Pharmacy Today

An official publication of the **American Pharmacists Association**

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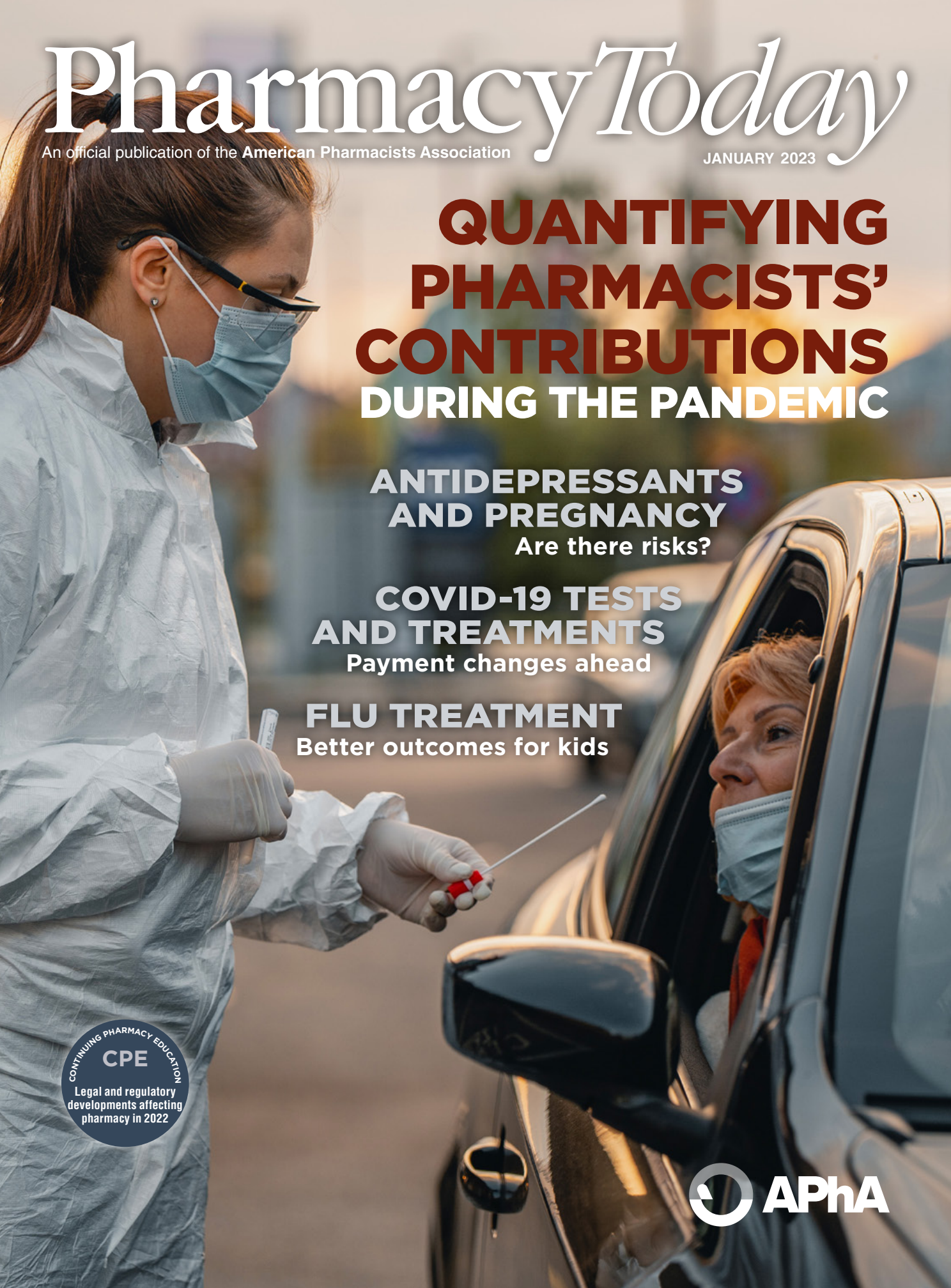

QUANTIFYING PHARMACISTS' CONTRIBUTIONS DURING THE PANDEMIC

ANTIDEPRESSANTS AND PREGNANCY
Are there risks?

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FLU TREATMENT
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APhA

SHINGRIX IS NOW $0 FOR ALMOST EVERYONE

Recommend with certainty: SHINGRIX is now $0 for most patients 50 years and older.[1-3,*]

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

Indication

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

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

Important Safety Information

- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
- Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope

For your patients with commercial insurance plans

More than 9 out of 10 are covered:
- Average copays are just $4 or less[1]
- 95% of commercial patients pay $0 for SHINGRIX[1,2,*]

For your Medicare Part D patients

Great coverage is now even better: All your Medicare Part D patients can receive SHINGRIX for $0 at their pharmacy.[1,3,*]

Scan the QR code or
visit **ProfilesSHINGRIX.com** to
SEE WHO YOU SHOULD VACCINATE

*SOURCE: Managed Markets Insight & Technology, LLC, Database as of October 2022. Coverage represents access to reimbursement from a health plan with restrictions appropriate to the Advisory Committee on Immunization Practices (ACIP) recommendation(s) and/or prescribing information. Veterans Affairs (VA) and Indian Health Service (IHS) lives have been omitted when calculating the percentage of lives.

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

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

References: 1. Data on file, GSK. **2.** Managed Markets Insights & Technology, LLC, Database as of October 2022. **3.** Kirchhoff, SM. Selected health provisions of the Inflation Reduction Act. Congressional Research Service. Accessed November 16, 2022. https://crsreports.congress.gov/product/pdf/IF/IF12203

BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

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

1 INDICATIONS AND USAGE

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

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 after a previous dose of SHINGRIX *[see Description (11) of full prescribing information]*.

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

5.2 Guillain-Barré Syndrome (GBS)

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

5.3 Syncope

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

Adults Aged 50 Years and Older

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

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

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

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

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

Adverse Reactions	Aged 50-59 Years		Aged 60-69 Years		Aged ≥70 Years	
	SHINGRIX	Placebo[c]	SHINGRIX	Placebo[c]	SHINGRIX	Placebo[c]
Local Adverse Reactions	**n=1,315 %**	**n=1,312 %**	**n=1,311 %**	**n=1,305 %**	**n=2,258 %**	**n=2,263 %**
Pain	88	14	83	11	69	9
Pain, Grade 3[d]	10	1	7	1	4	0.2
Redness	39	1	38	2	38	1
Redness, >100 mm	3	0	3	0	3	0
Swelling	31	1	27	1	23	1
Swelling, >100 mm	1	0	1	0	1	0
General Adverse Reactions	**n=1,315 %**	**n=1,312 %**	**n=1,309 %**	**n=1,305 %**	**n=2,252 %**	**n=2,264 %**
Myalgia	57	15	49	11	35	10
Myalgia, Grade 3[e]	9	1	5	1	3	0.4
Fatigue	57	20	46	17	37	14
Fatigue, Grade 3[e]	9	2	5	1	4	1
Headache	51	22	40	16	29	12
Headache, Grade 3[e]	6	2	4	0.2	2	0.4
Shivering	36	7	30	6	20	5
Shivering, Grade 3[e]	7	0.2	5	0.3	2	0.3
Fever	28	3	24	3	14	3
Fever, Grade 3[f]	0.4	0.2	1	0.2	0.1	0.1
GI[g]	24	11	17	9	14	8
GI, Grade 3[e]	2	1	1	1	1	0.4

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

[a] 7 days included day of vaccination and the subsequent 6 days.

[b] 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.

[c] Placebo was a saline solution.

[d] Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

[e] Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.

[f] 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.

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

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

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

(continued on next page)

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 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 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post-last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

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

6.2 Postmarketing Experience

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

General Disorders and Administration Site Conditions

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

Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

Nervous System Disorders

Guillain-Barré syndrome.

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

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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Lactation

Risk Summary

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

8.5 Geriatric Use

Adults Aged 60 Years and Older

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

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

17 PATIENT COUNSELING INFORMATION

- Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.
- Inform patients about the potential for adverse reactions that have been 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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BulletinToday

Shingles may increase risk for stroke, heart attack

A new study published in the *Journal of the American Heart Association* found that shingles, also known as herpes zoster, is associated with an almost 30% higher long-term risk of major cardiovascular events such as stroke or heart attack.

Researchers from Brigham and Women's Hospital in Boston conducted a large longitudinal study of more than 200,000 U.S. men and women who did not have a prior history of stroke or coronary heart disease.

The team collected information on shingles, stroke, and coronary heart disease using questionnaires collected every 2 years and confirmed the diagnoses with a medical record review.

Researchers followed the participants for up to 16 years and evaluated whether those who had developed shingles were at higher risk for stroke or coronary heart disease years after the shingles episode. They found that elevated risk may persist for 12 years or more after developing shingles. The researchers tracked incidences of stroke and coronary heart disease. They also evaluated a combined outcome of CVD, which included either stroke or coronary heart disease, whichever came first.

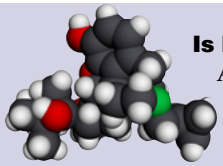
Additionally, they found that the risk may be greater among those with immunocompromising conditions or for those taking immunosuppressing treatments.

"Our findings suggest there are long-term implications of shingles and highlight the importance of public health efforts for prevention," said lead author Sharon Curhan, MD, from Brigham and Women's Hospital, in a news release. "Given the growing number of Americans at risk for this painful and often disabling disease and the availability of an effective vaccine, shingles vaccination could provide a valuable opportunity to reduce the burden of shingles and reduce the risk of subsequent cardiovascular complications."

Due to timing, much of the study took place in the period before the shingles vaccines became widely available. Even after its introduction, the uptake of this vaccination has been generally low. Because of these limitations, researchers were not able to evaluate whether vaccination status may influence the association of shingles and long-term risk of a major cardiovascular event.

"We are currently collecting vaccination information among our participants and hope to conduct these studies in the future," said Curhan.

As more people choose to receive the shingles vaccine, future studies could examine whether vaccination influences the relation of shingles to the risk of CVD. ■



Is buprenorphine or methadone better for opioid use disorder in pregnancy?

Authors of a new study published in the *New England Journal of Medicine* compared outcomes in pregnant patients with opioid use disorder based on whether they received opioid agonist therapy with buprenorphine as opposed to methadone.

The dataset included more than 2.5 million pregnancies in the Medicaid population that resulted in live births from 2000 to 2018, and it found a similar risk for unfavorable outcomes in the mothers regardless of treatment agent received. However, the risk for adverse outcomes in the newborn babies—including neonatal abstinence syndrome, preterm birth, low birthweight, and small size for gestational age—was lower with buprenorphine than with methadone.

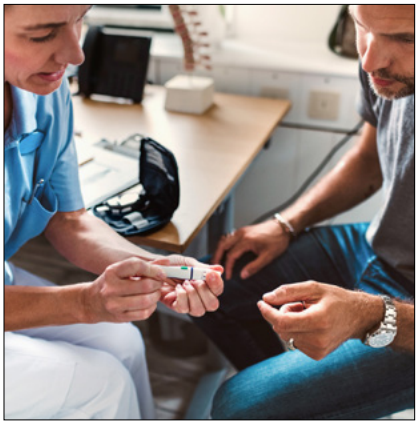
The study authors acknowledge that they do not yet know the biological mechanism underlying the differences between the treatment options, but they suspect that "differences in the pharmacologic mechanism of action" between the partial agonist buprenorphine and the full agonist methadone may come into play.

The National Institute on Drug Abuse sponsored the study. ■

Recovering COVID patients seem to have elevated risk for newly diagnosed diabetes

A new study in *BMC Medicine* found that people recovering from COVID-19 are at a higher risk of being newly diagnosed with diabetes.

The finding is based on a meta-analysis of 9 studies that included nearly 40 million participants, the largest study of its kind.



Researchers identified nearly 200,000 diabetes cases, estimating a post–COVID-19 incidence per 1,000 person-years of 15.53 and a relative risk of 1.62 compared with individuals who were not infected with COVID-19. The increased risk continued based on age, gender, type of diabetes, follow-up time, and COVID-19 severity, and it was significant even when the authors took undisclosed confounding into account.

Findings from the study also indicate a 20% higher risk for developing diabetes following COVID-19 compared with patients with other upper respiratory viruses, and an 82% increased risk compared with the general population.

Possible reasons for the higher risk include the effect of SARS-CoV-2 on pancreatic cells and the cytokine storm in people with excessive immune responses. The researchers said the findings underscore the need for health care providers to monitor patients' glucose metabolism during the post-acute phase of COVID-19, in particular during the first 3 months following infection. ■

Study finds benzodiazepines for sleep increased overdose risk for young adults

New findings from a recent study in *JAMA Network Open* suggest that benzodiazepines—compared with alternative pharmacologic treatments for common sleep disorders—were associated with an increased risk of drug overdose among young people, especially those with a recent opioid prescription.

The cohort study included privately insured people ages 10 to 29 years identified from a U.S. commercial claims database. Of the 23,084 young people initiating benzodiazepine treatment and the 66,706 initiating a comparator treatment, the risk of drug overdose in the 6 months after treatment start was elevated for young people starting benzodiazepine treatment compared with alternative treatments (e.g., trazodone, hydroxyzine, zolpidem, zaleplon, and eszopiclone) for sleep disorders. This risk was further heightened for young people with a recent opioid prescription, according to the results.

Although benzodiazepines are commonly prescribed, even for young people, they are recommended less frequently for insomnia among children than among adults given the lack of efficacy and safety data for younger age groups. When benzodiazepines are prescribed for any age group, short-term treatment is recommended.

"Drug overdose is an important safety consideration when treating young people with benzodiazepines," noted the study authors. ■

FDA grants fast track approval for OTC nasal spray

FDA has reportedly put an OTC version of naloxone nasal spray (Narcan—Emergent BioSolutions) on the fast track to approval.

Through the agency's priority review process, the opioid overdose antidote tentatively could receive clearance early this spring. If so, Emergent BioSolutions would be the first of several makers to get a green light in response to regulators' call for OTC formulations of overdose-reversal agents, which are needed to counter a surge in overdoses due to counterfeit fentanyl.

FDA informed prescription drug manufacturers in November 2022 that once enough data are available to support approval of a nonprescription naloxone product, any clinically comparable products sold only with a physician's order would be viewed as mislabeled. Per the vision of FDA Commissioner Robert Califf, MD, naloxone should be as commonplace and accessible as defibrillators. ■

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CPE

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Legal and regulatory developments affecting pharmacy in 2022

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Take the Crossword Challenge

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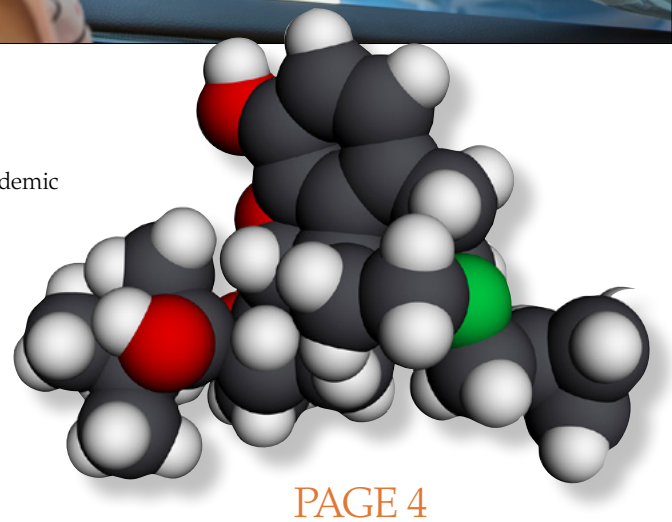
See solution at pharmacytoday.org



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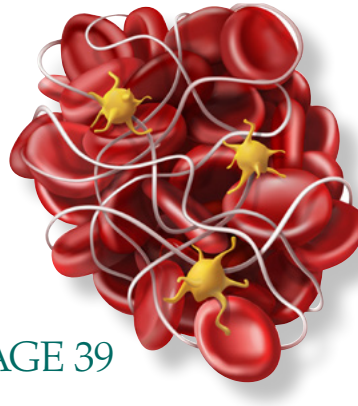
Health Systems



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Pharmacists: Heroes of the pandemic

According to the latest CDC data, the U.S. has experienced a bump in COVID-19 cases, hospitalizations, and death this winter. At the same time, this year's cold and flu season has been a difficult one, with the trio of COVID-19, flu, and respiratory syncytial virus placing stress on health care systems nationwide. Pharmacists continue to play a key role in responding to COVID-19 and related challenges.

This month's *Pharmacy Today* cover story digs into the data to illustrate just how essential pharmacists have been and continue to be in lessening the burden of COVID-19 and flu. According to a recent study published in *JAPhA* by John Grabenstein, RPh, PhD, FAPhA, pharmacists have delivered over 50% of COVID-19 vaccinations in the United States. In fact, from February 2020 to September 2022, pharmacists and technicians conducted over 42 million COVID-19 tests, provided over 270 million COVID-19 vaccinations in community pharmacies, and administered more than 50 million flu and other vaccinations annually. This feat is nothing short of amazing, with Grabenstein stating "the convenience, access, and competence of pharmacists was important and bore out in this enormous percentage."

In this month's issue of *Today*, you'll also find the latest on controlling heartburn, how to counsel your patients about evening primrose oil, and learn about the newest heart failure medication that's delivered via on-body infusion. You can also learn more about legislative, legal, and regulatory developments affecting pharmacy in 2022 in this month's CPE article.

I am constantly impressed by the way our profession has stepped up repeatedly and consistently to meet COVID-19, flu, and other health care needs. Although challenging, it is truly an honor that pharmacists have been given the opportunity to show what they can contribute to public health and infectious disease treatment and prevention in recent years. Take a moment today and congratulate yourself for being a part of this trusted profession that is continuing to identify ways to save lives and improve medication therapy outcomes.

Have a great *Today*! ■

Kristin Wiisanen
PharmD, FAPhA, FCCP
***Pharmacy Today* editor in chief**

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A new year and a turning point for pharmacy

The pharmacy profession and the patient care services delivered by the pharmacy team have evolved significantly over the past few years, bringing new opportunities and challenges. The pandemic has spotlighted the value of pharmacies as vital access points to care, leading policymakers and payers to explore new ways to engage pharmacists and the pharmacy team. There is a buzz of optimism that we are at a turning point and that our efforts toward pharmacy sustainability, services, payment, workforce well-being and resilience, and other factors influencing the pharmacy ecosystem, will finally come to fruition in 2023.

A top priority is sustainability of our nation's community pharmacies—keeping pharmacy doors open with financial stability, predictability, and growth. The current pharmacy reimbursement and payment model is ripe for change and disruption. We are seeing this with the emergence of cash-only pharmacies, which are filling gaps in health care access. Disruption also is needed to break the lopsided, unfair, and deceptive business practices of PBMs who are puppeteering and ravishing the health care industry, particularly pharmacies. In 2022, the Federal Trade Commission (FTC) began a study of PBM practices and announced the agency's intent to exercise its full statutory authority against companies that use unfair tactics to gain an advantage instead of competing on the merits. All eyes are on the FTC in 2023 to see them use their enforcement powers on PBMs. In addition, more states are expected to pass laws and regulations this year as courts continue to stand by the Supreme Court's two-year-old *Rutledge v PCMA* decision allowing state oversight of PBMs. We are also seeing readiness on the federal level to pass legislation that provides fairness, equity, and transparency in pharmacy payment.

Pharmacists have been giving away free patient care services for too long. Enough is enough. We need to push long-standing legislative efforts over the finish line in 2023 and get recognized as providers under Medicare for our nation's seniors. There is momentum to pass the Equitable Access to Pharmacy Services (ECAPS) Act, which would authorize pharmacists to provide care and receive direct reimbursement for testing, treating, and immunizing services for certain respiratory illnesses. Importantly, this legislation codifies the temporary scope of practice authorities gained during the pandemic and provides a payment mechanism for the covered services. Passage of this legislation would be a critical step in addressing payment challenges for pharmacists in the Medicare program, challenges that often trickle down to Medicaid and commercial health plans that follow Medicare policy. The Future of Pharmacy Care Coalition, which APhA co-leads with other pharmacy champions, and which is supported by a group of over 200 diverse organizations, is working diligently to get this legislation passed in 2023. Any pharmacy company/organization not involved is encouraged to join. Find more information at www.pharmacycare.org.

Change is ahead for pharmacy, along with many opportunities and challenges as we enter 2023. We have positive momentum for the changes and disruption needed for our profession. APhA stands ready, willing, and able for the work ahead, alongside our pharmacy partners, using a solutions-oriented approach to move the pharmacy profession and the sustainability of community pharmacies forward. ■

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20881

NEW INDICATIONS

IOFLUPANE I 123
(DaTscan—GE Healthcare)

Indication: DaTscan is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with suspected Parkinsonian syndromes or suspected dementia with Lewy bodies.

Recommended dosage and administration: The recommended dose of DaTscan in adults is 111 MBq to 185 MBq (3 mCi to 5 mCi) administered intravenously over at least 20 seconds. The patient dose should be measured using a dose calibrator immediately prior to administration. SPECT imaging should begin between 3 and 6 hours postinjection. A thyroid-blocking agent should be administered at least 1 hour before the dose of DaTscan is administered.

Common adverse effects: The most common adverse reactions in patients who are administered DaTscan include headache, nausea, vertigo, dry mouth, and dizziness.

Warnings and precautions: DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123. Hypersensitivity reactions such as dyspnea, edema, rash, erythema, and pruritus have been reported. Treatment measures should be available prior to DaTscan administration. Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. Ensure safe handling of DaTscan to minimize radiation exposure to the patient and health care providers. Advise patients to hydrate before and after administration and to void frequently after administration.

