



May/June 2021

The Journal

of the Pharmacy Society of Wisconsin



Geriatrics



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Up Front: Taking a Victory Lap

by Sarah Sorum, PharmD



How many of you have a hard time making noise when you accomplish a milestone? Do you toot your own horn? Do you cheerlead for those behind you and celebrate them? Maybe both?

PSW is a collection of dedicated healthcare professionals that inspire one another to do more. We are continually working to be better – go from great to greater. Check out my [April CEO Blog post, "A Growth Mindset"](#).

PSW has a reflex to downplay our role, but I think we are overdue for a victory lap.

We are on an advocacy hot streak

[PSW Month of Advocacy](#) in March served as the perfect backdrop to see PBM reform legislation signed into law. [2021 WI Act 9](#) requires PBMs to be licensed with the Wisconsin Office of the Commissioner of Insurance (OCI) and gives OCI the authority to enforce laws relating to PBMs. Other provisions include fair pharmacy audits; guardrails around accreditation requirements; and clawback, gag clause, and retroactive recoupment prohibitions. It's a leap forward for PBM transparency in Wisconsin.

With the allowance for technician final product verification, or

"tech-check-tech," in Phar 7; signing of 2021 [WI Act 3](#) (technician vaccination); and introduction of [SB300](#) (technician registration), PSW has greatly expanded pharmacy technician roles and laid the groundwork for desperately needed improvements in recruitment and retention of qualified pharmacy technicians.

Our Pharmacist Provider Status bill has been introduced in Wisconsin, [SB255](#). I hope you've seen our new [video](#), showcasing this important evolution for team-based care. Plus, be sure to check out the amazing [materials](#) created by the PSW Provider Status Core Team and supported by the PSW Practice Advancement Leadership Team.

We rock at virtual conferences and resources

PSW has pivoted on a dime to make virtual connection and community possible in our COVID times, including providing multiple virtual conferences; building a robust CE library shared nationally on a course marketplace; launching a brand new PSW website; and developing the new PSW Network platform that will debut this summer. While we are excited to return to in-person options later this year, PSW has demonstrated that virtual collaboration can be powerful, and we do it really well. Aspects of virtual connection are here to stay.

Caring for COVID patients and vaccinating the state

You know that moment when an Olympian is running their victory lap and they have members of their family or coaching team join them in the lap? We want to invite Wisconsin vaccinators and pharmacy department operations teams to join us for this part of the celebration. PSW and its members are part of the reason Wisconsin is in the top 10 for percentage of residents fully vaccinated, and Wisconsin is the number one state for rapid vaccine distribution.

The PSW staff, including me, have spent thousands of hours on COVID vaccine operations and advocacy discussions, partnership building, education, communication, and problem-solving. Our weekly COVID vaccine webinars, which we created in a matter of days, have provided absolutely essential information over the past several months. *FastFacts* has been full of information synthesized for Wisconsin pharmacists from countless meetings and information sources.

The provision of timely information from PSW included several virtual town halls on COVID-19, creating a [COVID-19 resource page](#) (and keeping it up to date!), and many special alert emails. I was reminded this past week of the collaborative calls PSW facilitated around the logistics of patient transfers to the Alternate Care Facility at State Fair Park. I was also reminded of the instrumental role PSW and our members played in the ethical allocation of bamlanivimab and other monoclonal antibody supplies. We've been through a lot, and PSW has served as a venue to connect and quickly adapt to improve patient care.

We know that we have lots of laps to go. We aren't going to stop running.

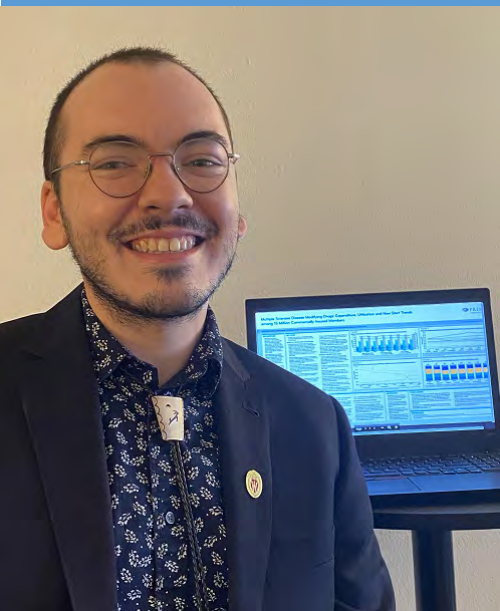
I have a vision for PSW

PSW is striving to be an inclusive leader that facilitates connection, engagement, and action together to advance our profession, strategically. The PSW Board of Directors has developed a [Plan 2025](#) that we can rally around. It includes breakthrough initiatives that build inclusivity and expand practice opportunities.

The servant leader in me is humbled by the selfless work that our members and our profession have done, day in and day out over the past year. I'm impressed seeing the walk-in vaccination clinics, the equity projects, and the investment in operational time creating new services and service models. I'm inspired by members' willingness to share, solve problems, and mentor residents and students virtually, and by pharmacy teams' work in understaffed crisis situations.

We've had a year like no other, a challenge like never before, and we have so much opportunity on the path ahead. All of this deserves cheerleading and celebration. As servant leaders, we lead with our hearts and would perhaps prefer to blend in, letting others take the accolades instead of standing up and taking a bow at the applause. But, it's time to take that bow, make some noise on behalf of PSW, and take a victory lap before we run the next one.

- Sarah Sorum, PharmD
Executive Vice President & CEO



Congratulations to 2018-2020 JPSW Open Access Coordinator

Nicholas Friedlander, the 2018-2020 JPSW Open Access Coordinator, received the Best Resident or Fellow Poster (Prime Therapeutics; "Multiple Sclerosis Disease Modifying Drugs: Expenditure, Utilization, and New Start Trends among 15 Million Commercially Insured Members.") from the AMCP Foundation and CVS Health at Academy of Managed Care Pharmacy (AMCP) 2021. The semi-annual Competition garnered 114 authors presenting cutting-edge research. Best Poster judges evaluated their research based on scientific merit, evidence that the research conducted was innovative and practical, strength and clarity of conclusions, and knowledge of the subject matter. Student pharmacists, residents, and fellows conducted live chats with over 2,000 leaders and professionals in the managed care setting.

I am a Pharmacy Professional and I... Learned a New Skill

Luiza K. Brenny, PharmD, BCPS

*Clinical Pharmacist - Acute Care and Primary Care
UW Health, Madison*

During the pandemic my new husband and I got a “COVID Puppy” named Cobalt. My new skill has been learning how to be a doggy mom and how to train him to be a little gentleman. We found an online puppy school and have been teaching him manners as well as some fun tricks. Having a new puppy over the summer months got us moving and doing more outdoor activities, like walking, going to the park, and having puppy playdates. In the winter, we’ve learned about unconditional love for another living being as we shiver in the extreme cold for potty breaks. We never would have gotten a puppy at this point of our lives if it weren’t for COVID, but we had the opportunity to become puppy parents and are so in love with our little buddy. This season taught us to slow down and gave us more time for training/acclimating to our new fluffy household companion.



July/August 2021
**Theme: I am a
Pharmacy Professional
and I... Enjoy Summer
Activities**

Email your response to
mgrant@pswi.org by June 1.

Responses should be <100 words
and include a photo.



Lynn Buss, RPh, BCPS

*Clinical Pharmacist
Froedtert Hospital, Milwaukee*

Inspired by my daughter, a talented euphonium player, I have been teaching myself to play the euphonium during the pandemic. I love the dark, rich, mellow timbre of this brass instrument. “On Wisconsin” was one of my first songs I learned!! My elderly parents, confined to their home due to the pandemic, enjoy impromptu outdoor performances of my burgeoning pastime. Currently, I am working on tone quality and expanding my range, with the goal of transitioning from the flute section to the euphonium section in the New Berlin Community Band.

Brittany Mejaki, PharmD, BCOP

*Oncology Pharmacist
Aurora Cancer Care, Milwaukee*

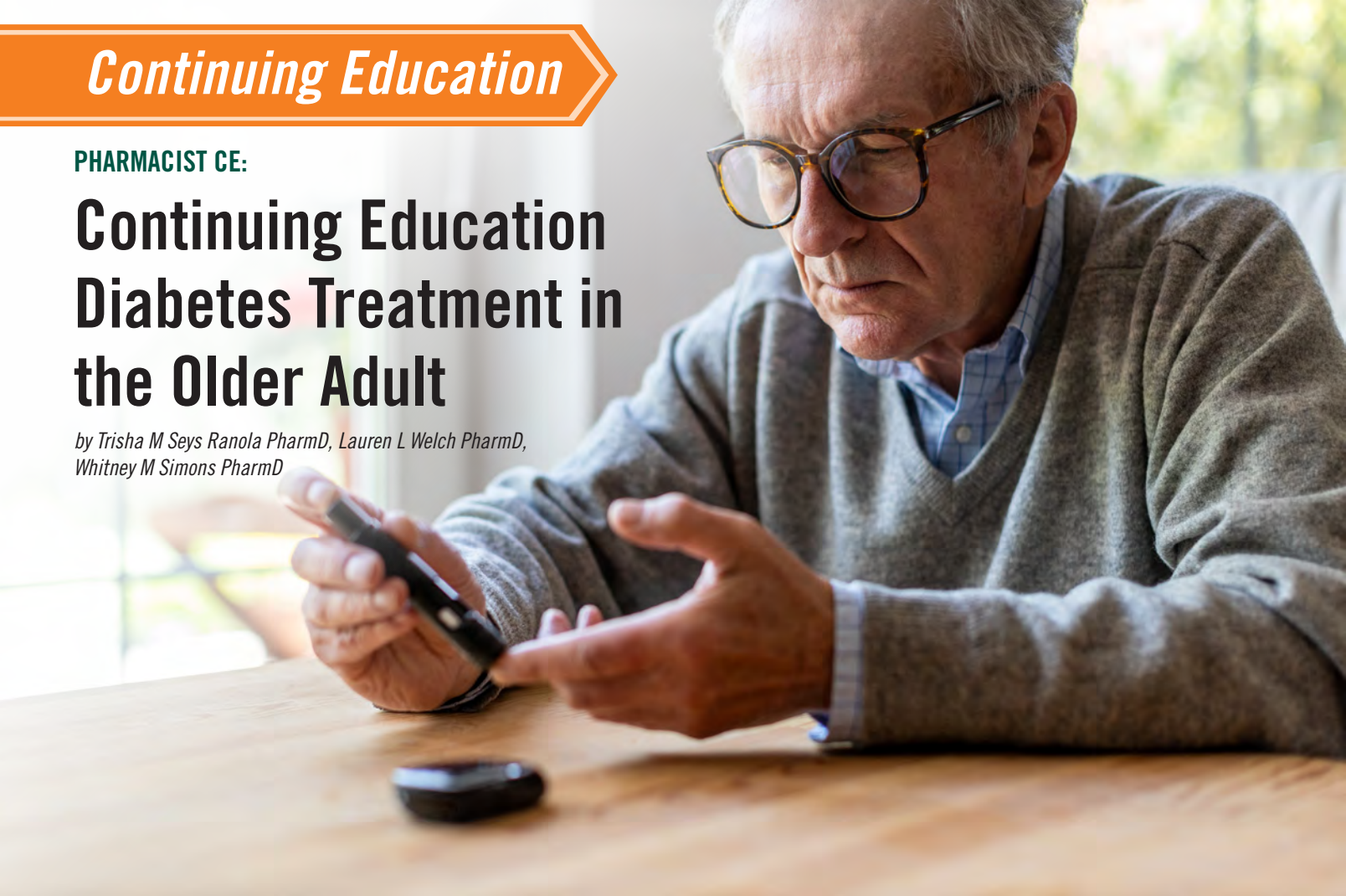
This fall, I volunteered to be the Outdoor Shelter Manager for the Urban Cat Coalition, a Nonprofit Organization dedicated to helping humanely reduce the homeless cat population in Milwaukee through trap-neuter-return (TNR). Despite never having built a shelter before, I learned how to do it! This winter I built and distributed over 30 shelters in the community. I was even able to record and present a video on how to build your own at the 2021 Virtual Great Lakes Pet Expo! I also learned how to socialize foster kittens; 3 of our 4 kittens have since been adopted!



PHARMACIST CE:

Continuing Education Diabetes Treatment in the Older Adult

by Trisha M Seys PharmD, Lauren L Welch PharmD,
Whitney M Simons PharmD



Type 2 diabetes mellitus (T2DM) has been on the rise over the past several decades. With the advances in diabetes treatment, we are seeing a growth in the number of older adults living with the condition. As treatments for all chronic conditions have improved, there are now more older adults living with T2DM.¹ In 2018, there were 14.3 million adults over the age of 65 (26.8% of that age group) living with T2DM; this is predicted to increase to 26.7 million by the year 2050.¹ The rise in diabetes rates brings up substantial questions for the geriatric provider: What treatments can we use safely for our older adults? Which medications will cause the fewest side effects? What therapies have the potential to improve or worsen comorbidities that diabetic patients are living with? In this article, we will address these geriatric considerations and offer an overview of diabetes therapies as they apply to this unique patient population.

Geriatric providers know that older adults are not a homogeneous

population. Many suffer from multiple morbidities, while others continue to lead active lives with few complications.² Despite this spectrum of differences, physiological changes do occur that impact recommended lifestyle modifications and diabetic medications.^{2,3} Among the most notable changes to physiology is a decrease in renal function, which can limit medication choices. Renal function decline also requires more self-monitoring for hypoglycemia, which in turn necessitates adequate dexterity and

often presents as a challenge for older adults. Likewise, vision might be impacted, making drawing up insulin or dialing a medication pen extremely challenging, and creating adherence and safety concerns. Neurohormone levels change, altering expression to the central nervous system. In turn, these changes can lead older adults to be less responsive to changes in position, thereby increasing the risk of falls.^{2,4} Digestive systems become sluggish, impacting the rate of food and medication absorption, and resulting in changes in

CE FOR PHARMACISTS

COMPLETE ARTICLE AND CE EXAM
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Learning Objectives

- Define the present and future epidemiology of diabetes in older adults
- Identify potential complications and considerations in older adults with diabetes
- Discover assessment tools including screening, diagnostic, and prevention strategies for diabetes in older adults
- Discuss individualization of care of diabetes in older adults
- Identify best practices to involve patients in decisions related to diabetes care in older adults

blood glucose. In older adults, the immune system response is not as robust, making infections more likely yet harder to diagnose and treat.² These considerations will be explored in more detail below.

In addition to physiological presentations/symptoms, older adults are often members of a vulnerable financial population. Older adults might be at increased risk for lack of financial independence, leading to food insecurity, unaffordable medications, and less overall access to healthcare.⁵ In 2017, an estimated 14.1% of adults over the age of 65 lived at or below the poverty threshold.⁵ Additionally, only 17% (55 million) of people age 65 and older are enrolled in Medicare. Of those enrolled, only 39 million are enrolled in Part D for prescription drug coverage.⁶ One in five uninsured adults in 2018 went without needed medical care due to cost.⁷ Together, these insecurities are part of a larger issue that comprises the social determinants of health (SDH). While SDH is a familiar term in population and public health, it is only recently being addressed by family medicine clinics.⁸ Additionally, the American Diabetes Association (ADA) states that the SDH, including socioeconomics; physical and neighborhood environment; food environment (food security); and health care and social support, have a significant impact on diabetes treatment and must be addressed to improve health outcomes.⁴ During clinical interactions with patients, pharmacists should routinely ask patients about aspects of SDH, including food security, feeling safe in their home, and what social supports they have available, among others.⁹ Often, the SDH are part of a lifelong risk and might be out of the control of the patient. Addressing limitations on finances, food insecurity, and social support might impact the lifestyle change recommendations and medication therapy selections given by healthcare professionals.

Due to the variance in older adult health, diabetes care for older adults requires shared decision making between the patient/caregiver and provider(s), and a shift in focus from targeting pre-determined glucose levels to improving overall quality of life for the patient.¹⁰

A team-based approach is considered best practice for older adults living with diabetes and should include discussions on what the patient values, the best methods to minimize side effects including hypoglycemia, the impact on mood, and cognitive decline. Additionally, attention should be placed on the patient's goals, including a discussion surrounding quality of life and function.¹⁰

Clinical Presentation

The majority of people with T2DM are diagnosed prior to the age of 65, after which the incidence and prevalence remain stable.¹¹ Hyperglycemia is a prominent feature of type 2 diabetes in older adults; national guidelines for diagnosing T2DM are based on hemoglobin A1c (A1c) and fasting blood glucose levels, leaving about one-third of older adults with diabetes undiagnosed due to a wide variety of factors that might include asymptomatic mild to moderate elevations in blood sugar, lack of follow-up or access to medical care.² Diagnosis after the age of 65 is more common in non-Hispanic whites and typically manifests with lower

A1c and decreased insulin requirements. Additionally, while retinopathy is more common with younger age of onset, there is no difference in cardiovascular disease or peripheral neuropathy compared with older cohorts.²

Symptoms of T2DM in the older adult population are not limited to the classic three polys (polyuria, polyphagia, and polydipsia), in part due to the physiologic changes seen with age. For example, consider an older adult male presenting to his provider with nocturia; this might be easily confused with prostate concerns.¹⁰ Typical symptoms might be vague, including feeling more confused, or feeling tired, or frequent urination. Often, these symptoms are simply attributed to "old age," when in fact they might be manifesting as a new condition, primarily related to hyperglycemia.¹⁰ Table 1 below provides a comparison of T2DM symptoms and co-conditions older adults could have that might lead to missed opportunities for screening of diabetes.²

TABLE 1. Symptoms of Type 2 Diabetes Mellitus and Other Conditions with Similar Symptoms in the Older Adult Population²

<i>Symptoms of Type 2 Diabetes Mellitus</i>	<i>Older Adult Co-conditions with Similar Symptoms</i>
Polyuria	Benign prostatic hyperplasia (BPH) Overactive bladder Stress incontinence
Polydipsia	Thyroid changes Or not present due to impaired thirst mechanism
Polyphagia	Thyroid changes
Confusion	Cognitive changes Dementia Infection
Fatigue	"Old age"
Poor wound healing	Peripheral vascular disease
Neuropathy	Peripheral vascular disease
Hyperglycemia	Medications Common to Older Adults: Thiazides Beta Blockers Statins Oral Steroids Antipsychotic Serotonin Inhibitors Others

TABLE 2. 2021 Standard of Medical Care in Diabetes

See [Table 12.1 in the 2021 Standard of Medical Care in Diabetes](#) for information on the treatment goals of glycemia, blood pressure and dyslipidemia in the older adult population.

Older Adults Considerations

Not only is it important to consider the physiological changes that might occur in later life, but other geriatric-related syndromes should also be considered when selecting the most appropriate diabetic medication choice for older adults. Some of these syndromes might be both physical and social in nature, and might include issues such as bladder control, sleep, weight gain or loss, balance, and dementia. The next section of the paper will explore several of these concerns and the impact they may have on therapy considerations.

Dexterity

Older adults are more susceptible to osteoarthritis (OA), which can greatly impact overall dexterity, especially in the hands. The prevalence of hand OA increases with age, and it is reported that 13% of men and 26% of women over the age of 70 suffer from OA.¹² Providers should ask whether patients have difficulty opening pill bottles with safety caps, especially if it appears that non-adherence may be impacting overall diabetes control. Limited dexterity can significantly impact a patient's ability to draw up and inject insulin or use glucagon-like peptide (GLP-1 RA) injectables. Insulin vial-and-syringe combinations are typically more cumbersome for these patients, and options using insulin pens/GLP-1 RA may be considered. Assessment of use of pens should still be undertaken, as dexterity may impact use of these devices as well. Dexterity can also impact the patient's ability to use a glucometer effectively to monitor blood glucose. Creative solutions might be needed to engage family members or caregivers to aid in either safe medication administration or effective blood glucose monitoring strategies for some of these patients.

Sensory Impairments

Vision impairments increase as patients age, impacting nearly one out of five older adults with diabetes.¹³ Cataracts are more commonly diagnosed in diabetic patients.¹³

Additional microvascular complications related to diabetic retinopathy can also impact overall vision quality for older adults. It is important to screen for vision impairments. Offering recommendations for corrective measures or appropriate vision aids can prevent medication-related errors and improve overall quality of life.¹³ Vascular disease and neuropathy have been linked to hearing impairments in older adults. Hearing impairments are twice as common in older adults with diabetes.² Both vision and hearing impairments should be factors to assess and consider when managing and educating patients on diabetic medication regimens and lifestyle modifications to reach specific patient diabetic goals. Large-print labels, medication bottles for the visually impaired, pocket talkers to assist with hearing, and talking blood glucose meters are all options during clinic appointments or when receiving counseling at the pharmacy that may promote independence and improved safety for patients with sensory impairments.

Polypharmacy

Given the increased complexity and additional comorbidities, polypharmacy is much more prevalent in this patient population. It is estimated that 40%-50% of people over the age of 65 have five or more medications, meeting the definition of polypharmacy agreed upon in the literature.^{14,15} The number of comorbidities typically results in an increase in prescribed medications.^{14,15} A direct correlation occurs between the number of medications and incidence of adverse drug events or drug-drug interactions (DDIs) resulting in increased incidence of adverse drug reactions. One study noted the prevalence of clinically relevant DDIs in older adults prescribed six or more medications was 26%; of these, 5% were classified as potentially serious DDIs.² Shared decision-making to address the patient's goals should be considered prior to adding additional medication therapy to treat a patient's

diabetes, due to the risks associated with polypharmacy in older adults.

Falls

It is estimated that one-third of community-dwelling adults aged 65 years or older fall at least once annually.² Falls can occur for a variety of reasons in older adults, but diabetes presents as an important risk factor. Microvascular complications related to diabetic neuropathy can contribute to decreased sensation in the feet, thereby increasing the risk of falls. Peripheral neuropathy is present in about 50%-70% of older adults with diabetes, increasing risks associated with postural instability and emphasizing more challenges associated with balance and muscle atrophy.² Overtreatment of diabetes can lead to unrecognized hypoglycemia, causing patients to feel more unsteady on their feet. Physical therapy in high fall-risk patients or patients who have recently experienced a fall can help minimize future falls. The longitudinal data from the Health, Aging and Body Composition study does imply that a heightened focus on diabetes-related complications, as noted above, has led to fall reduction.¹⁶

Mood

Mental health plays a role in every aspect of diabetes therapy, from self-care/effective lifestyle habits to taking medications correctly. It is estimated that about 14% of adults over the age of 55 have depression.¹⁷ People with diabetes typically have a higher prevalence of depression than non-diabetics, 32% vs. 16%.^{17,18} Given the higher incidence, the American Geriatric Society (AGS) recommends screening for depression within the first three months after initiation of diabetic treatment, utilizing tools such as the Geriatric Depression Scale.¹⁸ Many factors play a role in this increase in depression in older adults, but can also be mistaken for other geriatric conditions (e.g. fatigue, anemia) without a thoughtful assessment of mood symptoms. It is also thought that there is a bidirectional relationship between both major depressive disorder and diabetes.¹⁷ Poor mood or depressive symptoms can significantly impact other comorbidities, including

diabetes. Patients with poor mood may be apathetic in their approach to their health, and adherence to medications and healthy nutrition habits may decline. Studies have also found that improved blood sugars mitigate depressive symptoms and strengthen the desire for active self-care.¹⁹ Because of the impact that depression has on self-care, the ADA guidelines recommend providing psychosocial care to all people with diabetes and screening people 65 years and older for depression.⁴ Additionally, the American Geriatric Society (AGS) strongly recommends depression screening within the first three months after a new diabetes diagnosis, and treatment within two weeks of depression presentation. Re-evaluation should be completed every six weeks until depression is managed.²⁰

Cognitive Impairment

Cognitive impairment is a common syndrome in older adults for a variety of reasons. Medication-induced impairment, a dementia diagnosis, depression, vitamin deficiencies, and substance use can all be contributors to cognitive impairment. Mild cognitive impairment or mild dementia occurs in 10%-20% of older adults; 50% of these patients will progress into a diagnosis of dementia within five years, but it is estimated that 20%-30%

of these patients will return to normal cognitive functioning if risk factors are mitigated.²¹ It is also thought that patients with diabetes are twice as likely to develop cognitive impairment than non-diabetic patients.²² Unrecognized hypoglycemia can present as cognitive impairment; it is sometimes even misdiagnosed as delirium. Patients impacted by varying levels of cognitive impairment can present significant challenges for managing their diabetes. Safety with use of medications, especially insulin, should be a serious consideration in selection of agent and ongoing assessments for appropriateness of current treatments. Patients with cognitive impairment may forget to take their medications, accidentally take additional doses of medications, take different prescribed doses of medications/insulin, or refuse medications altogether. Medication simplification and eliciting assistance from caregivers/family members or visiting nurse services may become critical to successful outcomes for these patients. Safe use of insulin should be considered, especially with the shorter-acting varieties that are associated with higher rates of hypoglycemia events. Some patients with cognitive impairment forget to eat meals or do not take medications with meals, which can lead to a significant safety concern regarding hypoglycemia issues

as well. In these patients, avoiding agents such as bolus insulin and sulfonylureas is considered safe practice.¹

Hypoglycemia Unawareness

As we age, the counterregulatory responses to hypoglycemia, (e.g., sweating, palpitations, tremors) may decrease, impairing hypoglycemia symptoms.²³ Use of insulin continues to be a major contributor for hypoglycemia episodes in older adults, and other medications, such as beta-blockers, might mask some of the symptoms. The use of insulin is unavoidable for certain patients. In these situations, developing strategies to minimize risk, such as keeping the A1c above 6.5%, is recommended by the ADA.⁴ The newer treatment options, GLP-1 RA and sodium glucose co-transporter 2 (SGLT2i), have allowed for use of non-insulin therapies to treat diabetes with better efficacy and safety in the older adult population. Close monitoring of renal function is imperative, as several agents are renally cleared and will require dose adjustments based on renal function (e.g., sulfonylureas [SUs], SGLT2i, metformin). Severe hypoglycemia has been linked to an increased risk of dementia and, consequently, patients suffering with cognitive impairment experience hypoglycemia at a higher rate.²³

TABLE 3. Newer Treatment Considerations¹⁸

Medication Class	Pros	Cons
DPP-IVi	Used as monotherapy or combination therapy to lower A1c Minimal risk of hypoglycemia Weight Neutral	Avoid in heart failure Renal Adjustments
GLP-1 RA	ASCVD benefits >1% A1c lower potential Weight Loss Negligible risk of hypoglycemia Visiting nurse weekly administration possibility No renal dose adjustments Used as monotherapy or add on therapy	Weight loss Injectable High cost Gastrointestinal side effects Adherence may be impacted with once weekly formulation (pro/con)
SGLT2i	ASCVD benefits Renal benefits A1c lower potential Lower risk of hypoglycemia Weight loss	May worsen urinary incontinence leading to skin integrity issues and social isolation Increase risk of Urinary tract infections Renal dose adjustments Hypovolemia concerns Postural hypotension because of hypovolemia High Cost

ASCVD - Atherosclerotic Cardiovascular Disease; DPP-IVi - dipeptidyl peptidase; GLP-1 RA - glucagon-like peptide 1 receptor agonist ; SGLT2i - Sodium/glucose cotransporter-2 inhibitors

