The Kentucky PHARMACIST

Fall 2022

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Russellville native and owner of Riley-White Drugs, **Donnie Riley,** is the 2022 ***Bowl of Hygeia*** **Award Winner**

THE EDUCATION ISSUE

6 Hours of CE Inside

Mission Statement:

To advocate and advance the pharmacy profession to improve the health of Kentuckians

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Medicaid Medication Risk Reduction Program

We help state Medicaid agencies improve health-related outcomes and reduce total cost of care.

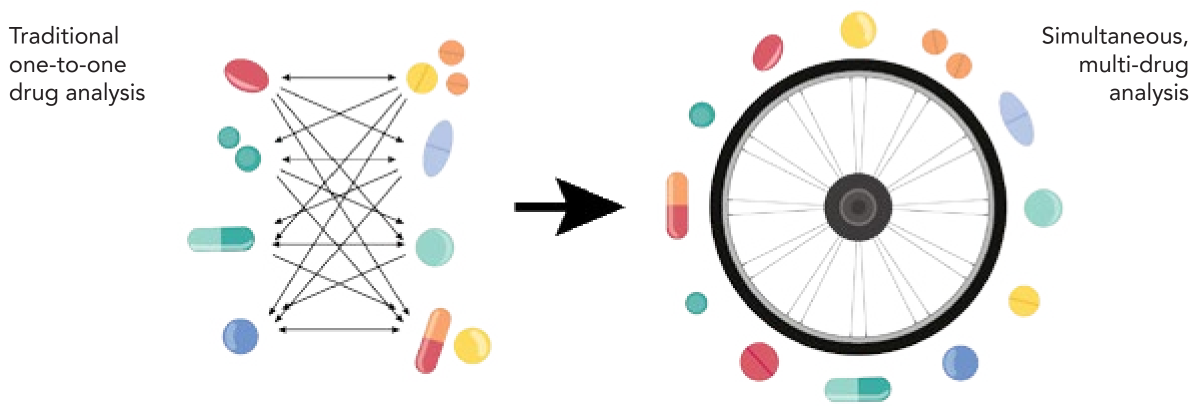
Problem:

Adverse drug events are the fourth leading cause of death in the U.S.[1, 2,3] The number of older adults taking five or more drugs tripled from 1994 to 2014. If the trend continues, medication overload could cause at least 4.6 million hospitalizations between 2020 and 2030, costing families a staggering $62 billion[4].
The annual cost of medication-related morbidity and mortality caused by non-optimized medication therapy costs the U.S. healthcare system more than $528 billion, that's 16 percent of expenditures in 2016[5].

Solution:

The MedWise HealthCare™ Medication Risk Reduction Program can help state Medicaid agencies by:

- Targeting the highest-risk populations, increasing efficiency
- Identifying medication-related risk through a simultaneous, multi-drug analysis, which enhances traditional risk stratification methods
- Reducing predictable and preventable adverse drug events
- Improving quality of care, health-related outcomes, and HEDIS® and CAHPS performance
- Lowering total cost of care



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Misty Stutz, PharmD
President
Kentucky Pharmacists Association

PRESIDENT'S PERSPECTIVE

Defining a Pharmacist

As I march forward through this year of presidency, the one thing that strikes me is the variability in what constitutes a pharmacist. In September, the KPhA staff and I roamed the state on our R.O.A.D. trip, visiting all types of practice settings. During that trip, I realized that each of us has a slightly different definition of what it is to be a pharmacist, and hence a different set of priorities. As we talked to the pharmacists at those sites and learned what they wanted from the organization, we heard many stories. We heard from those who struggled because of inadequate reimbursement of product, some lacked funding for positions, and no one was receiving payment for clinical services. We saw those who struggled with an overburdensome regulatory structure and, sadly, even those who lacked professional satisfaction. But we are all pharmacists, so shouldn't we share a common goal? Shouldn't we identify as a unified profession?

Identifying as a profession (professional identity) is a hot topic, especially in pharmacy education. While professionalism leads to ethical patient-centered care, professional identity is when a member of that profession thinks, feels, and acts like that professional. When you think about the professional identity of other occupations, you often think of the role that profession has had for decades. If I asked what a doctor does, you would say diagnose and treat illness. This identity has been consistent for thousands of years. But what about pharmacy? The American Association of Colleges of Pharmacy (AACP) has been intent on creating a professional identity in pharmacy in hopes of leading transformation to practice. But while other health professions have a long-standing identity in health care, the pharmacist's role has evolved from medicine maker to dispenser to patient-centered, clinical pharmacist. This leads to confusion not only from the public but even within our own profession.

So, how does our professional organization represent and prioritize the needs of its diverse set of members? Is there only one identity that we share? In a word, no. While those that may work in a subset of the profession have similar priorities, it doesn't take long for someone in another practice setting to share how those sets of priorities differ from their own. But we all have one goal, which is to protect and grow our profession. So, while PBM reform will be a legislative priority, so will enhancing our role in immunizations and payment for services from noncommercial payors. And we will continue to support the advancing roles of technicians through our work with the board of pharmacy and key items in workplace wellness and other regulatory issues. Our organization is as diverse as those we represent.

I don't know if we will ever settle on one professional identity in pharmacy, but I am confident your KPhA will continue to move pharmacy forward together.

Welcome to our NEW KPhA Members.

We are stronger together!

This list reflects all new members received from
August 10- November 8, 2022

All members reside in Kentucky unless noted

Lauren Belt, Lexington

Joseph Bickett, Louisville

Leslie Bidwell, Bowling Green

Jay Brainard, Somerset

Corey Brown, Louisville

Easton Bryant, Columbia

Christian Castro, Louisville

Randy Clark, Coxs Creek

Ernest Coscia, Middlesboro

Jessica Covington, Louisville

Viodalia Dalton, Lexington

Brittany Dean, Louisville

Michael Faulhaber, Edgewood

MacKenzie Firek, Lexington

Angela Gibson, Leitchfield

Yvette Greenwell, Maceo

Emily Hardrick, Dixon

Tori Hilkens, Nicholasville

Bailey Hoskins, Prestonsburg

Sam Howard, Paducah

Danny Hudspeth II, Lexington

Shonna Irvin, Thompkinville

Krista Kennedy, Simpsonville

Angela Kennedy, Simpsonville

Laura Martin, Langley

Callie Mills, Barborville

Kelli Myers, Georgetown

Candace Olusola, Lexington

Gerald Phillips, Louisville

John Price, Louisville

Amanda Prine, Louisville

Morgan Roberts, New Albany, IN

Josh Roper, Tompkinsville

Philip Roper, Glasgow

Brook Rucker, Glasgow

Philip Sandlin, Louisville

Kelsey Simpson, Hickman

Brooke Sorgi, Madison, WI

Natalie Stine, Simpsonville

Allison Swearingin, Louisville

Jace Swingle, Florence

Amanda Thurman, Crestwood

Jennifer Walston, Paducah

David Whitley, Russellville

Tina Yokley, Tompkinsville

My KPhA Rx

A Letter from Ben Mudd, PharmD, RPh
Executive Director Kentucky Pharmacists Association

Dear Colleague,

Happy fall to our KPhA members across the Commonwealth and beyond! It seems like this quarter has flown by; but boy, do we have a lot to catch up on. From the R.O.A.D. trip to the Fall Conferences and a few big wins along the way.

Members of the KPhA staff, including myself, joined KPhA President Misty Stutz on a KPhA R.O.A.D. trip throughout the state in August and September. From Pikeville to Owensboro, we enjoyed visiting with KPhA members along the way. It was great to interact with pharmacy teams across the Commonwealth and gain an even better appreciation for our profession's immense impact on the patients we serve. It is fascinating to witness how pharmacy practice can vary from location to location, even amongst stores with common ownership. Yet, we all practice with a core passion for helping people. People often ask if I miss working behind the counter. My response is a resounding "Yes!" I genuinely miss connecting with my patients and helping them live better lives, even when the odds seem stacked against them. Spending time with many of you reminded me of how invaluable we are to the healthcare system and further strengthened my desire to fight to protect and advance the pharmacy profession in Kentucky.

During our trek across the state, I had the pleasure of visiting the 2022 KPhA Bowl of Hygeia recipient, Mr. Donnie Riley, at his Riley-White Pharmacy in Russellville. This prestigious award is given annually to a Kentucky pharmacist who has demonstrated outstanding community service. Donnie's story is highlighted on page 46, but it was evident during our visit that Donnie was a servant to his community as I saw him interacting with his patients and staff. Congratulations to Donnie on his achievement!

In other news, KPhA released a statement in October highlighting a statewide opportunity for Kentucky pharmacists to join Anthem's provider network. The enrollment process has already begun, and pharmacists can begin billing as early as January 1, 2023. This means that Kentucky pharmacists can now seek reimbursement for most services provided to Anthem members within our scope of practice and otherwise covered if provided by a physician or midlevel provider. Because of your support through advocacy and membership, KPhA, along with others, emphasized pharmacists' pivotal role on the healthcare team and worked with Anthem to secure the contract. This is an excellent opportunity for our profession and an example of how your membership works for you. Seldom do we give credit to health plans, but I would be remiss if I didn't acknowledge the Anthem Kentucky team for their effort and dedication to this project over the past year. Although it took longer than initially expected, the Anthem provider enrollment team prioritized this and consistently included KPhA in the conversations.

The big news from Anthem came just in time for our Fall Conference and the Medical Billing Workshop led by Dr. Kyle Bryan. Thanks to everyone who joined us in Louisville for Friday's event at the Galt House! On Saturday, Dr. Bryan led an intensive hands-on training on care documentation and coding to assist in the implementation of medical billing for pharmacists' clinical services. The workshop received rave reviews from attendees and set the stage for a new revenue stream for pharmacists by increasing access to care for our patients.

We've also seen momentum in our fight against the abusive behaviors of PBMs. On September 29, the Interim Joint Committee on Health, Welfare, and Family Services allocated their monthly committee meeting to address PBM issues. The hearing lasted nearly two hours as numerous groups, including KPhA, educated legislators on the urgent issue and how PBMs are increasing medication costs and negatively impacting Kentuckians' health. House Bill 457, sponsored by pharmacist Rep Sheldon (R – Bowling Green) earlier this year, passed the Kentucky House of Representatives 88-3 but failed to receive a committee hearing in the Senate. However, after the hearing, committee co-chair Senator Ralph Alvarado (R -Winchester) made it clear that comprehensive PBM reform will continue to be a priority in the 2023 General Assembly. Our KPhA team is working hard to plan and prepare for a successful 2023 session with comprehensive PBM reform as our top priority, which the KPhA House of Delegates determined in October at the Fall Conference.

On behalf of the staff at KPhA and KPERF, I wish you a happy holiday season. I hope you cherish the time spent with your family and friends as we close out 2022. I always welcome the opportunity to connect with our members. Please reach out directly to bmudd@kphanet.org, and let's schedule a time to chat about your story and our KPhA. Until next time… keep being awesome, choose kindness, and stay involved. Together we can do anything.

Professionally Yours,

Unbreak my Heart: Heart Failure Guideline Updates 2022

Brittany DeJarnett, PharmD. Candidate; Christopher Betz, Pharm.D., BCPS, FKSHP, FASHP; Emily Frederick, PharmD., BCPS

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Unbreak my Heart: Heart Failure Guideline Updates 2022

Brittany DeJarnett, PharmD. Candidate; Christopher Betz, Pharm.D., BCPS, FKSHP, FASHP; Emily Frederick, PharmD., BCPS

Goal: Address the updates made in the 2022 guidelines for the treatment of heart failure.

Objectives:

- Summarize the major changes in the 2022 update to the ACC/AHA/HFSA Guideline for the Management of Heart Failure.
- Discuss new treatment algorithms for heart failure focusing on mortality improvement.
- Discuss new medications for heart failure.
- Assess the appropriateness of a patient's heart failure regimen.
- Explain patient counseling points for medications for heart failure

Introduction

In 2022, the American College of Cardiology (ACC)/American Heart Association (AHA)/ Heart Failure Society of America (HFSA) released a much-anticipated update to the heart failure treatment guidelines. Prior to this update, small, focused updates and guidance had been published to supplement the rapidly evolving field of cardiology. This is the first comprehensive update since 2013.[1]

Heart failure is a disease that encompasses any structural or functional impairment of the heart that affects ventricular filling or ejection of blood. The guidelines address a wide array of patients, from those without symptoms, but with underlying structural heart disease, to patients with advanced chronic heart failure and persistent treatment-refractory symptoms.[1]

The occurrence of heart failure is growing. Current projections of heart failure prevalence show growth of 46% from 2012 to 2030.[2] It is estimated to affect more than 8 million adults in the world. Heart failure is also a costly disease for both individual patients as well as the health system. Patients with heart failure will receive numerous medications, procedures, hospitalizations, and devices throughout the course of their lives. The estimated cost of heart failure in the United States by 2030 is $69.8 billion.[2]

In Kentucky, the leading cause of death is heart disease.[3] This data is echoed at the national level, with heart disease continuously ranking as the leading cause of death, even throughout the COVID-19 pandemic. With such a high concentration of heart disease within the state of Kentucky, pharmacists need to be acutely aware of how these patients should be managed. The initial treatment of heart failure is solely based on medications, making the pharmacists' role on the care team invaluable.[3]

This activity aims to help pharmacists within the commonwealth of Kentucky have a more comprehensive understanding of the nuances of heart failure management. The focus will be on the updated changes to the 2022 guidelines and medications that have already become a mainstay of heart failure management. Additionally, medications that serve as the standard of care treatment for heart failure will be discussed.

Changing the Classification System

In the treatment of heart failure, there are several different ways in which a patient can be categorized. The function of a patient's heart is essential for a provider to know when making care decisions. Patients are grouped based on the percentage of blood that is ejected from their left ventricle during systole. Since an average left ventricular ejection fraction (LVEF) is around 60% in healthy patients, patients are classified as having heart failure with preserved ejection fraction (HFpEF) if their LVEF is ≥ 50%. Also, patients are classified as having heart failure with reduced ejection fraction (HFrEF) if their LVEF ≤ 40%.[1]

In previous guidelines, patients with LVEF in between 40% and 50% were not explicitly addressed.4 However, the newest guidelines include these patients within a new category of heart failure with mildly reduced ejection fraction (HFmrEF). These patients have an LVEF between 41-49%. Additionally, the 2022 guidelines include a category called heart failure with improved ejection fraction (HFimpEF). These patients are those who were previously classified as HFrEF due to a baseline LVEF ≤ 40%, but subsequent echocardiograms show a ≥10-point increase from baseline and an LVEF > 40%.[1, 5]

In addition to new classification categories, the 2022 updated guidelines also include revised management strategies for patients at risk of developing heart failure (Stage A) and pre-heart failure (Stage B). While these staging categories did not change from the 2013 guidelines, the subsequent management did. In the 2022 update, there is a stronger emphasis on primary prevention for patients in stages A and B. Heart failure is a progressive disease that, like many others, can be slowed or even reversed by modifying specific risk factors. As heart failure progresses, survival rates decrease.[1]

Stage A patients are at an increased risk of developing heart failure but do not have any signs or symptoms or any structural or functional change affecting their hearts. Several comorbid conditions put patients at risk for heart failure, including hypertension, cardiovascular disease, diabetes, and obesity, as well as the use of cardiotoxic agents or genetic predisposition. At this stage, the guidelines focus on management and interventions that will modify the aforementioned risk factors and prevent the progression to actual heart failure.[1]

Patients are considered to have pre-heart failure, Stage B, if they have no symptoms of heart failure, but have either structural heart disease, increased filling pressure, or elevated biomarkers. These patients are at an increased risk of developing symptomatic heart failure, Stage C. Not only do these patients require the treatment and modification of the risk factors, but they also require the treatment of their structural heart disease to prevent progression to symptomatic heart failure.[1]

Not Just for Diabetes Anymore: SGLT2 Inhibitors in Heart Failure

One of the most impactful changes to the 2022 updated guidelines was the addition of a novel drug class to treat cardiovascular disease. Sodium-glucose cotransporter 2 inhibitors (SGLT2i) have been a part of diabetes management for almost a decade; however, they are relatively novel therapy in the heart failure world. Several clinical trials have been completed in the last few years that demonstrated that SGLT2i use benefits patients with heart failure regardless of the presence of diabetes.

SGLT2 inhibitors have several mechanisms of action, some fully elucidated while others remain unknown. The primary mechanism of action for diabetes control is due to the blockade of sodium-glucose-linked transporters type 2 in the proximal convoluted tubule in the nephrons of the kidney.[6] These transporters are responsible for reabsorbing 90% of the filtered glucose back into the blood. When these transporters are blocked, the concentration of glucose in the blood is lowered, thus increasing the amount of glucose excreted in the urine[6]

There have been several proposed mechanisms of action for heart failure. Cardiovascular benefits may be due to diuretic and antihypertensive effects. Since SGLT2i primarily work on sodium-glucose cotransporters in the kidneys, they decrease sodium, glucose, and water retention. Another proposed mechanism is the decrease of a patient's overall body weight. SGLT2i have been shown to increase erythropoietin production, which subsequently increases hematocrit. There are even potential direct cardiovascular effects through decreasing detrimental cardiac remodeling, leading to worsening heart failure.[6]

Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction (DAPA-HF) investigated the efficacy of SGLT2i in heart failure.[7] The study's primary outcome was a composite endpoint of worsening heart failure or cardiovascular death. DAPA-HF demonstrated that SGLT2i decreased hospitalizations and improved mortality for patients with HFrEF. Soon after the DAPA-HF trial, the EMPEROR-Reduced trial (Effect of Empagliflozin on the Clinical Stability of Patients with Heart Failure and a Reduced Ejection Fraction) demonstrated similar improvements with empagliflozin.[8]

More recently, the EMPEROR-Preserved trial (Empagliflozin in Heart Failure with a Preserved Ejection Fraction) was conducted to determine if the same benefits of SGLT2 inhibitors could be extended to patients with HFpEF. In this trial, patients were included if they had an LVEF >40%. The primary endpoint of this study was a composite of either cardiovascular death or hospitalization due to heart failure with the use of empagliflozin in patients with LVEF >40%. The benefits of empagliflozin can be extended to patients with HFpEF regardless of diabetes status.[9] Another trial with dapagliflozin, DELIVER (Dapagliflozin in Heart Failure with Mildly Reduced or Preserved Ejection Fraction), showed the same benefits could be extended to this SGLT2i.[10]

The key takeaway from these clinical trials is that SGLT2 inhibitors (specifically empagliflozin and dapagliflozin) are now an addition to GDMT for every classification of heart failure. SGLT2 inhibitors, once only for diabetic patients, are considered standard of care for the treatment of HFrEF, HFimpEF, HFmrEF, as well as HFpEF regardless of diabetes status.[1]

Now that many patients are being prescribed SGLT2 inhibitors for conditions other than diabetes, it is more important than ever that pharmacists can provide effective disease-specific counseling to patients. The two SGLT2 inhibitors currently indicated in the treatment of heart failure are dapagliflozin and empagliflozin. Both medications are dosed at 10 mg by mouth once daily for heart failure, without any dose titration. The primary adverse drug effect of SGLT2 inhibitors is an increased risk of genital mycotic infections, but otherwise, these are generally well-tolerated medications.[1, 11]

So, what exactly is GDMT?

Whether you are working with a heart failure patient in the hospital, ambulatory care, or community pharmacy setting, it is exceedingly important to know what medications patients take for their heart failure and if those medications are dosed appropriately. Medications are at the center of heart failure treatment. Properly dosed medications and proper adherence can mean the difference between life and premature death for a patient with heart failure. Table 2 summarizes GDMT for HFrEF.

