Jan 2020 Vol 55 ASHP Midyear 2020 NEWSLETTER

The RWJBH pharmacy residents participated in the 55th annual ASHP Midyear Clinical Meeting (and FIRST virtual meeting) this past December. This meeting is one of the largest gatherings of pharmacy practitioners in the world, hosting more than 25,000 pharmacy professionals annually.

The meeting provided a platform to recruit future residents for the upcoming residency year, and provided opportunities for educational development. The residents attended educational sessions offered during this meeting and summarized the clinical pearls for this newsletter.

RWJBarnabas

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Bite Size Advice for Integrating Life and Career for Busy Pharmacists

Newark Beth Israel RWJBarnabas Medical Center

Summarized by: Ashley Nhan, PGY-1 Resident, Newark Beth Israel Medical Center

Many pharmacists struggle with the demands of work and personal life. This CE was a compilation of 5-minute pearls that presented strategies to achieve work-life balance.

Yoga, Meditation, and Burnout Jill S. Bates, Pharm.D., MS, BCOP, FASHP

- Philosophy that trauma is a somatic issue that is in the body
- Yoga allows you to feel every aspect of your body's sensations and face trauma that has been stored
- The triple threat:
- By implementing yoga practices [asanas (physical postures), pranayama (breath work), and

meditation)] and practicing routine self-care, we can connect with ourselves and others to work toward compassion and life satisfaction

Automating More Than Just Your Refills Michelle Estevez, Pharm, D. DPLA, CPh, BCPS

- Routine, but joyless tasks are prime opportunities for busy
- pharmacists to rethink traditional methods Automate your life to spend your time on things you enjoy
- instead of tasks you are obligated to do Use grocery delivery services like Amazon Fresh, Instacart, and
- Shipt to save on travel time
- Get other essentials delivered (personal care products, pet supplies, clothing)
- Delegate tasks to those able to help you

Tips for Leaving Work on Time Cynthia Jeter, CPhT, BGS

- Consider what you value most: health, family, home,
- emotional well-being, purpose, safety, etc. Parkinson's Law: Work will expand to fill the amount of time
- available. Assign a time limit, break down projects into smaller chunks, decide/delegate/delete
- Compartmentalize tasks into things you can complete monthly, weekly, and daily
- Develop an end-of-day routine: set a reminder 2 hrs prior to quitting time, assign a time limit to answering emails, or set an important appointment that immediately follows work

Working Efficiently for Work Life Integration Angela Slampak-Cindric, Pharm.D., BCPS, BCCCP

- Identify your highest value activities
- Tackle the highest priority task of your day FIRST
- Declutter your to-do: delegate tasks to colleagues or family, utilize time-saving services, set a timer for social media
- Create a to-don't list: e.g. I will not allow email to prioritize my tasks, I will not answer the phone if I am unable to talk
- Change your perspective: "I don't have time for that." \rightarrow "That is not a priority to me.

Maximizing Productivity at Work: Conquering Your Email Delia Charest Carias, Pharm.D., BCPS, DPLA

- Avoid using email as your to-do list or filing cabinet
- Create 3 folders: 1) Archives 2) Follow-up (for responses that take >3 mins) 3) Hold (upcoming meeting agendas, responses you are waiting on)
- Create "rules" to file email for you. Examples include automatically filing email from a specific person, automatically delete out-of-office replies from colleagues
- Conditional formatting: highlight emails, change text size and color to draw your eye to important emails
- Never write the same email twice! Create template emails.

Bye-Bye FOMO: How to Get Rid of the Fear of Missing Out Rena Gosser, Pharm.D., BCPS

- FOMO is associated with lower mood and life satisfaction Signs of FOMO: comparing self to others, always saying yes
- and never saying no, constantly on social media Embrace the JOMO (Joy of Missing Out): focus on fewer tasks
- with more meaning, time is money (don't give it away freely), make a priority list, and reframe how and why you say yes

Professional Organization Involvement Amber J. Lucas, Pharm.D., MBA, BCPS, FASHP

- Professional organizations drive how we change the pharmacy profession, strive for optimal patient care, and are a career obligation
- Many opportunities at the national/state/local level for networking, writing and publishing, and mentoring
- Engagement > involvement: Getting involved means your heart is in it and is not just something to add to your CV. Start small with your engagement and grow.

Designing a Mission and Vision that Spans Both Professional and Personal Life Jessica N. Hill, Pharm.D., BCPS, BCACP

- Mission: how you aspire to serve others and what you will do to get there
- Vision: narrower future-oriented declaration of purpose and aspiration
- Purpose: communicates your reason for being
- These 3 words are interlocking gears that guide you in making decisions every day to live your best life
- Designing a mission and vision statement:

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- Distinguish Dictate Your Destination Successes Values
- Consult a trusted confidant for feedback on your statement

As life changes, so should your vision!

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors in Heart Failure Patients with or without Diabetes

Presented by: Joel C. Marrs, PharmD, MPH, BCACP, BCCP, BCPS, CHC, CLS, FAHA, FASHP, FCCP, FNLA

Sarah L. Anderson, PharmD, BCACP, BCPS, FASHP, FCCP

Prepared by: Brynna Crovetto, PharmD. PGY1 Pharmacy Resident- Robert Wood Johnson University Hospital Somerset.

Background:

In the 2017 ACC/AHA HF Guidelines, there is no mention of the role of SGLT2i in management of HF in patients with and without diabetes. Benefits of SGLT2i include osmotic diuresis and natriuresis which has proven benefits in blood pressure reduction, improved cardiac energetics, decreased arterial stiffness, decreased vascular resistance, decreased weight, decreased uric acid, and decreased oxidative stress. As of May 6th, 2020, the FDA approved Farxiga (dapagliflozin) for the treatment of heart-failure reduced ejection fraction (HFrEF) in adults with and without type 2 diabetes.

ACC 2020 Expert Consensus Decision Pathway on Novel Therapies for CV Risk Reduction in Patients with T2DM

Opportunities to Initiate SGLT2i or GLP1RA with Demonstrated CV Benefit



SGLT2i Meta-Analysis:

In a pre-specified meta-analysis of DAPA-HF and EMPEROR-reduced clinical trials (n=8474), the following was demonstrated:

All-cause death	13% reduction compared to placebo	Pooled HR 0.87, 95% Cl 0.77-0.98 (p=0.018)
CV death	14% reduction compared to placebo	Pooled HR 0.86, 95% CI 0.76-0.98 (p=0.027)
Combined CV death/first hospitalization for HF	26% relative reduction compared to placebo	Pooled HR 0.74, 95% CI 0.68-0.82 (p<0.0001)
Combined recurrent hospitalization for HF/CV death	25% decrease compared to placebo	Pooled HR 0.75, 95% CI 0.68-0.84 (p<0.0001)

Future Directions:

Two trials, DELIVER and DETERMINE-preserved, aim to assess the benefits of SGLT2i in patients with heart-failure preserved ejection fraction (HFpEF).

Change Management: How to Handle Change Before Change Handles You! Calm Amidst the Chaos!

Presented By: Kelli Vrila BBA, BA CRMC, CSP, CCSP. CEO of ENGAGE YOuniversity.

Summarized by: Stephanie Longshaw, PharmD, MS, PGY-2 Pharmacy Resident RWJBH Qualitas Pharmacy

The entrepreneur Walt Disney once said, "Times and conditions change so rapidly that we must keep our aim constantly on the future." As I child, I was mesmerized with antiquated "It's a Small World" and Tomorrow-Land that echoed the space-age dreams of the '60s, and the dazzling geodesic dome of the EPCOT center, chronicling the evolution of the motion picture industry. Fast forward to Midyear 2018 Anaheim, amidst the dazzling lights of Disney Land, networking with pharmacy colleagues, whizzing right along to the All-Virtual Midyear of 2020. Exciting innovations such a tele-health, RFID capsules, and gene therapy emerge on the horizon, amidst a monolith of antiquated yet reliable methods of practicing pharmacy.

With all of these changes, why do organizations have such a hard time doing it? This ASHP seminar presented by Kelly Vril focused on these questions, with multiple strategies in order to enact change at the organizational level. She begins with team building strategies, the mandatory executive buy-in, how to work with the change resistant "super-structured" individuals, or "perfect-worlders" who enjoy their carefully crafted routine within insular silos. Catchy terms such as AQ (adaptability quotient) WIIFM (What's in it for me), filling the GAP, and Texas humor pepper this engaging seminar, along with fill in the blank exercises to achieve change mastery.

The cloverleaf of change in Kelly's model: denial, resistance, acceptance and mastery, resistance, and exploring and understanding came to mind as our patients and physicians adapt to post COVID-19 disruptions in health care, lifestyles, and evolving strategies to combat the pandemic. I thought back to PGY-1 days of transitioning an entire hospital from Pyxis to Omnicell that ran the gamut of emotions! "Whee! Flashy green lights!" to "I want to take a bat to this thing! a seasoned grizzled medic exclaimed. Strategies to delegate responsibility, enhance communication, coping with change, and positive feedback are simply mapped out for pharmacists. I appreciate these quick strategies and catchy tools as a PGY-2, allowing feedback, consensus, and consulting with experts before enacting measures to enhance productivity.

The speaker engages the audience to coin their own change phrases, such as "SW, SW, SW, SW." (Some won't ever get it, some will get it. So what? Some will wait for others to get it.) and to "Shake it up a Little! Get out of the mental complacency zone! Drive a new way home from work!), in order to enact and adapt to change. At the end, Kelly concludes with 44 weekly tips to practice to achieve change such as: "Learning to accept imperfections with 85-95% knowledge in an area. Go out of the comfort zone in bite size pieces! Mental talking stick: understand the perspective of others. People remember 10% of what they hear. 60% of what they read. 90% of what they do!" Kelly provides antiboredom exercises: a visual gag video of an executive meeting room being placed in front of unsuspecting Port-a-Potty users to remind the power of humor with our staff. More serious advice is offered, "What we feed our minds is what we rely upon in a crisis." As we are in leadership roles directing and influencing others, this seminar is great food for thought.