Use should be avoided in pregnancy as DaTscan may cause fetal harm. Lactating patients should be advised to interrupt breastfeeding and pump and discard breastmilk for at least 6 days after DaTscan administration. Amoxapine, amphetamine, armodafinil, benztropine, bupropion, buspirone, cocaine, mazindol, phentermine, phenylpropanolamine, selegiline, sertraline, citalopram, and paroxetine may interfere with DaTscan imaging. The effects of dopamine agonists and antagonists on DaTscan imaging have not been established.

LEVONORGESTREL
(Liletta—Medicines360)

Indication: Liletta is a progestin-containing intrauterine system (IUS) indicated for prevention of pregnancy for up to 8 years.

Recommended dosage and administration: The initial release rate of levonorgestrel is approximately 20 mcg/day and declines progressively to approximately 6.5 mcg/day after 8 years. Liletta can be removed at any time but must be removed by end of the eighth year. Insertion instructions should be followed exactly as described. Liletta should be inserted into the uterine cavity with the provided inserter by a trained health care professional using strict aseptic technique. Re-examination and evaluation should be considered 4 to 6 weeks after insertion and during routine care, or more often if clinically indicated.

Common adverse effects: The most common adverse reactions reported in patients using Liletta are vulvovaginal mycotic infections, vaginal bacterial infections, acne, nausea, or vomiting.

Warnings and precautions: Liletta is contraindicated in pregnancy, use for postcoital contraception, congenital or acquired uterine anomaly that distorts the uterine cavity and would be incompatible with correct IUS placement, acute pelvic inflammatory disease, postpartum endometritis or infected abortion in the past 3 months, known or suspected uterine or cervical neoplasia, known or suspected breast cancer or other hormone-sensitive cancer, uterine bleeding of unknown etiology, untreated acute cervicitis or vaginitis or other lower genital tract infections, acute liver disease or liver tumor, increased susceptibility to pelvic infections, a previously inserted IUS that has not been removed, and hypersensitivity to any component of Liletta.

Remove Liletta if pregnancy occurs with Liletta in place and Liletta is in the uterus. If pregnancy occurs, there is increased risk of ectopic pregnancy, pregnancy loss, septic abortion, and premature labor and delivery. Severe infection or sepsis, including Group A streptococcal sepsis, have been reported following insertion of levonorgestrel-releasing IUSs. Before using Liletta, consider the risks of pelvic infection. Perforation may occur and reduce contraceptive effectiveness or require surgery. This risk is increased if inserted in patients who have fixed retroverted uteri, are postpartum, or are lactating. Partial or complete expulsion may occur. Evaluate persistent enlarged ovarian follicles or ovarian cysts. Bleeding patterns can become altered, may remain irregular, and amenorrhea may ensue.

PEMETREXED
(Pemetrexed—Actavis)

Indication: Pemetrexed is a folate analog metabolic inhibitor indicated

in combination with pembrolizumab and platinum chemotherapy for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations, in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic NSCLC, as a single agent for the maintenance treatment of patients with locally advanced or metastatic NSCLC whose disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, as a single agent for the treatment of patients with recurrent, metastatic NSCLC after prior chemotherapy and initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who otherwise are not candidates for curative surgery. Pemetrexed injection is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer.

Recommended dosage and administration: The recommended dose of Pemetrexed administered with pembrolizumab and platinum chemotherapy in patients with a creatinine clearance of ≥45 mL/min is 500 mg/m^2 as an intravenous infusion over 10 minutes, administered after pembrolizumab and prior to platinum chemotherapy, on day 1 of each 21-day cycle. The recommended dose of pemetrexed administered as a single agent or with cisplatin in patients with a creatine clearance of ≥45 mL/min is 500 mg/m^2 as an intravenous infusion over 10 minutes on day 1 of each 21-day cycle. Initiate folic acid 400 mcg to 1,000 mcg orally, once daily, beginning 7 days prior to the first dose of Pemetrexed and continue until 21 days after the last dose of pemetrexed. Administer vitamin B12, 1 mg intramuscularly, 1 week prior to the first dose of pemetrexed and every 3 cycles. Administer dexamethasone 4 mg orally, twice daily the day before, the day of, and the day after Pemetrexed administration.

Label change for Amoxil

In early November 2022, FDA approved several safety-related label changes for Amoxil (GSK). One of the most significant changes includes a new addition to the warnings and precautions section for "severe cutaneous adverse reactions" (SCARs). This new subsection states that Amoxil may cause SCARs like Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis. Skin rash accompanied by arthritis, arthralgia, myalgia, and fever was also listed as a possible immune reaction to the medication. Aseptic meningitis was listed as a potential central nervous system adverse reaction.

The label change also advises prescribers to educate patients about the signs and symptoms of serious skin manifestations and to instruct patients to discontinue treatment if rashes or skin lesions progress. Another notable change is related to the storage and special handling of Amoxil. The updated label states that while it is preferable to keep Amoxil suspensions in the refrigerator, it is not a requirement. Amoxil suspensions can be kept at room temperature as long as the lid is securely fastened between uses.

Common adverse effects: The most common adverse reactions of Pemetrexed when administered as a single agent are fatigue, nausea, and anorexia. The most common adverse reactions of Pemetrex ed when administered with cisplatin are vomiting, neutropenia, anemia, stomatitis/pharyngitis, thrombocytopenia, and constipation. The most common adverse reactions of Pemetrexed when administered in combination with pembrolizumab and platinum chemotherapy are fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, and pyrexia.

Warnings and precautions: Pemetrexed is contraindicated in patients with a history of severe hypersensitivity reaction to Pemetrexed. Pemetrexed can cause severe bone marrow suppression resulting in cytopenia and in increased risk of infection. Do not administer when the absolute neutrophil count is <1,500 cells/mm^3 and platelets are <100,000 cells/mm^3. Initiate supplementation with oral folic acid and intramuscular vitamin B12 to reduce the severity of hematologic and GI toxicity of Pemetrexed. Use can cause severe, and sometimes fatal, renal failure. Do not administer when creatinine clearance is <45 mL/min.

Permanently discontinue for severe and life-threatening bullous, blistering, or exfoliating skin toxicity. Withhold for acute onset of new or progressive unexplained pulmonary symptoms. Permanently discontinue if pneumonitis is confirmed. Radiation recall can occur in patients who received radiation weeks to years previously. Permanently discontinue if signs of radiation recall occur. Pemetrexed can cause fetal harm and patients should be advised of the potential risk to a fetus and to use effective contraception. Patients should be advised not to breastfeed. Ibuprofen use increases risk of Pemetrexed toxicity in patients with mild to moderate renal impairment. Modify the ibuprofen dosage as recommended for patients with a creatine clearance between 45 mL/min and 79 mL/min. ■

Also in this issue
FDA approves ScPharmaceuticals' heart failure therapy (page 18)

Cool that heartburn

Mary Warner

Heartburn is a very common gastrointestinal complaint, often described as a burning sensation in the chest. Heartburn most often occurs at night when patients are lying down. It is the main symptom of GERD, but it may also occur in patients with peptic ulcers, delayed gastric emptying, or gallbladder disease. It occurs when the lower esophageal sphincter muscle allows acidic stomach contents to flow back up into the esophagus and sometimes into the throat or back of the mouth. Heartburn can usually be treated effectively with OTC options, including antacids, H2 receptor agonists (H2RAs), and PPIs.

Antacids

Antacids, which contain magnesium, aluminum, or calcium salts, relieve heartburn by neutralizing gastric acid. Most antacids are relatively inexpensive and widely available, making them a good choice for the temporary relief of mild and infrequent heartburn. They act as buffering agents by reacting with acid to form water (and the corresponding salt).

Antacids are available as chewable tablets and liquids, with the liquid forms acting more quickly. When taken on an empty stomach, most antacids provide about 20 to 60 minutes of action; when taken within an hour after a meal, they can provide relief for up to 3 hours. Common brands of antacids include Tums (calcium carbonate), Mylanta (aluminum hydroxide and magnesium hydroxide), and Rolaids (calcium carbonate and magnesium hydroxide).

Antacids are usually well tolerated, and any adverse effects are generally associated with the specific cation in the active ingredient. Magnesium-containing antacids can cause diarrhea, which can be mitigated by including aluminum hydroxide with the magnesium salt. In addition, because magnesium excretion may be impaired in patients with renal disease, magnesium-containing antacids should not be used by these patients.

H2RAs

H2RAs relieve and prevent heartburn by inhibiting histamine, which reduces the amount of acid produced by the stomach. They typically start to work within 1 to 3 hours. Common OTC H2RAs include Tagamet HB (cimetidine) and Pepcid (famotidine). Two previously available OTC treatments for heartburn are no longer available: Azid AR (nizatidine) was discontinued by the manufacturer, and ranitidine (Zantac) was removed from pharmacy shelves in April 2020 because of contamination by *N*-nitrosodimethylamine (NDMA), a probable human carcinogen.

Heartburn relief with H2RAs is not as rapid as with antacids, but the duration of relief is longer, usually 4 to 10 hours. They can be taken either at the onset of symptoms or 30 to 60 minutes before heartburn is expected. Because tolerance to the effects of H2RAs may develop with daily use, patients should take these medications on an as-needed basis rather than regularly. A reduced dose is recommended for patients with impaired renal function.

H2RAs are associated with a low incidence of adverse effects, the most common of which are headache, diarrhea, constipation, dizziness, and drowsiness. Cimetidine is associated with a weak antiandrogenic effect and should not be taken by men at high doses.

PPIs

OTC PPIs are used to treat frequent heartburn (2 or more days per week). Because they may take up to 4 days for full effect, they are not intended for immediate relief of heartburn. PPIs reduce the amount of acid produced by inhibiting hydrogen potassium ATPase (the proton pump) and irreversibly blocking the final step in gastric acid secretion in the stomach. Bioavailability of PPIs is reduced if taken after a meal compared to fasting, so these medications should be taken 30 to 60 minutes prior to eating, preferably first thing in the morning.

OTC PPIs include Prevacid (lansoprazole), Nexium (esomeprazole), Prilosec OTC (omeprazole), and Zegerid OTC (omeprazole and sodium bicarbonate). Differences in efficacy among these PPIs have not been established. Tablets and capsules should never be chewed or crushed, as this would compromise the enteric coating that is necessary for effectiveness of the drug. Adverse effects with short-term use of PPIs are uncommon.

What to tell your patients

Because antacids, H2RAs, and PPIs can interact with a variety of other medications, patients should regularly check in with their pharmacist to ensure these interactions are avoided. If antacids are used more than twice a week or regularly for more than 2 weeks, patients should be advised to consider switching to a longer acting product, such as an H2RA or a PPI.

Interactions with OTC heartburn medications

Medication	Drug(s)/drug class	Potential interaction	Management/preventive measures
Antacids	Itraconazole, ketoconazole, iron, atazanavir	Increased gastric pH may decrease disintegration, dissolution, or ionization of drug leading to decreased absorption.	Separate doses by at least 2 hours.
	Amphetamines	Absorption of amphetamines is increased and excretion decreased.	Avoid concurrent use or monitor response to therapy.
	Rosuvastatin	Absorption of rosuvastatin is decreased.	Separate doses by at least 2 hours. Infrequent use of antacids is unlikely to cause clinically significant interaction.
	Enteric-coated medications	Increased gastric pH may cause premature breakdown of enteric coating.	Separate doses by at least 2 hours.
Calcium carbonate, magnesium hydroxide, aluminum hydroxide	Levothyroxine	Absorption of levothyroxine is delayed or impaired.	Separate doses by at least 4 hours.
	Tetracyclines	Absorption of antibiotic is decreased.	Separate doses by at least 4 hours.
	Fluoroquinolones	Absorption of antibiotic is decreased.	Take antibiotic 2 hours before or 6 hours after taking antacid.
Magnesium hydroxide, aluminum hydroxide	Azithromycin	Absorption of antibiotic is decreased.	Separate doses by at least 2 hours.
Sodium bicarbonate	Quinidine	Increased urinary pH may decrease renal excretion of quinidine.	Avoid concurrent use or monitor response to therapy.
	Salicylates	Increased urinary pH may increase renal excretion of salicylates.	Avoid concurrent use or monitor for decreased response to salicylates.
Antacids, H2RAs, PPIs	Erlotinib, dasatinib, gefitinib, other tyrosine kinase inhibitors, rilpivirine, ledipasvir/sofosbuvir	Increased gastric pH decreases absorption.	Avoid concurrent use of PPI or H2RA; separate from antacids by several hours.
H2RAs, PPIs	Itraconazole, ketoconazole, atazanavir, iron sulfate, calcium carbonate	Increased gastric pH may decrease disintegration, dissolution, or ionization of drug, leading to decreased absorption.	Avoid concurrent use or monitor response to therapy.
Cimetidine	Phenytoin, warfarin, amiodarone, clopidogrel, nifedipine, theophylline, tricyclic antidepressants, others	Cimetidine inhibits CYP450 1A2, 2C19, and to a lesser extent, 2D6, 3A4.	Avoid use of cimetidine in patients taking medications metabolized by these CYP enzymes.
Cimetidine, esomeprazole, lansoprazole, omeprazole	Citalopram	Inhibition of CYP450 2C19 increases citalopram concentrations and dose-dependent risk of QT prolongation.	Citalopram dose should not exceed 20 mg per day if used concomitantly.
PPIs	Warfarin, theophylline, tacrolimus, mycophenolate mofetil	PPI inhibition of CYP2C19 may result in increased concentrations of target drugs.	Avoid concurrent use or check with prescriber.
	Digoxin	PPIs may increase digoxin absorption.	Check with prescriber before use.
	Methotrexate	Concurrent use increases risk of toxicity of methotrexate.	Avoid concurrent use of high-dose methotrexate. Clinically significant toxicity is unlikely with lower weekly doses.
Omeprazole, esomeprazole	Clopidogrel	Inhibition of variants of CYP2C19 reduces conversion of clopidogrel to its active form.	Avoid concurrent use or check with prescriber. Clinically significant interaction is unlikely.
	Cilostazol, diazepam	Inhibited metabolism may result in increased concentration of target drug.	Avoid concurrent use. Lansoprazole may be a safer alternative.

Source: Chapter 13, APhA's *Handbook of Nonprescription Drugs.*

Patients who need an OTC PPI to control heartburn for more than 2 weeks or whose heartburn recurs within 4 months, should be advised to consult their physician for further evaluation.

For further information on heartburn and its treatment, see Chapter 13 of the *Handbook of Nonprescription Drugs,* available in print at pharmacist.com and online in Pharmacy Library. ■

Evening primrose oil

Mickie Cathers

Best known for treating inflammation, evening primrose oil (EPO) has been a popular supplement for centuries used to address a host of conditions, including acne, arthritis, bruises, eczema, rheumatoid arthritis, hemorrhoids, digestive problems, and menopausal and premenstrual symptoms. Though EPO is widely used for many conditions, there is little evidence to support using the supplement.

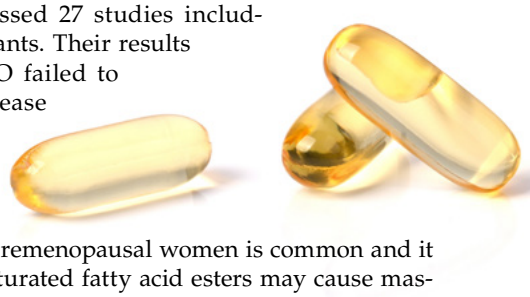
Background

Evening primrose (*Oenothera biennis)* is a plant native to the Americas, Europe, and parts of Asia with yellow flowers that open at sunset. The plant has been valued for centuries to soothe skin inflammation and GI complaints. Native Americans used parts from the plant to treat bruises and wounds and as topical treatments for skin inflammation. As the "King's cure-all," EPO became a popular folk remedy in 17th century Europe. More recently, EPO capsules, soft gels, and lotions are advertised as supporting women's health, boosting energy, and promoting healthy skin.

Is there a benefit?

Oil from the seeds of the flower contains a high concentration of omega-6 fatty acids. γ-linolenic acid (GLA), the active ingredient in the oil, is thought to provide anti-inflammatory benefits through direct action on immune cells and indirect effects on the synthesis of prostaglandins, cytokines, and cytokine mediators.

Most studies on EPO focus on evaluating treatment for atopic dermatitis or breast pain. A 2013 review by Bamford and colleagues published in *Cochrane Database Systemic Reviews* studied EPO and borage oil for eczema. The authors assessed 27 studies including 1,596 participants. Their results revealed that EPO failed to significantly increase improvement of eczema symptoms compared to placebo.



Breast pain in premenopausal women is common and it is thought that saturated fatty acid esters may cause mastalgia when circulating hormones induce hypersensitivity in breast epithelium. EPO may restore the balance between saturated and unsaturated fatty acids, decreasing sensitivity to steroidal hormones or prolactin.

A 2021 systematic review and meta-analysis in the *International Journal of Environmental Research and Public Health* by Adni and colleagues reviewed 13 trials and over 1,752 randomized patients. Results revealed that EPO has no significant difference in breast pain reduction or relief compared with placebo or other treatments. The authors wrote that current evidence is insufficient to recommend EPO for the treatments of atopic dermatitis, menopausal or premenstrual symptoms, diabetic neuropathy, or rheumatoid arthritis.

While consistent reports in the literature claim benefits from EPO for atopic dermatitis, psoriasis, asthma, and mastalgia, there is no significant data to prove the effectiveness of EPO for most clinical indications. Quality data are lacking and most published trials have methodologic limitations.

Dosage

EPO is generally obtained from cold pressing or solvent extraction from the seeds of the plant. Preparations are available as a topical moisturizing oil or capsules sold in 500 mg, 1,000 mg, and 1,300 mg dosages. In clinical trials evaluating atopic dermatitis, adult oral dosing ranged from 0.16 g to 0.64 g GLA per day, for 6 months.

What to tell your patients

While there is insufficient evidence to support the use of EPO for any health condition, EPO is considered safe and well-tolerated when taken in doses less than 6 g daily for up to a year.

Mild adverse effects may include upset stomach, nausea, diarrhea, and headache. Although EPO is considered safe for pregnant patients, taking EPO during the last weeks of pregnancy may delay labor. ■

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†IQVIA, ProVoice Survey: Latest 12 months rolling, ending Nov 2021.
‡U.S. News & World Report, Pharmacy Times, 2020-2021.

Patients with heart failure have a new treatment option

Lauren Howell, PharmD

After rejecting approval twice, FDA has approved Furoscix (ScPharmaceuticals), a therapy to treat heart failure that is administered by an on-body infusor. With more than 7 million heart failure patients in the United States, there is now an option for them to self-administer this treatment from the convenience of their own home.

Recommended dosage and how it works

Furoscix uses an on-body infusor to subcutaneously administer furosemide injection. It is indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. Furoscix is not indicated for emergency situations or in patients with acute pulmonary edema. Additionally, it is not intended to be used chronically and patients should be converted to an oral diuretic as soon as it is safe and practical to do so.

It is important to note that Furoscix is intended for use in a setting where the patient can limit their activity for the duration of administration.

The single use, on-body infusor is preprogrammed to deliver 30 mg of Furoscix over the first hour and then 12.5 mg per hour for the subsequent 4 hours. The injection is packaged in a single-dose prefilled cartridge that contains 80 mg per 10 mL and is copackaged with a single use on-body infusor. Furosemide acts by inhibiting the reabsorption of sodium and chloride in the proximal and distal tubules as well as in the loop of Henle, causing a high degree of diuresis.

Drug interactions

Furoscix should be avoided in combination with aminoglycoside antibiotics as there is an increased potential for ototoxicity when these medications are used together. Additionally, Furoscix should be avoided in combination with ethacrynic acid due to the risk of ototoxicity. There is a risk of salicylate toxicity when used in combination with salicylates.

If Furoscix is taken in combination with cisplatin and nephrotoxic drugs, there is a risk of both ototoxicity and nephrotoxicity. Coadministration with lithium can increase the risk of lithium toxicity. There is increased risk of hypotension and renal failure if Furoscix is administered with renin-angiotensin inhibitors.

Combination with adrenergic blocking drugs carries the risk of potentiation. Lastly, if Furoscix is used alongside drugs undergoing renal tubular secretion, there is a risk of toxicity potentiation.

Adverse effects and contraindications

Furoscix is contraindicated in patients with anuria, hypersensitivity to furosemide or medical adhesives, and hepatic cirrhosis or ascites. The most common adverse reactions during treatment with the Furoscix infusor were administration site and skin reactions such as erythema, bruising, edema, and infusion site pain. Patients should be monitored for fluid, electrolyte, and metabolic abnormalities.

Additionally, patients should be monitored for dehydration. Avoid higher than recommended doses of Furoscix and monitor for ototoxicity. Acute urinary retention has occurred in some cases so patients should be monitored for symptoms of urinary retention.

Patient counseling

Patients should be counseled on the potential for postural hypotension that sometimes occurs and informed that this can usually be managed by getting up slowly. Patients should be advised to let their health care provider know of any supplements that they are taking. Potassium supplements may be necessary to avoid hypokalemia.

Patients with diabetes should be notified that furosemide may increase blood glucose levels. Patients should also be advised that there is the potential for photosensitivity while taking furosemide. Hypertensive patients should be counseled on avoiding medications that may increase blood pressure such as OTC products for appetite suppression and cold symptoms.

Provide patients with administration instructions and counsel them on how to use the on-body infusor. It is important to note that Furoscix is intended for use in a setting where the patient can limit their activity for the duration of administration. Patients should inspect the prefilled cartridge prior to administration and should not use the Furoscix if the solution is discolored or cloudy. Furoscix should be a clear to slightly yellow color.