HFrEF GDMT

For patients with an LVEF ≤40%, and heart failure with reduced ejection fraction, the guideline recommends four standard medications with the addition of diuretics as needed for fluid overload. A good way to remember these mediations is the acronym ABS MD. The utilization of all four drug classes has been shown to reduce mortality by as much as 73%.[1]

A = Angiotensin receptor-neprilysin inhibitor (ARNi) or Angiotensin converting enzyme (ACEi) or Angiotensin receptor blocker (ARB)

Patients with symptomatic HFrEF should be prescribed a renin-angiotensin-aldosterone system (RAAS) inhibitor to reduce morbidity and mortality. The first recommendation within the guidelines is for an angiotensin receptor-neprilysin inhibitor (ARNi). The only drug on the market in this category currently is sacubitril-valsartan (Entresto®). This combination drug is an angiotensin receptor blocker (valsartan) plus a neprilysin inhibitor (sacubitril). It comes with an increased risk of symptomatic hypotension as well as a risk of angioedema. There are three different doses that patients may be on for heart failure: 24/26 mg, 49/51 mg, or 97/103 mg. All are dosed orally twice daily. The target dose of this medication is 97/103 mg twice daily.[1]

When an ARNi is not an option, the guidelines recommend the use of an angiotensin-converting enzyme inhibitor (ACEi). ACE inhibitors have also been shown to reduce morbidity and mortality in heart failure. All ACEi should be titrated to their target doses for maximum cardiovascular benefits.[1]

Lastly, in this category are angiotensin receptor blockers (ARB). In the guidelines, ARBs are intended to be used if ARNi or ACEi are not an option. There are three specific ARBs that have been studied and shown benefits in heart failure: candesartan, losartan, and valsartan.[1]

While these medications lower blood pressure through their inhibition of the RAAS, it is important to counsel patients on the importance of these medications for the treatment of heart failure due to their remodeling benefits. Although these medications will lower a patient's blood pressure, these patients may never have been diagnosed with hypertension. Telling a patient that this is hypertension or blood pressure medication may cause confusion and non-adherence. Counseling patients on these medications' morbidity and mortality benefits can substantially improve adherence.

B = Beta Blockers

Any patient with HFrEF with current or prior symptoms should be prescribed a beta-blocker. In heart failure, beta-blockers work to decrease the sympathetic tone of the heart and prevent detrimental remodeling. There are three beta-blockers with a proven mortality benefit in heart failure: bisoprolol, carvedilol, and metoprolol succinate. It is important that a patient with heart failure is on one of these three specific beta-blockers, as the mortality benefit is not a class-wide effect.[1]

S = SGLT2 inhibitors

All patients with symptomatic chronic HFrEF can benefit from an SGLT2i in terms of morbidity and mortality. The two medications specifically identified within the heart failure guidelines are empagliflozin and dapagliflozin. These medications are unique in heart failure management as they do not require any dose titration. Patients will be started on 10 mg daily and remain on that dose.[1]

M = Mineralocorticoid receptor antagonists (MRA)

Symptomatic patients with HFrEF can see morbidity and mortality benefits from an MRA. Before prescribing this medication, it is important to ensure that the patient has an estimated glomerular filtration rate (eGFR) > 30 mL/min and a serum potassium < 5.0 mEq. Additionally, patients should be routinely monitored for kidney function and electrolyte abnormalities. Spironolactone and eplerenone are the two drugs in this class and either may be used in heart failure. Of note, eplerenone has a lower incidence of gynecomastia in men and vaginal bleeding in women compared to spironolactone.[1]

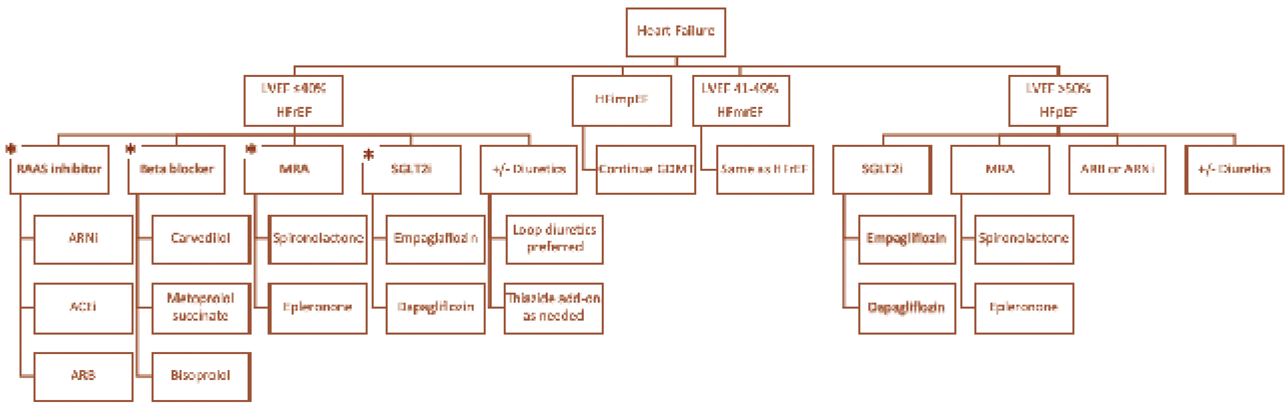
These medications have a unique titration schedule compared to other medications for heart failure. After initiation of an MRA, serum potassium levels and renal function should be assessed at

Table 1: Classification of Heart Failure[1,5]				
	HFrEF	HFimpEF	HFmrEF	HFpEF
LVEF	≤40%	Baseline ≤40%, with ≥10-point increase and second measurement >40%	41-49%	≥50%

Table 2: Drug Chart for HFrEF[1, 18]

A – RAAS Inhibitors	Drug	ARNi	Selected ACEi		ARB		
		Sacubitril/valsartan (Entresto®)	Lisinopril (Prinivil®, Zestril®)	Enalapril (Vasotec®)	Candesartan (Atacand®)	Losartan (Cozaar®)	Valsartan (Diovan®)
	Initial Dose	24/26 mg twice daily (for CrCl< 30 mL/min) 49/51 mg twice daily	2.5-5 mg daily	2.5 mg twice daily	4-8 mg daily	25-50 mg daily	20-40 mg divided twice daily
	Target Dose	97/103 mg twice daily	20-40 mg daily	10-20 mg twice daily	32 mg daily	50-150 mg daily	160 mg divided twice daily
	Titration	Every 1-2 weeks 36-hour washout of ACEi prior to stating ARNi	Every 1-2 weeks		Every 1-2 weeks		
	ADRs	- Hypotension - Hyperkalemia - Increased serum creatinine/acute kidney injury - Decreased Hematocrit and hemoglobin - Dizziness - Angioedema	- Hypotension - Dizziness - Hyperkalemia - Cough, dry - Increased serum creatinine/acute kidney injury - Agranulocytosis and neutropenia		- Hypotension - Dizziness - Hyperkalemia - Increased serum creatinine/acute kidney injury - Agranulocytosis and neutropenia		
	CI	- History of angioedema with ACEi or ARB - Pregnancy - Concomitant use with ACEi (36-hour washout) - Concomitant use aliskiren	- History of angioedema - Concomitant use aliskiren - Pregnancy - Bilateral renal artery stenosis		- Concomitant use aliskiren - Pregnancy		
B – Beta Blockers	Drug	Carvedilol (Coreg®)	Metoprolol Succinate (Toprol XL®)		Bisoprolol		
	Initial Dose	3.125 mg twice daily CR: 10 mg daily	12.5-25 mg daily		1.25 mg daily		
	Target Dose	25 mg twice daily (≤85 kg) 50 mg twice daily (>85 kg) CR: 80 mg daily	200 mg daily		10 mg daily		
	Titration	Every 1-2 weeks					
	ADRs	- Bradycardia - AV heart block - Pruritis - Dizziness - Fatigue, depression - Sexual dysfunction					
	CI	Severe bradycardia					
S – SGLT2 Inhibitors	Drug	Empagliflozin (Jardiance®)	Dapagliflozin (Farxiga®)				
	Dose	10 mg daily No Titration	10 mg daily No titration				
	ADRs	- Dyslipidemia - Nausea - Urinary tract infection and Genitourinary mycotic infections - Polyuria - Polydipsia - Increased Hematocrit					
	CI	Dialysis					
M – MRA	Drug	Spironolactone (Aldactone®)	Eplerenone (Inspra®)				
	Initial Dose	12.5-25 mg daily	25 mg daily				
	Target Dose	25-50 mg daily	50 mg daily				
	Titration	Every 4 weeks, pending renal function and serum potassium levels					
	ADRs	- Hyperkalemia - Increase serum creatinine - Gynecomastia in men (spironolactone)					
	DDI	Strong CYP 3A4 inhibitors					
	CI	- CrCl ≤ 30 mL/min - Serum K ≥ 5.0 mEq/L					
D – Loop Diuretics	Drug	Bumetanide (Bumex®)	Furosemide (Lasix®)		Torsemide (Damadex®, Soaanz®)		
	Initial Dose	0.5-1 mg daily or twice daily	20-40 mg daily or twice daily		10-20 mg daily		
	Max Dose	10 mg daily	600 mg daily		200 mg daily		
	ADRs	- Hyperuricemia - Hypokalemia - Hyponatremia - Hypocalcemia - Hypomagnesemia - Increase serum creatinine - Polyuria					
	CI	- Anuria - Poor renal perfusion (CrCl <30-40) will cause decrease efficacy					

Figure 1: Heart Failure Treatment Algorithm



* Indicates therapies with known mortality benefit

one week, four weeks, and six months. At four weeks, if the serum potassium and renal function are within range, the medication can be titrated.[1]

D = Diuretics

Not all heart failure patients will be on a diuretic. Diuretics are reserved for patients with fluid retention and congestive symptoms. Loop diuretics (bumetanide, furosemide, and torsemide) are the preferred agents. The goal of diuretics in heart failure is to achieve euvolemia with the lowest possible dose. If a patient is not responding to loop diuretics, a thiazide or thiazide-like diuretic, like metolazone, may be added as needed. Diuretics show improvement of symptoms but have no mortality benefit.[1]

HFmrEF GDMT

For patients with an LVEF between 41-49%, heart failure with mildly reduced ejection fraction (HFmrEF), the guidelines recommend the same four medications classes for patients with HFrEF: a renin-angiotensin-aldosterone system (RAAS) inhibitor (ARNi, ACEi, or ARB), one of the evidence-based beta-blockers (carvedilol, metoprolol succinate, or bisoprolol), an SGLT2i, as well as a mineralocorticoid receptor antagonist (MRA).[1]

HFimpEF GDMT

Patients with improved LVEF, baseline LVEF ≤40%, but subsequent readings show a ≥10-point increase from baseline and an LVEF >40%, must continue their GDMT to prevent any worsening in LVEF or what the guidelines refer to as relapse[1,5]. The importance of counseling a patient regarding this improvement is paramount. When used properly, the medication regimens used in heart failure can improve cardiac function and biomarkers. However, this is not curative in nature but more of a remission status. Patients need to be educated that this remission will only be maintained if the medications that brought about remission are maintained. Without GDMT, patients can see a relapse in symptoms and a worsening of cardiac function.[1]

HFpEF GDMT

New recommendations regarding the treatment algorithm for patients with heart failure with preserved ejection fraction (HFpEF) were also made in the 2022 update. The new algorithm includes the use of SGLT2i, MRA, and ARNi/ARB.[1]

The guidelines emphasize the importance of strict blood pressure control in patients with HFpEF. There is currently no preferred hypertension regimen for HFpEF, however, agents that inhibit the RAAS are recommended as a viable option. This includes ACEi, ARB, and potentially ARNi. The CHARM-Preserved trial showed a reduction in hospitalizations with candesartan, but no mortality benefit.12 Similarly, the PARAGON-HF trial did not show a statistically significant reduction in hospitalizations or mortality benefit with ARNi. However, in a subpopulation of patients with LVEF <57%, valsartan/sacubitril did show a statistically significant difference in the primary composite endpoint of reduction in cardiovascular hospitalization or death.[13] The guidelines do not make a specific recommendation as to which anti-hypertensive mediation is preferred for an HFpEF patient, but instead leaves the decision up to the provider and patient-specific factors.[1]

Mineralocorticoid receptor antagonists (MRA), like spironolactone, have been shown in clinical trials to improve diastolic function in patients with HFpEF.[14] In the TOPCAT trial, a mortality benefit was not seen for MRA in HFpEF.[15] However, in a post-hoc analysis that isolated the patients in the Americas only, there was a statistically significant reduction in cardiovascular hospitalizations.[16] The guidelines recommend the use of an MRA in HFpEF with close monitoring of renal function and serum potassium levels.[1]

As previously mentioned, SGLT2i have proven mortality benefit in HFrEF. For patients with HFpEF, the same two medications (empagliflozin and dapagliflozin) at the same 10 mg daily dose are recommended. The EMPEROR-preserved and DELIVER trials both demonstrated that

SGLT2i can reduce cardiovascular hospitalizations or death in patients with HFpEF.[9, 10] The guidelines recommend the use of an SGLT2i in patients with HFpEF regardless of their diabetes status.[1]

* Indicates therapies with a known mortality benefit

Additional Therapies for HFrEF

Within the treatment of heart failure, there are some additional medications that may be encountered in practice. These medications may serve a vital role in managing a patient's symptoms and preventing hospitalization.

Hydralazine-Isosorbide dinitrate

Hydralazine, in combination with isosorbide dinitrate, has morbidity and mortality benefits; however, it is reserved for patients who either cannot take first-line agents or self-identified black patients with symptoms despite maximized GDMT. These medications must be prescribed in combination for maximum benefits. Both medications are vasodilators; hydralazine vasodilates arterioles, while isosorbide dinitrate primarily vasodilates veins. The initial dose of this combination is 20-30 mg isosorbide dinitrate and 25-50 mg hydralazine 3-4 times daily with a target dose of 120 mg isosorbide dinitrate and 300 mg hydralazine daily in divided doses.[1]

Ivabradine (Corlanor®)

Recommended for patients with LVEF ≤ 35%, on GDMT, including a maximized dose of a beta blocker with a heart rate ≥ 70 beats per minute (bpm). Ivabradine has been shown to decrease cardiovascular hospitalization in patients with HFrEF. This medication works by inhibiting the funny (If) current and subsequently slowing the sinoatrial (SA) node and, thus, the heart rate. After a patient's GDMT beta-blockers have been maximized but the heart rate remains 70 bpm, ivabradine can be initiated at a dose of 5 mg by mouth twice daily and titrated to a target heart rate.[1]

Vericiguat (Verquvo®)

Patients with HFrEF on GDMT with progressively worsening heart failure symptoms despite foundational GDMT and who are at risk for hospitalization may be prescribed vericiguat. This medication works by increasing the production of cyclic guanosine monophosphate (cGMP), which produces vasodilation and smooth muscle relaxation. The VICTORIA trial showed a reduction in hospitalizations with vericiguat.[17] The initial dose of vericiguat is 2.5 mg by mouth daily with a target dose of 10 mg by mouth daily.[1]

Digoxin

This historically used medication is still part of the updated 2022 guidelines. It is an option for patients with persistently symptomatic HFrEF on maximally tolerated GDMT or for patients who are unable to tolerate GDMT. Digoxin does not have an impact on reducing mortality but has data to support its use in decreasing hospitalizations. The recommended dose range is 0.125 – 0.25 mg by mouth daily.[1]

Pharmacy Pearls

Vaccinations

Patients with heart failure are at high risk for poor outcomes when infected with respiratory infections. Community pharmacists serve an important role in ensuring that patients are up to date on their vaccinations. In the PARADIGM-HF study, patients annually vaccinated against influenza were associated with lower rates of mortality. In addition to an annual influenza vaccination and other vaccinations recommended for a patient's specific age range by the CDC, both pneumococcal and SARS-CoV-2 vaccinations should be recommended for all patients with heart failure.[1]

Medications to Avoid

Several medications may be harmful to patients with heart failure. When counseling patients with heart failure, recommend that they avoid the following medications: non-steroidal anti-inflammatory drugs (NSAIDs), thiazolidines, saxagliptin, alogliptin, flecainide, disopyramide, sotalol, dronedarone, doxazosin, diltiazem, verapamil, nifedipine, TNF-alpha inhibitors, antimalarial agents (chloroquine and hydroxychloroquine), and cilostazol.[18]

Non-selective COX inhibitors and COX-2 inhibitors all increase systemic vascular resistance. The mechanism of action of these drugs, prostaglandin inhibition, works against the treatment of heart failure by increasing sodium and water retention. This can prevent the therapeutic effects of diuretics and lead to fluid retention, worsening heart failure symptoms, and increased mortality. Although several NSAIDs are prescription drugs, many patients are getting these over the counter, which means that counseling patients on the risks is even more vital. Patients should be counseled on using acetaminophen as an alternative for pain.[1]

Patients with heart failure that require antiarrhythmics have a limited selection of options. Most antiarrhythmic agents have an increased risk of mortality. Flecainide, disopyramide, dronedarone, and sotalol have all been shown to increase mortality in heart failure patients. The only medications with neutral effects on mortality are amiodarone and dofetilide.[1]

Some medications used in the treatment of diabetes can worsen heart failure. Thiazolidinediones (pioglitazone and rosiglitazone) can increase fluid retention. Dipeptidyl peptidase 4 (DPP-4) inhibitors (alogliptin and saxagliptin) have been associated with an increased risk of heart failure associated hospitalizations. Both drug classes should be avoided in diabetes and heart failure patients.[1]

Calcium channel blockers are a first-line agent for hypertension; however, some medications in this drug class are associated with a higher risk of heart failure recurrence. Specifically, the non-dihydropyridine calcium channel blockers (diltiazem and verapamil) have a pronounced negative inotropic effect and diminish cardiac output.[1]

These medications and more may increase risk and harm for patients with heart failure. Pharmacists are poised to help evaluate these scenarios and provide education on drugs best avoided in this patient population.

Conclusion:

As a pharmacist in the Commonwealth of Kentucky, you have a vital role in the care of patients with heart failure. As medications are at the center of heart failure treatments, pharmacists are essential in appropriate management. The 2022 update to the ACC/AHA/HFSA Guideline for the Management of Heart Failure includes several new medications as well as standards of care that continue to serve as a pillar of treatment. With the rate of growth of heart failure in Kentucky and across the United States, we need to manage these vulnerable patients' care effectively to improve their standard of living and prolong their lives

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POST-ASSESSMENT QUESTIONS:

1. Per the 2022 ACC/AHA heart failure guidelines, what is the recommended dose of dapagliflozin for heart failure?

a. 5 mg twice daily
b. 25 mg daily
c. 10 mg daily
d. 100 mg daily

2. TJ is a 59-year-old asymptomatic patient with a history of HFrEF. He presents at the pharmacy counter to pick up the following medications for his heart failure:

100 mg metoprolol tartrate by mouth twice daily
40 mg lisinopril by mouth once daily
10 mg dapagliflozin by mouth once daily
25 mg spironolactone by mouth once daily

What would you recommend to his provider regarding his heart failure regimen?

a. Recommend a decrease in the dose of lisinopril
b. Dapagliflozin should be dosed twice daily
c. Patient needs to be on a diuretic if they have HFrE
d. Recommend a switch from metoprolol tartrate to succinate

3. Which of the following original diabetes medications is a first-line medication for heart failure?

a. Metformin
b. Empagliflozin
c. Sitagliptin
d. Rosiglitazone

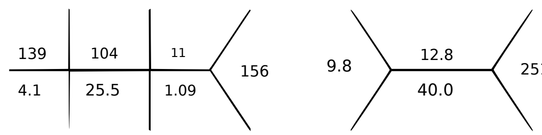
4. What is the primary side effect that you should counsel a patient on when initiating a new prescription for carvedilol?

a. Urinary tract infections
b. Fatigue
c. Angioedema
d. Increased urination

5. WL is a 59-year-old patient with a history of HFrEF. Most recent LVEF is 30%. Patient presents to the heart failure clinic appointment with the following medications, labs, and vitals.

49/51 mg Entresto PO twice daily
50 mg metoprolol succinate PO daily
10 mg dapagliflozin PO once daily
25 mg spironolactone PO once daily
40 mg torsemide PO twice daily

Blood Pressure: 125/65 mmHg
Heart Rate: 85 bpm



What recommendation would you make to the provider regarding this patient's heart failure regimen?

a. Increase the dose of metoprolol succinate to 75 mg daily
b. Increase the dose of dapagliflozin to 25 mg
c. switch torsemide to bumetanide
d. Decrease the dose of Entresto to 24/26mg twice a day.

