels. Other monitors, like the FreeStyle Libre, require the patient to scan the device for a reading.

However, “blood capillary testing is still recommended with CGM use” in certain situations such as during a hypoglycemic episode, as there may be a lag of 5 to 15 minutes in interstitial glucose readings,” Mason said.

**Insulin**

Patients with T1D require basal insulin to maintain steady BG levels while fasting or sleeping. At mealtimes, insulin is required for intake of carbohydrates and other macronutrients like fat and protein. At other times, correction insulin can be administered to treat hyperglycemia.

“The treatment approach should be individualized to the patient based on patient preferences, cost, psychosocial support, and the risk of hypoglycemia and weight gain,” Mason said.

Insulin can be delivered by multiple daily injections—when the patient injects a basal insulin analog as well as a rapid-acting or ultra-rapid-acting insulin analog for mealtime or correction doses—or through pumps. Pumps use a continuous insulin infusion of a rapid-acting insulin analog, which serves as the basal insulin, combined with mealtime and correction doses.

**Hypoglycemia**

“Hypoglycemia continues to be the limiting factor in the management of T1D,” Mason noted. Hypoglycemia levels are as follows:

- **Level 1:** BG between 54 and 69 mg/dL
- **Level 2:** BG lower than 54 mg/dL
- **Level 3:** any hypoglycemia level at which the patient has an altered mental or physical state and needs the help of a third party for recovery

The patient’s endocrinologist should provide a treatment plan for hypoglycemia which generally consists of up to 15 grams of fast-acting carbohydrates (such as glucose tablets) or more if required. Capillary measurement with a BG meter is recommended during hypoglycemic episodes in order to prevent overtreatment of hypoglycemia.

**Helping Patients With T1D**

Mason cautioned pharmacists that there are many challenges unique to each person with T1D and in daily management. “Use best practices as a framework, keeping in mind the patient’s needs and abilities,” she said.

Mason also suggested that providers assess patient’s barriers to treatment, including financial, psychosocial, and literacy barriers, in addition to regimen complexity. Pharmacists can help patients by reinforcing treatment goals, including target A1c, preprandial and postprandial BG targets, and time in range. Pharmacists can also ensure every patient with T1D has a prescription for glucagon and understands how to use it—and can train their friends and family in how to use it in case of emergency.

Pharmacists can also offer additional resources to patients with T1D, Mason said. These resources include “recommending a diabetes education class, referral to a registered dietitian, information on an exercise program, and smartphone applications to assist with carbohydrate counting or help with stress reduction (e.g., meditation applications).”

Patients with T1D are not homogeneous, and by working to understand the unique needs of each patient, pharmacists can emerge as important members of the health care team for patients with T1D.

For references, visit drugtopics.com.

Karen Berger, PharmD, is a graduate of the University of Pittsburgh School of Pharmacy. Her experience includes chain and independent pharmacy, as well as medical writing and reviewing.
Five New Year’s Resolutions for Independent Pharmacy Owners

Let’s raise a glass to all the pharmacy owners who are improving patient health outcomes by providing innovative services. **By Jennifer Gershman, PharmD, CPh**

Cheers to 2022. There’s no doubt that the upcoming year will be filled with many exciting opportunities for pharmacy owners. Independent pharmacies have played an important role during the COVID-19 pandemic, especially as community advocates for vaccine education and administration. In the National Community Pharmacy Association’s 2021 NCPA Digest, the organization highlighted a variety of services offered by independent community pharmacies, ranging from medication therapy management and medication synchronization services to vaccines and blood pressure monitoring.† Drug Topics® interviewed 3 pharmacy owners who are making a difference in their communities by going above and beyond for their patients to find out what their New Year’s resolutions are for 2022.

Mayank Amin, PharmD, MBA, owner of Skippack Pharmacy in Schwenksville, Pennsylvania, can often be seen dressed as Superman as he administers vaccines in his community, where he is considered a true hero. Skippack Pharmacy offers a variety of services, such as medication therapy management, free prescription delivery, drug disposal, and medication synchronization. “COVID-19 has brought a variety of challenges to many different professions, especially health care,” Amin said. “These challenges have led to opportunities for pharmacists and pharmacy personnel as we have been given our biggest task of providing direct patient care to millions in our country.” Amin’s New Year’s resolution is to be a trusted and accessible health care provider in his community through providing immunizations and preventive-health programs.

Damien Simmons, PharmD, is the owner of Atlantis Pharmacy in Atlantis, Florida, where Amanda Bensin, PharmD, is a star pharmacist who has played an active role in educating patients about and administering COVID-19 vaccines across south Florida. In 2022, Simmons and Bensin are hoping to bridge the gap between the medical community and the patients they serve, so that they can be the pharmacy that meets patient needs. Simmons and Benson’s New Year’s resolution is to provide even more point-of-care services now that they have increased pharmacy staff.

Beverly Schaefer, RPh, is the co-owner of Katterman’s Sand Point Pharmacy in Seattle, Washington, a community pharmacy that offers a variety of unique services including travel immunizations, travel health consults, and compounded pet prescriptions. “COVID-19 has taught people that pharmacies are accessible in every community and have the ability to provide high-demand services in a timely and easily accessible manner. My goal for 2022 is to move my pharmacy business to a more health-oriented focus, staying healthy at every stage and age of life,” Schaefer said. This health-focused resolution would include a new patient consultation service focused on health for the first half of 2022 and would assist individuals in changing or improving their diet and nutrient intake, as well as their use of supplements and prescription drugs.