The prefilled cartridge should be loaded into the on-body infusor, and the cartridge holder should be closed. Then the patient should peel away the adhesive liner on the on-body infusor and apply onto a clean, dry area of the abdomen between the top of the beltline and the bottom of the ribcage that is not tender, bruised, red, or indurated. The distance from the top of the beltline to the bottom of the ribcage should be at least 2 ½ inches.

The injection is started by firmly pressing and releasing the blue start button. The patient should not remove the infusor until the injection is complete, which is signaled by a solid green status light and beeping sound. ■

Antidepressant use in pregnancy comes more into focus

Loren Bonner

Studying antidepressant use in pregnancy has led to an abundance of research, but without many answers. A large study recently published October 3, 2022, in *JAMA Internal Medicine* could hopefully offer some clarity—or at least add to the growing body of literature.

Researchers from Brigham and Women's Hospital and Harvard Medical School found that antidepressant use during pregnancy does not seem to increase the risk of neurodevelopmental disorders in children.

"While exposure to antidepressants in pregnancy may indicate that a child is at greater risk for neurodevelopmental disorders, our results provide evidence that it's not the antidepressant that is increasing the risk, but instead other factors associated with antidepressant use," said lead author Elizabeth Suarez, MPH, PhD.

The research team found that children exposed to antidepressants in utero had double the incidence of ADHD compared to children not exposed to antidepressants. "But our results show this likely isn't because of the antidepressant," said Suarez, who is now a faculty member at the Center for Pharmacoepidemiology and Treatment Science at the Rutgers Institute for Health, Health Care Policy and Aging Research in New Jersey. She said other factors related to antidepressant use—including the indication for the antidepressant, such as depression or anxiety, health and lifestyle considerations associated with depression and anxiety, or genetic and environmental causes, are probably responsible for the doubling risk of ADHD.

"Our study wasn't designed to determine what the true causal factor is, but it was striking to see this large difference in neurodevelopmental disorders," she said.

Once the researchers accounted for confounding, the potential increases in risk for neurodevelopmental disorders after antidepressant use in pregnancy almost disappeared.

The researchers used two large health care databases with data on publicly and privately insured pregnant individuals and their infants in the United States. A total of 1.93 million pregnancies from one database and 1.25 million pregnancies in another database were recorded. Children were followed from birth until outcome diagnosis, disenrollment, death, or end of study. The research team analyzed the data between August 2020 and July 2021.

Results were generally consistent for antidepressant classes and drugs and across exposure windows, too.

"We believe these results indicate that neurodevelopmental disorders are likely not a major risk to be concerned about when counseling pregnant patients on whether to use antidepressants in pregnancy."

Counseling

"Every decision to continue or start a medication in pregnancy is a balancing of risks and benefits," said Suarez. "We believe these results indicate that neurodevelopmental disorders are likely not a major risk to be concerned about when counseling pregnant patients on whether to use antidepressants in pregnancy." The American Psychiatric Association, along with the American College of Obstetricians and Gynecologists, advise women currently on medication for depression to always discuss with their health care provider the risks and benefits of staying on medication.

Potential risks of not treating depression during pregnancy include maternal suicide, inadequate prenatal care, poor maternal weight gain leading to low birthweight, risk of premature birth, marital or relational discord, and increased prenatal stress in the mother, which has been linked to effects on infant brain plasticity and cognition.

Study context

Several studies have attempted to clarify whether antidepressant exposure in utero increases the risk of neurodevelopmental disorders in children. Most of this research to date has focused on risks for ADHD and autism spectrum disorder.

"There was a lot of prior research in this area, but most of the results had been conflicting," said Suarez. Whether antidepressant exposure increases the risk of these childhood disorders remains controversial.

What makes their study stand out, according to Suarez, is its size.

"Our study was much larger than previous studies, allowing us to present results with a greater degree of precision. We also addressed confounding in multiple ways. Because of this, we believe our study is a valuable addition to existing evidence," Suarez said.

She noted that results of their study generally agree with other research that appropriately addressed confounding by the indication for the antidepressant, such as anxiety or depression.

They controlled for confounding by indication, environment, and genetics through various design and analytic approaches. ■

What medications can be taken with and without food?

Lauren Howell, PharmD

Many medications can be taken without regard to meals, but which ones need to be taken with food? What about those that have to be taken on an empty stomach to be effective? Taking some medications at the same time as eating can cause the medicine to not be absorbed optimally. In other situations, food can interact with the medicine and either increase or decrease the amount of drug that is available in the blood, causing it to either be dangerously abundant or in an amount that is too low to be effective.

These 11 medications may have interactions with food and are good to review when counseling patients.

1. Antibiotics

While not all antibiotics need to be taken on an empty stomach, several, including ampicillin, should be taken separately from certain foods, such as dairy products. To optimize absorption, these antibiotics should be taken with a full glass of water and 30 minutes before or 2 hours after meals.

2. Iron

Iron products are best absorbed when taken on an empty stomach. Ideally, they should be taken with water or fruit juice, 1 to 2 hours after a meal. However, in some patients, iron can cause stomach upset and may be taken with food to lower the chance of this adverse effect.

3. Statins

In the case of statins, not all food has to be avoided. Specific foods, such as grapefruit juice, can elevate the levels of the medication in the bloodstream and lead to symptoms of toxicity, such as myopathy.

4. Thyroid replacements

Thyroid medications, such as levothyroxine, should be taken without food to ensure that the medication is absorbed enough to be effective. Patients are often advised to take these medications first thing in the morning. Foods such as walnuts, high-fiber foods, and soybean flour, as well as drinks such as grapefruit juice, coffee, and milk have been shown to affect the absorption of these medications. For this reason, thyroid replacement medications should be taken 30 to 60 minutes before breakfast and should be separated from other medications by at least 4 hours, unless otherwise specified.

While not all antibiotics need to be taken on an empty stomach, several, including ampicillin, should be taken separately from certain foods, such as dairy products.

5. Bisphosphonates

This class of drug that is commonly used to treat osteoporosis can bind to some foods, antacids, and supplements in the stomach. For these medications, it is recommended to take doses at least 30 minutes to 1 hour before the first food, drink, or medication of the day. It is important to remind patients to drink a full glass of water with these medications to ensure that it moves to the stomach quickly and does not cause any damage to the esophagus.

6. Proton pump inhibitors

These medications work by preventing acid secretion in the stomach. Because food can signal acid production to begin, proton pump inhibitors need time to be absorbed and work before food is consumed in order to prevent acid secretion. Patients using these medications should take them 1 hour before meals. Of note, pantoprazole is the exception to this rule and works well with or without food.

7. Bethanechol

This medication is used to treat urinary retention and should be taken without food to prevent adverse effects, such as nausea and vomiting. Scheduling this medication correctly can require effort because it is often taken 3 or 4 times a day. It should be taken 1 hour before or 2 hours after meals.

8. Captopril

Captopril can be taken for a variety of conditions including hypertension, heart failure, and kidney problems in patients with diabetes. Taking captopril with food can decrease absorption, so it should be taken 1 hour before or 2 hours after meals.

9. Sildenafil

Some medications, such as sildenafil, do not have to be taken on an empty stomach but can work quicker when taken without food. In this case, high-fat foods specifically can increase the length of time before the medication takes effect.

10. Sucralfate

Sucralfate is used to treat intestinal ulcers and works by forming a protective coating over the ulcer. It needs to be taken at least 1 hour before or 2 hours after a meal so that it can coat the ulcer effectively. Other medications, such as antacids, can also lower the ability of sucralfate to coat the ulcer.

11. Digoxin

Serum concentrations of digoxin are decreased if taken with food. More specifically, fiber and pectin can decrease the absorption of this medication. ■

USPSTF recommends anxiety screening for youth

Johanna Taylor Katroscik, PharmD

The US Preventive Services Task Force (USPSTF) now recommends that children and adolescents should be screened for anxiety. The task force detailed this recommendation for children and adolescents between the ages of 8 and 18 years in an October 11, 2022, *JAMA* article. Data to support their recommendation came from a systematic review of evidence looking at whether screening children and adolescents for anxiety would benefit or harm this patient population.

The task force reviewed 10 studies (n = 3,260) to evaluate the accuracy of different tests used. These studies were considered to be of fair quality and looked at 12 different screening tools that are used to assess for anxiety disorders. The anxiety disorders that were screened for included generalized anxiety disorder, panic disorder, and social anxiety disorder. The review did not focus on other types of anxiety disorders, such as obsessive-compulsive disorder or post-traumatic stress disorder.

Additionally, the task force noted that the accuracy of the tools varied widely between studies when looking at different types of anxiety disorders.

Risk versus benefit in early screening

USPSTF believes that early screening for anxiety does have a moderate benefit to patients who are 8 to 18 years. Although there were no trials that directly assessed screening children or adolescents for anxiety disorders, the task force did look at trials that assessed treatment of these disorders. In doing so, they hoped to make a connection between the accuracy of the screening and the benefit of treatment.

Treatments in these studies included both cognitive behavioral therapy as well as pharmacotherapy. In the studies that were reviewed, pharmacotherapy showed a reduction of anxiety symptoms while cognitive behavioral therapy was associated with an improvement in overall outcomes. The potential risks of early screening were also not directly assessed. Rather, outcomes were reviewed by making connections between inaccurate screening or diagnosis that may have led to harm from treatment received. USPSTF did not find any statistically significant risks associated with screening children or adolescents for anxiety.

The reality of clinical practice

While USPSTF does recommend anxiety screening for children and adolescents, they have not made recommendations on which screening tools to use or how to implement screening into practice.

USPSTF recognizes there are gaps in available data. Some of the areas they believe need more research include looking at direct benefit or harm caused by screening, the accuracy of the screening tools that are used, and the ability to screen in different settings (including primary care).

USPSTF also notes that "Anxiety screening tools alone are not sufficient to diagnose anxiety. If the screening test is positive for anxiety, a confirmatory diagnostic assessment and follow-up is required." Although they don't go too deeply into this, it brings up a more important issue on how to triage a patient who has been screened for anxiety and will need follow-up care—a point that will be particularly important if screenings are conducted outside of primary care or other settings. ■

Summary of USPSTF rationale for screening patients ages 8–18

Detection	Adequate evidence shows that there are accurate screening tools for identifying anxiety in this patient population.
Benefits of early detection and intervention	There is no direct evidence of benefit on overall health outcomes for individuals screened but indirect evidence does suggest benefits for patients who receive either cognitive behavioral therapy or pharmacotherapy.
Harms of early detection and intervention	There is no direct evidence of harm to patients who are screened.
USPSTF assessment	Patients in this age range who are screened for anxiety may have improved health outcomes–screening is recommended.

Adapted from USPSTF. *JAMA*. 2022;328(14):1438–1444.

Quantifying the 'heroic' work of pharmacists during the pandemic

LOREN BONNER

Nearly 3 years have passed since COVID-19 upended the world and pharmacists' roles expanded. Now the time has come for that history to be documented. In a new research paper published in *JAPhA*, the contributions of pharmacists and their teams that took place as COVID-19 spread across the country have not only been recorded, but they have been quantified.

Reviewing published literature, relevant web pages, and queries to national and state professional pharmacy associations and government agencies, John Grabenstein, RPh, PhD, FAPhA, found that from February 2020 through September 2022, pharmacists and their teammates conducted over 42 million COVID-19 tests, provided over 270 million COVID-19 vaccinations within community pharmacy programs alone, and gave over 50 million influenza and other vaccinations per year.

"Pharmacists plausibly accounted for more than 50% of COVID-19 vaccinations in the United States," wrote Grabenstein in the research study.

In an interview with *Pharmacy Today*, Grabenstein said he did not expect that number to be so high. "We knew pharmacists helped, but this was half and it speaks to the volume," said Grabenstein, who is director for Scientific Communications at Immunization Action Coalition. "The convenience, access, and competence of pharmacists was important and bore out in this enormous percentage."

Findings from the research also point out that pharmacists prescribed, dispensed, and administered an "enormous" number of antibody products and antiviral medications, including care for 5.4 million inpatients and countless outpatients.

Using conservative estimates, interventions by pharmacists and their teams averted over 1 million deaths, over 8 million hospitalizations, and nearly $450 billion in health care costs, according to the study.

"This is the first peer-reviewed study that documents the incredible impact that pharmacy had on the health and well-being of our nation, across the entire spectrum of potential patient interventions," said Ilisa BG Bernstein, PharmD, JD, FAPhA, interim CEO and executive vice president of APhA. "There's only one conclusion to draw from this impressive report—the work of pharmacists during the pandemic has been heroic."

Start at the beginning

The study comprised data from pharmacists and pharmacy personnel from all practice settings: Community, ambulatory care, hospital inpatient, long-term care, academia, public health, and

others. Interventions within these practice settings ranged from prevention, treatment, and support to diagnostic testing, convalescent plasma, monoclonal antibodies, antiviral medications, supportive therapies, and, of course, vaccination.

Findings conclude that pharmacists and pharmacy personnel supplied more than 350 million clinical interventions to more than 150 million people via testing, parenteral antibodies, vaccinations, antiviral therapies, and inpatient care.

"The paper is organized in time," said Grabenstein, who is also president of Vaccine Dynamics. "The first thing pharmacists could do was deal with the crisis and the crush of extra patients."

As the virus spread quickly in early 2020, hospitals began to overflow and supply shortages were felt everywhere. Grabenstein wrote in the research study that the first priority for pharmacists was to continue providing prescription medications, medication therapy management, and consulting services for hundreds of millions of Americans each week.

Hospitals soon began to overflow and supply shortages were felt everywhere. "Pharmacists hastened to require extra distance between an increased volume of clients, arrange plexiglass barriers, and protect inventory. They moved scarce hand sanitizer, alcohol swabs, masks, thermometers, sterile water (for sleep-apnea devices), and other products behind the pharmacy counter to preclude hoarding," according to the study.

In the hospital setting, managing shortages amid workflow disruption was an ongoing effort.

According to an American Society of Health-System Pharmacists survey from 2021, 46% of U.S. hospital pharmacists increased intensive care unit bed capacity in 2020.

The study found that almost all had to change their usual pharmacy supply-chain acquisition processes. Hospitals experienced shortages of many medications, including asthma inhalers (60%), sedatives and anesthetic agents (58%), neuromuscular blockers (43%), corticosteroids (34%), cardiovascular agents (24%), investigational agents (24%), and dialysis solutions (6%). Medication-use changes were put in place by 86% of hospitals across the country, most commonly involving guidelines for COVID-19 treatment (79%) and opening compassionate use or investigational drug studies (55%). Shortages of personal protective equipment and other basic supplies compounded the struggle to continue care delivery, the study found.

COVID-19 testing

COVID-19 testing became available in April 2020, and the federal government gave pharmacists permission to order and administer FDA-authorized COVID-19 tests. The study found that pharmacists administered more than 42 million COVID-19 tests.

In April 2020, the federal government also formed a partnership with community pharmacies for pharmacist-based COVID-19 testing, integrating pharmacists into the Community-Based Testing Sites (CBTS) program. This began with 362 sites across 45 states and the District of Columbia.

The pharmacist-based components of the program grew quickly:

- By June 2020: 623 sites in 48 states, DC, and Puerto Rico (PR); >700,000 samples tested (cumulative).
- By January 2021: 3,300 sites in 50 states, DC, and PR; >5.6 million samples tested.
- By March 2021: 6,211 sites in 50 states, DC, and PR; >9.8 million samples tested.

In January 2021, HHS noted that more than 70% of pharmacy sites within the CBTS program were located in communities with moderate-to-high social vulnerability.

Under the PREP Act, not only did HHS authorize pharmacists to order or administer FDA-authorized COVID-19 tests, but also pharmacy interns and pharmacy technicians.

Convalescent plasma

Convalescent plasma—or passive immunization using preformed antibodies to prevent or ameliorate infection—came next when clinicians needed to find ways to treat the SARS-CoV-2 virus early on in the pandemic.

Grabenstein wrote that pharmacists in many hospitals contributed to multidisciplinary efforts to recruit plasma donors, harvest and process the plasma, and administer it to eligible patients. The Expanded Access Protocols (EAPs) for COVID-19 convalescent plasma eventually included more than 2,700 U.S. hospitals through August 2020. The EAPs were succeeded by an EUA issued by FDA in August 2020.

Convalescent plasma was short lived, however, due to several obstacles and regulatory hurdles. Plus, the availability of specific monoclonal antibody products from November 2020 onward offered therapeutic products in ready-to-use formulations with more standardized potency and a clearer basis of evidence, the study pointed out.

Monoclonal antibodies

Findings from the *JAPhA* study indicate that pharmacists provided more than 100,000 monoclonal antibody treatments for COVID-19, although Grabenstein noted that figure is probably an underestimate.

In November 2020, FDA issued EUAs for Lilly's bamlanivimab and Regeneron's casirivimab with imdevimab (also called REGEN-COV) for certain adult and pediatric patients with an elevated risk for severe COVID-19. Both products are administered by I.V. infusion.

Pharmacists at most U.S. hospitals stepped up to engage in patient selection, counseling, administration, and monitoring for this clinical service.

Grabenstein said he was particularly struck by one pharmacist at the University of Pittsburgh Medical Center who administered casirivimab/imdevimab as a set of 4 subcutaneous injections and led monoclonal treatments for more than 22,000 patients.

"These were the pharmacists who filled the needs of their hometowns," said Grabenstein during the interview with *Pharmacy Today.*

In the study, Grabenstein said statistics are interspersed with vignettes to help bring dry numbers to life.

Under the PREP Act, HHS authorized pharmacists to order and administer certain COVID-19 therapeutics, like monoclonal antibodies, by injection or I.V. infusion. They allowed pharmacy interns and pharmacy technicians to administer these products. Several states, including Arkansas, Mississippi, and Oregon, put in place statewide standing orders or protocols to allow pharmacists to independently order and administer casirivimab/imdevimab COVID-19 monoclonal antibodies.

Pharmacists and pharmacy personnel supplied more than 350 million clinical interventions to more than 150 million people via testing, parenteral antibodies, vaccinations, antiviral therapies, and inpatient care.

Later, subcutaneous or intramuscular injection products were suitable for administration by outpatient providers, including pharmacists. An Arkansas pharmacist, the study pointed out, who treated more than 300 patients this way reported that her patients had often been placed on waiting lists at nearby hospitals, but were able to receive the medication conveniently in her community practice. Overall, pharmacists administered monoclonal antibodies in community, inpatient, and nursing home settings.

COVID-19 vaccination

The federal government singled out pharmacists as critical partners in vaccinating the public from the get-go. In fact, HHS announced an initial plan in November 2020 to distribute vaccines through large community pharmacies as well as networks like Community Pharmacy Enhanced Services Network (CPESN) USA, which are high-performing pharmacies clustered together by state or region.

In the first few months of COVID-19 vaccine availability, pharmacists were the most frequent vaccinators at long-term care facilities, according to the study. Vaccination for residents and staff of long-term care facilities occurred first during the phased rollout plan beginning in December 2020 when FDA granted EUA status to mRNA vaccines.

In January 2021, the White House released updated vaccination plans featuring community pharmacies as prominent providers of COVID-19 vaccinations. The federal program developed into a partnership with 21 national pharmacy chains, independent pharmacy networks, and long-term care pharmacists offering COVID-19 vaccinations at more than 41,000 community and long-term care pharmacy locations across the country. Vaccine distribution through this channel began in February 2021 and accounted for a large piece of COVID-19 vaccinations across the board:

- Between mid-December 2020 and September 2022, pharmacists' teams administered more than 270 million doses of the COVID-19 vaccine.

These doses include 8.1 million doses administered onsite at long-term care facilities. During this interval, the total number of COVID-19 vaccinations reported across all 50 states and U.S. territories numbered 606 million.

- Through the Federal Retail Pharmacy Program alone, community pharmacists and their teammates delivered 45% of COVID-19 vaccinations across the United States, although that proportion has been higher or lower at specific points in time.
- Pharmacists within health systems often led their institutions' vaccination programs for workers and surrounding communities. Through August 2021, CDC officials reported that pharmacists had administered 3,203,104 vaccine doses at 11,449 mobile clinics across the country.
- Between October 2021, when the Pfizer–BioNTech pediatric COVID-19 vaccine received EUA status for children aged 5–11 years in the United States, and January 2022, pharmacists and their teammates administered 46.4% of doses to this pediatric age group. This included 48.7% of doses in areas of high social vulnerability and 44.4% in low social vulnerability index areas.

Under the PREP Act, HHS not only authorized pharmacists to provide COVID-19 vaccination, but also pharmacy interns and pharmacy technicians.

By the end of 2022, pharmacists and their teams are projected to have given over 300 million COVID-19 vaccinations. Visit CDC's website at www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html to see the most updated numbers.

Equitable COVID-19 vaccination and beyond

Roughly 70% of vaccinating pharmacies are located in communities with moderate-to-high social vulnerability. According to the study, pharmacy teams vaccinated a disproportionately greater share of non-Hispanic Asian and Hispanic or Latino individuals.

Grabenstein wrote that "Pharmacies collaborated with rideshare companies, deployed mobile vaccination units, and went door to door through underserved communities. Community pharmacies helped address the needs of those with limited mobility, such as the elderly or people with disabilities. In multiple instances, people opted to receive their second COVID-19 vaccine dose from local, trusted, and easy-to-access community pharmacies, rather than returning to a mass-vaccination clinic or another venue."

Pharmacy teams also filled a significant gap in vaccinating people against influenza and other vaccine-preventable diseases, the study found.

A CDC report released in May 2020 found that rates of childhood immunizations had sharply declined nationwide as a result of the pandemic.

