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PHARMASCRIPT

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Azole antifungal prophylaxis in patients with acute leukemias

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Patients with acute leukemias undergoing induction and consolidation chemotherapy are at high risk for invasive fungal infections (IFIs). Prophylaxis against IFIs is recommended by the National Comprehensive Cancer Network[1] and the American Society of Clinical Oncology (ASCO)/Infectious Diseases Society of America (IDSA)[2] for patients with prolonged (> 7 days) and profound neutropenia (< 100 neutrophils/microliter). Advanced Practitioners (APs) should refer to these guidelines for additional information on antibacterial, antiviral, and anti-*Pneumocystis jirovecii* prophylaxis. Of patients with hematologic malignancies, those with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) are generally at the highest risk for acquiring an IFI.[3] Agents used for antifungal prophylaxis in this population most often include echinocandins (e.g., micafungin [Mycamine®]), and azole antifungals.

Due to prolonged neutropenia and other impaired host defenses, patients undergoing treatment for acute leukemias are at risk for infection with both yeasts and molds. Portals of entry for Candida and other yeasts include the gastrointestinal tract and intravenous catheters, while molds are often acquired through inhalation.[3] Invasive candidiasis is common in the bloodstream, invasive aspergillosis in the lungs and sinuses, and zygomycosis and mucormycosis are often seen in the lungs and orbito-sinus-facial structures.[4] While prognosis for patients with IFI are improving, morbidity and mortality remain high and justify the use of aggressive prophylaxis.

Mechanism of Action

Azole antifungals inhibit formation of ergosterol, a critical component of the fungal cell membrane, by inhibition of the cytochrome P-450 dependent enzyme lanosterol 14-alpha-demethylase.[5] This results in increased permeability of the cell membrane, leading to cell lysis and death. While they share a common mechanism of action against fungi, the spectrum of activity varies from drug to drug. Fluconazole (Diflucan®) is active against most species of yeast, while posaconazole (Noxafil®), voriconazole (Vfend®), and isavuconazole (Cresemba®) additionally have broad anti-mold activity. Itraconazole (Sporanox®) is not discussed here, as it is generally not preferred due to its safety profile.

Pertinent Studies

The efficacy of posaconazole for prophylaxis was established in 2007 in a randomized trial comparing posaconazole with fluconazole or itraconazole in patients with AML or MDS.[6] For the primary efficacy analysis, there was a lower incidence of proven or probable IFIs in patients receiving posaconazole compared with fluconazole or itraconazole (2% vs. 8%, -6% absolute reduction, 95% CI -9.7% to -2.5%, P<0.001). Select secondary endpoint findings included a lower rate of invasive aspergillosis with posaconazole (1% vs. 7%, P<0.001), and improved survival at day 100 (33% relative reduction in mortality).

Evidence for voriconazole as prophylaxis mainly comes from the allogeneic HSCT population.[7] Compared with posaconazole, voriconazole has a similar spectrum of activity against yeasts and molds, however it has poor activity against *Zygomycetes.*[1]

The role of isavuconazole for prophylaxis is unclear. Isavuconazole is a moderate CYP3A4 inhibitor, as opposed to posaconazole and voriconazole which are strong CYP3A4 inhibitors. Therefore, isavuconazole may often be used with concomitant therapies that would otherwise be prohibited (including some investigational therapies) or require significant dose adjustment (e.g., venetoclax [Venclexta®]). Isavuconazole is also associated with modestly lower hepatotoxicity, and exhibited QT-interval shortening

in clinical trials, whereas other azoles are QT-interval prolonging. While an appealing alternative to posaconazole or voriconazole for these reasons, therapeutic drug monitoring is not widely available, and evidence is mixed, including reports of breakthrough IFI.[8,9] NCCN guidelines do not recommend isavuconazole for prophylaxis.[1]

Available Formulations

Azole antifungals are available as oral and parenteral products (Table 1). The specific formulations available for inpatient or clinic-administered doses may be limited based on the institution's formulary. Importantly, the oral formulations of posaconazole must not be interchanged on a milligram-to-milligram basis. The dosing for the delayed-release tablet is typically 300 mg twice daily on day one (loading dose) followed by 300 mg once daily for prophylaxis, while the oral suspension is given at 200 mg three times daily.[10] Each dose of the oral suspension must be taken with a full meal, oral liquid nutritional supplement, or acidic carbonated beverage to ensure adequate absorption. As the tablet formulation is well absorbed without regard to diet, this formulation is preferred. Nausea, vomiting, and mucositis often preclude oral administration of medications in this population, and intravenous formulations should be employed in such cases.