6. Which of the following medications have shown mortality benefit in patients with HFrEF in clinical trials? (Select all that apply)

a. Dapagliflozin
b. Digoxin
c. Sacubatril/valsartan
d. Furosemide

Answer Sheet

2022

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Title: Unbreak my Heart: Heart Failure Guideline Updates 2022

Name: ______________________________

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Completion Date: ______________________________

Please circle: Pharmacist

UNIVERSAL ACTIVITY #: 0143-0000-22-094-H01-P
| **CONTACT HOUR**: 1.5 | **EXPIRES**: 10/15/2025

PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D 2. A B C D 3. A B C D 4. A B C D 5. A B C D

6. A B C D

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS __ YES __ NO
FIGURES AND TABLES WERE USEFUL __ YES __ NO
ACHIEVED THE STATED OBJECTIVES __ YES __ NO
POSTTEST WAS APPROPRIATE __ YES __ NO
WAS WELL WRITTEN __ YES __ NO
IS RELEVANT TO MY PRACTICE __ YES __ NO
COMMERCIAL BIAS WAS PRESENT __ YES __ NO IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET
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Anticholinergic Use in Older Adults: Pharmacists' Role in Identifying At-Risk Patients and Reducing Anticholinergic Burden

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Anticholinergic Use in Older Adults: Pharmacists' Role in Identifying At-Risk Patients and Reducing Anticholinergic Burden

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OBJECTIVES FOR PHARMACISTS:

- Describe the risks associated with anticholinergic use in older adults
- Describe the clinical utility of using the Anticholinergic Risk Scale to identify the anticholinergic burden
- Identify opportunities for pharmacist interventions to reduce anticholinergic use and mitigate anticholinergic side effects
- Describe alternative therapies to consider when deprescribing anticholinergic medications

Introduction

Anticholinergic drugs are widely used to treat many conditions, such as nausea, vomiting, allergies, sleep disorders, Parkinson's disease symptoms, and others[1,2]. They are available both as prescription and over-the-counter (OTC) medications. A 12-year retrospective study showed that 26% of Medicare beneficiaries from 2006 to 2017 took at least one anticholinergic prescription medication, and 3% of beneficiaries took at least two different anticholinergic medications for at least 30 days[3]. Since these percentages do not include nonprescription medications, this likely underestimates the extent of anticholinergic use in Medicare beneficiaries.

Anticholinergic medications can cause acute side effects such as constipation, increased heart rate, decreased saliva production, tears, urine, and sweat[1,2]. These medications can also lead to chronic side effects like impaired cognition which is associated with hallucinations, delirium, dementia, increased risk of falls, and all-cause mortality[1,2,4]. Older patients are more at risk for these side effects due to risk factors such as declining mobility, concurrent medical conditions, polypharmacy, multiple anticholinergic medication use, and altered mental status at baseline. Other physiological changes that occur naturally with age, such as a more permeable blood-brain barrier and less p-glycoprotein activity, increase the influx and retention of anticholinergic drugs in the central nervous system, which may contribute to the increased risk of adverse effects. Additionally, older adults are more sensitive to cognitive impacts such as impaired memory and increased risk of falls due to decreased acetylcholine synthesis and fewer acetylcholine receptors in the brain[4]. Given the adverse effect profile and high rates of use in the older adult population, healthcare providers must maintain awareness of anticholinergic use in older adults.

Overview of Risks associated with Anticholinergic Side Effects and Strategies to Reduce Them

Anticholinergic side effects can be bothersome and lead to detrimental health outcomes in older adults[1]. In situations where anticholinergic use is needed, or patients are reluctant to reduce its use, there are non-pharmacologic and OTC treatments to mitigate anticholinergic side effects.

How to Assess Anticholinergic Burden

Anticholinergic burden is a strong predictor of cognitive and physical impairment, especially in the elderly population[14]. Anticholinergic burden refers to the cumulative effect of taking one or more medications with anticholinergic activity[14]. Medications contributing to anticholinergic burden can include prescription or OTC medications. Multiple scales have been developed to try to capture the cumulative effect of various medications with anticholinergic properties and evaluate the impact of anticholinergic burden on clinical outcomes[15]. For example, the Anticholinergic Risk Scale (ARS) is one of the scales that showed an association between anticholinergic burden and an increase in hospitalizations, mortality,

Table 1: Anticholinergic adverse effects and non-pharmacological strategies to manage them		
Adverse Effect	Risks associated with anticholinergic side effects	Non-Pharmacological Recommendations
Dry Mouth[5]	Increased cavity risk, difficulty wearing dentures, impaired taste and smell, impact on chewing, swallowing, and talking. May increase risks of caries and secondary fungal infections.	Maintain good hydration, sip water or sugar-free drinks throughout the day. Eat sugar-free or candy or gum, sugar-free citrus drops or tablets. Use fluoride-containing mouthwash or toothpaste and avoid alcohol-containing mouthwash. Avoid smoking, alcohol, and coffee.
Dry eyes[6,7]	Increased risk of eye infections, eye inflammation, abrasion of the corneal surface, corneal ulcers and reduced vision.	Use OTC artificial tears during the day and lubricants during the night. Wear large-frame glasses to minimize tear evaporation when in a low-humidity environment, such as a long airplane or car ride. Use humidifiers at home.
Constipation[8,9]	Increased risk of hemorrhoids, impacted bowel, anal fissure, and rectal prolapse.	Increased fiber and fluid in diet. Try to defecate after meals, especially in the morning. Use dietary fiber and bulk-forming laxatives such as psyllium or methylcellulose. Use stool softener and laxatives.
Urinary retention[10,11]	Increased risk of urinary incontinence, urinary tract infections, bladder and kidney injury.	Practice pelvic floor exercises. Train the bladder by planning times to urinate. Attempt urination twice during one bathroom visit to fully empty the bladder.
Sedation/Fall[12, 13]	Increased risk of bone fractures, traumatic brain injuries, increased weakness, and overall increased complications and decreased quality of life.	Organize furniture, wires, and other belongings so that there are no tripping hazards on the floor. Fix broken staircases and handrails. Use night lights to illuminate dark rooms, stairways, and hallways. Install grab bars and place high friction mats near the toilet and shower. Increase physical activity to increase balance and strength. Wear sensible shoes and use a cane or walker. Wear an alarm device to call for help in the event of a fall.

Table 2 Anticholinergic Risk Scale[17]

3 Points	2 Points	1 Point
Amitriptyline Atropine Benztropine Carisoprodol Chlorpheniramine Chlorpromazine Cyproheptadine Dicyclomine Diphenhydramine Fluphenazine Hydroxyzine Hyoscyamine Imipramine Meclizine Oxybutynin Perphenazine Promethazine Thiothixene Tizanidine Trifluoperazine	Amantadine Baclofen Cetirizine Cimetidine Clozapine Cyclobenzaprine Desipramine Loperamide Loratadine Nortriptyline Olanzapine Prochlorperazine Pseudoephedrine Tolterodine	Carbidopa-levodopa Entacapone Haloperidol Methocarbamol Metoclopramide Mirtazapine Paroxetine Pramipexole Quetiapine Ranitidine Risperidone Selegiline Trazodone Ziprasidone

as well as cognitive side effects[16]. The following risk scale does not include all anticholinergic medications as it is sourced from only one version of the scale.

Table 2 shows the ARS that pharmacists can use to evaluate anticholinergic burden. Anticholinergic activity is expressed by scores ranging from 0 to 3, with 0 representing no anticholinergic burden and 3 representing high anticholinergic burden[17]. The anticholinergic burden is calculated by summation of ARS scores for each anticholinergic drug[17]. Suppose the overall ARS score for one patient is three or greater. In that case, the patient is at high risk for adverse effects and 70% of these high-risk patients experienced at least two anticholinergic adverse effects during the creation of this scale[17]. Pharmacists can utilize this scale to swiftly evaluate the extent of anticholinergic burden and identify an opportunity for intervention.

Considerations for using the Anticholinergic Risk Scale

While useful, this scale shows a cumulative risk for anticholinergic burden without accounting for chronic versus acute use. Furthermore, it does not account for different strengths and frequencies of administration. Thus, pharmacists must recognize the impact of acute anticholinergic use and varying dosages on the patients' ARS score and evaluate how that may increase the risk of anticholinergic side effects.

Stop and reflect: :

A 70-year-old female comes to the pharmacy and has the following medications on her profile: acetaminophen, hydroxyzine as needed, docusate, metoprolol, and metformin. She brings a box of Benadryl (diphenhydramine) to the counter and asks if you think she could take it safely because she has been having some trouble sleeping. What is her current ARS core? Based on this score, how would you classify her risk of anticholinergic side effects?

Feedback: With her current medications, her current ARS score is three, which represents a high risk for anticholinergic side effects. This score should alert the providers to counsel this patient on non-pharmacological options for her insomnia. In this case, Benadryl would not be an ideal option because it would increase her ARS score to six. This example shows that even when anticholinergic medications are used as needed, they can greatly increase a patient's ARS score. It is also important to get more information from the patient on how they use their hydroxyzine since it is listed as "as needed." The frequency of as-needed medications that contribute to the ARS score may impact therapy recommendations.

Deprescribing

Deprescribing anticholinergic medications is an option for reducing

Table 3 - Alternative Therapies for Highly Anticholinergic Drugs		
Condition	**Anticholinergic Drugs**	**Alternative Therapies**
Allergy	1st generation antihistamine	2nd generation antihistamines, Intranasal normal saline, Intranasal steroids, Leukotriene inhibitors, Allergy shots Air purifiers, smoking cessation, avoiding outdoor activities when allergen is high, wearing masks when doing high allergen activities such as dusting or yard work.
Depression	Tricyclic antidepressants (TCA), Paroxetine	Selective serotonin reuptake inhibitors (SSRIs) Serotonin norepinephrine reuptake inhibitors (SNRIs) Cognitive behavioral therapy (CBT)
Neuropathic Pain	TCA	SNRI, Gabapentin, Topical Capsaicin, Lidocaine patch Exercise, acupuncture, CBT, Percutaneous Electrical Nerve Stimulation (PENS), Transcutaneous electrical nerve stimulation (TENS).
Muscle Spasms	Cyclobenzaprine Orphenadrine	Acetaminophen, Non-steroidal anti-inflammatory drugs (NSAIDs) Stretching, massages, light exercise
Behavioral Symptoms	Antipsychotics (Haldol, clozapine, etc.)	CBT, Massage/touch, music therapy, supervised exercise, caregiver coaching Addressing and treating the cause of behavioral issues such as uncontrolled pain, depression, boredom, etc.
Insomnia	Diphenhydramine Doxylamine	Melatonin, CBT, sleep hygiene, exercise Address adjustable factors such as alcohol or caffeine consumption or diuretic use in near bedtime causing nighttime voiding.
Urinary Incontinence or Overactive Bladder	Oxybutynin Tolterodine Darifenacin Trospium Solifenacin Fesoterodine	Pelvic floor exercise, scheduled voiding/toileting, pessaries, undergarments, weight loss, B3-agonists (Myrbetriq®, Gemtesa®), Botulinum toxin A Identify therapies that may worsen urinary incontinence such as diuretics, alpha antagonists, calcium channel blockers, sedatives, hypnotics, antipsychotics, or ACE-inhibitors. Avoid bladder irritants such as alcohol, caffeine, chocolate, spicy and acidic foods.
Parkinson's Disease	Trihexyphenidyl Benztropine	Carbidopa/levodopa

anticholinergic burden. When an opportunity to deprescribe is identified, there are a few steps to ensure that deprescribing is the best option and that it would be sustained. This abbreviated 5-step method[18] can be utilized in pharmacist interventions such as Medication Therapy Management (MTM) and discharge counseling.

5-Step Method for Deprescribing

1. Assess the appropriateness and efficacy of anticholinergic medication. It is crucial to assess why, how, and when the anticholinergic medication was prescribed. Evaluate the indication, length of therapy, and history of alternative medication trials. Most importantly, evaluate anticholinergic therapies' efficacy and side effects to assess risk versus benefit.

2. Identify the patient's willingness to modify therapy. Pharmacists should have an open discussion with the patient, presenting the benefits and risks of anticholinergic therapy. Emphasize that reduction in overall anticholinergic burden is important for cognitive health and reducing side effects. While risks are present with anticholinergic medications, pharmacists must consider the impact discontinuation will have on a patient's health and quality of life.

3. Set a goal for deprescribing through shared decision-making. The goal should be set for a better overall health outcome for the patient. While discontinuation of the anticholinergic can be the final goal, reducing use frequency or a slow taper can be more beneficial for the patient. This approach may increase a patient's willingness to try discontinuation while ensuring that their health conditions are still appropriately managed. The goal should be based on anticholinergic burden and side effect management. Side effect management-based goals should be centered around the patient's specific needs, such as reducing dry mouth, urinary retention, or drowsiness.

4. Recommend alternative pharmacologic and non-pharmacologic therapy to the patient and provider. Providing non-pharmacologic treatment alternatives is crucial to sustaining a reduction in anticholinergic burden. If tapering off is preferred, a tapering schedule individualized to the patient and the drug is recommended. Discuss the taper schedule with the patient and utilize a calendar to maximize the patient's understanding of the taper schedule. Refer to table 3 for recommendations.

5. Maintain communication with the patient and provider for follow-up and assessment of efficacy. A follow-up date should be set to ensure that discontinuation goals are being met and to address any issues that may arise. Clear communication with the patient and prescriber must occur to minimize confusion and ensure that the deprescribing is sustained long-term.

Considerations for Deprescribing

Evaluating the efficacy of the anticholinergic agents and offering alternative therapy is a crucial component in deprescribing. For example, an overactive bladder is often treated with anticholinergic medications noted in table [3]. However, one retrospective cohort study found that 95% of patients fail treatment after the first four months, and many discontinue them because of intolerable side effects such as confusion, functional impairment, and somnolence[19]. On the other hand, pelvic muscle exercises reduce urinary incontinence in 70% of patients after two to three months of training[20,21]. Presenting the level of efficacy and comparing it to an alternative therapy may increase patients' willingness to discontinue anticholinergic agents.

While there are many non-anticholinergic medication alternatives for allergy, neuropathic pain, and depression, there are limited medication alternatives to urinary incontinence and insomnia medications. Thus, non-pharmacological therapy and lifestyle modification listed in table 3 are imperative when describing anticholinergic use for those conditions. However, pharmacists must consider the cost of alternative medications and lifestyle modifications. Also, there are comorbid conditions or concurrent drug therapies that may contribute to increased side effects or use of anticholinergic agents. As pharmacists are best equipped to optimize medication therapy, all the factors above should be considered for the best health outcome for the patient.

Stop and Reflect:

A patient reports taking diphenhydramine and oxybutynin due to urinary incontinence and waking up in the middle of the night. Their past medical history also includes hypertension. What other drug interactions would you want to inquire about? What medication changes would be beneficial for the patient?

Feedback:

As the pharmacist, you would want to know what medications the patient is taking for hypertension. It is also important to know when the patient takes their medications. In this case, antihypertensive therapy with a diuretic may worsen urinary incontinence and diuretic use near bedtime may cause nighttime voiding, making them wake up in the middle of the night. The pharmacist can also encourage lifestyle modifications, such as pelvic muscle exercises for urinary incontinence, that can eliminate the need for oxybutynin use. The patient might also be interested in trying an alternative to diphenhydramine; an option would be melatonin and sleep hygiene.

Opportunities for intervention by pharmacists

Many pharmacists establish prolonged relationships with their patients, building trust and rapport. With pharmacists' unique role in patient interaction and access to medication lists, pharmacists are the key to identifying opportunities for patient intervention for reducing anticholinergic use and mitigating side effects. Here are some examples of interventions for pharmacists in different patient care settings.

Outpatient:

In an outpatient setting, there are opportunities for intervention when an at-risk patient purchases over-the-counter medications. In addition, the anticholinergic burden should be evaluated when a patient is filling a new prescription with anticholinergic effects. Another proactive intervention is MTM Services. This is a method for pharmacists to be compensated for their services. There are five core elements of MTM services: (1) Medication therapy review, (2) Gathering a personal medication record, (3) A medication-related action plan, (4) Intervention or referral, (5) Documentation and follow-up[24]. MTMs provide a great opportunity to overview all of the patients' medications, comorbidities, and risk factors to determine if the anticholinergic therapies are appropriate or putting the patient at risk for anticholinergic side effects[24]. In addition, it may help bridge any gaps that exist between patients, prescribers, and insurance companies.

Inpatient:

Pharmacists can review a patient's medication list for anticholinergic activity and inform other team members if a new symptom, such as confusion, urinary retention, etc., may be caused or exacerbated due to anticholinergic burden. If a patient were to be of older age, admitted due to falls, has a fall risk, or has any comorbidities that may exacerbate anticholinergic side effects such as impaired cognitive function, the pharmacist can evaluate anticholinergic burden more extensively. During discharge counseling, pharmacists can assess if any anticholinergic side effects are present and offer to counsel about managing those side effects. By educating patients about OTC medications which may have anticholinergic properties, the patients' anticholinergic burden and adverse effects may be reduced as well.

Conclusion

Anticholinergic medications are widely used and their side effects have significant ramifications in the older adult population that can lead to worse health outcomes and quality of life[25,26]. Pharmacists play a crucial role in identifying patients with a high anticholinergic burden due to their unique ability to access medication lists and build personal relationships[27]. There are many points in the patient care process where the pharmacist can screen and intervene for overuse of anticholinergics. Using tools such as ARS, pharmacists in all settings can make an impact on patient care by performing ongoing reviews of patient medications to ensure safety, efficacy, and appropriateness.

The 5-step method for deprescribing may be utilized to provide comprehensive care when an opportunity for deprescribing anticholinergic medication is identified. During this process, the priority should be placed on having an open discussion with the patient to determine the deprescribing goal based on their comfort level and individual health factors. The severity of symptoms, side effects, comorbid conditions, quality of life, and life expectancy should be taken into account[28]. It is important to have a discussion with patients to ensure they fully understand the risks and benefits associated with anticholinergic medications and deprescribing[26]. During this discussion, the pharmacist should be mindful not to discourage a patient from taking anticholinergic medication when the benefit outweighs the risk. With increased awareness and effort to reduce anticholinergic burden, the healthcare team can work together to minimize adverse health outcomes in older adults.