In August 2020, HHS authorized pharmacists to provide all Advisory Committee on Immunization Practices (ACIP)–recommended vaccines to children aged 3 to 18 years during the COVID-19 public health emergency, regardless of state laws and regulations. Soon after, HHS issued federal guidance authorizing pharmacists to order and administer FDA-authorized or licensed COVID-19 vaccines to patients aged 3 years and older. The guidance applied to pharmacy intern administration of COVID-19 vaccines as well.

Antiviral prescribing

In the study, Grabenstein wrote that the next big advance was the availability of oral antiviral medications. In December 2021, FDA issued an EUA for Pfizer's Paxlovid (nirmatrelvir tablets co-packaged with ritonavir tablets), and an EUA for molnupiravir capsules (Lagevrio–Merck with Ridgeback Bio).

Recognizing the benefits of improving COVID-19 antiviral access and equity, FDA amended the Paxlovid EUA in July 2022 to allow skilled pharmacists with access to patient-specific information to order and prescribe this medication.

As this story went to press, pharmacists prescribing Paxlovid are still not being reimbursed for the associated clinical services required for prescribing. Pharmacists providing patient assessment and prescribing Paxlovid are currently requiring patients to self-pay for the service.

Grabenstein said that the research was conducted not only for pharmacists, but for those outside of the profession to realize what pharmacists are capable of. ■

THE ESSENTIAL ROLE OF PHARMACY IN RESPONSE TO COVID-19

Pharmacists and pharmacy team members contributed to America's health and recovery throughout the COVID-19 pandemic*

Pharmacists administered **290+ million COVID-19 vaccinations—more than half** of all COVID-19 vaccinations administered in the U.S.

From December 2020 – November 2022

Pharmacists provided 350+ million clinical interventions to 150+ million people

42+ MILLION COVID-19 TESTS CONDUCTED

100,000+ COVID-19 MONOCLONAL ANTIBODIES ADMINISTERED

1.3+ MILLION COVID-19 VACCINATIONS ADMINISTERED BY STUDENT PHARMACISTS

Located to serve the most vulnerable

70% of pharmacies are located within the most vulnerable communities in the U.S.

8.1 million COVID-19 vaccinations provided to LTC residents, leading to a 2/3 drop in COVID-19 related deaths

5.5+ million hospitalized patients received care from pharmacists

Pharmacists contributed to billions in savings

$900 BILLION

Health care cost savings by preventing 2.2 million deaths, 17 million hospitalizations, and 66 million infections through vaccinations performed between December 2020 and March 2022

$2.6 BILLION

Savings for Medicare beneficiaries by reducing hospitalizations through vaccinations performed between January and May 2021

*For specific data and dates, see Grabenstein JD. Essential services: Quantifying the contributions of America's pharmacists in COVID-19 clinical interventions. *JAPhA*. 2022;62(Nov-Dec):1929-1945.E1. doi.org/10.1016/j.japh.2022.08.010

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APhA

Out-of-pocket expenses for COVID-19 tests, treatments, and vaccines on horizon for patients

Clarissa Chan, PharmD

Once the COVID-19 public health emergency (PHE) is lifted, COVID-19 tests, treatments, and vaccines will no longer be "free" for all. Patients with private insurance, Medicare, and Medicaid may experience more cost-sharing, but patients who are underinsured or uninsured will be most affected.

"It's easy to see that there wasn't additional funding for testing and vaccination to offset provider costs to care for uninsured patients after the Provider Relief Fund was exhausted in March/April 2022," said Lisa Schwartz, PharmD, RPh, referring to a Kaiser Family Foundation timeline for federal support. A few funding bills in Congress have comprised funding in response to the COVID-19 pandemic.

"This has been a challenge for [pharmacists] and other testing and vaccine providers," said Schwartz, who is senior director of professional affairs at the National Community Pharmacists Association (NCPA).

Schwartz helped answer some pressing questions to prepare pharmacists and their communities for the changes ahead.

How will future changes to COVID-19 supply funding affect consumers?

Once vaccines and treatments are no longer purchased by the federal government, consumers will bear the cost—either with their health plan benefit (e.g., private insurance, Medicare, Medicaid) or out of their own pocket if they are uninsured.

"Consumers who have insurance will need to get vaccines from in-network providers rather than walking into any vaccine site," said Schwartz.

Medicare Advantage is already limiting vaccine administration fee reimbursement to in-network providers, but the current vaccine supplier agreement for U.S. government-owned vaccines prohibits out-of-network providers from charging patients with this type of coverage, said Schwartz.

Will the manufacturing, procurement, and pricing of supplies change?

"I expect that the overall effect of commercialization, manufacturing, procurement, and pricing for treatments, vaccines, and supplies will be more responsive to consumer demand and health plan utilization management (e.g., prior authorization)," said Schwartz. Overall, manufacturers make different business decisions when the federal government isn't the sole customer in the United States.

Two things that may be different are checking ahead that the vaccine provider is in-network for the insurance plan and making an appointment to be sure that the provider has the correct primary series or booster dose in stock.

Will insurance provide limited coverage for COVID-19 products?

Schwartz expects that employer-sponsored plans, marketplace plans, Medicaid-managed care plans, and Medicare PDP and Advantage plans will use traditional utilization management tools to encourage formulary compliance if the plan has preferred products in the vaccine or treatment categories.

The cost of treatments such as monoclonal antibodies and oral antivirals will depend on plan deductibles, cost-sharing, and formulary tiers, according to Schwartz.

Will COVID-19 vaccines be 100% covered like most vaccines?

"Everything I hear points to the COVID-19 vaccine being covered at $0 copay just like most other vaccines," said Schwartz.

Two things that may be different are checking ahead that the vaccine provider is in-network for the insurance plan and making an appointment to be sure that the provider has the correct primary series or booster dose in stock, Schwartz said.

NCPA is working with other pharmacy associations to ensure that pharmacy interns and certified technicians continue to have the opportunity to administer vaccines.

How can pharmacists help people adjust to COVID-19 cost-sharing changes?

Patients have been mostly satisfied with the shift from walk-in to appointment-based vaccine services at the pharmacy. Vaccine appointments give the pharmacy staff time to verify eligibility and coverage, and check for other vaccination gaps that could be addressed during the same appointment.

Coverage and reimbursement for treatments such as oral antiviral drugs are more wait-and-see.

"The emergency use authorization allows pharmacists to prescribe Paxlovid, but I don't expect that will be part of the new drug application approval," said Schwartz. "Pharmacy-based test-to-treat will revert to pharmacist scope of practice and whether the state practice act allows or would require a collaborative practice agreement with a prescriber will remain to be seen."

Antiviral prescriber access in some states will shrink, so review dispensing records now for a potential collaborating prescriber if there is uncertainty that pharmacies will offer test-to-treat after the PHE expires, cautioned Schwartz. ■

Rationing common among insulin users, study finds

Sonya Collins

A research report published November 15, 2022, in *Annals of Internal Medicine* confirms what many dispensing pharmacists know all too well through firsthand experience: Insulin rationing is common among adults with type 1 or type 2 diabetes.

Among the 982 insulin users surveyed, 1 in 6 reported rationing insulin. Study participants represent more than 7 million U.S. adults living with diabetes of whom an estimated 1.3 million ration insulin.

"This isn't just happening with insulin," said Wendy Mobley-Buckstein, PharmD, CDCES, who wasn't involved with the report. "With all medications, especially those for chronic diseases, we are seeing people trying to stretch them."

The study findings

The study by Gaffney and colleagues defined rationing as patients having done any of the following to save money in the last 12 months: Skipping a dose, taking less insulin than needed, or delaying buying insulin. Rationing was common across all insulin users, but some were more likely to ration than others.

According to the study, adults under 65 were twice as likely as their older counterparts to stretch out their insulin supply. Middle-income patients were more likely than high- or low-income patients to ration. Nearly 1 in 4 Black patients rationed compared to 1 in 6 white and Hispanic patients. Nearly 1 in 3 uninsured adults rationed, followed by those with private insurance, and then those on Medicare or Medicaid.

Delaying purchase was the most common form of rationing across all users. Among those with type 1 diabetes, taking less insulin than needed was the most common way to make the supply go further. Across subsets of patients, insulin rationing was associated with feeling overwhelmed by the demands of living with diabetes.

Help is on the way—for some

The Inflation Reduction Act, which would limit insulin copays to $35 per month for Medicare beneficiaries, would improve access for seniors, among whom about one in nine reported rationing. The legislation will not, however, protect the privately insured or the uninsured.

"The commercial insurance companies are the ones we're going to have to lobby individually to get those copay caps," said Mobley-Buckstein, who is an associate professor of pharmacy practice at Drake University in Des Moines, IA. "A lot of organizations are lobbying for that in their states."

Message for pharmacists

Until patients get relief from state or federal legislation, pharmacists can expect insulin rationing to continue. Counseling on the dangers of underutilizing insulin may help.

"There are so many different complications that can arise from not taking insulin, but I don't think people realize that," Mobley-Buckstein said.

She recommends reviewing the risks—which include disease progression, sores, amputation, loss of eyesight, kidney failure, heart attack, and stroke—with patients who may be rationing.

Pharmacists may also point patients to resources that might make insulin more affordable for them.

Federally qualified health centers, and other 340B entities, offer insulin at a lower cost to eligible patients, such as those in the Medicare "donut hole."

"We take an oath to help our patients," Mobley-Buckstein said, "so if that means taking a few extra minutes to help a patient find an affordable way to get their insulin, then that's what we need to be doing." ■

Financial aid for prescription drugs

Patient assistance programs may help commercially insured patients afford their insulin. The following websites offer information on various financial aid programs to help patients pay for prescription drugs:

- American Diabetes Association Insulin Help (insulinhelp.org)
- Medicine Assistance Tool (medicineassistancetool.org)
- Needy Meds (needymeds.org)
- RxAssist Patient Assistance Program Center (www.rxassist.org)

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PHARMACISTS' PICKS OF THE TOP SELF-CARE PRODUCTS

Pharmacy Today proudly presents APhA's Self-Care Product Survey. Conducted using scientifically valid methodology, the survey determines those nonprescription products most often recommended by pharmacists in the United States to consumers.

The winners were selected based on a survey of 1,682 pharmacists practicing in the United States who gave their unaided write-in opinions on which brands they'd recommend to patients in 86 categories. The highest share of citations as Most Trusted in the category determined the winner. If the margin of citation share between the leading brands did not exceed the estimate of sampling error at 90% statistical confidence, a tie was declared.

Please also see APhAs *Handbook of Nonprescription Drugs,* the definitive source of professional information about OTC products. The Handbook is available in print in the bookstore at pharmacist.com and online at PharmacyLibrary.com.

The n listed is the total number of responding pharmacists' recommendations for each product category. These data may not be used without the prior permission of the American Pharmacists Association.

Cough, cold, and allergy

Allergic reaction treatment (Adult) (n = 554)

Benadryl	67%
Zyrtec	6%
Claritin	2%
Cortizone 10	1%
Walgreens	1%

Nasal decongestant spray (n = 555)

Afrin	43%
Flonase	21%
Vicks Sinex	2%
Sudafed	2%
Ocean	1%

Adult cough suppressant — Topical treatments (n = 590)

Vicks VapoRub	32%
Delsym	11%
Robitussin	9%
Chloraseptic	4%
Halls	4%

Sinus rinse (n = 645)

NeilMed	33%
Neti Pot kit	13%
Ocean	8%
Navage	2%
Ayr	1%

Cough lozenges (n = 509)

Halls	38%
Cepacol	18%
Ricola	15%
Ludens	3%
Fisherman's Friend	2%

Liquid cough suppressant (dry cough) (n = 587)

Delsym	43%
Robitussin	24%
Mucinex	6%
Vicks Dayquil Nyquil	2%
Walgreens	0%

Cold medication (n = 510)

Vicks Dayquil Nyquil	25%
Tylenol	11%
Mucinex	9%
Robitussin	8%
Sudafed	5%

Cough, cold, and flu medication (n = 587)

Vicks Dayquil Nyquil	27%
Mucinex	15%
Robitussin	12%
Tylenol	8%
Sudafed	5%

Adult seasonal allergy relief (n = 635)

Zyrtec	34%
Claritin	27%
Allegra	13%
XYZAL	3%
Flonase	3%

Cough medication (n = 598)

Robitussin	30%
Delsym	30%
Vicks Dayquil Nyquil	4%
MucinexDM	2%
CVS Health	1%

Flu medication (n = 598)

Theraflu	19%
Vicks Dayquil Nyquil	14%
Tylenol	11%
Mucinex	4%
Alka-Seltzer Plus	2%

Liquid cough expectorant (n = 561)

Robitussin	37%
Mucinex	31%
Delsym	8%
Vicks Dayquil Nyquil	1%
Equate	1%

Sore throat lozenges (n = 655)

Cepacol	34%
Halls	21%
Chloraseptic	8%
Ricola	8%
Sucrets	3%

Diagnostics

Blood pressure monitors (n = 646)

Omron	42%
Walgreens	4%
CVS Health	2%
FreeStyle	2%
ReliON	1%

Lancets (n = 487)

OneTouch	27%
FreeStyle	9%
Accu-Check	8%
BD	5%
ReliON	3%

Blood glucose monitoring (n = 600)

OneTouch	27%
FreeStyle	17%
Accu-Check	9%
Dexcom	5%
Contour Next	4%

Digital thermometer (n = 466)

Braun	10%
Vicks	10%
BD	3%
Walgreens	2%
Omron	2%

Ears, eyes, nose, and throat

Eye drops for allergies (n = 540)

Alcon (Pataday/Zaditor)	51%
Visine	9%
Bausch + Lomb	7%
Refresh	3%
Clear Eyes	2%

Snoring cessation aids (n = 431)

Breathe Right	32%
Nicorette	1%
CVS Health	1%
SleepRight	1%

Eye drops for redness (n = 636)

Visine	42%
Alcon (Systane)	12%
Clear Eyes	10%
Refresh	4%
Lumify	3%

Snoring treatment (n = 460)

Breathe Right	30%
CPAP	1%
SnoreStop	1%
Walgreens	1%
Smart Nora	1%

Contact lens solution (n = 529)

Bausch + Lomb	37%
Alcon	19%
Boston	2%
Acuvue	1%
Equate	1%

Ear ringing treatment (Tinnitis) (n = 454)

Lipo-Flavonoid	16%
Similasan	4%
Hyland's	1%
CVS Health	1%
Sundown Naturals	1%

Earache relief (n = 463)

Similasan	14%
Debrox	7%
Hyland's	6%
Tylenol	3%
Motrin IB	2%

Water-blocked ear treatment (n = 531)

Swim Ear	21%
Debrox	16%
Auri-Dri	6%
Walgreens	1%
CVS Health	1%

Eye drops for dry eyes (n = 547)

Alcon (Systane)	25%
Refresh	23%
Visine	11%
Clear Eyes	4%
TheraTears	3%

Family planning

Emergency contraceptive pill (n = 595)

Plan B	64%
My Way	2%
Take Action	2%
Aftera	1%
Ella	1%

Ovulation test (n = 565)

Clearblue	25%
First Response	6%
e.p.t.	1%
One Step	1%
CVS Health	1%

Prenatal vitamins (n = 509)

Nature Made	16%
One A Day	12%
Stuart Prenatal	4%
Nature's Bounty	3%
Centrum	2%

Pregnancy testing (n = 628)

Clearblue	26%
First Response	23%
e.p.t.	5%
CVS Health	1%
Equate	1%

First aid

First aid bandages (n = 551)

Band-Aid	70%
Nexcare	3%
Walgreens	2%
CVS Health	1%
Equate	1%

Sunburn relief (n = 621)

Solarcaine	13%
Banana Boat	6%
Demoplast	5%
Alocane	2%
Sun Bum	2%

Burn treatment (n = 468)

Neosporin	11%
Solarcaine	7%
Alocane	5%
CVS Health	1%
Foille	1%

Insect bite/Sting relief (n = 592)

Benadryl	15%
After Bite	13%
Cortizone 10	10%
Off	3%
StingEze	3%

Gastrointestinal

Lactose digestive aids (n = 585)

Lactaid	67%
Schiff Digestive Advantage	1%
Walgreens	1%
Equate	1%
Kirkland	1%

Diarrhea relief (n = 618)

Imodium	66%
Pepto Bismol	9%
Kaopectate	1%
CVS Health	1%
Equate	1%

Gas relief (n = 572)

Gas-X	61%
Mylicon	7%
Phazyme	2%
Gasex	2%
Beano	1%

Hemorrhoid relief (n = 571)

Preparation H	61%
Tucks	7%
Anusol	3%
CVS Health	1%
Walgreens	1%

Upset stomach relief (n = 564)

Pepto Bismol	52%
Tums	10%
Pepcid Complete	4%
Maalox	3%
Emetrol	3%

Fiber supplements (n = 629)

Metamucil	48%
Benefiber	12%
FiberCon	6%
Fiber One	2%
Citrucel	1%

Stool softener (n = 545)
Colace 48%
Dulcolax 12%
Walgreens 2%
CVS Health 2%
Senna-S 2%

Heartburn relief (n = 575)
Tums 35%
Pepcid 18%
Prilosec OTC 8%
Nexium 4%
Mylanta 3%

Laxative (n = 560)
MiraLAX 25%
Dulcolax 23%
Senokot 7%
Colace 6%
Ex-Lax 3%

Nausea treatment/Relief (n = 591)
Dramamine-N 20%
Emetrol 19%
Pepto Bismol 10%
Bonine 4%
Nauzene 3%

Oral care

Toothpaste for sensitivity (n = 591)
Sensodyne 72%
Crest 6%
Colgate 6%
Sensodyne Pronamel 1%
Arm & Hammer 1%

Cold sore relief (n = 574)
Abreva 64%
Orajel 3%
Carmex 2%
Herpecin-L 2%
Campho-phenique 1%

Dry mouth relief (n = 619)
Biotene 52%
XyliMelts 3%
Therabreath 1%
ACT 1%
Good Neighbor Pharmacy 1%

Oral pain relief (n = 610)
Orajel 50%
Anbesol 8%
Tylenol 6%
Advil 3%
Motrin 2%

Sore gum relief (n = 464)
Orajel 41%
Anbesol 12%
G.U.M. 1%
Colgate 1%
DenTek 1%

Denture cleaner (n = 500)
Polident 21%
Efferdent 10%
Fixodent 2%
Colgate 1%
CVS Health 1%

Denture adhesive (n = 482)
Fixodent 17%
Polident 10%
Super Poligrip 9%
Sea-Bond 4%
PreviDent 1%

Pain and inflammation

Migraine headache products (n = 564)
Excedrin Migraine 53%
Tylenol 7%
Advil Migraine 5%
Motrin IB 2%
Aleve 1%

Headache relief (n = 549)
Excedrin 26%
Tylenol 25%
Advil 16%
Aleve 6%
Motrin 5%

Back pain relief (n = 553)
Aleve 13%
Advil 9%
Salonpas 9%
Tylenol 7%
Motrin IB 6%

Pediatrics

Children's cough, cold, and flu (n = 488)
Children's Mucinex 15%
Children's Dimetap 12%
Children's Tylenol 11%
Children's Robitussin 10%
ZarBee's Naturals 3%

Children's allergic reaction treatments (n = 556)
Children's Benadryl 63%
Children's Claritin 7%
Children's Zyrtec 6%
CVS Health 1%
Equate 1%

Children's multivitamins (n = 556)
Flintstones 38%
Centrum 5%
One A Day Kids 4%
L'il Critters 3%
OLLY 2%

Children's topical cough suppressant (n = 507)
Vicks VapoRub 33%
Children's Delsym 7%
Children's Robitussin 6%
Children's Mucinex 2%
ZarBee's Naturals 2%

Colic relief (n = 491)
Mylicon 13%
Little Remedies 4%
Gerber 3%
Hyland's 2%
Mylanta 1%

Children's seasonal allergies (n = 567)
Children's Claritin 36%
Children's Zyrtec 30%
Children's Benadryl 5%
Children's Allegra 4%
Children's Flonase 1%

Sunscreen for kids (n = 584)
Coppertone 21%
Banana Boat 14%
Neutrogena 12%
Aveeno Baby 6%
Blue Lizard 2%

Children's cough medication (n = 562)
Children's Delsym 21%
Children's Robitussin 16%
Children's Mucinex 9%
Children's Dimetapp 9%
ZarBee's Naturals 6%

Children's cold medication (n = 543)
Children's Dimetapp 18%
Children's Tylenol..... 14%
Children's Mucinex 11%
Children's Robitussin..... 6%
Zarbee's Naturals..... 4%

Supplements

Adult multivitamin (n = 588)
Centrum 43%
One A Day..... 17%
Nature Made..... 7%
Vitafusion..... 2%
Nature's Bounty 1%

Memory support supplement (n = 497)
Prevagen 30%
Neuriva..... 4%
Nature Made..... 2%
Focus Factor..... 1%
Nature's Bounty 1%

Menopause supplement (n = 473)
Estroven 24%
Nature Made..... 2%
Nutrafol 1%
Nature's Bounty 1%
Walgreens 1%

Vitamin D supplement (n = 581)
Nature Made..... 30%
Nature's Bounty 10%
CVS Health 2%
Spring Valley 2%
Kirkland..... 1%

Joint supplement (n = 598)
Osteo Bi-Flex..... 23%
Schiff Move Free..... 6%
Cosamin DS 4%
Nature Made..... 3%
Kirkland..... 2%

Omega-3 supplement (n = 497)
Nature Made..... 20%
Nature's Bounty 7%
MegaRed 3%
Nordic Naturals..... 3%
CVS Health 2%