Table 1. Azole antifungal formulations

Agent	Formulations
Posaconazole (Noxafil® and generic)	Oral tablet (delayed release) Oral suspension IV solution
Voriconazole (Vfend® and generic)	Oral tablet Oral suspension IV solution
Isavuconazole (Cresemba®)	Oral capsule IV solution

Selected Adverse Effects

Posaconazole and voriconazole are associated with QTc prolongation, with the exception of isavuconazole, which demonstrated QTc shortening in clinical trials.[11] Electrocardiographic monitoring is prudent in patients with known QTc prolongation, or additional medications known to prolong the QT interval are co-administered. Transient elevations in liver enzymes occur relatively commonly, in about 1 in 5 patients taking voriconazole[10–12] however severe liver injury is rare. Pre-existing liver disease appears to increase the risk for elevated aminotransferases and severe acute liver injury with azoles.[13]

Voriconazole is associated with reversible visual disturbances, including abnormal vision, color vision changes, and photophobia, occurring in 21% of patients in clinical trials. Hallucinations, optic neuritis, and papilledema have also occurred.[14] Visual effects are more common with serum concentrations above 1 to 3 mcg/mL.[15] Other adverse effects include cutaneous photosensitivity, and fluorosis and periostitis with long-term use.[14]

Posaconazole may cause pseudohyperaldosteronism characterized by hypertension and hypokalemia.[16] This syndrome has been associated with higher serum posaconazole levels[17] and may require management with additional medications, if posaconazole is not discontinued.

Financial Toxicity

Azole antifungals are costly medications. The cash price for a one-month supply of oral tablets/capsules is $6,660 for posaconazole, $265 to $1,422 for voriconazole, and $6,840 for isavuconazole (Lexicomp, 2021). Prior authorization is frequently required, and even if covered by commercial or governmental insurance, patients are often responsible for high copayments. Patient assistance programs, including free drug from manufacturers, or grant funding, are often needed to ensure patients have access to these medications.

Implications for the Pharmacist

Therapeutic drug monitoring (TDM) is available for posaconazole and voriconazole. It is recommended that TDM should be performed in patients receiving prolonged azole prophylaxis.[19] The goal trough concentration for posaconazole is generally >0.7 mcg/mL.[20] Risk factors for subtherapeutic trough include concomitant proton pump inhibitor use, diarrhea, and weight over 90 kg.[21] Voriconazole trough concentrations should be at least 0.5 mcg/mL for prophylaxis, with some investigators advocating for at least 2 mcg/mL[22] or >1.5 to 4 mcg/mL[23] based on evidence of breakthrough IFI with lower goals. TDM is not widely available for isavuconazole at this time.

Pharmacists should be aware of the significant and numerous drug-drug interactions between azole antifungals and anti-cancer therapies. For example, anthracyclines are substrates of CYP3A4, therefore, it is expected that concomitant strong CYP3A4 inhibitors such as posaconazole and voriconazole would increase exposure to anthracyclines, potentially increasing the risk for toxicities including cardiotoxicity. For patients receiving intensive induction chemotherapy for AML including cytarabine and daunorubicin (or idarubicin), "7+3," or liposomal daunorubicin-cytarabine, our approach is to delay initiation of azole antifungal prophylaxis until at least 48 hours after the last dose of anthracycline. In neutropenic patients with MDS and AML, NCCN guidelines recommend posaconazole, with voriconazole, fluconazole, micafungin and amphotericin B products as alternatives.[1]

Many induction regimens for acute lymphoblastic leukemia (ALL) include weekly doses of vincristine, which is a CYP3A4 substrate. The use of azole antifungals, primarily the strong CYP3A4 inhibitors, together with vincristine has been associated with an increased risk of neuropathy, including gastrointestinal, peripheral, autonomic, and seizure.[24] NCCN guidelines recommend fluconazole or micafungin for prophylaxis in patients with ALL.[1]

In addition, medications used for immunosuppression after hematopoietic cell transplantation, such as sirolimus and tacrolimus, have significant interactions with azole antifungals. The involvement of a clinical oncology pharmacist is important to ensuring the safe use of azole antifungals in the context of each patient's oncologic and supportive treatment plan.