“No other health professional is doing what pharmacists [are] doing to improve patient health,” Schaefer added. Schaefer’s other New Year’s resolution is to return to traveling, one of her passions that also helps to bring new insights to her travel immunization and travel consult programs. “For references, visit drugtopics.com.”

Jennifer Gershman, PharmD, CPh is a drug information pharmacist and medical writer residing in South Florida.
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In partnership with: Drug Topics®
As change continues to sweep the industry, we take a closer look at the trends that may be coming to a pharmacy near you.

By Frieda Wiley, PharmD
The long reach of the COVID-19 pandemic has engulfed every industry, including pharmacy. Although many industries have worked to adapt or survive, the variety of issues affected by the pandemic has triggered positive shifts in community pharmacy practice overall, according to Bri Morris, PharmD, senior director of program development at the National Community Pharmacists Association (NCPA) in Alexandria, Virginia.

Across the country, many pharmacists have long been waiting to practice closer to the top of their licenses. These emerging trends offer community pharmacists unprecedented opportunities to do exactly that. Here are some potential pharmacy trends to watch in 2022.

**Expect to See an Uptick in Point-of-Care Services**

Community pharmacies increased their point-of-care testing services during the pandemic—a feat that Morris says many pharmacists have “embraced...to meet their patients’ immediate needs.”

“Now that so many pharmacists have [obtained] their CLIA (Clinical Laboratory Improvement Amendments) certificates of waiver and introduced COVID-19 testing into their regular practice, there is an opportunity to branch into other acute infectious disease and chronic disease management,” Morris told *Drug Topics*. “In many states, pharmacists are able to test and treat these patients for minor ailments as well.”

**Immunization Services Are Here to Stay**

Immunization services have been trending in pharmacy for years, and the surge in recommended infectious diseases immunizations has only increased patient demand. Yet despite the apparent opportunity, providing these services remains a significant pain point for pharmacists on the front line, who often operate under the mounting pressure of meeting high prescription volumes with minimal staff support. Morris, though, is optimistic that recent technological interventions and logistic strategies have helped alleviate some of the pressure.

“Now community pharmacies have adopted scheduling platforms and designed a staffing workflow to integrate immunizations into pharmacy workflow,” she said. “Gaps still exist in routine immunizations for both adults and children, and community pharmacies can meet those gaps.”

The numbers speak for themselves: As of November 9, 2021, community pharmacies and federal programs had administered and reported nearly 163 million doses of COVID-19 vaccines, according to data collected by the NCPA. This number does not include the data for vaccine doses administered and reported by state-administered programs.

**Expanding Roles for Pharmacy Technicians**

The soaring demand for immunizations has expanded roles for pharmacy technicians. Much like the pharmacist’s role, that of pharmacy technicians’ has evolved over the years, and the concept of expanding the services that technicians provide is not new either.¹

The COVID-19 pandemic led to the declaration of the Public Readiness and Preparedness (PREP) Act. Initially enacted by Congress on December
In the pharmacy world, the PREP Act allows medical professionals to engage in the provision of services that may exceed their ordinary scope of services under usual circumstances, in an effort to address the shortage of responders and improve the availability of services and resources.

On February 2, 2021, Acting Secretary of the Department of Health and Human Services Norris Cochran moved to amend the PREP Act declaration for the COVID-19 pandemic to define the list of individuals able to prescribe, dispense, and administer vaccines. The amendments culminated with one defining pharmacy technicians as “qualified persons” able to administer the seasonal influenza vaccine to adults in the state in which they are legally allowed to practice.

Secretary Xavier Becerra was responsible for the final amendment, which also grants pharmacist interns similar authority to administer seasonal influenza vaccines to adults in the state in which they are legally allowed to practice.

The act also allows pharmacy technicians to facilitate point-of-care testing during the pandemic. Both pharmacy technician–provided immunizations and point-of-care services require pharmacist supervision.

Morris anticipates that these services temporarily allowed by the PREP Act are the gateway for an entire suite of services that pharmacy can expect to fall under technician ownership.

“This expansion of scope combined with increased workforce demands brings about new roles for pharmacy technicians,” Morris said. “Medical billing specialist, immunization administrator, med sync (medication synchronization) lead, and community health worker are just a few of the titles we can expect technicians will have in the coming years.”

At Home Services Will Expand

“With more than 10,000 Americans aging into Medicare daily, providing medical-at-home services to keep patients who might otherwise be in a nursing home in the familiarity of their homes is a patient care no-brainer, and many pharmacies are currently caring for these patients,” Morris explained. “Currently, the incentives and payment don’t match the effort.”

However, Morris anticipates that the historically poor reimbursement for the services that pharmacies provide will change with services that allow patients to age in place.

For example, a new clinically integrated network focused on helping patients age in place, combined with advocacy efforts led by NCPA’s long-term care division, helps pharmacies capitalize on potential business opportunities. According to its website, NCPA has asked the Centers for Medicare & Medicaid Services (CMS) to formally “recognize medical at-home pharmacy services regardless of where the patient resides.”

The Community Pharmacy Enhanced Services Network (CPESN) USA started CPESN At-Home, a new network that contracts for enhanced services designed to address the needs of patients. Such patients would otherwise be candidates for a nursing facility, including those who are homebound, have trouble accessing a pharmacy, or require some level of caregiving assistance.

“You, as the pharmacist, are able to provide the same level of care that that same patient would receive in the nursing home, but you’d provide it at their home,” Morris said.