TABLE 4. Medication Dose Adjustments and Considerations⁴

Medication Name	Therapeutic Dose	Renal Dose Adjustments				Expected A1c Reduction	Effect on Blood Glucose	Caveats/Things to Consider
Metformin	2000 mg daily	Guideline	Do not initiate	Do not use	Max dose	1 - 2%	Fasting & Basal	<ul style="list-style-type: none">Older adults may develop diarrhea, from metformin, even if they have tolerated it for years.Vitamin B12 deficiency secondary to metformin us, may lead to worsened neuropathy symptoms.
		AGS	Max dose of 1000 mg per day if eGFR is 30 - 60 mL/min/1.73m ²					
		AACE/ACE	eGFR < 45 mL/min/1.73m ²	eGFR < 30 mL/min/1.73m ²	500 mg BID if eGFR is between 30-45 mL/min/1.73m ²			
Sulfonylureas (SUs)								
Glipizide (IR and ER)	2.5 mg daily up to 20 mg daily	eGFR ≥ 50 mL/min/1.73m2		eGFR ≥ 10 - 49 mL/min/1.73m2	eGFR < 10 mL/min/1.73m2	1 – 2%	Post prandial	Should be taken 15-30 minutes prior to eating a meal. This may be difficult for the older adult to accomplish, especially if they use a medication box.
		No dose adjustment warranted		Initial 2.5 mg daily. May increase to 20 mg daily, cautiously	Avoid if possible. If necessary, initial 2.5 mg daily and may cautiously increase to 20 mg daily			The 2019 Beer's Criteria by the AGS put forth a strong recommendation to avoid use in older adults.
Glyburide	Conventional Tablets: 2.5 mg up to 20 mg daily	No dose adjustments warranted. However, glyburide is typically avoided in chronic kidney disease. Glipizide is the preferred agent, if sulfonylurea therapy is necessary.				1 – 2%		
	Micronized Tablets: 1.5 mg up to 12 mg daily							
Glimepiride	1 mg daily up to 8 mg daily	Initial of 1 mg daily; dose titration and maintenance dosing should be conservative to avoid hypoglycemia. Alternate therapy should be considered if eGFR < 15 mL/min/1.73m ²				1 – 2%		
Thiazolidinedione (TZD)								
Pioglitazone	15 mg daily up to 45 mg daily	No dose adjustments warranted. May use in HD and PD without adjustment, as well.				0.5 – 1.4%	Fasting & Basal	<ul style="list-style-type: none">Weight gain and peripheral edema typically occur with 30 mg doses or higher.It is not recommended to use more than 30 mg daily with insulin therapy.
Dipeptidyl Peptidase IV inhibitors (DPP-IVis)								
Alogliptin	25 mg daily	CrCL ≥ 60 mL/min	CrCL ≥ 30 - 59 mL/min	CrCL ≥ 15 – 30 mL/min	CrCL < 15 mL/min or HD	0.6%	Post Prandial	It is ideal to avoid DPP-IVis if a patient has comorbid HF. However, if limited therapy options remain to assist with blood glucose lowering while minimizing risk for hypoglycemia, consider the use of sitagliptin or linagliptin. These two agents have the lowest incidence of increasing HF hospitalizations.
		No dose adjustment warranted	12.5 mg daily	6.25 mg daily	6.25 mg daily			
Linagliptin	5 mg daily	No dose adjustments warranted and can use in dialysis (HD & PD)				0.4%		
Saxagliptin	5 mg daily	eGFR ≥ 45 mL/min/1.73m2	eGFR < 45 mL/min/1.73m2	Dialysis		0.4 – 0.5%		
		No dose adjustments warranted	2.5 mg daily	HD: use 2.5 mg daily and administer post-dialysis				
				PD: not studied				
Sitagliptin	100 mg daily	eGFR ≥ 45 mL/min/1.73m2	eGFR ≥ 30 - 44 mL/min/1.73m2	eGFR < 30 mL/min/1.73m2	Dialysis	0.5 – 0.8%		
		No dose adjustments warranted	50 mg daily	25 mg daily	HD: 25 mg daily			
					PD: 25 mg daily			

TABLE 4. Medication Dose Adjustments and Considerations Cont.⁴

Medication Name	Therapeutic Dose	Renal Dose Adjustments				Expected A1c Reduction	Effect on Blood Glucose	Caveats/Things to Consider		
Sodium Glucose co-Transporter 2 inhibitors (SGLT2is)										
Canagliflozin	100 mg daily up to 300 mg daily	eGFR ≥ 60 mL/min/1.73m ² No dose adjustments warranted	eGFR 45-59 mL/min/1.73m ² 100 mg daily	eGFR 30-44 mL/min/1.73m ² 100 mg daily	eGFR < 30 mL/min/1.73m ² 100 mg daily	0.7 – 1%	Post Prandial	<ul style="list-style-type: none">The black box warning regarding leg/foot amputation has been removed		
Dapagliflozin	5 mg daily up to 10 mg daily	eGFR ≥ 45 mL/min/1.73m ² No dose adjustments warranted		eGFR 30-44 mL/min/1.73m ² Manufacturer recommends against use	eGFR < 30 mL/min/1.73m ² Use is contraindicated			<ul style="list-style-type: none">May also be prescribed for heart failure therapy at 10 mg daily.		
Empagliflozin	10 mg daily up to 25 mg daily	eGFR ≥ 30 mL/min/1.73m ² No dose adjustments warranted		eGFR < 30 mL/min/1.73m ² Manufacturer recommends against use*	Dialysis Use is contraindicated in HD and PD			<ul style="list-style-type: none">As the kidney function declines, there is less glucose control.		
Glucagon Like Peptide-1 Receptor Agonists (GLP-1 RAs)										
Albiglutide	30 mg once weekly up to 50 mg once weekly	No dose adjustments warranted. No recommendations provided when eGFR < 15 mL/min/1.73m ² .						0.6 – 1.3%	Fasting & Post Prandial	<ul style="list-style-type: none">The pen contains a diluent and a powder, which need to be mixed 15-30 minutes prior to injection of 30 mg and 50 mg doses, respectively
Dulaglutide	0.75 mg once weekly up to 4.5 mg once weekly	No dose adjustments warranted.						0.7 – 0.9%		<ul style="list-style-type: none">The needle is housed within the pen device, lessening the number of steps required for the injection.The pen device only has 1 dose option thus limits concern about administering the incorrect dose.Good option for those with poor dexterity and low/poor vision.
Exenatide	IR: 5 mcg BID and may increase to 10 mcg BID	CrCL ≥ 30 mL/min	CrCL < 30 mL/min	ESRD						
		No dose adjustments warranted. Use with caution when titrating dose if CrCL is between 30 – 59 mL/min	Use is not recommended.	Use is not recommended.						
	ER: 2 mg once weekly	eGFR ≥ 45 mL/min/1.73m ²	eGFR < 45 mL/min/1.73m ²	ESRD						
		No dose adjustments warranted.	Use is not recommended.	Use is not recommended.						
Liraglutide	1.2 mg daily up to 1.8 mg daily	No dose adjustments warranted. Use with caution in HD and PD.				1 %	Fasting & Post Prandial	<ul style="list-style-type: none">Daily injectionRequires a titration schedule of 0.6 mg daily for 7 days then increase to 1.2 mg daily. May increase to max dose of 1.8 mg daily, if needed/tolerated		
Semaglutide	0.5 g once weekly up to 1 mg once weekly	No dose adjustments warranted.				1.3–1.8%		<ul style="list-style-type: none">Weekly injectionRequires a titration schedule of 0.25 mg weekly for 4 weeks then increase to 0.5 mg weekly. May increase to 1 mg weekly after 4 weeks on 0.5 mg, if needed and toleratedMost potent in class		
*In patients established on empagliflozin, some experts continue to use empagliflozin 10 mg daily in patients with eGFR < 30 mL/min/1.73m ² off-label AAACE/ACE - American Association of Clinical Endocrinologists/American College of Endocrinology; AGS - American Gem Society; BID - Twice a day; CrCl - Creatinine Clearance; eGFR - Estimated glomerular filtration rate; ER - Extended release; ESRD - End-Stage Renal Disease; HD - hemodialysis; HF - Heart failure; IR - Immediate release; PD - Peritoneal dialysis										

Functional Impairments

Aspects of a patient's executive functioning may decline because of aging, cognitive changes, and change in social supports. This can greatly impact how patients are able to appropriately manage their medications (e.g., non-adherence or inappropriate dosing). Cooking and shopping for food may be limited based on food insecurities as previously discussed. Team-based approaches to care are key to addressing many of these functional or social issues that are common for older adults.²² Older adults are at higher risk for malnutrition due to factors such as anorexia, altered taste and smell, swallowing difficulties, and dental complications.¹³ Patients having difficulty in meal preparation may require assistance from a dietician, choosing pre-packaged meals that meet their functional abilities and nutritional and energy needs. Difficulty in meal preparation also leads to erratic meal schedules, which can lead to either hyperglycemia or hypoglycemia. Alternatively, patients may be unable to get to the store, or finances may be prohibitive, which limits food access altogether. As a result, unintentional weight loss due to not eating appropriately may lead to hypoglycemia, especially if unnecessary medications are continued after this weight loss occurs or if unintentional weight loss is not detected. Nutritional screening assessments exist to screen for food insecurities and can assist with determining when referral to a dietician is warranted.¹² Addressing functional impairments through additional assistance in the home (e.g. visiting nurse services, meals on wheels, senior centers, family and friends, etc.) can significantly improve outcomes for these diabetic patients.²³

Therapeutic Approach and Risk Reduction

Unfortunately, despite the high prevalence of diabetes in older adults, there is a limited presence of this patient population in clinical trials.²² In this article, we draw from four main clinical trials: the UK Prospective Diabetes Study (UKPDS); Action to Control Cardiovascular Risk in Diabetes (ACCORD); Action in Diabetes

and Vascular Disease: Preterax and Diabetes Controlled Evaluation (ADVANCE); and Veterans Affairs Diabetes Trial (VADT).²⁴⁻²⁷ These trials suggest that the legacy effect of tightly controlled blood glucose early in diagnosis prevents microvascular and macrovascular events from occurring. However, later in the disease process, tightly controlled blood sugars significantly increase the risk of severe hypoglycemia. These trials help direct therapy, but the lack of empirical evidence leaves much of the treatment guidance left to expert opinion for management.⁴ Treatment considerations should always include an assessment of the patient's comorbidities, functional status, atherosclerotic cardiovascular disease (ASCVD) risk, goals of care, and hypoglycemia risk. Using this information, goal setting should include establishing individualized A1c and blood glucose goals. Thoughtful consideration should be applied to insulin delivery devices, and how often patients should monitor blood glucose.

As described earlier, shared decision making about medication and life-style therapy is the gold standard in caring for older adults. This process also applies to setting patient-specific blood glucose goals. Given the homogeneity of the population, one level/goal does not apply to all patients. The 2021 American Diabetes Association (ADA) Standards of Care recommend less stringent goals for patients who have higher risk of hypoglycemia, shorter life expectancy, established vascular complications, patient preferences such as not using injections or preferring not to check blood sugars, and poor social support systems in place.⁴ Many older adults have one or more of these factors. The Standards of Care provide further clarification for older adults based on the number of comorbidities, categorizing patients into three groups: Healthy Adults, Complex/Intermediate, and Very Complex/Poor Health. Blood glucose and A1c goals become less stringent with advancement through the groups to help protect against hypoglycemia.⁴ All categories should maintain an A1c over 6.5% to decrease risk of hypoglycemia, potential negative cardiac outcomes, and falls.⁴ Healthy adults over the age of 65 with few comorbidities or functional limitations and no cognitive impairment should have tighter blood

glucose goals with an A1c goal of less than or equal to 7.5%. The Complex/Intermediate group is defined as having multiple comorbidities, 2+ activities of daily living (ADL) impairments, and mild to moderate dementia. This Intermediate group's A1c goal is less than or equal to 8%. The Very Complex/Poor Health group is defined as living in a long-term care facility, moderate to severe dementia, greater than 2 ADL impairments, and/or end-stage chronic illness. The A1c goal in this group is less than 8.5%. These goals can be found in table format, along with blood pressure, aspirin, and statin therapy goals outlined by the ADA in Table 2.⁴ All aspects of the treatment plan should be reviewed by the health care team with the patient and family, if indicated.

The 2021 ADA guidelines include specific recommendations for medication therapy following lifestyle modifications and metformin.⁴ The ADA recommends considering indicators of high risk or established ASCVD, chronic kidney disease (CKD) or heart failure (HF) and then utilizing GLP-1 RA if patients have predominating cardiovascular disease, and SGLT2i when heart failure or nephropathy predominates. If there are no indicators of high risk or established ASCVD, CKD, or heart failure, and a compelling indication to minimize hypoglycemia, consider alternative agents such as DPP-IVi or TZD. If there is a goal to minimize weight gain or promote weight loss, consider GLP-1 RA or SGLT2i agents. Finally, if cost is a major issue and there is no concern for hypoglycemia, consider using a preferred SU in older adults. If patients have significant renal disease or a history of pancreatitis, limit use of oral agents or GLP-1 RA and consider utilizing basal insulin. Special consideration to the newer agents as they pertain to older adults can be found in Table 3.

The patient's therapy goals, and treatment considerations, should be continually reassessed, yearly if stable, or every six months or as needed if therapy or condition changes occur.^{3,20} When choosing a medication to initiate or transition to or from, it is important in our older adult population to consider the agent's potential for hypoglycemia, especially as renal function declines. Generally, in the older

adult population, it is best to avoid the use of SUs due to their risk for hypoglycemia and appearance on the Beer's List.^{4,23} Additional hypoglycemia risk-reduction strategies include: avoiding sliding scale insulin due to risk for error; limiting prandial insulin use as much as possible to minimize risk for using incorrect amounts, or using the incorrect (longer-acting) insulin; reviewing other concurrent medications for possible additive effects; and ensuring adequate nutrition. Insulin degludec may be appropriate if nocturnal hypoglycemia is an issue and the therapy is acceptable and affordable to the patient.²⁹

Medication Therapy Overview

Metformin

Metformin is the preferred first-line agent, along with lifestyle modifications, according to ADA and AGS.^{4,20} Additionally, it has established cardiovascular and mortality benefits important to many older adults. Studies have found that metformin can safely be used to an estimated Glomerular Filtration Rate (eGFR) of greater than or equal to 30. It should not be used with severe renal failure; caution should be used with hepatic impairment and heart failure, due to increased risk of lactic acidosis. Important side effects to consider in our older adult population are weight loss, anorexia, and diarrhea. Consideration to change metformin from the immediate release formulation to the sustained action formulation is a minor but impactful change, even if patients have tolerated the immediate release formulation previously; as the body changes and dietary intake diminishes, gastrointestinal (GI) upset and diarrhea can develop.⁴

Sodium Glucose co-Transporter 2 Inhibitors (SGLT2i)

According to the ADA, these are the preferred second-line agents for those with ASCVD risk factors ([ASCVD Risk Calculator](#)), established CKD, or HF, given the established cardiovascular and renal benefits.⁴ It should be noted that as eGFR declines, there is demonstrated lower glycemic benefit with use of these agents. Side effects may limit use in older adults

and include weight loss, genitourinary infections, polyuria, dehydration, urinary tract infections, and decreased blood pressure, which can increase the risk of falls.⁴ Of special note, while weight loss may be beneficial for some, it may not be in older adults. Special monitoring of fluid status and adjustment of other medications, such as diuretics and hypertension medications, should be considered. Cost may also be a prohibitive factor in initiation for these medications.⁴

Glucagon-like Peptide Receptor Agonists (GLP-1 RA)

Along with SGLT-2is, GLP-1 RA are considered second line for those with ASCVD risk factors, or established ASCVD. The GLP-1 RA have established cardiovascular event rate reduction and mortality in patients with established cardiovascular disease. No dose adjustments are warranted for the older adult population or for patients with renal impairment. Side effects to consider are weight loss, nausea, vomiting, diarrhea, and reduced appetite. Reduced appetite, in the setting of older adults, should be monitored closely to avoid other complications with excessive weight loss. As an example, poor oral intake can also lead to unintended dehydration leading to falls and potentially acute kidney injury.⁴

Dipeptidyl Peptidase IV inhibitors (DPP-IVi)

According to the ADA, DPP-IVi is a preferred second-line medication class if there is no established CKD or HF, and if there is compelling need to minimize hypoglycemia. Alogliptin, saxagliptin and sitagliptin are dosed based on renal function, while linagliptin does not require dose adjustments though should be used with caution when eGFR is less than 15 mL/min. Alogliptin and sitagliptin may be used when eGFR is less than 15 mL/min and/or in end stage renal disease requiring dialysis. Saxagliptin should be avoided when eGFR is less than 15 mL/min. These medications should be avoided in patients with a history of or recurrent pancreatitis and, in general, avoided in patients with HF.⁴ Side effects include nasopharyngitis and headache. These agents are beneficial for postprandial hyperglycemia control

with low risk for hypoglycemia. Until generics become available, cost may be a barrier for use.⁴

Thiazolidinediones (TZD)

According to the ADA, TZDs are a preferred second-line medication class if there is no established CKD or HF, if there is compelling need to minimize hypoglycemia, or if cost is a major issue. TZDs may be used with older adults but have significant considerations in this population, including risk of worsening HF, osteoporosis, falls or fracture, and macular edema.⁴ There are no dose modifications needed for renal impairment. TZDs should be avoided in patients with HF and with a history of bladder cancer. Side effects include peripheral edema, upper respiratory tract infections, headache, and weight gain. These agents may lower serum triglycerides and provide basal control with low risk for hypoglycemia.⁴

Sulfonylureas (SU)

The ADA notes that SUs may be used as a second-line medication class if cost is a major concern. Sulfonylureas, and other insulin secretagogues, are associated with hypoglycemia and should be avoided, if possible. Glyburide appears on the Beer's List due to its long half-life resulting in hypoglycemia risk.²⁸ However, should patients have difficulty paying for medications, SUs may be the best option due to the low cost. In these situations, shorter acting agents, such as glipizide, are preferred.⁴ Side effects include hypoglycemia, nausea, and weight gain.

Insulin

The ADA recommends deintensification of complex insulin regimens to prevent hypoglycemia and polypharmacy.⁴ The SIMPLE study shows that insulin regimen simplification can reduce risk of hypoglycemia without compromising glycemic control.³⁰ In the older adult population, consider reducing or discontinuing prandial insulin while continuing and titrating basal insulin as needed. If using a premixed insulin, consider using 70% of the total daily dose as a basal dose, administered in the morning, only to minimize risk of nocturnal hypoglycemia.³⁰ If possible, the

initiation of GLP-1 RA or SGLT2i could be considered in this patient population with the goal to de-escalate or discontinue insulin therapy.⁴ Use of premixed insulin may have a role in those patients who maintain predictable eating schedules.²² The use of U-200 and U-500 should be used cautiously in this vulnerable patient population due to the high concentration and higher risk of hypoglycemia with inappropriate use. Unfortunately, insulin resistance becomes more common in older adults and may require higher insulin doses. In these situations, the use of U-200 and U-500 insulins may be appropriate if the patient is cognitively intact and has appropriate social support systems to monitor their wellbeing. U-200 and U-500 insulin types do come in insulin pens that can further help reduce risk of dosing errors that can be seen with use of U-500 insulin vial and syringe dosing.³¹ However, the overarching goal with older adults is de-intensification of insulin whenever possible to avoid hypoglycemia.^{4,20} The 2021 ADA Standards of Care have provided strategies for clinicians to de-intensify insulin which can be found in Table 4.⁴

Summary

In conclusion, older adults with T2DM are a heterogeneous population with varied needs. Shared decision-making discussions among the patient, family/caregivers, and the healthcare team focusing on enhancing quality of life are essential and considered the gold standard. Older adult considerations should be considered when developing goals of care for these patients to ensure that the most effective and safest treatment course is selected. Metformin, plus lifestyle interventions, remains the first-line therapy due to its known effectiveness in controlling diabetes and carrying a very low risk of hypoglycemia. Newer agents, GLP-1 RA and SGLT2i, should be considered as second-line treatment options based on renal function, ASCVD risk, and demonstrated safety with a lower hypoglycemia risk profile. These newer agents should also be considered as replacements for insulin to further minimize risks associated with insulin use. Therapeutic decisions for older adults with T2DM include several important factors, highlighting the importance of

reviewing patients' social determinants of health, evidence-based medicine approaches, geriatric-related syndromes, and recent guidelines, with an emphasis on risk reduction, and patients' preferences. Treatment of older adults living with T2DM continues to be an evolving area with newer, safer therapies coming to the market over the last decade, patient goals of therapy changing over time, and a shared decision-making approach to care. Caring for these individuals requires a comprehensive approach to care, utilizing an interdisciplinary team approach that can be extremely rewarding for pharmacists in all types of care settings.

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- d. All of the above
 2. **True or False:** Social determinants of health should be reviewed in clinic and taken into consideration with treatment plans.
 - a. True
 - b. False
 3. A provider sets a new A1c goal of <7% for a 90-year-old patient with advanced dementia, heart failure, and a history of falls. The patient currently lives in an assisted living facility. The current A1c is 8.3%. What might be your next step(s) as the pharmacist working on with this patient?
 - a. Discuss concerns over the potential for hypoglycemia with lower A1c goals with the health care team.
 - b. Review social determinants of health including, but not limited to, access to clinic appointments, living situation, social support, and functional abilities of the patient.
 - c. Increase the patient's medication doses and add medication as needed to achieve the A1c goal set by the provider.
 - d. All of the above
 - e. A and B
 4. Symptoms of hyperglycemia in older adults can be overlooked due to the following potential co-conditions:
 - a. BPH
 - b. Peripheral vascular issues
 - c. Cognitive changes
 - d. All of the above
 5. Multiple professional associations have published dosing guidance on metformin. According to the American Geriatrics Society (AGS) they recommend a maximum of ____ dose if the eGFR is between 30-60 mL/min/1.73m²:
 - a. 500 mg BID
 - b. 1500 mg daily
 - c. 500 mg daily
 - d. 1000 mg BID
 6. There are many glucagon-like peptide 1 receptor agonist (GLP-1 RA) medications on the market with various delivery systems. Which GLP-1 RA agent may be the most user friendly, for an older adult with dexterity concerns?
 - a. Albiglutide
 - b. Dulaglutide
 - c. Liraglutide
 - d. Semaglutide
 7. Mr. S is a 74-year-old gentleman with past medical history of T2DM, CHF, mild cognitive impairment and depression. His diabetes is complicated by albuminuria and peripheral neuropathy. Currently, Mr. S is on metformin 500 mg BID and alogliptin 25 mg daily. Unfortunately, Mr. S's A1c increased to 9.2%. After discussing Mr. S's goals of care, it was determined that he would like to achieve an A1c goal of < 8.5% and minimize his risk for hyper- or hypoglycemia symptoms. Which medication therapy would be the most appropriate next step for Mr. S?
 - a. No changes
 - b. Add glyburide
 - c. Add empagliflozin
 - d. Add insulin glargine

An 85yo male presents to your pharmacy and appears more confused and disoriented than normal baseline when picking up his monthly prescriptions for glipizide, lisinopril and amlodipine. His past medical history includes: DM2, CAD, HTN, CKD stage 3, BPH, and history of falls.

8. Based on his presentation what would be your next differential to consider for this patient:
 - a. Assess recent use of anticholinergics that may be impacting cognition.
 - b. Obtain consent from patient to contact PCP to provide suggestions to conduct a brief cognitive screen.
 - c. See if patient has a home blood glucometer to check blood glucose while in your pharmacy to assess potential for hypoglycemia.
 - d. Make sure patient uses his cane when coming into the pharmacy to minimize fall risk.

Further review of patient's record. Full list of medications include:
 Lisinopril 10mg daily
 Aspirin 81mg daily
 Glipizide 10mg BID
 Amlodipine 5mg daily
 Calcium/Vitamin D 1 tablet BID
 Tamsulosin 0.4mg daily

Labs:
 A1c: 8.2%
 SCr: 1.4mg/dL (EGFR: 32mL/min)
 Vit D: 38ng/mL
 BP: 138/69

9. Upon further discussion with patient, he reports that his wife has recently moved into a SNF and he isn't eating as well as he had before since she primarily cooked meals for him. He does tell you that

Assessment Questions

1. It is estimated that 14.3 million adults over the age of 65 years old are living with T2DM. This is predicted to increase to 26.7 million by the year 2050. What issues does living longer with T2DM have for the patient and provider?
 - a. Medications may have more side effects due to changes in physiology
 - b. Blood glucose goals may need to be adjusted to decrease risk of hypoglycemia
 - c. Providers will need to include caregivers and family members in
2. **True or False:** Social determinants of health should be reviewed in clinic and taken into consideration with treatment plans.
 - a. True
 - b. False
3. A provider sets a new A1c goal of <7% for a 90-year-old patient with advanced dementia, heart failure, and a history of falls. The patient currently lives in an assisted living facility. The current A1c is 8.3%. What might be your next step(s) as the pharmacist working on with this patient?
 - a. Discuss concerns over the potential for hypoglycemia with lower A1c goals with the health care team.
 - b. Review social determinants of health including, but not limited to, access to clinic appointments, living situation, social support, and functional abilities of the patient.
 - c. Increase the patient's medication doses and add medication as needed to achieve the A1c goal set by the provider.
 - d. All of the above
 - e. A and B
4. Symptoms of hyperglycemia in older adults can be overlooked due to the following potential co-conditions:
 - a. BPH
 - b. Peripheral vascular issues
 - c. Cognitive changes
 - d. All of the above
5. Multiple professional associations have published dosing guidance on metformin. According to the American Geriatrics Society (AGS) they recommend a maximum of ____ dose if the eGFR is between 30-60 mL/min/1.73m²:
 - a. 500 mg BID
 - b. 1500 mg daily
 - c. 500 mg daily
 - d. 1000 mg BID
6. There are many glucagon-like peptide 1 receptor agonist (GLP-1 RA) medications on the market with various delivery systems. Which GLP-1 RA agent may be the most user friendly, for an older adult with dexterity concerns?
 - a. Albiglutide
 - b. Dulaglutide
 - c. Liraglutide
 - d. Semaglutide

his daughter is able to check in on him weekly and assist in filling his med box that wife used to assist with. He has had some home blood sugars ranging from 60-80 recently and some elevated readings >200 post meals. Patient has insurance to cover medication costs. What might be a recommendation to make to the patient's PCP?

- Discontinue glipizide, initiate metformin 500mg daily and increase to 500mg BID after 7 days as tolerated
 - Discontinue glipizide, start semaglutide 0.25mg once weekly
 - Discontinue glipizide, start empagliflozin 12.5mg daily
 - Provide patient with contact for meals on wheels service in the community
10. Did the activity meet the stated learning objectives? (if you answer no, please

email sarahs@pswi.org to explain)

- Yes
 - No
11. On a scale of 1 – 10 (1-no impact; 10-strong impact), please rate how this program will impact the medication therapy management outcomes or safety of your patients.
12. On a scale of 1 – 10 (1-did not enhance; 10-greatly enhanced), please rate how this program enhanced your competence in the clinical areas covered.
13. On a scale of 1 – 10 (1-did not help; 10-great help), please rate how this program helped to build your management and leadership skills.
14. How useful was the educational material?
- Very useful
 - Somewhat useful
 - Not useful

15. How effective were the learning methods used for this activity?
- Very effective
 - Somewhat effective
 - Not effective
16. Learning assessment questions were appropriate.
- Yes
 - No
17. Were the authors free from bias?
- Yes
 - No
18. If you answered "no" to question 18, please comment (email info@pswi.org).
19. Please indicate the amount of time it took you to read the article and complete the assessment questions.

CE FOR PHARMACISTS

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- | | |
|----------------------|---------------|
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| 2) a b | 12) _____ |
| 3) a b c d e | 13) _____ |
| 4) a b c d | 14) a b c |
| 5) a b c d | 15) a b c |
| 6) a b c d | 16) a b |
| 7) a b c d | 17) a b |
| 8) a b c d | 18) _____ |
| 9) a b c d | 19) _____ |
| 10) a b | |

May/June 2021

Continuing Education Diabetes Treatment
in the Older Adult

ACPE Universal Activity Number:
0175-0000-21-056-H04-P

Target Audience: Pharmacists

Activity Type: Knowledge-based

Release Date: May 1, 2021

(No longer valid for CE credit after May 1, 2024)

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PRECEPTING SERIES:

The Mindful Preceptor: Tips for Incorporating Well-being and Mindfulness into Pharmacy Rotations

by Rachele Arnoldussen, PharmD, Beth Buckley, PharmD, CDCES, Mathew Letizia, PharmD

As stress, burnout, and mental health issues appear to be on the rise in the United States, efforts to improve wellness have increased. The alarming rates of burnout in healthcare professionals of all settings have been shown to have serious, wide-ranging consequences that range from reduced job performance to medical error and clinician suicide.¹ As a possible intervention strategy to reduce perceived stress and decrease the risk of burnout in healthcare workers, including pharmacists, mindfulness training has received recent attention.²

What is Mindfulness?