Emergency Medicine Pearls 2020

Angela Antoniello, PharmD, BCPS PGY-2 Emergency Medicine Pharmacy Resident Robert Wood Johnson University Hospital | Rutgers University

Alteplase, Tenecteplase, A New Plase in Therapy? Presenter: Emily Spencer, PharmD

Tenecteplase is a fibrin-specific tissue plasminogen activator that degrades the thrombus fibrin matrix. In comparison to alteplase, tenecteplase has a longer plasma half-life, more fibrin specificity, and a single intravenous push administration. The 2019 AHA/ASA guideline recommends that tenecteplase at a dose of 0.25 mg per kg (maximum of 25 mg) may be a reasonable alternative to alteplase in certain patients as described in the 2018 EXTEND-IA TNK trial. This trial determined tenecteplase's noninferiority to alteplase for brain reperfusion in patients with the following characteristics: acute ischemic stroke, symptom onset within 4.5 hours, no contraindications to fibrinolysis, large vessel occlusion on CT angiography, and eligibility for thrombectomy. Safety protocols should be implemented prior to using tenecteplase for acute ischemic stroke because there are different doses depending on indication, confusing abbreviations (TNK vs. tPA), and the potential for erroneous combination of both fibrinolytics.

Fomepizole Use in Acetaminophen Overdose Presenter: Joseph Plott, PharmD

Acetaminophen is one of the most common overdoses in the emergency department that may potentially lead to liver failure. Glucuronidation and sulfation are the two primary metabolic pathways, whereas only five to ten percent of the drug is metabolized via CYP2E1 to NAPQI, a hepatotoxic metabolite, in therapeutic ingestions. With excessive ingestions, sulfation and glucuronidation pathways become saturated,



thereby leading to excess NAPQI. Fomepizole, dosed as 15 mg per kg intravenously once, may decrease the metabolism of acetaminophen to NAPQI through potent CYP2EI inhibition. Use in humans for acetaminophen toxicity is limited to case reports and case series, but animal studies have demonstrated decreased hepatoxicity. However, fomepizole has demonstrated an overall favorable safety profile in humans when utilized for toxic alcohol ingestions at similar doses.

Prophylactic Antibiotics for Open Fractures Presenter: Spencer Kruggel, PharmD

Open fractures are classified in order of increasing severity from Grades I to III by the Gustilo-Anderson system. Factors considered when grading include wound size, extent of soft tissue damage, bone damage, and arterial involvement requiring immediate repair. The 2011 EAST Guideline recommends cefazolin prophylaxis for a duration of 24 hours with Grades I and II open fractures. Grade III open fracture recommendations include cefazolin plus gentamicin with or without high dose penicillin in cases of fecal or soil contamination. Duration of therapy for Grade III open fractures is 24 hours postwound repair or up to 72 hours post-injury. A 2014 study of a newly implemented protocol resulted in no significant difference in infection rates when gentamicin and cefazolin combination therapy was replaced with ceftriaxone monotherapy for Grade III open fractures. Therefore, ceftriaxone in place of gentamicin and cefazolin in Grade III open fractures may allow for appropriate gram positive and negative coverage, less side effects, no laboratory monitoring, and similar incidences of wound infections.

Specialty Pharmacy Impact: Optimizing Clinical Outcomes in Hepatitis C Negative Transplant Recipients Receiving Hepatitis C Positive Organs

Robert Wood Johnson University Hospital

Holly B. Meadows, PharmD, BCPS; Kristin Beeker, PharmD, MBA; Alicia Carver, PharmD, BCPS, CSP

HaYoung Ryu, PharmD PGY-1 Pharmacy Resident

> REACTIVE TREATMENT

Background

- Increased donor pool with hepatitis C virus (HCV) as a result of deaths due to opioid overdose
- In 2018-2019, approximately 40% of kidneys from HCV+ donors discarded
- In 2019, over 5000 patients died while active on the transplant list waiting for an organ

There have been major advances in clearing HCV with direct-acting antiviral (DAA) therapies, which are far more effective and safer compared to previously used interferon-based regimens. Studies assessing patient outcomes in HCV+ donor to HCV- recipient cases have demonstrated high rates of sustained viral responses (SVRs) with the use of DAAs. Furthermore, transplantation of HCV+ organs in HCV- recipients have shown to decrease waiting time, increase life expectancy and decrease overall healthcare cost.

Management of HCV in HCV- transplant recipients receiving HCV+ organ

- Rapid initiation of DAA regimen immediately following transplant
 - Benefits include risk minimization of complications related to HCV viremia,
 - shorter treatment duration, and elimination of the need for genotyping

PRE-EMPTIVE TREATMENT

- Challenges and critiques include DAA acquisition and funding issues, increased drug interactions, possible DAA failure and resistance, and medication wasting in non-viremic patients
- Initiation of DAA regimen once the recipient tests positive for HCV viremia
- Allows the use of targeted treatment based on genotype
- Benefits include decreased drug interactions, decreased risk of treatment failure and resistance
- Challenges include increased risk of HCV-related complications, the need for genotyping for insurance coverage, and possible treatment delay

AASLD/IDSA: Recommend early initiation of a pan-genotypic DAA in HCV- patients who receive HCV+ organ Available pan-genotypic DAA regimens Factors that guide drug selection

- Available pan-genotypic DAA regimens • sofosbuvir/velpatasvir [Epclusa]
- nroconco of honotic or
 - presence of hepatic or renal impairment
- glecaprevir/pibrentasvir [Mavyret]
 sofosbuvir/velpatasvir/voxilaprevir [Vosevi]
- drug interactions
- insurance formulary/coverage

Role of specialty pharmacy in transplantation of HCV+ organs in HCV- recipients

An integrated specialty pharmacy can provide the resources necessary to allow patients to gain access to and remain adherent to DAA therapy. Service opportunities include: 1) clinical support, 2) medication procurement, and 3) on-treatment support, regardless of which treatment approach is utilized.

Pharmacists can provide support with treatment selection based on individual patient factors and also play a vital role in patient education and adherence to DAA regimen and improve patient outcomes. In addition, specialty pharmacy services can aid in the transition of care by expediting insurance approval (i.e., prior authorization) and identifying resources for financial assistance at the individual level.

CE Title: Using the KIDs List and Checking it Twice!

Date & Time: Tuesday, December 8, 2020 at 10-11am EST

Presenters:

David Hoff, PharmD, BCPPS, FCCP, FPPA Clinical Leader Children's Hospitals and Clinics of Minnesota

Rachel S. Meyers, PharmD, BCPS, BCPPS, FPPA Clinical Associate Professor Ernest Mario School of Pharmacy, Rutgers University

The newest "KID" on the block is the "KIDs List", or the Key Potentially Inappropriate Drugs in Pediatrics, published in *The Journal of Pediatric Pharmacology and Therapeutics* in April 2020.¹ Think about it as the pediatric equivalent of the American Geriatric Society's Beers Criteria.² Prior to the KIDs List, there were relatively few standards or guidelines to support safe and judicious medication use specifically in pediatric patients. Adverse drug reactions (ADRs) occur in about 1.5% of pediatric outpatients and in 16.8% of pediatric inpatients - higher than their adult counterparts.^{1,3-4} They are the cause of 0.4-10.3% of pediatric hospitalizations.³ Moreover, 50% of medications in the U.S. lack labeling in children, leading to poorly-defined dosing strategies that increase the risk of ADRs.⁵ Furthermore, age is correlated with drug pharmacokinetics resulting from changes in absorption, distribution, metabolism, and excretion.¹ The persistent rate of ADRs due in part to unstudied medication use in pediatric patients is necessary. That's where the KIDs List comes along.

From October 2017 to January 2019, a panel of 7 pediatric pharmacists from the Pediatric Pharmacy Association (PPA) evaluated primary, secondary, and tertiary literature; FDA Pediatric Safety Communications; the Lexicomp electronic database; and product information for drugs that should be considered potentially inappropriate for use in pediatric patients (**Figure 1**). Potentially inappropriate medications were defined as "medications or medication classes that should generally be avoided in persons younger than 18 years because they pose an unnecessarily high risk for children and a safer alternative is available." To be included in the List, the medication/class had to have an ADR incidence, frequency, or severity that was greater in the pediatric population than the adult population. Key exclusion criteria included vaccines, devices, herbals, illicit drugs, and pharmacokinetic differences alone. The final list includes 67 medications/classes and 10 excipients, each with a risk/rationale, recommendation, strength of recommendation (weak/moderate/strong), and quality of evidence (very low/low/moderate/high) (**Table 1**).

The KIDs List is meant to serve as an evidence-based guide to improve the safety of medication use in pediatric patients. One example is the "strong" recommendation based on "high" quality of evidence to avoid codeine in children unless pharmacogenetic testing is used, due to the risk of respiratory depression and death in CYP2D6 ultra rapid metabolizers. The List also reviews the risks of excipients like benzoic acid commonly found in preparations of lansoprazole and caffeine. The KIDs List has even helped dispel historical dogma in pediatric care. One notable finding is that the risk of tooth discoloration in patients age < 8 years, believed to apply to all agents in the tetracycline class, apply solely to demeclocycline and tetracycline. Fluoroquinolones were excluded from the List as the risk of tendon rupture and arthropathy applied equally to patients of all ages, and not more-so in children.

The KIDs List is the first iteration of a list of drugs and excipients that should generally be avoided or used with caution in all or select subgroups of pediatric patients. It serves as a tool to improve drug safety in children and a reference to combat historical dogma. The KIDs List has been endorsed by the PPA, Academy of Neonatal Nursing, Institute for Safe Medication Practices, and the National Association of Pediatric Nurse Practitioners. This list is the first step in the ongoing work of clinicians and researchers to continuously improve the safety of pediatric pharmacotherapy. It will undoubtedly help us take better care of our "KIDs."