POST-ASSESSMENT QUESTIONS:

1. Which of the following is NOT an alternative therapy recommendation for an anticholinergic medication in neuropathic pain?

a. NSAIDs
b. Gabapentin
c. SNRI
d. PENS

2. Which of the following medications would contribute the most to an ARS score?

a. Cetirizine
b. Meclizine
c. Trazodone
d. Pseudoephedrine

3. Which patient would be at the highest risk of experiencing an anticholinergic side effect?

a. A 23-year-old coming to purchase cetirizine over-the-counter who takes no other medications
b. A 47-year-old patient picking up their maintenance medications: trazodone, ibuprofen, and metformin
c. A 64-year-old patient picking up their maintenance medications: oxybutynin, low-dose aspirin, atorvastatin, and lisinopril
d. A 51-year-old patient coming to purchase Tylenol over-the-counter who takes no other medications

4. What is the correct order for the 5-step method for deprescribing?

1. Assess appropriateness and indication of anticholinergic medication.
2. Set a goal of deprescribing.
3. Maintain communication with patient and provider for follow-up and assessment of efficacy.
4. Recommend alternative pharmacologic and non-pharmacologic therapy to the patient and provider.
5. Identify patients' willingness to modify therapy.

a. 1, 3, 4, 5, 2
b. 2, 1, 5,4 ,3
c. 5, 2, 1, 3, 4
d. 1 ,5 ,2, 4, 3

5. Which of the following is NOT a risk associated with an anticholinergic side effect?

a. Dry mouth leading to difficulty wearing dentures
b. Dry eyes leading to increased risk of eye infections
c. Urinary retention leading to an increased risk of bladder cancer
d. Falls leading to increased risk of bone fractures

6. Which of the following is NOT a potential risk factor to consider when adding additional anticholinergic therapy?

a. Fall risk
b. Rheumatoid arthritis
c. Benign prostatic hyperplasia
d. Impaired cognitive function

7. Which of the following is true regarding Medication Therapy Management?

a. It provides the opportunity to bridge gaps in therapy
b. It is not an effective tool
c. Pharmacists are unable to be compensated for this service
d. It creates gaps in communication

8. Which of the following is NOT a risk factor for more severe side effects following anticholinergic use in older adults?

a. Poor adherence
b. Concurrent medical conditions
c. Multiple anticholinergic medication use
d. Altered mental status at baseline

9. Patient TY's current medication list includes: aspirin, systemic cetirizine, amitriptyline, and topical hydrocortisone. What is her ARS risk score?

a. 0
b. 2
c. 4
d. 5

10. Which of the following is NOT true about anticholinergic drugs?

a. They are used to treat many different conditions
b. Older adults are less sensitive to cognitive adverse effects
c. They can impair cognition and decrease the production of several types of bodily fluids
d. There are non-pharmacologic and over-the-counter treatments to mitigate anticholinergic side effects

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Answer Sheet

2022

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Name: ______________________________

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Birthdate (MM/DD): ______________________________

Completion Date: ______________________________

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PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D	2. A B C D	3. A B C D	4. A B C D	5. A B C D
6. A B C D	7. A B C D	8. A B C D	9. A B C D	10. A B C D

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS __ YES __ NO
FIGURES AND TABLES WERE USEFUL __ YES __ NO
ACHIEVED THE STATED OBJECTIVES __ YES __ NO
POSTTEST WAS APPROPRIATE __ YES __ NO
WAS WELL WRITTEN __ YES __ NO
IS RELEVANT TO MY PRACTICE __ YES __ NO
COMMERCIAL BIAS WAS PRESENT __ YES __ NO IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET
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Staying Alive: An Update on Opioid Use Harm Reduction

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Expiration Date: 10/15/2025
0.15 CEU for pharmacists and technicians

Staying Alive: An Update on Opioid Use Harm Reduction

Martika Martin, PharmD, MBA, BCGP, RPh

Pharmacist Objectives:

- Describe the current formulations of naloxone.
- Discuss the role of harm reduction for opioid use disorder.
- Recommend harm reduction strategies based on a patient case.
- Describe various harm reduction strategies for opioid use disorder.

Pharmacy Technician Objectives:

- List the currently available formulations of naloxone.
- Define harm reduction as it relates to opioid use disorder.
- Describe various harm reduction strategies for opioid use disorder.
- Discuss the benefits of harm reduction for opioid use disorder.

Introduction

It is no secret that Kentucky has a reputation for opioid use disorder and, as a result, high rates of opioid overdoses, fatal and nonfatal. The Kentucky Injury Prevention and Research Center (KIPRC) collects and analyzes data on fatal and nonfatal overdose deaths in the state and presents this information in easy-to-use formats, including an interactive dashboard at https://uky-edu.maps.arcgis.com/apps/dashboards/0317b21f4833452d9b762bf35cfd1656.

While opioid-involved overdose deaths in Kentucky had decreased in 2017 (26.2 per 100,000 population) and 2018 (22.2 per 100,000 population, 2019 (23.4 per 100,000 population), 2020 (37.9 per 100,000 population) and 2021 (53 per 100,000 population) saw an increase in age-adjusted rates of opioid-involved overdose deaths (Figure 1)[1]. Of the 2,251 Kentucky drug overdose deaths in 2021, 1,791 deaths, or 79.6%, involved at least one type of opioid[1]. In 2021, the total number of opioid overdose deaths in Kentucky increased by 12.4% compared to 2020. Of particular concern, opioid overdose deaths increased by 41.1% among black Kentucky residents, compared to 9.3% in white Kentucky residents, signifying the need for more targeted interventions for black individuals[1]. The counties with the highest drug overdose mortality rates in 2021 are shown in Table 1.

Figure 1 Age-adjusted Rates of Opioid Overdose Deaths

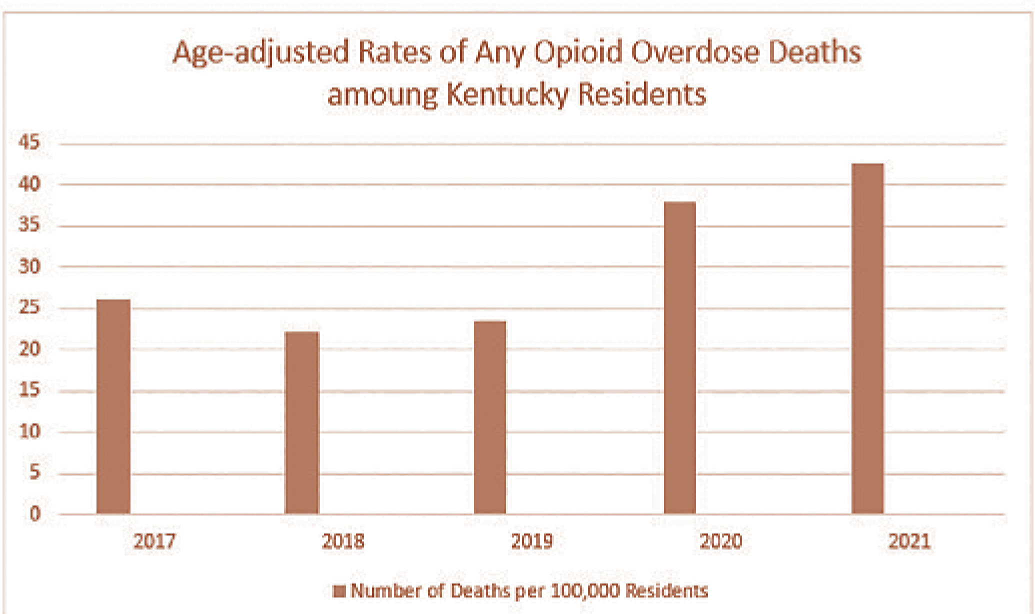


Table 1: Top Ten Kentucky Counties with Highest Drug Overdose Mortality Rates 2021[1]		
County	Rate of Drug Overdose Deaths per 100,000 Residents	Number of Drug Overdose Deaths
Estill	150.3	22
Gallatin	149.2	12
Perry	144.7	35
Rowan	130.5	27
Knott	127.1	16
Montgomery	116.3	30
Carroll	112.2	10
Boyd	106.1	47
Lawrence	102.7	15
Powell	100.9	11

Table 2: Harm Reduction Resources in Kentucky
Kentucky Harm Reduction Coalition
Kentucky Opioid Response Effort
NEXT Distro
Kentucky Harm Reduction Summit
Kentucky Department of Public Health
Kentucky Injury Prevention and Research Center
Kentucky Pharmacists Association
Local Health Departments and Syringe Services Programs
Findhelpnowky.org

Figure 2 Foundational Principles Central to Harm Reduction[4]

Accepts, for better or worse, that licit and illicit drug use is part of our world and chooses to work to minimize its harmful effects rather than simply ignore or condem them.

Understands drug use as a complex, multifaceted phenomemon that encompasses a continuum of behaviors from severe use to total abstience, and acknowledges that some ways of using drugs are clearly safer than others.

Establishes quality of individual and community life and well-being - not necessarily cessation of all drug use- as the criteria for successful interventions and policies.

Calls for the non-judgemental, non-coercive provision of services and resources to people who use drugs and the communities in which they live in order to assist them in reucing attendant harm.

Ensures that people who use drugs and those with a history of drug use routinely have a real voice in the creation of programs and policies designed to serve them.

Affirms people who use drugs (PWUD) themselves as the primary agents of reducing the harms of their drug use and seeks to empower PWUD to share information and support each other in strategies which meet their actual conditions of use.

Recognizes that the realities of poverty, class, racism, social isolation, past trauma, sex-based discrimination, and other social inequalities affect both people's vulnerability to and capacity for effectively dealing with drug-related harm.

Does not attempt to minimize or ignore the real and tragic heam and danger that can be associated with illicit drug use.

KIPRC also collects data on nonfatal opioid overdoses from hospitals and emergency medical services. This is important as the Centers for Disease Control and Prevention (CDC) estimates that 65.9% of drug overdose deaths had at least one potential opportunity for intervention prior to death[2]. Analyzing nonfatal overdoses illustrates some of those opportunities for intervention before a fatal overdose. Between April 2021 through March 2022, there have been 11,830 nonfatal overdoses reported in Kentucky[3]. Through harm reduction, pharmacists, pharmacy technicians, and other healthcare providers can provide those interventions to prevent opioid overdose and death, giving the patient an additional opportunity to seek treatment.

Harm Reduction

According to the National Harm Reduction Coalition, "Harm reduction is a set of practical strategies and ideas to reduce negative consequences associated with drug use. Harm Reduction is also a movement for social justice built on a belief in and respect for the rights of people who use drugs.[4]" (Figure 2). Not all individuals who use drugs are ready and committed to treatment, which decreases their chance of success. Harm reduction is aimed at those individuals who cannot or will not seek treatment for their drug use and to help keep them as safe as possible while using drugs so that in the future, when they are able and willing to get treatment, they may do so. Harm reduction saves lives and ensures those struggling with addiction can get treatment.

Harm reduction for opioid use disorders includes many strategies that address overdose prevention and infectious disease prevention, including:

- Preventing overdoses with naloxone
- Providing fentanyl test strips
- Syringe services programs
- Human immunodeficiency virus (HIV) and Hepatitis C testing
- Safer sex kits
- Sharps disposal and medication disposal kits
- Wound care supplies
- Medication lock boxes
- Education materials on safer injection practices, HIV and hepatitis, and care services[5].

Harm reduction services are meant to be accessible and available in a way that emphasizes compassion toward people who use drugs. Each harm reduction service is an opportunity to connect people who use drugs with healthcare, social services, and treatment. Harm reduction services have been proven to prevent death, disease, injury, overdose, and substance misuse. Benefits of harm reduction services include:

- Connections to overdose education, counseling, treatment referrals
- Provide naloxone to individuals at high risk of opioid overdose or those who might respond to an overdose
- Lessen harms associated with drug use, such as infectious diseases
- Reduce disease transmission among persons who use drugs
- Reduce overdose deaths, promote linkages to care, facilitate co-location of services as part of an integrated network
- Reduce stigma associated with substance use and co-occurring disorders
- Promote hope and healing by using those with lived experience of recovery in managing harm reduction services and connecting those who express interest in treatment to peer support workers and other recovery support services[5].

A list of harm reduction resources in Kentucky is included in Table 2

Naloxone

Initially approved in1971, naloxone is an "opioid antagonist indi-

Table 2: Harm Reduction Resources in Kentucky
Kentucky Harm Reduction Coalition
Kentucky Opioid Response Effort
NEXT Distro
Kentucky Harm Reduction Summit
Kentucky Department of Public Health
Kentucky Injury Prevention and Research Center
Kentucky Pharmacists Association
Local Health Departments and Syringe Services Programs
Findhelpnowky.org

Table 3: Naloxone Warnings and Precautions	
Warning/ Precaution	Formulation
Precipitation of severe opioid withdrawal- naloxone is expected to cause abrupt opioid withdrawal in opioid-dependent individuals. Abrupt reversal of opioid depression after using naloxone may result in nausea, vomiting, sweating, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema, and cardiac arrest.	All[6-9]
Risk of recurrent respiratory and central nervous system depression- the duration of most opioids may exceed that of naloxone resulting in a return of respiratory and/or central nervous system depression after an initial improvement in symptoms. It is necessary to seek emergency medical assistance immediately after delivering the first dose of naloxone and keep the patient under continued surveillance. Additional supportive measures may be helpful while awaiting emergency medical assistance.	All[6-9]
Risk of limited efficacy with partial agonists or mixed agonists/antagonists- reversal of partial agonists or mixed agonists/antagonists such as buprenorphine and pentazocine, may be incomplete. Larger or repeated doses may be required	Nasal sprays[7,8], prefilled syringe[9]
Risk of cardiovascular effects – abrupt postoperative reversal of opioid depression may result in adverse CV effects, primarily occurring in patients with pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in a healthcare setting.	Nasal sprays[7,8], prefilled syringe[9]
Risk of accidental needlestick injury – after use, the needle of the prefilled syringe is exposed until the safety guard is deployed. Stress to patients the importance of familiarizing themselves with the device and its operation before experiencing an emergency, and to immediately seek medical attention should a needlestick occur.	Prefilled syringe[9]

cated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and central nervous system depression.[6]" Often known as the overdose reversal drug, naloxone works by competitively blocking opioid receptors during an opioid overdose. Good Samaritan Laws in Kentucky protects bystanders or those who administer naloxone in good faith to a person suspected of an opioid overdose. The warnings and precautions of naloxone are listed in Table 3.

In 2015, Kentucky authorized pharmacists, with specific training, to dispense naloxone per a protocol. The Department of Public Health created a statewide protocol for pharmacists to dispense naloxone. This allowed increased access to naloxone to patients at high risk of overdose and individuals who may have to respond to an opioid overdose. At the time, the primary formulation of naloxone that was commercially available was generic naloxone 0.4mg/mL for injection. Because it was only labeled for intravenous, intramuscular, or subcutaneous use, the earlier formulations of naloxone were not ideal for administration by non-medical professionals. As a result, many pharmacists provided off-label naloxone kits that included the naloxone for injection in a prefilled syringe and a mucosal atomizer device. Patients were instructed to spray half of the volume of the syringe, approximately 1 mL, into the nostril using the atomizer.

In November 2015, naloxone 4mg nasal spray (Narcan®) became the first commercially available nasal spray that non-healthcare professionals could easily use. Additional formulations and strengths have recently become available, including a generic nasal spray. Table 4 summarizes the available formulations of naloxone. In an effort to increase naloxone to patients and other individuals who can assist in an overdose, the Kentucky Opioid Response Effort

Table 4: Currently Available Forms of Naloxone for Non-Healthcare Professionals
Naloxone 4mg nasal spray (Brand Narcan® and generic)
Naloxone 8mg nasal spray (Brand Klaxxado™)
Naloxone 5mg prefilled syringe (Brand Zimhi™)

(KORE) maintains a mobile harm reduction unit and participates in community events, such as the Kentucky State Fair and events hosted by local health departments, to provide education on, and dispense naloxone. Since the KORE grant began in 2017, 168,187 two-dose units of naloxone have been dispensed.

Naloxone hydrochloride nasal spray

The United States Food and Drug Association (FDA) approved the first generic naloxone hydrochloride nasal spray on April 19, 2019. Commonly known as Narcan®, this naloxone nasal spray is available in a 4mg spray to be administered in one nostril in case of a known or suspected opioid overdose[7]. Individuals can administer it without medical training. The sprays are dispensed in a package of two, allowing for a second dose to be administered, preferably in the alternate nostril, if needed[7]. Because naloxone has a shorter duration of action relative to the opioid, a patient administered naloxone should remain supervised to watch for recurrent respiratory and central nervous system depression while emergency medical assistance arrives[7].

On April 20, 2021, the FDA approved the higher dose of naloxone HCl spray (Kloxxado™). This nasal spray provides an 8mg dose of naloxone intranasally to adults or pediatric patients for the emergency treatment of known or suspected opioid overdose8. Like the 4 mg naloxone nasal spray, the 8 mg dose can be repeated every 2-3 minutes, using alternating nostrils, until emergency medical assistance arrives[7,8]. Both the 4mg and 8mg naloxone nasal sprays have the same warnings and precautions, including the risk of recurrent respiratory and CNS depression, risk of limited efficacy with partial agonists or mixed agonist/antagonists, precipitation of severe opioid withdrawal, and risk of cardiovascular effects[7,8].

Naloxone hydrochloride injection

When first approved by the FDA in 1971, naloxone was supplied as single or multi-use vials or single-use ampules to be used intramuscularly, subcutaneously, or intravenously, which was not conducive to administration by non-healthcare professionals. Commercial products have been approved since to make the administration of injectable naloxone easier for individuals without medical training. In 2016, the FDA approved an autoinjector to provide 2mg of intramuscular or subcutaneous naloxone HCl (Evzio®). Each package contained 2- 2mg auto-injectors and a single trainer. This autoin-

Figure 3 Administration of naloxone prefilled syringe[9]

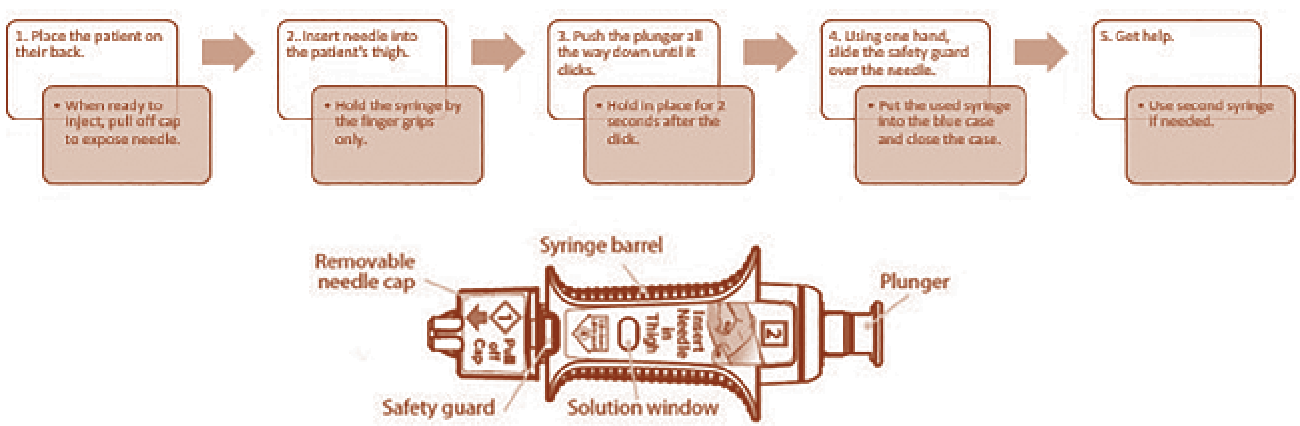
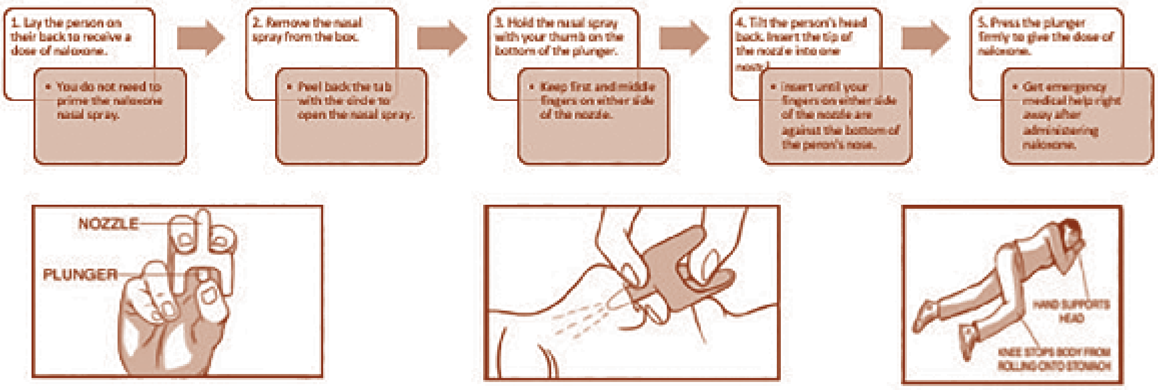


Figure 4 Administration of naloxone nasal spray[7,8]



jector contained a speaker that provided voice instructions to guide the user through the injection process[10]. This was the highest-priced naloxone product at the time. Currently, the manufacturer has discontinued the medication and its generic. According to the U.S. Department of Justice, in 2021, the manufacturer of this naloxone autoinjector agreed to pay $12.7 million to resolve allegations that the manufacturer caused the submission of false claims related to the naloxone autoinjector[11].

A prefilled syringe containing a 5mg dose of injectable naloxone (Zimhi™) was approved by the FDA in October of 2021, providing an additional option for patients. It is also approved for the emergency treatment of known or suspected opioid overdose in adult or pediatric patients[9]. Because it is an injection, it has the additional warning of accidental needlestick injury[9]. Patients should be cautioned that the needle is exposed until the safety guard is deployed. Administration steps for the naloxone prefilled syringe and nasal sprays are included in Figures 3 and 4.