Probiotic supplement (n = 578)
Culturelle 24%
Align Probiotic 11%
Florastor..... 9%
Florajen 8%
Nature Made..... 2%

Weight loss aid (n = 457)
Alli 13%
Hydroxycut..... 2%
Slimfast..... 2%
Diurex..... 1%
Align 1%

Immune system booster (n = 526)
Emergen-C 21%
Airborne 11%
Nature Made..... 3%
Zicam 3%
Nature's Bounty 2%

Vitamin C supplement (n = 557)
Nature Made..... 23%
Emergen-C 15%
Nature's Bounty 6%
CVS Health 3%
Walgreens 2%

Eye vitamins (n = 572)
PreserVision..... 26%
Ocuvite 21%
Bausch + Lomb 3%
Icaps..... 2%
Nature Made..... 1%

Magnesium supplement (n = 586)
Nature Made..... 21%
Mag-Ox 400 ..... 17%
SlowMag MG 5%
Nature's Bounty 4%
CVS Health 2%

Iron supplement (n = 584)
Nature Made..... 16%
Feosol..... 14%
Slow Fe..... 9%
Nature's Bounty 3%
Walgreens 3%

Calcium supplement (n = 636)
Nature Made..... 13%
Caltrate..... 13%
Citracal 12%
Os-Cal..... 11%
Tums..... 3%

Topicals

Scar treatment (n = 548)
Mederma..... 49%
ScarAway 2%
Bio-Oil 2%
CeraVe 1%
Cicatricure..... 1%

Lice treatment (n = 498)
Nix 49%
RID 13%
Walgreens 1%
Skilice..... 1%
Licefree Spray..... 1%

Topical pain relief (n = 527)
Voltaren..... 26%
Aspercreme..... 10%
Icy Hot..... 7%
BIOFREEZE..... 6%
Salonpas 6%

Athlete's foot treatment (n = 535)
Lotrimin..... 30%
Lamisil..... 19%
Tinactin 10%
Dr. Scholl's..... 2%
CVS Health 2%

Stretch mark treatment (n = 472)
Mederma..... 18%
Palmer's 11%
Bio-Oil 7%
Mother's Friend..... 1%
Equate 1%

Sunscreen (n = 567)
Neutrogena 23%
Coppertone 18%
Banana Boat..... 10%
Sun Bum..... 3%
Aveeno..... 2%

Toe/Foot/Nail antifungal treatment (n = 453)
Lotrimin..... 16%
Lamisil..... 14%
Fungi Nail 6%
Tinactin 4%
Kerasal 4%

Eczema relief (n = 504)
Aveeno..... 14%
Eucerin 14%
CeraVe 9%
Aquaphor..... 3%
Gold Bond 2%

Women's health

Yeast infection treatment (n = 632)
Monistat..... 58%
AZO 4%
Diflucan One..... 1%
Walgreens 1%
CVS Health 1%

UTI prevention (n = 474)
AZO 49%
Cystex..... 2%
Uristat Ultra..... 1%
Monistat..... 1%
UTI-Stat..... 1%

Other

Incontinence products (n = 516)
Depend..... 32%
Poise..... 7%
Always..... 2%
TENA 2%
Walgreens 1%

Sleep aid (n = 568)
Unisom..... 23%
Benadryl..... 11%
Vicks ZzzQuil..... 7%
Nature Made..... 2%
Sominex 2%

Smoking cessation (n = 600)
Nicorette 32%
NicoDerm 23%
Nicotrol..... 3%
CVS Health 2%
Equate 1%

Court rules that pharmacy information sheets fulfill duty to warn

David B. Brushwood, BSPharm, JD

A Connecticut court recently issued a ruling that places an otherwise "ordinary" pharmacist duty to warn case into the category of "interesting."

Background

A patient's dentist prescribed ondansetron, clarithromycin, and meclizine after the patient complained of vertigo. These prescriptions were accurately processed at the pharmacy. The pharmacy provided no verbal counseling related to a drug–drug interaction between ondansetron and clarithromycin. The pharmacy did, however, provide the patient with written information about the drugs.

The patient used the medications as directed for 4 days, after which he was found to be "unresponsive, sweating, and having difficulty breathing." The patient was transported to a hospital where he was pronounced dead. The patient's estate filed a lawsuit claiming that alleged negligence by the dentist and the pharmacy resulted in the patient's death due to the interaction of ondansetron and clarithromycin.

The pharmacy moved for dismissal of the case, arguing that there was no duty to warn the patient of the drug–drug interaction. Alternatively, the pharmacy argued that even if a duty to warn existed, that duty had been fulfilled by providing information sheets to the patient describing the possible drug–drug interaction.

Rationale

The court first referred to the established legal precedent that there is "no generalized duty" for pharmacists to warn every patient of every possible risk of every medication. The court then considered 3 commonly recognized exceptions to this precedent of "no generalized duty" to warn.

The first exception applies when a pharmacist has "specific knowledge of potential harm to specific persons in a particular case." This exception most frequently arises when a patient has a drug allergy that is known to a pharmacist and the pharmacist dispenses medication without addressing the allergy. The court held that this drug–drug interaction case did not qualify for the first exception.

The court ruled that "the warnings provided by [the pharmacy] were more than adequate to satisfy a duty to warn."

The second exception occurs when a pharmacist "makes a representation that they will engage in a process of evaluation of the possible side effects caused by the administration of a drug or a combination of drugs." There was evidence that the dispensing pharmacist had contacted the dentist to discuss the prescribed medications. The plaintiffs contended that this consultation triggered the second exception to the "no generalized duty" to warn rule. The court disagreed, ruling that "communication by a pharmacist with a physician does not create a duty for the pharmacist to provide information to the patient."

The third exception is recognized by courts when "there is something patently and obviously wrong with the prescription itself," such as a "fatal dose" or an "absolute contraindication." The court noted that there were no allegations of any such facts in the drug–drug interaction case, and the third exception was rejected.

The court then turned to the pharmacy's alternative argument that the duty to warn, if there was a duty, had been fulfilled. The court said that the information sheets provided by the pharmacy to the patient with both ondansetron and clarithromycin stated that the medications "may cause a condition that affects the heart rhythm (QT prolongation)" and that "the risk of QT prolongation may be increased if you have certain medical conditions or are taking other medications that may cause QT prolongation."

The court ruled that "the warnings provided by [the pharmacy] were more than adequate to satisfy a duty to warn."

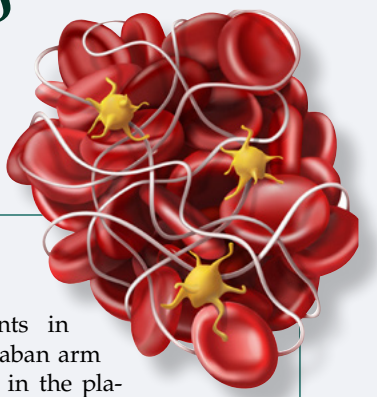
The case against the pharmacy was dismissed.

Takeaways

As a matter of practice, the best approach may be for pharmacists to both verbally counsel patients and to provide patients with a drug information leaflet. As a matter of law, this case suggests that the information leaflet, by itself, may meet the pharmacist's duty to warn.

Providing patients with drug information leaflets (what FDA calls "Written Consumer Medication Information" or "CMI") is not only effective patient care, but also a useful risk management tool. ■

Inpatient*Insights*

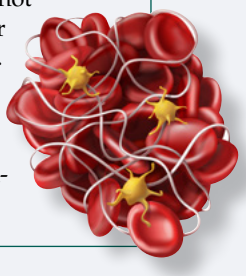


Extended rivaroxaban treatment could reduce risk of recurrent venous thromboembolism

The optimal duration of treatment for symptomatic isolated distal deep vein thrombosis (DVT) remains controversial. A recent study published on November 23, 2022, in *the BMJ* used a randomized, double blind, placebo-controlled clinical trial at 28 outpatient clinics in Italy specializing in venous thromboembolism to compare two different treatment durations of rivaroxaban in patients with symptomatic isolated distal DVT. After receiving standard dose rivaroxaban for 6 weeks, participants were randomly assigned to receive rivaroxaban 20 mg or placebo once daily for an additional 6 weeks. The primary outcome was recurrent venous thromboembolism during follow up, defined as the composite of progression of isolated distal DVT, recurrent isolated distal DVT, proximal DVT, symptomatic pulmonary embolism, or fatal pulmonary embolism.

The primary outcome occurred in 23 (11%) patients in the rivaroxaban arm and 39 (19%) in the placebo arm while recurrent isolated distal DVT occurred in 16 (8%) patients in the rivaroxaban arm and 31 (15%) in the placebo arm. Proximal DVT or pulmonary embolism occurred in 7 (3%) patients in the rivaroxaban arm and 8 (4%) in the placebo arm. No major bleeding events occurred.

The researchers noted that their findings do not apply to patients with cancer-associated isolated distal DVT, who were excluded from the study, and should not be extrapolated to other anticoagulant treatments. Additional investigation is needed to identify low-risk patients who may not require anticoagulant treatment. ■



Adding oral antimicrobial prophylaxis decreases surgical site infection

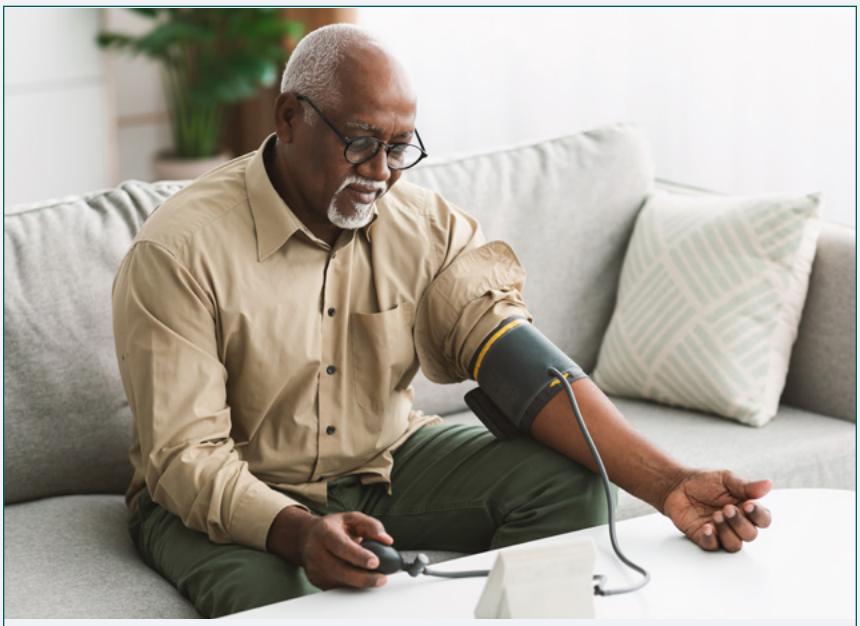
Surgical site infection is among the most common hospital infections, and patients who undergo colorectal surgery are particularly at risk, with reported incidence rates of up to 26%. In a paper published in *the BMJ* on November 3, 2022, members of the COMBINE study group, representing 11 university and non-university hospitals in France, investigated the ability of oral antimicrobial prophylaxis as an adjunct to the standard I.V. antibiotic prophylaxis to reduce surgical site infections after elective colorectal surgery.

The multicenter, randomized, double blind, placebo-controlled trial involved 926 adult patients scheduled for elective colorectal surgery in French hospitals between May 25, 2016, and August 8, 2019. Patients were randomized to receive either a single 1-g dose of ornidazole or a placebo orally 12 hours before surgery in addition to the I.V. antimicrobial prophylaxis.

The primary outcome was the proportion of patients with surgical site infection within 30 days after surgery. Secondary outcomes included individual types of surgical site infections and major postoperative complications (Clavien-Dindo classification grade 3 or higher) within 30 days after surgery.

Surgical site infection within 30 days after surgery occurred in 60 (13%) of the patients in the oral prophylaxis group and in 100 (22%) of patients in the placebo group. The proportion of patients with deep infections was 4.8% in the oral prophylaxis group and 8.0% in the placebo group, while the proportion of patients with organ space infections was 5.0% in the oral prophylaxis group and 8.4% in the placebo group. Major postoperative complications occurred in 9.1% patients in the oral prophylaxis group and 13.6% in the placebo group.

The authors concluded that compared with those receiving a placebo, participants who received oral prophylaxis had a 40% lower relative risk of surgical site infection and lower rates of other secondary outcomes, including a 33% lower relative risk of major postoperative surgical complications. They believe that their findings suggest that the effect of oral prophylaxis versus placebo was attributed primarily to a reduction in the rates of deep and organ space surgical site infections. ■



Baxdrostat shows promise for treatment-resistant hypertension

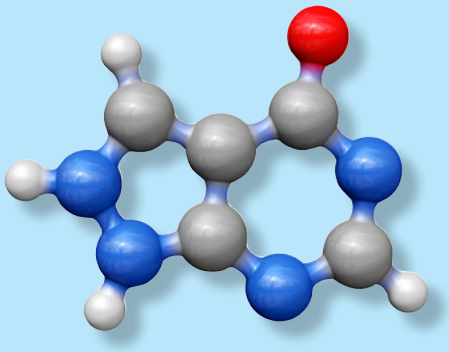
Treatment-resistant hypertension, defined as elevated BP despite concurrent use of at least 3 antihypertensive drugs of different classes, including a diuretic, affects an increasing number of patients each year. These patients have a substantially increased risk of cardiovascular adverse events.

According to the authors of a recent paper in the *New England Journal of Medicine*, aldosterone synthase inhibitors could target treatment resistance by suppressing hormone synthesis. To explore this avenue of treatment, the researchers examined the efficacy and safety of baxdrostat in patients with treatment-resistant hypertension.

In the multicenter, placebo-controlled trial, patients who had treatment-resistant hypertension, with BP of 130/80 mm Hg or higher, and who were receiving stable doses of at least 3 antihypertensive agents, including a diuretic, were randomly assigned to receive baxdrostat (0.5 mg, 1 mg, or 2 mg) once daily for 12 weeks or a placebo. The primary endpoint was the change in systolic BP from baseline to week 12 in each baxdrostat group as compared with the placebo group.

Results of the study, published online on November 7, 2022, indicated dose-dependent changes in systolic BP of –20.3 mm Hg, –17.5 mm Hg, –12.1 mm Hg, and –9.4 mm Hg in the 2-mg, 1-mg, 0.5-mg, and placebo groups, respectively. No deaths occurred during the trial, no serious adverse events were attributed by the investigators to baxdrostat, and there were no instances of adrenocortical insufficiency.

The authors concluded that further phase 3 trials involving more patients over a longer period are needed to confirm that the selective action of baxdrostat may avert the risk of inducing adrenal insufficiency and the loss of BP–lowering efficacy that can result from the accumulation of mineralocorticoid receptor–activating steroid precursors seen with first-generation aldosterone synthase inhibitors. ■



Lower initial doses of allopurinol could be beneficial for older adults with CKD

Allopurinol, a xanthine oxidase inhibitor, decreases the amount of uric acid produced by the body, is used to treat gout, kidney stones, and high uric acid levels caused by cancer medicines. According to a recent study published in the December issue of the *American Journal of Kidney Diseases*, initial doses of allopurinol should be started at low doses in patients with chronic kidney disease (CKD) to avoid adverse effects.

The researchers examined the risk of severe cutaneous reactions in older adults with CKD who were newly prescribed allopurinol at varied doses using a population-based cohort study with linked health care databases. They studied the records of more than 47,000 patients in Ontario, Canada between 2008 and 2019 who were more than 66 years old and had an estimated glomerular filtration rate of <60 mL/min/1.73 m^2, and who were new users of allopurinol.

The primary outcome was a hospital visit with a severe cutaneous reaction within 180 days of starting allopurinol. Secondary outcomes included all-cause hospitalization and all-cause mortality.

The results of the study showed that 55% of the studied patients started allopurinol at >100 mg/day, which was associated with an increased risk of a severe cutaneous reaction as well as an increased risk of all-cause hospitalization but not all-cause mortality.

The authors concluded that older patients with CKD were twice as likely to visit a hospital with a severe cutaneous reaction within 180 days if their initial dose was more than 100 mg/day and suggest that these patients should be started at low doses of allopurinol. ■

What proportion of individuals experienced common long COVID symptom clusters?

Mariecus CM Jarvis-Mays, PharmD, MEd

In an effort to better understand and diagnose long COVID, researchers of a new study published October 10, 2022, in *JAMA* looked at the proportion of individuals who experienced common self-reported long COVID symptom clusters 3 months after initial symptomatic SARS-CoV-2 infection in 2020 and 2021.

Approximately 6.2% of individuals who had symptomatic SARS-CoV-2 infection experienced at least 1 of 3 long COVID symptoms clusters after adjusting for health status before SARS-CoV-2 infection. A total of 51.0% had persistent fatigue with bodily pain or mood swings; 60.4% had ongoing respiratory problems, and 35.4% had cognitive problems.

The estimated mean duration of long COVID was 9 months among hospitalized individuals and 4 months among non-hospitalized individuals and occurred in 27.5% and 5.7% of individuals, respectively. Of those admitted to ICUs, 43.1% experienced long COVID. An estimated 15.1% of individuals meeting long COVID criteria continued to experience symptoms 12 months after initial infection. Researchers also noted that symptom clusters were more common in women than men.

Trial design and overview

The three common clusters studied were persistent fatigue with bodily pain or mood swings; cognitive problems (forgetfulness or difficulty concentrating, commonly referred to as brain fog); and ongoing respiratory problems (shortness of breath and persistent cough as the main symptom).

The main outcome was proportion of individuals with at least 1 of the 3 self-reported long COVID symptom clusters 3 months after SARS-CoV-2 infection and 12 months after COVID-19 illness. Estimates were separated for hospitalized and non-hospitalized individuals, those aged older or younger than 20 years, and males and females. Secondary outcomes included duration and relative severity of long COVID symptom clusters.

In this observational analysis, the research team used data from 56 distinct sources. A pooling of 44 published studies, 10 collaborating cohort studies, and 2 electronic medical record databases were used to evaluate 1.2 million individuals from 22 countries with symptomatic SARS-CoV-2 infection between March of 2020 and January of 2022. Data ranged from full account of SARS-CoV-2 infection to volunteer reporting via an app and medical insurance claims.

Quantifying long COVID can help policy makers provide adequate access to recovery services, aid in the return to workplace or school, and help restore mental health and social life.

Potential impact

Thus far, most surveillance of COVID-19 has concentrated on the number of infections, hospital admissions, and deaths. This study, however, focused on the proportion of patients with long COVID and the duration of symptoms. Quantifying long COVID can help policy makers provide adequate access to recovery services, aid in the return to workplace or school, and help restore mental health and social life.

WHO released a clinical case definition for long COVID, or post-COVID-19, in October of 2021, which necessitates a 3-month duration after SARS-CoV-2 infection and exclusion of alternative causes. Eighty-four long-term symptoms have been identified, but the most common are fatigue, cognitive problems, and respiratory problems.

According to the research findings, long COVID by sex is distinct from severe acute SARS-CoV-2 infection. Females tend to experience less severe disease with viral infection and mount higher antibody response. X-linked chromosomes are thought to influence susceptibility to viral infection and autoimmune diseases, which long COVID is thought to be. An estimated 63.2% of individuals with long COVID are female with a statistically significant difference of 5.1% between sexes.

Age also showed statistically significant differences in estimated long COVID risk. There was a 2.0% difference for males aged 20 years and older and those younger than 20 years old. In females, there was a 7.2% difference between the two age groups.

Researchers noted that the amount and quality of data used in the analysis varied per source. Very few studies included asymptomatic individuals and some studies lacked information regarding prior health status, thus necessitating exclusion of those individuals and a correction factor, respectively.

Additionally, the WHO case definition requiring a duration of 3 months was used. Durations as low as 3 weeks have been suggested as no competent virus has been replicated beyond 3 weeks of infection. Data did not cover the Omicron variant wave as the analysis only accounted for symptomatic SARS-CoV-2 infection through the end of 2021.

Generalizability is limited as it was assumed that long COVID follows a similar course in all countries and duration estimates for long COVID were based on data from only high-income countries. Additionally, new symptoms and events have been reported to occur more frequently since the study first commenced as there have been data reporting lags. Some common reports include cardiovascular complications, thromboembolic events, and kidney, liver, gastrointestinal, endocrine, and skin disorders. There are 84 different long COVID symptoms and all could not be evaluated.

These estimates do not reflect the full burden and range of long COVID as a result, researchers noted. Geographical, economic, and symptomology differences could become clearer with additional research and future findings. ■

Perioperative medication management guidance available for clinicians

Olivia C. Welter, PharmD

The ever-rising complexity of patient health has prompted the Society for Perioperative Assessment and Quality Improvement (SPAQI) to address the lack of resources for perioperative medication management through publication of their own guidance.

SPAQI has released articles in *Mayo Clinic Proceedings* since December 2021 with recommendations for holding medications preoperatively specific to distinct disease categories: gastrointestinal and pulmonary; psychiatric; rheumatologic and HIV; and neurologic.

The full guidance articles include notes with more information about each recommendation. Some common medications and drug classes need to be held at certain time points prior to surgical procedures.

Biologics are known to cause increased risk of infection for patients, and some biologics impair or delay wound healing.

Continue perioperatively

SPAQI generally recommends some classes of medications to be continued as usual prior to any surgery. Antiretrovirals, anti-anxiety medications, antidepressants, mood stabilizers, antipsychotics, glucocorticoids, interferons, acetylcholinesterase inhibitors, methotrexate, proton pump inhibitors, most inhaled medications, anticonvulsants, and medications used in management of Alzheimer disease are all included in this category.