Given our current climate, the ability to pause, breathe, and self-reflect amid peripheral noise is more important than ever. Developing the skills to achieve this can be done through the practice of mindfulness. According to mindful.org, mindfulness is “the basic human ability to be fully present, aware of where we are and what we’re doing, and not overly reactive or overwhelmed by what’s going on around us.” We all possess the ability to be mindful; we just have to learn how to access that part of ourselves.³ As we learn to get into this present state of mind, we feel better, think more clearly, and appreciate more about our daily lives. Mindfulness has

been practiced for centuries, with a more recent mainstream acceptance as many have searched for new coping skills to deal with this long year of pandemic changes, uncertainty, and changing home and work lives. The purpose of this article is to describe the advantages of mindfulness-based practices and provide ideas for how preceptors can incorporate mindfulness into pharmacy rotations.

The Advantages of Mindfulness

Mindfulness has over three decades of evidence-based research helping people to shift their focus to the present and deal more effectively with anxiety, stress, and the demands of everyday life.^{4,5} Studies conducted to examine the impact of mindfulness-based training on healthcare professionals and trainees have provided strong evidence to support the efficacy of mindfulness practice to reduce job burnout, perceived stress, and depression, and to promote resilience in healthcare professionals.^{2,6,7} The mountain of evidence behind the value of mindfulness continues to grow, with exponentially positive results within the studies of this decade.⁸

The 2019 National Consensus Conference brought together several national pharmacy associations to evaluate

factors that contribute to well-being and develop strategies to fuel improvements in resilience.¹ Based on recommendations from this conference, pharmacy students at the Medical College of Wisconsin (MCW, since 2020) and Concordia University Wisconsin (CUW, since 2018) are familiar with these practices, as the first year Patient Skills Labs at both schools include a weekly practice with reflection. Survey results from the first two years of this incorporation into the skills laboratory curricula were impressive. The results affirmed that students were receptive to the incorporation of mindfulness techniques. Student responses revealed that mindfulness creates a positive and engaging culture; helps professors build warm, empathetic, and trusting relationships with students; and provides students with valuable resources to aid in their resiliency and well-being. After learning mindfulness practices, students from both schools reported a plan to use some type of mindfulness tool when working with patients in their future practice, with common themes of breathing exercises, active listening, mindfulness of thought, and the use of empathy and self-compassion. For these reasons, we believe that pharmacy preceptors should be aware of these remarkable skills that students have learned and are currently practicing in both their professional and personal

TABLE 1. Resources for Suggested Activities

<i>Activity Name</i>	<i>Timing / Duration</i>	<i>Resources</i>
The Maui Habit	10 seconds	Book: BJ Fogg. Tiny Habits: the small changes that change everything. Thorndike Press. May 2020. You tube: https://www.youtube.com/watch?v=2L1R7OtJhWs&t=420s
PRO: Pause, Relax, Open to what matters in this moment	10 seconds	https://elishagoldstein.com/less-stress/
Mindful Eating	Varies	https://www.mindful.org/6-ways-practice-mindful-eating/
Mindful walking	~ 10 minutes	https://ggia.berkeley.edu/practice/walking_meditation
G.L.A.D. Technique or G.L.A.D. Daily Snapshot practice	~ 5 minutes	https://www.psychologytoday.com/us/blog/practical-mindfulness/201908/get-glad-and-scrub-away-rumination-and-anxiety
Breath Micropractice: Stop and take 3 deep, intentional breaths	< 30 seconds	https://siyli.org/downloads/SIY_Handouts_Micropractices_1day.pdf
STOP: Stop, Take a breath, Observe, Proceed	~ 2 mins	Video: https://elishagoldstein.com/videos/the-stop-practice/ Source: https://elishagoldstein.com/audio/mindful-solutions-for-success-and-stress-reduction-at-work/
Mindful Breathing: Many techniques available: square/box breathing, body scans, guided imagery.	~ 1 minute	http://www.freemindfulness.org/download https://www.anahana.com/wellness-blog/breathing/square-breathing
Diaphragmatic Breathing	~ 2 minutes	https://www.lung.org/lung-health-diseases/lung-disease-lookup/copd/patient-resources-and-videos/belly-breathing-video
5-4-3-2-1 Coping Technique for Anxiety	< 5 minutes	https://www.urmc.rochester.edu/behavioral-health-partners/bhp-blog/april-2018/5-4-3-2-1-coping-technique-for-anxiety.aspx

lives. Pharmacy preceptors now have the opportunity to also embed mindfulness techniques into their rotations to nurture positive and engaging relationships with their students and help to keep the focus on patient-centered care.

Overcoming Barriers

Precepting, in addition to the responsibilities of clinical practice, can be labor intensive. Additionally, the thought of embedding yet another activity into a learner's rotation can seem intimidating. Fortunately, the process of integrating mindfulness into a learner's daily regimen is easier than anticipated. Most mindfulness techniques, such as the practice of gratitude, guided deep breathing, or self-reflection, take only a few minutes and can have a valuable impact on mindset. Although the type and duration of activity might vary, data shows that even short-duration interventions elicit positive outcomes related to stress and anxiety levels.⁸

If you are not already using these skills, their newness and the fear of leading these activities can seem daunting. However,

comfortability and confidence with mindfulness develops with practice, and these negative feelings quickly diminish. Moreover, many students are already aware of these techniques and have developed these skills. The reinforcement of mindfulness practice throughout their rotations would allow learners to transform their skills into proven abilities as they engage in patient-centered care. Keep in mind that leading these skills does not require you to be an expert. And there are many ways to practice mindfulness. If you are not comfortable taking the lead to initiate these tools, there are many evidence-based meditation apps that can be used for your own practice, and with your family, your patients, and your students (Tables 1-3).

Incorporating Mindfulness

To incorporate mental health and well-being into rotations, look for natural places where a pause can give the preceptor and learner a chance to connect, ground, re-center, and set a mindset for being fully present in the moment. The most common place to take a needed pause for reflection

is before or after an encounter, or at the beginning or end of the day.

A few potential times of day with specific examples are outlined here (see Table 1 for specific activity resources):

1. **Start of the workday:** As you outline the flow and objectives for the day, consider setting an intention. An intention is "a determination to act in a certain way"⁹ or "a purposeful awareness of how you want to experience something: how you want to act and feel."¹⁰ The intention can be for yourself or can include the learner. It can be something simple, like using the Maui Habit to establish that "it's going to be a great day."¹¹ It can also be more involved such as taking some breaths, connecting with how you are feeling, and then setting an intention for the day's focus. This is not a goal with an outcome but instead allows the individual to set the tone for the day. For example: "This morning is going to be busy; let's take it one patient at a time, with a smile on our face and an open, patient-centered heart."

TABLE 2. Suggested Apps

<i>App Name</i>	<i>WHY the authors love and recommend</i>
The Mindfulness App	Beginners: 5 day guided practice and introduction to mindfulness. Various meditations with different timings available.
Headspace	Beginners: 10 day basics course with animations. Easy to use courses based on user needs. Available on app and website. See Netflix series for more information.
Insight Timer	The largest variety of free guided meditations for a wide range of experiences. Constantly adding new resources - daily habits, discussion groups, learning series.
Smiling Mind	Completely free (no in-app purchases). Developed as a school program in Australia, then expanded to include a wide breadth of exercises on both the app and website. Organized by groups: Adults, Kids, Youth, Families, Classroom, Work, Healthcare. Includes “bite size” meditations
CALM	Includes a large variety of calming exercises, breathing techniques, and a Calm Kids section with options for sleep, music, scenes, and relaxing sounds.
Healthy Minds Program	Beginners: 5 part Foundations course with self-assessment for awareness, connection, insight, and purpose. UW Madison developed and evidence based. Easy to follow “learn” and “practice” sessions.

2. Lunchtime: This is a great time to purposefully promote and role-model the importance of breaks to rejuvenate ourselves and build energy and resiliency. An example would be to use the mindful acronym P.R.O. Both you and the student sit down together to practice Pause, Relax your body, and be Open to what matters

most in the moment. Another example would be to practice mindful eating. This is simply savoring your food by noticing the smell, the complexity of taste, and taking a moment of gratitude for all the work it took to get this nourishment from seed to your plate. After eating, a refreshing walk with mindful

awareness of the beauty around us (even better if you can go outside) is another way to relieve unnecessary tension from your mind and body.

3. End of the Day: Preceptors know how much an end-of-day debrief can enhance learners’ insight and solidify unsure concepts. Mindful reflection questions can be added to this interaction. For example, consider using G.L.A.D. to address learning, build gratitude, and enhance resiliency through the development of positive mindfulness with less bias and judgment:

When the intention is to practice GLAD at the end of the day, your brain searches for these positive moments to remember for later.

G = GRATITUDE – What are you grateful for today?

L = LEARNING – What was the most profound/interesting/surprising thing you learned today?

A = ACCOMPLISHMENT - What did you accomplish today?

D = DELIGHT – What brought you a sense of delight today?

4. Preparation for communication:

Before entering a room for a patient

TABLE 3. Suggested Websites

<i>Website Name</i>	<i>Resources</i>	<i>WHY the authors love and recommend</i>
Mindful.org	https://www.mindful.org/meditation/mindfulness-getting-started/	An excellent place to start and then to expand learning: filled with resources and practices
Mindfulness Exercises.com	https://mindfulness-exercises.com/mindfulness-exercises-for-beginners/	A variety of exercises for beginners - can choose by topic
National Academy of Medicine: The Clinician Well-being Knowledge Hub	https://nam.edu/clinicianwellbeing/solutions/individual-strategies/	Includes resources and publications specifically related to health care clinicians
UW Madison Center for Healthy Minds	https://centerhealthyminds.org/	A great resource for the science behind well-being and the current research in Wisconsin
Berkeley Greater Good in Action	https://ggia.berkeley.edu/	A large variety of practices in addition to a monthly “happiness calendar” with daily ideas for creating joy
AACP Wellness and Resiliency in Pharmacy Education	https://www.aacp.org/resource/wellness-and-resilience-pharmacy-education	Excellent supportive resource to incorporate well-being into academia
American Mindfulness Research Association	https://goamra.org/	A professional resource with current, evidence based research on mindfulness and its applications
Action for Happiness	https://www.actionforhappiness.org/	Programs and actionable suggestions to create a happier and kinder world
APhA Well-being index	https://app.mywellbeingindex.org/login?id=60	Free resource for pharmacists to assess current levels of well-being, and then utilize resources to improve
The Free Mindfulness Project	http://www.freemindfulness.org/home	Free to download mindfulness meditation exercises

encounter, preparing to talk with another health care professional, or answering the phone, a simple pause to connect with the breath can be encouraged. For example, S.T.O.P.: “Stop; Take a few deep breaths; Observe your thoughts, emotions, body; then Proceed with awareness.”

5. **To de-escalate stressful moments:**

When you have an overwhelmed learner or patient, one of the easiest ways to engage mindfulness is to focus on the breath. For example, diaphragmatic breathing or “belly breathing” involves taking slow, deep inhalations, followed by an extended exhalation.¹² This is a recommended technique to help with shortness of breath from COPD and asthma. It stimulates the vagus nerve and enables the parasympathetic nervous system to affect a state of calm in the body.¹³ Other examples include “breath micropractice” (take 3 deep, intentional and attentive breaths), “counting breaths” (breathe naturally and count one for breath in, two for breath out, up to the count of 10), or “square/box breathing” (breath in for count of 4, hold or count of 4, breath out for count of 4, hold for count of 4, and repeat for 1 minute).

6. **Direct patient care:** In addition to helping our COPD and asthma patients, mindful breathing can be an essential tool to teach our patients to overcome stress and anxiety as they face difficult challenges. Mindful breathing can also be helpful for patients making positive, yet difficult, lifestyle changes such as smoking cessation and weight loss. Another technique to use is focusing on the senses for grounding and to decrease anxiety in the moment. The 5-4-3-2-1 Coping Technique includes acknowledging:

- 5 things you can see
- 4 things you can touch
- 3 things you can hear
- 2 things you can smell
- 1 thing you can taste

7. **Anytime!** – Explore the apps, and then use it to lead you through a short (from 1 to 5 minute) practice based on what you are feeling or

needing. This is an excellent way to learn the practices, get comfortable with the thought process, and find go-to meditations that work for you. Suggested times to listen to an app guided meditation include: in the morning while waiting for coffee to brew, while eating, during your commute, during breaks/downtime/ any time you want to center yourself and learn something new. The app practices can be used to connect with family by listening to a practice and then discussing it: after school/work, dinner time, bedtime. If you are a beginner, Headspace, Healthy Minds, and Smiling mind all have beginner foundation curriculum. Table 2 includes free apps with descriptions of their basic functions. Choose one and get started! In addition, Table 3 provides some of the authors’ favorite website to further explore mindfulness.

To help sort through the abundance of valuable resources to explore, Tables 1, 2, and 3 provide the authors’ favorite resources to explore mindfulness.

Conclusions

Mindfulness is a practice that helps us learn to pay attention and be present in our lives. Though it cannot eliminate life’s stresses, it has been shown to improve the well-being of healthcare professionals, including pharmacists and pharmacy students. Therefore, it would be advantageous for preceptors to embrace mindfulness as a tool for themselves and to coach learners on how to use mindfulness throughout the workday to stay centered and provide quality patient care. Preceptors can consider integrating mindfulness into their rotations through specific activities or consider adapting their precepting style to include mindful elements to reduce perceived stress, decrease the risk of burnout, and build resiliency in our future pharmacists.

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ID CORNER

Proceed with Caution: Antibiotic Considerations in the Geriatric Population

by Kelvin Gandhi, PharmD, Kelsey Zeeck, PharmD, Allison Gobble, PharmD, BCIDP



Individuals aged 65 years and older currently account for approximately 14.5% of the United States population. With aging baby boomers and advancements in medicine and technology, there is a rapidly increasing elderly population, which is projected to double over the next 25 years.¹ Age is a potential risk factor for infection, increased length of hospital stay, and many other complications. The elderly are generally more susceptible to infections than the younger population because of the potential association of aging with exposure to infections, anatomical and functional changes, and immune dysfunction.²⁻⁴ A previous study showed that elderly patients used more antibiotics per person per year compared to the younger population.¹ With more medications being prescribed, there is an exponential increase in adverse effects.⁵ Managing infections with antibiotic therapy in the elderly poses many obstacles to health care professionals, due to variable pharmacokinetic properties, decreased immune function, and increased risk for drug-drug interactions and adverse effects.¹ Using safe and effective pharmacotherapy is crucial in minimizing the collateral damage that can come with antibiotic agents, especially in the geriatric population.

Pharmacokinetic Considerations

As people age, their bodies undergo various anatomical and functional changes, potentially altering the safety and efficacy of medications. Changes in pharmacokinetic factors may impact the medication's absorption, distribution, metabolism, and elimination.

Absorption

There have been many proposed theories that gastric acid production decreases with age, although more recent studies have not found clinically significant alterations in gastric acid secretion.^{1,5,6} Elderly patients are also more commonly on acid-suppressive medications (such as antacids, histamine-2 receptor antagonists, and proton-pump inhibitors) than the younger population, which may result in a higher gastric pH.¹ Many oral antibiotics, including azithromycin, amoxicillin, cephalexin, and cefadroxil, are dependent on gastric acid for optimal bioavailability.⁷

Distribution

Each drug has a specific volume of distribution; however, there can be interpatient variability, especially in the elderly.⁷ Generally, the geriatric population has an increased proportion of adipose tissue and decreased lean body mass; decreased total body water;

and decreased serum albumin.^{1,5} This may have a considerable impact on drug pharmacokinetics, because an increase in the proportion of body fat increases the distribution of lipophilic agents (e.g. rifampin, metronidazole, fluoroquinolones, macrolides, and tetracyclines), prolonging their half-life.^{1,5} With a lower proportion of lean body mass and total body water, this will result in reduced distribution of hydrophilic agents (e.g. aminoglycosides, beta-lactams, and glycopeptides), leading to a greater concentration within the intravascular compartment. Studies have shown decreased efficacy of highly protein-bound drugs (e.g. ceftriaxone and ertapenem) in patients with hypoalbuminemia.^{1,5-9} Due to the reduced serum protein concentration, there is initially an increased free-fraction of active drug, but it is then rapidly cleared, leading to an overall reduced drug exposure and half-life.

Metabolism

With normal physiological aging effects on the liver, there may be decreased hepatic blood flow and cytochrome P450 (CYP450) enzyme activity, which can possibly prolong the half-life of hepatically metabolized drugs (e.g. metronidazole, macrolides, and fluoroquinolones). The high rate of polypharmacy in the older patient population further increases likelihood of drug-drug interactions,

which can affect the metabolism of certain antibiotics, potentially exposing the individual to toxicities or sub-optimal dosing.¹ In a recent cohort study assessing polypharmacy (≥ 5 drugs) in the aging population, the investigators found that polypharmacy and potential drug-drug interactions were much more prevalent in the elderly population.¹⁰

Elimination

Aging, even without accompanying renal disease, often results in reduced renal function due to decreased renal blood flow and glomerular filtration rate.^{1,5} Serum creatinine concentration can be a misleading marker of renal function in the elderly because of reduced muscle mass, potentially overestimating the creatinine clearance (CrCl). However, it is still beneficial to trend this marker for renal function, especially when dosing antibiotics, since a change from baseline may indicate a need to reassess dosing for those requiring renal dose adjustments or a need to obtain levels for those requiring therapeutic drug monitoring (TDM). Antibiotics such as aminoglycosides, beta-lactams, and glycopeptides are heavily dependent on renal filtration for drug clearance and thus require dosing adjustments in the presence of renal impairment in order to prevent accumulation and supratherapeutic drug levels.

Antibiotic Considerations

Prior to antibiotic selection, one of the first considerations should be whether antibiotic use is necessary. Urinary tract infection (UTI) is one of the most common indications for antibiotic prescribing, but is often inappropriately diagnosed and managed, especially in the elderly population.¹¹ Inappropriate antibiotic use may lead to further resistance in uropathogens and an increase in adverse events.¹² Asymptomatic bacteriuria, which is the presence of bacteria in a urine culture without signs or symptoms of a UTI, is frequently seen in the elderly and often does not warrant antibiotic therapy.^{13,14} The provider must weigh the risks and benefits of antibiotic selection, as they all carry potential toxicities, and cautious decision-making should be considered, especially

in the geriatric population. Antibiotics discussed in this article include those that are commonly used for treatment of UTIs.

Nitrofurantoin

Nitrofurantoin is an antibacterial agent commonly used in treating an uncomplicated UTI. Previously, contraindication of nitrofurantoin in patients with a CrCl <60 mL/min was based on data with several major limitations and poorly defined clinical endpoints.¹⁵ The American Geriatrics Society has revised its recommendation in the 2015 Beers Criteria Update to avoid nitrofurantoin in those with a CrCl <30 mL/min.^{16,17} More cases of neurotoxicity, including peripheral neuropathy, dizziness, and cerebellar dysfunction, are reported in women than men, and more in the elderly than the younger population.^{18,19} A retrospective study by Geerts et al. investigated treatment failure within 30 days or serious adverse events leading to hospitalization within 90 days in women with renal impairment treated for uncomplicated UTI with nitrofurantoin. Moderate renal impairment, defined as an estimated glomerular filtration rate (eGFR) between 30–49 mL/min/1.73 m², was not significantly associated with treatment failure. However, there was a significant increase in adverse events in individuals with renal impairment (eGFR <50 mL/min/1.73 m²; adjusted hazard ratio =4.13) than in those without renal impairment.^{17,20} Therefore, the health care provider should be cautious when using nitrofurantoin in renal impairment, especially in the elderly, because of the risk of adverse events that is still present.

Sulfamethoxazole-Trimethoprim

Another common first-line option for UTIs is sulfamethoxazole-trimethoprim (SMX-TMP). This drug should be used with caution in patients with renal impairment due to an increased risk of nephrotoxicity and hyperkalemia.^{16,21–25} SMX-TMP plays a major role in the clearance of creatinine via inhibition of transporters in the kidney, and thus may lead to further enhancement of creatinine elevation, although it may not be an entirely accurate indicator of the degree of acute renal injury.²⁶ Inadequate

hydration while on oral SMX-TMP may lead to crystal precipitate damaging the renal tubules. The trimethoprim component competitively inhibits the sodium channels in the kidney, thereby hindering renal excretion of potassium.²⁷ The geriatric population is also commonly prescribed angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, or potassium-sparing diuretics, due to comorbidities, which can lead to an additive hyperkalemic effect when taken with SMX-TMP. A population-based, nested case-control study conducted in Ontario, Canada identified 6,903 hospital admissions due to hyperkalemia over an 18-year span.²² Of that total, 10.8% of spironolactone users received at least one prescription for SMX-TMP. Compared with amoxicillin, SMX-TMP was associated with an increased risk of admissions due to hyperkalemia (adjusted odds ratio 12.4, 95% CI 7.1–21.6), and 60% of the elderly taking spironolactone and antibiotics for a UTI could have been avoided if an alternative agent to SMX-TMP was used.²² SMX-TMP is an appropriate antibiotic option in the elderly but should be avoided or closely monitored in patients with renal impairment and concomitant agents increasing the risk of hyperkalemia.

Beta-lactam Antibiotics

Beta-lactam antibiotics are commonly prescribed for infections that affect the elderly population, such as pneumonia and UTI.²⁸ Aging patients often exhibit factors that impact beta-lactam pharmacokinetics, including decreased serum albumin, decreased renal blood flow, decreased hepatic blood flow, and increased fluid volume.²⁹ These pharmacokinetic changes could inhibit the ability to achieve pharmacokinetic/pharmacodynamic (PK/PD) targets, such as time of drug concentration above the minimum inhibitory concentration, as well as put patients at increased risk for toxicities. This is evidenced by a population pharmacokinetic study by Lonsdale et al. that described a 50% decrease in clearance of beta-lactams by 71 years of age.³⁰ Appropriate dose adjustments are a necessity because of the potential for reduced clearance of beta-

lactam antibiotics, which may result in drug toxicities. Beta-lactam antibiotics are first-line agents for treatment of many infections, not only due to their efficacy but also because they are well-tolerated even in the elderly population. However, there are a few notable beta-lactam antibiotic toxicities to be particularly mindful of in the geriatric population. Cefepime and ertapenem neurotoxicity is theorized to be related to the concentration-dependent antagonism of gamma-aminobutyric acid. Kidney dysfunction and excessive cefepime dosing resulting in increased cefepime concentrations have been associated with neurotoxicity and are potential issues in the elderly population.³¹ Similarly, decreased renal function, low body weight, and advanced age have all been identified as risk factors for ertapenem neurotoxicity.³² Ertapenem mean AUCs have been reported to be 39% higher in the elderly compared with younger subjects.³³ Due to the increased risk for beta-lactam-associated toxicities in older patients, TDM is a potentially useful tool to optimize beta-lactam antibiotic dosing in this population.³⁴ Although use is increasing, it is still not commonly employed for beta-lactam antibiotics, which makes it even more crucial to optimize its use.³⁵ Beta-lactams, especially cefepime and ertapenem, should be monitored carefully for signs of neurotoxicity in elderly patients with decreased renal function and low body weight.

Fluoroquinolones

Fluoroquinolones are notorious for a multitude of adverse effects in any patient population. The Food and Drug Administration has issued a recommendation that fluoroquinolones be used only when other treatment options are not available for management of acute bacterial sinusitis, chronic bronchitis, and uncomplicated UTIs.³⁶ Special consideration should be given to the possible adverse effects and the subsequent implications specifically in the elderly patient population. For example, fluoroquinolones have been associated with risks of dysglycemia, QTc prolongation, and aortic aneurysm and aortic dissection.^{36,37} Elderly patients may be at higher risk for these issues, due to the

increased prevalence of comorbidities or interacting medications pre-disposing these issues.

Fluoroquinolones additionally carry Black Box warnings regarding the possibility of central nervous system (CNS) effects, exacerbation of myasthenia gravis, and tendonopathies, including tendon rupture.³⁶ In a large retrospective study of patients with quinolone-related tendonopathies, aged over 60, corticosteroid use and impaired renal function were associated with higher risk for tendonopathies.³⁸ CNS effects seen with fluoroquinolones may include psychosis, seizures, or delirium.³⁷ Despite the known CNS risks of fluoroquinolone use, increased risk specifically in the elderly population has not been well-characterized.^{39,40}

In elderly patients who may have altered drug clearance as well as other comorbidities that may increase their risk for side effects, the decision to initiate fluoroquinolone therapy should not be taken lightly and alternate therapy should be considered.

Clostridioides difficile Infections

Clostridioides difficile infection (CDI) is an unfortunate risk that accompanies most antibiotic use, though the specific risk of CDI varies based on antibiotic class. Lincosamides, such as clindamycin, have been found to pose the highest risk.^{41,42} Comparative rates of other antibiotics have varied in literature, but beta-lactams and fluoroquinolones do certainly carry a risk.^{41,42} Elderly patients are disproportionately affected, with 70%-80% of global cases impacting patients over the age of 65.⁴³ Furthermore, patients with advanced age were at increased risk for hospitalization related to CDI and for recurrence of CDI.⁴³ Treatment of CDI is largely the same in elderly patients as in younger ones, but given the high morbidity and mortality associated with CDI in the elderly patient population, extra consideration should be given to prevention, such as infection prevention and antimicrobial stewardship.

Concluding Remarks

The elderly population is especially susceptible to the negative impacts of antibiotic use. Unfortunately, excessive and inappropriate use of antibiotics is common in this vulnerable demographic. Ensure appropriate indication, antibiotic selection, dose, and duration of therapy to minimize antibiotic exposure and the associated risks.¹¹ In a retrospective cohort study by Dylis et al., only 46% of antibiotics prescribed to elderly patients were in accordance with guidelines.²⁸ Furthermore, interviews conducted with primary care providers revealed that they are more likely to use broader spectrum antibiotics and longer durations of therapy for elderly patients as compared with the general population.⁴⁴ A potential driver of antibiotic use that deviates from guideline recommendations is the underrepresentation of aging patients in clinical trials. A systematic review by Avni et al. found that elderly patients were commonly excluded from randomized controlled trials for the management of pneumonia because of their comorbid diseases.⁴⁵ Additionally, there were limited subgroup analyses of specific age groups, which limits generalizability of results from these studies to the elderly population.⁴⁵ This data has shed light on the importance of increasing representation of elderly patients in infectious diseases literature in the future. In the meantime, it is important to use the information we do know about this unique population to help optimize antibiotic therapy.

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Efficacy of Tocilizumab in Reducing Steroid Requirements in Giant Cell Arteritis (GCA) at a Veterans Hospital

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Giant Cell Arteritis (GCA) is a form of vasculitis involving large- and medium-sized arteries, commonly affecting the cranial branches of the carotid arteries. GCA most commonly occurs in patients who are 50 years old or older. While there is no definitive diagnostic test for GCA, it is typically diagnosed by temporal artery biopsy and/or imaging, within the context of a suggestive clinical presentation. Symptoms of GCA can commonly include headaches, fevers, fatigue, weight loss, and jaw pain. One of the more severe manifestations is blindness, which is considered a medical emergency.¹ Lab data such as erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) often help with differential diagnosis; however, these are not diagnostic.²

Prompt treatment of this disease is imperative, particularly when visual manifestations are experienced, with the mainstay of therapy being chronic glucocorticoids.³ Given the concern for potential adverse effects with long-term glucocorticoid therapy, glucocorticoid-sparing agents should be considered to facilitate tapering when possible. In 2017, the FDA approved tocilizumab as a glucocorticoid-sparing agent for GCA.