Fentanyl Test Strips

Illicitly manufactured fentanyl has now outpaced prescription opioids and heroin as the most frequently detected drug in overdose deaths in Kentucky, as evidenced by the presence of the precursor 4-aniline-N-phenethylpiperidine, abbreviated 4-ANPP (Table 5)[3]. As fentanyl is more potent than many prescription opioids and heroin, individuals who use drugs are at a higher risk of overdose and death, especially if they are unaware of the fentanyl in the

Table 5: Most Frequently Detected Drugs among Kentucky Overdose Decedents Q2 2021- Q1 2022)[3]

Drug	Number
Fentanyl	1,639
4-ANPP	1,362
Methamphetamine	1,075
Amphetamine	945
Gabapentin	503
THC	464
Ethanol	393
Morphine	309
Cocaine	300
Acetylfentanyl	256

substances they are using sold as heroin or counterfeit painkillers. One survey of individuals currently on medication for opioid use disorder found that 77% of respondents reported the likelihood of past unintentional fentanyl use[12]. According to the CDC, deaths involving synthetic opioids, including fentanyl and fentanyl analogs, have increased by over 56% from 2019 to 2020[13].

Since individuals may not be aware that the drugs they are using have been adulterated with illicitly manufactured fentanyl, the CDC and SAMHSA have encouraged harm reduction programs to provide individuals who use drugs with rapid fentanyl test strips (FTS). FTS allows individuals who use drugs the opportunity to detect traces of fentanyl in substances before use and enables them to make their own choices regarding their overdose risk[14]. Harm reduction programs in San Francisco, California, have found that providing FTS:

- Provide a useful engagement tool to encourage discussion with people who use drugs about universal precautions and anticipating fentanyl in their drug supply.
- FTS are easy to use by people who inject drugs with minimal instruction and people who use drugs respond positively to the availability of FTS.
- Fentanyl is increasingly present in various drug supplies.
- FTS allow people who use drugs to be informed about the drugs they buy and sell, encouraging behavior change and adopting more harm reduction measures, including sharing information with others.
- FTS allows healthcare providers to engage better with non-injectors and non-opioid users on overdose prevention, leading to increased naloxone trainings with non-opioid users.
- Persons who use drugs are more likely to implement one or more harm-reduction strategies when learning that their drugs contain fentanyl.
- FTS use increases general awareness and understanding of fentanyl among persons who use drugs and healthcare providers[18].

Fentanyl test strips were initially designed to detect fentanyl and its major metabolite, norfentanyl in urine. These strips are user-friendly (Figure 5), inexpensive, and give immediate test results. A study looking at the selectivity and sensitivity of 4 brands of fentanyl test strips found that the strips were broadly sensitive and recognized 15-22 of 28 fentanyl analogs. Still, the results were highly dependent on the concentration and therefore suggested that the tests be interpreted less rigorously than suggested in manufacturers' guidelines[15]. FTS should not be relied upon to detect the presence of carfentanil[16].

A study in Rhode Island identified the benefits of FTS in people who use drugs. The study found that overall, participants regarded FTS positively, finding the FTS easy to use and that they provided valuable information[16]. The information was especially valuable when a dug supply source was deemed untrustworthy. Some subjects in the study redistributed FTS to people they considered at high risk of using a drug contaminated with fentanyl[16]. Participants in the study valued the ability to test their drugs privately rather than at a local health organization, a common practice in other countries, such as supervised injection facilities in Canada. Of importance, participants in the study reported adapting their behavior as a result of a positive result from an FTS, including sharing information about the potential of fentanyl contamination (Figure 6)[16].

There are important counseling points when educating a patient on FTS. It is especially important to note that FTS do not provide information on the amount of fentanyl in a sample and that FTS may return false negatives. Patients should be counseled that a negative result does not mean an absence of overdose risk, and positive results do not indicate the amount of fentanyl present, so caution should be used.

In Kentucky, FTS are considered drug paraphernalia under Kentucky Revised Statute 218A.510. However, individuals wishing to obtain FTS for free may do so through syringe services programs or the partnership with KORE, the Kentucky Harm Reduction Coalition, and Next Distro at https://nextdistro.org/kyfentstrips.

Syringe Services Programs

In 2015, Kentucky enacted Senate Bill 192. The bill established the process for local health departments to implement syringe services programs (SSPs), known as syringe exchange programs[19]. SSPs are programs that provide sterile needles, syringes, and other drug preparation equipment and disposal services to persons who inject drugs.

Figure 5: How to Use Fentanyl Test Strips[17]

1. **Dissolve a small amount of drug in water. Then dip a test strip in the liquid for 15 seconds. Only a small amount of drug is needed.**
2. **Set the test strip on a flat surface until the results appear. Usually within 5 minutes.**
3. **One line indicates fentanyl is present in a sample. Two lines means there is no fentanyl detected.**

Figure 6: Reducing Overdose Risk with Fentanyl[14]

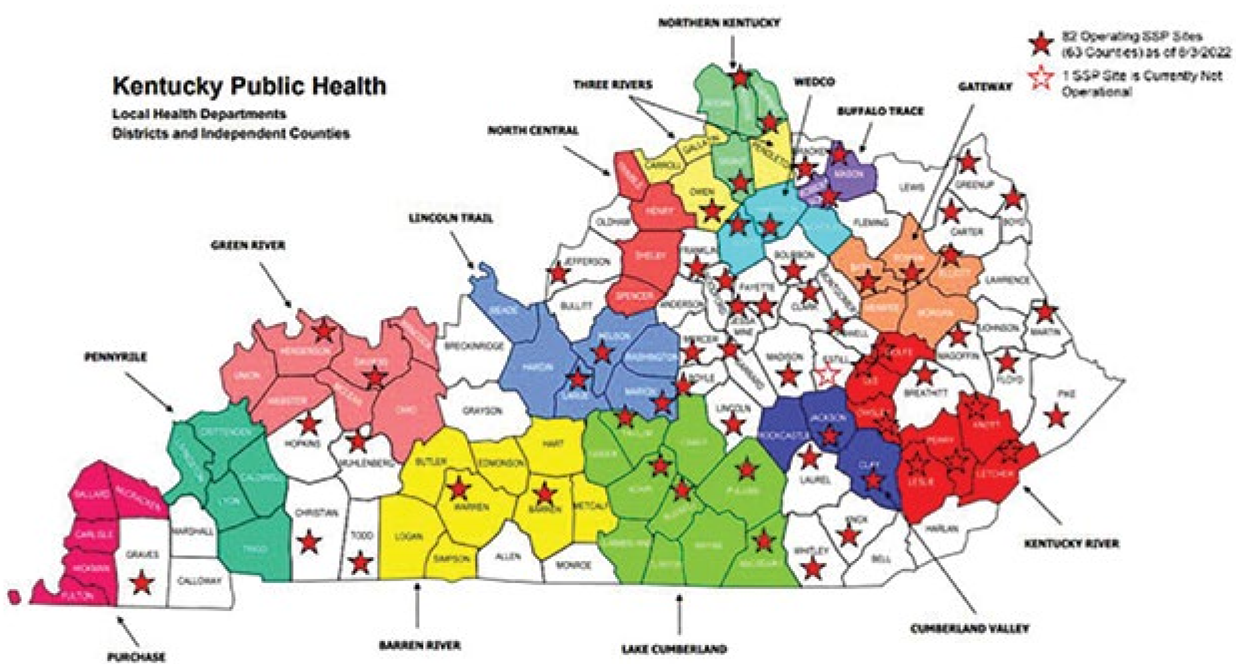
Use slow and use less. Fentanyl is more potent than heroin. Overdoses can occur quickly, sometimes before a person has finished injecting the dose.
Try snorting or smoking instead of injecting. Injecting has the highest risk of overdose. Snorting or smoking may reduce the risk. A person can still overdose by snorting or smoking, so start slow.
Space out doses. Take time between doses because fentanyl acts quickly and acts differently for everyone.
Practice extra caution when using alone. Try to have someone you know check on you if you must use alone so they can intervene in the event of an overdose.
When using in a group, stagger use. Make sure someone is always alert and that at least one person has naloxone on them.
Test it. Knowing what is in drugs can help with the decision of how much and how best to use them.
Always carry naloxone. Be familiar with the signs of an overdose and be ready to respond.
Listen to your body. Overall health influences overdose risk. Stay hydrated, eat, and rest as much as possible.

The CDC lists the goals of SSPs, which include:

- Prevent transmission of blood-borne infections
- Reduce or stop substance use
- Prevent overdose deaths
- Reduce publicly discarded needles
- Increase HIV and sexually transmitted infections treatment initiation and retention[22].

SSPs may also provide other harm reduction services such as:

- Sexual and injection risk reduction counseling
- HIV, viral hepatitis, sexually transmitted infections, and tuberculosis screening.
- Provision of naloxone
- Referrals and linkage to care and treatment for HIV, viral hepatitis, sexually transmitted infections, and tuberculosis
- Referral and linkage for hepatitis A and B vaccination
- Referral to treatment for substance use disorders, mental health services, physical health care, social services, and recovery support services[20].



One of the significant benefits of an SSP, as studied over decades of research, is the reduced risk of acquiring injection diseases from sharing needles, such as hepatitis C. A Cochrane Library meta-analysis of the impact of high exposure to SSPs in Europe showed a 76% reduction in the acquisition risk of Hepatitis C21. According to the CDC, syringe services programs are associated with an estimated 50% reduction in HIV and hepatitis C incidence. By combining SSP with medications for opioid use disorder, the risk of HIV and hepatitis C transmission is reduced by greater than two-thirds[22]. Because of the high expense of treating infectious diseases such as HIV and hepatitis C, SSPs have shown to be cost-effective[24].

A study examining SSP use in three rural Kentucky counties found that 97% of participants were repeat SSP users, indicating that SSPs provide multiple opportunities for interventions for this population[23]. Of the participants in the study, 66% met the criteria for past 90-day severe substance use disorder and 78% reported severe mental distress in the past 90-days, demonstrating the importance of expanded services, such as referrals to mental healthcare in SSPs[23]. The authors also found that participants in the SSPs displayed high levels of substance-related problem recognition and moderate levels of confidence to change, illustrating the value of SSPs in referring to treatment as these patients are likely ready to begin making changes in their substance use[23].

In Kentucky, there are 82 operating SSPs in 63 counties (Figure 7). There are misconceptions about SSPs that can be a barrier to implementation. Some believed that SSPs would increase the number of syringes left out in the community, posing a risk for needlestick injury. Data from Scott County Indiana Health Department disproves this, showing similar numbers of syringes are received by the SSP for disposal as are supplied[24]. Another concern is that SSPs will increase crime; however, a 2000 study comparing arrest records six months prior and six months after the introduction of an SSP program demonstrated that drug-related arrests were not greater in areas with an SSP than without. SSPs have not been shown to encourage the initiation of drug use or the frequency of drug use among people who use drugs[19].

In June 2021, a change in the regulations in Kentucky regarding the sale of over-the-counter syringes allowed pharmacies to sell syringes without a prescription and without the previously required log that required the identification of the purchaser and the medical need for the syringes[26]. The pharmacy must meet specific requirements regarding patient education to sell the syringes (Figure 8). The new regulation allows greater access to clean syringes without increased stigma. The bill also removed syringes sold by a pharmacist without a prescription and without the logbook from being considered drug paraphernalia[26].

Conclusion

Harm reduction practices benefit people who use drugs by providing interventions and promoting practices that decrease the risk of harm associated with drug use. This includes reducing the risk of overdose and death, as well as the risk of infectious diseases like HIV and Hepatitis C. Harm reduction allows persons who use drugs the opportunity to live and eventually seek treatment when they are ready. Harm reduction strategies include: the provision of naloxone, providing FTS, and SSPS. Pharmacists and pharmacy technicians can promote harm reduction programs in their communities and make referrals to SSPs and providers of FTS. Pharmacists can also make naloxone and clean syringes available in a stigma-free environment.

Figure 8: Requirements to Offer Hypodermic Needles to Any Person Who Wants to Purchase Them

1. Written or electronic educational materials on safe and proper disposal hypodermic syringes and needles.
2. Written or electronic educational or referral information for syringe exchange service programs and substance use disorder treatment.
3. A verbal, physical, or electronic offer to provide a naloxone prescription for opioid overdose.

POST-ASSESSMENT QUESTIONS:

1. Which of the following is a commercially available form of naloxone (select all that apply)?

a. Prefilled syringe with atomizer
b. Nasal spray
c. Prefilled syringe
d. Vial

2. Which of the following is a goal of harm reduction (select all that apply)?

a. Prevent overdose and death
b. Encourage substance use
c. Prevent infectious disease
d. Make it easier for someone to access drugs

3. A person who uses drugs comes to your pharmacy wanting to buy syringes. When told the price for a box of syringes, the patient states they don't have that much money and asks if they can get a lower quantity. What harm reduction service can you recommend to the patient?

a. Naloxone
b. Fentanyl test strips
c. Syringe Services Program
d. Safe injection technique education

4. True or false: fentanyl test strips can detect carfentanyl.

a. True
b. False

5. True or false: Syringe services programs only provide clean syringes to patients

a. True
b. False

6. Which of the following is an important counseling point for fentanyl test strips (select all that apply)?

a. Fentanyl test strips tell a person how much fentanyl is in a sample.
b. A negative result does not mean an absence of overdose risk.
c. Fentanyl test strips can result in a false negative.
d. Fentanyl test strips are not considered drug paraphernalia in Kentucky.

7. Evidence has shown that syringe services programs may:

a. Decrease the risk of acquiring Hepatitis C.
b. Increase the number of syringes left out in the community.
c. Increase the amount of crime in an area.
d. Increase the risk of acquiring HIV.

8. Harm reduction services have been shown to (select all that apply):

a. Provide referrals for treatment for substance use disorder and mental health
b. Lessen the disease transmission among persons who use drugs
c. Increase stigma
d. Discourage people from seeking treatment for substance use disorder

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Answer Sheet

2022

CONTINUING
EDUCATION

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Title: Staying Alive: An Update on Opioid Use Harm Reduction

Name: ______________________________

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NABP eProfile ID #: ____________________________

Birthdate (MM/DD): ______________________________

Completion Date: ______________________________

Please circle: Pharmacist or Technician

UNIVERSAL ACTIVITY #: 0143-0000-22-096-H01-P/T
| **CONTACT HOUR**: 1.5 | **EXPIRES**: 10/15/2025

PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D	2. A B C D	3. A B C D	4. A B	5. A B
6. A B C D	7. A B C D	8. A B C D		

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS	__ YES __ NO	
FIGURES AND TABLES WERE USEFUL	__ YES __ NO	
ACHIEVED THE STATED OBJECTIVES	__ YES __ NO	
POSTTEST WAS APPROPRIATE	__ YES __ NO	
WAS WELL WRITTEN	__ YES __ NO	
IS RELEVANT TO MY PRACTICE	__ YES __ NO	
COMMERCIAL BIAS WAS PRESENT	__ YES __ NO	IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET

UNMET OBJECTIVES: ____

The Kentucky Pharmacy Education & Research Foundation is accredited by The Accreditation Council for Pharmacy Education as a provider of continuing Pharmacy education.

Quick Review of Pharmacy Screenings

0143-0000-22-097-H01-P/T
Original release date: 10/15/2022
Expiration Date: 10/15/2025
0.05 CEU for pharmacists and technicians

Quick Review of Pharmacy Screenings

Martika Martin, PharmD, MBA, BCGP, RPh

Pharmacist Objectives:

- Describe screening tests that can be performed in a pharmacy.
- Evaluate the screening needs of a patient based on a patient case.

Pharmacy Technician Objectives:

- Describe screening tests that can be performed in a pharmacy.
- Evaluate the role of the pharmacy technician in pharmacy screening services

Introduction

Patients visit their pharmacies more frequently than their primary care physicians. According to a cross-sectional study of Medicare beneficiaries, the median number of visits to community pharmacies was 13, while the median number of visits to their primary care physician was seven over a year[1]. This difference was larger in rural areas. This shows that community pharmacies are accessible locations for healthcare. As healthcare payers focus on preventative services, these frequent patient encounters provide many opportunities to offer screening services for many disease states, including hypertension, diabetes, hypercholesteremia, and depression.

Hypertension

An estimated 116 million adults in the United States have hypertension. Of these, 92.1 million adults do not have their hypertension under control[2]. High blood pressure puts patients at increased risk of heart attack, heart failure, kidney disease or failure, vision loss, sexual

Figure 1: Steps for Measuring Blood Pressure

1. **Before measurement, the patient should be seated quietly for at least 5 minutes.**
2. **Have the patient seated at a table, relaxed, but not slouched, with feet flat on the floor. Any other wear such as jackets or sweaters should be removed and sleeves rolled up loosely to the shoulder.**
3. **Have the patient position their arm so that it is resting on the table at heart level.**
4. **Put the cuff on the patients arm. Ensure the correct size of cuff is used. Position the cuff so that they artery marker is aligned over the brachial artery. The cuff should be wrapped in a circular manner. The cuff should fit snuggly and should not slip or come off with gentle tugging.**
5. **Place the head of a stethoscope over the brachial artery and under the cuff.**
6. **Connect the inflation tubing to the monitor. Close the airflow valve and inflate the cuff to about 30 mm Hg above the expected systolic pressure or until you cannot hear the pulse in the stethoscope.**
7. **Slowly release the pressure in the cuff by opening the airflow valve, allowing the pressure to fall by 2-3 mm Hg with each heartbeat.**
8. **As soon as you hear the first pulse beat, note the reading on the gage. This is the systolic blood pressure.**
9. **Continue to slowly deflate the cuff until the sound of the pulse disappears. Once no longer heard, note the reading on the gage. This is the diastolic pressure.**
10. **Provide the patient the results both verbally and in writing.**

Figure 2: Tips for Measuring Blood Pressure[5]

The patient should not eat or drink anything for 30 minutes before taking the measurement.

Have the patient empty their bladder before the measurement if needed.

The patient should be sitting in a comfortable chair with back supported for at least 5 minutes before the reading.

Patient's feet should be flat on the ground and legs uncrossed.

The blood pressure cuff should be snug but not too tight. Preferably, the cuff should be against the patient's bare skin and not over clothing.

The patient should not talk while blood pressure is being measured.

dysfunction, and stroke[3]. The United States Preventative Services Task Force (USPSTF) recommends screening for hypertension in adults aged 18 or older with no known hypertension. USPTF also suggests annual screening for adults aged 40 and older and those at increased risk for high blood pressure[4].

Screening for hypertension is a simple procedure using a sphygmomanometer (blood pressure monitor). This screening can be performed by a pharmacist, pharmacy intern, or pharmacy technician. Patients may already be used to monitoring their blood pressure at home. The steps for measuring blood pressure are listed in Figure 1. Important tips for measuring blood pressure are listed in Figure 2. Blood pressure readings may be affected by nervousness about having blood pressure checked (also known as white coat syndrome), smoking, drinking alcohol or caffeine, exercising within 30 minutes of the blood pressure reading, and how the patient is sitting[5].

After the screening, the pharmacist should educate the patient on their results. The American Heart Association has patient-friendly education using a color system to explain blood pressure measurements (Figure 3)[6]. All patients with elevated blood pressure should be counseled on lifestyle education (Figure 4)[7]. Patients with Stage 1 hypertension (blood pressure between 130-139/80-89 mm Hg) and clinical atherosclerotic cardiovascular disease or estimated 10-year cardiovascular risk of 10% or greater or patients with Stage 2 hypertension (blood pressure greater than 140/90 mm Hg) should be referred for pharmacologic treatment[7].

Diabetes

The CDC estimates that 37.3 million Americans have diabetes. The

FIGURE 3

Blood Pressure Categories

American Heart Association.

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120-129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130-139	or	80-89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

heart.org/bplevels

Figure 4: Lifestyle Recommendations for Hypertension[7]

Weight loss in patients with elevated blood pressure with are overweight or obese.
A heart-healthy diet, such as the Dietary Approaches to Stop Hypertension (DASH)
Sodium reduction
Potassium supplementation, preferably in dietary modification, unless contraindicated by the presence of chronic kidney disease or use of drugs that reduce potassium excretion.
Increased physical activity with a structured exercise program
Limit alcohol consumption no more than 2 standard drinks for men or 1 standard drink for women per day.