Improvements in Access to Equitable Health

Pharmacists’ longstanding battle for formal recognition by the US government and payors as health care providers continues, and with that comes the challenge not only of seeking compensation but also of gaining respect. However, a 2021 article by Deloitte, The Pharmacist of the Future, suggests that a lack of the latter may prove advantageous from an accessibility standpoint.

“Pharmacists are not seen as authority figures the way that doctors are seen,” said an anonymous educator and research scientist who was quoted in the article. “If in a way, that’s probably sad, but what it means is that the pharmacist is more approachable than the doctor, and that can be really useful.”

The article’s authors also highlighted how pharmacists’ approachability, coupled with frequent patient contact, automatically enhances the opportunity to build trust. The patient-pharmacist rapport establishes a gateway into the patients’ worlds, with pharmacists able to form a bond that allows them to take a deep dive into their patients’ experiences and collect vital problem-solving information. Being central figures in the health care equation uniquely allows pharmacists to identify additional resources for their patients and help them navigate the health care system.

Watching these and other trends unfold over the past year suggests the consulting firm’s crystal ball is quite clear. Only time can tell how the industry will truly take shape.

For references, visit drugtopics.com.

Frieda Wiley, PharmD, is a medical writer and independent journalist. She has written for numerous organizations such as the National Institutes of Health, and more. She began her pharmacy career as a community pharmacist.

Did we miss any upcoming pharmacy trends for 2022? Email your comments to lbiscaldi@mjhlifesciences.com.
# Year in Review: 2021 Top News from Drug Topics

This year, our Drug Topics audience read more of our news than ever before. As we kick off the New Year, take a look back at the top 15 articles published on Drug Topics last year.

## 1. The #PizzasNotWorking: 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.

## 2. Finerenone for Heart Failure and Kidney Disease Associated With Type 2 Diabetes
The FDA has approved finerenone (Kerendia) for the treatment of adults with CKD associated with type 2 diabetes.

## 3. Evidence-Based Solutions for Stopping the Opioid Crisis
A coalition of 240 organizations came together to urge Congress to pass legislation to fight the opioid crisis.

## 4. COVID-19 Vaccines Change the Role of Community Pharmacy
At some independent pharmacies, pharmacists are voluntarily working longer, unrecorded hours to provide patient care.

## 5. Pharmacists’ Public Health Role Grows as Birth Control Prescribing Authority
An increasing number of pharmacists are now prescribing birth control, further expanding their role as public health service providers.

## 6. First Interchangeable Biosimilar Insulin Approved by FDA for Diabetes
The FDA has granted approval of the first interchangeable biosimilar insulin product, insulin glargine-yfgn (Semglee), for diabetes.

## 7. How Social Distancing Amid COVID-19 Pandemic Affected Migraine Patients
Migraineurs reported worsened symptoms during social distancing, which may be attributed to reduced sleep quality and physical activity.

## 8. Video: Biosimilars and Women’s Health, Part 1: Expert Interview with Monica Mallampalli, MSc, PhD
Drug Topics sat down with Mallampalli to discuss the importance of biosimilar education for women, empowering them to make better health care choices.

## 9. Boost Revenue and Patient Satisfaction With Point-of-Care Testing
In a session from the PDS 2021 Virtual Super-Conference, experts discussed how POC testing capabilities enhance patient services and address antimicrobial resistance.

## 10. CMS Issues COVID-19 Vaccine Mandate for Staff Across Health Care Facilities
The vaccine mandate applies to employees at facilities that participate in the Medicare and Medicaid insurance programs.

## 11. New Advances in Breast Cancer Therapy
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.

## 12. NCPA Encourages DOJ and HHS to Defend Price Transparency Rule
PBMs are fighting to keep patients and consumers in the dark on prescription drug costs and attempting to reverse a rule created to promote drug price transparency.

## 13. Survey: Rise in Retail Health Services, Retail Pharmacy Customer Satisfaction
Retail pharmacies have proved successful in expanding their role in primary care services and patients are responding positively.

## 14. FDA OKs Shingrix for Immunocompromised Adults 18 Years and Older
The agency expanded the indication for the recombinant zoster vaccine, adjuvanted (Shingrix) to include the prevention of shingles in immunocompromised adults aged 18 and older.

## 15. American Pharmacists Month: 4 Pharmacists Helping Their Communities
In honor of American Pharmacists Month, here are 4 pharmacists making a significant difference in the communities they serve.
Despite Aggressive Recruiting, a Surplus of Pharmacy Jobs Remain Unfilled

Burnout, COVID-19 vaccines, and increased demands have created the perfect storm of labor shortages within the industry. By Christine Blank

During the last year, pharmacists and pharmacy technicians have been leaving the profession in droves. Driven in part by high rates of burnout, that—coupled with the increased demand for COVID-19 vaccinations and an increase in other point-of-care services—has led to a massive labor shortfall within the profession. As a result, some pharmacies began closing locations for several hours a day due to a lack of staffing and a labor force that was already stretched thin.

“We are seeing a fallout from folks [who] were working in some of these large retail chains that were pressured as far as staffing. Now they are trying to hire new folks and are backfilling folks who...decided to leave [once] the pandemic began,” said Aaron Dunkel, executive director of the Kansas Pharmacists Association.