References:

1. National Comprehensive Cancer Network. Prevention and Treatment of Cancer-Related Infections. (Version 2.2020). Published 2020. Accessed April 14, 2021. https://www.nccn.org/professionals/physician_gls/pdf/infections.pdf
2. Taplitz RA, Kennedy EB, Bow EJ, et al. Antimicrobial Prophylaxis for Adult Patients With Cancer-Related Immunosuppression: ASCO and IDSA Clinical Practice Guideline Update. *J Clin Oncol*. 2018;36(30):3043-3054. doi:10.1200/JCO.18.00374
3. Zaas AK. Antifungal prophylaxis: An ounce of prevention is worth a pound of cure. In M. A. Ghannoum & J. R. Perfect (Eds.), Antifungal therapy (2nd ed., pp. 87-95). CRC Press. In: ; 2019. https://doi.org/10.1201/9780429402012
4. Bhatt VR, Viola GM, Ferrajoli A. Invasive Fungal Infections in Acute Leukemia. *Ther Adv Hematol*. 2011;2(4):231-247. doi:10.1177/2040620711410098
5. Ashley ESD. Pharmacology of antifungal agents. In M. A. Ghannoum & J. R. Perfect (Eds.), Antifungal therapy (2nd ed., pp. 193-206). CRC Press. In: ; 2019. https://doi.org/10.1201/9780429402012
6. Cornely OA, Maertens J, Winston DJ, et al. Posaconazole vs. Fluconazole or Itraconazole Prophylaxis in Patients with Neutropenia. *N Engl J Med*. 2007;356(4):348-359. doi:10.1056/NEJMoa061094
7. Wingard JR, Carter SL, Walsh TJ, et al. Randomized, double-blind trial of fluconazole versus voriconazole for prevention of invasive fungal infection after allogeneic hematopoietic cell transplantation. *Blood*. 2010;116(24):5111-5118. doi:10.1182/blood-2010-02-268151

8. Fung M, Schwartz BS, Doernberg SB, et al. Breakthrough Invasive Fungal Infections on Isavuconazole Prophylaxis and Treatment: What Is Happening in the Real-World Setting? *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2018;67(7):1142-1143. doi:10.1093/cid/ciy260
9. Rausch CR, DiPippo AJ, Bose P, Kontoyiannis DP. Breakthrough Fungal Infections in Patients With Leukemia Receiving Isavuconazole. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2018;67(10):1610-1613. doi:10.1093/cid/ciy406
10. *Noxafil [Package Insert]. Whitehouse Station, NJ: Merck & Co., 2015.* Accessed April 14, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022003s018s020,0205053s002s004,0205596s001s003lbl.pdf
11. Cresemba [package insert]. Northbrook, IL: Astellas Pharma US, Inc. 2019. Accessed April 14, 2021. https://www.astellas.us/docs/cresemba.pdf
12. Voriconazole. In: *LiverTox: Clinical and Research Information on Drug-Induced Liver Injury*. National Institute of Diabetes and Digestive and Kidney Diseases; 2012. Accessed April 15, 2021. http://www.ncbi.nlm.nih.gov/books/NBK547891/
13. Re VL, Carbonari DM, Lewis JD, et al. Oral Azole Antifungal Medications and Risk of Acute Liver Injury, Overall and by Chronic Liver Disease Status. *Am J Med*. 2016;129(3):283-91.e5. doi:10.1016/j.amjmed.2015.10.029
14. Vfend [package insert]. New York, NY: Pfizer Inc., 2021. Accessed April 14, 2021. http://labeling.pfizer.com/showlabeling.aspx?id=618
15. Xiong WH, Brown RL, Reed B, Burke NS, Duvoisin RM, Morgans CW. Voriconazole, an Antifungal Triazol That Causes Visual Side Effects, Is an Inhibitor of TRPM1 and TRPM3 Channels. *Invest Ophthalmol Vis Sci*. 2015;56(2):1367-1373. doi:10.1167/iovs.14-15270
16. Thompson GR, Beck KR, Patt M, Kratschmar DV, Odermatt A. Posaconazole-Induced Hypertension Due to Inhibition of 11β-Hydroxylase and 11β-Hydroxysteroid Dehydrogenase 2. *J Endocr Soc*. 2019;3(7):1361-1366. doi:10.1210/js.2019-00189
17. Nguyen MVH, Davis MR, Wittenberg R, et al. Posaconazole Serum Drug Levels Associated With Pseudohyperaldosteronism. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2020;70(12):2593-2598. doi:10.1093/cid/ciz741
18. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com.
19. Patterson TF, Thompson GR, Denning DW, et al. Executive Summary: Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America. *Clin Infect Dis Off Publ Infect Dis Soc Am*. 2016;63(4):433-442. doi:10.1093/cid/ciw444
20. Dekkers BGJ, Bakker M, van der Elst KCM, et al. Therapeutic Drug Monitoring of Posaconazole: an Update. *Curr Fungal Infect Rep*. 2016;10:51-61. doi:10.1007/s12281-016-0255-4
21. Tang LA, Marini BL, Benitez L, et al. Risk factors for subtherapeutic levels of posaconazole tablet. *J Antimicrob Chemother*. 2017;72(10):2902-2905. doi:10.1093/jac/dkx228
22. Trifilio S, Singhal S, Williams S, et al. Breakthrough fungal infections after allogeneic hematopoietic stem cell transplantation in patients on prophylactic voriconazole. *Bone Marrow Transplant*. 2007;40(5):451-456. doi:10.1038/sj.bmt.1705754
23. Mitsani D, Nguyen MH, Shields RK, et al. Prospective, observational study of voriconazole therapeutic drug monitoring among lung transplant recipients receiving prophylaxis: factors impacting levels of and associations between serum troughs, efficacy, and toxicity. *Antimicrob Agents Chemother*. 2012;56(5):2371-2377. doi:10.1128/AAC.05219-11
24. Moriyama B, Henning SA, Leung J, et al. Adverse interactions between antifungal azoles and vincristine: review and analysis of cases. *Mycoses*. 2012;55(4):290-297. doi:10.1111/j.1439-0507.2011.02158.x