Patients taking immunosuppressants to treat severe lupus erythematosus (SLE) can typically continue on these medications, including on the day of surgery. It's recommended that medications used to manage Parkinson disease are to be continued preoperatively, unless the patient is undergoing placement of deep brain stimulators under monitored anesthesia, in which case they should be held on the day of surgery.

Hold for entire dosing cycle

SPAQI recommends that most biologic medications used to treat rheumatologic disease be held for a full dosing cycle before surgery. Biologics are known to cause increased risk of infection for patients, and some biologics impair or delay wound healing. For belimumab and rituximab specifically, these medications should only be held in patients who have non-severe SLE. Janus kinase (JAK) inhibitors are the main exception for preoperative discontinuation, as SPAQI recommends they be held only for 3 days prior to the operation rather than an entire dosing cycle. Anifrolumab can be continued uninterrupted in all patients, regardless of surgical status.

In addition to biologics, SPAQI also includes several gastrointestinal immunomodulators, such as tumor necrosis factor inhibitors, on its list of recommended drugs to hold for an entire dosing cycle preoperatively.

Hold 4 weeks to 3 days prior

Medications that are not on specific, extended dosing cycles may need to be held for 4 weeks, 7 days, or 3 days before surgery. At the 4-week mark, cyclophosphamide is the main medication SPAQI recommends being held.

At 7 days, the guidance suggests that immunosuppressants used for patients with non-severe SLE, such as azathioprine, cyclosporine, tacrolimus, and mycophenolate can be held. Pegylated interferons used to treat viral hepatitis are also recommended to be held at 7 days.

Due to bleeding complications, SPAQI recommends that all NSAIDs except celecoxib be held for 7 days before surgery. The guidance includes additional notes to consider for each individual medication within the class, as the amount of time they're required to be held differs based on several variables.

Three days before a surgery, lithium can be held for major procedures. If the patient is only undergoing a mild operation, SPAQI recommends continuing lithium as usual.

Hold on day of surgery only

Many common medications that patients take regularly are on the list of drugs that SPAQI says can be continued as usual up until the day of the surgery. This includes allergy medicine, antacids, laxatives, antidiarrheals, antiemetics, weight loss drugs, and medicine like pseudoephedrine.

Other medications that appear in these recommendations are theophylline, pegylated interferons, and drug combinations used to treat hepatitis infections. SPAQI also recommends that adults using ADHD medication do not take their dose on the day of surgery, except for guanfacine which does not need to be held.

The full guidance released by SPAQI should be consulted for additional details to better inform clinical decision-making for surgical teams when identifying which medications should be held prior to an operation. ■

Early oseltamivir use in hospitalized children improved outcomes, study finds

Sonya Collins

Influenza hospitalizes as many as 45,000 children per year. The virus causes up to 600 annual deaths in the pediatric population. In both children and adults with flu, oseltamivir (Tamiflu–Genentech), when taken no later than 48 hours after symptom onset, is a powerful medication to shorten the duration and lessen the severity of the illness in the outpatient setting. In pediatric outpatients, oseltamivir shortens the duration of symptoms by an average of 29 hours.

Based on these data, the American Academy of Pediatrics and the Infectious Diseases Society of America recommend oseltamivir for children hospitalized with flu. But, in the absence of large datasets on this population, the practice continues to be a topic of debate. Some clinicians question whether it improves outcomes or reduces later use of resources among these patients. New research by Walsh and colleagues, however, may offer answers to these questions.

A recent study published September 19, 2022, in *JAMA Pediatrics* found that early oseltamivir use was associated with multiple positive outcomes: Shorter hospital stays and lower risk for 7-day readmission, transfer to ICU, and in-hospital mortality or use of extracorporeal membrane oxygenation (ECMO).

"A study like this gives us the inpatient picture and clarifies the usefulness of oseltamivir in that setting since we do not have a randomized controlled clinical trial of oseltamivir in hospitalized patients," said Katherine Lusardi, PharmD, a clinical pharmacist for antimicrobial stewardship and infectious diseases at University of Arkansas for Medical Sciences Medical Center in Little Rock, AR, who was not involved in the study.

Study findings

The study was a multicenter retrospective analysis of data on 55,799 children under age 18 who were hospitalized with flu in 36 U.S. hospitals between 2007 and 2020. Children treated with oseltamivir on days 0 or 1 of hospital admission stayed in the hospital an average of 3 days compared to 4 days for those who did not get the medication. Their odds of 7-day readmission were 3.5% compared to 4.8% for the other children. They were less than half as likely to transfer to the ICU. Their combined odds of death or ECMO use were 0.9% compared to 1.4%.

The study emphasized administration early in the hospital stay but did not include data on onset of symptoms prior to hospital admission.

"That's an interesting detail because most clinicians would say that if you're past the first 48 to 72 hours, you're out of the window to take oseltamivir," said Lusardi.

"A study like this gives us the inpatient picture and clarifies the usefulness of oseltamivir in that setting since we do not have a randomized controlled clinical trial of oseltamivir in hospitalized patients."

Advice for clinical practice

The study does not stratify data by flu strain—of which there are many of varying severity across a 13-year study period. It does, however, provide an overall picture of the effects of the medication among all children hospitalized with flu.

"I do not think this is the end-all-be-all study that says definitely do this, but I think it makes a strong point in the case, and it is definitely the largest set of data that is in this inpatient pediatric space," Lusardi said.

Until there is a large, randomized controlled clinical trial of oseltamivir in children hospitalized with flu, this study can help justify the use of the drug in this population. Lusardi also highlighted the favorable cost benefit of administering the generic medication, though it is not explicitly indicated for hospitalized patients.

"That's something that can be encouraged in the hospital," she said, "and if you're going to start it, start it early." ■

Novel clinical decision support technology could reduce CAP mortality

Corey Diamond, PharmD

Over the past decade, reported morbidity and mortality rates from community acquired pneumonia (CAP) have stagnated. While treatments have improved, tightening the gap between guideline-directed CAP treatment and general medical practice using electronic decision support systems remains unexplored.

A recent study published by Dean and colleagues in the *American Journal of Respiratory and Critical Care Medicine* from March of 2022, investigated the deployment of an electronic pneumonia clinical decision support tool (ePNa) to improve physician adherence to the 2007 and 2019 American Thoracic Society/Infectious Diseases Society of America pneumonia treatment guidelines. Researchers found that ePNa deployment was associated with improved processes of care and lower mortality in patients diagnosed with CAP.

Unique design with interesting results

Dean and colleagues conducted a cluster-controlled trial, which looked at the outcomes of patients with CAP before and after deployment of an ePNa program. ePNa was used across 6 clusters of 16 hospital emergency departments (EDs) at 2-month intervals between 2017 and 2018. The intention-to-treat analysis included 6,848 patients, of whom 4,536 were seen before, and 2,312 were seen after ePNa deployment.

Confounders were controlled for using a step-wedge cluster design but were not randomized due to ethical concerns that arose from prior research the same authors conducted, which showed ePNa implementation may present a mortality benefit. The sequential roll out of the ePNa in clusters was required to facilitate the intensive education, monitoring, and feedback required of the program.

Patients were included in the analysis if they were older than 18 years and had radiographic pneumonia on ED chest imaging, plus a discharge diagnosis of pneumonia. The study's primary analysis used a mixed-effects model to evaluate the relationship between ePNa deployment and severity-adjusted 30-day mortality. Secondary statistics included observed trends in antibiotic use, patient disposition (level of care needed throughout treatment), and physician ePNa use.

The regression analysis revealed that 30-day all-cause mortality was 8.6% in clusters before ePNa deployment versus 4.8% after ePNa deployment.

ePNa was used in 67% of eligible patients with CAP, and more so in larger hospitals. Its' deployment was associated with a statistically significant increase in guideline-concordant prescribing from 79.5% to 87.9%. Additionally, there was a significant reduction in anti-MRSA agent use, time to first antibiotic use, and inpatient disposition.

Researchers found that ePNa deployment was associated with improved processes of care and lower mortality in patients diagnosed with CAP.

What is ePNa?

Dean and colleagues' study used an ePNa that integrated pneumonia detection with a management tool, which presented needed information to ED clinicians assessing patients with suspected pneumonia. The ePNa software first automatically identified patients with possible CAP, based on documented presentation in the electronic health record (EHR), using symptomatic, radiographic, and laboratory evidence. The ePNa software then calculated the percent probability of pneumonia and alerted ED clinicians if the probability of pneumonia was greater than 40%.

The ED clinicians could then opt to launch ePNa through the hospital's EHR. ePNa would then calculate the patient's pneumonia illness severity using validated severity factors—such as eCURB score, PaO2/FiO2 ratio, sCAP score, and pleural effusion size. If the combined severity factors warranted a higher level of care, the ePNa algorithm triggered a recommendation for either a hospital admission or an intensive care admission.

Finally, ePNa calculated the patient's risk of antibiotic-resistant pathogens using risk factor logic derived from the American Thoracic Society/Infectious Diseases Society of America pneumonia treatment guidelines. The patient's risk score prompted ePNa to provide recommendations for antibiotic coverage, with coverage recommendations becoming broader as the patient's drug resistance risk score increased.

Considerations

While Dean and colleagues' ePNa technology is encouraging, the study itself has notable limitations. For instance, there was a significance decrease in median age of patients after ePNa use. Similarly, the pre-ePNa patient clusters had significantly more comorbidities, including higher rates of chronic renal disease, chronic heart disease, COPD, and diabetes.

Considering the baseline demographic imbalances in the comparison groups, the study's results are much more susceptible to bias. Despite the use of adjusted regression model, the decline in pre-existing morbidity in the patient population after ePNa implementation may have confounded the reduction in mortality observed.

Overall, however, the mortality results of Dean and colleagues' study are encouraging and have the potential to smooth transitions of care for patients with CAP. ePNa technology may provide the support that general medicine needs to compartmentalize patient risk and allow future studies to discover which interventions drive which benefits. ■

A minute with ...

Jason Martinez, PharmD, BCACP

Chief Population Health Officer, Community Health & Wellness, Columbus, OH

Member since 2003

"Being a part of APhA has been an extremely important part of my professional life. At each step of my career, from when I was a student pharmacist until now, APhA has provided important learning, networking, and leadership opportunities. Having the privilege of both being involved in and supported by a professional organization is a blessing that each pharmacist should enjoy."

How has APhA helped you establish meaningful connections?

APhA has given me the opportunity to work with pharmacists from across the country on important topics such as caring for underserved patients, provider status, and advancing the role of digital health. No matter what interest a pharmacist may have, APhA can help foster mentoring relationships that I've found invaluable throughout my career.

How does APhA help you thrive in your everyday practice?

APhA helps me thrive in everyday practice by providing connections and resources to improve clinically whether that is through increased knowledge or new practice models.

What excites you about the profession of pharmacy?

Pharmacy is one of those professions that has a respected history but is full of thought-leaders who are making people rethink what a pharmacist can do. One of the most fulfilling roles I have is precepting the next generation of pharmacists to continue to explore new and innovative ways that pharmacists can improve their patient's lives and the communities in which they live and work.

Can you share a meaningful story about a time you interacted with a patient? Perhaps a time you felt like you really made a difference for them?

The types of barriers that patients face in a rural area require innovative problem solving. Being able to practice alongside a patient's primary care provider affords me the unique ability to influence prescribing patterns and habits to improve the care of individual patients as well as entire patient populations.

I recall we had a new patient at our clinic who had struggled with diabetes since their teenage years with no recollection of an A1C ever below 10. This patient was hesitant to make changes to their regimen because they had already worked with countless diabetes specialists in the past without success while still experiencing hypoglycemia that frequently resulted in emergency medical services being dispatched to their home.

After spending time with the patient reviewing various aspects of diabetes education and attempts at optimizing their insulin regimen, I suggested a continuous glucose monitor to help them understand their blood glucose patterns.

Although the patient initially declined, after a few more months of discussion they finally started on a continuous glucose monitor and continued to gain trust in me. I finally was able to transition them to an insulin pump which has reduced their hypoglycemia while improving their A1C control to below 7. The patient and their family now talk frequently about how they wished that they had made the transition to an automated insulin delivery system earlier! ■

Get involved

The opioid epidemic and subsequent increase in substance use disorder (SUD) has been a prevalent concern within health care for the past decade. At the same time, ensuring patients get proper pain management has also become somewhat of an obstacle due to concerns surrounding the overprescribing of opioids. The APhA Pain, Palliative Care, and Addiction (PPCA) Special Interest Group (SIG) strives to educate pharmacists and student pharmacists on how to care for patients with all types of pain and patients who may experience SUD. Pharmacists are able to play a key role in pain management and SUD due to having unique knowledge about medication use and adverse events. This knowledge allows pharmacists to assist not only with patient access to opioids, but also misuse prevention and SUD assistance.

"The PPCA SIG is passionate about advancing the care for those with substance use disorders, specifically opioid use disorder (OUD)," said Emily Leppien, PharmD, BCPS, BCPP, clinical assistant professor of pharmacy at Binghamton University and PPCA SIG coordinator. "Top initiatives of the SIG involve decreasing stigma associated with OUD and dispensing naloxone, advocating for the Mainstreaming Addiction Treatment (MAT) Act to increase access to buprenorphine by removing the X-waiver requirement, and educating health care professionals on alternative pain management therapies." Visit apha.us/PPCA_SIG to learn more. ■

APhA advocacy

In September 2022, APhA wrote a letter to FDA alongside other organizations critiquing a newly proposed rule that would allow prescription-only products to be switched to OTC status under an "additional condition for nonprescription use" category. This rule would enable patients to purchase these products after taking a self-assessment without any sort of pharmacist assistance. APhA's letter stated appreciation for FDA's intent behind this proposal, but also expressed several concerns related to logistical and operational issues. Additionally, APhA argued this proposal has not appropriately considered the essential role of pharmacists in helping patients with medication management and safe medication use.

FDA reacted to this letter and joined an APhA-led listening session in November 2022. In this session, APhA members shared concerns about the newly proposed rule and provided helpful insights from a pharmacist's perspective to help FDA better understand from where these concerns stem. APhA urged FDA to consider the importance of the pharmacist in patient assessments and determining if a therapy is appropriate on an individual basis. FDA appreciated APhA's input and official written comments in response to the proposed rule were submitted by APhA at the end of November 2022. ■

APhA pharmacy law matters: A year in review

Legislative, legal, and regulatory developments affecting pharmacy in 2022

As the federal government continues to extend the federal public health emergency (PHE) to respond to the ongoing COVID-19 pandemic, it has become clear from the data that both the federal and state governments rely upon pharmacists as a key part of our nation's public health infrastructure.[1]

Under two presidential administrations, HHS has repeatedly expanded pharmacists' scope of practice through 10 amendments under the federal Public Readiness and Emergency Preparedness (PREP) Act to temporarily authorize pharmacists to test, treat, and immunize patients.[2] Many states have also taken a cue from the federal government to similarly expand pharmacists' state scope of practice. These new authorities and responsibilities for pharmacists, layered on top of routine patient care, have been vital for meeting our nation's health care needs and moving the practice of pharmacy forward. However, new requirements and a challenging payment system continue to threaten the sustainability of pharmacies, the wellness of pharmacists and pharmacy teams, and the resources necessary to provide that care.

In 2022, analysis of federal data confirmed pharmacists were responsible for administering[3]

- More than 50% of the COVID-19 vaccinations nationwide
- Over 12 million more influenza vaccinations to adults in 2020–2021 compared to the previous season
- A total of 42 million tests and 270 million vaccinations during the COVID-19 pandemic

In August 2022, the U.S. also declared monkeypox—now called "mpox"— a PHE shortly after WHO named the disease a global health emergency which impacted patients, communities, pharmacists, and other health care professionals worldwide; they also renewed the mpox PHE emergency in November.[4–7] Once again under the PREP Act, HHS also authorized pharmacists, pharmacy interns, and pharmacy technicians as appropriate to administer mpox vaccines and therapeutics under certain conditions, effective September 28, 2022.[8]

Despite pharmacists' heroic efforts during the ongoing PHEs, pharmacist-provided patient care services continue to lack recognition under key sections of relevant laws. This limits patients' access to pharmacists' services that can improve medication and health outcomes and ensure the sustainability of the profession.

APhA's advocacy team has been busy working to make the temporary scope of practice expansions permanent by working with federal, state, and commercial payors to recognize and reimburse pharmacists for the services pharmacists provide and addressing the ongoing harmful PBM business practices that continue to hurt pharmacists and patients. This article, which is current as of December 2022, describes a few of the top 2022 federal legislative and regulatory policy issues that affected pharmacy practice over the course of 2022.

Pharmacists' recognition as patient care providers

Pharmacists and pharmacists' patient care services currently are not included in key sections of the laws that determine eligibility for health care programs such as Medicare Part B, under which physicians' and other health care professionals' outpatient services are covered. This limits Medicare beneficiaries' access to pharmacists' services in the outpatient setting and pharmacists' contributions to improving medication and health outcomes. Over the years, several federal bills have been introduced to add pharmacists as eligible providers for Medicare beneficiaries. Although these federal bills have had bipartisan support, none have been passed into law.

Federal legislation

Public health response

Pharmacists' services have grown well beyond functions tied only to dispensing medications. Many pharmacists also provide medication management, comprehensive medication reviews with ongoing medication monitoring,

Pharmacist learning objectives

At the conclusion of this knowledge-based activity, the pharmacist will be able to:

- Discuss government action (legislative and regulatory) to advance pharmacists' practices.
- Describe the latest federal regulations related to the practice of pharmacy.
- List examples of state advocacy (payment for pharmacists' services, expansion in scope of practice, pharmacy benefit manager reform).

Preassessment questions

Before participating in this activity, test your knowledge by answering the following questions. These questions will also be part of the CPE assessment.

1. What bill is the pharmacy profession advocating for to achieve pharmacist provider status under Medicare?

a. The Equitable Community Access to Pharmacist Services Act
b. The renewal of the Public Health Emergency
c. The ARPH-H bill
d. The omnibus funding bill

2. What provision was included in the new drug pricing law (Inflation Reduction Act)?

a. Elimination of all out-of-pocket costs for Medicare vaccines starting next year (2023)
b. Medicare payment for pharmacist prescribing of Paxlovid
c. $37 insulin cap for all commercial health plans, beginning in 2023
d. Increased reimbursement for biosimilar substitution

3. What role would FDA require for pharmacists in patient self-selection under the recently proposed rule offering additional conditions for nonprescription use?

a. FDA requires patients to ask pharmacists to consult medication histories prior to patient self-selection for a new nonprescription use of a medication.
b. FDA requires pharmacists to purchase and display kiosks in pharmacies for patient self-selection for a new nonprescription use of a medication.
c. FDA does not provide any scenarios where a pharmacist would be involved with this patient self-selection process.
d. FDA only requires pharmacist consultation in patient self-selection at pharmacies with certified electronic health records.

chronic disease management, disease education, care transition services, prevention and wellness services, and patient education.[9] Pharmacists also contribute to primary health care by providing a variety of health and wellness, medication management, and acute and chronic care management services.[9] Pharmacies are the most accessible access point for patients to receive care. Ninety percent of Americans live within 5 miles of a pharmacy, and the neighborhood pharmacy in minority, underserved communities, and rural areas may be the only health care provider for miles.[10,11]

This year, APhA was a founding member of the Future of Pharmacy Care (FOP) coalition.[12] The coalition brings together all of the different facets of the pharmacist and pharmacy community to help draft new federal legislation to capitalize on the care and access that pharmacists have been providing during the pandemic to recognize pharmacists as Medicare providers.

The FOP coalition is addressing the previously unanswered questions posed by policymakers that have served as barriers to the pharmacy community over the past decade and hindered the passage of federal legislation to provide a direct payment pathway under Medicare Part B for pharmacist-provided patient care services. These questions include

- 1) What would (and would not) federal legislation accomplish?
- 2) What would the passage of federal legislation cost?
- 3) Who supports and opposes a legislative solution?

The new legislation that the pharmacy profession is advocating for, H.R. 7213, also called the Equitable Community Access to Pharmacist Services (ECAPS) Act, would authorize pharmacists to provide care and receive reimbursement for pandemic-related services for our nation's seniors and respond to future public health threats.[13]

First, it was important to specifically define for policymakers and stakeholders what the ECAPS Act would and would not do. H.R. 7213 would

- Add pharmacists as eligible providers for Medicare Part B beneficiaries of pharmacies and pharmacists' services related to the COVID-19 pandemic and specific infectious diseases, such as testing (for COVID-19, influenza, respiratory syncytial virus, and strep throat), treatment (for COVID-19, flu, and strep throat), and vaccinations (for COVID-19 and flu)
- Help prepare for future emergencies by creating a mechanism to establish Medicare coverage and payment for pharmacy services and pharmacist-provided services when there is a public health need such as during a PHE
- Authorize the HHS secretary to identify services as needed, including to close gaps in health equity
- Be limited to state scope of practice or incident to physician's services, or more broadly under a PREP Act declaration
- Enable pharmacists across the country to provide services to Medicare beneficiaries in order to address COVID-19 and other pressing health needs in all areas of the country

However, H.R. 7213 would not

- Provide Medicare reimbursement for all services such as medication and chronic disease management, health and wellness screenings, and education
- Recognize pharmacists as health care providers for all Medicare patients
- Supersede a state's scope of practice laws
- Conflict with our efforts to pass other provider status–related legislation

Second, it was important to understand what H.R. 7213 would cost to implement. H.R. 7213 is very affordable. A preliminary "score" or cost to the federal government to implement the legislation found that

- Codifying pharmacists' role in providing vaccinations into federal law so that pharmacists continue to operate within the state scope of practice guidelines, would have no budgetary impact.
- Reimbursing pharmacists for providing testing and treatment to Medicare beneficiaries under a state's scope of practice would have a minimal budgetary impact (only $2.2 billion over 10 years), which is a significantly lower cost to the federal government than current hospitalization and associated health care costs. For example, a recent study found that 90,000 lives and over $56.5 billion would be saved under an effective COVID-19 booster campaign in which pharmacists continue to serve as our nation's primary vaccinators and 80 percent of eligible individuals receive their booster dose by the end of 2022.[14,15]

Third, it was important to clarify for policymakers the broad stakeholder support for H.R. 7213 as well as to identify and respond to opposition:

- Support: The FOP coalition worked to garner the support of over 98 pharmacy and pharmacist organizations and over 82 patient, senior, and rural organizations—including the National Hispanic Medical Association and the National Black Nurses Association—due to pharmacists' ability to help address our nation's health care disparities and equity efforts as the only health care provider for many underserved populations.[16,17]
- Opposition: On April 12, 2022, the American Medical Association (AMA) issued a letter opposing H.R. 7213.[18] However, AMA does not represent all of the physicians who work alongside our nation's pharmacists and improve the health care of our patients every day.