To meet the demand, pharmacists and pharmacy technicians have reported aggressive recruiting practices by CVS, Walgreens, and other large pharmacy chains. One managed care pharmacist in Ohio told Drug Topics® that a Walgreens representative emailed her in November, offering a $50,000 sign-on bonus if she agreed to work at the company for at least 2 years. And even though CVS is closing 900 stores over 3 years, the chain still has a significant need for pharmacy positions.

“Through our recent nationwide hiring effort,” Matt Blanchette, manager of retail communications at CVS Health, told Drug Topics®.

The company is also offering affected employees roles at other locations or different opportunities within the company, Blanchette added.

Even with these aggressive recruiting practices, many pharmacy jobs remain unfilled. There were 11,356 pharmacy job postings through the third quarter of 2021, compared with 9901 postings through the third quarter of 2020, according to the American Association of Colleges of Pharmacy’s Pharmacy Workforce Center (PWC).³

“The incentives [that retail pharmacy chains are offering] are great, but do we have the bodies to fill those? That’s one of the challenges,” said Mitchel C. Rothholz, RPh, MBA, chief of Governance & State Affiliates at the American Pharmacists Association (APhA) and executive director of the APhA Foundation.

Although some Walgreens and CVS stores are reducing hours or closing their pharmacies for certain periods of time, independent community pharmacies are not doing that, according to Dunkel. “They are not going to close the store. They have enough staff and they try to workflow it appropriately.”

It’s not only retailers seeking additional pharmacy staff: clinical pharmacists were most in demand during the third quarter of 2021 with 4201 job postings, followed by retail pharmacists, other pharmacist occupations, hospital pharmacists, and pharmacy directors, per the PWC.³

This shortfall can primarily be attributed to stress and burnout. “We know there is movement out of [both] retail and hospital pharmacy,” Rothholz said, adding that if jobs like nursing assistants and pharmacy technicians offer equitable pay, “why not go into a less stressful job?”

Some pharmacists are retiring earlier, leaving the profession, or transitioning from retail into other types of pharmacy jobs.

APhA’s Well-Being Index (WBI) for pharmacy personnel¹ found that of the 5927 pharmacists who have used the tool, 34.6% were at high risk of distress; according to Mayo Clinic investigators, those individuals are at a greater risk for a number of adverse outcomes, including low quality of life, burnout, high fatigue, intent to leave their current job, and medication error, APhA told Drug Topics®.

“People are reporting burnout, fatigue, [and] the intent to leave their jobs,” said Sandra Leal, PharmD, MPH, APhA president, executive vice president at Tabula Rasa HealthCare, “and [employers] are not supporting pharmacists as they need to be supported.”

For references, visit drugtopics.com.

“People are reporting burnout, fatigue, [and] the intent to leave their jobs.”

Sandra Leal, PharmD, MPH, APhA president, executive vice president at Tabula Rasa HealthCare
The Best of the Best: 2021 Pharmacy Award Winners

Four winners of the SingleCare Best of the Best Pharmacy Awards joined Drug Topics® to share their knowledge with fellow pharmacists and pharmacy technicians.  By Lauren Biscaldi

When Drug Topics® sat down with a group of winners of the 2021 SingleCare Best of the Best Pharmacy Awards, humbled quickly became the word of the day.

“I’m very honored, very humbled, by this national award,” said Triet “Tony” Nguyen, RPh, pharmacy manager at Safeway in Annandale, Virginia, and winner of the 2021 Above and Beyond Award. “I guess my customers appreciate my service to them, and that’s why they nominated me.”

For the third year, prescription savings service SingleCare held their Best of the Best Pharmacy Awards, recognizing 25 outstanding pharmacy professionals from around the United States. This year’s awards generated thousands of nominations and honored 10 pharmacists, 10 pharmacy technicians, and 5 pharmacy teams who go above and beyond on a daily basis.

“We are honored to be able to celebrate the pharmacists, techs, and teams that continue to go above and beyond to provide exceptional care and support for their customers,” said Rick Bates, founder and CEO of SingleCare. “As pharmacy staff across the country have been stretched beyond their limits over the past year, these awards are especially meaningful in recognizing the critical work pharmacists do to support their communities each and every day.”

Jennifer Bourgeois, PharmD, of Market Street Pharmacy in McKinney, Texas, was recognized by her customers as winner of the 2021 Best Pharmacist Award. For Bourgeois, the recognition is proof positive that she is serving where she is best fit.

“I think being in health care sometimes seems thankless,” she said. “We’ve put in so many hours, and we’re happy to do that, but just to be recognized by the people that we’re actually showing up for means the most. That’s really what we’re all there to do: to take care of our people, our patients.”

Eric Geyer, PharmD, winner of the 2021 Most Influential Pharmacist Award, was also humbled by the recognition.

“For the past 2 years, I’ve really leaned in to trying to be a voice for professional pharmacy,” he said. Geyer recently transitioned from a retail pharmacist role to working as pharmacy director for The Centers for Families and Children in Cleveland, Ohio, overseeing operations for 5 outpatient or community-based pharmacies, in addition to managing the operations of pharmacy residents and a clinical team—all while navigating the complexities of the COVID-19 pandemic.

“It’s exciting for us in community pharmacy to be able to have such an instrumental role in the availability of the vaccine for our communities,” said Bourgeois, who transitioned into a clinical role at her pharmacy just as the COVID-19 vaccine rollout began. “But also, the demands on community pharmacy right now are at an all-time high. Our roles and our responsibilities... the list just keeps getting longer.”

For Sidrah Alam, a pharmacy intern at Wegmans Pharmacy in Leesburg, Virginia, and 2021’s Best Up-and-Coming Pharmacist, these challenges demonstrate the impact that the pharmacy profession has on the wider health care industry.