New drug update: Aducanumab

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On June 7, 2021, the U.S. Food and Drug Administration (FDA) approved aducanumab (Aduhelm™, ADU) through the accelerated approval pathway.[1] As the first approved drug in its class, ADU provides a novel mechanism of action in the management of mild Alzheimer's disease. It is a monoclonal antibody targeting aggregated amyloid beta (A*β)*, a defining pathophysiological feature of Alzheimer's disease, to reduce A*β* plaques. This overall reduction is theorized to prevent further damage to brain cells, ultimately slowing the progression of Alzheimer's disease.[2,3]

The EMERGE and ENGAGE trials are two identical phase three, multicenter, randomized, double-blind,

placebo-controlled, parallel-group studies that evaluated the efficacy and safety of ADU in subjects with early Alzheimer's disease. Treatment groups for both studies contained two arms, low (3 or 6 mg/kg) and high dose ADU (6 or 10 mg/kg later changed to 10 mg/kg only) vs placebo. The primary outcome was the change from baseline in Clinical Dementia Rating Scale Sum of Boxes (CDR-SB) score. In the EMERGE trial, the change in the CDR-SB score differed in comparison to the placebo group for the low dose and high dose ADU groups by -0.26 (-15%) and -0.39 (-22%), respectively (P=0.0901 and P=0.0120). In the ENGAGE trial, neither ADU groups resulted in statistical benefit. However, post-hoc analysis of the high dose ADU supported the findings of EMERGE with patients who received at least 14 doses of ADU 10 mg/kg, showing statistical benefit (-0.45 (-27%)). Interpretation of the results are highly debated because of the many trial limitations, including the high dropout rate, the potential bias from unblinding with the high dose ADU group, the post-hoc analyses of smaller groups, and inconsistency in efficacy outcomes for the high dose groups in both trials. Also, it is unknown if the reduction in the CDR-SB scores and A*β* biomarkers (secondary outcome) correlates with cognitive benefit. Lastly, the larger decline in CDR-SB score in the placebo group within the EMERGE trial could possibly account for the discrepant outcomes.[4,5,8]