Written by: Timothy H. Amin, PharmD, PGY-1 Pharmacy Resident at Saint Barnabas Medical Center



Drug	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Ev
Topical corticosteroids (medium, high and very high potency) ^{vecue}	Adrenal suppression; higher rate of systemic absorption in children than adults	Avoid in <1 year for diaper dermatitis	Strong	Low
Tramadol ^{60,80}	Respiratory depression	Caution in children unless pharmacogenomic testing is used	Weak	Low
Tricyclic antidepressants ^{on-na} Desipramine Imipramine	Sudden cardiac death	Avaid In children (desipramme) Caution in children (impramine)	Strong	High (desipra Moderate (Imipramine)
Valproic ecid and derivatives ^{tal-res}	Pancreatitis, fatal hepatotoxicity	Avoid in intents Caution in <6 years	Strong	High
Verapamil ^{es-es}	Asystole	Avoid in <1 year	Weak	Law

References:

- 1. Meyers RS, Thackray J, Matson KL, et al. Key potentially inappropriate drugs in pediatrics: the KIDs list. JPPT 2020;25(3):175-191.
- The American Geriatrics Society Beers Criteria Update Expert Panel American Geriatrics Society 2019 Updated AGS Beers Criteria(R) for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674–694.
- 3. Aagard L, Christenesen A, and Hansen EH. Information about adverse drug reactions reported in children: a qualitative review of empirical studies. *Br J Clin Pharmacol* 2010;70(4):481-491.
- 4. Smyth RM, Gargon E, Krikham J, et al. Adverse drug reactions in children--a systematic review. *PLoS One* 2012;7(3):e24061.
- 5. Sachs AN, Avant D, Lee CS, et al. Pediatric information in drug product labeling. JAMA 2012;307(18):1914-1915.

(Management Case Study) Implementing a Pharmacy Telemedicine Clinical and Residency Training Program During the COVID-19 Pandemic Within a Family Medicine Practice

Presenter: Kevin L. Lee, Pharm.D., AAHIVP <u>Co-Author:</u> Natalie Goode, Pharm.D., BCACP Penn Presbyterian Medical Center Philadelphia, PA <u>Summarized by:</u> Jonathan Gonzalez, Pharm.D., Newark Beth Israel Medical Center

<u>Overview</u>: Penn Presbyterian Medical Center is an entity of the University of Pennsylvania Heath System located in West Philadelphia, PA. The specialty pharmacy operations were initiated in 2012. The pharmacy referral clinic conducts patient visits to optimize care and clinical outcomes for patients with chronic diseases and serves as the longitudinal training environment for their PGY1 pharmacy residents. Due to the increasing rates of COVID-19 infections, leadership advised transitioning to off-site work beginning March 17, 2020 for pharmacy personnel who could work remotely. All patient visits scheduled with the pharmacy referral clinic were to be converted to a secure virtual platform and re-integration of pharmacy residents was the reasonability of the clinical pharmacy team.

<u>Course of Action</u>: The Penn Presbyterian Medical Center clinical pharmacists designed and optimized a remote workflow and converted patients to a secure, virtual telemedicine visit. The most difficult part of this transition was maintaining a level of training for PGY-1 Pharmacy Residents. The clinical pharmacy team worked together with physicians in deciding whether to remain 100% remote or implement a hybrid model of both in-person and telemedicine visits.

Solution:

- 1. Communicated plan for ongoing Pharmacy referral services to all stakeholders
- 2. Developed and piloted a telemedicine workflow
- 3. Optimized the workflow in collaboration with stakeholders
- 4. Standardized and finalized the workflow
- 5. Created a detailed telemedicine workflow specific for the PGY-1 residents
- 6. Provided extensive training and orientation
- 7. Re-integrated residents into the clinic to conduct telemedicine visits
- 8. Collected and evaluated resident feedback
- 9. Conducted monthly reassessment to provide in-person care

<u>Results:</u> The Penn Presbyterian Medical Center pharmacy referral service experienced no gaps or cancellation of scheduled pharmacy clinical sessions. The overall show rates for telemedicine visits were 63% (84/134) over a 60-day period compared to the 51% show rates for in-person office visits over a 60-day period. The clinical pharmacists developed a workflow document which allowed for seamless transition to a telemedicine platform for their residents. The residents believed that their performance with telemedicine visits and virtual preceptor communication was better or no different than in-person visits or face-to-face preceptor communication. The pharmacy residents also thought the training/orientation was useful and preferred a combination of both in-person and telemedicine visits for their training. The

An Unforgettable Session: The Pharmacist's Role in Mild Cognitive Impairment

Presented by: Gina Ayers, PharmD, BCPS, BCGP; Noll Campbell, PharmD, MS; Kristin Zimmerman, PharmD, BCGP, BCACP By: Christine Arquero, PharmD, PGY-2 Geriatric Pharmacy Resident, Saint Barnabas Medical Center

Mild Cognitive Impairment (MCI)	Dementia
white cognitive impairment (wich)	Dementia
 Minor neurocognitive disorder 	 Major cognitive disorder
 Modest cognitive decline with no 	 Significant cognitive decline with
interference with independence in	interference with independence in
everyday activities	everyday activities
 It is not diagnosed in the context of 	 It is not diagnosed in the context of
delirium and not better explained by	delirium and not better explained by
another mental	another mental disorder
disorder	





Annual cognitive screening for patients \geq 65 yrs

- Identifying target patient population, standardizing documentation of results and standardizing process for positive screening
- Mini-Cog Assessment has multiple benefits such as:
- •Pharmacists can administer as there is no required training
- •Available in multiple languages
- •Less educational or cultural bias
- •Patients who test positive for cognitive screening require further assessment

Avoidance of anticholinergic medications for patients with MCI

- Interventions to reduce risk of cognitive impairment may need to occur earlier in life
- •ADR increase with increasing dose or duration of medication
- •Cumulative dose studies suggest each dose contributes to long-term cognitive risk
- Anticholinergic adverse cognitive effects may correlate with time-dependent anticholinergic exposure and may be most significant in patients with higher baseline cognitive status
- •Deprescribing medications with central activity should be performed cautiously with attention to occurrence of withdrawal and symptoms recurrence

Improve care gaps by educating patients on pharmacologic and non-pharmacologic strategies

•No agent is FDA-approved for treatment of MCI

- Acetylcholinesterase Inhibitors (AChI) have been subject of potential benefits in patients with MCI
- •Donepezil, Galantamine and Rivastigmine may or may not be effective for reducing risk of progression
- •Vitamins and supplements may or may not be effective for reducing risk of progression; however, implementing a MIND diet was associated with reduced odds of 12-yr cognitive impairment
- •Exercising with aerobic activity has been tied to improvements in global cognitive ability; however, there is insufficient evidence regarding prevention, delay or slowing of MCI
- •New disease-modifying therapies in MCI emphasize importance of early diagnosis, imaging and biomarkers

System Level Considerations

- •4M framework in MCI allows opportunity for pharmacist to intervene
- •What matters: implications of MCI diagnosis, cognitive conversation, reversion on therapeutic and social decisions
- •Mentation: prevention/risk modification and importance of medication reviews
- Mobility: utilization/interpretation of biomarkers, address improvement/decline in independence
- •Medication: reconciliation, management and alignment of what matters

Addiction in the ICU: Dealing with latrogenic Withdrawal

Presenters: Scott Bolesta, PharmD, BCPS, FCCM, FCCP; Lisa Burry, PharmD, BScPharm, FCCM, FCCP; Marc M. Perrault, PharmD, MSc, BCPS

Prepared by: Savanna San Filippo, PharmD PGY1 Pharmacy Reisdnet, Robert Wood Johnson University Hospital Somerset

Withdrawal is very prevalent in the ICU but data is lacking and is hard to differentiate from delirium, agitation, psychological conditions, and neurologic deficits. Studies are limited to mostly pediatric patients. The few adult studies that have been performed are have inconsistent data in between them. Established associated outcomes in adults include the increased need for mechanical ventilation, increased ICU length of stay and ventilation, and increased outpatient opioid prescribing.

Signs and symptoms of iatrogenic withdrawal syndrome				
CNS	Sympathetic stimulation GI disturbances			
Agitation	Hypertension/ tachycardia	Diarrhea		
Anxiety/ irritability	Tachypnea	Nausea/ vomiting		
Crying	Mydriasis	Gagging		
Grimacing	Sweating			
Muscle aches	Lacrimation/ rhinorrhea			
Confusion and delirium	Yawning			
Tremor	Sneezing			
Seizures				
Sleep disturbances				

	Risk factors in adults					
Duration of exposure	Peak opioid dose	ppioid dose Total opioid and benzodiazepine Speed of total dose		Speed of wea	ning	Medication use prior to admission
	Agents leading to iatrogenic withdrawal					
Opioids	Benzodiaze	Benzodiazepines		detomidine		Steroids

All tools, including the WAT-1, SOS, and NAS, have many limitations in the adult setting. None have been validated in adults and the diagnosis of iatrogenic withdrawal is largely objective. Sensitivity, specificity, and interrater reliability are lacking. The tools do not differentiate well between iatrogenic withdrawal syndrome and delirium. Adults have different symptoms than children and therefore tools do not work well between populations.

Key takeaways:

- Exposure to offending agents in ICU is significant and should be monitored.
- Accurate and complete medication reconciliations are important.
- Improved clinical tools to diagnose IWS and differentiate from delirium are needed.
- More evidence to identify, manage, and prevent IWS is needed, particularly in adults and because research is heterogenic and lacking.