Tocilizumab (Actemra®, Genentech, Inc) is an interleukin-6 (IL-6) receptor antagonist that is FDA-approved for the treatment of rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular and systemic juvenile idiopathic arthritis, and cytokine release syndrome.

Inflammatory stimuli induce endogenous IL-6 among other immunological responses, and tocilizumab inhibits these receptors, which leads to decreased cytokine and acute phase

reactants.⁴ Tocilizumab should not be used in patients who have already been prescribed another biologic disease-modifying antirheumatic drug (DMARD); who have active infections or untreated hepatitis B, latent tuberculosis, coccidioidomycosis or histoplasmosis; whose baseline absolute neutrophil count (ANC) is less than 2,000/mm³; whose baseline platelet count is less than 100,000/mm³; and/or whose baseline alanine transaminase (ALT) and/or aspartate

transaminase (AST) is greater than 1.5 times the upper limit of normal. Live or live-attenuated vaccines should not be given during treatment with tocilizumab.⁵

Tocilizumab's effect on inflammatory markers has been shown to occur in as little as two weeks after initiation. Given its immunosuppressive properties, tocilizumab can increase the risk for infections and malignancies; serious warnings include activation of latent tuberculosis, invasive fungal infections, and bacterial and viral

Abstract

Objective: Giant Cell Arteritis (GCA) is a form of vasculitis involving large and medium-sized arteries, commonly affecting the cranial branches of the carotid arteries with the mainstay of therapy being glucocorticoids. In 2017, the FDA approved tocilizumab as a glucocorticoid-sparing agent for GCA. The purpose of this review was to evaluate the efficacy and safety of tocilizumab therapy in patients with GCA, and its efficacy in aiding in glucocorticoid de-escalation at a veterans' hospital.

Methods: A retrospective chart review was performed for patients at the William S. Middleton Memorial Veterans Hospital with prescriptions for tocilizumab for GCA from May 2017 to May 2019.

Results: Laboratory monitoring was appropriate for each patient in accordance with monitoring recommendations, with no instances of significant abnormal changes. Tocilizumab therapy was interrupted in one patient due to illness and in another due to a planned procedure. Tocilizumab therapy was discontinued in one patient diagnosed with prostate cancer who also showed remission of GCA and in another patient who chose to discontinue therapy after 33 months of therapy. All patients were able to be tapered off glucocorticoids while on tocilizumab.

Conclusions: Tocilizumab dosed weekly and every other week led to glucocorticoid-free remission of GCA at 52 weeks in the available literature. This review showed similar results, with the majority of patients having been glucocorticoid-free after approximately 15 months of treatment with tocilizumab.

infections. Safety recommendations for screening prior to and monitoring during tocilizumab therapy for GCA include testing for tuberculosis and hepatitis B prior to initiating therapy; monitoring neutrophils and platelets at baseline and at 4 to 8 weeks after the start of therapy and every 3 months thereafter; testing ALT, AST, and total bilirubin at baseline, then every 4 to 8 weeks after the start of therapy for the first 6 months and every 3 months thereafter; and obtaining a lipid panel at baseline and at 4 to 8 weeks following the start of therapy, then as recommended by current prescribing guidelines. All patients should be monitored for signs and symptoms of infection and of central nervous system demyelinating disorders.⁴

For patients with GCA, the FDA-approved standard tocilizumab dosing is a 162 mg subcutaneous injection, once weekly or once every other week, based on clinical considerations.⁴ The efficacy and safety of tocilizumab 162 mg once weekly has been supported by a placebo-controlled study in 251 patients with GCA. This study concluded that tocilizumab, combined with a 26-week steroid taper, was superior to placebo when looking at the primary outcome of sustained, glucocorticoid-free remission at 52 weeks.⁶

At the William S. Middleton Memorial Veterans Hospital, there is a specialty rheumatology clinic staffed by rheumatologists; a clinical pharmacy specialist and pharmacy residents; and resident and fellow physicians. On average, at the time of data collection for this review, about 30% of the prescriptions for tocilizumab at this facility were prescribed for GCA. Given the high cost of this medication in the setting of limited literature and recent FDA approval for this indication, this review was conducted to evaluate the efficacy and safety of tocilizumab therapy in patients with GCA, and its success in helping with glucocorticoid de-escalation at this facility.

Methods

A retrospective chart review was performed for seven patients at the William S. Middleton Memorial Veterans Hospital with recent prescriptions for tocilizumab for GCA at the time of data collection. This evaluation was determined not to

TABLE 1. Baseline Characteristics

<i>Characteristic</i>	<i>Value</i>
Mean age \pm SD upon initiation	69 \pm 4.5 years
Gender	100% Male
Race	<ul style="list-style-type: none"> • 86% White (n=6) • 14% Native Hawaiian or Other Pacific Islander (n=1)
SD: standard deviation	

TABLE 2. Patient Outcomes

<i>Characteristic</i>	<i>Value</i>
Time to glucocorticoid discontinuation after start of tocilizumab	<ul style="list-style-type: none"> • 24 months (n=1) • 15 months (n=3) • 14 months (n=1) • 12 months (n=1) • 11 months (n=1)
Tocilizumab interrupted or discontinued	<ul style="list-style-type: none"> • 2 of 7 patients discontinued therapy (29%) • 2 of 7 patients interrupted therapy (29%)

meet the federal definition of research and IRB review was not required per the University of Wisconsin-Madison Health Sciences IRB Not Research Determination Decision Tool. Baseline characteristics collected included patient demographics, tocilizumab start date and initial dose, and glucocorticoid dose at the time of tocilizumab start. The identified outcomes included time to glucocorticoid discontinuation; duration of tocilizumab treatment; and any clinically significant changes in neutrophils, platelets, liver transaminases, ESR, and CRP during therapy.

Results

Seven patients were identified with recent prescriptions for tocilizumab for GCA. As shown in Table 1, all patients were males, with an average age of 69. Laboratory monitoring was appropriate for each patient in accordance with monitoring recommendations,⁵ with no instances of significant abnormal changes. One patient had evidence of increased liver transaminases while on 8 mg/kg IV once monthly dosing, and upon holding the dose of tocilizumab, the enzymes normalized and tocilizumab was able to be restarted at a lower dose of 4 mg/kg IV once monthly with no further complications. No other patients

experienced significant adverse drug reactions.

As shown in Table 2, tocilizumab therapy was interrupted for two patients. One interrupted therapy for a gastrointestinal illness, which led to two doses of tocilizumab being held. This patient held another dose of tocilizumab two months later after presenting to the emergency department to rule-out a deep vein thrombosis. This patient was on 8 mg/kg IV dosing and able to restart at a 4 mg/kg dose with no further complications. The second patient interrupted therapy due to a scheduled surgical procedure. Tocilizumab 162 mg subcutaneous injection was held for two weeks prior to and following surgery, then restarted with no documented complications.

As shown in Table 2, tocilizumab therapy was discontinued in two patients. One patient was diagnosed with prostate cancer after 19 months of therapy and had shown remission of GCA, leading to drug discontinuation. The other patient had chosen to self-discontinue tocilizumab after 33 months of therapy. Four months after the last injection of tocilizumab, the patient's inflammatory markers had increased; however, there was no documented evidence of disease relapse. At the time of this review, the remaining patients were on tocilizumab

TABLE 3. Tocilizumab Prescribing Trends

Characteristic	Value
Tocilizumab Initiation Dose	<ul style="list-style-type: none"> • 4 mg/kg IV once monthly (n=3) • 162 mg SQ once weekly (n=4)
Maintenance Dose at Time of Data Review	<ul style="list-style-type: none"> • 162 mg SQ once weekly (n=2) • 162 mg SQ once every 2 weeks (n=5)
Glucocorticoid initial dose (upon tocilizumab initiation)	<ul style="list-style-type: none"> • 20 mg once daily (n=4) • 30 mg twice daily (n=1) • 35 mg once daily (n=1) • 80 mg once daily (n=1)
<i>IV: intravenous; SQ: subcutaneous</i>	

followed by a Veterans Administration (VA) rheumatology service.

Regarding efficacy of tocilizumab, the patient mentioned above whose therapy was interrupted showed a significant increase in CRP and ESR after two held doses. Their ESR increased from 17 mg/dL to 71 mg/dL, with an increase in CRP from 0.5 mm/hr to 7.98 mm/hr. After resuming therapy, one dose of tocilizumab led to normalization of the inflammatory markers. Another patient started therapy with their CRP and ESR at 8.63 mm/hr and 40 mg/dL, respectively; after one dose of subcutaneous tocilizumab, inflammatory markers decreased significantly to undetectable and 4 mg/dL, respectively. A third patient presented with an extremely elevated ESR at 105 mm/hr and after two doses of IV tocilizumab, the levels decreased to 95 mm/hr and then 23 mm/hr. The ESR continued to decrease with each consecutive dose until it eventually normalized.

All patients were able to taper off glucocorticoids while on tocilizumab with an average time to discontinuation of 15 months after tocilizumab start.

Discussion

The results show that tocilizumab therapy was both well-tolerated and efficacious, in line with what available literature has shown. As noted in Table 3, there were differences in the dosing and administration of tocilizumab upon initiation. Three patients were initiated on IV tocilizumab based on literature supporting its use, prior to the subcutaneous dose being studied.⁷ The FDA announced its approval on May 22, 2017, and these patients were

all transitioned to the FDA-approved subcutaneous dosing.

Although all data showed positive outcomes, this review does not come without limitations. One limitation is the small sample size of patients on this therapy for the treatment of GCA, given that this is a newer indication for tocilizumab. Another limitation of this review is the fact that adverse reactions to tocilizumab were not observed. While this is a positive finding, it also proves difficult to generalize the outcomes to a larger population where adverse effects might be more apparent. Given the retrospective nature of this review, and the fact that it is a snapshot in time, another limitation is the inability to assess the rate of disease recurrence after discontinuation of tocilizumab. While a significant improvement in lab surrogate markers (ESR, CRP) was evident with this therapy, the clinical significance of these surrogate changes on the progression of the GCA itself is unknown.

Conclusions

Tocilizumab dosed weekly and every other week has led to glucocorticoid-free remission of GCA at 52 weeks in the available literature. This review showed similar results, with the majority of patients having been glucocorticoid-free after approximately 15 months of treatment with tocilizumab. Based on the results of the review, tocilizumab can be considered as a therapy option for patients diagnosed with GCA on glucocorticoid maintenance therapy, who experience disease-flare during a steroid taper. Given the limited data showing a correlation between surrogate lab markers and GCA progression, it is important to continue to monitor patient

symptoms and not solely rely on ESR and CRP to determine disease remission. Additionally, it is important to have a discussion with each patient regarding risks versus benefits of continuing tocilizumab therapy after 52 weeks, given that future studies are needed to determine the safety and efficacy of tocilizumab beyond 52 weeks for this indication.

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Improving Medication Label Readability and Functionality: The Children's Wisconsin Experience

by Brianne K. Bakken, PharmD, MHA, Megan Ose, PharmD, MHA, Emily E. Hansen, PharmD

Medication errors cause 134 million adverse events annually, costing \$42 billion and contributing to 2.6 million deaths.¹ The Institute for Safe Medication Practices (ISMP) attributes 33% of all medication errors and 30% of fatalities from medication errors in the United States to poor medication labeling and packaging.² The ISMP has identified several factors related to medication labeling that contribute to medication errors. Such factors include small and illegible fonts, inconsistent label content and organization, and having multiple labels associated with a single medication.³

The ISMP developed key recommendations to prevent medication errors, reduce misinterpretation, and improve patient adherence. These recommendations include the inclusion of end-users in the design of the medication labeling. In the hospital setting, end-users would include pharmacy technicians, pharmacists, nurses, and other clinical practitioners.² It is recommended that medication labels use a sans serif font (common ones include Arial, Tahoma, and Calibri) and a minimum size of 12 points. All information should be printed in black ink on a white background in order to prevent restrictions for those with color blindness. The amount of white space on the label should also be maximized to increase readability. In organizing information on the label, conceptually related content should be placed together or in the same section. One section might include the provider or prescriber information, such as prescriber name, phone number, and dispense date. That information should be separated from patient-directed information, such as directions for use. Another section might

include the patient-specific information, such as patient name, location/unit, bed number, and identification number, such as the medical identification number (MRN). Another section might include the medication-related information, such as the drug name, strength, dose, route, frequency, and any medication bar codes or identification numbers.

One research manuscript seeking to improve intravenous medication labels for inpatient use identified several components for an ideal or improved inpatient label.⁴ Such items included emphasizing the patient name, drug, dose, and administration route; emphasizing internal information requirements of allergies, weight, drug concentration, and expiration dates; and expanding the use of color coding to differentiate information and drug types. Incorporation of these recommended best practices has the potential to improve medication safety and increase end-user satisfaction.

Objective

The primary objective of this project was to review the facility-generated medication labels at Children's Wisconsin with the goal of changing the label stock and design in order to ensure compliance with legal standards, align with best practices, enhance medication safety, and optimize pharmacy workflow.

Practice Description

Children's Wisconsin is an independent health system based in Milwaukee, Wisconsin, that provides primary care, specialty care, urgent care, emergency care, community health services, foster and adoption services, child and family counseling, child advocacy services, and family resource centers to pediatric patients in Milwaukee and throughout the state

of Wisconsin. Children's Wisconsin's flagship hospital located in Milwaukee is a 297-bed tertiary care teaching hospital with a Level 1 trauma center and a Level 4 neonatal intensive care unit (NICU). The pharmacy department provides centralized distributive services 24 hours a day and has decentralized pharmacists in acute care units, intensive care units, and ambulatory clinics. The Milwaukee hospital provides care to nearly 10,000 patient admissions and dispenses almost 1 million medication doses annually. The pediatric population necessitates a significant number of weight-based, patient-specific doses. The pharmacy department prepares approximately 300,000 patient-specific oral liquid syringes and 225,000 patient-specific injectable syringes annually. Children's Wisconsin uses the Epic electronic health record system, Intermec thermal label printers, and label stock supplied by Nev's Ink.

Assessment of Original Labels and Workflow:

Various medication product types are organized under "dispense codes" in the Epic electronic health record. Each pharmacy record has an Epic pharmacy label routing table that determines where labels print based on the dispense code and the action type (e.g. first dose, cart fill, redispense). Prior to this project, there were more than 50 Epic dispense codes and 8 pharmacy label routing tables used at Children's Wisconsin. Each Epic dispense code had a unique, corresponding label template that would need to be individually edited once a new, standardized label design was approved. Furthermore, each pharmacy label had a unique routing table that would also need to be manually updated to reflect the new label design.

The initial assessment of the medication labels at Children's Wisconsin

FIGURE 1. Concerns with the Original Label Design and Printing

a) Lack of Standardized Location For Information

b) Printing on Perforations

c) Force Re-Print Inversion

revealed significant variability among the medication label templates across Epic dispense codes. First, an assortment of different border colors were used on the label stock to differentiate different dispense codes and product types. The colors included white (no border) for oral solids, blue for oral liquids, orange for injectables, and pink for inhalation. Each border color came as a separate label stock and required a separate printer in the pharmacy. In addition, first doses and batch doses were routed to separate printers in the pharmacy as well. The colored borders on label stock, and differentiation between first dose and batch dose printers, were features the pharmacy staff wanted to keep.

The layout or location of information on the label templates was also highly variable across dispense codes. For example, a tablet label looked very different from an injectable label for a medication dispensed in a syringe (Figure 1a). There was a desire to create a standardized template or layout where important information would be available in the same location across all dispense codes. There were also concerns about the size of the label. For example, the injectable syringe and oral liquid syringe labels, specifically, were very short in height (0.64 inches) in order to allow the label to fit above the flange of the syringe without impeding the markings

on the syringe. The short label height made flagging the medication label on the syringe difficult. Alternatively, some of the pharmacy staff would wrap the medication label around the barrel of the syringe, often causing misalignment of the labels, and ultimately leaving portions of the sticky side of the label exposed. The exposed sticky labels would cause syringes to get stuck to one another or to the bag they were delivered in, creating issues for nurses on the inpatient units. The short label height also resulted in the use of a very small font size in order to fit in all of the required information. Furthermore, the injectable syringe and oral syringe dispense codes would first generate a "header" label, containing the patient-specific information, followed by additional labels containing the medication-specific information for each dose of the medication for that patient. While this system worked well for batches of doses for a given patient, it produced more medication waste for individual doses and first doses. More importantly, the header label created risk for bagging errors, whereby the header label for one patient could be placed in a bag for another patient's syringes. Ideally, the syringe labels would contain both the patient-specific information and the medication-specific information in order to prevent these bagging errors.

There were also concerns about the effects of label size on printing. From a technology standpoint, the narrow label height often contributed to printer malfunction because the printer struggled to detect the label perforations or tear lines accurately. As a result, important information would often be printed on top of the perforations, making the information very difficult to read (Figure 1b). The printer misalignment would also frequently result in overall printer malfunction, whereby multiple batches would stop printing partway through or would not print at all. This printer malfunction would require a pharmacy staff member to manually force the printer to reprint the entire batch of labels. Reprinting labels is both costly and time intensive. Furthermore, the forced reprint resulted in other unintended safety consequences. When Epic was implemented at Children's Wisconsin in 2012, the decision was made to request the labels print in an inverse format, which would allow pharmacy staff to read the labels as they scrolled off the printer. Unfortunately, this inverse setting in Epic proved to be a hindrance when batch labels required reprinting. When a batch of labels was reprinting, the inverse formatting was not retained, and the order of the labels, including the header labels, was shuffled. For example, where a header

FIGURE 2. Label Revision Project Objectives

Project Objectives:

- Invert the printing logic in Epic to ensure labels always print in the correct sequential order
- Increased label length
- Use a new, easier-to-read font
- Use a larger font size
- Standardize the location of information on medication labels across all Epic dispense codes
- Eliminate the header label and incorporate the patient-specific information on the label for each medication dose
- Design a new label stock with a perforated midline to guide folding in order to simplify flagging on medication syringes
- Incorporate two identical bar codes, one on each side of the syringe label, to assist with scanning
- Ensure labels for home-going medications, such as bulk products (e.g. inhalers, creams, ointments) contain all necessary items for compliance with state and federal laws
- Convert from using the Contact Serial Number (CSN) to the Medical Record Number (MRN) to help with looking up patients in Epic
- Create a new route of administration “Enteral - See MAR” to be used for PO, NJ, NG, GT, GJ administration routes, which will be indicated in the patient's MAR
- Create a new label icon “DE,” or Discharge Expected, to indicate that a patient might be leaving the hospital that day in order to prevent preparing unnecessary doses

Abbreviations used in the figure include: contact serial number (CSN), medical record number (MRN), medication administration record (MAR), by mouth (PO), nasogastric (NG), nasoduodenal (ND), and nasojejunal (NJ)

label would customarily print first, followed by the dose labels, the reprint would cause the dose labels to print first followed by the patient-specific header label (Figure 1c). This deviation from standard practice caused confusion for pharmacy staff and ultimately led to errors where the doses prepared would be placed in a bag with a header label for a different patient.

Practice Innovation

Step 1: Exploring Opportunities For Improvement

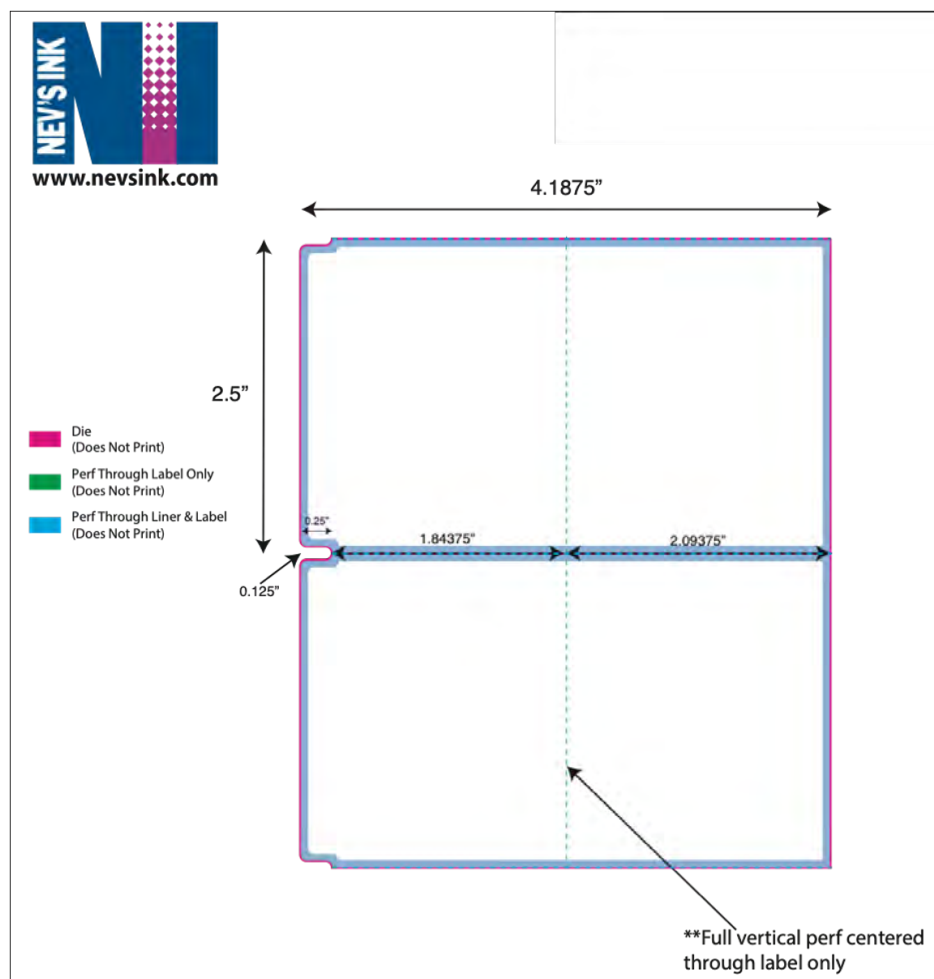
The pharmacy management team reviewed medication label designs from multiple pediatric hospitals across the United States and gathered input from Children's Wisconsin staff on current labeling issues, readability, and workflow. In November 2018, the pharmacy management team asked pharmacists and technicians to provide feedback on current

labels, including what they liked, what they would change, and what an ideal label would look like. This was achieved through email requests to the entire department, individual conversations with pharmacists and technicians working in the main pharmacy, and an announcement on the pharmacy bulletin board soliciting anonymous comments or ideas. Initial mock label designs were created based on the first round of pharmacy feedback and focus groups. The mock designs were distributed to pharmacy staff a second time via email and were also posted on display in the main inpatient pharmacy. Pharmacy staff were encouraged to provide feedback on the proposed mock label designs either by email or by anonymous comments. The initial mock label designs were also shared with the clinical nurse specialist from each nursing unit in order to request feedback from nurses across the organization.

During the feedback gathering process, two additional label features were proposed that would potentially improve workflow and generate cost savings for the pharmacy department. As a pediatric hospital, Children's Wisconsin prepares a large number of weight-based, patient-specific enteral liquid doses each day. Enteral liquid syringes are prepared in one large batch during the first shift at 0930. Enteral liquids can be given using several routes of administration, including by mouth (PO), nasogastric (NG), nasoduodenal (ND), and nasojejunal (NJ) delivery. There are many situations where the prescriber would desire to maintain the same enteral medication and dose, but would necessitate changing only the route of administration. For example, when a patient's NG tube was removed, the patient could then begin taking medications orally by mouth. Each time the prescriber changed the route of administration in Epic, new medication labels would be generated in the pharmacy. The pharmacy would prepare new doses and send them to the nursing unit. Because the enteral liquids are weight-based and patient-specific, the previously prepared doses cannot be returned to stock for future use and would therefore be wasted. The first new feature proposed was the creation of a new route of administration for enteral medications that would print as “Enteral – See MAR” on the label, whereby the more specific route of administration (e.g. PO, NG, NJ) would be displayed on the Medication Administration Record (MAR) in Epic to provide administration instructions for nursing. This change would prevent medications from being wasted and remade, prevent delays in administering medication to patients, and ultimately create operational efficiency for both pharmacy and nursing.

The second new feature proposed was the development of a system for identifying patients likely to discharge from the hospital later that day and flag the medication labels for that patient to prevent preparing patient-specific doses, such as oral syringes and injectable syringes, during the morning batch that would later be wasted if the patient was discharged. The nursing units were already indicating the expected date of discharge for each patient in Epic. Creating a new Epic SmartLink

FIGURE 3. New Label Stock Design with Perforated Center



based on the existing date of discharge in Epic would then print “DE” (Discharge Expected) on the label for patients expected to discharge from the hospital in the next 12 hours. A new pharmacy workflow would need to be created to determine where the new discharge expected labels would be stored, along with when, how, and who would determine whether the patient was discharged or whether the doses ultimately needed to be prepared.

The alternative label designs from other hospitals, staff feedback, and new label feature ideas were compiled and reconciled against best practices, legal requirements, and the technical capabilities of the electronic health record and thermal printers at Children’s Wisconsin in order to create the project scope and objectives (Figure 2).

Step 2: Building & Testing

Willow is the pharmacy module within

the Epic EHR. The information systems department at Children’s Wisconsin employs several individuals, including several pharmacy technicians and pharmacists, who have become specially trained and certified to build and maintain the Willow pharmacy module within Epic. The first step undertaken by the pharmacy management team at Children’s Wisconsin was to submit a project intake form to request resources and support from the Epic Willow team. The information gathered during the initial assessment of the labels, along with the project scope and objectives, were essential to ensuring the project intake request form was accurate and thorough. The project intake request form was submitted on January 17, 2019.

Two Epic Willow analysts were assigned to the project to lead the building, testing, and implementation in Epic. Additional members of the project team included one pharmacist specializing in medication

quality and safety and three pharmacy managers: one to lead the project, one with Epic Willow training, and one with operational oversight of the inpatient pharmacies. Once assembled, the project team drafted a timeline and selected an implementation “go-live” date. The implementation required on-site support from the Children’s Wisconsin Epic team to manually adjust each printer across the organization, along with remote support from the Epic server team to invert the printing order of the labels. The project timeline was developed based on the anticipated go-live date when all necessary groups were available. The project team met once per week over a 10-month period to develop the new Epic medication label design based on the mock designs and project objectives. During the three months preceding go-live, the project team increased their meeting frequency to twice per week in order to maintain the implementation timeline.

One of the key project objectives was to change the label size and incorporate a perforate midline on the label stock, which would allow the label to be easily folded when flagging syringes. The project team decided to incorporate features from the medication label stock used at the University of Iowa Stead Family Children’s Hospital (UI SFCH). The label stock supplied to UI SFCH was also designed and distributed by Nev’s Ink, which also supplies label stock to Children’s Wisconsin. The project team consulted with Nev’s Ink to review the label stock options and the technical specifications of the thermal printers in order to develop the new label stock for Children’s Wisconsin (Figure 3).

The project team incorporated a perforated line, similar to the UI SFCH design. However, rather than using a perforated first inch in the center of the label stock, the project team opted for a fully perforated line down the center of the label for easier folding. The new label stock was increased in height from 0.64 inches to 2.5 inches, which was not to exceed the length of the 0.5 mL enteral syringes barrel used at Children’s Wisconsin. The label stock width was expanded to 4.1875 inches, which was just smaller than the printer’s maximum printable width. The

goal was to optimize the printable area while maintaining printer functionality and preventing printer errors. The project team considered reducing the number of color borders used to identify dispense codes when printing. During the feedback gathering process, nursing expressed consensus that they were not aware of what the colors indicated and, therefore, did not use the colors in any meaningful way. The pharmacy technicians, however, strongly favored maintaining the color borders to assist with their workflow and identifying product storage locations. The current border colors were retained, but the size of the border was reduced to maximize the printable area. The team also considered incorporating a solid black line on the back of the label stock to potentially increase printer alignment. This was determined to be unnecessary, as the increased label height would likely resolve the existing printer issues. The label stock retained the 0.25-inch notch used for printer alignment and to guide peeling the label from the label backing.