The EMBARK TRIAL is a currently active, phase 3b open-label, single arm study of 2,400 previous ADU trial participants, receiving monthly infusions of 10 mg/kg for two additional years through 2023. The primary outcome will address the safety and tolerability of ADU. Secondary outcomes include the same efficacy measures and biomarker endpoints of the EMERGE and ENGAGE trials.[6]

Aducanumab is administered as an intravenous infusion over one hour every four weeks and at least twenty-one days apart. Initiation and titration is recommended as follows: 1 mg/kg for infusions one and two, 3 mg/kg for infusions three and four, 6 mg/kg for infusions five and six, and 10 mg/kg for infusions seven and thereafter. Steady state is reached by 16 weeks with a systemic accumulation of 1.7-fold, plus a half-life of 24.8 days. Due to lack of clinical data, no dose adjustments are currently recommended in the setting of renal or liver impairment.[2,3]

The most frequently reported adverse events include amyloid related imaging abnormalities (ARIA)-Edema (most common), headache, ARIA-Hemosiderin (ARIA-H) microhemorrhage, ARIA-H superficial siderosis, and falls.[2] In both the EMERGE and ENGAGE trials, 4-5% and 6-8% of patients discontinued ADU due to ARIA events in the low dose and high dose groups, respectively.[5] Due to the possible emergence of ARIA, brain magnetic resonance imaging scans should be obtained within one year prior to initiating treatment and prior to the seventh and twelfth infusions. In the two trials, resolution of ARIA-E occurred in 68% of affected patients by 12 weeks, 91% by 20 weeks, and 98% overall after detection.[7] Angioedema and urticaria, rare hypersensitivity reactions, should prompt ADU discontinuation and initiation of appropriate therapy.[2,3]

Aducanumab presents clinicians with a novel mode of action for management of Alzheimer's disease. By acting directly against the amyloid plaques, ADU targets the proposed pathophysiology associated with the disease. Although it does not reverse the progression of Alzheimer's disease, ADU paves the path for further research towards a more promising future for individuals with Alzheimer's disease. Currently, many different organizations have formally rejected or restricted the use of ADU in Alzheimer's disease; forthcoming studies will assist in confirming ADU clinical and cost benefit, safety, and place in therapy.

References:

1. FDA grants accelerated approval for Alzheimer's drug. Food and Drug Administration Web site. https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug. Published June 7, 2021. Accessed September 30, 2021.
2. Aduhelm [package insert]. Cambridge, MA. Biogen Inc.; 2021.
3. Aducanumab. In: Lexi-Drugs. Lexi-Comp, Inc. Updated September 30, 2021. Accessed September 30, 2021.
4. Haeberlein SB, Von Hehn C, Tian Y, et. al. EMERGE and ENGAGE Topline Results: Two Phase 3 Studies to Evaluate Aducanumab in Patients with Early Alzheimer's Disease. [online] Accessed September 10, 2021. https://investors.biogen.com/static-files/8e58afa4-ba37-4250-9a78-2ecfb63b1dcb.
5. Haeberlein SB, Von Hehn C, Tian Y, et. al. EMERGE and ENGAGE Topline Results: Two Phase 3 Studies to Evaluate Aducanumab in Patients with Early Alzheimer's Disease. [online] April 2020. Accessed September 10, 2021. https://investors.biogen.com/static-files/f91e95d9-2fce-46ce-9115-0628cfe96e83
6. Hoffman, M. Aducanumab EMBARK Trial Seeks to Characterize Treatment Durability, Effects of Interruption. Neurology Live. April 18, 2021. Accessed September 10, 2021. https://www.neurologylive.com/view/phase-3b-embark-aducanumab-treatment-interruption-durability.
7. Aducanumab-acwa. *American Journal of Health-System Pharmacy*. 2021;78(19):1745-1747.
8. Knopman DS, Jones DT, and Greicius MD. Failure to demonstrate efficacy of aducanumab: An analysis of the EMERGE and ENGAGE trials as reported by Biogen, December 2019. *The Journal of the Alzheimer's Association.* 2020;17(4):696-701.

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Student spotlight: Notre Dame of Maryland University

Annual Residency Roundtable

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As students move through pharmacy school, they are presented with multiple potential career paths leaving many students with the challenge of narrowing focus into a specific field post-graduation. Student pharmacists and pharmacists today live in an ever-evolving world, with new career possibilities becoming available each year. One of the most popular post-graduation career paths for students is to pursue residency training, with almost 6,000 student pharmacists applying for residency each year, according to pharmacytimes.com. Residencies are an opportunity to further prepare newly licensed pharmacists in the workforce and provide additional training that goes beyond the classroom.