Outlook

Due to 2022 being an election year, there have been limited opportunities to include H.R. 7213 in must-pass legislation.

The pharmacy profession is targeting a potential large omnibus year-end funding bill to attach H.R. 7213. However, as of the time of publication of this article, Congress is in a stalemate and it is unclear if an omnibus funding bill (in which H.R. 7213 could be added) will be passed.

In addition, report language in the federal appropriations bill for the Labor, HHS, and other major governmental divisions, which funds HHS, instructs CMS to specifically address the following issues to help advance pharmacists as patient care providers[19]:

- Ensuring access to lifesaving COVID–19 oral medications from pharmacists: "The Committee is concerned about patients' access to these lifesaving medications and encourages CMS to review policy options for Part D sponsors to cover all the necessary services to ensure the safe pharmacy dispensing of COVID–19 oral medications."
- Pharmacists and patient care services: "The Committee encourages CMS to create a mechanism to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists."
- Pharmacist-provided incident to physician services: "The Committee encourages CMS identify mechanisms to attribute, report, and sustain pharmacists' patient care contributions to beneficiaries in the Medicare Part B program."
- Pharmacists and COVID–19 authorities: "The Committee requests a report within 180 days of the date of enactment of this Act on the impact of these authorities on public health and proposed actions and recommendations on whether to make these authorities permanent."

Opioid response

On September 29, 2022, the HHS secretary declared a renewal of the federal declaration that an opioid PHE exists nationwide.[20]

As part of the response to this ongoing crisis, H.R. 1384, the Mainstreaming Addiction Treatment (MAT) Act, would remove barriers, including the "X-waiver," that are preventing health care providers, including pharmacists, from prescribing buprenorphine for opioid use disorder.[21]

H.R. 1384 passed the U.S. House of Representatives in June 2022 as part of a larger piece of legislation, H.R. 7666, the Restoring Hope for Mental Health and Well-being Act, which is bipartisan legislation that includes the reauthorization of more than 30 programs that support mental health care,

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Visit www.pharmacist.com/Advocacy/Issues for regularly updated legislative and regulatory information.

prevention, education, and workforce training through 2027.[22]

Outlook

The MAT Act is expected to pass the U.S. Congress before the end of 2022 as a part of the larger H.R. 7666 package or in a potential omnibus bill, representing a step forward for pharmacists to help address the nation's ongoing opioid crises.

Pharmacogenomic consultations

More than 90% of patients have DNA variants that could affect their response to a medication.[23] Each individual has a unique genetic makeup that affects drug absorption, efficacy, metabolism, and response. Pharmacogenomics (PGx) addresses how an individual's DNA influences the response to a medication. With recent advances in health sciences, we can predict a patient's phenotype, such as metabolic activity, from the genotype (including genetic variants) to prevent serious adverse effects and therapeutic failure or to optimize treatment efficacy.

Pharmacists are best equipped to implement PGx and support health care decision-making to help patients benefit from personalized medicine. By interpreting PGx test results, pharmacists could recognize the risk of adverse drug events or treatment failure and provide alternatives based on patients' genetics. Legislation supporting PGx implementation would allow pharmacists to take the leadership role in PGx implementation and be reimbursed for these services.[24]

H.R. 6000, the Cures 2.0 Act, is a large, bipartisan health care bill with several provisions aimed at speeding up the delivery of new cures, treatments, and innovations.[25] If signed into law, Section 408 of the law, "Medicare Coverage for Pharmacogenetic Consultations," would provide Medicare coverage for pharmacogenetic consultations by qualified clinical pharmacists and genetic counselors.[25]

Outlook

Although the Cures 2.0 Act is unlikely to pass in 2022, it is a promising piece of legislation to watch in the next Congress that could provide a direct payment mechanism for pharmacist-provided PGx consultations.

PBM reform

Pharmacists continue to stress to policymakers that a large part of addressing rising prescription drug and health care costs lies with increased oversight of the harmful practices of PBMs and their use of "clawbacks" or retroactive direct and indirect remuneration (DIR) fees. Retroactive DIR fees are price concessions not reflected at the point of sale for pharmacies participating in Medicare Part D networks. These fees increase costs for patients at the counter and often force pharmacists to dispense drugs below their acquisition costs.

Outlook

S. 4293, the Pharmacy Benefit Manager Transparency Act of 2022, would make it illegal for PBMs to engage in "spread pricing," in which PBMs charge health plans more for a prescription drug than they reimburse that pharmacy, and then pocket the difference.[26] S. 4293 would also prohibit PBMs from clawing back payments made to pharmacies or arbitrarily, unfairly, or deceptively increasing fees or lowering reimbursements to offset reimbursement changes in federally funded health plans.

While S. 4293 has passed the Senate Commerce, Science and Transportation Committee, it is unclear if S. 4293 will pass this Congress or if it will be included in a larger piece of legislation before the end of 2022.

Regulatory action

In November 2022, CMS released the annual physician fee schedule final rule, which outlines payment and coverage requirements for Medicare physicians and other qualified health care professionals.[27] While pharmacists currently are not providers under Medicare Part B, pharmacists do provide a number of services to Medicare beneficiaries through team-based care, which are impacted by the final rule.

Areas addressed in CMS' final rule that impact pharmacists include[27]

- Virtual direct supervision: CMS will continue to allow virtual direct supervision through the end of calendar year 2023.
- Telehealth: CMS allows physicians and practitioners to continue to bill with the place of service indicator that would have been reported had the service been furnished in-person through the end of 2023 or the PHE. CMS did not extend coverage of audio-only telehealth to the end of 2023 except for behavioral health care. CMS believes two-way audio and video communication technology is the appropriate standard that will apply for telehealth services after the PHE ends.
- Chronic pain management (CPM): CMS finalized 2 new CPM codes and permitted them to be provided via telehealth as clinically appropriate. However, the initial CPM services visit billed must be provided in-person without the use of telecommunications technology.
- Behavioral health: CMS will allow these services to be provided by clinical staff, including pharmacists, under general rather than direct supervision.
- Submitting Part B discarded drug data: CMS requires pharmacists and pharmacy technicians to submit new data on a Medicare Part B drug claim to report the amount of drug or biological product that is discarded and eligible for payment under the discarded drug policy.
- Rural health centers (RHCs)/Federally qualified health centers (FQHCs): CMS recognized that pharmacists can be a valuable part of the health care team, but they do not have the authority to add providers to the list of RHC and FQHC practitioners. However, incident to services furnished by clinical staff, including pharmacists, are allowed if provided in a medically appropriate timeframe.
- In-home additional payment amount for COVID-19 vaccine administration: CMS increased this amount to $36.85 for 2023.
- COVID-19 vaccine administration rates: CMS will continue the higher COVID-19 vaccine administration

rate ($41.52 for 2023) through the end of the year in which the PHE ends and provide an appropriate transition period to the other vaccine administration rates.

- Other vaccine administration rates: CMS will pay $31.14 (geographically adjusted) in 2023 for influenza, pneumococcal, and hepatitis B virus vaccine administration.
- Monoclonal antibody products used for pre-exposure prophylaxis: CMS will continue to pay for these products and their administration under the Part B vaccine benefit even after the EUA declaration for drugs and biological products is terminated as long as these products have market authorization.

States

Increased scope of practice and payment at the state level for pharmacists' patient care services continued to gain momentum this past year. Throughout 2022, state lawmakers across the United States recognized the potential of pharmacists and expanded authorities to allow pharmacists to practice at a level more aligned with their extensive education and training. In addition to a greater alignment of the pharmacists' scope of practice, there have been numerous achievements in the recognition of pharmacists as medical providers by public and private health plans and the establishment of programs to reimburse pharmacists for their patient care services.

Across the country, general trends of expansions in pharmacists' scope of practice have been in vaccination authority and improvements in collaborative practice agreements as well as in prescribing and services for hormonal contraceptives, HIV pre- and postexposure prophylaxis, nicotine cessation, and others. Including payment for expansions in services under public and/or private health plans is a growing trend within expanded scope of practice efforts.

A common goal of updating scope of practice over the past year has been codifying the temporary expansions granted during the COVID-19 PHE through declarations of the PREP Act. These declarations expanded pharmacists', pharmacy interns', and pharmacy technicians' vaccination authority and pharmacists' ability to test for COVID-19 and furnish intramuscular, subcutaneous, and oral treatments for COVID-19. In states where these expansions had not already been included in pharmacy law and rules, efforts were focused on codifying these temporary authorities to ensure that patients maintain access to vaccination provided by pharmacists, pharmacy interns, and pharmacy technicians as well as tests and treatments provided by pharmacists.

The following are examples and not intended to represent a comprehensive list of all state policy changes impacting the profession of pharmacy in 2022.

Scope of practice

At the time of this writing, examples of states that passed or implemented expanded scope of practice laws or regulations include

Alaska

HB 145 made comprehensive changes and expansions to pharmacists and pharmacy technicians' authority and expanded reimbursement opportunities for pharmacist services.[28]

Arizona

HB 2490 expanded and streamlined pharmacists' ability to provide care under a collaborative practice agreement.[29] SB 1374 expanded pharmacists' authority to order and administer all CDC ACIP-recommended vaccines to patients 6 years and older and all influenza vaccines to patients 3 years and older. Pharmacists can administer all vaccines to patients 3 years and older with a prescription or under a collaborative practice agreement and can order and administer corticosteroids, albuterol, oxygen, and antihistamines to manage an acute allergic reaction.[30]

Delaware

HB 399 allowed pharmacists to test and treat (pursuant to a statewide written protocol) for influenza, group A streptococcus pharyngitis ("strep"), COVID-19, a number of minor ailments, and other emerging and existing public health threats identified by the Delaware Division of Public Health.[31]

Florida

SB 544 authorized pharmacists to order and dispense emergency opioid antagonists.[32] HB 1209 authorized pharmacy technicians to provide immunizations under the supervision of the pharmacist.[33]

Illinois

SB 4018 expanded pharmacists' ability to delegate responsibilities to pharmacy technicians.[34]

HB 4430 allowed pharmacists to provide HIV pre-exposure prophylaxis and postexposure prophylaxis services and requires reimbursement of these services by the state's Medicaid program and other payers.[35]

Illinois Medicaid shortly after published its billing guidance for pharmacists to bill for hormonal contraceptive services.[36]

Iowa

HF 2169 allowed pharmacists to order vaccinations under a statewide protocol and registered nurses to administer the vaccination under the pharmacist's order.[37]

Maryland

HB 229/SB 19 authorized pharmacists to administer injectable medications for the treatment of sexually transmitted diseases and requires coverage of this service by health plans and the state Medicaid program.[38]

HB 28/SB 62 expanded pharmacists' ability to prescribe and order nicotine replacement therapy medications.[39]

Missouri

HB 2162 expanded pharmacists' ability to order naltrexone as an addiction mitigation medication under a statewide standing order or physician protocol.[40]

New Hampshire

SB 335 removed administrative burdens for entering into a collaborative practice agreement. SB 229 expanded the authority of pharmacy technicians to administer influenza and COVID-19 vaccines under the supervision of a pharmacist.[41]

Pennsylvania

HB 2679 allowed pharmacists and pharmacy interns under the supervision of a pharmacist to administer influenza and COVID-19 vaccines to patients 5 years old and older.[42]

South Carolina

SB 628 allowed pharmacists to dispense hormonal contraceptives pursuant to a standing order and allowed pharmacists to be reimbursed for these services by the state Medicaid program.[43]

Tennessee

HB 2131 expanded pharmacy technician's role to perform tasks delegated by the pharmacist if the tasks are aligned with the pharmacy technician's education, training, and experience.[44]

Virginia

HB 1323/SB 672 allowed pharmacists to dispense tobacco cessation therapies and tests for COVID-19, allowed pharmacy technicians and pharmacy interns to administer vaccinations under the supervision of a pharmacist, and required the reimbursement of these services under the state Medicaid program.[45]

West Virginia

HB 4324 removed regulatory barriers to the establishment of collaborative practice agreements.[46]

Wyoming

SB 24 expanded pharmacy technician and pharmacy intern authority to provide vaccines to patients under the supervision of a pharmacist.[47]

Payment for services

At the time of this writing, examples of states that passed or implemented payment for services laws or regulations include

Arkansas

CMS approved Arkansas Medicaid's request to add pharmacists to its list of other licensed practitioners, opening the door for pharmacists to be reimbursed for services as specified by Arkansas Medicaid.[48]

Colorado

In December 2021, CMS approved the request submitted by the Colorado Department of Health Care Policy & Financing (HCPF), which administers the state's Medicaid program to expand reimbursable services provided by pharmacists.[49] In early 2022, HCPF published its billing guide for pharmacists allowing pharmacists to enroll as Medicaid providers and bill for certain services.[50]

Kentucky

Kentucky Anthem Blue Cross and Blue Shield announced it will begin enrolling pharmacists as providers under commercial plans in Kentucky. This is one of the first commercial plans in Kentucky to recognize and reimburse pharmacists as providers following the 2021 passage of HB 48, which required reimbursement of pharmacists' services by commercial plans in the state.[51]

Oklahoma

HB 2322 recognized pharmacists as essential community providers and requires the state Medicaid program to reimburse pharmacists for health care services at the same rate as other providers.[52]

Nevada

CMS approved the request from the State of Nevada Department of Health and Human Services' Division of Health Care Financing and Policy (DHCFP) to begin enrolling pharmacists as providers and reimbursing them for hormonal contraceptive and HIV-prevention services.[53] DHCFP shortly after published its billing guidance for pharmacists.[54]

Pennsylvania

CMS approved Pennsylvania Medicaid's request to add pharmacists to its list of other licensed practitioners opening the door for pharmacists to be reimbursed for services as specified by Pennsylvania Medicaid.[55]

Outlook

The future of expanding scope of practice and payment for pharmacists' services at the state level continues to grow brighter every year. As programs paying pharmacists for their services becomes more of a norm across the country, it is expected that these programs will expand and grow more rapidly. Knowing that the temporary authorities that expanded scope or practice pharmacy personnel during the PHE may end within the next 2 years, it is expected there will be a focus on further codifying of these vaccination, testing, and treatment authorities in 2023.

Reforming pharmacy payment practices

For years PBMs' have imposed harmful business practices—such as "clawbacks" or retroactive DIR fees, which are price concessions not reflected at the point of sale—for pharmacies participating in Medicare Part D networks. Such practices inflate the patient's out-of-pocket coinsurance costs at the pharmacy and leave pharmacies not knowing the true transaction cost until later, because the fees are imposed months after the transaction. CMS attempted to lower patients' out-of-pocket costs for medicines and address these fees by issuing a final rule to move the fees to the point of sale, thus lowering the negotiated cost used as a basis for a patient's out-of-pocket coinsurance. CMS notes that these fees have skyrocketed a staggering 107,400% over the last 10 years.[56]

What's in CMS' final Part D rule?

- CMS' final rule includes all price concessions (including retroactive DIR fees) in the "negotiated price" at the pharmacy counter, beginning on January 1, 2024 (contract year 2024). This will increase consistency for Part D plans and transparency for patients as well as help pharmacies better determine whether they can afford to stay open. It also allows PBMs' unrestricted use of DIR fees for 2 more years.
- CMS also addresses Part D plans' and PBMs' use of "network access fees," "administrative fees," "technical fees," and "service fees" for pharmacies to participate in Part D plans' networks. If these "fees" are deducted from payments made to pharmacies for purchases of Part D drugs,

CMS treats these costs as "price concessions," and they must also be reflected in the "negotiated price" at the point of sale. CMS also states that it may provide further clarification of "pharmacy administrative service fees" in a future rulemaking if PBMs use these "fees" in attempts to retain additional profits.

- CMS' proposal sets a floor for pharmacy payment as the "lowest possible reimbursement" and allows for bonus payments for improved performance. Applying all pharmacy price concessions to the "negotiated price" at the point of sale should provide pharmacies with more information on the reimbursement they will receive for achieving or not achieving performance metrics.[56]

Who benefits and why?

- Patients will have reduced out-of-pocket costs. The final rule moves all pharmacy price concessions, including retroactive DIR fees, to the point of sale to benefit patients with lower cost-sharing.
- Pharmacists will have increased predictability. Effectively eliminating PBMs' use of retroactive DIR fees should increase predictability for pharmacies and begin to address a regulatory loophole CMS opened in 2014 that allowed PBMs to have unlimited license to apply retroactive DIR fees.

What's not in CMS' final Part D rule?

- CMS does not eliminate PBMs' use of DIR fees. Under the final rule, PBMs will still be able to use DIR fees to extract arbitrary fees by moving them to the point of sale (i.e., utilizing a bonus payment model) in addition to extracting other concessions from pharmacies.
- CMS acknowledges, but does not address, the impact on pharmacy cash flow to address the transition period for pharmacies from calendar year (CY) 2023 to CY 2024. Under the final rule, pharmacies will receive the "lowest possible reimbursement" in 2024 while PBMs continue to collect pharmacy DIR fees from 2023, which could create significant cash flow issues for pharmacies during the transition. While CMS "encourages Part D plans to consider options, such as payment plans or alternate payment arrangements, to minimize impacts to vulnerable pharmacies and the patients they serve," there is no requirement for Part D plans to address these cash flow concerns at the beginning of 2024. In fact, the final rule acknowledges the "possibility that changes in cash flow may cause some already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks."
- CMS does not close other PBM loopholes. PBMs are still able to continue other harmful business practices such as negative reimbursements (through which the PBM reimburses the pharmacy less than it costs to acquire the drug) and "patient steering" for brand, generic, and specialty drugs to PBM-affiliated pharmacies.

Outlook

Although the pharmacy community has been pushing to eliminate retroactive DIR fees, how the final rule is implemented could still create some uncertainty and financial impacts on pharmacies. CMS and/or Congress must do more to address the harmful and anticompetitive business practices by PBMs.

State PBM oversight

Following the U.S. Supreme Court decision for *Rutledge v PCMA*, opening the door for state regulations of PBMs, many states have passed, or are attempting to pass, legislation providing greater oversight and transparency and regulation of PBMs.

Across the country, PBM policies are focused on preventing patient steerage, ensuring equitable reimbursement of medications, creating protections for the 340B program, and establishing standards for pharmacy networks. Enforceability continues to be a theme as states created systems of oversight, often through the state insurance commissioner; established guardrails around pharmacy audits; and in some instances established that the PBM had a fiduciary responsibility.

The following are examples and this list not intended to represent a comprehensive listing of all state policy changes impacting PBMs in 2022.

At the time of this writing, examples of states that passed or implemented PBM laws or regulations include

Florida

HB 357 created protections for pharmacies by clarifying how PBMs may conduct an audit of a pharmacy, establishing a process to allow pharmacies to appeal PBM audits and setting a $10,000 fine if PBMs fail to register in the state.[57]

Iowa

HF 2384 prohibited pharmacist gag clauses, allowed patients greater autonomy in choosing where to fill their prescriptions, prohibited PBMs from mandating a patient receive their medications through a mail-order pharmacy, and banned PBMs from reimbursing a pharmacy less than they would reimburse a pharmacy with which they are affiliated.[58]

Nebraska

LB 767 created a process of licensure and regulation of PBMs, increased the transparency of the maximum allowable cost list, and set out provisions to protect the reimbursement of medications under the 340B program.[59]

New York

S. 3762 Breslin/A1396 Gottfried, S4807A Stavisky/A6476A Hyndman, and S3566 Breslin/A5854A Joyner set a minimum reimbursement for all prescriptions, required the licensure of PBMs, and prevented PBMs from requiring patients to use a mail-order pharmacy.[60]

Ohio

Ohio Medicaid created a more equitable reimbursement model for pharmacies under the state's Medicaid programs[61] and rolled out its single PBM.[62]

Tennessee

HB 2660/SB 2457 required the Tennessee commissioner of commerce and insurance to create further rules for the purpose of governing PBMs.[63]

Vermont

H 353 specified that PBMs owe a fiduciary responsibility to health plans, expanded the prohibition on pharmacist gag clauses, and prohibited PBMs from discriminating against 340B-covered entities or reimbursing pharmacies at an amount less than they would reimburse a pharmacy with which they are affiliated.[64]

Virginia

HB 1162, SB 359, and SB 428 prohibited PBMs from discriminating against contract pharmacies when operating under the 340B program; prohibited PBMs from interfering with a patient's right to choose a pharmacy based on the pharmacy's status as a contract pharmacy; specified the frequency that reports from PBMs need to be sent to the Virginia Commissioner of Insurance; and required PBMs to provide contemporaneous cost information to pharmacists and patients, including cost-sharing or prior authorization requirements.[65]

West Virginia

HB 4112 gave patients the right to choose their pharmacy by prohibiting PBMs from limiting pharmacy network access, banned limited access to medications by designating specialty drugs, and provided clarification for how drug acquisition costs are determined.[66]

Outlook

After the *Rutledge* decision, states will continue to pursue legislation that increases oversight of PBMs and provides for greater transparency into the price of medications.