After the label stock specifications were finalized, the project team was ready to begin building the new label design in Epic. The resulting Epic label template included three columns. The two outer columns contained the SmartText links for medication information. The center column was only 0.25 inches and was left blank to prevent text from printing over the center perforation where the label would be folded.

The project team chose to build the label for the most difficult dispense code first, which was determined to be the investigational, hazardous, injectable medications, due to their high-risk nature; the presence of two label components (the compounding/production label and the medication label); the additional label fields/features needed; and the large amount of free text space required for instructions and warnings. The project team sought to standardize and reduce label comment length to prevent overflow onto multiple labels. To do this, they removed “hazardous” from the label comments in favor of creating a new banner at the top of the label for all of the hazardous dispense codes. Long label comments across other dispense codes were, and continue to be, an

issue with the new label design. Long label comments currently extend or overflow onto a second label.

The team continued to prioritize label build sequence based on the level of difficulty. Other notably difficult builds included: compounded injectables due to the presence of multiple components; hazardous medications due to the additional banners and warnings required; and bulk products that eventually go home with discharged patients due to the additional legal requirements for outpatient labels. These additional outpatient labeling requirements include the prescriber name, pharmacy address/phone, and quantity of refills, all of which are not otherwise required on inpatient medication labels. Each subsequent dispense code label design was built to mirror the previous label designs to ensure important information and key features were always in the same place across dispense codes. Each of the 50 dispense code labels had to be manually edited and converted to the new standardized design. Each of the 50 dispense code labels required several rounds of testing and reconfiguration to prevent overlapping text, prevent text being cut off during printing, and ensure overall printing alignment. Furthermore, the project team conducted several collective, side-by-side reviews of the label designs, followed by revisions and modifications to ensure consistency and standardization across dispense codes.

Step 3: Timing Trials

One of the primary concerns from technicians regarding the transition to the new perforated label stock was the transition to using the “flagging” method consistently on all medication syringes. The technicians expressed that they were concerned that the flagging method would be slower than the wrapping method they were using previously. One of the Longitudinal Advanced Pharmacy Practice Experience (LAPPE) students at Children’s Wisconsin was asked to develop a timing trial that would compare the amount of time required to label a syringe using the two different label stock designs. This was assigned as her longitudinal project.

The timing trials were performed twice, once with pharmacy students from

the Medical College of Wisconsin School of Pharmacy and once with pharmacy technicians from Children’s Wisconsin. The first timing trial was performed with pharmacy student volunteers because of their lack of previous experience or exposure to either label stock variety. The lack of experience would reduce the potential for bias or timing differences based on experience, which was more likely to occur among the pharmacy technicians who had weeks to years of experience using the original label stock.

Before students arrived for the timing trial, tables were set up with all of the necessary supplies and instructions for the timing trial. Tables were set up using one of four configurations based on the size of the syringe they would be using and which label type they performed first. One side of each table contained a large piece of paper marking the station for Label Type A (the original label stock) in red ink. The opposite side of the table contained a large piece of paper marking the station for Label Type B (the new label stock) in blue ink. Half of the groups used 1 mL syringes and the other half used 3 mL syringes. The appropriate syringes and medication label stocks (A or B) were provided at each of the respective stations on the table.

Two students were paired together and placed at a table. One student was identified as “Student 1” and their partner was identified as “Student 2” for recording purposes on the worksheet. No student identifiers were collected. Students were provided instructions and a brief tutorial on how to label the syringes with each label stock variety prior to the trial. Each student performed two trials with each label stock, for a total of eight trials completed by each table pairing. Each trial consisted of labeling five oral syringes and placing them into a basket. During the trial, one student would label while the other acted as the timer and recorder. Students used their smart phones for timing. The time it took to label each individual syringe was recorded on a color-coded worksheet provided to each pair of students. The same general protocol was used to perform timing trials with pharmacy technicians at Children’s Wisconsin. However, instead of having tables pre-configured with stations, syringes and baskets, the trials were

conducted in the inpatient pharmacy on a clean table. The LAPPE student performed the timing and recording of data for each technician.

Timing data was collected by the LAPPE student and transcribed from the paper worksheets into Microsoft Excel 2016 (Microsoft Corporation, Redmond, Washington, USA) for further analysis. Results from the timing trials demonstrated that the original label stock took longer on average to label compared to the new label stock, at 9.6 seconds and 7.6 seconds per syringe, respectively. Additionally, the average time to label syringes decreased by 0.2 seconds between the first trial and second trial using the new label stock. This improvement indicates that individuals will likely become more efficient with repetition as they gain experience working with the new label stock.

Step 4: Education

Educational documents for the pharmacy staff and the nursing staff were created by the project team in preparation for the new label go-live. The educational documents included photos comparing the old version to the new version (Figures

4-6), summarized the key changes, and provided the contact information for the project manager. The nursing-specific education document was shared with the Nursing Education Committee at Children's Wisconsin to ensure the content would be easily understood by nurses. The Nursing Education Committee provided recommended edits to simplify the documents and improve readability. The final version of the nursing-specific educational document was distributed via email to the clinical nurse specialist representing each nursing unit for further distribution and discussion during the nursing unit huddle meetings. Members of the project team attended various nursing unit huddles as well to provide clarification and answer any questions regarding the new labels. Similarly, the pharmacy-specific educational document was distributed to all members of the pharmacy department via email and discussed during the monthly pharmacy all staff meeting.

Step 5: Implementation

The pharmacy medication label redesign project at Children's Wisconsin took approximately 16 months from the initial

assessment of labels to implementation. The new label changes were implemented in two phases. Phase I went live on October 16, 2019 and included implementation of the new label stock, the new label template, inversion of the printing direction, and addition of the "Discharge Expected" feature. Phase II went live on February 24, 2020 and included the implementation of the "Enteral – See MAR" feature on the medication label, which required additional nursing education and training, along with changes to pharmacy workflow.

The Phase I implementation was scheduled to take place on October 16, 2019 from 0500 to 0700. The goal for implementation was to have all of the printers converted prior to the start of first shift when the labels for several large batches would be printed. The first step of implementation at 0500 involved the Epic server team inverting the printers. The printer inversion flipped the labels 180 degrees so the labels would print in the direction preferred or recommended by Epic. The second step at 0515 involved the Epic Willow team at Children's Wisconsin moving the new label designs from the build environment

FIGURE 4. Education Explaining New Standardized Location of Information

a) Oral Solid BEFORE

"Patient has LATEX allergies"

1 **Miller, Tester**
CSN:62106452 [14 yrs] 2 **W03-W0306-A**
3 Ord# 5228998020 9

4 **warfarin (COUMADIN) tablet 4.5 mg**

5 Frequency: **Nightly** Route: **Oral**

Dose: **0.1 mg/kg x 45 kg**

Medication	Dose	Admin	Disp
6 warfarin 0.5 MG Tab	0.5 mg	1 tablet	1 x 1 tablet
warfarin 4 MG Tab	4 mg	1 tablet	1 x 1 tablet

7 ****HAZARDOUS Medication****

8 Due: 7/8/19 2100
Exp: / / 22:00 By CB
[CF REPRINT] 7/10/19 1436 Tech RPh

b) Oral Solid AFTER

****HAZARDOUS Medication**** W03-W0306-A 1 **Miller, Tester** 2
MRN: 6012787 3
Ord# 5228998020
CB [REDISP REPRINT] 9

4 **warfarin (COUMADIN) tablet 4.5 mg**

5 Dose: **4.5 mg**
Route: **Oral**
Freq: **Nightly**

Medication	Dose	Admin	Doses x Disp
6 warfarin 0.5 MG Tab	0.5 mg	1 tablet	1 x 1 tablet
warfarin 4 MG Tab	4 mg	1 tablet	1 x 1 tablet

8 Exp: / / 9 ****HAZARDOUS Medication**** 7

KEY

- | | |
|--|-------------------------------------|
| 1 Patient Name | 6 Medications and Quantities Needed |
| 2 Patient Room Number | 7 Auxiliary Warning Label |
| 3 Medication Order Number | 8 Expiration Date |
| 4 Medication Name, Strength, and Dosage Form | 9 Barcode |
| 5 Medication Dose, Frequency, and Route | |

FIGURE 5. Oral Solid Medication Labels Before and After Redesign



FIGURE 6. Oral Syringe Medication Labels Before and After Redesign



to the production environment in Epic. The third step involved changing out the old label stock with new label stock and manually reconfiguring each printer across the hospital. The central pharmacy printers were the first priority due to the large number of printers and the high volume of doses dispensed from the location. Subsequent printers would be temporarily re-routed to the inpatient pharmacy printers during the reconfiguration. Subsequent printers were the satellite pharmacy locations located

in the operating room, oncology, PICU and NICU. Unfortunately, several printers took significantly longer to reconfigure than anticipated. The implementation ultimately ended once all printers were successfully reconfigured and re-routed at approximately 1100.

Practice Implications

A retrospective analysis was conducted to estimate the potential cost savings from waste avoidance associated with implementing the “Discharge Expected”

feature on the labels. The retrospective analysis included the period of October 16, 2019 through November 17, 2019. During this period of time, 677 doses were set aside, never prepared, and ultimately not wasted when the patients discharged prior to needing the dose. The projected annual cost savings associated with the introduction of the “Discharge Expected” feature on the labels was approximately \$250,000 per year based on the cost of medications at the time of the analysis. The cost savings calculation included the cost of the medications, the cost of the containers or packaging, and the average technician hourly wage. The majority of the cost savings (71%) was attributed to enteral liquids prepared in oral syringes.

An additional retrospective analysis of delivery errors was also conducted for the period of March 26, 2019 through December 26, 2019. The analysis included a manual review of patient charts in Epic and the Children’s Wisconsin error-tracking system. The average delivery error rate prior to implementation of the new labels was 1.6 errors per day compared to 0.89 delivery errors per day following implementation. The average number of delivery errors decreased by 56% during the look back period.

Conclusions

Pharmacists and pharmacy departments have an important role to play in medication safety. While there are many legal requirements that dictate what is included on medication labels, opportunities for innovation and improvement exist. Applying best practices and incorporating innovative ideas have the potential to reduce medication waste, create operational efficiencies, reduce errors, and ultimately improve patient care.

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PR

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IRB: This quality improvement project was reviewed by the Institutional Review Board (IRB) at Children's Wisconsin on 1/27/20. The IRB determined it does NOT constitute research or human subjects research.

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Addition of Pharmacist versus Usual Care Impact on Heart Failure with Reduced Ejection Fraction Management in a Cardiology Clinic

by Brooke Foster, PharmD, Kristina Cha-Vang, PharmD, Zachary Pape, PharmD, BCACP, Erin Wilkes, PharmD, BCPS

In the United States, heart failure costs \$30.7 billion in health care and missed work annually. A large source of this cost is admissions and re-admissions with the primary diagnosis of heart failure. On average, 25% of all patients with heart failure will be re-admitted to the hospital within 30 days of being discharged. Additionally, the five-year mortality rate for patients diagnosed with heart failure is about 50%.¹ Fortunately, there are well-studied, effective medication therapies available for use in heart failure, specifically heart failure with a reduced ejection fraction (HFrEF), that reduce morbidity and mortality. To achieve clinical benefits, these medications must be titrated to target doses. When patients cannot tolerate target doses, these medications should be titrated to maximally tolerated doses. There are a total of seven HFrEF medication classes that are considered Guideline-Directed Medical Therapies (GDMT) as outlined in the American College of Cardiology (ACC)/American Heart Association (AHA) Guideline for the Management of Heart Failure.^{2,3} The GDMT are: beta blockers (BB), angiotensin receptor neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitor (ACEi), angiotensin II receptor blocker (ARB), aldosterone receptor antagonists (ARA), vasodilators (i.e. hydralazine and isosorbide), and ivabradine.

Titration of patients to goal or maximally tolerated doses of GDMT in a timely and safe manner requires close follow-up and monitoring. Because of this, a multidisciplinary approach to heart failure management can improve the quality of medication-related care. Pharmacists are particularly well-positioned to optimize heart failure medication therapies as the medication experts on the healthcare team.

Several previous studies showed that when patients with heart failure are managed by a pharmacist in addition to the rest of their care team, versus a more typical care model, the patients with pharmacist support had better heart failure outcomes. These outcomes included a reduction in admissions, reduction in mortality, and an

improvement in reaching goal or maximally tolerated heart failure medication doses.⁴⁻⁶

Froedtert & the Medical College of Wisconsin's (F&MCW) Center for Advanced Care (CFAC) Cardiology Clinic manages patients with heart failure, among other cardiovascular disease states. Pharmacists in this clinic work under a

Abstract

Objectives: Well-studied heart failure with a reduced ejection fraction (HFrEF) medications reduce morbidity and mortality when titrated to evidence-based target or maximally tolerated doses. External studies showed benefits when pharmacists manage HFrEF medications, but internal validation at Froedtert & the Medical College of Wisconsin (F&MCW) had not been done. This study aimed to describe the differences in HFrEF medication-related management between patients who were and were not followed by a pharmacist.

Methods: A retrospective chart review was conducted of patients who were followed by an F&MCW Cardiology Clinic provider and prescribed a new HFrEF medication over a one-year period. Patients were stratified into the provider or pharmacist group and were compared based on reaching target or maximally tolerated doses for prescribed HFrEF medications; appropriate lab monitoring; number of visits; time between visits; number of heart failure admissions and re-admissions; and change in left ventricular ejection fraction (LVEF).

Results: Patients in the pharmacist group met their target or maximally tolerated doses at a higher rate than the provider group for four of seven HFrEF medications. There was no appreciable difference in appropriate lab monitoring. Patients in the pharmacist group had more visits and were seen more frequently. The pharmacist group saw a larger average LVEF increase and fewer admissions and re-admissions.

Conclusions: These results suggest that when pharmacists are included in a patient's care team, the team provides superior, more efficient medication-related care to patients with HFrEF. Pharmacists can effectively titrate HFrEF medications because they are able to focus on a patient's medications.

collaborative practice agreement (CPA) to assist providers in heart failure medication titrations and general medication management. Pharmacists follow up with patients regularly to titrate HFrEF medication doses, monitor relevant vitals and labs, educate patients on their medications and disease state, and manage adverse drug reactions based on guidance from national heart failure treatment guidelines and expert consensus reports.^{2,3,7}

The benefit of having pharmacists take part in HFrEF medication management has been proven in external studies, but no internal validation of this concept had been conducted at F&MCW. This study aims to add to the existing evidence regarding the pharmacist's impact in heart failure medication management while also providing internal validation of existing pharmacist services.

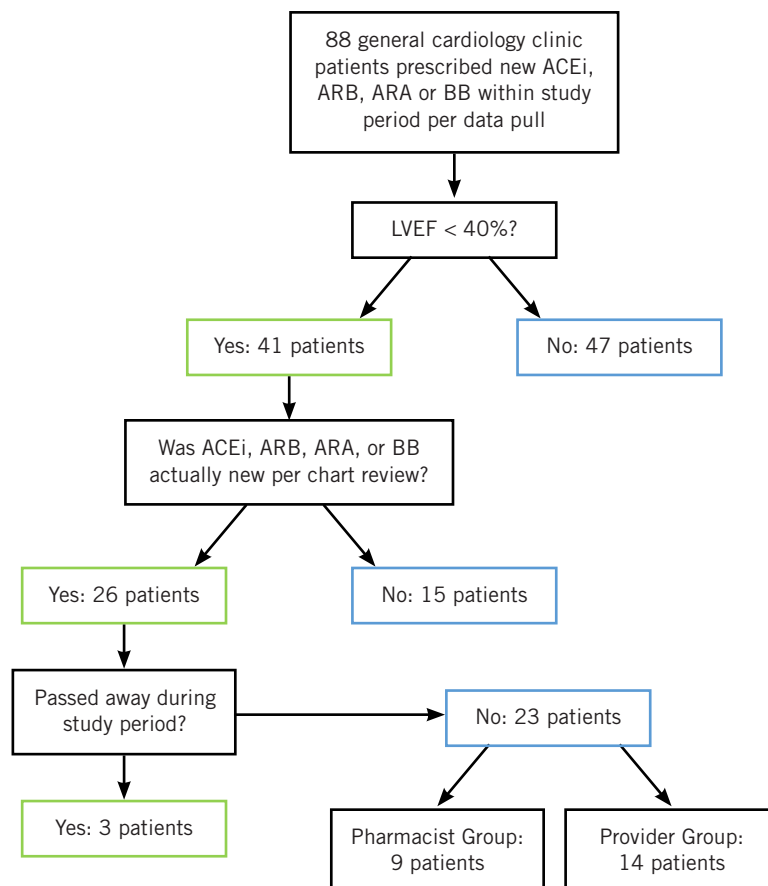
Methods

Study Site

The F&MCW health system is a regional network of one academic medical center, four community hospitals, and more than 45 clinics located in southeastern Wisconsin. This study took place at F&MCW's CFAC Cardiology Clinic on the Froedtert Hospital campus. This clinic encompasses both general cardiology and advanced heart failure clinics. This study focused on HFrEF patients that follow with general cardiology only, as the advanced heart failure clinic functions under a medical home model with increased provider and staff support.

Pharmacists in this clinic work alongside physicians, advanced practice providers, nurses, and medical staff. They work under robust CPAs to see patients independently for heart failure, hyperlipidemia, hypertension, and tobacco abuse disease states. Cardiology providers refer patients to the pharmacist for a pre-specified reason, and the pharmacist can start, adjust, or discontinue medications, monitor relevant vitals, order labs, and educate patients on their medications and disease states. The pharmacist follows patients primarily via in-person office visits but can also provide follow-up care via telephone and MyChart when preferred by the patient or to increase access to care. For heart failure management, the pharmacist

FIGURE 1. Screening Patients for Inclusion and Exclusion Criteria



Abbreviations: angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor antagonist (ARA), beta blocker (BB), left ventricular ejection fraction (LVEF)

prefers to follow up with the patient every 2 weeks when possible to ensure efficacy and tolerability of the medication regimen. Once the patient has reached their medication-related disease state goals or the pharmacist has exhausted available resources, the pharmacist discharges the patient back to the referring cardiology provider and no longer follows up with the patient. Cardiology providers typically

follow patients indefinitely and prefer to see patients via in-person office visits every few months.

Study Design

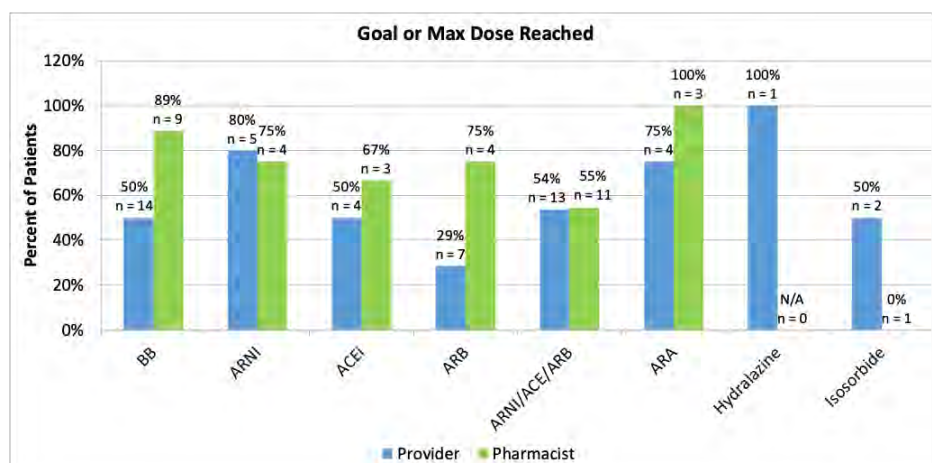
This was a single-center, retrospective chart review of patients with HFrEF followed by a cardiology provider at F&MCW's CFAC Cardiology Clinic. This project was deemed a quality improvement

TABLE 1. Baseline Characteristics

	All (N=23)	All (N=14)	Pharmacist Group (N=9)	p-value
Mean Age (SD)	64.83 (14.62)	65.29 (16.23)	64.11 (12.60)	0.729
Gender				0.214
Male	11 (47.8%)	5 (35.7%)	6 (66.7%)	
Female	12 (52.2%)	9 (64.3%)	3 (33.3%)	
Average Baseline LVEF	32.5%	33.9%	29.6%	

Abbreviations: left ventricular ejection fraction (LVEF)

FIGURE 2. Goal or Maximally Tolerated Dose Reached



Abbreviations: beta blocker (BB), angiotensin receptor neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor antagonist (ARA)

project by the F&MCW Pharmacy Research Committee in August of 2019. The index event qualifying patients for inclusion into the study cohort was being prescribed a new angiotensin-converting enzyme inhibitor (ACEi), angiotensin II receptor blocker (ARB), angiotensin receptor neprilysin inhibitor (ARNI), or beta blocker (BB) medication between December 1, 2017 and December 1, 2018.

Patients were included if their left ventricular ejection fraction (LVEF) was 40% or less based on any type of cardiac imaging done before the date the new medication that triggered patient inclusion was first prescribed. Charts of patients who met inclusion criteria were reviewed to determine whether the patient was referred to and seen by a clinical cardiology

pharmacist for heart failure medication titration. Patients were then stratified into two groups: those referred to the clinical pharmacist for medication titration (pharmacist group) and those not referred to the clinical pharmacist (provider group). The study period for the pharmacist group lasted from the time of the first visit with the pharmacist to the last visit. The study period for the provider group was a standard six months, starting with the date the new medication that triggered patient inclusion was first prescribed. This six-month time period was based on the presumed length of time that pharmacists follow HFrEF patients, as providers typically follow patients indefinitely.

Patients were excluded if they were followed by an F&MCW advanced heart

failure provider, not seen by an F&MCW cardiology clinical pharmacist or F&MCW cardiology provider during the study period, or seen by a cardiology clinical pharmacist for a referral reason other than heart failure medication titration. Medication-related outcomes were reviewed for the following seven groups of GDMT: beta blockers (BB), angiotensin receptor neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitor (ACEi), angiotensin II receptor blocker (ARB), aldosterone receptor antagonists (ARA), hydralazine, and isosorbide. Medication-related outcomes, such as medication adjustments and lab monitoring, were counted when they were completed by any cardiology clinic team member for both groups, as long as they occurred within the study period. This was done to capture the overall team's impact on HFrEF outcomes. Medication adjustments and lab monitoring completed by a non-cardiology clinic health care professional were not counted for either group.

Outcomes

The overall objective of this study was to describe differences in medication-related management between patients in the pharmacist group and provider group. The primary outcome was the number and percent of patients in each group who reached a target or maximally tolerated dose for each individual as well as the sum of all GDMT they were prescribed.

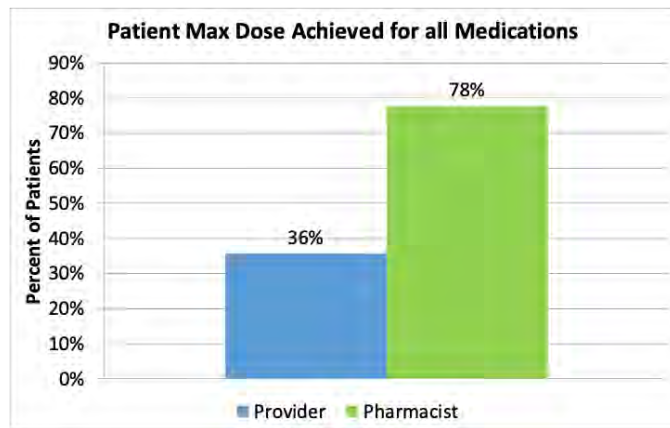
Several secondary outcomes were assessed during the retrospective review. The percent of patients in each study group with appropriate medication-related lab monitoring was assessed. Appropriate lab monitoring was defined as having a basic metabolic panel (BMP) lab ordered within 2 weeks of ACEi, ARB, ARNI, or aldosterone receptor antagonist (ARA) initiation, or when the medication dose was increased was assessed. The average number of office visits, telephone encounters, MyChart encounters, and total encounters was tracked. Groups were compared based on the average time between office visits. The average change in LVEF based on cardiac imaging completed before the start of the study period and the first cardiac imaging completed within 6 months of the end of the study period was assessed. The

TABLE 2. Primary Outcome

Medication	All (N=23)	Provider Group (N=14)	Pharmacist Group (N=9)	p-value
BB	15 (65.2%)	7 (50.0%)	8 (88.9%)	0.086
ARNI	7 (77.8%)	4 (80.0%)	3 (75.0%)	> 0.999
ACEi	4 (57.1%)	2 (50.0%)	2 (66.7%)	> 0.999
ARB	5 (45.5%)	2 (28.6%)	3 (75.0%)	0.242
ARA	6 (85.7%)	3 (75.0%)	3 (100.0%)	> 0.999
Hydralazine	1 (100.0%)	1 (100.0%)	0 (–%)	
Isosorbide	1 (33.3%)	1 (50.0%)	0 (0.0%)	

Abbreviations: beta blocker (BB), angiotensin receptor neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor antagonist (ARA)

FIGURE 3. Goal or Maximally Tolerated Dose Reached for All GDMT Patient Taking



type of LVEF imaging varied from patient to patient, but imaging was only included for comparison if the patient's pre-intervention and post-intervention LVEF imaging modality was the same. Additional secondary outcomes included the total number of patients admitted and total number of patients re-admitted with heart failure as the primary diagnosis during the study period.

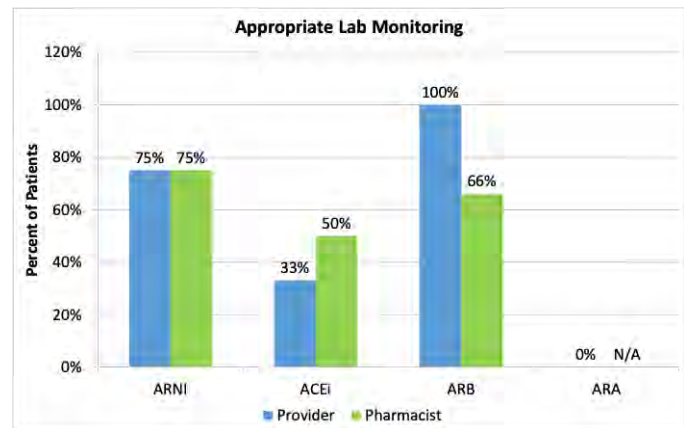
Descriptive statistics were employed. Study variables were summarized by the mean and standard deviation for continuous variables. Frequency and percentage were used for categorical variables. Baseline characteristics and outcomes were compared between groups using Wilcoxon rank-sum tests for continuous variables and Fisher's exact tests for categorical variables. All statistical analyses were performed using R version 3.6.0 (R Foundation for Statistical Computing, <http://www.R-project.org>). All tests were two-sided and $p < 0.05$ was considered statistically significant. All analyses employed an "available-case" approach to missing data. No adjustments were made for multiple testing.

Results

Patient Population

A total of 88 patients were screened for inclusion and exclusion criteria. Results of the screening process are outlined in Figure 1. After screening, 23 patients were included for retrospective analysis. There were 14 patients in the provider group and 9 patients in the pharmacist group. Baseline characteristics for the included patient

FIGURE 4. Appropriate Lab Monitoring



Abbreviations: angiotensin receptor neprilysin inhibitor (ARNI), angiotensin-converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB), angiotensin receptor antagonist (ARA)

number of each encounter type and total clinical encounters per patient are outlined in Figure 5. Patients in the pharmacist group had statistically significantly more total clinical encounters over the course of the study period compared to the provider group. The average times between office visits are outlined in Figure 6. Pharmacist patients were followed for 4.11 months on average, which was less than the standard six-month period that patients in the provider group were followed. The pharmacist group saw patients more

frequently, and this result was statistically significant.