Psyching Out Your Opponent: A Debate on the Use of Antipsychotics in the ICU

Presented by: Paul M. Szumita, PharmD, BCCCP, BCPS, FASHP, FCCM; Jeremy R. DeGrado, PharmD, BCCCP, BCPS Prepared by: Ahmed Nagy, PharmD, PGY-1 Pharmacy Resident

Antipsychotic Medications Should NOT Routinely be Used in the ICU

The pathophysiology of delirium in critically ill patients is multifactorial (e.g. toxic-metabolic or alternation of neurotransmitters) and requires treatment to be multi-modal. Management should include treating the underlying cause, preventing/treating pain, reducing the use of deliriogenic medications, and non-pharmacologic measures. The 2018 SCCM PADIS guideline recommends for pain to be managed with a routine pain assessment and that pain should be treated before sedatives are used. The use of acetaminophen compared to placebo had a lower probability of the development of delirium in patients who had cardiac surgery. PADIS guideline states that the level of arousal may influence delirium and that rapidly reversible delirium is associated with outcomes similar to never experiencing delirium. When the effect of sedation level on the prevalence of delirium was studied, there was a lower prevalence of delirium two hours after a spontaneous awakening trial than when a patient was sedated to a RASS of -2/-3. PADIS also states both modifiable (e.g. benzodiazepine use) and non-modifiable (e.g. age, dementia, etc.) risk factors for delirium.

Medications that should not be used to prevent delirium include haloperidol, atypical antipsychotics, dexmedetomidine, statins, and ketamine as these medications did not show any difference in delirium incidence when used prophylactically. In addition, some of the agents can lead to adverse effects (e.g. increase of QT_c interval with quetiapine). Dexmedetomidine can be useful for treating agitated delirium in ventilated patients when agitation is precluding weaning/extubation. Preventative and treatment strategies are mainly nonpharmacologic and involve multidisciplinary action; correct the underlying cause, early mobilization, use of pain/sedation scales, medication review, promote sleep-wake pattern, and others. ABCDEF bundle consists of <u>A</u>wakening and <u>B</u>reathing trial coordination, <u>C</u>hoice of sedative/analgesics, <u>D</u>aily delirium monitoring, <u>E</u>arly mobility exercise, and <u>F</u>amily involvement. Every 10% increase in bundle compliance increased hospital survival by 15%.

Key Takeaways

- Delirium pathogenesis is multifactorial
- Antipsychotic medications have not proven to be effective to either prevent/treat delirium consistently
- Focus on multicomponent, nonpharmacologic interventions to prevent/treat delirium

Antipsychotic Medications CAN be Used in the ICU

Both presenters accepted the key takeaways from the previous argument. However, the argument here is that there an inconsistency in how trials are evaluated. Providers tend to focus on mortality outcomes and may not realize the importance of other outcomes. In addition, ICU literature is full of inconsistencies such as tight glycemic control, stress dose steroids in septic shock, the neuromuscular blockade in ARDS, and others. Risperidone was shown to decrease the incidence of delirium in patients that underwent cardiac surgery. The use of haloperidol after non-cardiac surgery showed a decreased prevalence of delirium in the first three days after surgery, but the effect became similar to placebo afterward. Both risperidone and haloperidol showed some benefit in reducing the cumulative incidence of delirium and reducing time agitated, respectively, in subsyndromal delirium. If not antipsychotics, other agents that can be used include dexmedetomidine, clonidine, benzodiazepines, barbiturates, opioids, valproic acid, and melatonin. This inconsistent information leads to wondering who should get antipsychotics. Possibly can be used in patients with insomnia with or without delirium. In acute and severe agitation, particularly to avoid respiratory depression in high-risk patients. Also, can be possibly used as a sedative adjunct or to wean off sedatives, but more studies are needed in this area. The other aspect to think about is whether to use typical vs atypical antipsychotics and discuss the benefits/risks of either since they have different side-effect profiles.

Key Takeaways

- Treatment of the underlying etiology of agitation/delirium is essential
- Antipsychotics have a role in acute agitation/delirium and may be useful in high-risk patients
- Antipsychotics may allow dose minimization of sedatives known to accumulate and prolong the duration of mechanical ventilation and ICU length of stay
- Medications added to patients in the ICU for ICU indications need to be weaned when clinically appropriate so that they are not continued on other medical floors

Truth Be Told: Strategies for Setting Expectations in Pain Management

Presenters: Nicole Eye, PharmD, Tanya Uritsky, PharmD, BCPS, and Lee Kral, PharmD Written by: Emily Seidl, PharmD

When 79% of patients are not satisfied with their pain management treatment, clear communication is needed between the patient and the healthcare team. However, little research exists about how to communicate about pain, which can lead to unproductive conversations. Pain is subjective, which makes it difficult to pinpoint an etiology and severity. The ways pain has been assessed is by patient's history of disease states, physical assessment, psychological/social evaluation, allergies, medication history, previous pain medication use, and prescription drug monitoring programs. In the past, this has been the end of the conversation; however, a conversation needs to be had about pain management expectations.

In order to ensure patients have proper expectations when dealing with their pain, a discussion must be had about their goals of treatment. These goals then need to be analyzed to see if they are ideal goals or realistic goals. Ideal goals are ones that are aspirations, desires, and hopes. Many times, these types of goals are unattainable. An example of this is if a patient has had 5/10 back pain for 20 years and their goal is to get to 0/10 pain. There are also normative goals, which are what is expected to happen. For example, after a surgery, how much pain the doctor expects, or what is considered normal. The last type of expectations is predicted. This is when a patient predicts how much pain they will be in from a procedure. An example is a patient expecting to be in a lot of pain from a total knee replacement since his sister had a total knee replacement and was in a lot of pain. Ensuring that goals are more normative is a way to manage expectations for a patient with pain.

Pain management is often complex to treat, and often involves multimodal therapy. Nonpharmacological therapy, such as physical therapy, acupuncture, meditation, or therapy can be very helpful with patients and their perception and management of pain. For pharmacological therapy, there are acetaminophen, non-steroidal anti-inflammatory drugs, gabapentin/pregabalin for neuropathic pain, and antidepressants such as duloxetine and venlafaxine can be used to manage pain. Opioids can be used as well when pain is nociceptive in nature and other modalities have been maximized. This allows for a lower risk of dependence on opioid therapy.

To manage expectations of patients and to ensure patients are adherent to treatment, motivational interviewing is a tool that is used. Motivational interviewing is direct, patient-centered counseling in order to ensure patients are at ease with decisions regarding their therapy and encourages patients to make changes as well. As the provider, the goals of the conversation must be determined before meeting with the patient. The 4 steps of motivational interviewing are Engaging (getting to know the patient), Focusing (what are you changing), Evoking (why you're changing), and Planning (how of change). This will allow patients to have a high level of adherence to their medication regimens, which will help them fulfill the expectations they have for their pain management.

PrEParing Pharmacists to Prevent HIV

Presented by: Elyse Tung, PharmD, BCACP and Renee-Claude Mercier, PharmD, PhC, BCPS-ID, FCCP Summarized by: Lakhini Vyas, PharmD, Clara Maass Medical Center

Pre-exposure prophylaxis (PrEP) is a way for people who do not have HIV but are at very high risk to prevent infection by taking a pill every day. Studies show that PrEP reduces the risk of getting HIV from sex by about 99% and from injectable drugs by at least 74% when taken daily. Pharmacists can play a pivotal role in screening patients for initiation of PrEP and counseling patients appropriately to increase adherence.

Indications for PrEP: CDC Recommendations on Adult Candidates

Men Who Have Sex With Men	Transgender Individuals	Heterosexual Men and Women	People Who Inject Drugs
 HIV-positive sexual partner Recent bacterial STI High number of sexual partners History of inconsistent/no condom use Commercial sex use 	- Engaging in high-risk sexual behavior	 HIV-positive sexual partner Recent bacterial STI High number of sexual partners History of inconsistent/no condom use Commercial sex use High-prevalence area or network 	 Injection of any nonprescribed drugs AND ONE OF THE FOLLOWING: Any sharing of injection or drug preparation equipment in the last 6 months Treatment with methadone, buprenorphine, or suboxone in the last 6 months Risk of sexual transmission

Eligibility Criteria

- HIV negative status confirmed within 7 days of initiation and every 3 months
- Renal function
 - o Truvada requires eGFR > 60 mL/min
 - Descovy requires eGFR > 30 mL/min
- Hepatitis B virus serology: close management required for starting or stopping PrEP in patients with acute or chronic hepatitis B virus infection
 - This is NOT a contraindication to PrEP therapy

FDA Approved Products

	Truvada (Emtricitabine/tenofovir disoproxil fumarate) 200/300mg	Descovy (Emtricitabine/tenofovir alafenamide) 200/25mg
Dose	1 tablet daily	1 tablet daily
Adverse	New onset or worsening renal impairment	Similar profile to Truvada with lower incidence rates
effects	including acute renal failure and Fanconi	due to lower plasma levels of tenofovir alafenamide
	syndrome, decreases in bone mineral density,	
	lactic acidosis and severe hepatomegaly with	
	steatosis	
Drug	High dose or multiple NSAID use,	High dose or multiple NSAID use, aminoglycosides,
Interactions	ledipasvir/sofosbuvir, velpatasvir/sofosbuvir	P-gp inducers and inhibitors

Key Counseling Points

- Take medication daily If dose is missed, take it as soon as you remember. Do not double up.
- Common side effects upset stomach, nausea, headache, loss of appetite, changes in serum creatinine
- Less common side effects bone changes, risk of hepatitis B viremia, lactic acidosis
- Starting and stopping therapy
 - o 7 days until protection for receptive anal sex and 21 days for receptive vaginal sex
 - 0 Do not stop taking PrEP If you do stop, do NOT restart without getting HIV test
- PrEP does not protect against STIs
- Regular follow up recommended every 3 months

DON'T WORRY, BE "APPY": WHEN TECH MEETS MEDICINE

Presented By: Betsy Cernero, PharmD; Carolyn J. Oxencis, PharmD, BCOP

Summarized By: Dwiti Patel, PharmD



OVERVIEW

Digital medicine technologies are available for cardiology, endocrinology, and oncology. Self-monitoring devices and mobile applications for hypertension and atrial fibrillation can confirm a diagnosis, determine appropriateness of pharmacotherapy, detect irregular heartbeats, perform home ECGs, and monitor patient adherence. Continuous glucose monitors allow for less testing, provide real-time data, detect asymptomatic hypoglycemia, and are useful in patients with complex insulin regimens.