CDC also estimates that 1 in 4 individuals with diabetes are unaware that they have diabetes[8]. Screening for type 2 diabetes should begin in all people at the age of 35. Screening for prediabetes and type 2 diabetes should also be considered in adults of any age with a BMI greater than 24 kg/^{m2} or 23kg/^{m2} in Asian Americans (Figure 5). For individuals whose screening tests are normal, screening should be repeated at least every three years or sooner based on symptoms or risk factors[9].

Asymptomatic patients may be screened for prediabetes and type 2 diabetes with an informal assessment of risk factors or a validated risk calculator, fasting plasma glucose, or A1C[9]. All of these screenings could be performed in a pharmacy setting. The CDC has a prediabetes risk test that can be printed or done online to prioritize patients who may need a fasting plasma glucose or A1C test based on risk factors such as age, sex, family history, physical activity, and weight. Fasting plasma glucose can be performed with a blood glucose monitor and there are also A1C CLIA-waived point-of-care tests that can be performed by a pharmacist, pharmacist intern, or pharmacy technician. The procedures of these tests vary by manufacturer; however, they all include a finger-prick with a lancet. For the fasting blood glucose, the patient should not have eaten or drank anything in the past 8 hours, or the test could be falsely elevated.

Table 1 lists the criteria for defining prediabetes and diabetes. Patients

Figure 5: Criteria for Screening for Diabetes or Prediabetes in Asymptomatic Adults[9]

1. **Testing should be considered in adults with overweight or obesity (BMI ≥25 kg/m^2 or ≥23 kg/m^2 in Asian Americans) who have one or more risk factors:**
   - **First-degree relative with diabetes**
   - **High-risk race/ethnicity (e.g. African American, Latino, Native American, Asian American, pacific Islander)**
   - **History of cardiovascular disease**
   - **Hypertension (≥140/90 mm Hg or on therapy for hypertension)**
   - **HDL cholesterol <35 mg/dL and/or triglyceride level >250 mg/dL**
   - **Women with polycystic ovary syndrome**
   - **Physical inactivity**
   - **Other clinical conditions associated with insulin resistance (e.g. severe obesity, acanthosis nigricans)**
2. **Patients with prediabetes (A1C ≥ 5.7%) should be tested yearly**
3. **Women who were diagnosed with gestational diabetes should have lifelong testing at least every 3 years.**
4. **For all other patients, testing should begin at age 35 years.**
5. **If results are normal, testing should be repeated at a minimum of 3-year intervals, with consideration of more frequent testing depending on initial results and risk status.**
6. **People with HIV.**

Table 1: Criteria for Prediabetes and Diabetes

Criteria	Prediabetes	Diabetes
Fasting blood glucose	100-125 mg/dL	≥126 mg/dL
A1C	5.7-6.4%	≥6.5%
Random plasma glucose	n/a	≥200 mg/dL and symptoms of hyperglycemia or hyperglycemic crisis

Figure 6: Cardiovascular Risk Factors[13]
Recent acute coronary syndrome within the past 12 months
History of myocardial infarction
History of ischemic stroke
Symptomatic peripheral artery disease (history of claudication with ankle brachial index <0.85, or previous revascularization or amputation)
Age ≥65 years
Heterozygous familial hypercholesterolemia
History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD events
Diabetes mellitus
Hypertension
Chronic kidney disease (eGFR 15-59 mL/min/1.73m^2)
Current smoking
Persistently elevated LDL ≥ 100mg/dL despite maximally tolerated statin therapy and ezetimibe
History of congestive heart failure

with prediabetes and diabetes should be encouraged to participate in lifestyle changes such as increasing physical activity, reducing carbohydrate intake, and weight management[10]. Diabetes prevention programs, such as the CDC Prevent Type 2 program, have been shown to prevent or delay the progression of prediabetes to type 2 diabetes[10]. Patients with prediabetes may also be referred for metformin therapy. If a patient meets the criteria for type 2 diabetes, they should be referred for pharmacologic therapy[11].

Hypercholesterolemia

Hypercholesterolemia, or high cholesterol, affects nearly 94 million adults over the age of 20 in the United States. Twenty-eight million of these individuals have total cholesterol levels greater than 240 mg/dL and 17% of adults over 20 had high-density lipoprotein levels (HDL or "good cholesterol) levels less than 40mg/dL[12]. High cholesterol increases the risk of heart disease and stroke, among the leading causes of death in the United States[12]. Patients may not be aware of their elevated cholesterol levels because high cholesterol has no symptoms like high glucose levels or high blood pressure can have.
The CDC recommends screening for hypercholesterolemia early in ife, including for children and adolescents. Cholesterol screening should be repeated every five years for people over the age of 20 who are at low risk for cardiovascular disease and more frequently for individuals with cardiovascular disease risk factors (Figure 6). Atherosclerotic cardiovascular disease (ASCVD) risk can be assessed for patients using online calculators, including one from the American College of Cardiology. Pharmacists, pharmacy interns, and pharmacy technicians can perform non-fasting cholesterol measurements using CLIA-waived meters. These require a finger prick from the patient. The 2018 Cholesterol Clinical Practice Guidelines state that in adults 20 years of age or older and not on lipid-lowering therapy, measuring either a fasting or a non-fasting plasma lipid profile effectively estimates ASCVD risk and documenting baseline LDL-C.

Like hypertension and diabetes, lifestyle factors are important in preventing and treating hypercholesterolemia. Patients at risk or with elevated cholesterol should be encouraged to emphasize vegetables, fruits, whole grains, legumes, and healthy protein sources in their diet while limiting their intake of sweets, sugar-sweetened beverages, and red meats[13]. Overweight/obese patients should be encouraged to lose weight and all adults should be advised to engage in aerobic physical activity[13]. Based on patients' ASCVD risk, co-morbidities, and lipid levels, a statin may be indicated (Table 2).

Table 2: Statin Recommendations for Primary Prevention[13]	
Patient Group	Recommendation
LDL-C ≥190 mg/dL, no risk assessment	High-intensity statin
Diabetes mellitus and age 40-75 y/o	Moderate-intensity statin
Diabetes mellitus and age 40-75 y/o and risk assessment	Consider high-intensity statin
Age 40-75 y/o LDL-C ≥70<90 mg/dL	Use 10-year ASCVD risk percent to begin risk discussion: • <5%: lifestyle changes • 5% - <7.5%: If risk enhances present, consider moderate-intensity statin • ≥7.5% - <20%: moderate-intensity statin • ≥20%: high-intensity statin

Figure 7: Patient Health Questionnaire - 9

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tires or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed? Or the opposite- being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Total Score				
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?				
	Not at all difficult	Somewhat difficult	Very difficult	Extremely difficult

Table 3: Potential Billing Codes for Preventative Services[16-20]	
Service	Code
Blood-pressure check	99211 (must involve some evaluation and management of the patient and not done as a part of another evaluation/management service.
Blood glucose check	82962 – blood glucose monitoring by devices cleared by the FDA for home use
A1c	83036QW – measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes 83037QW – measures the percent concentration of hemoglobin A1c in blood, using devices cleared by the FDA
Cholesterol check	82465QW – cholesterol monitoring
Depression screening	96127 – brief emotional/behavioral assessment with scoring and documentation, per standardized instrument
The QW modifier indicates a CLIA-waived test. If the procedure is a preventative service recommended by the USPSTF, Advisory Committee on Immunization Practices, Women's Preventative Services Initiative, or Bright Futures, using modifier 33 should reduce the patient's copay to $0.	
**Check insurance billing requirements before using these codes. **	

Depression

Depression is one of the most common mental health issues in the United States. An estimated 21.0 million adults in the United States had at least one major depressive episode in 2020[14]. Of the adults with a major depressive episode, 66% received treatment in 2020. An estimated 14.8 million adults in the U.S. had at least one major depressive episode with severe impairment in 2020. Prevalence rates vary by sex, age, race/ethnicity, education, marital status, geographic location, and employment status.

The United States Preventative Task Force (USPSTF) recommends screening for depression in all adults regardless of risk factors[15]. One of the most used screening instruments is the Patient Health Questionnaire (PQH) (Figure 7). This is a 2 or 9 question screening that can be completed by a pharmacist, pharmacist intern, or pharmacy technician on behalf of the patient or by the patient. The PQH-2 can be done to identify patients who should complete the entire PQH-9. The PQH-2 is the first two items on the PQH-9.

The primary non-pharmacological treatment for depression is psychotherapy. The patient may need psychotherapy in combination with an antidepressant, so pharmacists must be able to refer patients that screen positive for depression to their primary care provider, psychotherapy treatment, or a psychiatrist for follow-up.

Pharmacy Technician's Role in Screening Services

All of the screenings mentioned above could be performed by a pharmacy technician, with interpretation and counseling performed by the pharmacist. Pharmacy technicians can also assist in identifying patients who are eligible for screenings, schedule patient screenings, and assist in any referrals or follow-up necessary after the screening. Documentation of the screening performed, and the results are vital and a great opportunity for pharmacy technicians. As medical billing becomes more common in the pharmacy setting, pharmacy technicians can also aid in the coding and billing of preventative services. See table 3 for examples of codes to use for the screening services discussed.

Conclusion

Patients tend to have more encounters with their pharmacy than their primary care physician, making pharmacies great places for patients to receive screening services such as hypertension screening, diabetes screening, hypercholesterolemia screening, depression screening, and others. By providing these services, pharmacists and pharmacy technicians can increase the quality of care and create positive health outcomes for patients while advancing their roles as healthcare team members.

POST-ASSESSMENT PHARMACIST QUESTIONS:

1. How often should hypertension screening be performed in a patient with an increased risk of high blood pressure?

a. Weekly
b. Monthly
c. Yearly
d. Every 5 years

2. Which is a validated screening test for depression in adults?

a. PQH-9
b. GAD-7
c. MDQ
d. ASRS

3. A 45 y/o patient with a BMI of 26 presents to the pharmacy for screening services. Patient has a history of depression and diabetes. Medications include metformin and citalopram. Which of the following screening tests is appropriate for the patient?

a. Hypertension
b. Hypercholesterolemia
c. Diabetes
d. Depression

POST-ASSESSMENT TECHNICIAN QUESTIONS:

1. How often should hypertension screening be performed in a patient with an increased risk of high blood pressure?

a. Weekly
b. Monthly
c. Yearly
d. Every 5 years

2. Which is a validated screening test for depression in adults?

a. PQH-9
b. GAD-7
c. MDQ
d. ASRS

3. Which of the following can a technician do to assist in pharmacy screening services? (Select all that apply)

a. Perform the CLIA-waived A1c test
b. Identify patients eligible for screening
c. Counsel the patient on the results of the screening
d. Documentation and billing

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Answer Sheet

2022

CONTINUING EDUCATION

This activity is a **FREE** service to members of the Kentucky Pharmacists Association.
The fee for non-members is $30. Mail completed forms to: KPERF, 96 C Michael Davenport Blvd., Frankfort, KY 40601. Credit will be applied to your CPE Monitor Profile.

Title: Quick Review of Pharmacy Screenings

Name: ______________________________

Email: ______________________________

NABP eProfile ID #: ___________________________

Birthdate (MM/DD): ______________________________

Completion Date: ______________________________

Please circle: Pharmacist or Technician

UNIVERSAL ACTIVITY #: 0143-0000-22-097-H01-P/T | **CONTACT HOUR**: 0.5 | **EXPIRES**: 11/01/2025

PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D 2. A B C D 3. A B C D

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS __ YES __ NO
FIGURES AND TABLES WERE USEFUL __ YES __ NO
ACHIEVED THE STATED OBJECTIVES __ YES __ NO
POSTTEST WAS APPROPRIATE __ YES __ NO
WAS WELL WRITTEN __ YES __ NO
IS RELEVANT TO MY PRACTICE __ YES __ NO
COMMERCIAL BIAS WAS PRESENT __ YES __ NO IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET
UNMET OBJECTIVES: ____

The Kentucky Pharmacy Education & Research Foundation is accredited by The Accreditation Council for Pharmacy Education as a provider of continuing Pharmacy education.

2022 Incentive Grant Program Announces Winners

The Kentucky Pharmacy Education and Research Foundation (KPERF) was honored to award five $1,000 grants this year for projects aimed at patient-centered care by pharmacists and innovative pharmacy practice. KPERF established the grants to provide financial support for research, education, and promotion of innovative pharmacy practice initiatives with a focus on patient-centered services within Kentucky.

Applications for 2023-2024 will open in July 2023.

COVID-19 Test Result Evaluation and Treatment (TREAT): A Pharmacy-Based Pilot Implementation Study
Primary Investigator: Dr. Dustin Miracle
Current Position: UK College of Pharmacy PhD candidate in Pharmaceutical Outcomes and Policy
Co-Investigator(s): Dr. Trish Freeman

Objective: Assess a community-based pharmacy SARS-CoV-2 Test to Treat program both before and after implementing a set of clinical and logistical operational improvement interventions and create a replicable workflow that best meets the needs of both pharmacy stakeholders and patients seeking care

Pilot Site: Poole's Pharmacy Care

Detecting Hypertension – Pharmacy Detection and Counseling Outcomes
Primary Investigator: Dr. Jessica Mills
Current Position: Pharmacist at Owensboro Family Pharmacy
Co-Investigator(s): Daisy Thomason & Ernest Mills

Objective: Identify patients who have not previously been diagnosed with hypertension or patients who are medically managed for hypertension with blood pressure readings not at goal to provide education and resources to improve their blood pressure management and overall outcomes.

Clinic-Based and Community-Based Pharmacy Collaboration to Improve Hypertension Control (CACC-HTN)
Primary Investigator: Dr. MacKenzie Firek
Current Position: PGY-1 UK College of Pharmacy Community-Based Pharmacy Resident with Kroger
Co-Investigator(s): Drs. Brooke Hudspeth, Melody Turpin, Corey Allen, Aric Schadlet, and Clark Kebodeaux

Objective: Determine the impact of a standardized hypertension intervention at the community-based pharmacy (Kroger) to improve control of hypertension at the clinic-based follow-up visit (Bluegrass Community Health Center) and to identify potential adherence barriers to hypertension control.

Implementation of Pharmacist-Led Patient Education and Preventative Care Screening within a Gastroenterology Specialty Office
Primary Investigator: Dr. Suzi Francis
Current Position: Pharmacist and Manager of Ambulatory Clinical Pharmacy at St. Elizabeth Healthcare in Edgewood
Co-Investigator(s): Drs. Paige Harrison and Annie Esselman

Objective: Currently, pharmacists working in St. Elizabeth's Inflammatory Bowel Disease Medication Management Clinic are limited to managing oral and SQ medications. This project aims to expand pharmacist-led patient care to patients receiving infusion therapy at a nearby GI office and collect data to demonstrate the pharmacists' impact.

Implementation of a Pharmacogenomic Testing Service in an Independent Community Pharmacy and Its Impact on Medication Optimization
Primary Investigator: Dr. Nicholas Hudson
Current Position: Fellow with Save Rite Drugs Independent Ownership and Practice Advancement Fellowship Program at Save Rite Drugs in Brandenburg
Co-Investigator(s): Drs. Adam Robinson, Brooke Hudspeth, Scott King, Jamie Wilkey, & NP Holly-Schultz-Pollock

Objective: The project aims to implement and show the benefits of PGX testing at a community pharmacy. The project will look at a patient's PGX profile and then review medication to ensure optimal therapy.

Questions

Please direct any questions to Clark Kebodeaux, Chair of the Kentucky Pharmacy Education & Research Foundation (KPERF), at clark.kebodeaux@uky.edu, or Emily Wilkerson, Executive Fellow, at fellow@kphanet.org.

Local Community Pharmacist Awarded for a Lifetime of Service

KPhA's Board Chair Cathy Hanna and Past-President Representative Joel Thornbury present their friend and colleague Donnie Riley with The Bowl of Hygeia, Pharmacy's most prestigious award.

Russellville native, devout Catholic, and owner of Riley-White Drugs, Donnie Riley, is among this year's Kentucky Pharmacists Association's (KPhA) distinguished award winners.

Riley won the 2022 Bowl of Hygeia Award for his unwavering service to his beloved community. While his commitment to serving others has been seemingly woven through every aspect of his life—personally, professionally, and spiritually—when COVID hit Kentucky, his role as a healthcare provider and business owner soared to unmatched heights.

Long hours and staff shortages created unexpected demand for his employees. Without hesitation, Riley shared the PPE loan with his 30+ employees, ensuring families suffering job loss and increased childcare would navigate the pandemic side-by-side. With businesses closed and people out of work, Riley purchased gift cards from local retail and restaurants and conducted a weekly drawing for his patients.

He bought food at local restaurants and fed the Russellville Police Department, Logan County Sheriff's Department, and the entire staff at Logan Memorial Hospital. Likewise, the Russellville City Street Department, Fire Department and Electric Plant Board, Pennyrile Electric, and several doctor's offices were all recipients of Riley's generosity and kindness throughout the pandemic. All the while, Riley's patients remained his most significant priority, and he kept a pharmacist on call 24 hours a day to meet the medical needs of those they cared for.

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. The Award is presented annually to one pharmacist in each of the 50 states, the District of Columbia, and Puerto Rico. The recipients are selected by their respective associations for their outstanding records of community service. The American Pharmacists Association Foundation and the National Alliance of State Pharmacy Associations sponsored the Bowl of Hygeia Award.

Riley was honored in June, accompanied by his wife Lilian of 43 years and surrounded by over 200 of his peers, at the Ray Wirth Awards Banquet in conjunction with KPhA's Annual Meeting in Lexington. Award winners are nominated by the KPhA members and chosen by the KPhA Organizational Affairs Committee.

"Donnie Riley is a true servant leader," said Dr. Ben Mudd, executive director of The Kentucky Pharmacists Association. "He represents the best of the best, not just in pharmacy but in humanity. Service runs through his blood, and his colleagues feel just as fortunate to be on the receiving end of his grace."

Pharmacy Law Brief

Author:
Joseph L. Fink III, BSPharm, JD, DSc (Hon), FAPhA, Professor Emeritus of Pharmacy Law and Policy,
Department of Pharmacy Practice and Science,
UK College of Pharmacy

Question: I recall several incidents in recent years where "friends" of a high-profile individual released audio recordings of the person making highly inappropriate remarks. The speaker clearly did not consent to either the recording or its release to the public. In a pharmacy context, is it permissible for a disgruntled patient, or perhaps even an unhappy employee, to covertly record a conversation, either in person or over the phone, without the knowledge of the other person and then release that or even use it in court or during an administrative proceeding? What's the law in Kentucky on that?

Response: The first response is to refer one to an excellent piece covering some of these issues by Dr. Scotty Reams that appeared in the Pharmacy Policy Issues column for May/June 2021.[1] A good point of departure for consideration of these issues is the relevant Kentucky statutes. It is a felony to overhear or record, through the use of an electronic or mechanical device, a wire or oral communication without the consent of at least one party to that communication.[2] A person is guilty of eavesdropping when he intentionally uses any device to eavesdrop, whether or not he is present at the time.[3] Doing so is treated as a Class D felony. Divulging information obtained through illegal eavesdropping is a separate crime, punishable as a Class A misdemeanor.[4]

There also is a relevant opinion from the Office of the Kentucky Attorney General: Anyone who inadvertently hears a conversation transmitted through a wireless telephone or a radio receiver does not violate the eavesdropping statute, but if that same conversation is recorded or passed on to others without the consent of a party to the original conversation, a violation occurs.[5]

So, the bottom line in Kentucky appears to be that if the communication is recorded by one of the parties involved in the communication exchange, that would be permissible. That means Kentucky is in the majority of states that use the one-party-consents approach.[6]

Federal law on the point is similar, stating that it is not unlawful "for a person not acting under the color of state law to intercept a wire, oral, or electronic communication where such person is a party to the communication or where one of the parties to the communication has given prior consent to such interception unless such communication is intercepted for the purpose of committing any criminal or tortious act in violation of the Constitution or laws of the United States or any state."[7]

It has been reported that one 2015 study found that 15 percent of patients surreptitiously recorded visits with their physicians and an additional 11 percent reported knowing someone who had done so. A majority, 70 percent, wanted to make such recordings during future visits. Of those, 35 percent would proceed to do so secretly, with an additional equal percentage doing so if given permission.[8]

Patients reported referring back to the recordings to supplement recall as questions arose. The recommended approach is to ask the physician if recording is acceptable, rather than just announcing that it will be done. This is especially appropriate when family or caregivers are unable to accompany the patient to the visit. That reasoning certainly would be equally applicable to exchanges between pharmacists and patients.