The average baseline, end, and change in LVEF are displayed in Table 4. The pharmacist group saw slightly more LVEF improvement than the provider group on average. None of the patients in the pharmacist group were admitted or re-admitted to the hospital with heart failure as the chief concern. There were 3 hospital admissions and 0 re-admissions in the provider group. One patient in the provider group was admitted twice, but these

TABLE 3. Secondary Outcome

Variable	All (N=23)	Provider Group (N=14)	Pharmacist Group (N=9)	p-value
Mean # cardiology office visits during study period (SD)	3.30 (1.84)	3.14 (1.92)	3.56 (1.81)	0.678
Mean # cardiology telephone encounters during study period (SD)	3.48 (3.76)	2.57 (2.47)	4.89 (5.04)	0.170
Mean # cardiology MyChart encounters during study period (SD)	0.48 (0.99)	0.43 (0.76)	0.56 (1.33)	0.838
Mean # total cardiology encounters during study period (SD)	7.26 (4.29)	6.14 (2.77)	9.00 (5.70)	0.405
Mean # cardiology encounters with pharmacist during study period (SD)	1.78 (3.06)	0.29 (0.73)	4.11 (3.86)	0.004
Average time elapsed between office visits in weeks (SD)	8.59 (6.80)	10.54 (6.91)	5.56 (5.70)	0.021
Abbreviations: standard deviation (SD)				

FIGURE 5. Average Number of Encounters per Patient

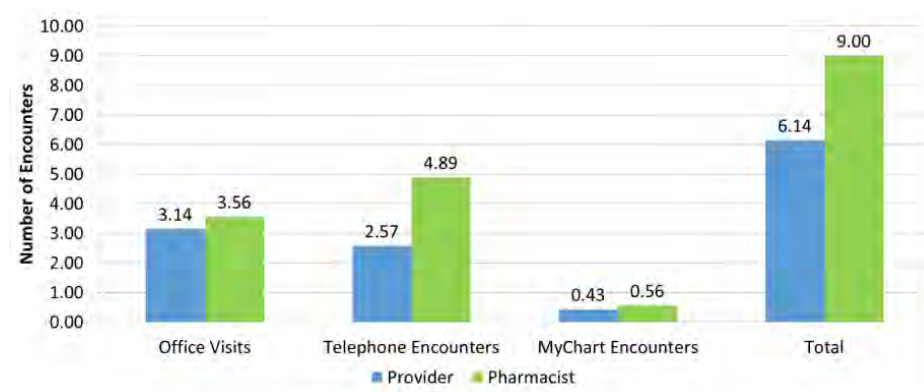
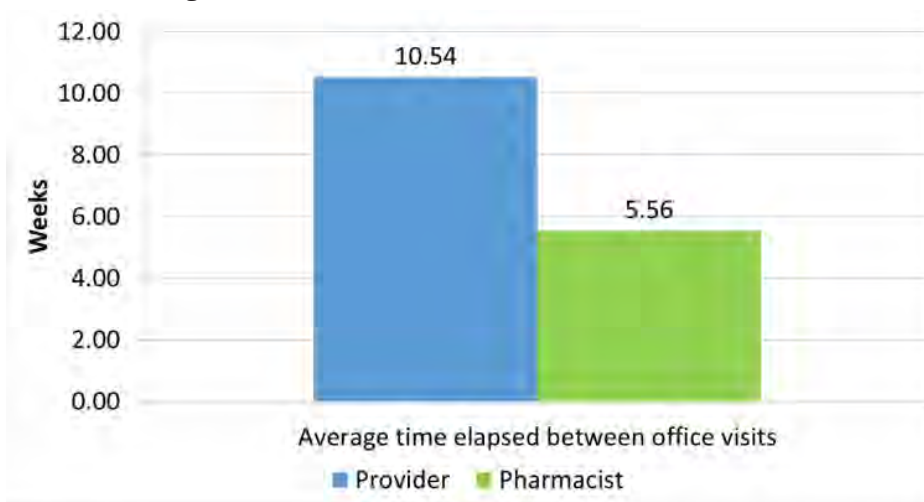


FIGURE 6. Average Time between Visits



population are outlined in Table 1. There was a non-statistically significantly higher percentage of males in the pharmacist group than in the provider group. The average age was similar for both groups, with an average age of 64.83 years for all included patients. The average baseline LVEF was slightly lower in the pharmacist group.

Outcomes

Results for the primary outcome are outlined in Figures 2 and 3. Statistical analysis of the primary outcome is outlined in Table 2. The pharmacist group achieved a higher percent of patients on target or maximally tolerated doses for four of seven GDMT categories. The pharmacist group also achieved a higher percent of patients on target or maximally tolerated doses for all the GDMT each patient was prescribed. None of the primary outcome components reached statistical significance.

Table 3 outlines the statistical

analyses for all secondary outcomes. The difference between the pharmacist and provider groups in ordering appropriate lab monitoring for each applicable type of medication is outlined in Figure 4. This outcome did not reach statistical significance. The two groups varied in their rates of appropriate lab monitoring for each individual medication type but had overall similar rates of lab monitoring when considering all medications where lab monitoring is beneficial. The average

admissions were more than 30 days apart, so they did not meet the criteria to be considered a re-admission. Neither of these outcomes reached statistical significance.

Discussion

The primary outcome was impacted by a couple of factors. There were no patients in the pharmacist group on hydralazine, so there is no meaningful comparison for hydralazine. Also, there was only one patient in the pharmacist group who was prescribed isosorbide, and this patient did not reach a target or maximally tolerated dose. This study found that there is room for improvement regarding ordering labs when appropriate, as well as ensuring patients follow through on having ordered labs drawn, as neither group had complete adherence for all relevant medication classes.

The average number of office visits and MyChart encounters patients had with their cardiology care team were about the same in both groups. However, patients in the pharmacist group had more telephone encounters, and thus had more total encounters. This was not surprising, since pharmacists are well-positioned to be able to conduct clinical visits via the phone due to billing constraints and frequency of encounters. Patients in the pharmacist group had more frequent follow-up than the provider group, even though this metric was based on time between office visits only and did not include telephone encounters. If all visit types were considered, it is likely this difference would be larger.

Although the number of office visits was not very different between the groups, the total time the pharmacist followed patients was only 4.11 months, while provider group patients were followed for a standard six months. This means that the pharmacist

TABLE 4. Left Ventricular Ejection Fraction

	Provider Group (N=14)	Pharmacist Group (N=9)	p-value
Average Baseline LVEF	33.9%	29.6%	
Average End LVEF	38.9%	37.2%	
Change in LVEF	5.0%	7.6%	0.767
Abbreviations: left ventricular ejection fraction (LVEF)			

group fit more visits into a shorter period of time. This variance in study period length is a limitation of the study. The study period length varied because pharmacists in the cardiology clinic only follow patients until they reach their medication-related disease state goals or the pharmacist has exhausted available resources, while cardiology providers typically follow their patients indefinitely. At the beginning of the study it was estimated that pharmacists follow patients with HFrEF for six months on average; therefore, the standard six-month study period was established for the provider group. This ended up being an over-estimation and resulted in a difference in study period lengths. If these time periods were better matched, it is possible the results would have more accurately reflected pharmacist contribution.

A limitation to this study is the small sample size, which limited the ability to show statistical significance. The sample size was limited because patients were only included if they were prescribed a new ACEi, ARB, ARNI, or BB during the study period. This was done because the study needed to have the same inclusion trigger for both the pharmacist and provider groups in order to minimize bias when assessing analytical statistics. In a cardiology clinic, many patients are prescribed an ACEi, ARB, or BB for an indication other than heart failure even before they are diagnosed with heart failure, so this eliminated many patients. It was not possible to use a diagnosis of HFrEF as the inclusion trigger, because the way diagnoses are entered in the electronic health record is

unreliable for data collection purposes.

Conclusion

This study suggests that when pharmacists are involved in the care team for patients with HFrEF, it leads to similar or possibly better outcomes compared to providers alone. These findings are similar to studies done outside F&MCW. Pharmacists are well-positioned to effectively titrate HFrEF medications because they can dedicate time to focus on a patient's medications. This information can and will be used to support existing pharmacist services in the cardiology clinic as well as to encourage continued pharmacist referrals from cardiology providers.

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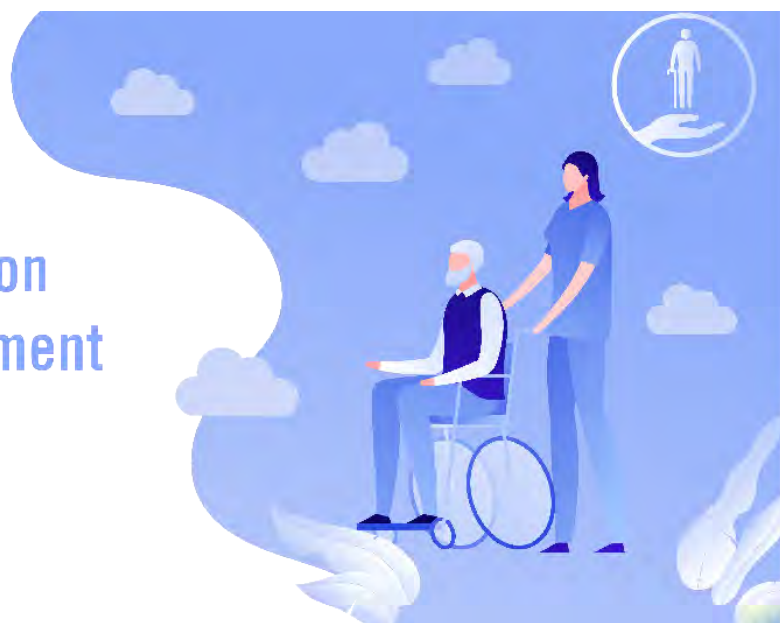
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Assessment of Inpatient Pharmacists' Clinical Interventions Following Implementation of a Pharmacist Intervention Tracking Tool

by Allison R Behrens, PharmD, Melissa E. Ha, PharmD, BCCCP, Berook Addisu, PharmD, BCPS

Clinical pharmacists practicing in the inpatient setting frequently intervene to optimize patient care. Multiple studies illustrate that clinical pharmacists are integral members of the patient care team by dosing medications, providing pharmacy-pertinent recommendations to the medical team to optimize medication regimens, and closely monitoring the clinical status of patients, among other activities.¹⁻³ Pharmacist interventions have benefited the healthcare system and improved patient outcomes, including reductions in adverse drug events, length of stay, end organ damage, and mortality.³⁻⁷ A 2018 systematic review, including 28 controlled trials, found that inpatient pharmacist-led interventions improved the quality of medication use, reduced number of hospital visits, and decreased length of stay.⁸ Additionally, tasks performed by clinical pharmacists have been shown to lead to cost savings.^{6,9} Jourdan et al assigned clinical impact scores to pharmacist interventions and correlated this to the number of prevented hospitalization days and cost savings.⁹ This study found that pharmacist interventions prevented 213 potential hospitalization days and a total of \$281,981 cost avoidance.⁹

The documentation practices of inpatient pharmacists vary widely across organizations and may depend on the type of clinical intervention being performed.¹⁰ According to the 2016 American Society of Health-System Pharmacists' national survey of pharmacy practice in hospital settings, 56.9% of responding hospitals document clinical services in the patient's permanent medical record.¹¹ The survey did not specify the types of clinical activities that are documented. Pharmacists frequently intervene to improve patient

Abstract

Objectives: Pharmacists are highly involved in patient care throughout daily practice. The primary objective of this study was to evaluate the most common disease states in which clinical pharmacists intervene using an intervention-tracking tool called the PhARMD template.

Methods: This was a single-site, prospective evaluation assessing inpatient pharmacist interventions. Baseline data was collected for a six-month period prior to implementation of the template and compared to two post-implementation phases. Phase I included voluntary use of the template for activities that pharmacists were already documenting in the electronic medical record, and Phase II included use of the template for all pharmacist interventions.

Results: The number of documented interventions per day increased from baseline 0.67 interventions per day to 32.54 and 46.8 interventions per day in Phase I and Phase II, respectively. During Phase II, the most common categories documented were medication reconciliation, anticoagulation, and inpatient clinical interventions. Of the inpatient clinical interventions, the most common disease states intervened in included antimicrobial stewardship (16.7%) and "additional pharmacotherapy" (19.7%), which includes ordering tests and labs; addressing adherence; and other non-pharmacological interventions. Actions most frequently performed by pharmacists included initiation of medications (28.6%), adjusting dose/frequency (24.2%), and monitoring of medications (19.7%).

Conclusions: Pharmacists impact patients through independent practices and clinical recommendations resulting in changes to patient care plans. Use of the PhARMD template provides quantification of these interventions, including the number of disease states that pharmacists may affect, as well as the quality of these interventions.

care throughout the day-to-day course of business; however, these recommendations are often made verbally and are not documented in the electronic medical records (EMR).¹⁰ Therefore, the discussion and communication are limited to the

provider and pharmacist who were directly involved, and future providers may not be aware of the pharmacists' recommendations previously made and any related changes to the care plan.

The Department of Veterans Affairs

TABLE 1. Pharmacy Services Documented through PhARMD Template Utilization

<i>Intervention</i>	<i>Number of Interventions</i>			<i>Interventions per Day</i>		
	<i>Baseline</i>	<i>Phase I</i>	<i>Phase II</i>	<i>Baseline</i>	<i>Phase I</i>	<i>Phase II</i>
Medication Reconciliation	13	1,695	1,284	0.071	13.78	21.40
Anticoagulation	15	1,212	730	0.082	9.85	12.17
Inpatient Clinical	2	398	427	0.011	3.24	7.12
Pharmacokinetics	11	547	273	0.060	4.45	4.55
Mental Health Education Group	77	38	35	0.421	0.31	0.58
Tube Feeding	4	53	34	0.022	0.43	0.57
Tobacco Treatment	0	59	25	0.000	0.48	0.42
Total	122	4,002	2,808	0.67	32.54	46.81

(VA) Pharmacy Benefits Management Clinical Pharmacy Practice Office (CPPO) created a pharmacist intervention tracking tool called the Pharmacists Achieve Results with Medications Documentation (PhARMD) template to demonstrate the clinical interventions that pharmacists make in daily practice.¹² The PhARMD template is a documentation tool connected to the EMR, which allows pharmacists to track interventions by selecting from a pre-set list of interventions based on relevant disease states and type of intervention made to the particular disease state (e.g., medication initiation, discontinuation, change in dose). In order to use the template, the pharmacist must first enter a note into the EMR containing relevant background information and clinical decision making, and they must link that note with a clinical pharmacist encounter service such as anticoagulation, pharmacokinetics, or medication reconciliation. Then, before completing the note, the pharmacist must use the PhARMD template to briefly characterize the intervention(s) documented in the note. This template then auto-populates at the end of the note. The PhARMD template data can then be reviewed to track and trend interventions.

The decentralized, team-based inpatient pharmacists at the William S. Middleton Memorial Veterans Hospital in Madison, Wis. frequently intervene

to increase medication safety and optimize patient care. The pharmacists provide care by monitoring patients' status through the EMR, assessing the patient's therapy, providing clinical recommendations to medical teams they're part of, and performing pharmacist-led activities. Pharmacists are highly involved in transitions of care by performing medication reconciliation and discharge counseling for all admitted patients. Pharmacists intervene both by communicating recommendations to providers and through the use of their scope of practice. A scope of practice within the VA authorizes the pharmacist to independently order medications and laboratory tests as the ordering provider without the need for an accompanying protocol or additional provider signature/review.¹³ This method of autonomous practice has been reported in 7.2% of U.S. hospitals¹¹ and, within the VA, requires accompanying documentation. In addition to scoped activities, pharmacists provide care through recommendations to the medical team. Pharmacist recommendations to the medical team have not historically been documented in the medical record at this site. Prior to formal implementation of the PhARMD template in the inpatient setting, there had been minimal use of the template, with the exception of a psychiatry service that was already using the tool to

document education. Therefore, the type and quantity of scoped interventions and recommendations provided to the medical team by the entire inpatient clinical pharmacist staff is unknown.

The primary aim of this evaluation was to identify pharmacy services that were documented through the PhARMD template. Secondary outcomes included determining which disease states clinical pharmacists most commonly intervened in, the most common actions that the pharmacists were performing to optimize patient care, the percentage of time interventions were made within the pharmacists' scope versus recommendations made to and accepted by the treatment team, the percentage of time pharmacists were compliant with use of the template, and describing the end user experience with the template through survey data.

Methods

This single-site, prospective evaluation was performed at the William S. Middleton Memorial Veterans Hospital. This evaluation was determined not to meet the federal definition of research and IRB review was not required per the University of Wisconsin-Madison Health Sciences IRB Not Research Determination Decision Tool.

Baseline use of the PhARMD template was collected for approximately a six-month period (183 days) from May 1, 2018 to

TABLE 2. Quantity of Inpatient Clinical Interventions by Disease State (11/1/18-5/4/19)

<i>Intervention</i>	<i>Number of Interventions</i>	<i>Percent of Total Interventions</i>
Additional Pharmacotherapy	163	19.8%
Antimicrobial Stewardship	138	16.7%
Anticoagulation	73	8.8%
Nutrition Support	69	8.4%
Gastrointestinal	46	5.6%
Arrythmia	42	5.1%
Type II Diabetes	40	4.8%
Pain Management	39	4.7%
Coronary Artery Disease	25	3.0%
Chronic Obstructive Pulmonary Disease	22	2.7%
Hypertension	19	2.3%
Shock	19	2.3%
Sedation	16	1.9%
Transplant	16	1.9%
Gout	12	1.5%
Neurology	11	1.3%
Constipation	10	1.2%
Chronic Heart Failure	9	1.1%
Lipids	9	1.1%
Chronic Kidney Disease	7	0.8%
Alcoholic Liver Disease	6	0.7%
Urology	6	0.7%
Alcohol Withdrawal	5	0.6%
Vascular	4	0.5%
Acute Coronary Syndrome	3	0.4%
Delirium	3	0.4%
Mental Health - Depression	3	0.4%
Coronary artery bypass grafting	2	0.2%
Mental Health - Insomnia	2	0.2%
Oncology	2	0.2%
Alcohol Use	1	0.1%
Anemia	1	0.1%
Rheumatology	1	0.1%
Tobacco Cessation	1	0.1%
Total	825	100.0%

October 31, 2018 prior to implementation, to identify the quantity of template use without formal implementation. Use of the PhARMD template was then formally implemented in two phases. Phase I was conducted over a four-month period (123 days), between November 1, 2018 and March 4, 2019. During Phase I, use of the PhARMD template was mainly emphasized for activities where the

pharmacists were already documenting services within a templated note, including clinical interventions on anticoagulation, pharmacokinetic dosing, tube feeding, and tobacco cessation. Pharmacists then added PhARMD template information to the end of the note for tracking purposes. This phase served as a partial rollout of the template. Inpatient pharmacists were trained prior to the implementation of

Phase I at a voluntary inpatient pharmacist meeting. Step-by-step guides were also provided via email. Use of the template was encouraged but not required.

Phase II started on March 5, 2019 and data were gathered for the 60-day period between March 5, 2019 and May 4, 2019. During Phase II, pharmacists expanded use of the template with an emphasis on the documentation of the wide range of daily interventions, whether through the use of their scope or through accepted recommendations to the medical team. During Phase II, all Phase I practices were continued. In addition, a new non-templated pharmacy note was created specifically for pharmacists to document all other daily clinical interventions made, and the PhARMD template was used in a similar manner to that of Phase I. Pharmacists were trained prior to the implementation of Phase II on the necessary components of a complete clinical encounter within the new, non-templated clinical intervention note and appropriate use of the template, via a voluntary training at an inpatient pharmacist meeting and through email communication.

Prior to implementation of Phase II, a small group of pharmacists participated in a Phase II pilot over a one-month period from February 4, 2019 to March 4, 2019. The goal of this pilot was for the participants to try the Phase II documentation process and provide feedback. Two in-person check-in meetings with this pilot group occurred during the pilot phase. Based on discussions with the pilot group, training materials were created and distributed to the entire pharmacist team prior to full Phase II implementation. The pilot group continued to document all interventions included in Phase I. Due to the pilot period occurring during Phase I and only a limited number of Phase II interventions being documented, data from the pilot period is included with the data for Phase I. The data was analyzed using descriptive statistics for baseline, Phase I, and Phase II periods.

Primary Outcome:

The primary outcome of this evaluation was to identify the pharmacy services that were documented through the PhARMD

TABLE 3. Classification of Interventions by Action Type (11/1/18-5/4/19)

<i>Category of Intervention</i>	<i>Action Type (n= number of interventions)</i>								
	<i>Initiate</i>	<i>Adjust dose/frequency</i>	<i>Monitor</i>	<i>Change/discontinue</i>	<i>Non-pharmacologic</i>	<i>Change form</i>	<i>Manage/prevent ADE</i>	<i>Education</i>	<i>Other</i>
Anticoagulation	309	435	1,084	74	30	1	1	7	1
Inpatient Clinical	190	224	33	252	25	75	15	1	10
Med Reconciliation	1,141	596	13	520	9	12	5	672	11
Mental Health Education Group	0	0	0	0	73	0	0	0	0
Pharmacokinetics	222	386	188	15	1	3	3	0	2
Tobacco Treatment	80	1	0	3	0	0	0	0	0
Tube Feeding	4	7	26	13	0	35	0	0	2
TOTAL	1,946	1,649	1,344	877	138	126	24	680	26

template. These core pharmacy services documented through the template were sorted by the type of service encounter to which the pharmacist linked their note. Encounter selections included medication reconciliation, anticoagulation, pharmacokinetic, mental health education group, tube feeding, tobacco treatment, and inpatient clinical. The “inpatient clinical” category was used for all interventions on disease states that did not appropriately fit into one of the previously listed encounters. The total number of interventions and the average number of interventions per day were sorted by when they occurred: baseline, Phase I, or Phase II.

Secondary Outcomes:

Secondary outcomes include the following items: determine the clinical disease states in which pharmacists were commonly intervening; identify the types of actions being taken with respect to these interventions (e.g., initiate medication, discontinue medication); find the quantity of scoped versus recommended interventions; identify compliance with the PhARMD template; and evaluate the end user experience with the PhARMD template.

The interventions that were included in the “inpatient clinical” category were further quantified for a composite of the

Phase I and Phase II periods to identify the common disease states that pharmacists intervened in. Of note, the term “disease state” in this context refers to the list of predefined options within the PhARMD template, whose names might not accurately describe an actual disease state (e.g., antimicrobial stewardship, urology, pain management) but rather an area of clinical practice.

Additionally, each intervention was assessed for the type of action taken. All interventions in Phase I and Phase II were classified as one of the following: initiate, adjust dose/frequency, monitor, change/discontinue, non-pharmacologic change, change in dosage form, manage/prevent an adverse effect, education, or other. The category of “other” included all interventions that did not fit into one of the previously defined categories.

Pharmacists at this site manage certain processes, such as anticoagulation and pharmacokinetic dosing. These processes are considered within the pharmacists’ scope, and as such, pharmacists are able to make changes to the therapy plan without contacting the medical team. Other changes are made by pharmacists identifying an area of therapy optimization and contacting the medical team, and the medical team accepting and implementing the change. When completing an entry in the PhARMD template, pharmacists select

whether the intervention was within their scope or whether it was a recommendation to the provider. Data were analyzed to identify the percentage of interventions that were made within scope versus a recommendation to the provider.

Pharmacists were encouraged, but not required, to use the template. A report was generated from VA CPPPO to analyze compliance with the PhARMD template during Phase II when full use of the template was implemented. Compliance was measured by comparing the number of clinical encounters that had the opportunity for PhARMD template use to the number of encounters in which the PhARMD template was actually used.

The experience pharmacists had using the template was measured at the completion of Phase I. All pharmacists were encouraged to complete a voluntary, online survey, which consisted of Likert scales to measure the pharmacists’ confidence, willingness, and satisfaction. The survey included the following three questions: “On a scale of 1 to 5 (1=not at all, 5=the most), what is your confidence in using the PhARMD template?” “On a scale of 1 to 5 (1=not at all, 5=the most), what is your willingness to use the PhARMD template?” “On a scale of 1 to 5 (1=not at all, 5=the most), what is your satisfaction in using the PhARMD template?”

TABLE 4. Recommendations within Scope vs. Made to a Provider (11/1/18-5/4/19)

<i>Intervention</i>	<i>Recommendation within Scope</i>	<i>Recommendations Made to Provider</i>	<i>Total Interventions</i>	<i>% of Interventions within Scope</i>
Mental Health Education Group	73	0	73	100.00%
Tobacco Treatment	84	0	84	100.00%
Anticoagulation	1,934	8	1,942	99.59%
Pharmacokinetics	801	19	820	97.68%
Medication Reconciliation	2,628	351	2,979	88.22%
Tube Feeding	74	13	87	85.06%
Inpatient Clinical	382	443	825	46.30%

Results

Thirty-two pharmacist were included and encouraged to use the PhARMD tool in both Phase I and Phase II of implementation; however, the use of the template was voluntary.

Primary Outcome:

The first primary outcome was to determine the pharmacy services that were documented through use of the PhARMD template (Table 1). At baseline, use of the tool was minimal, with a total of 122 interventions logged during the six-month period, for an average of 0.67 interventions logged per day. The majority of the interventions logged at baseline were categorized under “mental health education,” as the inpatient mental health pharmacists have historically used the tool to log education that is performed in group classes. Throughout the Phase I period, the average interventions per day increased to 32.54, with the primary interventions being related to medication reconciliation. In Phase II, where all pharmacists were encouraged to use the tool to document all interventions, the average increased to 46.8 interventions logged per day. During Phase II, the most common logged interventions were the medication reconciliation category, followed by anticoagulation, and inpatient clinical interventions that were not classified into one of the previously defined categories.

Secondary Outcomes:

For the interventions that were categorized as general “inpatient clinical” interventions that did not fit within specific pharmacist services, the most common clinical disease states intervened in were

antimicrobial stewardship (n=138, 16.7%) and “additional pharmacotherapy” (n=163, 19.7%), which includes interventions such as ordering tests and labs; addressing adherence; and other non-pharmacological interventions (Table 2).

The most common actions performed by pharmacists were initiation of a medication (n=1946, 28.6% of interventions), followed by adjusting dose/frequency (n=1649, 24.2% of interventions), and monitoring of medications (n=1344, 19.7% of interventions). Education, which encompassed discharge counseling, anticoagulation teaching, and other forms of education, was also a common intervention (n=680, 10% of interventions) (Table 3).

The majority of interventions made and recorded were interventions that were within the pharmacists’ scope of practice. These intervention often included mental health education group (100%), tobacco treatment (100%), anticoagulation (99.59%), pharmacokinetics (97.69%), medication reconciliation (88.22%), and tube feeding (85.06%). However, interventions that were recorded in the “inpatient clinical” category were only within scope 46.30% of the time (Table 4).

There was an average of 94.74% compliance with PhARMD template use during the Phase II period (Table 5). A total of 16 out of 32 pharmacists completed the End User Experience survey, and responses ranged between 1 and 5 with mean scores of 3.81, 4.38, and 3.94 for confidence, willingness, and satisfaction, respectively.

Discussion

Primary Outcome:

The most commonly documented services were consistent throughout Phase I and Phase II of the PhARMD template implementation. The services in which pharmacists were most commonly intervening were pharmacist-managed processes. The most common interventions in both Phase I and Phase II were through the provision of medication reconciliation. This is likely due to the robust, pharmacist-managed medication reconciliation process at the facility, which pharmacists complete for each patient who is admitted and discharged. The second most common intervention was anticoagulation, which is also a pharmacist-managed process at this facility. In the Phase II period, the “inpatient clinical” interventions were the third most common intervention. This category identifies and quantifies the interventions that pharmacists are making through the day-to-day workflow that previously were not documented, tracked, or trended.