Wearable drug delivery devices are hands-free, connected to the body, and administer medication over a period of time. They can increase ease of administration, minimize pain and complexity, and increase adherence. Some patient considerations include health literacy, provider support, travel restrictions, access to technology, etc.

Medication adherence remains an overarching concern for many patients. Digital health has paved the way for innovative solutions to tackle this challenge. Strategies for adherence center around reminders, behavioral changes, and education. Barriers to electronic adherence monitoring include ease of use, reliance on reminders and self-reporting, and lack of integration into electronic health records.

DIGITAL MEDICINE DOMAINS

- Mobile Health: smart devices and patient monitoring devices
- Health Information Technology: electronic health records, electronic prescribing, secure messaging
- Wearable Devices: fitness trackers, smartwatches
- Telemedicine: video visits, remote monitoring of vitals
- Precision Medicine: genetic variant diseases

DIGICEUTICALS

Digital therapeutics and ingestible technology can improve adherence rates, healthcare services utilization, patient safety, and both patient and prescriber satisfaction. Digimeds are medications with sensors that can report data directly to the treatment team upon ingestion. Digital health formularies can be curated to allow employers and health plans to manage electronic healthcare, streamline coverage, provide a list of approved and/or evidence-based applications, and integrate data into electronic health records.

KEY TAKEAWAYS

- Regulation of digital health applications and wearable drug devices continues to evolve
- Integrating mobile health applications into routine clinical practice and electronic health records will be essential to optimize digital health technology
- Affordable and equitable access to technology for all patients must be addressed

COVID-19: Care of the Critically III Patient: A Focus on the Management of Acute Respiratory Distress Syndrome and Coagulopathy

Presented by: Lauren A. Igneri, Pharm.D., BCPS, BCCCP

Prepared by: Kayla Riggs, Pharm.D, PGY2 Critical Care Pharmacy Resident

Introduction:

- SARS-CoV-2 is the pathogen responsible for the 2019 coronavirus disease (COVID-19) pandemic. In patients who develop COVID-19 associated pneumonia, up to 26% require ICU admission and up to 42% develop acute respiratory distress syndrome (ARDS).
- ARDS is an inflammatory process affecting lung parenchyma via protein-rich pulmonary edema, injury to alveolar-capillary barrier, surfactant depletion, and loss of aerated lung tissue. Patients with ARDS typically present with severe hypoxemia, decreased lung compliance, and increased intra-pulmonary shunt and dead space.

Definition of ARDS:

	Berlin Definition	Direct		Indiract	
Parameter	Criteria	Direct	Pneumonia	India ecc	Sensis
Timing	Within 7 days of insult or new/worsening respiratory symptoms		Theamonia		Separa
Chest radiographic	Bilateral pulmonary opacities not fully explained by effusions, lobar collapse, or nodules				
Origin of edema	Respiratory failure not fully explained by cardiac failure or fluid overload		Aspiration		Trauma
Oxygenation					
Mild	$200 < PaO_2/FiO_2 \le 300$ mmHg with PEEP or CPAP >5 cm H ₂ O		Inhalation		Pancreat
Moderate	100 < PaO ₂ /FiO ₂ ≤ 200 mmHg with PEEP >5 cm H ₂ O				
Severe	$PaO_2/FiO_2 \le 100 \text{ mmHg with PEEP >5 cm H}_2O$				
aO ₂ /FiO ₂ = ratio partial pressure a	rterial oxygenation to fraction of inspired oxygen		Near Drowning		Blood Transfus

PEEP = positive end expiratory pressure CPAP = continuous positive airway pressure

Phases of ARDS:

Time	Phase	Characteristics
1-2 weeks	Acute, Exudative	Diffuse alveolar damage Edematous fluid accumulation in the lungs Deposition of proteins (albumin and fibrin) and Inflammatory cells (neutrophils and macrophages)
2-3 weeks	Fibroproliferative	 Inflammatory, epithelial, and fibrobiast cells amplify inflammatory response and activate procoagulant pathways Patients may rapidly recover in this phase or progress to fibrotic phase
3-4 weeks	Fibrotic	Collagen deposition leads to fibrosis Changes in lung function may or may not partially reverse

Changes in lung t
 over time

Therapies Associated with Reduced Mortality in ARDS



COVID-19 Associated-Acute Respiratory Distress Syndrome:

The SARS-CoV-2 virion bunds to the ACE2 receptor, located on host airway cells. The Transmembrane Serine Protease 2 (TMPRSS2) activates the viral spike protein, cleaves ACE2 receptor to allow viral binding to host cell membrane through endocytosis. SARS-CoV-2 RNA is then released and uses the host cell to replicate and produce more virions, further releasing hundreds of new virions through exocytosis resulting in progression of infection.

Causes of Acute Lung Injury:



COVID-19 Associated Coagulopathy:

Observational data suggest 15-39% of patients with COVID-19 who require mechanical ventilation have acute PE/DVT. Early studies suggested elevated D-dimer associated with mortality, suggesting a possible coagulation disorder with COVID-19. Clinical utility of abnormal coagulation tests to predict bleeding, thrombosis, and severity of illness are still being investigated.

Approach to VTE prophylaxis in COVID-19:

All hospitalized patients	
unless bleeding risk	

outweights risk of thrombosis • Hold if platelets <25 x10⁹/L or

LMWH

- fibrinogen <0.5 g/L or active hemorrhage
 Dose adjust for obesity
- Fondaparinux if HIT

Prophylaxis

- When anticoagulation contraindicated
- Not recommended in combination with chemical prophylaxis.

Should be reserved for patients with indication for therapeutic anticoagulation (VTE, Afib, MV) Consider VTE on differential diagnosis if rapid deterioration

of pulmonary, cardiac, or neurological function

Drug Dosing in Morbid Obesity

Speakers: Brian L. Erstad, PharmD, MCCM, FASHP; Jeffrey F. Barletta, PharmD, FCCM

Prepared by: Christie Denton, PharmD PGY2 Resident

A lack of dosing information for drugs persists in obese patients, with most FDA approved medications not containing dosing information for patients with extremes of body weight. In 2018 nearly 70 out of 100 commonly used critical care injectable drugs that were assessed contained no reference to a weight descriptor. This is an issue of significance in critically ill and other patient populations, since the pharmacokinetic metabolism of medications is affected by obese and morbidly obese patients (BMI \ge 40 mg/m²). V_d and clearance increases are rarely in proportion to weight gain, which makes estimating the correct dose difficult. When dosing medications, determining the most appropriate weight calculation is an important starting point.

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Organ/Tissue	Direction of Change in Obesity
Blood volume	\uparrow , but not proportional with higher values
Cardiac Output	↑, but not proportional with higher values
Cerebral blood flow	\leftrightarrow , but \downarrow as fraction of cardiac output
Renal blood flow	\downarrow , but $\downarrow\downarrow$ as fraction of cardiac output
Splanchnic blood flow	\uparrow with \leftrightarrow as fraction of cardiac output
CSF volume	\downarrow , but much variability
GFR (measured)	\uparrow , but not proportional with higher values
CrCl (measured)	?, one small study found no difference
Hepatic metabolism	\downarrow CYP3A4, \uparrow for other isoforms

Weight Descriptors Used in Practice Lean Body Weight (LBW)

- Fat Free Mass is often a measurement of LBW
- LBW in kg (men) = [9,270 x ABW in kg]/ [6,680 + (216 x BMI)]
- LBW in kg (women) = [9,270 x ABW in kg]/ [8,780 + (244 x BMI)]

Ideal Body Weight (IBW)

- Underestimates LBW
- Only based on height, does not take into account 1 in lean tissue that patients gain in obesity (~20% of weight gain is lean tissue gain)

Adjusted Body Weight (ABW)

 Usually for dosing in mild-moderate obesity (actual weight ≥ 130% of IBW, but less than 200% of IBW)

Adipose Tissue = 80% fat, 14% water, 6% protein

Implications for Medications

- Drug primarily distributed into lean tissue would still have small increase in V_d in obese compared to normal weight person of same height
- Drug with extensive fat distribution (i.e., high lipophilicity) would have large increase in V_d in obese compared to normal weight person of same height
- Renal clearance would mostly be affected by increase in lean tissue in obese patient

Conceptual Framework for Drug Dosing:

Step 1: Evaluate clinical studies involving the medication to determine the weight descriptor used for dosing & range of patient weights.

Step 2: Search literature for kinetic studies of medication in obese patients. Assess whether pk parameters of medication increase proportionally with increasing weight, which suggests use of ABW may be appropriate.

Step 3: Evaluate the literature for medications with similar physicochemical & PK parameters

Step 4: Assess risk/benefits of using TBW (weightbased dosing) or a larger (non-weight-based dosing)

• Should always take into account potential comorbidity confounders such as renal or liver dysfunction



ANTI(X)DOTES FOR ALL? THE ROLE OF REPLACEMENT AND REVERSAL STRATEGIES IN MANAGING LIFE-THREATENING BLEEDING AND EMERGENT PROCEDURES FOR PATIENTS ON FACTOR XA INHIBITORS

PRESENTED BY: BRYAN D. LIZZA, PHARM.D., M.S., BCCCP, KATELYN W. SYLVESTER, PHARM.D., BCPS, CACP PREPARED BY: SHIVANI PATEL, PHARM.D., PGY-1 PHARMACY RESIDENT, ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL IN NEW BRUNSWICK

Anticoagulation is the cornerstone therapy for both the prevention and treatment of thromboembolic diseases. Apixaban and rivaroxaban are the most prescribed direct oral anticoagulants, but they are also the top 10 drugs that contribute to emergency department visits. The incidence of major bleeding in patients using DOACs is approximately 3.6-5.4 events/100 person-years.

What is an appropriate hemostatic therapy for patients presenting with acute, lifethreatening hemorrhage due to factor Xa inhibitors?