How many times have you encountered a patient who asks what the medication being picked up is for, and what is it to treat? Some patients get so intimidated by health professionals and their white coats that information goes in one ear and right out the other. And certainly, it could be that the information was communicated to the patient using terminology with which the patient was unfamiliar. Recordings could help address those situations, giving the patient the opportunity to do Internet searches to get the information.

When you're speaking to a patient and can see the cell phone protruding from his pocket, how do you know whether the "record" feature is activated? You don't, so it is always best to do your best.

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Disclaimer: *The information in this column is intended for educational use and to stimulate professional discussion among colleagues. It should not be construed as legal advice. There is no way such a brief discussion of an issue or topic for educational or discussion purposes can adequately and fully address the multifaceted and often complex issues that arise in the course of professional practice. It is always the best advice for a pharmacist to seek counsel from an attorney who can become thoroughly familiar with the intricacies of a specific situation, and render advice in accordance with the full information.*

Submit Questions: jfink@uky.edu

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Prescription Quantity Changes Require Documentation

Anytime you dispense a quantity different from what was prescribed, you should note why. PAAS National® has seen recoupments when quantities dispensed were **decreased** or **increased** from the original prescribed quantity.

Valid reasons for decreasing quantity include patient request, med sync program, "dispense in original container," and plan limitations. In these situations, you should be documenting the reason on the prescription or within the pharmacy's software. Many PBMs require this documentation, including OptumRx, Express Scripts, Elixir, CVS/Caremark, and MagellanRx, all of which have discrepancy codes related to "cut quantity." The rationale behind these discrepancies is that the PBM believes the pharmacy is trying to acquire excessive dispensing fees and/or circumvent plan limitations. Having documentation stating otherwise is essential.

Contractual obligations must also be taken into consideration when dispensing lesser quantities of a medication. If you are not already aware, PAAS has one of the largest troves of PBM contracts in the nation. PAAS has seen a prominent PBM recently insert language in their extended days' supply agreements that require pharmacies to use "commercially reasonable efforts" to dispense an Extended Days' Supply. Not only does the PBM frown upon cut quantities, but they also want pharmacies intervening to dispense more extended days' supply prescriptions. Evidence to the contrary can result in required corrective action plans and decreased reimbursement on 30 days' supply claims going forward (either at the point of sale, or through the reconciliation process). Indiscriminately changing patients to a 30 days' supply resulting in increased reimbursement for the pharmacy can give the appearance of profiteering and be a slippery slope.

There are also some things to consider when increasing a quantity:

- If your state allows you to change a patient to a 90 days' supply without consulting the prescriber, document accordingly (e.g., increased to 90 DS per state regulation xxx.xx) and ensure you do not go over the original total quantity and refills prescribed.
- If your state does not allow you to increase the quantity, you must contact the prescriber first and make a clinical note about the approval for a quantity increase.
- If the prescriber ordered a quantity less than the smallest package size, you still cannot go over the total quantity and refills prescribed without consulting with the prescriber
    - For example, insulin pens written for a quantity of 3 mL with 2 refills. The total quantity prescribed is only 9 mL. You must clarify the quantity and refills with the prescriber to dispense a full box of 15 mL.

PAAS Tips:

- Document the reason for any quantity change
    - Insurance Limits Quantity (ILQ)
    - Patient requests one-month supply
    - Med sync program
    - Must dispense in original container
- Do not cut the quantity to work around negative reimbursement or to acquire additional dispensing fees
- Do not cut the quantity to work around a plan limit rejection
- If the quantity written is less than the package size, and there are not enough refills to cover the actual quantity, verify the quantity and refills to dispense with the prescriber
- Clinical notes should contain four elements: date, name and title of who you spoke with, what was discussed, and your initials

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By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

A Medication Safety Review

Martika Martin, PharmD, MBA, BCGP

A Medication Safety Review

Homes Study Release Date: 11/1/2022
Expiration Date: 11/1/2025
Knowledge-based
Target Audience: Pharmacists and Technicians
UAN: 0143-0000-22-093-H05-P/T
0.15 CEU for pharmacists and technicians

Pharmacist Objectives:

- Describe the common types of medication errors
- Identify safeguards or prevention efforts that can reduce the risk of medication errors in your practice
- List high-alert and commonly confused medications that may require additional safeguards to prevent errors
- List resources for preventing medication errors

Pharmacy Technician Objectives:

- Describe the role of the pharmacy technician in the prevention of medication errors
- Describe the common types of medication errors
- Identify safeguards or prevention efforts that can reduce the risk of medication errors in your practice
- List high-alert and commonly confused medications that may require additional safeguards to prevent errors
- List resources for preventing medication errors

Introduction

Since the Institute of Medicine's (IOM) report titled To Err is Human, medical errors have been a top priority of healthcare providers, regulators, and payers. Medication errors are one of the most common medical errors, complicated by an increasing number of patients needing medication therapy. It is estimated that at least 1.5 million people are harmed yearly by medication errors, costing the healthcare system billions in additional medical costs. The U.S. Food and Drug Administration (FDA) receives over 100,000 reports associated with a suspected medication error annually through the agency's MedWatch safety and adverse event reporting system.

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer." Medication errors can occur at any point in the medication-use system, from prescribing (or not prescribing), order entry, dispensing, storage, or administration. Medication errors can increase the cost of care resulting in patient harm such as birth defects, hospitalizations, disability or death.

Common types of medication errors

Most healthcare professionals look to the "Five Rights" of medication use when discussing the potential for medication errors (Figure 1).

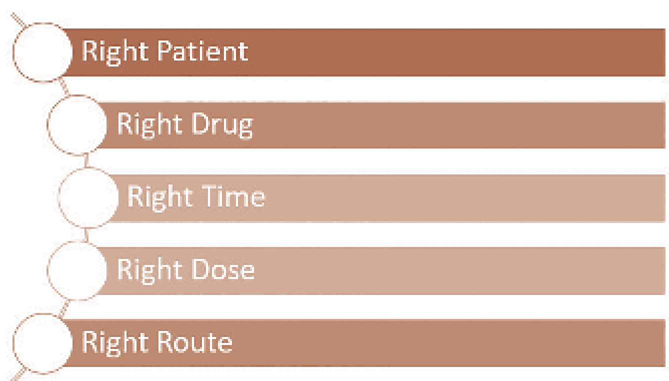
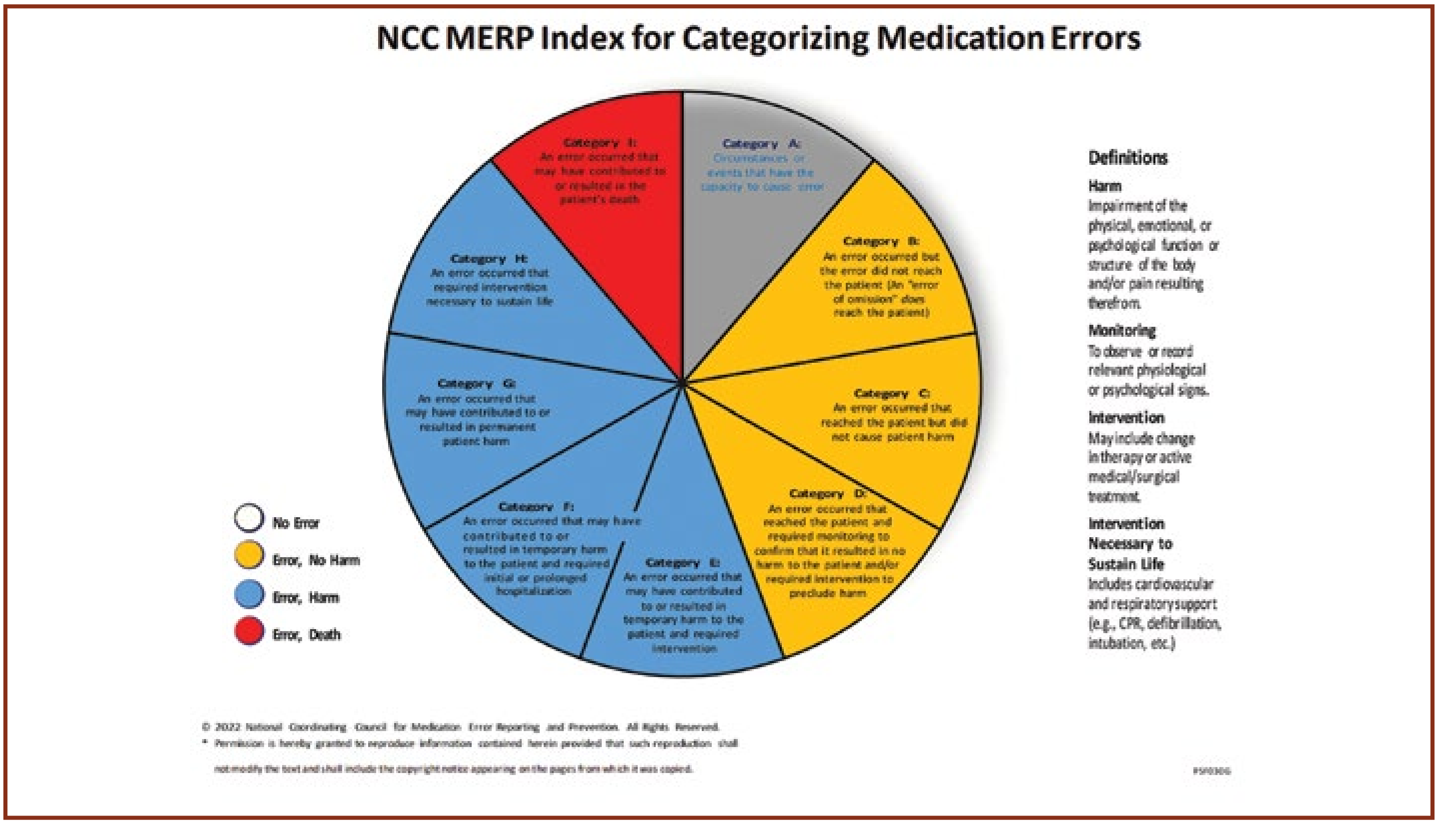


Figure 1: The Five Rights of Medication Use

While a baseline for ensuring patient safety, the "Five Rights" do not consider the entirety of the medication use process. It focuses on an individual's actions, not the entire system the patient and provider are in.

In 1996, the NCC MERP created a standardized categorization for medication errors, called the Medication Error Index (Figure 2). This classifies errors by the severity of the outcome. The Medication Error Index considers factors such as whether the error reached the patient, if the patient was harmed, and the degree of harm. This allows healthcare providers, including pharmacies, to track medication



errors consistently and systematically in order to review policies and procedures that may need to be changed to promote patient safety.

Medication errors can occur at any point in the medication-use system. Generally, medication errors usually occur during one of these processes in the system:

- Ordering/prescribing
- Documenting
- Transcribing
- Dispensing
- Administering
- Monitoring

Approximately half of medication errors occur during the ordering/prescribing stage. These errors could be prescribing the wrong drug, dose, route, or frequency. Of these errors, pharmacists or nurses identify 30-70%.

There are multiple types of errors (See Table 1 for examples). These include:

- Prescribing errors: these errors include the ordering of the wrong drug, dose, route, or frequency.
- Error of omission: a necessary medication or procedure is forgotten or not prescribed.
- Wrong time error: medication was administered at the wrong time.
- Unauthorized drug error: medication is given to a patient without legal authorization.
- Improper dose error: medication was prescribed at too high or too low a dose.
- Wrong dose prescription/wrong dose preparation: patient received the wrong dose of medication on dispensing or the wrong dosage form.
- Administration error: error during the administration of medication.
- Monitoring error: error during the medication monitoring stage.
- Compliance error: error following the protocols or rules for the prescribing or dispensing of medication.

ISMP Top Ten Most Common Medication Errors

The Institute for Safe Medication Practices (ISMP) publishes regular newsletters focusing on frequently reported medication safety issues that could be avoided or minimized with attainable system and practice changes. In 2019 the top ten most common medication errors and safety problems ISMP addressed were:

1. Selecting the wrong medication after entering the first few letters of the drug name.

By entering the first few letters with or without the strength, increases the risk of pulling up a similar-looking drug name on the technology screen (look-alike drugs). As a result, selection errors or entering the incorrect drug is more likely. This type of error can occur during electronic prescribing and order entry. This error has increased in frequency as the use of technology has grown. The frequency has increased so much that wrong selection errors now may meet or exceed those from handwritten orders. Depending on the circumstances, this could result in a prescribing error, unauthorized drug error, wrong dose prescription error, administration error, or compliance error. A very popular case that involved this kind of error and resulted in patient death is described in case 1.

2. Daily instead of weekly oral methotrexate for non-oncologic conditions.

ISMP has addressed the error of daily instead of weekly oral methotrexate for non-oncologic conditions more than 60 times in their safety alerts. This error can occur during the administration by patients who are confused about the frequency of administration or by healthcare providers who prescribed, labeled, and dispensed methotrexate daily when weekly was intended. An analysis by the FDA estimates that up to 4 per 1,000 patients may inadvertently take the drug daily instead of weekly. Daily administration of methotrexate puts the patient at increased risk of side effects and adverse reactions, including life-threatening bone marrow suppression and increased risk of serious infections. Caution and extra counseling should be given to patients also taking folic acid to lessen the toxicity of methotrexate, as round, yellow methotrexate tablets look similar to commonly prescribed folic acid. This could be the result of a prescribing error or could result in a wrong time error, an improper dose error, or a compliance error.

3. Errors and hazards due to look-alike labeling of manufacturer's products.

Look-alike packages and labels are common as manufacturers add graphics, corporate names, and logos that overshadow important information. Packaging with similar cap and label colors make products with similar names and dosages, used in the same setting, and stored together easier to mix up. This increases confirmation bias, in which a person sees what they want to see rather than what is actually there. While the FDA reviews new medication packaging and labeling before the medication reaches the market, these are often larger, two-dimensional proofs that may not readily show vulnerabilities in practice. This can result in unauthorized drug errors or improper dose errors.

4. Misheard drug orders or recommendations during verbal/telephone communication.

The use of electronic orders has decreased the need for verbal or telephone orders, however, in some instances, verbal or telephone orders are still received. Being in a noisy environment with many distractions can increase the chance that the order will be misheard or misunderstood. This can result in a prescribing error, unauthorized drug error, or improper dose error. See case 2 for an example.

5. Unsafe "overrides" with automated dispensing cabinets.

Table 1: Examples of Medication Errors

Error Type	Example
Prescribing error	A prescriber inadvertently selects atomoxetine instead of atorvastatin from the drop-down menu while e-prescribing.
Error of omission	During hospitalization, a patient was started on sacubitril/valsartan for heart failure. During discharge, the new medication is not included on the patient's new medication list.
Wrong time error	A patient was administered furosemide at 8pm instead of 8am.
Unauthorized drug error	A pharmacy technician refills a prescription for a patient despite the prescription having no refills.
Improper dose error	A pharmacist miscalculates the dose of vancomycin for a patient.
Wrong dose prescription/wrong dose preparation	A patient is dispensed betamethasone augmented ointment instead of betamethasone dipropionate cream.
Administration error	A pharmacy intern administers an influenza vaccine subcutaneously instead of intramuscularly.
Compliance error	A pharmacist dose not check a urine-drug screen for opioids before administering long-acting naltrexone.

Case 1: Vecuronium vs Versed
In 2017, a Tennessee nurse used an override to type in "VE" to retrieve a medication from an automated dispensing cabinet. Instead of pulling the ordered medication, midazolam (Versed), for sedation, the nurse pulled vecuronium, a paralytic. As a result of the error, the patient died. Situational factors that may have contributed to the error included a recently updated electronic records system at the hospital that caused delays in medication retrieval from the automated dispensing cabinets. Vecuronium is prepared for administration differently than midazolam and the packaging includes warnings. 1. What type of error(s) was this? 2. Using the NCC MERP Index, what category of medication error is this? 3. What practices or procedure could have aided in the prevention of this error?

Case 2: Misheard Order
A physician calls in a prescription for fluvoxaMINE, but the order was misheard as FLUoxetine. The patient was dispensed fluoxetine. The error was not discovered until their next follow-up appointment a month later. 1. What type of error(s) was this? 2. Using the NCC MERP Index, what category of medication error is this? 3. What practices or procedures could have aided in the prevention of this error?

While automated dispensing cabinets can support safety while allowing access to needed medications, overriding or not utilizing the safety functions can increase the risk of error if the wrong drug is pulled from the cabinet. ISMP identified three unsafe conditions involving removing medication from an automated dispensing cabinet without a pharmacist reviewing the order. These include:

- Overuse of overrides – especially when the override is unnecessary and the risk is not perceived.
- Removal of a drug without an order – this includes pulling a medication in anticipation of an order, but before the order has been verified.
- Removal of an ordered drug from a non-profiled automated dispensing cabinet- this means that the pharmacist may not be notified about the order or have a chance to review the order.

This can result in an unauthorized drug error.

6. Unsafe practices associated with IV push medications.

These errors are generally associated with the preparation and administration of IV push medications. If a medication has more complicated preparation or administration processes, there is a higher likelihood of error. This can result in a medication dose error or medication administration error.

7. Wrong route (intraspinal injection) errors with tranexamic acid.

ISMP states multiple cases of accidental intraspinal injection of tranexamic acid, commonly used to reduce or stop hemorrhage or bleeding. Many case reports appear to result from mistaking tranexamic acid for obstetric spinal anesthesia used for cesarean deliveries, as both are commonly packaged as similar-looking ampules. This can result in an unauthorized drug error or administration error.

8. Unsafe labeling of prefilled syringes and infusions by 503b compounders.

503b compounders are not required to follow FDA labeling of prefilled syringes and premixed IV bags. ISMP received many reports where the strength on the prefilled syringes or premixed IV bags were stated in strength per milliliter instead of the FDA-required strength per total volume, and the strength per milliliter was mistaken for the total amount of drug in the container. There has also been reported confusion with look-alike syringes within the same drug class, unnecessary volume statements, and the product's strength. This practice can result in improper dose errors.

9. Unsafe use of syringes for vinca alkaloids.

ISMP, the National Comprehensive Cancer Network, and The Joint Commission have all urged the FDA to remove administration by a syringe from the prescribing information for vinca alkaloids. All errors reported with vinca alkaloids are from inadvertent administration by

Table 2: ISMP High-Alert Medications in Community/Ambulatory Care Settings
Classes/Categories of Medications
Antithrombotic agents, oral and parenteral, including: • Anticoagulants (warfarin, enoxaparin, heparin) • Direct oral anticoagulants and factor Xa inhibitors (dabigatran, rivaroxaban, apixaban, edoxaban) • Direct thrombin inhibitors (dabigatrain)
Chemotherapeutic agents • Oral and parenteral chemotherapy (capecitabine, cyclophosphamide) • Oral targeted therapy and immunotherapy (Palbociclib, imatinib, bosutinib) • Excludes hormonal therapy
Immunosuppressant agents, oral and parenteral (azaTHIOprine, cycloSPORINE, tacrolimus)
Insulins, all formulations and strengths (U-100, U-200, U-300, U-500)
Medications contraindicated during pregnancy (ISOtretinoin)
Moderate and minimal sedation agents, oral, for children (chloral hydrate, midazolam, ketamine)
Opioids, all routes of administration, including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug
Pediatric liquid medications that require measurement
Sulfonylurea hypoglycemics, oral (chlorproPAMIDE, glimepiride, glyBURIDE, glipiZIDE, TOLBUTamide)
Specific Medications
CarBAMazepine
EPINEPHrine, IM, subcutaneous
LamoTRIgine
Methotrexate, oral and parenteral, nononcologic use
Phenytoin
Valproic acid

the intrathecal route because the medication was available in a syringe instead of the safer minibags. These are administration errors.