“It’s amazing to see how we have [an] impact no matter what setting we’re in,” Alam said. “I think a lot of people don’t realize that all of health care is important, and that we’re all part of this team to make sure that all of our patients are comfortable and getting the best care.”

Alam is a pharmacy student at Shenandoah University Bernard J. Dunn School of Pharmacy in Fairfax, Virginia, and will be graduating in May 2022 with dual degrees: Alam will receive her doctor of pharmacy degree as well as a master of science degree in pharmacogenomics.

“Pharmacists have been on the front lines, and I hope that we stay that way” she said. “I hope that everyone realizes the impact that we can have.”

To view all of our interviews with the 2021 Best of the Best Pharmacy Award winners, visit drugtopics.com.
Interchangeable Insulin Biosimilars: A Game Changer in Diabetes Management

In this Drug Topics® Pharmacy View K-Cast, Diana Isaacs, PharmD, BCPS, BCACP, BC-ADM, CDCES, interviewed Thomas C. Blevins, MD, ECNU, FACE, FNLA, over a 6-video series to discuss how the recent FDA approval of the first interchangeable insulin biosimilar—insulin glargine-yfgn (Semgle)—is set to change the game in diabetes management.

Basal Insulin Therapies for Diabetes Management
According to Blevins, interchangeability of insulin products is “a big deal.”

“The pathophysiology in type 1 diabetes is straightforward. People don’t make insulin; therefore, they need insulin replacement and a hormone replacement treatment,” Blevins explained. Since Blevins’ time in medical school during the 1970s, the state of bolus and basal insulins has evolved.

“The way we used [insulin] back then—diabetes management was an art and a science,” he added. Early iterations of insulin like Ultralente, protamine-based insulin Neutral Protamine Hagedorn, and insulin detemir (Levemir) were followed by insulin glargine, developed about 20 years ago and currently the most commonly used basal insulin around the world today. Later, insulin degludec (Tresiba) and U300 glargine were developed. These insulins allow providers to simulate natural physiology as best they can.

Role of Interchangeable Biosimilars in the Management of Diabetes
Biologics are pharmaceutical agents created in living cells, Blevins explained. This simple definition, though, is anything but: “This is a very complicated process. Making a biologic is not like making a generic statin,” he said.

Biosimilars—like insulin glargine-yfgn—is a biologic medicine that is highly similar to the reference biologic, having no clinically meaningful, notable, or significant difference in terms of safety, purity, and potency. For insulin glargine-yfgn, the reference biologic will always be Sanofi Lantus insulin.

The goal, said Blevins, for biosimilars is to create a version of a biologic medication with an identical amino acid structure sequencing. “The intent is to make it as close as possible in every way to the reference biologic,” he added.

For those concerned about potential safety issues with biosimilar medications, the approval process is robust, requiring FDA review of data showing that the pharmacokinetic and pharmacodynamic profile are similar, as well as a demonstration of mitogenicity. Insulin glargine-yfgn, for example, underwent large clinical studies in patients with type 1 or type 2 diabetes to demonstrate that the product had similar efficacy, safety, and immunogenicity to insulin glargine.

In order for insulin glargine-yfgn to receive its status as an interchangeable medication, the FDA required studies showing that patients taking this new product achieved the same clinical result as the reference product—“with no diminished efficacy, no sign of safety issues, and no sign of difference in immunogenicity,” Blevins explained.

Added Isaacs, “One of the big things about interchangeable insulin is it means [that] if a prescription is sent to the pharmacy for insulin glargine or for Lantus [insulin glargine], the pharmacist can change it to Semglee [insulin glargine-yfgn] and not have to contact the prescriber to be able to do that. That’s a big deal.”

Results of INSTRIDE Studies for Diabetes Management
The INSTRIDE studies—INSTRIDE 1, INSTRIDE 2, and INSTRIDE 3—were the clinical studies used to evaluate insulin glargine-yfgn in patients with type 1 and type 2 diabetes. INSTRIDE 3 was the study used to evaluate the interchangeability of insulin glargine-yfgn with its reference product.
Results of INSTRIDE 1 showed that in 558 people with type 1 diabetes, there was no difference between the insulin glargine-yfgn and insulin glargine groups. “The [HbA1c levels] were the same from start to finish,” said Blevins. Nor was there a between-group difference in plasma glucose, demonstrating noninferiority in the results.

INSTRIDE 2 results were similar: in a study of 560 people with type 2 diabetes, between weeks 12 and 24, there were no significant differences in HbA1c levels, serious adverse events, or hypoglycemia.

“Long story short, the INSTRIDE 1 and INSTRIDE 2 studies...were very similar,” Blevins said.

INSTRIDE 3, said Blevins, was the switching study. Here, participants from the INSTRIDE 1 and 2 studies who agreed to continue were divided into 2 groups. One group received the reference product for 36 weeks; the other group alternated, over 12-week periods, the biosimilar and reference insulin product. The results? No significant differences in fasting glucose, monitor glucose, or immunogenicity.

**Impact of Interchangeable Insulin Biosimilar on Cost of Biologics**

“Biologics are never going to be as cheap as generics because even though they’re biosimilars, they’re still very complicated,” said Blevins when asked by Isaacs about how he thinks these products may impact both formulary and pricing in the insulin marketplace.