American College of Cardiology recommends administering CoFaXa-zhzo (andexanet alfa) for apixaban and rivaroxaban reversal, high dose of CoFaXa-zhzo for betrixaban and edoxaban. If CoFaXa-zhzo is not available, then consider using PCCs. There are no large clinical trials comparing CoFaXa-zhzo and PCC headto-head. The true efficacy of CoFaXa-zhzo at preventing hematoma expansion resides between 80-89% and about 60-90% for PCC. However, using CoFaXa-zhzo can pose a significant financial burden on the institution. For instance, medical hospital reimbursement for Intracranial hemorrhage (ICH) is \$12,961 but the cost of CoFaXa-zhzo alone is \$24,750.

How do uou monitor coagulation status following CoFaXa-zhzo administration?

Conventional assays such as PT/aPTT lack sensitivity to quantify the amount of DOACs in the body. Instead, an anti-fXa assay calibrated for apixaban and rivaroxaban provides the most reliable correlation with the degree of anticoagulation. In the absence of calibrated assays for apixaban and rivaroxaban, the anti-fXa assay for LMWH can be used.

How do you reverse oral fXa inhibitors before emergency/urgent surgery?

The Anticoagulation Forum Guidance Document and American College of Emergency Physicians 2019 suggest treatment with andexanet alfa at the same dosing used for major bleeding. They only suggest the use of 4F-PCC when the first-line agent is not available.

What does this mean for patients with reversal prior to cardiac surgery requiring heparin for the cardiopulmonary bypass?

Andexanet alfa reverses both direct and indirect Xa inhibitors. It binds with a higher affinity to apixaban and rivaroxaban than UFH or LMWH. Andexanet alfa reverses anti-fXa activity of UFH in a dose-dependent manner which limits the anticoagulant efficacy of UFH and delays safe initiation of cardiopulmonary bypass.

	Total Hospital Payments	Cost of PCCs	Cost of CoFaXa- zhzo	Fondapannux
All	\$11,492	\$5,670	\$22,120	UFH, LMWH
Intracranial hemorrhage (ICH)	\$12,961	\$6,075	\$24,750	Rivaroxaban 3
Gastrointestinal bleed	\$10,143	\$5,670	\$15,827	Appeadan / 포
Intra- abdominal/thoracic bleed	\$11,492	\$4,860	\$18,121	

IN SICKNESS AND IN HEALTH: CARDIORENAL BENEFITS AND RISKS ASSOCIATED WITH NEWER DIABETES MEDICATIONS

<u>Presented by:</u> Jennifer Rosselli, PharmD, BCPS, BCACP, BC-ADM, CDCES; Amanda Stahnke, PharmD, BCACP <u>Authored by:</u> Jennifer Weiss, PharmD, PGY1 Pharmacy Resident

Background

About 2.6 million patients have diabetes in the US and the majority of these patients are at high risk for developing end stage renal disease (ESRD) and cardiovascular disease (CVD). In 50% of patients who have type 2 diabetes mellitus (T2DM), CVD is the cause of death. In recent years, cardiovascular outcome trials (CVOTs) have emerged evaluating the use of newer anti-diabetic medications for renal and cardiovascular benefit in patients with T2DM. Sodium Glucose Transporter Inhibitors (SGLT-2i) and Glucagon Like Peptide 1 Receptor Agonists (GLP-1 RAS) have been studied in these trials. The purpose of this discussion is to review the risks and benefits of these new agents.

Cardiorenal Indications

CVOTs conducted of agents within both classes have permitted their approval for various cardiorenal indications including prevention of major adverse cardiac events (MACE), heart failure hospitalizations, CV death, and ESRD. Canagliflozin, dulaglutide, and semaglutide showed a benefit in the reduction of MACE in adults with T2DM and CV. For reduction of the risk of CV death, empagliflozin and liraglutide are indicated. To date, dapagliflozin has been shown to reduce the risk of CV death and hospitalizations for heart failure with reduced ejection fraction. Lastly, canagliflozin is indicated for the reduction of risk of ESRD, acute kidney injury, hospitalization for heart failure and CV death.

Safety

The most common safety concerns with GLP-1 RAs include nausea, vomiting, and diarrhea. There is an increased risk of hypoglycemia when either GLP-1 RAs or SGLT-2 inhibitors are used in addition to insulin or sulfonylureas. Additionally, use of GLP-1 RAs should be avoided in patients with severe gastrointestinal disease (gastroparesis), acute pancreatitis history, acute renal injury, and acute gallbladder disease. Lastly, patients could experience retinopathy when taking a GLP-1 RA, specifically with dulaglutide and semaglutide. The most common side effects with SGLT-2 inhibitors include genital fungal infections, urinary tract infections, lower limb ulcerations and soft tissue infections. Lastly, SGLT-2 inhibitors should be used with caution in patients with prior amputation, severe peripheral neuropathy, severe peripheral vascular disease, active foot ulcers or soft tissue infections.

Takeaway Points

Ultimately, SGLT-2 inhibitors reduce ASCVD risk, kidney disease outcomes, and risk of heart failure hospitalizations in patients with T2DM and established CVD, CV risk factors, or renal disease. Additionally, GLP-1 RAs reduce ASCVD risk in patients with T2DM with established ASCVD or ASCVD risk factors. Ultimately, the routine addition of a SGLT-2i or GLP-1 RA to metformin and lifestyle therapy is recommended to decrease the incidence of these outcomes because the benefits significantly outweigh the risks.

Managing Sepsis in Older Adults

Presented by: Steven Pass, PharmD, MSEd, FCCM, FCCP, FASHP, BCPS Prepared by: Sandra Eid, PharmD, PGY-1 Pharmacy Resident

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. More than 1.7 million cases of severe sepsis are reported annually with more than 270,000 associated deaths. Morbidity and mortality due to sepsis are especially high in geriatric patients. The increased incidence is due to multiple factors including diminished physiologic reserve, immunosenescence, preexisting comorbidities, subtle clinical presentation, frequent use of instrumentation and residence in long-term-care facilities. The Society of Critical Care Medicine recommends the Hour-1 Bundle for sepsis treatment. The bundle entails rapid diagnosis, measuring serum lactate level, obtaining blood cultures, administering broad-spectrum antibiotics, providing fluid resuscitation with 30 mL/kg of crystalloid fluids and using vasopressors for persistent hypotension.

Advanced age can be challenging in the management of sepsis due to the atypical presentation of illness. Certain common symptoms such as fever, leukocytosis, elevated heart rate can be absent in older adults. On the other hand, some symptoms such as muscle stiffness, gradual hearing loss and dental problems can go unreported due to attribution to old age. Older adults can present with non-specific symptoms such as falls, confusion, incontinence, immobility, delirium, changes in behavior, functional status and mental status. While the main diagnostic criteria of sepsis are heart rate >90 bpm, systolic blood pressure (SBP) <100 mmHg or temperature >100.9 F, older adults can have their heart rate blunted by age or medications, higher baseline blood pressure and lower basal body temperature. Diagnosis of sepsis in older adults should be dependent on Quick Sequential Organ Failure Assessment (qSOFA) score with 2 or more positive criteria (respiratory rate ≥ 22 breaths/min, altered mentation, SBP ≤ 100 mmHg). Fluid resuscitation should be done in small boluses of 500 mL due to increased risk of volume overload in elderly. If vasopressors are indicated, norepinephrine is the agent of choice with vasopressin as an add on therapy. Dopamine is a last-line option in older adults due to the associated tachycardia and arrhythmias. Clinical goals include mean arterial pressure ≥ 65 mmHg, urine output ≥ 0.5 mL/kg/hr and normalization of lactate levels.

There are differences between older and younger adult infection characteristics. Older adult respiratory infections tend to have an increased severity, mortality, incidence of co-infection with influenza, incidence of multidrug-resistant organisms, duration of mechanical ventilation and ICU lengths of stay. Geriatric patients also experience slower wound healing and high incidence of pressure ulcers. Obtaining source control is very important in sepsis management and should be a priority. Empiric antimicrobial therapy should be initiated after cultures are obtained unless this would result in significant delay. Dosing in older adults may require alterations based on pharmacokinetic and pharmacodynamic principles. Other prophylactic therapies should be used in patients who meet the criteria. Deep vein thrombosis prophylaxis with low molecular weight heparin is recommended. Stress ulcer prophylaxis with proton pump inhibitors or histamine-2 receptor antagonists should be initiated in patients at risk of gastrointestinal bleeding. Pharmacists play an important role in the management of sepsis in older adults by ensuring appropriateness of therapies based on patient characteristics and optimizing medication dosing. Overall, management of sepsis should be a shared decision making between the patient's care team and family.

Anticoagulation Stewardship: Meaningful Movement, Improved Outcomes

Presenters: Nadine Shehab, PharmD, MPH, Allison E. Burnett, PharmD, Ph.C., CACP, William Dager, PharmD BCPS, FASHP, FCCM, FCCP, MCCM

Summarized by: Michelle Mei, PharmD, PGY-1 Pharmacy Resident at Jersey City Medical Center

The Evolution of Anticoagulation Stewardship

The initial anticoagulants came out in the 1950s starting with heparin, shortly followed by warfarin. In the last 70 years, the use of anticoagulants has been constantly refined and improved upon with the broadening of anticoagulation options such as factor Xa inhibitors, low molecular weight heparin, utilizing monitoring parameters such as aPTT, PT, INR, and anti-Xa levels, and lastly, the development of reversal agents such as KCentra, Praxbind, and Andexanet. In 2005, the National Patient Safety Goals came out for anticoagulation therapy which propelled momentum for pharmacists and hospital systems to engage in trying to provide a higher level of anticoagulation care.