On April 22nd, 2022, the SSHP chapter at Notre Dame of Maryland University (NDMU) School of Pharmacy hosted its annual residency roundtable featuring residents from various programs in the surrounding Baltimore area to speak with current pharmacy students. Our chapter's roundtable featured five pharmacy residents with 37 NDMU pharmacy students from either the P1, P2, or P3 class in attendance. We elected to hold our event virtually through Zoom to reduce the burden of traveling and time commitment for the residents and which also helped make this event more accessible to the students. SSHP's main goal for this event was to educate and give perspective to students on different residency pathways and help them explore their interests in residency and post-graduate training.

In preparation for the event, the chapter project coordinator and project co-coordinator gathered a list of residents who may be interested in participating in the roundtable and emailed the residents an invitation to participate in the event. These initial emails were sent at the beginning of the Spring semester, with communication regarding resident availability and willingness to participate coordinated throughout the semester. After finalization of the list of residents who would be attending, the project coordinator and project co-coordinator collected a short biography from the residents. The biographies were used to help introduce the residents to the students and to help the students begin thinking of meaningful questions to ask the residents. Prior to the event, SSHP used an online form to collect questions from students to ask the residents during the event.

On the night of the event, the residents and interested students signed in on the Zoom link to attend. The project coordinator introduced the residents and asked the questions that were previously collected from the students. The residents discussed with students specific details about their residency program and what an average day as a resident looks like. Another valuable perspective for our students was to hear about the residency application process and how to set themselves up for success in a residency program. The residency roundtable was a success because it offered a unique and impactful opportunity for NDMU pharmacy students to speak with current pharmacy residents, learn about different residency pathways, and help them gain a better idea on how to apply for residency training. When asking students for feedback on the event, they had an overwhelming positive response and thought the event was informative and enjoyable.

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Pharmacy technician challenges during the COVID-19 pandemic

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The COVID-19 outbreak presented the world with an unprecedented challenge in the healthcare system. Before COVID-19, the pharmacy was a growing industry and an excellent opportunity to be in healthcare; however, working as a pharmacy technician during the pandemic has been highly challenging. Many technicians in the hospital settings went unnoticed - working understaffed and underpaid, while also working long hours without hazard pay, and always ensuring the demands of rising inpatient care were met. Although technicians are not first responders, they are an integral part of our healthcare system. Pharmacists have also stepped in to fill a void due to technician shortages and rising demands. Pharmacies across the nation have faced numerous drug shortages and backorders. Compounding medications also became very time-consuming and challenging for technicians due to not having the proper sterile compounding ingredients or personal protective equipment on hand. It was evident that pharmacies nationwide continued to be affected by the pandemic at a rapid pace. However, pharmacy technicians demanded to be heard and respected as much as other healthcare workers. Additionally, they have asked for livable wages and the ability to be more of an asset to the profession. As expressed, technicians have called for our government and local officials to hear our demands and make the necessary changes going forward. The Public Readiness and Emergency Preparedness (PREP Act) by the U.S. Department of Health and Human Services (HHS) enacted regulation changes to expand the capacity of healthcare workers to administer vaccinations.[1,2,4] This change in regulations have seen technicians valued more than ever. Today, a qualified pharmacy technician can engage in direct patient care by administering COVID-19 vaccines. The pandemic has changed the role of pharmacy technicians and expanded the services they can provide. These changes have proved that pharmacy technicians are more than capable of playing a pivotal role in the healthcare crisis. Thus, the pandemic has created a paradigm shift in the healthcare system because there will be relief in pharmacies and increased access to vaccinations. After the PREP Act was enacted, there was a surge in demand for personnel able to administer COVID-19 vaccinations. This provided the opportunity for more than 400,000 pharmacy technicians to be deployed to relieve the burden of the strained healthcare system. A national pharmacy chain was reported to have hired over 10,000 technicians in readiness for the rollout of the vaccination process.[3] However, the actions taken by HHS are a temporary solution to the issues affecting the healthcare system. There are still future opportunities for much-needed changes to the roles of pharmacy technicians.