The interchangeability, said Blevins, is a big deal. Isaacs agreed, noting that she was able to commiserate with the challenges of sending a prescription for Lantus and receiving Basaglar instead—for which the pharmacist is not allowed to make an automatic substitution.

“Each person’s insurance plan might be a little different, and some may prefer the reference product,” she said. “In some cases, they may prefer Basaglar [and] in some cases they may prefer Semglee. It’s very complicated.”

**Challenges to Biosimilar Adoption of Insulin Glargine-yfgn**

How can health care providers get patients to use a biosimilar medication—especially when they may think that they are receiving an inferior product?

“We need to talk to practitioners and educate them more about interchangeability,” said Blevins. “That means educating ourselves and the practitioners to understand the data in a general way. It needs to be repeated over and over.”

“There will need to be a big education effort, especially because people may have never heard of the name Semglee [insulin glargine-yfgn],” said Isaacs. “Or they see insulin glargine with those additional letters—what does that mean? Why are there those extra letters? It’s different.”

Blevins added that, in addition to guidelines—like those published by the American Diabetes Association and the American Association of Clinical Endocrinology—pharmacists will likely be the biggest part of the education push around interchangeable biosimilar products.

**Future Directions for the Use of Biosimilars in Diabetes**

When it comes to other biosimilar insulin products, a new era may be about to start.

“There are biosimilar insulin asparts, the NovoLog biosimilars that have been approved by the European group...Sanofi has the biosimilar of Eli Lilly’s Humalog (insulin lispro) and that’s Admelog (insulin lispro),” said Blevins. “There’s another aspart that’s going to be approved from Sanofi biosimilar before long.”

Blevins added that insulin glargine-yfgn will be the leader in interchangeability—which, he believes, will become the standard. “Every biosimilar will go after interchangeability, as it should.”
HEALTH SYSTEMS

ASHP 2021: News and Updates

The team at Drug Topics® joined pharmacy professionals at the 2021 ASHP Midyear Clinical Meeting and Exhibition.

By Marissa Fox

For the second year, the American Society of Health-System Pharmacists (ASHP) took to the web, hosting its Midyear Clinical Meeting and Exhibition virtually from December 5 through 9, 2021. The team at Drug Topics® joined one of the largest gatherings of pharmacy professionals to provide the latest clinical news. For full meeting coverage, visit the conference page at drugtopics.com.

Evaluating Analgesic Use During COVID-19

During the COVID-19 pandemic, costs associated with the use of opioid analgesics were significantly reduced, according to a poster presented at ASHP Midyear 2021. In the single-center, retrospective study, investigators sought to evaluate the use of both opioid and nonopioid analgesics during the COVID-19 pandemic. They compared data from before and after the COVID-19 pandemic, which they measured using days of therapy per 1000 patient-days and drug cost per 1000 patient-days.

Nonopioid drug classes included anxiolytics, induction agents, nonsteroidal anti-inflammatory drugs, regional or local anesthetics, sedatives, sedatives or hypnotics, skeletal muscle relaxants, and other analgesics.

Following the start of the pandemic, the study center experienced a “significant reduction” in mean opioid and nonopioid days of therapy per 1000 patient-days (1024.1 ± 79.6 vs 898.8 ± 121.4 and 1415.6 ± 40 vs 1357.3 ± 84.6). A significant reduction in mean drug cost per 1000 patient-days for opioids was also noted ($2.98 ± $0.57 vs $2.15 ± $0.31); the same reduction was not seen with nonopioid medications.

“Many variables may have contributed to the significant decrease in opioid use during the COVID-19 pandemic,” the authors noted, adding that these variables include ongoing provider education and a decrease in elective surgeries.

Addition of Pharmacists to Diabetes Management Teams Enhances Care

Including a pharmacist on diabetes management teams can improve patient care while increasing therapy optimization and enhancing medication access, according to a poster presented at the 2021 American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition.

The study was conducted over a 3-month period, with patients chosen through reports taken from the electronic health record. Participants were included in the study if they were patients at 1 of 2 main primary care clinics, had a baseline hemoglobin A1c (HbA1c) level of 9% or greater, and their diabetes was being managed by a primary care provider. A total of 52 patients met the criteria and underwent a comprehensive medication review. The average patient age was 57.5 years (≥ 65 years, 28.8%) and 55.8% were men. Patients had an HbA1c level of 10.5% ± 1.6%, blood pressure of 136 ± 20/80 ± 11 mmHg, a body mass index of 34.4, and an estimated glomerular filtration rate of 92.5 mL/minute/1.73 m².

A total of 80 interventions occurred, involving provider recommendations, therapy optimization, patient education, and counseling. Among the 44 interventions recommended to providers, 4 patients

Magnesium supplementation may lead to a “significant difference” in blood pressure control.
**Study: Increasing Naloxone Access Improves Opioid Outcomes**

Opioid-related deaths have been on the rise over the past 20 years in the United States. Data show that in 2018, approximately 47,000 deaths from opioid overdoses occurred. The CDC has since released guidelines for health care providers prescribing naloxone; however, study findings presented at the 2021 American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition revealed that naloxone is prescribed to only about 1% of patients.3

To study naloxone prescribing and the role that community pharmacists have on the opioid crisis, investigators at 5 retail pharmacies screened patients with an opioid prescription. Inclusion criteria included a total daily morphine milligram equivalent (MME) greater than 50 or an opioid coprescribed with a benzodiazepine, gabapentin, or pregabalin.