It is anticipated that state activity increasing the transparency and oversight of PBMs will continue to grow in the coming years. As these bills advance at the state level, it will be vital for pharmacists and researchers to document results of the legislation to ensure enforcement of laws is having the intended impact for patients' access to medications and pharmacy business sustainability.

FTC activity

In 2022, the Federal Trade Commission (FTC) increased their focus and interest in vertically integrated PBMs. In June 2022, FTC initiated a study "to scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs."[67] The study requires major PBMs to submit annual pharmacy reimbursement data for each of the top 100 drugs by the annual total amount paid.

In October 2022, FTC issued a statement restoring the agency's policy of rigorously enforcing the federal ban on unfair methods of competition and intent "to exercise its full statutory authority against companies that use unfair tactics to gain an advantage instead of competing on the merits."[68]

Outlook

The pharmacy community is watching the FTC closely to see if they will use their enforcement authority against PBMs' anticompetitive business practices.

Drug pricing law

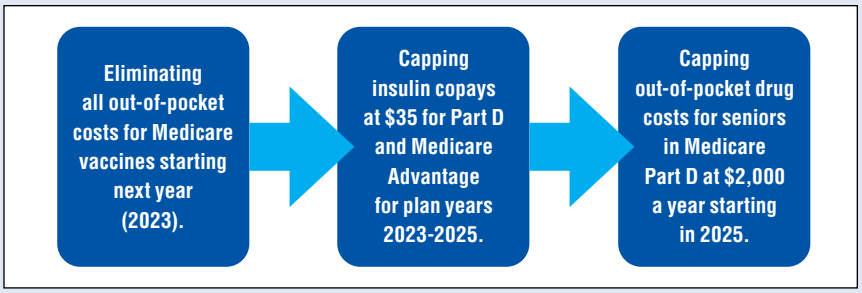
On August 16, 2022, President Biden signed into law, H.R. 5376, also known as the Inflation Reduction Act (IRA),[69] which includes several Medicare prescription drug provisions impacting pharmacists and patients:[70]

- Medicare drug negotiations: Permits the HHS Secretary to negotiate a "maximum price" for 10 of the most expensive Part D drugs, beginning in 2026, increasing to 20 drugs (including Part B drugs) by 2029, with stiff penalties for manufacturers that do not negotiate. The bill would also delay negotiation for biologics if a biosimilar is highly likely to be licensed within 2 years of the biologic drug becoming eligible for negotiation.
- Impact on pharmacists: Pharmacists have expressed concerns that lower government negotiated prices may not cover the full costs of drugs, dispensing and any associated pharmacist services. Reimbursement for pharmacies may also be lower under the new price negotiation framework, as any difference between the "negotiated price" and new "discounted price" may be subject to remuneration ("clawbacks" and/or DIR) by Part D plans. APhA is working on a clarification from Congress that this provision will not reduce pharmacy reimbursement.
- Inflation rebates: Requires dug manufacturers to repay the government the difference in profits above the cost of inflation on Medicare Part B and Part D drugs if they raise the price of a drug above inflation beginning in 2023 or face stiff penalties.
- Impact on pharmacists: Manufacturers may look to make up lost profits through PBM contracts with pharmacies and from shifting costs to enrollees in private health plans.
- Vaccine cost-sharing: Requires Medicare Part D plans to cover all ACIP-recommended vaccines with no cost-sharing or deductible, beginning January 1, 2023. It would also retroactively reimburse Medicare Advantage plans the lost cost-sharing for 2023.
- Impact on pharmacists: Eliminating cost-sharing for vaccine administration should encourage more Medicare patients to get vaccinated.
- Insulin copays: For plan years 2023–2025, the monthly copayment spend on insulin is capped at $35 for Part D and Medicare Advantage plans.
- Out-of-pocket (OOP) drug costs: Under Medicare Part D starting in 2025, Medicare patients will not have to pay more than $2,000 OOP a year.

Outlook

The IRA included provisions to help lower Medicare beneficiaries' drug prices (Figure).

An important area not addressed in the new law that continues to drive up prescription drug prices paid by plan sponsors and patients is the uncompetitive and deceptive trade practices of large, vertically merged PBMs that target patients with chronic conditions and force them to use PBM-



owned specialty, mail-order, and network pharmacies.

FDA

Pharmacist Paxlovid prescribing

In July 2022, FDA recognized pharmacists' expertise by revising the EUA for Paxlovid (Pfizer) to include pharmacists among other health care professionals permitted to prescribe the oral antiviral under certain conditions, for eligible patients who test positive for COVID-19.[70] However, pharmacist prescribing of Paxlovid is currently underutilized, especially in underserved communities, where beneficiaries are at high risk for progression to hospitalization and death from COVID-19.

Data confirms that patients' access to pharmacist prescribing of Paxlovid is a health equity issue. FDA authorized pharmacist prescribing of Paxlovid following an analysis by CDC, which found dispensing rates were the lowest in the highest vulnerability ZIP codes despite these ZIP codes having the largest number of dispensing sites.[71] CDC's findings confirmed APhA's earlier analysis clearly delineating inequitable access of COVID-19 oral antivirals.[72]

Patients seeking Paxlovid at a community pharmacy must be assessed for potential drug interactions as well as renal and hepatic function that may contraindicate pharmacist prescribing of Paxlovid. However, patient self-attestation is not permitted under FDA's frequently asked questions for pharmacists as it is for other health care providers. Rather, "[s]tate-licensed pharmacist prescribers must have access to sufficient information from health records to assess renal and hepatic function. Health records include access to an electronic health record system containing this information in progress notes or laboratory records, reviewing a printed health record such as a laboratory report provided by the patient, or reviewing information in electronic health records the patient may have access to through a phone app or other means."[73]

Another barrier to pharmacist prescribing of Paxlovid is a clear payment pathway under Medicare for the "patient assessment," or service that pharmacists must provide to determine if a patient is eligible for a Paxlovid prescription. CMS issued a memorandum to Part D plans that only "encourages," but does not require, plans "to consider paying a dispensing fee for these drugs that may be higher than a sponsor's usual negotiated dispensing fees given the unique circumstances during the PHE."[74]

Outlook

APhA has compiled resources for pharmacists to reference for prescribing and dispensing Paxlovid.[75] Widespread pharmacist prescribing of Paxlovid is unlikely until FDA or HHS eases the EUA's restriction that pharmacists must have access to lab values to review a patient's renal status before prescribing Paxlovid and CMS establishes a direct payment pathway for the required patient assessment.

OTC hearing aids

In August 2022, FDA established a new category of OTC hearing aids, which enabled patients with mild to moderate hearing impairments to purchase hearing aids directly from stores or online retailers without the need for a medical exam, prescription, or a fitting adjustment by an audiologist.[76]

FDA also issued the final guidance to clarify the differences between hearing aids, which are medical devices, and personal sound amplification products, which consumer products that help people with normal hearing amplify sounds.[77]

Outlook

Pharmacists play and important role helping patients assess the need for, and to safely choose, an OTC hearing aid device. The pharmacy profession had proactively prepared for OTC hearing aid availability and demand by participating in consensus-building processes that developed 26 competency statements that describe a framework for the abilities needed for pharmacists to safely assist patients seeking OTC hearing aids. APhA also plans to develop additional training and resources for pharmacists.

Additional condition for nonprescription use

In June 2022, FDA published a proposed rule that would establish requirements for marketing a nonprescription drug product with an "additional condition for nonprescription use" that ensures patients can appropriately self-select and/or appropriately use a medication without the supervision of a health care practitioner.[78]

As described in the proposed rule, the OTC drug could have the same active ingredient, dosage form, strength, route of administration, and indication as its prescription-only counterpart. The proposed rule provides examples of how patients might determine if it the product is appropriate for them, including completing a questionnaire or viewing a video with assessments to confirm their understanding of the medication. Alternatively, drug manufacturers could provide information to customers via in-pharmacy kiosks, apps, and websites. The proposed rule does not provide any scenarios in which a pharmacist would be involved in patient self-selection to determine if a product was appropriate for a patient, failing to recognize the essential role a pharmacist plays in assessing appropriate use and sale of medications.

The proposed rule raises significant operational and logistical issues associated with implementation that

will impact pharmacies and pharmacy teams.

Outlook

The pharmacy community submitted comments and met with FDA, expressing significant concerns about the proposed rule and the urgency for FDA to consider the role of the pharmacist in patient assessment and the impact on pharmacies as well as to provide standardized mechanisms for assessing whether a product is appropriate before a patient can purchase the product.

DSCSA implementation

The Drug Supply Chain Security Act (DSCSA)—known as the "track-and-trace" law—outlines a stepwise approach for implementing certain requirements for enhanced drug distribution security. DSCSA creates an electronic, interoperable exchange of information that identifies and traces certain prescription drugs down to the package level as they move through the supply chain. DSCSA requires pharmacies, called "dispensers" in the law, to have systems and processes to comply with the law. Certain DSCSA requirements are already in place, with full implementation of the law on November 27, 2023.

However, FDA has not yet conducted a small business dispenser assessment that was required by November 23, 2013.[79]

Outlook

APhA is concerned that some dispensers may not be ready to comply by November 2023 because pharmacists and pharmacies have been busy on the front line during the pandemic. In addition, the health care ecosystem has been imposing financial strains on some pharmacies, including community, hospital and health system, and long-term care pharmacies. In addition, FDA has not conducted the necessary small business assessment, and there will not be adequate time for affected dispensers to implement of any of the alternative methods for compliance. Until there is some certainty, many dispensers are reluctant to invest or consider what they will do to meet the requirements, including whether they will rely on their wholesalers for implementation. Failure to comply with the DSCSA can result in penalties, including imprisonment and/or fines; therefore, it is important for pharmacists to understand both the current and future DSCSA requirements that go into effect in November 2023. Pharmacists can check the "Track and Trace" section of APhA's website and FDA's DSCSA website for helpful resources, talk to their wholesalers about compliance, and stay tuned for additional educational materials from APhA and our partners on meeting the core DSCSA requirements.[80,81]

Conclusion

More than 200 organizations and growing, including physician and provider groups, patient advocacy organizations, health equity groups, rural health groups, pharmacists, health systems, and many others across communities, support H.R. 7213, bipartisan federal legislation that would ensure patient access to essential pandemic and pandemic-related health services provided by pharmacists.

Every effort should be made on the state and federal levels to make pharmacists' temporary expansions of scope in practice permanent. Pharmacists should work with their state and national pharmacy associations and reach out to state and federal legislators, pharmacy boards, and regulators in order to make the case for ensuring enduring access to pharmacists' patient care services for testing, immunizing, treating, and more.

The barriers to advancing the profession and addressing harmful actions by corporate or government entities continue to be challenging. APhA and our partners have proven that when pharmacy joins together, we can achieve what we once thought was impossible. The stakes are high for pharmacy to continue our current momentum. We need the support of every pharmacy advocate to make an impact.

APhA offers regular comprehensive reviews of legislative and regulatory issues and provides numerous tools and resources for pharmacists who wish to advocate on behalf of their profession. APhA's advocacy efforts include legal, legislative, and regulatory actions on behalf of pharmacists and the patients who rely on our care. We will continue to drive change and keep our members, including pharmacists, student pharmacists, pharmacy technicians, pharmaceutical scientist members, and other relevant parties, up to date and engaged in a variety of important ongoing national developments to keep moving the pharmacy profession forward.

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CPE assessment

This assessment must be taken online; please see "CPE information" in the sidebar below for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. What bill is the pharmacy profession advocating for to achieve pharmacist provider status under Medicare?
a. The Equitable Community Access to Pharmacist Services Act
b. The renewal of the PHE
c. The ARPH-H bill
d. The omnibus funding bill

2. What provision was included in the Inflation Reduction Act?
a. Elimination of all out-of-pocket costs for Medicare vaccines starting next year (2023)
b. Medicare payment for pharmacist prescribing of Paxlovid
c. $37 insulin cap for all commercial health plans, beginning in 2023
d. Increased reimbursement for biosimilar substitution

3. What role would FDA require for pharmacists in patient self-selection under the recently proposed rule offering additional conditions for nonprescription use?
a. FDA requires patients to ask pharmacists to consult medication histories prior to patient self-selection for a new nonprescription use of a medication.
b. FDA requires pharmacists to purchase and display kiosks in pharmacies for patient self-selection for a new nonprescription use of a medication.
c. FDA does not provide any scenarios where a pharmacist would be involved with this patient self-selection process.
d. FDA only requires pharmacist consultation in patient self-selection at pharmacies with certified electronic health records.

4. What is the 2023 in-home additional payment amount for COVID-19 vaccine administration?
a. $41.52
b. $31.14
c. $36.85
d. $40.00

5. What did CMS' final Part D rule do with DIR fees?
a. Move all price concessions (including all DIR fees) in the "negotiated price," at the pharmacy counter, beginning on January 1, 2024 (contract year 2024)
b. Eliminate all DIR fees
c. Provide beneficiaries with a breakdown of DIR fees included the "fixed price" at the pharmacy counter
d. Include performance-based DIR in all standardized Part D contracts

6. What U.S. Supreme Court decision opened the door for state regulations of PBMs?
a. *Rutledge v PCMA*
b. *Marbury v Madison*
c. *HHS v PCMA*
d. *Michigan v Ohio State*

7. What federal agency is undertaking a study of the impact of vertically integrated PBMs?
a. CMS
b. FDA
c. FTC
d. IRS

8. What legislation includes a provision providing Medicare Coverage for Pharmacogenetic Consultations?
a. The Affordable Care Act
b. The CARES Act
c. The Omnibus Reconciliation Act
d. Cures 2.0

9. What bill number in Delaware gave pharmacists the authority to test and treat for influenza, group A streptococcus pharyngitis (strep), COVID-19, a number of minor ailments, and other emerging and existing public health threats?
a. HB 357
b. HB 2322
c. HB 399
d. SB 661

10. What is the current status, at the time of the writing of this article, of the MAT Act?
a. It passed the Senate Finance Committee but still requires a floor vote.
b. It was included in the most recent continuing resolution on December 16.
c. It passed the House of Representatives.
d. It was attached to the National Defense Authorization Act.

CPE information

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Across

1 Pain reliever commonly used to treat fever
8 Concerned one
9 Part of the nucleus of a cell where ribosomes are made
11 Fatty tissue
12 By virtue of worthiness (two words)
13 Bit of wisdom
15 Pharmacists _____ more than 290 million patients during the pandemic
18 Time when some patients reach for 1-across for pain relief
19 Cancel
21 Skin wounds
24 Another name for Hansen's disease
26 A frightening but harmless figure
27 Experimental phase of the drug approval process
28 Type of event that results in many cases of a disease such as COVID-19

Down

2 Connective tissue found in the nose and outer ear
3 Trunk of the human body
4 Classic theory of inheritance
5 Prefix meaning death
6 Lung infection
7 One on a moray foray
8 Muscle contraction
10 Satisfied
14 Attraction on the banks of the Thames
16 It landed at Plymouth Rock
17 Sunscreen ingredient (two words)
18 Hemorrhoids by another name
20 Devoted
22 Big mess
23 Tender spots
25 Ancient city in Jordan

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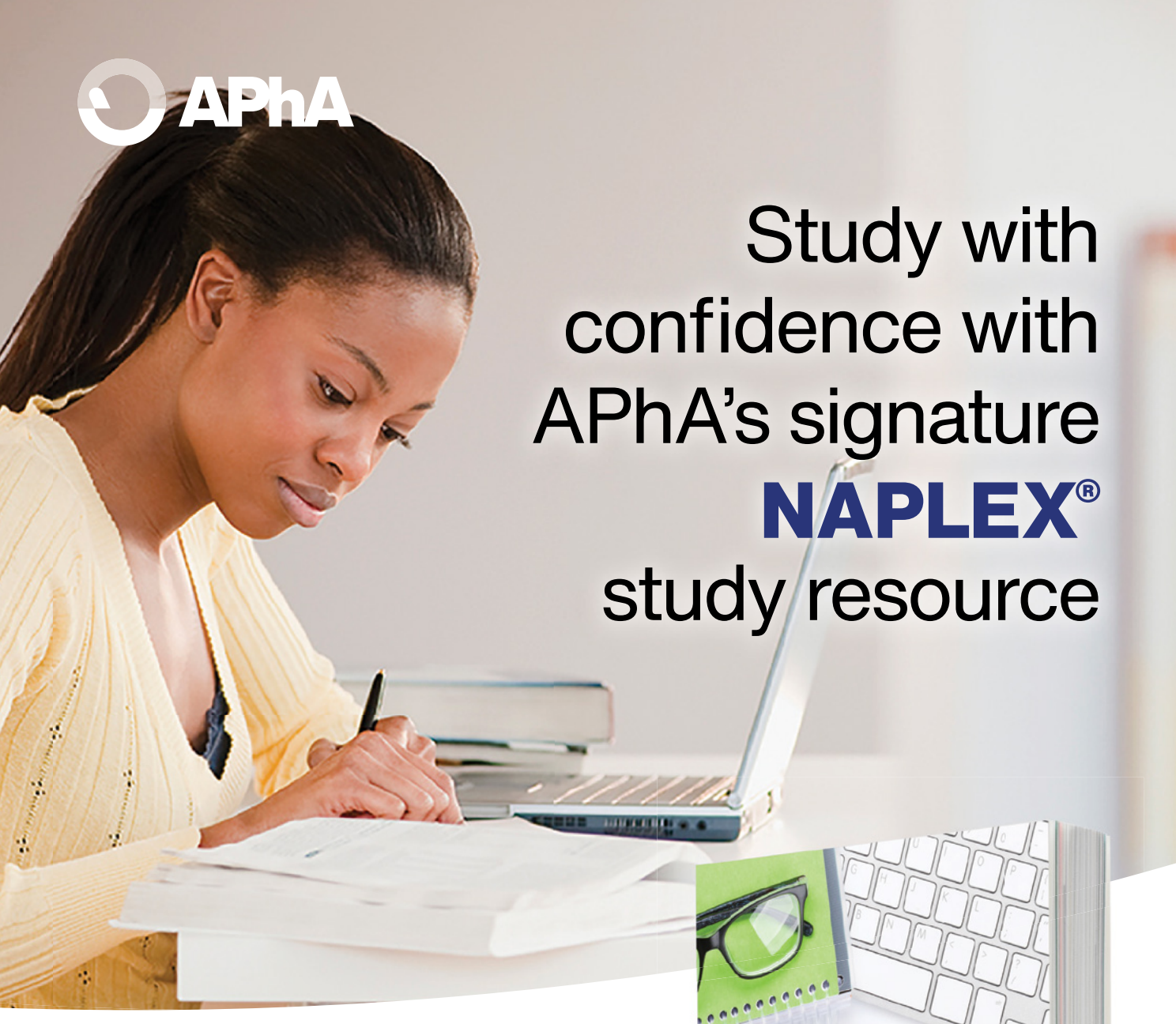

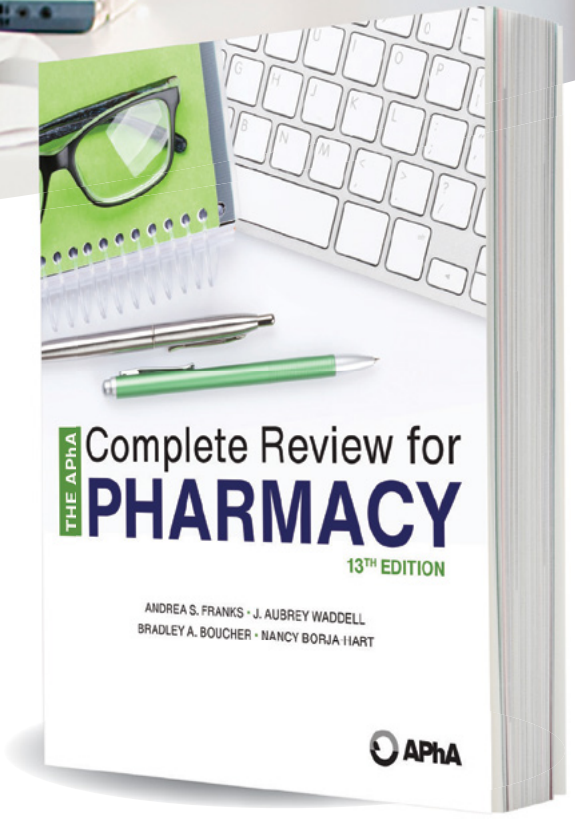

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RSV MAY RAISE THE STAKES FOR OLDER ADULTS

Respiratory syncytial virus (RSV) is a common and contagious virus that typically produces mild, cold-like symptoms but can put older adults at risk for severe outcomes.[1,2,*]

Each year in the US, approximately 177,000 older adults are hospitalized and an estimated 14,000 of them die due to RSV infection.[2]

*The CDC states that adults at highest risk for severe RSV infection include older adults, especially those 65 years and older, adults with chronic heart or lung disease, and adults with weakened immune systems. Data are limited in assessing the risk of severe outcomes due to RSV infection in adults 60-64 years of age.[3,4]

CDC=Centers for Disease Control and Prevention;
CHF=congestive heart failure; COPD=chronic obstructive pulmonary disease.

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Learn about the risks of RSV at RSVinAdults.com