Initial anticoagulation stewardship involved pharmacists as part of utilizing knowledge to facilitate good care. Community and hospital pharmacists provided drug interaction screening/education and also provided pharmacokinetic and therapeutic drug monitoring services. Starting in the 1970s, pharmacists also became involved in anticoagulation clinics and ran warfarin management under a physician's guidance. Data has shown that usual care for warfarin were not as successful as "Coumadin" clinics: Samsa et al compared incidence of VTE and major bleed in patients receiving usual care (UC) versus patients receiving care form an anticoagulation clinic (ACC); results show that VTE occurred in 8.3% UC patients compared to 2.4% ACC patients. Pharmacists are now involved in many areas of anticoagulation therapy such as the verification of orders, clinical oversight of anticoagulant use, providing information, education, research, professional organizations and administration.

Key Takeaways: Pharmacist Impact on Anticoagulation Therapy

- <u>Hard outcomes</u>: shortened length of hospital stay, reduction in cost of therapy, reduced hospital re-admissions, decreased anticoagulation related complications and mortality, reduced bleeding complications
- Other Outcomes: INR more likely in range and reduction in critical values, decreased time to therapeutic INR levels

Public Health Considered and Implications for Anticoagulation Stewardship

Adverse drug events (ADE) are the most common cause of iatrogenic harm in hospitals. ADEs associated with anticoagulants are ranked #1 most common in acute care and long-term care hospitals. Anticoagulants ADEs are also the most common drug class to cause iatrogenic deaths in the acute care setting. An ADE adds approximately \$10,000 to the cost of inpatient stay. With the increased utilization of DOACs in recent years, we have seen an increase in DOAC related bleed compared to warfarin: In 2013-2014, warfarin accounts for 15.1% of emergency department visits implicated by drugs; in more recent data, warfarin accounted for 11.6% of ED visits while apixaban and rivaroxaban accounted for 3.7% each. ADE action plans have been implemented to provide interdepartmental coordination, identify federal approaches to ADEs, and highlight approaches in the National Action Plans, 2014. The National Action Plan provides surveillance, research, incentives, oversight and evidence-based prevention.

Implementing a Stewardship Program

7 Core Elements of Anticoagulation Stewardship Programs:

- Secure Administrative Leadership Commitment
- Establish Professional Accountability and Expertise
- Engage Multidisciplinary Support
- Perform Data Collection, Tracking, and Analysis
- Implement Systemic Care
- Facilitate Transitions of Care
- Advance Education, Comprehension, and Competency

Key Takeaways:

- Despite the availability of newer agents, anticoagulants continue to be commonly associated with adverse events
- The role of pharmacists as key leaders and innovators in optimizing AC therapies continues to rapidly expand
 Stewardship programs have the potential to provide broader, more sustainable improvements in the care of
- anticoagulation patients



ISMP Medication Safety Update for 2021

<u>Presented by:</u> Christina Michalek, BS, RPh, FASHP; Matthew Grissinger BSPharm, FASCIP, FISMP <u>Summarized by:</u> Mary Ibrahim, PharmD, PGY-1 Pharmacy Resident at Jersey City Medical Center

Overview: This presentation reviewed the top safety issues reported to ISMP in 2020 and strategies to mitigate harm. Additionally, strategies related to effective event investigation and responses to harmful errors were also evaluated.

ISMP's Top Medication Safety Issues from 2020

COVID-Related Safety Issues: The first issue that arose from the pandemic was preserving personal protective (PPE) equipment and limiting staff exposure to COVID. As a result, many hospitals began positioning infusions pumps outside of COVID-19 patients' rooms to conserve PPE and reduce exposure. However, factors to consider if an institution utilizes this includes: availability of extension sets, occlusion alarms either being delayed or increased, flow rate accuracy due to downstream resistance of some pumps, increased need for priming volume, and an impact on barcode scanning and double-checks. Another issue brought upon by the pandemic was drug shortages of many medications used for mechanically ventilated patients. One of these major shortages included propofol 1% (DIPIVAN and generics, 10mg/mL). To combat this shortage, the FDA allowed for importation of propofol 2% (PROPOVEN 2%, 20mg/mL) emulsion in 100 mL vials but this could have potentially led to errors due to double concentration. Therefore, recommendations for preventing drug databases/smart pump libraries, and affixing the barcode if the international barcode does not work. Another drug shortage included vecuronium and rocuronium vials. As a result, manufacturers were allowed to produce these medications without the warning cap on the vial. This could have potentially led to fatal drug selection errors with look- alike vials. Recommendations to resolve this consist of alerting staff, affixing auxiliary labels noting the paralyzing agent warning, storing vials lying down so the labels are visible, and utilizing barcode scanning.

Other safety issues: A major safety issue from 2020 included a peel off overlay on the label of Fresenius Kabi rocuronium 5mL vials which expressed the concentration as 10 mg per mL, not 50 mg per 5 mL. Staff can mistaken the vial for containing 10 mg, not 50 mg. Recommendations to prevent errors include: Fresenius Kabi removing the peel-off overlay from vial, pharmacy should remove overlay until removed by manufacturer, and using additional peel-off labels in vial cartons for syringe labeling. An international error that has been ongoing includes issues with two component vaccines. There are numerous reports of improper mixing such as incorrect diluent or omission of the vaccine. In one instance, two infants died in Samoa due to the improper mixing of vaccines with atracurium. Recommendations to help combat the issue include: highlighting critical information such as diluent for staff, avoiding storing high alert drugs near vaccines, clearly labeling each component, using barcode scanning systems for both components during preparation, documenting product information, and labeling areas where vaccines are stored. Another key issue in the US, was that bupivacaine, ropivacaine, and tranexamic acid instead of spinal anesthesia. Recommendations to reduce the risk consist of separating vials in different storage locations, consider labeling with "contains tranexamic acid", utilizing barcode scanning, and considering NRFit syringes and connectors for local anesthetics to prevent misconnections with drugs intended for IV use.

Targeted Medication Safety Best Practices for Hospitals: To prevent the misuse of extended-release/long acting opioids and fentaNYL patches, the new best practices published include: verifying and documenting patient's opioid status and type of pain, defaulting order entry systems to lowest initial starting dose, eliminating prescribing of fentaNYL patches for opioid naïve patients, and eliminating storage of fentanyl patches where acute pain is treated. An additional best practice recommendation arose from the potential of automated dispensing cabinets (ADC) misuse. Best practice recommendations comprise of limiting the variety of medications that can be removed from ADC on override function, requiring a medication order prior to removing any medication from ADC, monitoring overrides that occur, and reviewing the list of medications available using override function.

We've Had an Error! What's next?: When evaluating medication errors, it is important to understand the root cause and the contributing factors. Therefore, the "why" must be understood. The goal of root cause analysis is to create a chronological sequence of events, identify the underlying causes of each human error and incorrect behavioral choice, and determine how we were managing the risk before the event. It's important to determine the different types of behavioral choices which include human error, at-risk behavior, and reckless behavior. Evaluating system based causes also plays a role when determining medication error causes.

Final Takeaways: The COVID pandemic triggered medication safety concerns related to drug and medical supply availability.

- Organizations must act to avert errors due to accidental spinal injection of tranexamic acid instead of a local anesthetic by implementing prevention measures.
- In order to identify all the human errors and behavioral choices that led to an event, one must dig deep into the "whys."

Dose, Selection, Volume, and Timing — Establishing the Therapeutic Index of Fluids in Sepsis

Presenters: Paul M. Reynolds, BCCP; Robert MacLauren, MPH, FCCM, FCCP; Gretchen L. Sacha, PharmD, BCCP

Prepared by: Keely Morris, PGY1 Resident at Saint Barnabas Medical Center

Hospital pharmacists verify thousands of orders for intravenous fluids every year, but many fail to appreciate these agents as the diagnostic, curative, and preventative medications they are. In the 2016 Surviving Sepsis Campaign guidelines, a 30 ml/kg crystalloid fluid bolus serves as a key treatment to mitigate hypotension and prevent progression to shock. Fluid administration in septic patients is divided into 4 key phases: resuscitation, fluid optimization, stabilization, and evacuation/de-escalation. Fluid balance is net positive in the resuscitation phase which occurs over minutes. Fluid optimization is done over the next few hours to optimize cardiac perfusion and function, with a net positive or neutral fluid balance. Stabilization occurs over days, in which fluids are only administered to replete normal losses and promote homeostasis. Fluid evacuation occurs over weeks after the initial insult and promotes a negative fluid balance in a patient who has recovered.

The pharmacokinetics of fluids are altered in critical illness. Crystalloid fluids such as normal saline or lactated ringer's are small molecules that can cross semi-permeable membranes. Crystalloids have an increased half-life of 80 minutes in stress states or in periods of decreased mean arterial pressure. For every one liter of crystalloid, only about 300 ml stay in the intravascular space. Colloids such as albumin or blood are unable to cross semipermeable membranes, which provides as low as 40% of the actual volume provided in septic patients. Fluid distribution into the interstitial space can be accelerated with use of vasopressors such as phenylephrine or norepinephrine. Both types of fluids undergo renal elimination, which is a saturatable process that can be reduced by excess chloride provided by fluids such as normal saline or 5% albumin.

Data supports crystalloids over colloids in sepsis patients, with lactated ringer's being the fluid of choice if a patient has known hyperchloremic acidosis. Albumin may be considered in patients with tolerance to crystalloids and evidence of volume overload, especially in the presence of pulmonary edema, renal/hepatic dysfunction, or heart failure. The 2016 Surviving Sepsis Campaign Guidelines outline a care bundle that has been shown to improve mortality in patients with sepsis that includes a 30 ml/kg intravenous crystalloid fluid bolus administered within the 1st hour of presentation. However, no definitive data evaluates this specific fluid dose, and higher fluid volumes have been associated with increased mortality. Despite this, CMS mandates all hospitals to comply with the 30 ml/kg recommendation in septic patients with persistent hypotension.