Secondary Outcomes:

As demonstrated in Table 1, pharmacists are intervening on disease states throughout the entire spectrum of patient care. Not only are interventions medication-focused, but pharmacists are also involved in the patient’s treatment through laboratory monitoring, non-pharmacological interventions, and education of patients. Most interventions pharmacists made required a change as opposed to monitoring. Almost 1/5 of the interventions made by pharmacists were in the form of education. Transitions of care are a focus at this site, and, therefore,

each patient receives detailed discharge counseling and may receive additional counseling if they are discharging on a high-risk medication such as a new anticoagulant.

The majority of interventions that were made were within the pharmacists' scope with the exception of interventions that fell into the "inpatient clinical" category. This outcome is important because demonstrating the frequency of pharmacist interventions that require authorization from the medical team may guide future expansion of the pharmacists' scope where appropriate.

Overall, the pharmacists' compliance with the template was above 90%. Therefore, this may be an appropriate measurement tool for common pharmacist interventions. Compliance was lower when used for the "medication reconciliation" and "tube feeding" categories. This may be due to confusion about the appropriate times to use the PhARMD template (e.g., whether the template should be used when no medication changes are recommended). Further education regarding appropriate use of the template would likely increase compliance in these categories.

Overall, the pharmacists were satisfied, confident, and willing to use the PhARMD template, which indicates that the template may be beneficial for continued use and tracking/trending of interventions.

Results of this study are similar to results demonstrated at other VA sites that are using the PhARMD template in either the inpatient or outpatient setting. Groppi et al evaluated the use of the PhARMD template at all VA sites where it was in use, in both the inpatient and outpatient settings.¹² Compliance with template use was similar in the Groppi et al study, which found 95% compliance.¹² Additionally, the most common actions taken by the pharmacists were medication monitoring, adjusting dose or frequency of medication; changing or discontinuing a medication; and initiating medication, respectively, which were also the four most common actions demonstrated in our study.¹² Groppi et al found a mean of 6 interventions per patient.¹² Our study was unable to look at patient-specific data but demonstrated a growing number of documented interventions with the

TABLE 5. Compliance with PhARMD Template Use in Phase II (3/5/19-5/4/19)

<i>Row Labels</i>	<i>% PhARMD Encounters</i>
Inpatient Clinical	100.00%
Anticoagulation	94.49%
Pharmacokinetics	94.49%
Tobacco Treatment	92.59%
Mental Health Education Group	92.11%
Medication Reconciliation	84.79%
Tube Feeding	67.74%
Average Compliance	94.74%

implementation of each phase.

Limitations:

One limitation of this study was that the use of the PhARMD template was entirely voluntary; therefore, the number of clinical interventions is likely underrepresented, as it is likely that not all interventions were logged with the PhARMD template. Clinical pharmacists were simply encouraged to use the template and multiple email and in-person reminders were delivered to remind pharmacists to use the template. A second limitation was that the template does not include all possible disease states or possible interventions, which, therefore, increases the subjectivity and variability of the template use. To combat this, a small group of pharmacists highly interested in template use participated in the Phase II pilot, and provided feedback on use and suggestions for standardization. Based on feedback from the pilot group, standard work documents were created and emailed to the entire inpatient pharmacy staff prior to full implementation of Phase II. Interventions during the Phase II pilot period were included with Phase I data, given that the timeline overlapped and that the included pharmacists were still actively involved in Phase I interventions. Therefore, the number of interventions during Phase I would have been slightly lower if no pilot group existed, and, thus there would have been a larger difference in the number of interventions between Phase I and Phase II. A final limitation includes the functionality of the PhARMD template for measuring activities that are within the pharmacists' scope of practice. The template may be

used for multiple interventions during a single encounter in the electronic medical record; however, the pharmacist only has the ability to indicate whether the interventions were within scope or were recommendations to the provider. Instruction by CPPO recommends logging all interventions as within scope, even if the interventions were a combination of scoped activities and recommendations to providers. Therefore, the number of scoped interventions versus the recommendations to providers was overstated.

Conclusion

Pharmacists impact patient care on a daily basis by independently intervening and making clinical recommendations that result in changes to patient care plans. Use of a tracking tool, such as the PhARMD template, allows clinical pharmacists to demonstrate the quantity and quality of touchpoints they have within the patient care teams, as well as the variety of disease states in which they are intervening. Overall, pharmacists at this site were satisfied with the template use and willing to track and trend their interventions.

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“

I take great pride in being a part of the COVID-19 vaccination efforts and am grateful that my career in pharmacy allows me to have an impact on the health of the individuals in my community!

- Alicia Johnson

Alicia is a fourth year Concordia Pharmacy student completing a rotation at the community-based COVID-19 vaccination clinic in Rock County.

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Impact of COVID-19 Pandemic on Overall Vaccination Rates and Ways to Improve Public Education

by Erika R. Buchel, B.S., 2022 PharmD Candidate, Magdelene A. Kissel, B.S., 2022 PharmD Candidate, Kayla I Pearsall, 2022 PharmD Candidate

The COVID-19 pandemic has brought to light many systemic healthcare issues; one of the most important is the decline in vaccination rates in Wisconsin. The Wisconsin Department of Health Services reported a staggering decrease in vaccination rates in all age groups compared to the 2015-2019 average data (Figure 1).¹ Maintaining high vaccination rates among children and adults is critical to keeping vaccine-preventable diseases, such as measles, hepatitis, and tetanus, at low prevalence rates. The global COVID-19 pandemic is quickly becoming a global immunization pandemic, as Blue Cross Blue Shield member survey data reported that 40% of parents said their children missed vaccinations due to the pandemic.² These national trends give some idea of what to expect at the state level if appropriate actions are not taken to combat the vaccination rate decline.

Several factors have provoked the decline in vaccination rates in Wisconsin since the pandemic began. One of these factors is the state's Safer At Home order, which went into effect on March 25, 2020.³ The order's prohibition of nonessential travel might have decreased the public's ability to acquire vaccinations they otherwise would have. The order forced healthcare facilities to implement new protocols to combat COVID-19, and to cancel elective appointments, which in turn eliminated or delayed routine vaccinations that patients otherwise would have obtained. Another major factor in the decline in vaccination rates is patients' need to weigh the importance of vaccinations against the coronavirus. Many individuals might have been more concerned with

Abstract

Since the beginning of the COVID-19 pandemic, overall vaccination rates in Wisconsin have drastically declined. High vaccination rates are essential for maintaining herd immunity for preventable diseases. The decline in vaccination rates might be partially attributed to the state's "Safer At Home" order, which required people to stay home except for essential functions. This order, and new discussions about the COVID-19 vaccine itself, might have changed some public perception of vaccinations. Common misconceptions about vaccinations in general are also a reason for declining rates. Some people believe that vaccinations cause autism, or that the ingredients of vaccinations are harmful to people. Some people also have religious, ethical, or political beliefs that might prevent them from obtaining vaccinations. Due to decreasing vaccinations rates, it is essential that healthcare professionals take the initiative to improve these rates. This can be done via education, both professionally in the healthcare facilities where they work, and personally in the communities where they live. Motivational interviewing and social media are also essential tools for raising awareness of the importance of vaccinations. In order to accomplish these goals, it is essential that pharmacists and all healthcare professionals work together to increase vaccination rates to promote building a healthier future for all, as outlined by Healthy People 2030 goals.

staying home to avoid getting COVID-19 than going out to obtain their routine vaccinations.³ As more people avoid going out in public unless deemed necessary, and more office visits are virtual, getting routine vaccinations has become less convenient for the public.

While COVID-19 has continued to prevail as the year has progressed, the public fear of contracting the virus has contributed to the overall decline in vaccination rates when compared to rates before the pandemic. Pharmacists must take initiative to help maintain vaccination rates by addressing patients'

fears and barriers to obtaining routine vaccinations. Pharmacists and pharmacies are well-positioned to assist in helping to close the vaccination gap as patients continue to visit pharmacies to pick up essential medications. The objective of this article is to educate pharmacists regarding the decline in overall immunization rates since the COVID-19 pandemic began, discuss the misconceptions surrounding vaccinations, and discuss ways pharmacists can increase education surrounding vaccinations.

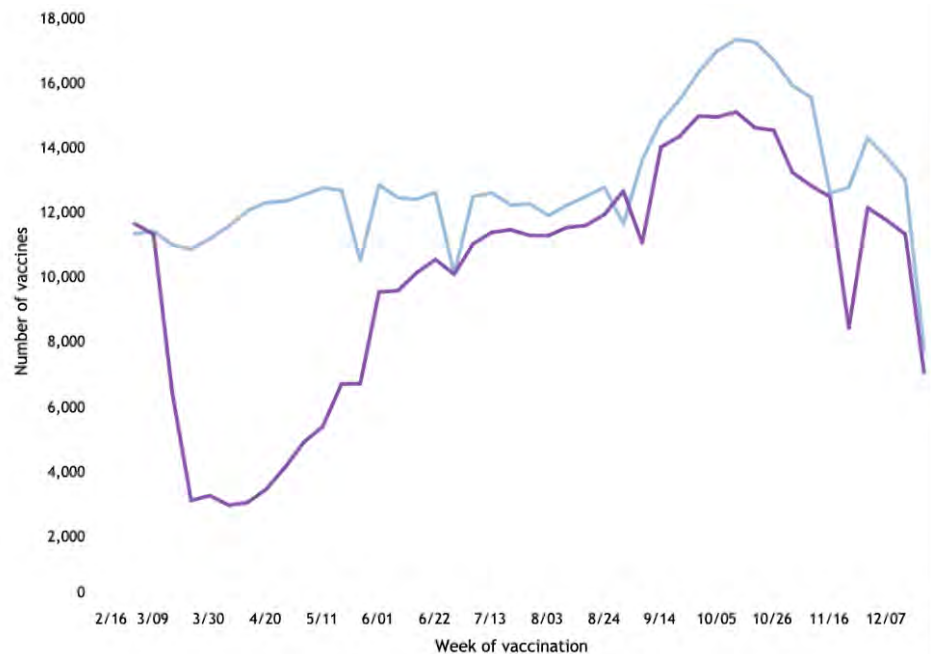
Vaccine Misconceptions

Prior to the COVID-19 pandemic, vaccination rates were already declining due to the increasing hesitancy around vaccines. A major cause of vaccine hesitancy is the many misconceptions regarding them.⁴ It is easy to find false information, as there are web pages and social media groups dedicated to spreading misconceptions or unproven beliefs about vaccinations. Some misconceptions have existed since the beginning of vaccination use and might be related to people's religious or ethical beliefs, fear of adverse side effects, the contents of vaccines, and even distrust of the government.

While many religious groups either encourage or do not have strict rules regarding childhood vaccinations, some strongly influence their members on whether or not to vaccinate. The Church of Christ, Scientist is a faith-healing group that believes that prayer will heal their ailments rather than medicine, and therefore strongly opposes vaccinations. The Roman Catholic Church, however, does recognize the importance of vaccinations and their impact on protecting the public against preventable diseases.⁵ However, there have been some religious groups that have started to protest vaccines because of the long-held belief that vaccines are made from aborted human fetuses. Three vaccines did use cell lines that were derived from fetal tissue: the MMR-II, Varivax® (varicella), and Havrix® (hepatitis A). The tissue was harvested from fetuses that were electively aborted during the 1960s, and while their efficacy since then has been evident, some people focus on the fact that they were derived from aborted fetuses.⁶

Another common misconception regarding vaccinations is that they cause autism. This belief is related to the rising number of autism diagnoses, which most commonly occur when a child is between the ages of 15 months and 18 months old.⁷ This timeframe coincides with childhood vaccination schedules, so many individuals have begun to associate the rise in autism diagnoses with receiving childhood vaccinations. The accusations grew astronomically after a well-known article was published in *The Lancet* in 1998 that made the statement that the

FIGURE 1. Routinely Administered Vaccinations in Persons Aged 19 years and older in 2020 versus the 2015-2019 average.



Courtesy of Wisconsin Department of Health Services.

Measles-Mumps-Rubella (MMR) vaccine caused autism.⁸ This fueled the perception of the link between autism and childhood vaccinations for many years, until the article was retracted because the author failed to disclose the source of funding for his research and shared false data. This myth has been disproved, but a lot of the people involved in the anti-vaccination movement still associate autism with vaccines.

Another common misconception about vaccinations is that their ingredients are harmful. One of the ingredients that concerns the public is thimerosal. Thimerosal is a mercury-containing compound that is often used as a preservative in vaccines to prevent the growth of bacteria. There is no scientific evidence against the use of thimerosal in vaccines due to exposure to thimerosal or adverse effects caused by exposure to thimerosal.⁷ Regardless of the lack of evidence of the dangers of using thimerosal as a vaccine preservative, it has been recommended by the Food and Drug Administration (FDA) that thimerosal should not be used as a preservative in any of the childhood vaccines.⁹ The FDA still suggests getting the annual influenza vaccine, even if it contains thimerosal, because the benefits of getting the annual

influenza vaccine will generally outweigh the risk of getting it.⁹

Many individuals in the anti-vaccination movement also believe the government mandating vaccines, especially for children, is reason enough to oppose them.¹⁰ The Centers for Disease Control and Prevention (CDC) spends a lot of time, money, and resources promoting childhood vaccination schedules and the annual influenza vaccine. Some believe the government infringes on their rights by mandating vaccination schedules; many public schools also require vaccines for their students.¹⁰ Others believe the government connection with "Big Pharma" encourages vaccinations and is another reason to distrust government recommendations. Overall, people who lack trust in the government are less likely to vaccinate themselves and their children.¹⁰

Strategies to Overcome Vaccine Hesitancy

Vaccination rates have decreased due to misconceptions and the mandated Safer at Home order; therefore, it is important for pharmacists to use effective methods when educating patients. A few examples of ways to implement education are motivational interviewing and social media. Table 1

TABLE 1. Additional Resources for Overcoming Vaccination Hesitancy

<i>Organization</i>	<i>Summary of information</i>	<i>Link for more information</i>
CDC: Make Shots Less Stressful	Information for pharmacists to provide to patients to make vaccinations less scary for children.	https://www.cdc.gov/vaccines/parents/visit/less-stressful.html
Questionnaire for Healthcare Provider Use	Resource that pharmacists might use to help determine which vaccines are appropriate for patients.	https://www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf
Vaccine Finder	Resource pharmacists might give to their patients to inform patients about the vaccinations they need and where they can go to obtain them.	https://vaccinefinder.org/find-vaccine
Tips for Motivational Interviewing	Comparing traditional and motivational interviewing tips.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7145430/table/t3/
Vaccine Communication Tips	Suggested words and phrasing pharmacists might use to improve vaccine acceptance among patients.	https://debeaumont.org/covid-vaccine-poll/

provides a summary of helpful resources for educating yourself and your patients regarding vaccination.

Education

Educating patients about vaccinations is crucial, because patients should be well educated about a topic before making a decision. Pharmacists are essential when it comes to educating the public about vaccinations, because people interact with pharmacists more frequently than with other healthcare providers. Most patients see their doctor several times a year at most; however, many people have frequent access to a pharmacy, whether it be a privately owned pharmacy in their hometown, or a retail pharmacy located in a grocery store. One study has shown that individuals with a higher education are more willing to participate in current vaccine recommendations, indicating that education is essential.¹¹ However, patients also have access to a wide variety of information via the internet and social media, which might lead to common misconceptions regarding vaccinations. It is essential to take these misconceptions into account, as data shows that 76%-88% of anti-vaccination websites have manipulated the public's emotions and 20%-50% of those have underestimated the risk and severity of vaccine-preventable diseases.^{12,13} When patients firmly believe these misconceptions, it becomes difficult for them to participate in preventative health measures.¹⁴ While pharmacists are essential in educating patients regarding vaccinations, community members who are parents might also advocate in their communities. They often already have

trustworthy relationships built with other parents and community members.¹⁵ These relationships within communities are of utmost importance during the pandemic, as there is a collective desire to return to normalcy.¹⁶

Not only is education important, but the way in which pharmacists communicate this information to their patients is also important. This is especially true for vaccinations. The language used with patients about vaccines can help patients make informed decisions about their health. A recent poll conducted by the de Beaumont Foundation (in partnership with the American Public Health Association, the National Collaborative for Health Equity, and Resolved to Save Lives) surveyed a diverse group of 1,400 registered voters on their preferred phrasing related to vaccinations.¹⁷ Based on its findings, the group published a tip sheet highlighting words and phrases that work best to educate the public and overcome vaccine hesitancy. For example, focusing the conversation on the benefits of vaccination rather than the consequences of not receiving a vaccine was preferred by survey respondents. Also, words that evoke personal safety and the health of the family performed better compared with phrasing that evokes benefits to the community or society at large. Finally, it is important that pharmacists have the proper tools to guide vaccine education. One helpful tool is SHARE, an acronym used by the CDC, which allows pharmacists to make strong recommendations regarding any vaccination.¹⁸ This approach sheds light on the importance of sharing (S) why the potential vaccine is appropriate for the

patient; highlighting (H) positive personal stories relating to this vaccine; addressing (A) any patient concerns that arise during the encounter; reminding (R) that the vaccine helps protect the patient or their loved ones; and explaining (E) the potential costs that can come with not getting vaccinated, such as the risks associated with the illness or time spent away from work due to the illness.¹⁸

Motivational Interviewing

Education is one piece that helps a patient in their decision about vaccinations; however, it is not the only thing that guides a decision. Therefore, another important tool pharmacists might use is motivational interviewing. Motivational interviewing uses patient beliefs to guide decisions and enhance motivation to make a change. The goal of motivational interviewing is to provide the patient with accurate information while relying on their own knowledge. It is essential to remain respectful and keep in mind the patient's personal beliefs while interviewing them. It is essential that pharmacists actively listen to patient concerns while adapting the conversation to attend to any negative emotions of fear and anxiety, while also working to activate positive emotions regarding vaccinations, such as good for the community and themselves.¹⁴ When motivational interviewing is successful, it can lead to partnerships, acceptance, evocation, and altruism for the whole community.¹⁹

Social Media

Finally, social media can be a great way to overcome vaccine hesitancy because it

can reach the greatest number of people and is the method of choice since the emergence of COVID-19. There are several ways pharmacists might use social media to educate the public about the importance of vaccines; however, it is essential to know what patients rely on regarding information obtained from social media. One study found that it is more important to focus on personal stories from individuals rather than using compelling data from thousands of individuals, due to the stories' ability to trigger emotional connections.¹⁹ This particular study looked at men who have sex with men (MSM) because they tend to rely on social media and mobile apps to obtain health information and seek sexual partners. The study concluded that the applications they were using might be important in HPV vaccine promotion, demonstrating how applications can influence patient perceptions.²⁰ Not only are applications persuasive in this case, but some individuals might feel less embarrassed or more independent if they can refer to an app rather than a healthcare provider for information.

Conclusion

Vaccination rates have drastically decreased during the pandemic; therefore, it is important that, as pharmacists who are a part of an interprofessional team, we work together to increase these vaccination rates. In order to do this, it is crucial that pharmacists understand common misconceptions regarding vaccinations and consider patients' personal beliefs. Once we understand the patients' concerns, we might use our knowledge regarding vaccinations and immunity to educate the public and trend the vaccination rates back upward as they once were.

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MEDICAL COLLEGE OF WISCONSIN SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Tebipenem Pivoxil Hydrobromide: Review of a New Oral Carbapenem in Development

by Jose Roig, 2022 PharmD Candidate, Justin Sorenson, 2022 PharmD Candidate, Melissa Staffin, 2022 PharmD Candidate, Alyssa Amrhein, 2022 PharmD Candidate, Kristen Bunnell, PharmD, BCCCP, BCIDP

Since the 1985 approval of the first carbapenem antibiotic, imipenem, carbapenems have played an important role in the treatment of serious bacterial infections. Compared to other β -lactam antibiotics, carbapenems have the most broad-spectrum *in vitro* activity against gram-negative bacteria, including those that express extended-spectrum β -lactamases (ESBLs).¹ Guidelines from the Infectious Diseases Society of America for gram-negative bacterial infections published in 2020 considered carbapenems the preferred antibiotic class to treat infections caused by ESBL-producing bacteria outside of the urinary tract.² All of the currently approved carbapenems in the United States (U.S.) are available only in an intravenous dosage form. This can pose a challenge for patients who require treatment with a carbapenem in the outpatient setting, due to the need for a central intravenous line, coordination of outpatient infusion services, and limited stability of many carbapenems after reconstitution.³ An oral carbapenem would thus provide a welcome alternative for the treatment of outpatients with challenging infections.

Tebipenem pivoxil is an oral prodrug of tebipenem, representing the first orally bioavailable carbapenem. Tebipenem pivoxil was approved in Japan to treat bacterial infections in pediatric patients in 2009.⁴ Clinical trials and post-marketing surveillance studies demonstrated tebipenem's efficacy and safety for pediatric community-acquired pneumonia and upper respiratory tract and otolaryngologic infections.^{5,6} The efficacy and safety of tebipenem is currently being investigated in the U.S. in adult patients with complicated urinary tract infection (cUTI) and acute pyelonephritis (AP).^{7,8}

Carbapenem Market Analysis

There are no oral carbapenems currently marketed in the U.S. Faropenem, an oral penem antibiotic with structural similarities to carbapenems that is available in India and China, was rejected by the U.S. Food and Drug Administration (FDA) in 2006 due to inadequately designed clinical trials and lack of quality evidence.^{9,10} Another oral penem, sulopenem etzadroxil, was recently submitted to the FDA for review as a combination product with probenecid in December 2020.¹¹ The expected clinical indication is uncomplicated urinary tract infection (uUTI), based on the results of the SURE-1 trial, which demonstrated sulopenem superiority over ciprofloxacin for the treatment of adult women with uUTI caused by fluoroquinolone non-susceptible pathogens.¹² Tebipenem pivoxil hydrobromide (TBPM-PI-HBr) is also in the pipeline for approval in the U.S., having obtained the Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA.¹³ TBPM-PI-HBr is expected to be submitted for the indications of cUTI and AP in the second quarter of 2021.¹⁴

Medicinal Chemistry and Mechanism of Action

Like other marketed carbapenems, tebipenem has a carbapenem nucleus with the 1- β -methyl group in C1, rendering it stable against chemical degradation and hydrolysis by dehydropeptidase-I.¹⁵ However, tebipenem is unique in structure due to the bicyclic azetidine, thiazole side chain attached to the sulfur in C2 (Figure 1).^{16,17} Another unique feature is the addition of a pivaloyloxymethyl moiety to the carboxylic acid, turning this agent into an orally bioavailable prodrug referred

to as tebipenem pivoxil.¹⁸ The version of this drug in the FDA approval process is formulated as a hydrobromide salt.¹⁷

All β -lactam antibiotics, including carbapenems, exhibit bactericidal activity by binding to the penicillin-binding protein (PBP) in gram-positive and gram-negative bacteria.¹⁶ When the carbapenem binds to the PBP, it prevents the bacteria from forming the peptidoglycan strands' cross-linking, thus disrupting the integrity of the bacterial cell wall.¹ The peptidoglycan layer in gram-positive bacteria is the outermost layer; therefore, carbapenems have direct access to the PBP. In gram-negative bacteria, the peptidoglycan layer is surrounded by an outer membrane composed of lipopolysaccharides, proteins, and phospholipids. Hydrophilic antibiotics need the help of integral membrane proteins known as porins to cross the outer membrane to reach the periplasmic space where the peptidoglycan layer is located.¹⁹

In Vitro Characterization

Tebipenem has shown broad-spectrum activity against gram-negative and gram-positive bacteria, as expected from this class of β -lactam antibiotics.²⁰ In surveillance studies, tebipenem had potent activity against a range of *Enterobacterales* species, with a 90% minimum inhibitory concentration (MIC₉₀) value $\leq 1 \mu\text{g/mL}$. In general, tebipenem's activity against uropathogens in the *Enterobacterales* family was similar to meropenem and ertapenem, and several-fold more potent than imipenem.²⁰ The presence of an identified ESBL or AmpC enzyme did not significantly affect the *in vitro* activity of tebipenem against *E. coli*, *K. pneumoniae*, or *P. mirabilis*.^{20,21} Tebipenem was less active against non-fermenting gram-negatives including *Acinetobacter*

baumannii, *Stenotrophomonas maltophilia*, and *Pseudomonas aeruginosa*, with an overall spectrum that is similar to ertapenem, which has poor/no activity against these organisms.²²⁻²⁴

Tebipenem has *in vitro* activity against methicillin-susceptible *Staphylococcus aureus* (MSSA), but not against methicillin-resistant *Staphylococcus aureus* (MRSA).^{23,25} Tebipenem exhibited MIC₉₀ >1 µg/mL for *Enterococcus faecalis* and *Enterococcus faecium*.^{23,25,26} It should be noted that susceptibility breakpoints for tebipenem have yet to be established. Table 1 summarizes the *in vitro* activity of tebipenem in surveillance studies.

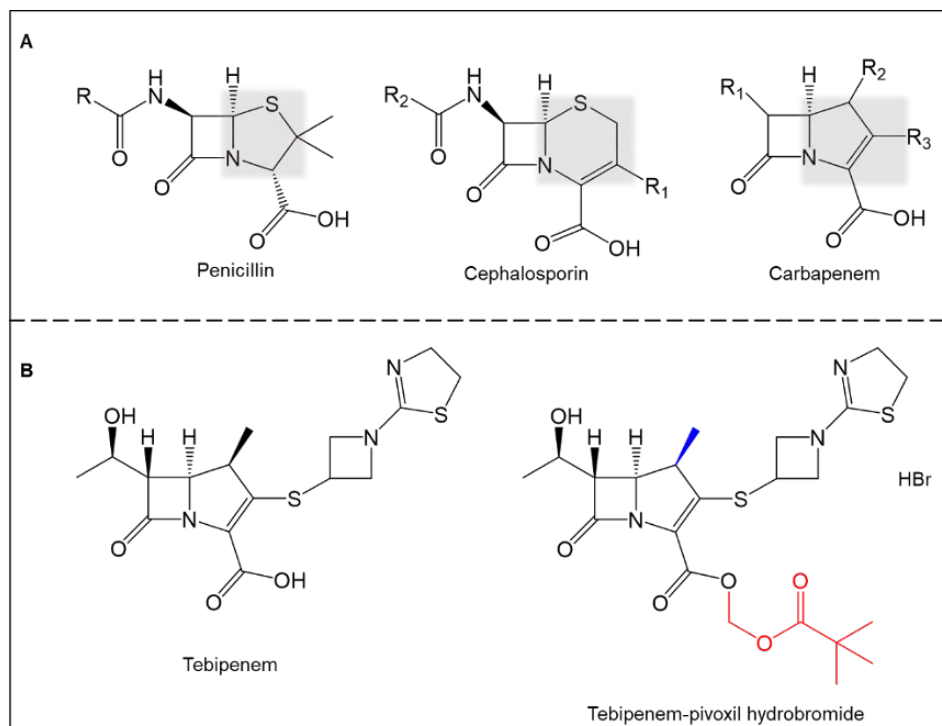
Pharmacokinetics

In contrast to its Japanese counterpart, the formulation of tebipenem being investigated in the U.S. is formulated as a hydrobromide salt to improve its stability.^{21,28} Differences in pharmacokinetic parameters between this formulation and the Japanese formulation have not been directly assessed at this time.^{21,28} The pharmacokinetics of TBPM-PI-HBr have been studied in healthy subjects in both single- and multiple-dose ascending doses in fed and fasting states. Both immediate-release (IR) and extended-release (ER) formulations of TBPM-PI-HBr were evaluated.²⁸ Because ER formulations of TBPM-PI-HBr did not result in predictable and sustained plasma concentrations, IR formulations were chosen for the multiple-dose phase of the study and subsequent phase III studies. The data that follow refer specifically to 300 mg or 600 mg IR TBPM-PI-HBr.