**Magnesium Supplements Affect Patient Blood Pressure Control**

Use of magnesium supplementation may lead to a “significant difference” in blood pressure control, according to the results of a retrospective chart review presented at the 2021 American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting and Exhibition.4

Investigators evaluated whether there is a correlation between magnesium supplementation and blood pressure control in patients with a cardiovascular diagnosis. In particular, the aim of the study was to examine whether magnesium supplements would increase, decrease, or show no difference in blood pressure control. The investigators also evaluated the baseline characteristics linked with blood pressure control.

The study cohort included adults presenting to a family medicine clinic in 2018 and 2019. Patients were categorized based on the treatment they received. Group A included those prescribed daily magnesium supplements who were adherent to daily magnesium supplementation. Group B included patients who were not prescribed daily magnesium supplementation.

A total of 569 charts were evaluated of long-term patients who had a cardiovascular diagnosis such as hypertension. Patients were excluded if they were pregnant, outside the age range, or taking a dosage of daily elemental magnesium above 1000 mg.

Patients who were not prescribed magnesium were more likely to have high blood pressure (14%) compared with patients who were prescribed magnesium (8.4%). The odds of having high blood pressure were 1.78 times greater for those not taking magnesium compared with patients who were taking magnesium (95% CI, 1.04-3.05). The review demonstrated a significant difference in blood pressure control and the use of the vitamin magnesium, the investigators concluded, adding that the increase in use of vitamins and other alternative therapies will “demand more education on the selection of these therapies and how they can make an impact on a patient’s life.”

From April 1 to May 31, 2021, 490 patients were counseled on the need for naloxone to be available for them to use if needed. New York state’s naloxone copay assistance program and organization 340b reallocation funds were used to help mitigate high costs.

If patients were open to receiving naloxone, it was dispensed. A total of 315 patients—approximately 64.3%—accepted the naloxone, were trained in use by the pharmacist, and had the medication dispensed along with their opioid. Both the patient and family members were trained on the use of naloxone and handed an informational page to read. Health care providers were additionally notified that naloxone had been dispensed to their patient, and that the patient had been counseled and trained on its use.

Overall, 171 patients declined the naloxone, and 2 patients had not presented to the pharmacy for pick up.

The investigators concluded that, “increasing the availability of naloxone to patients at risk due to prescription opioid use can be achieved by pharmacists at the community level in states where naloxone is available, and if costs can be reduced for patients.”

For references, visit drugtopics.com.
Pharmacists’ Plates Are Piled High

As pharmacists administer more immunizations than ever, managers must provide a larger tray (pharmacy technicians) or smaller plates (fewer responsibilities) to balance things out.

“More liver and onions? ...belum!”

January 2022 has finally rolled around, and every pharmacist’s plate is full and—in most cases—running over. I use this plate analogy knowing full well that we are in the midst of “eating season,” which starts with Thanksgiving and ends with the Super Bowl. Having fought the “Battle of the Bulge” since elementary school, gaining weight is something I am an expert in. People can gain as much as 10 pounds during the eating season, often because they overload their plates.

Unless they are an owner, the average pharmacist doesn’t really have control over what is put on their plate. Unlike our university dining hall days, when students could take their fill and discard the rest, pharmacists must eat everything on their daily plate. It doesn’t matter how large the plate is, or how high it is piled, it is expected to be cleaned off by the end of the shift.

We might look around at our fellow pharmacists who have big plates piled high. Social media tells us of pharmacies providing upwards of 50,000 COVID-19 vaccines. I read about these amazing achievements with widening eyes. My wife Denise managed COVID-19 clinics in State College, Pennsylvania, immunizing thousands of patients on 1 Saturday. I was able to help her out by reconstituting and drawing up vaccines.

She had at least 24 volunteer immunizers, at least a dozen reconstituting and drawing vaccines, and at least 2 dozen more helping out with intake, monitoring, and traffic control. It was a fun 8 hours, working with at least 60 health professionals and run-of-the-mill volunteers. Doing the math, Denise’s 8-hour clinic administered 2400 shots with 60 workers, coming out to 40 shots per person which equals 5 shots per person per hour. By the way, they did no billing whatsoever and only used the computer to enter data into the Statewide Immunization Information System.

Can we extrapolate these efforts down to the community pharmacy level, where you have 1 pharmacist to do the drawing up, administering, and monitoring? In the pharmacy where I work, we are required to use 3 different databases—all clunky at best—when we administer a COVID-19 vaccine. One database links to our federal health partner, our pharmacy software is used for billing, and another system is used to access the Statewide Immunization Information System.

There are, essentially, 3 different operations to fill 1 prescription, all before the shot can even be administered. And did I mention that we’re still filling prescriptions at a sometimes breakneck pace?

We as pharmacists need to start looking at our own plate. No longer should our plate consist of liver, onions, and brussels sprouts day after day but it should have an occasional filet mignon and baked potato. We need to go to the pharmacy cafeteria and fill our plates with well-balanced activities. If we are to provide immunizations, then we must take something off our plates. If someone keeps piling up our plates, and insisting we clean off the plates, it is only a matter of time until something must give.

Either a larger tray with more plates (technicians) or a smaller one with fewer plates (less responsibilities) is needed in exchange for pharmacists providing immunizations. In Malay, Indonesia there is a term used instead of the word “no,” which is too absolute. The word belum means “not yet”—a response that reflects on the possibilities of uncertainty and a positive answer that needs to be considered more deeply.

Belum is a word that I would like to see incorporated into every pharmacist’s vocabulary. When the district manager has another addition to an already busy schedule, we can avoid saying “no” and instead say “belum”—not just yet. Our plates are full and we can’t eat another bite.