Fluid responsiveness, defined as an increase in cardiac output of 10-15% after fluid administration, should be used to optimize fluids after the initial resuscitation phase. Dynamic markers of responsiveness, including pulse pressure variation, inferior vena cava collapsibility, and the passive leg raise test are the best predictors of fluid responsiveness but lack clear places in current patient management. The current sepsis guidelines do not recommend additional fluid administration in a patient who is not expected to respond positively and provide no guidance on deresuscitation. Two types of de-resuscitation exist in clinical practice; active, which involves diuresis, and passive, which involves fluid restriction. De-resuscitation may be considered as soon as 6 hours after the initial fluid bolus once the patient is stabilized or no longer fluid responsive. Approximately, 50% of patients will require some form of active de-resuscitation. A retrospective review of septic patients found that cumulative non-resuscitation fluids, including those given with other medications or maintenance fluids, provide a larger impact on fluid balance on resuscitation fluids. Protocolized diuresis has shown a mortality benefit in critically ill patients. Fluid restriction and diuresis should be recommended to patients with a positive fluid balance as tolerated.

CE Title: "Siri, Get Me My Pharmacist": The Virtual Health Pharmacist Role Presented By: John Beyer, Pharm.D., M.S., M.B.A., BCPS; LaTasha Riddick, Pharm.D. Prepared By: Brian Bishop, Pharm.D., PGY-1 Pharmacy Resident

Before the COVID-19 pandemic, telemedicine was considered optional for many patients. In March of 2020, there was a growing pressure to minimize in-person contact requiring healthcare providers rush the development and deployment of telemedicine solutions. Telemedicine is nothing new and has steadily grown in popularity over the past decade, but has failed to reach mass audiences due to the substantial capital investment required and the lack of reimbursement models and the urgency to deploy these tools. The pandemic acted as a catalyst for telemedicine to reach the mainstream. Insurance companies were forced to create reimbursement models and medical offices were forced to invest in technologies in order to "keep the lights on". This CE presents two innovative telemedicine ideas that address the pharmacist's role in telemedicine.

TeleNaloxone:

TeleNaloxone addresses a growing concern for the increasing rate of opioid overdose deaths during the COVID-19 pandemic. With statewide shutdowns and shelter in place orders, patients are avoiding seeking care and follow-up due to the COVID-19 pandemic. In the past year, there has been up to a 20% increase in reports of opioid overdoses to national agencies.

TeleNaloxone is a pharmacist driven service that allows patients to receive free naloxone shipped to their houses following a scheduled telemedicine appointment with a licensed pharmacist. Funding for this service came from the Iowa Department of Public Health and 340B reimbursement. This program remained staffing neutral which also drove down implementation costs. The program became more efficient over time which allowed for patients to receive naloxone within an average of days from their initial contact. The authors noted that there were problems with patients not answering calls, several technological issues with the video platform, and difficulty following-up. There were also concerns about the sustainability of funding and the cost of marketing to maintain patient volume.

MyChart Patient Surveys:

MyChart has functionality for patients to access their medical information on a HIPPA compliant online portal. This tool allows providers to assign custom-built surveys to their patients. The Johns Hopkins Specialty Pharmacy implemented six surveys for different specialty migraine medications. The surveys were designed to take less than five minutes and addressed refills, assessment questions, and side effect reporting. The authors compared the average amount of time it took to complete the same survey through a telemedicine phone call to the electronic MyChart survey. They found that the phone call took on average 10.8 minutes compared to 3.9 minutes for the online survey. However, the authors found that the response rate for a 3-month follow-up was 14% compared to an 86% response rate for a 1-week follow-up. This problem is not unique to online surveys and continues to be a problem across healthcare. Overall, MyChart communications take significantly less time than a phone call and can be a cost-effective telemedicine solution for institutions already using this EMR.



Avoidable Mistakes: Preventing Staff Burnout During a Pandemic

Presented by: Ellen Revak Pharm.D., MBA, BCPS Written by: Hasna Esseghir Pharm.D., PGY1 Resident MMC

SUMMARY

This continuing education session presented at ASHP midyear focused on the consequences and contributing factors of clinician burnout and provided actionable solutions for pharmacy departments.

DEFINITION

Burnout – a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed. It is characterized by three dimensions:

- Feelings of energy depletion/exhaustion
- Increased mental distance from one's job, or feelings of negativism or cynicism related to one's job
- Reduced professional efficacy

WHY SHOULD WE CARE ABOUT BURNOUT?

In 2019, the National Academies of Sciences, Engineering, and Medicine, published a report titled: *Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being.* It explores the extent, consequences, and contributing factors of clinician burnout. The report provides a framework for a systems approach to clinician burnout and professional well-being, a research agenda to advance clinician well-being, and recommendations for the field.

This report provided the framework for a case management study at the pharmacy department of Aurora St. Luke's Medical Center in Milwaukee, Wisconsin. The experiences and results of the study were the basis of this continuing education course, as Dr. Revak shared how her department recognized and managed clinician burnout during the COVID-19 pandemic. Clinician burnout is a common issue in healthcare professionals and pharmacy staff are no exception. This is especially true during a global pandemic that is putting severe strain on our healthcare system and healthcare workers. The consequences of burnout range in severity, but can have great impact on patients, the clinicians themselves, health care organizations, and society as a whole.

Contributing Factors to Clinician Burnout



Job Demands Time pressure, encroachment on personal time Moral distress Patient factors Inadequate technology Workflow interruptions & distractions

Administrative burden

ve workload



Work-life integration Alignment in values & expectations Organizational Culture Meaning and purpose in work Job control, flexibility, and autonomy Rewards Professional relationships, social suppor

SOLUTIONS

Dr. Revak shared her key takeaways in managing pharmacy staff burnout: encourage and support discussion in the department about well-being and burnout prevention and partnering with staff to prevent burnout by identifying at risk individuals such as ICU and ID pharmacists on the frontlines of the pandemic. In essence, preventing and managing burnout starts with overall awareness and communication between staff and leadership as we navigate through the unprecedented challenges facing our healthcare systems.

Roadmap for Successful Adoption of Biosimilars: Clinical, Operational and Payer Coverage Consideration

Presented by Osama Abdelghany, PharmD, MHA, BCOP and David L. Crosby, PharmD, BCOP, BCPS Written by Sonia Kim, PGY-1 Pharmacy Resident at Clara Maass Medical Center

As price trajectories of biologics outpace inflation, the national per capita health expenditure has been consistently increasing in the United States. In 2018, biologics represented 42% of the total medicine market. As more biosimilar products are approved by the FDA, biologics price competition is expected to increase in the upcoming years. For the healthcare providers, there can be several challenges to biosimilar adoption such as provider comfort, patient education, 3rd party payer issues, financial impact on patient, clinical consideration, and impact to healthcare operation. Clinical, operational, and financial factors should be considered while considering whether to add a biosimilar product to formulary.

There are 3 approaches of formulary review process: individual drug review, class review and global umbrella review. Class review is often done when multiple biosimilars for a single product require simultaneous review. If global approach is used, biosimilars are considered to be therapeutically equivalent to the reference drug for the biosimilar's FDA approved indications.

Strategy	Advantages	Disadvantages
Individual drug review	Consistency Careful evaluation of every new entry to market	Time and efforts spent on the review process Conversion delay
Class review	Opportunity to identify unique drug characteristics within a class	Relative delay to start conversion
Global umbrella review	Saves the time and effort Fastest to implementation	Unique drug aspects or indications could be missed

In addition to selecting an appropriate formulary review strategy, establishing formulary and drug use policy guidelines helps successful adoption of biosimilars in practice. For example, structured guidance on consents and orders for newly adopted biosimilars used in existing patients will facilitate conversion to biosimilars. Complete financial analysis should be performed with considerations for payers' preferences and restrictions. Solution to coverage denials or policy restriction can be a patient receiving treatment in the alternate sites of care.

Lastly, comprehensive operational checklist is also necessary for conversion to formulary agents. Checklist must include following: communication and education, electronic medical record integration, prior authorization review, pharmacy procurement and dispensing, integrated delivery network, regular review of adjustment and denials and monitoring of success. As biosimilar market and payer policies are currently volatile, providers should be prepared for the potential changes with these strategies in their mind.

Aligning a Hospital-Owned Ambulatory Pharmacy with a Health System's Strategic Objective with Market Leading Outcomes

Presenters: Gregory Shaeffer, MBA, RPh, FASHP; William Cooper, PD; Mit Patel, PharmD Candidate

By: Lalitha Sukumar, PharmD, PGY-2 RWJBH Ambulatory Care Pharmacy Resident

It is important that there is collaboration between the ambulatory/outpatient pharmacy leadership team and the human resource benefits leadership team in order to optimize the organization's pharmacy benefits management (PBM) contract for clinical and economic savings for employees, dependents, and the health care system. There needs to be a complete understanding of the contract language to negotiate the PBM contract. There are key stakeholders involved in the process of which include:

- Executive sponsor: Provides oversight and mediates issues, risks, project changes, and acts as a client sponsor for the project
- Project manager: Manage client resources, timelines, assigned tasks, and ensure that all deadlines are met in a quality manner. Schedule necessary meetings with internal staff
- **Director of pharmacy:** Provide consultant information in regards to ambulatory care services and pharmacy strategy
- Vice President, HR: Provide guidance for proposed employee pharmacy benefit plan and integration into the Employee Benefits offering



It is important that all of these key players come together to discuss a plan to prepare the team for contract negotiations with the PBM company.

The plan negotiations discussed with the PBM in this educational session mainly were involved with specialty pharmacy. If a health system has a specialty pharmacy, in order to contain the revenue, the specialty pharmacy product formulary will be dispensed by the Health System Pharmacy. We must streamline the formulary to meet employee and dependents' therapeutic needs. Formulary should be at a reduced cost to employees and the institution. There should also be a transparency with the PBM with rebates that are involved. Another strategy for negotiation included co-pay incentives for the employees/dependents to increase their interest in the use of the hospital ambulatory/outpatient pharmacy.

Overall, the outcomes of building an ambulatory pharmacy include enhancing medication compliance, convenience, and prescription plan benefit savings and in collaboration with the HR benefits leadership team can greatly benefit employees, dependents, and the health care system.