Absorption

TBPM-PI-HBr has demonstrated linear increases in plasma exposure following administration in the fasted state across all formulations.²⁸ Median time to maximum concentration (T_{max}) in serum has been shown to range from 0.5 to 1.3 hours, indicating rapid absorption following oral administration.²¹ Administration of TBPM-PI-HBr following a high-fat meal decreased the maximum concentration, but not the area under the concentration-time curve (AUC_{last}), for a 300 mg IR dose. A high-fat meal did not appear to impact the pharmacokinetics of a 600 mg IR

FIGURE 1. (A) General chemical structures of penicillins, cephalosporins, and carbapenems. (B) *left* – chemical structure of tebipenem (parent drug); *right* – chemical structure of tebipenem pivoxil hydrobromide (pivoxil moiety in red) (methyl group in C1 that prevents degradation by dehydropeptidase-I in blue).



dose.^{28,29} This suggests that standard dosing of TBPM-PI-HBr can be administered without regard to food.

Distribution

The mean volume of distribution of tebipenem at steady-state was 36.5 L for the 300 mg dosing regimen and 31.8 L for the 600 mg regimen.²⁸ Studies are underway to characterize the distribution of tebipenem in the respiratory tract.³⁰

Metabolism and Excretion

Tebipenem is likely excreted mostly in the urine as unchanged drug following either fed or fasted administration.²⁸ It has a short half-life in patients with normal renal function, ranging from 0.72 to 0.83 hours in multiple-dose studies. No significant accumulation has been shown to occur following the administration of multiple doses in healthy subjects.²⁸ Studies to characterize the renal clearance of TBPM-PI-HBr in subjects with varying degrees of renal function have been completed but not yet published. The renal route of excretion suggests a potential need for dose modification in individuals with

compromised renal function.^{28,29}

Pharmacodynamics

In a neutropenic murine thigh infection model, tebipenem demonstrated time-dependent pharmacodynamics (PD), consistent with the other members of the carbapenem class.²⁹ These studies investigated the magnitude of drug exposure required for stasis with 11 strains of *Enterobacteriales* spp., and found that the PD target was best described by the ratio of the free drug area under the concentration-time curve ($fAUC_{0-24}$) to the MIC, corrected for the length of the dosing interval ($fAUC_{0-24}/MIC \cdot 1/\tau$). This parameter differs from other carbapenem agents, for which the optimal PD index is the amount of time that free concentrations exceed the MIC ($fT > MIC$). The median value for the achievement of stasis in the strains with an every 8 hour dosing interval was $fAUC_{0-24}/MIC \cdot 1/\tau = 23$, while a $fAUC_{0-24}/MIC \cdot 1/\tau$ greater than 35 was needed for bactericidal effects and suppression of resistance.²⁹

TABLE 1. Activity of Tebipenem Against Gram-negative and Gram-positive Pathogens from Surveillance Studies

Pathogen	MIC ₉₀ (µg/mL)	Reference
Gram-negative		
<i>Escherichia coli</i>	0.015-0.03	20, 21, 27
<i>Klebsiella pneumoniae</i>	0.03-0.06	20, 21, 27
<i>Proteus mirabilis</i>	0.125-0.25	20, 21, 27
<i>Enterobacter cloacae</i>	0.25-1	23, 27
<i>Enterobacter aerogenes</i>	≤0.125	23, 27
<i>Citrobacter freundii</i>	0.03-0.25	23, 27
<i>Acinetobacter baumannii</i>	64	23
<i>Stenotrophomonas maltophilia</i>	64	23
<i>Pseudomonas aeruginosa</i>	8-64	21, 23
<i>Clostridium difficile</i>	1-2	21, 24
<i>Bacteroides fragilis</i>	0.06	24
Gram-positive		
<i>Staphylococcus aureus</i> - MSSA	0.03-0.125	21, 23
<i>Staphylococcus aureus</i> - MRSA	16	21, 23, 26
<i>Enterococcus faecalis</i>	2-32	21, 23
<i>Enterococcus faecium</i>	128	23

MIC₉₀= minimum inhibitory concentration that encompasses 90% isolates in the sample
MSSA= methicillin-sensitive *Staphylococcus aureus*
MRSA= methicillin-resistant *Staphylococcus aureus*

Clinical Data

The phase III randomized clinical trial ADAPT-PO evaluated an all-oral regimen of TBPM-PI-HBr compared to intravenous ertapenem for the treatment of cUTI and AP, with a regimen duration of 7 to 10 days. ADAPT-PO was conducted at more than 100 sites in 15 countries, including the United States, and included 1,372 hospitalized patients.⁸ TBPM-PI-HBr was statistically non-inferior to ertapenem, achieving clinical cure in 93.1% of patients compared to 93.6% with ertapenem. Side effects were similar between the groups, with headaches and diarrhea being the most common in approximately 25% of the subjects in both groups. There were three reported cases of *Clostridium difficile* treatment-emergent adverse events, and they all occurred in the IV ertapenem group.⁸

Implications for Practice

The potential FDA approval of TBPM-PI-HBr marks a new milestone in the world of antimicrobial agents with the introduction of an oral carbapenem.

While this is expected to expand access to carbapenems in the outpatient setting, its introduction raises important antimicrobial stewardship concerns.

Inpatient antimicrobial stewardship programs routinely implement restriction processes for broad-spectrum antibiotics, including carbapenems. Studies have shown that carbapenem restrictions may decrease institutional rates of carbapenem-resistant *Pseudomonas aeruginosa* and non-pseudomonal gram-negative bacilli.³¹⁻³³ It is unlikely that a restriction process overseen by an antimicrobial stewardship team could exist for TBPM-PI-HBr, given the process for oral antibiotic prescribing in most health systems. Mechanisms to limit overutilization of TBPM-PI-HBr could include medication use criteria established by insurance companies or by manufacturer requirements that limit the settings in which TBPM-PI-HBr can be dispensed. Other recently approved oral antibiotics, such as lefamulin and omadacycline, have restricted dispensing to specialty pharmacies or hospital pharmacies. The need for and mechanisms

to restrict TBPM-PI-HBr prescribing have yet to be elucidated. A theoretical concern with unchecked use of TBPM-PI-HBr in the community is increased incidence of multidrug-resistant infections in individuals who have used this agent.

The current indication for which TBPM-PI-HBr seeks approval is the treatment of cUTI and AP in adults.²¹ It is unknown whether the manufacturer will seek to limit the approval to treatment of pathogens that are resistant to first-line therapies for cUTI. Regardless of the approved indication, the most prudent application of this agent is likely to be reserving it for treatment of patients who cannot receive other oral agents, such as sulfamethoxazole-trimethoprim, cephalosporins, or fluoroquinolones, due to resistance, allergies, or drug-drug and drug-disease contraindications.²¹

Conclusion

TBPM-PI-HBr is a novel, orally bioavailable carbapenem antibiotic. It has been studied in a phase III trial of AP and cUTI and will likely be submitted to the FDA to consider approval for these indications in 2021. Tebipenem may fill a niche role in treating resistant infections in the outpatient setting, with the potential for use in the treatment of challenging infections well beyond its initial FDA-approved indication. Availability of an oral carbapenem, however, will be accompanied by several antimicrobial stewardship concerns. Emerging data will likely better inform clinical decision-making about the role of tebipenem in U.S. practice settings.

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ROSALIND FRANKLIN UNIVERSITY OF MEDICINE AND SCIENCE SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Business Member Spotlight: Chet Johnson Drug

by Jessica Schwartzwald, 2024 PharmD Candidate, Myrrh Elan Cagas, 2023 PharmD Candidate

As the only full-service pharmacy in a 15-mile radius, “We are pretty busy all day long,” said Matthew Johnson, RPh, the owner of Chet Johnson Drug (CJD). Johnson’s grandfather first opened the store in Amery, Wisconsin in 1932, and it was passed down to Johnson’s father and uncle before Johnson began to carry on the family legacy. The pharmacy is staffed by Johnson and two other full-time pharmacists and four technicians. His sister, Sarah Flannum, is the general manager, who supervises about 25 additional employees. On a typical day, CJD is busy filling prescriptions all day long. As Johnson explains, “We have got a very strong and robust synchronization program with about 1600 patients.” The pharmacy operates at two locations: the main store in downtown Amery and another in partnership with the local medical center. At the downtown store, besides being a full line pharmacy, they also sell food, household goods, toys, and gifts, all while providing the community with a year-around ice cream and coffee shop. Being the sole provider of pharmacy services in the Amery community, CJD is often collaborating with physicians and other healthcare providers nearby to create the best experience for patients. Because the

Amery community is rural, CJD is one of the only places nearby for the residents to find prescription counseling; prescription pick-up and delivery; an array of over-the-counter medications; and more. This makes the work CJD does each day a vital part of the city of Amery.

Stepping It Up

Chet Johnson Drug stores are always striving to be the best they can be. Johnson stated, “In a world where everything is electronic and technology is ever changing, we have to adapt to the times ... we have, in the recent years, already remodeled twice.” Johnson acts for the betterment of his community, is willing to make changes when it benefits his patients. The independent pharmacy tries to be a one-stop place for all patients and goes even the extra mile. Johnson explained, “If the patients need their medication, even in the late hours of the night, then I will deliver.”

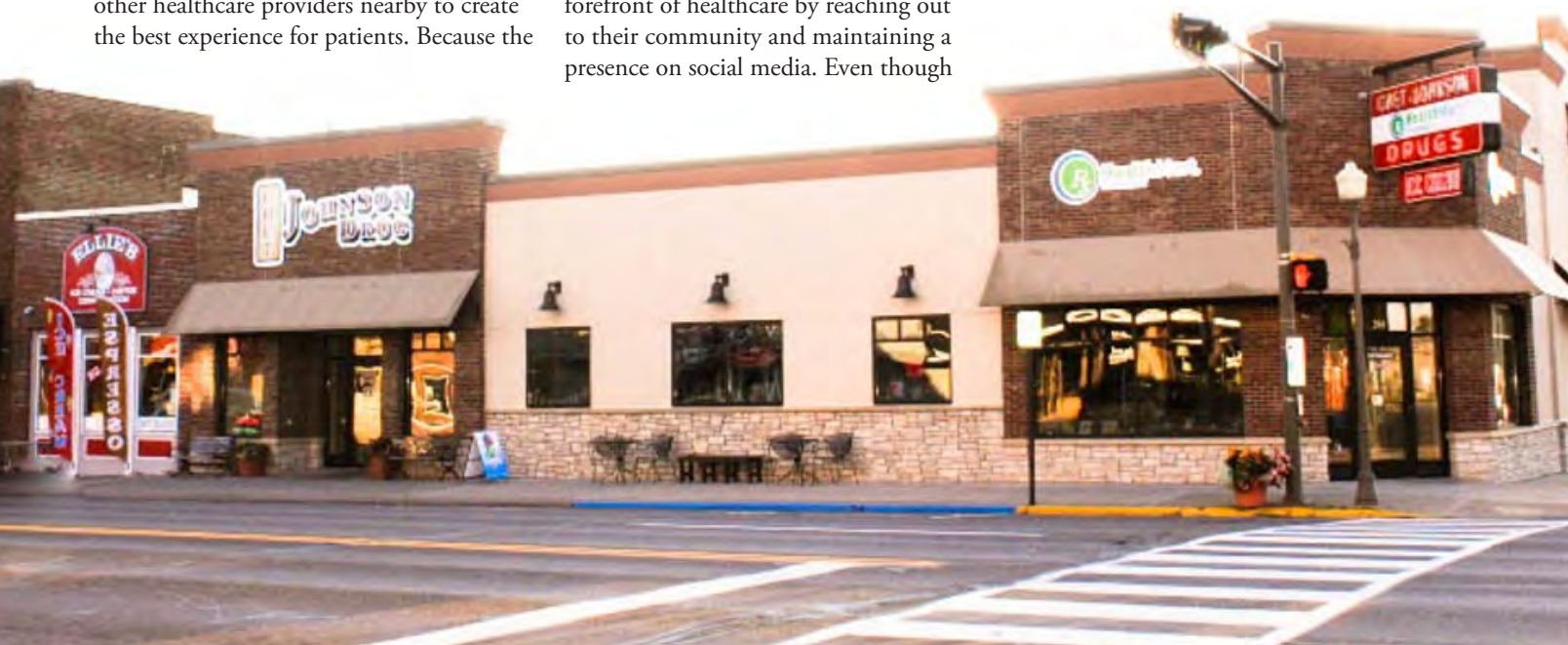
Chet Johnson Drug always tries to raise the bar in healthcare. One of the unique services that this independent pharmacy offers is custom-fit shoes for extra protection for the diabetic patient population, many of whom have decreased feeling in their feet.

No matter what, they remain at the forefront of healthcare by reaching out to their community and maintaining a presence on social media. Even though

resources can be limited, especially under the circumstances of COVID-19, CJD wants to set an example as a top-notch pharmacy, not only for their city but for the rest of the country.

COVID-19 Complications

As the pandemic began, “it was hard, things were changing by the minute, and the uncertainty of how we were going to take care of patients, ourselves, and the drug supply went on for quite a while,” Johnson stated. While things have calmed down as of this writing, and the residents of Amery have adjusted to this new normal, it is still a challenge for CJD to stay on top of things while following Wisconsin’s latest protocols. When asked about how his community is adjusting, Johnson said, “Most of our patients and customers do a really good job with wearing a mask and physical distancing.” As one of the few businesses in the city that remained open during Wisconsin’s stay-at-home order, CJD worked tirelessly to provide the same care their patients were used to in a safe and ethical manner. Surprisingly, pharmacy benefits manager (PBM) issues were not halted by the pandemic for CJD. According to Johnson, “between egregious PBM behaviors and forced audits based on



small clerical errors, we have been through a lot these past few months.” As they have gotten a better grasp on the pandemic, CJD has been able to devote more time to combating these PBM challenges, while still providing the Amery community with a thorough pharmacy experience. Johnson is a member of a pharmacy owners group, with owners from across the country. This board of directors meets quarterly for two days to discuss the individual business operations of each pharmacy, and to help each other with challenges. Johnson described it as “an invaluable time to get the knowledge and insight from other owners from different regions of the country and try to give and get advice on a wide array of issues.”

Additional Challenges

At a time when COVID-19 still circulates, other challenges tend to get deprioritized. Johnson stated, “One of our top priorities now is to keep everyone healthy and safe in this pandemic. As for one challenge that remains true in the world of pharmacy, is for us to get the provider status.” Pharmacies today are finding it difficult to receive adequate reimbursement for the services that pharmacists are able to provide. At CJD, pharmacists provide medication synchronization, point of care testing, blood pressure screening, and genetic testing, among other services; in rural Wisconsin, these services prove to be vital, as other accessibility to health screenings can be limited, including in the city of Amery.

One approach to advocating for provider status is coming from pharmacy colleges. Colleges of pharmacy are adjusting their curricula to provide their students with more clinical knowledge. As a result, there has been a surge in residency opportunities available to recent graduates, compared to years past. Pharmacists are now expanding their role with medication therapy management and becoming more integral team members in healthcare. Johnson wants pharmacists to remain clinically driven and hopes in the near future that pharmacists get provider status.



Above: Chet Johnson Drug Pharmacists, Matthew Wlodyga (left), Matthew Johnson (center), and Nicole Sheldon (right).
Bottom Left: Outside Chet Jonson Drug in Amery, WI.

Looking Ahead

With the potential for new pandemic protocols looming ahead, CJD remains optimistic and continues to work toward growth for both their business and their community. Johnson explained, “We are heavily involved in the Community Pharmacy Enhanced Services Network (CPESN) initiative, where we are hoping for opportunities to learn more and help patients in disease state management, as well as finding ways to profit from our services while still prioritizing the well-being of the patient.” In addition to CPESN, the pharmacy promotes influenza vaccines and other vaccines to every patient they encounter, and provides health insurance counseling when the time comes for Medicare open enrollment each year. Looking ahead in the world of pharmacy, Johnson shared his recommendations for future pharmacists: “Always take the initiative to learn, get as much experience as you can, [and] be the role model in your pharmacy when providing care to patients.” Working in and being around the pharmacy his entire life, Johnson knows the

profession well. As a business owner and a pharmacist himself, Johnson’s goal for his own pharmacy is for “Chet Johnson Drug to work to be ahead of the game, providing top-notch service to our community for years to come.”

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MEDICAL COLLEGE OF WISCONSIN SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Business Member Spotlight: Bread of Healing Clinic

by Sanaya R. Bhathena, 2021 PharmD Candidate, Dani M. Schuyler, 2022 PharmD Candidate

The Bread of Healing Clinic laid its foundation 20 years ago when a parish nurse and a medical resident developed a clinic to serve the uninsured population of Milwaukee. Many patients at their previous workplace, Mt. Sinai, had chronic medical conditions that were undiagnosed and therefore untreated. The Bread of Healing Clinic is now a medical “home” to the many uninsured people of Milwaukee County. Their goal is to provide high-quality primary, specialty, and tertiary care to patients with chronic conditions who are challenged due to socioeconomic constraints. Through their interdisciplinary practice care model, which includes social workers, nurses, dentists, pharmacists, physicians, nutritionists, and many other healthcare professionals, they aim to practice patient-centered care through institutional incorporations.

The Bread of Healing Clinic is entirely volunteer based. All healthcare providers at the clinic are volunteers who enjoy sharing their skills and time. Generally, in the current COVID-19 era, a new patient is seen via a telehealth visit. Telehealth calls usually run between 45 minutes and an hour, but the length is unlimited to ensure that patients get the thorough workup and care they need without feeling rushed. After the initial telehealth visit, a patient is typically scheduled for an in-person appointment at the clinic a few days later.

Besides having access to a doctor and pharmacist, patients also have access to social workers. The only requirement for receiving care at the clinic is a lack of insurance. Most patients are usually in a transient situation with insurance coverage, or are on BadgerCare. Social workers meet with each patient to discuss how they can best overcome barriers to care. After the first appointment, there are follow-up visits 28 days later to see whether the chronic

conditions are managed or need additional assistance.

For the Bread of Healing team, every morning includes a huddle during which they can review and discuss each patient chart. In fact, the process of profile review starts even before the patient steps into the clinic, approximately a week in advance. Each appointment has a sticky note associated with it, which summarizes how the clinic can help personalize care and what providers should focus on.

If needed, medications can be prescribed at the end of the patient’s appointment. The pharmacist helps with patient care by walking patients through all their medications and providing medication counseling. Pharmacists work closely with other providers to discuss medications.

Everyone at the clinic is on a first-name basis, and the floorplan of the space invites collaboration and openness, with a goal of encouraging conversation and brainstorming.

Raising the Bar

The Bread of Healing Clinic isn’t strictly a pharmacy; it is a clinic where pharmacists practice as a part of an interprofessional healthcare unit. The practice setting is akin to a dispensary. Physicians delegate medication-related decisions and tasks to the pharmacy, thereby broadening and expanding the role and responsibilities of the pharmacists. With the established collaborative practice agreement under medical regulatory guidance, pharmacists may add or change medication doses, perform therapeutic substitutions, make medication initiation suggestions, and many other medication-related tasks.

Though there is no specific training provided to pharmacy volunteers, morning huddles are organized to help

them familiarize themselves with the patient details. Pharmacists are proactive throughout patient appointments. Pharmacists interpret labs alongside physicians and offer their health management solutions. The open communication helps engage volunteering student pharmacists to contribute their perspectives as well.

The Bread of Healing Clinic believes that touching base with each patient is essential. Therefore, they are committed to following up with patients every 30 days; this is the biggest factor in making the practice successful. This follow-up helps increase medication adherence. To maintain the high compliance in the community, the clinic arranges for a pill box or tablet splitters to be given, as the provision of these supplies help with patient adherence.

Bumps in the Road

As with most organizations, the Bread of Healing Clinic has encountered its share of challenges. A recurring challenge this clinic sees is patients cycling in and out of the Medicaid system. It is common for a patient to attend the clinic while they are uninsured for six months, and then become ineligible for six months while they have insurance. While this creates difficulties with care continuity, as patients might go somewhere different for care, it is essential that the clinic remains within its capacity limits and creates space for other patients who are eligible to receive care.

Another challenge the Bread of Healing Clinic faces is finding ways for patients to appropriately take medications within economic limitations. For example, there is a portion of the patient population who, on average, eat one meal per day. This might affect medication efficacy when a given medication needs to be taken consistently with a meal. A patient might be prescribed

insulin with a regimen that requires three doses per day, but the patient eats only one meal (or no meals) a day. The clinic approaches these challenges by working to understand each patient's situation, creating individualized medication therapy plans, and referring patients to additional local agencies to help with meeting these needs.

In addition to year-round challenges, adapting to COVID-19 presented unique difficulties. The Bread of Healing Clinic adjusted workflows, through the implementation of telehealth, to minimize in-person contact. For a nonprofit organization, telehealth was a large capital expense that required additional funding through a six-month grant. The employee demand increased more than 15 hours per week with the implementation of telehealth, and it is estimated to require three times as much work as having patients on site. Although telehealth has increased employee demand at the clinic, it proved to be a quick and successful solution to navigating the difficulties that COVID-19 presented.

Moving Forward

In the future, the Bread of Healing Clinic plans to grow by providing its patients with influenza and pneumonia vaccinations. The implementation of these vaccination services will bring additional workload, so the clinic will see a need to reorganize workflows. The clinic intends to

use vaccine-certified student pharmacists for administration and integrating the required 15-minute post-vaccination wait time into their workflow. The clinic plans on offering immunizations to patients upon entry into the clinic, prior to other services provided, to enhance efficiency. The implementation of these immunization services, as well as the recent implementation of telehealth, will require additional funding from sponsoring donors.

Prospective patients can find the Bread of Healing Clinic by dialing 211 on a telephone and asking for a list of free clinics. The Bread of Healing Clinic is near the top of the list, and they are open five days per week among three locations. Additionally, the Bread of Healing Clinic is a resource for hospital emergency departments. Local emergency departments have access to patient scheduling and can set up appointments for patients directly through the Bread of Healing Clinic's scheduling system.

The Bread of Healing Clinic is a neighborhood-based clinic for individuals with financial or other barriers to quality health care. We commit ourselves to respect, love, and learn from the people we serve believing that the atmosphere we create reflects Jesus' healing ministry.

To keep its doors open for uninsured patients, the Bread of Healing Clinic relies heavily on its volunteer staff and funding from donors to remain sustainable. The clinic's interdisciplinary set-up and practice, along with patient follow-ups every 30 days, continues to improve patient care and medication adherence/efficacy. While the Bread of Healing Clinic has its share of obstacles, the clinic continually works to overcome these challenges by maintaining its goal of providing high-quality, patient-centered care.

Sanaya Bhatena and Dani Schuyler are 3rd Year Doctor of Pharmacy Candidates at the Medical College of Wisconsin School of Pharmacy in Milwaukee, WI.

Disclosure: The author(s) declare no real or potential conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.



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*A final decision regarding in-person attendance will be made by mid-June. Check the PSW Annual Meeting webpage for more information.

2021 Month of Advocacy Recap

by Jillian Allen, 2022 PharmD Candidate

In a year unlike any in our lifetime, extending PSW's annual Legislative Day to a month-long virtual conference was only fitting. Advocacy in pharmacy is especially important this year, because pharmacists are on the front line in the fight against COVID-19. Just as we adapted to the pandemic as community members, students, and professionals, we must also adapt to advocating for the pharmacy profession in a new format. It has been an incredibly productive year for pharmacists in Wisconsin, as we have made strides in vaccination efforts, in PBM reform, and as healthcare providers in our communities.

PSW's Month of Advocacy began with a Pharmacy Law Update for 2021. Over the past year, legislation advancing Wisconsin pharmacy practice has made unparalleled strides. Among the highlights is the long-awaited revision of Phar 7, which included simplifying counseling requirements. Additionally, to help the fight against the pandemic, Acts 3 and 42 expanded immunization abilities to pharmacy students and pharmacy technicians across the state. Additionally, among many other accomplishments, the passing of Act 9 brings comprehensive pharmacy benefit manager reform into law. During another update, Pharmacy Examining Board (PEB) members John Weitekamp, Philip Trapskin, and Tiffany O'Hagan reviewed Phar 7 topics, COVID-19 legislative variances, changes to the NAPLEX exam by NABP,

and upcoming projects for the PEB.

In another session, Antonio Ciaccia, the cofounder of 46Brooklyn, presented on pharmacy benefit managers, how to increase drug cost transparency, and how PBMs affect competitive markets. He explained the difference between list prices and the prices patients, pharmacies, and suppliers actually pay for drugs and how this correlates to the viability of our healthcare system. He argued that we operate in a fundamentally broken system with an economic disincentive to spend time with patients. Wisconsin PBM reform is just a first step toward fixing the current system.

In federal legal matters, the Alliance for Pharmacy Compounding's legal counsel, David Pore, elaborated on the FDA's Compounding Memorandum of Understanding (MOU) and how it might affect pharmacies throughout Wisconsin. Although the deadline to sign the MOU is officially in October 2021, Pore was emphatic that the deadline should be extended and would be extended by current legal proceedings. The MOU puts state legislatures in a compromised position: they must either take on an unfunded administrative burden, or challenge pharmacies that rely on outsourcing their compounded products. In the end, it will be essential for pharmacists in Wisconsin to prepare for this upcoming change in federal policy.

In the state legislative panel, Senators

Patrick Testin and Jon Erpenbach, and Representative Lisa Subeck, elaborated on Wisconsin legislators' priorities. Priorities include expanding access to quality healthcare, improving and continuing an adequate COVID-19 response, expanding Medicaid, and improving access to mental healthcare. The legislators also discussed issues like legalizing marijuana and mask mandates. Concerning the COVID-19 response, legislators seek to enhance the vaccine rollout, increase flexibility for healthcare providers during the pandemic, and prepare for future public health crises in a less partisan manner.

Guest speakers Tom Dilworth, Luke Schulz, Janelle Heinrich, and Karen Timberlake delved into the logistics of Wisconsin's COVID-19 response. Wisconsin is the nation's leader in vaccination rate when taking into account vaccine supply received, which is a tremendous feat. Public health administrators now seek to create predictability for vaccinators with consistent supply, to equalize information flow to citizens, and ensure equity in vaccination through trusted local messengers. Although we are top in the country, seeking an 80% community immunization rate will be a challenge in the coming months and will require pharmacists to lead the way. Guest speakers also discussed how politics influence science and our public health response methods. Most importantly, the COVID-19



response panel emphasized preparing for the next pandemic, and increasing public health awareness and preparedness, while balancing COVID-19 concerns with other relevant public healthcare concerns.

Overall, PSW has been essential to incorporating pharmacies in the vaccination efforts across Wisconsin. Governor Tony Evers shared his thanks to the pharmacy profession for playing such a critical role in the COVID-19 defense, recognizing the pharmacist's role in testing and vaccinating citizens for COVID-19. Throughout PSW's Month of Advocacy, moderators asked us to reflect upon the past year through the lens of pharmacy. Though we are apart, our shared interest in pharmacy advocacy brings us together. Our voice is stronger as a community. As we face tough challenges ahead, our leadership in the community is a key to advancing our profession and closing the door on the COVID-19 pandemic.

The PSW Good Government Awards are normally announced annually on Legislative Day for pharmacists and students who partake in significant grassroots advocacy, and display growing advocacy skills. Although we could not recognize the recipients of these awards in person, we congratulate the 2021 PSW Good Government Award recipient, Michelle Farrell, owner of Boscobel Pharmacy and Center Pharmacy; and the 2021 PSW Student Good Government Award recipients Antonio Pusateri, Jillian Allen, and Daniel Funk at Concordia, MCW, and UW-Madison, respectively. Finally, if you were unable to attend the PSW Month of Advocacy sessions, they are available to view as recordings via the [PSW webpage](#).

Jillian Allen is a 3rd Year Doctor of Pharmacy Candidate at the Medical College of Wisconsin School of Pharmacy in Milwaukee, WI.



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