Peter A. Kreckel, RPh, practices community pharmacy in Lemont Furnace, Pennsylvania.
TICOVAC Vaccine to Prevent Tick-Borne Encephalitis

James Thurston, PharmD Candidate; and Cassandra R. Doyno, PharmD, BCPS, BCCCP

On August 13, 2021, the FDA approved a biologics license application for the tick-borne encephalitis (TBE) vaccine TICOVAC® for individuals 1 year or older. The primary 3-dose vaccination series is recommended for individuals who plan to travel to TBE-endemic areas (primarily northern Europe and northern Asia) and should be completed at least 1 week prior to travel. The vaccine induces the production of anti-TBE antibodies, which are believed to confer protection against the virus.

Immunogenicity of the TBE vaccine was evaluated in an open-label, phase 3 trial of healthy participants aged 1 through 15 years. Children who were administered a 0.25-mL dose of the vaccine at 0, 1, and 6 months had a 99.5% seropositivity rate 21 days after the third vaccination. In 2 nonrandomized, open-label, phase 3 trials, adults participants who received 0.5-mL doses at either 0, 1, and 6 months or at 0 months, 14 days, and 6 months were evaluated for seropositivity 21 days following the third vaccination. Seropositivity rates ranged from 98.7% to 100% between both trials.

Two open-label, multicenter follow-up studies assessed immunogenicity 3 years after the third vaccination; seropositivity ranged between 82.9% and 100%. Between 2000 and 2011, an Austrian postmarketing study of 2 TBE vaccines estimated the worst- and best-case TBE vaccine effectiveness for preventing hospitalization in patients with TBE at 96.3% and 98.7% following a primary immunization series.

In clinical trials of healthy children aged 1 to 15 years (n = 3240) who received at least one 0.25-mL dose of the vaccine, the most common adverse reactions were local tenderness (18.1%), local pain (11.2%), headache (11.1%), fever (9.6%), and restlessness (9.1%). Serious adverse events (SAEs) and death were reported in 62 and 1 participants, respectively; only 1 SAE (febrile convulsion 2 days post vaccination) was related to the vaccine, and no deaths were vaccine-related.

In clinical trials of adults aged 16 or older (n = 4427) who received at least one 0.5-mL dose of the vaccine, the most common adverse events were local tenderness (29.9%), local pain (13.2%), fatigue (6.6%), headache (6.3%), and muscle pain (5.1%). SAEs and death were reported in 54 and 2 participants, respectively; none of these events were related to the vaccine. Available human data are insufficient to establish the safety of this product in pregnant or lactating populations or its potential to cause carcinogenicity, genotoxicity, or impairment of fertility.

A primary immunization series of the TBE vaccine consists of 0.25-mL doses for patients aged 1 to 15 years, and 0.5-mL doses for patients aged 16 years or older. The primary vaccination series for patients aged 1 to 15 consists of an initial dose, followed by a second dose in 1 to 3 months and a third dose in 5 to 12 months. For patients aged 16 or older, the vaccination series includes an initial dose followed by a second dose administered 14 days to 3 months later, and a third dose administered 5 to 12 months later. A booster dose can be considered if the patient completed their primary immunization series over 3 years ago and expected continued exposure or reexposure to TBE. The vaccine is administered by intramuscular injection and should be refrigerated between 2 ºC and 8 ºC (36 ºF to 46 ºF).
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SCAN ME
HOW IMPORTANT IS IT TO COMPLETE THE 2-DOSE SERIES?

VERY IMPORTANT

MAKE SURE YOU ADMINISTER A SECOND DOSE OF SHINGRIX 2-6 MONTHS AFTER THE FIRST.

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 (e.g., 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

Important Safety Information (cont’d)
• 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

Reference: Prescribing Information for SHINGRIX.

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

Get the facts at
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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 INDICTIONS AND USAGE

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

Limitations of Use:

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

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 to a previous dose of SHINGRIX.

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 another 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 (46%), 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 1. Percentage of Subjects with Solicited Local and General Adverse Reactions within 7 Days* of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older* (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Local Adverse Reactions</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>n = 1,315</td>
<td>n = 1,312</td>
<td>n = 1,311</td>
</tr>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>15</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Fatigue</td>
<td>20</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td>Headache</td>
<td>22</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Shivering</td>
<td>7</td>
<td>6</td>
<td>5</td>
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<tr>
<td>Fever</td>
<td>3</td>
<td>3</td>
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<td>Gl</td>
<td>2</td>
<td>1</td>
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</tbody>
</table>

| Grade 3†                |                 |                 |               |
| Myalgia                 | 9               | 5               | 3             | 0.4       |
| Fatigue                 | 20              | 17              | 14            | 14        |
| Headache                | 22              | 16              | 12            | 12        |
| Shivering               | 7               | 6               | 5             | 5         |
| Fever                   | 3               | 3               | 2             | 2         |
| Gl                      | 2               | 1               | 1             | 1         |
| Grade 3†                |                 |                 |               |

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.
† 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.
‡ Placebo was a saline solution.
§ Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
|| Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.
|| 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 50 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). General adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.2%, 3%, 4%, 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-last 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-last vaccination. One subject (<0.01%) reported lymphadenitis 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 0.8% 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 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.

Immunological Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the HSK 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 Code databases 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

Husk 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 temporally associated with administration of SHINGRIX.

Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

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Jim C. RPh, Missouri

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