10 1,000-fold overdoses with zinc.

This error commonly happens when parenteral nutrition is ordered, especially for pediatric patients. This error can occur because of template default units of milligrams instead of micrograms and when dose warnings are overridden or missing. These are improper doses or wrong prescription dose errors.

High-alert and commonly confused medications

ISMP maintains lists of high-alert and commonly confused medications. The high-alert medication lists are based on practice type (ambulatory, acute care, long-term care).

High-alert medications are drugs with a higher risk of causing significant patient harm when involved in errors. Mistakes may or may not be more common with these medications, but when a mistake happens, it can be more devastating for patients. Table 2 includes the ISMP High-Alert Medications in Community/Ambulatory Care Settings. Table 3 is the ISMP High-Alert Medications in Acute Care Settings. Table 4 is the ISMP High-Alert Medications in Long-term Care Settings.

ISMP's List of Confused Drug Names includes look-alike and sound-alike (LASA) name pairs. This list can be used to identify which medications may need additional strategies to reduce errors and prevent harm. Examples of LASA medications are listed in Table 5.

Prevention of errors and resources

ISMP has multiple resources and information to help strengthen a pharmacy's medication safety procedures to help prevent medication errors. See table 6 for a list of other error prevention resources. Since medication errors can occur at any step in the medication use process, analyzing the pharmacy's current practices and reviewing past mistakes can help identify shortfalls or areas for improvement. Examples of strategies that can be used to reduce the risk of medication errors include:

Table 3: ISMP High-Alert Medications in Acute Care Settings
Classes/Categories of Medications
Adrenergic agonists IV (EPINEPHrine, phenylephrine, norepinephrine)
Adrenergic antagonists IV (propranolol, metoprolol, labetalol)
Anesthetic agents, general inhaled, and IV (propofol, ketamine)
Antiarrhythmics IV (lidocaine, amiodarone)
Antithrombotic agents, including: • Anticoagulants (warfarin, enoxaparin, heparin) • Direct oral anticoagulants and factor Xa inhibitors (rivaroxaban, apixaban, edoxaban, betrixaban, fondaparinux) • Direct thrombin inhibitors (argatroban, bivalirudin) • Glycoprotein IIb/IIIa inhibitors (eptifibatide) Thrombolytics (alteplase, reteplase, Tenecteplase)
Cardioplegic solutions
Chemotherapeutic agents, parenteral or oral
Dextrose, hypertonic, 20% or greater
Dialysis solutions, peritoneal and hemodialysis
Epidural and intrathecal medications
Inotropic medications, IV (digoxin, milrinone)
Insulin, subcutaneous and IV
Liposomal forms of drugs (liposomal amphotericin B) and conventional counterparts (amphotericin B desoxycholate)
Moderate sedation agents IV (dexmedetomidine, midazolam, LORazepam)
Moderate and minimal sedation agents, oral, for children (chloral hydrate, midazolam, ketamine)
Opioids, including: IV Oral (including liquid concentrates, immediate-and sustained-released formulations) Transdermal
Neuromuscular blocking agents (succinylcholine, rocuronium, vecuronium)
Parenteral nutrition preparations
Sodium chloride for injection, hypertonic, greater than 0.9% concentration
Sterile water for injection, inhalation and irrigation (excluding pour bottles) in containers of 100mL or more
Sulfonylurea hypoglycemics, oral (chlorproPAMIDE, glimepiride, glyBURIDE, glipiZIDE, TOLBUTamide)
Specific Medications
EPINEPHrine, IM, subcutaneous
Epoprostenol, IV
Insulin U-500 (special emphasis*) (*All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin)
Magnesium sulfate injection
Methotrexate, oral, nononcologic use
Nitroprusside sodium for injection
Opium tincture for injection
Oxytocin, IV
Potassium chloride for injection concentrate
Potassium phosphates injection
Promethazine injection
Vasopressin, IV, and intraosseous

Table 4: ISMP High-Alert Medications in Long-Term Care Settings
Classes/Categories of Medications
Anti-Parkinson's drugs, including carbidopa, levodopa, and combination products that contain at least one of these ingredients.
Antithrombotic agents, parenteral and oral, including: • Anticoagulants (warfarin, enoxaparin, heparin) • Direct oral anticoagulants (dabigatran, rivaroxaban, apixaban, edoxaban, betrixaban) • Direct thrombin inhibitors (dabigatran)
Chemotherapeutic agents • Oral and parenteral chemotherapy (capecitabine, cyclophosphamide) • Oral targeted therapy and immunotherapy (Palbociclib [IBRANCE], imatinib [GLEEVEC], bosutinib [BOSULIF]) • Exclude hormonal therapy
GABA analogs (gabapentin, pregabalin) used to treat neuropathic pain
Immunosuppressant agents, oral and parenteral (azaTHIOprine, cycloSPORINE, tacrolimus cyclophosphamide, abatacept [ORENCIA], adalimumab [HUMIRA])
Insulins, all formulations, and strengths (U-100, U-200, U-300, U-500)
Opioids, all routes of administration, including liquid concentrates, immediate- and sustained-release formulations, and combination products with another drug
Parenteral nutrition preparations
Sulfonylurea hypoglycemics, oral (chlorproPAMIDE, glimepiride, glyBURIDE, glipiZIDE, TOLBUTamide)
Specific Medications
Concentrated morphine solution (20mg/mL), oral (special emphasis*)
Digoxin, parenteral and oral
EPINEPHrine, IM, subcutaneous
Insulin U-500
Iron dextran, parenteral
Methotrexate, oral and parenteral, nononcologic use (special emphasis*)
Phenytoin
Sacubitril and valsartan (ENTRESTO)
*All routes of opioids, all parenteral and oral chemotherapy, and all subcutaneous and IV insulin are considered high-alert medications. These specific medications have been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with these medications.

Table 5: ISMP List of Confused Drug Names	
acetaminophen	acetaZOLAMIDE
Actonel	Actos
ALPRAZolam	clonazePAM
aMILoride	amLODIPine
ARIPiprazole	proton pump inhibitors
atomoxetine	atorvastatin
buprenorphine	HYDROmorphone
carBAMazepine	OXcarbazepine
cloNIDine	cloZAPine
dexamethasone	dexmedetomidine
dilTIAZem	diazePAM
dimenhyDRINATE	diphenhydrAMINE
DOCEtaxel	PACLitaxel
DULoxetine	PARoxetine
ePHEDrine	EPHEPHrine
Fanapt	Xanax
gabapentin	gemfibrozil
HumaLOG	HumuLIN
HumaLOG	NovoLOG
hydroxyurea	hydrOXYzine
Jantoven	Janumet
LaMICtal	labetalol
lamoTRIgine	levothyroxine
metFORMIN	metroNIDAZOLE
oxyCODONE	oxybutynin
PARoxetine	piroxicam
ribavirin	riboflavin
risperiDONE	rOPINIRole
sAXagliptin	SITagliptin
tacrolimus	tamsulosin
traMADol	traZODone
*This is not the complete list. To view the entire ISMP List of Confused Drug Names visit: https://www.ismp.org/recommendations/confused-drug-names-list	

Table 6: Medication Error Prevention Resources		
Resource	Description	Website
Institute for Safe Medication Practices (ISMP)	Nonprofit organization devoted to preventing medication errors. ISMP runs a voluntary practitioner medication error reporting program, publishes newsletters with error information, and provides tools and guidelines for healthcare professionals.	ISMP.org
National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)	NCC MERP's mission is to maximize the safe use of medications and to increase awareness of medication errors. They provide recommendations and promote improvements in the medication use process to reduce errors.	nccmerp.org
MedWatch	Receives voluntary reports form the public on medication adverse events and publishes safety alerts. Adverse events can be the result of medication errors.	fda.gov/medwatch
Pharmacy associations and State Board of Pharmacy	Pharmacy associations and the Board of Pharmacy may offer resources and guidance on preventing medication errors.	

Procurement:

- When possible, avoid purchasing products with large trademark symbols or corporate logos larger than the product's name.
- When new products are first received, review the product packaging for any unanticipated LASA concerns.
- Determine if the risk of a mix-up will be reduced if LASA drugs are purchased from different manufacturers, and if so, purchase from different manufacturers.
- When possible, stock different concentrations/strengths of drugs with potentially confusing or problematic names.

Prescribing:

- Avoid drug name abbreviations, stemmed names, or other shortened names. Use the full generic name and/or the current brand name.
- If possible, display both the brand and generic name for LASA medications.
- Prebuild order sets with the drug's indication.
- Limit verbal or telephone orders for LASA medications. Use the read-back method to ensure the order was heard correctly.

Dispensing:

- When verifying a medication order, ensure the medication, dose, dosage form, route, and indication make sense. If needed, clarify with the prescriber.
- Employ barcode scanning technology.
- Never rely on a partially turned label or color of the label, cap, auxiliary warning, or company graphics to identify a product. Read the container label to confirm it is the correct product.

Administration:

- Before administration, verify that the medication's indication, dose, dosage form, and route make sense.
- Review the medication's purpose with the patient or car giver BEFORE administration.

Storge:

- Store medications with problematic, error-prone, look-alike and/or sound-alike names in separate physical locations away from each other.
- Change the appearance of LASA medications displayed on shelves and bins, using tall man letters, bold font, different colored font, and/or highlighting or circling differentiating information.

Nomenclature

- For LASA medications, use tall man lettering.
- If short names are permitted to search for products or populate fields without entering the full drug name, require practitioners to enter at least five letters to reduce the number of medications that appear.

Staff Education

- During orientation, and annually, educate staff on the risks of problematic, error-prone, look-alike and/or sound-alike medication names and abbreviations.
- Encourage error reporting.
- Educate on the importance of not overriding safety features or procedures.

Patient Education

- Encourage patients to question medications that look different than expected.
- Require mandatory patient education in the outpatient setting before dispensing medication with a known, problematic LASA name. When possible, open the prescription bottle with the patient to visually confirm the expected medication.

Metrics

- Track and investigate errors in dispensing.
- Establish process and outcome measures and collect data periodically to assess the effectiveness of safeguards intended to reduce medication errors. Act on issues identified during the assessment of these processes.

Resources

There are many resources available to pharmacists and pharmacy technicians to help prevent medication errors in the pharmacy. These include governmental agencies and patient safety groups. Table 6 lists some of the resources available for medication errors.

Pharmacy Technician Role

The pharmacy technician can bring additional safety to the pharmacy and pharmacists. Pharmacists and patients rely on pharmacy technicians to conduct their role with safety at the forefront. To aid in this process, pharmacy technicians can educate themselves on medical/pharmacy terminology and drug names and understand the safety features of the pharmacy dispensing and automation systems, using second identifiers (additional information such as birthdate or address to identify the patient in addition to their name). Drug alerts and other safety features should not be overridden to improve efficiency or to avoid bothering the pharmacist. Remember to refer all alerts that involve medication interactions, allergies, duplications, and other clinical warnings to the pharmacist.

One of the best things pharmacy technicians can do to help mitigate errors, is to report errors and aid in tracking when an error occurs. Error reporting should be non-punitive. Reporting and tracking errors can help identify areas of improvement where additional safeguards or training is necessary. As integral professionals in the medication use system, pharmacy technicians can provide valuable insight into where errors may occur and what solutions are available to decrease the risk.

Conclusion

Medication errors occur regularly in the medication use system. Patient safety should be a priority for all healthcare professionals. As the medication experts, pharmacists and pharmacy technicians can identify potential errors and develop processes and systems to help reduce the frequency of medication errors.

Post-Assessment Questions:

1. **A pharmacy technician fills a prescription for hydralazine 50mg for hypertension with hydroxyzine HCl 50mg. The pharmacist catches the error before it is dispensed to the patient. What type of error is this?**

    a. Prescribing error
    b. Wrong dose error
    c. Unauthorized drug error
    d. Monitoring error

2. **Which of following medications is considered a high-alert medication?**

    a. Insulin
    b. Metformin
    c. Lisinopril
    d. Olanzapine

3. **A pharmacy technician fills a prescription for hydralazine 50mg for hypertension with hydroxyzine HCl 50mg. The pharmacist catches the error before it is dispensed to the patient. What additional safeguards could be implemented to prevent this error from occurring again?**

    a. Using a second identifier to verify the patient
    b. Requiring pharmacists and technicians to type the full name of the drug or at least 5 letters of the drug name when entering a prescription
    c. Encouraging the patient to question medications that look different than expected
    d. Storing look-alike, sound-alike medications away from each other in the pharmacy

4. **Which of the following is a resource for preventing medication safety or promoting patient safety? (Select all that apply)**

    a. ISMP
    b. FDA Orange Book
    c. NCC MERP
    d. MedWatch

5. **In what ways can a pharmacy technician help promote medication safety and prevent errors in the pharmacy? (select all that apply)**

    a. Educate themselves on medical/pharmacy terminology
    b. Bypass drug alerts and safety features to improve efficiency
    c. Handle all alerts for medication interactions themselves
    d. Report errors and near misses

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Answer Sheet

2022

CONTINUING EDUCATION

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Completion Date: ______________________________

Please circle: Pharmacist or Technician

UNIVERSAL ACTIVITY #: 143-0000-22-093-H05-P/T | **CONTACT HOUR**: 1.5 | **EXPIRES**: 11/01/2025

PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D 2. A B C D 3. A B C D 4. A B C D 5. A B C D

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS	__ YES __ NO	
FIGURES AND TABLES WERE USEFUL	__ YES __ NO	
ACHIEVED THE STATED OBJECTIVES	__ YES __ NO	
POSTTEST WAS APPROPRIATE	__ YES __ NO	
WAS WELL WRITTEN	__ YES __ NO	
IS RELEVANT TO MY PRACTICE	__ YES __ NO	
COMMERCIAL BIAS WAS PRESENT	__ YES __ NO	IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET

UNMET OBJECTIVES: ____

The Kentucky Pharmacy Education & Research Foundation is accredited by The Accreditation Council for Pharmacy Education as a provider of continuing Pharmacy education.

CAMPUS CORNER

Paving the Groundwork for Future Success

By: Jenna Brophy, *SUCOPHS Student Representativef 2023*

Sullivan Students participated at KPhA's Fall Conference in Louisville Kentucky

As the field of medicine continues to evolve and change to the needs of patients, the field of pharmacy is also in a state of evolution. Sullivan University is working to meet these ever-growing changes and ensuring students are trained on the latest and greatest, prepared for a life-long career in pharmacy.

APhA-ASP's Vice President, Eden Harmon, recently attended the 7th annual Functional Pharmacy Symposium in Nashville, Tennessee. The symposium focused on current gaps in today's healthcare system involving the prevention, treatment, and management of autoimmune disorders, which presents unique opportunities for current and future pharmacists. Some studies have found that up to 70% of chronic autoimmune disorders result from poor nutritional intake, medication-induced nutrient depletion, and poor lifestyle choices. Eden stated: "My favorite part of the symposium was the discussion on drug-induced nutrient depletion, which occurs with most commonly prescribed medications." The symposium provided resources and step-by-step guides to enhancing patient care. Eden established connections with several pharmacists involved with the Functional Medicine Pharmacists Alliance (FMPhA) and has invited Dr. Lauren Castle, the founder of FMPhA, to Sullivan's campus as part of our Guest Lecture Series.

As pharmacy applicant numbers decrease across the country, Sullivan University is establishing new connections to make the application process easier for students. In partnership with Indiana University Southeast, high school seniors can now apply for a Direct to PharmD program. This program enables high school seniors to obtain their pre-pharmacy prerequisites and their PharmD in five years. Currently, IUS and Sullivan have six students enrolled in the Direct to PharmD program, and KPhA extended an invitation for them to attend the 2022 Fall Conference.

Through the Direct to PharmD program, students can actively engage in their future profession even before beginning classes at Sullivan University. As the program grows, Sullivan is looking forward to admitting more students via the Direct to PharmD program. They also are thrilled to help those students kindle professional relationships by connecting them to KPhA during their undergraduate studies.

Additionally, Sullivan University has recently updated its pre-requisite coursework for PharmD applicants, eliminating the Economics course requirement and decreasing the minimum semester credit hours to 62. These changes were made after extensive discussion across multiple committees and student polling to assess what coursework provided fundamental preparation for success in pharmacy school.

As the field of medicine continues to develop, the necessity grows for the field of pharmacy to fill the gaps and provide communities with easily accessible healthcare providers. Sullivan University is committed to adapting its program to ensure the most up-to-date, skilled healthcare professionals.

CAMPUS CORNER

Pharmacy Student Presents Opioid Research in Denmark

By: Rosa Mejia-Cruz

Pursuing a Ph.D. was not part of the original plan for Dustin Miracle, Pharm.D., M.S. While enrolled in the Pharm.D. program at the University of Kentucky College of Pharmacy (UKCOP), Miracle was accepted to the dual Master of Science in Pharmaceutical Sciences program. The master's program steered his interest in pharmaceutical outcomes and policy, complementing his passion for community pharmacy. With a dual degree under his belt, Miracle now studies health policy processes to improve patient care, including opinions and outcomes regarding community-based pharmacy service provision.

"Community pharmacy was always my goal going into the PharmD program," said Miracle. "I fell in love with the community-based setting while working at an independent pharmacy during my time as an undergraduate student. I have tremendous respect for community pharmacists; they are often the most accessible healthcare professionals in many rural areas. The Ph.D. program now allows me to research the population-level outcomes of expansion of pharmacy services and interventions where previously one would require a clinic appointment."

Part of the expansion of pharmacy services includes protocol-driven contraceptive care for patients. A survey by Miracle showed that community-based pharmacists across the Commonwealth are overwhelmingly supportive of providing prescription hormonal contraception, as well as over-the-counter emergency contraception, to adult patients. Upon publication of the survey, a protocol, drafted with support from UKCOP's Center for the Advancement of Pharmacy Practice (CAPP), was approved by the Kentucky Board of Pharmacy in September 2020. The CAPP team then developed a continuing education program that allows pharmacists to meet the requirements necessary to initiate the dispensing of self-care contraception to adults.

Now a second-year trainee, Miracle received a competitive travel scholarship from the International Society for Pharmacoepidemiology to present his research at the annual meeting in Denmark. "The College has extended incredible opportunities for me to grow as a professional," said Miracle, "and I knew immediately upon visiting UK that this was the best place for collaboration while remaining focused on serving the community."

Opioid research took Miracle across the Commonwealth to thirteen independent pharmacies to validate the accuracy of reported opioid prescription days' supply (the number of days for which a prescription is intended to be used). Some of the more up-to-date national guidelines for chronic pain management currently do not show a preference between as-needed or fixed-dose medication. The research findings showed that the accuracy of the submitted day supply is much lower for any as-needed prescription, which calls into question the quality of the evidence available on as-needed prescriptions. Miracle's findings may impact the public by affecting future national guidelines for prescribing opioids for chronic pain, as opioid use disorder continues to affect the nation.

Miracle presented his project in August 2022 at the ICPE Annual Meeting in Copenhagen, Denmark.

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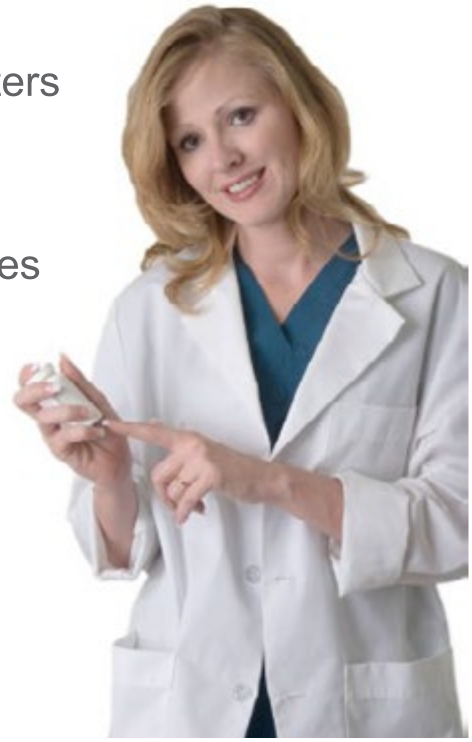

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