References:

1. Adams AJ, Bright D, Adams, J. Pharmacy technician-administered immunizations: A five-year review. *J Am Pharm Assoc*. 2022; 62(2):419-423.
2. Goff DA, Ashiru-Oredope D, Cairns KA, et al. Global contributions of pharmacists during the COVID-19 pandemic. *J Am Coll Clin Pharm.* 2022 Dec; 3(8):1480-1492.
3. Hohmeier KC, McKeirnan KC, Akers JM. Pharmacy technicians are valued more than ever: Insights into a team-centered immunization approach. *Pharmacy Times*. https://www.pharmacytimes.com/view/pharmacy-technicians-are-valued-more-than-ever-insights-into-a-team-centered-immunization-approach (accessed 2022 Jan 31).
4. Guidance for PREP Act coverage for qualified pharmacy technicians and state-authorized pharmacy interns for childhood vaccines, COVID-19 vaccines, and COVID-19 testing. Washington, DC: U.S. Department of Health and Human Services; 2020 Oct 20. https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf (accessed 2022 Jun 21)

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Bedside delivery pharmacy technician

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MedStar Health's pharmacies are committed to providing world-class, compassionate care to every patient, every time, at every touch point. One role that helps us achieve this goal is the bedside delivery pharmacy technician. Associates who staff in this role are responsible for all pharmacy tasks relating to the bedside delivery program, including: facilitating patient participation; acting as pharmacy liaison between patients and physicians, social workers, nurses, and inpatient/outpatient pharmacy staff; preparing prescriptions; and coordinating payment and deliveries. Initiated originally as a program to help patients obtain hard-to-fill medications, MedStar Health has evolved the Meds to Beds program into filling all discharge prescriptions for patients who opt into our services. The goal of the program is to discharge patients with their medications, identify any barriers and increase overall adherence in order to improve patient outcomes, reduce avoidable healthcare spend related to medication errors and decrease readmissions rates.

The advanced role of the bedside delivery pharmacy technician, under the supervision of MedStar pharmacists, is in compliance with the rules and statutes of the State of Maryland. The technician applying for this position is required to be a licensed pharmacy technician, obtain the Pharmacy Technician Certification Board (PTCB) certification or the Exam for the Certification of Pharmacy Technicians (ExCPT) and have three years retail or ambulatory care pharmacy experience. The primary role and unique responsibilities of this position include:

- Identify discharge patients, explain the benefits of the bedside delivery program, and encourage and facilitate participation. Obtain insurance information and patient demographics.
- Attend daily/weekly/monthly meetings with interdisciplinary teams to grow the program through promotional events, education, and relationship building.
- Organizes bedside delivery prescriptions in designated area of the pharmacy in order of priority: retrieves labels from printer and arranges paperwork for filing.
- Work to eliminate any potential barriers to patient participation in bedside delivery program. Bring to the attention of a pharmacist any claims requiring overrides. Troubleshoot insurance claim rejects and follow up on problem prescriptions.
- Work directly with Social Workers, Nurses, Physicians and other Pharmacy staff to troubleshoot any issues requiring intervention including prior authorizations, clarifications, re-writes, and referrals to social work.
- Communicate with patient regarding prescription cost/co-pays and their ability to pay. Collect payment for prescriptions; process cash, check, credit card transactions; secure appropriate signatures; and, ensure compliance with HIPAA requirements.
- Deliver prescriptions to patient's room and shows medications to patient; offer and facilitate counseling by a pharmacist if requested; hand prescriptions to patient's nurse in secure bag for storage on the floor until patient is discharged.
- Participate in meetings and on committees and represents the department and hospital in community outreach efforts. Participate in multi-disciplinary quality and service improvement teams.

Currently, there are 6 pharmacy technicians in this advanced technician role at four of our MedStar Maryland Hospitals who support the bedside delivery program.

Medication Safety Committee

ISMP special alert: Medication safety issues with newly authorized PAXLOVID™ (nirmatrelvir and ritonavir)

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The Institute for Safe Medication Practices (ISMP) recently published a special alert to bring awareness of medication safety issues associated with PAXLOVID™, a combination of two oral medications nirmatrelvir, an oral protease inhibitor, and ritonavir, an HIV-1 protease inhibitor. This medication received an Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA) on December 22, 2021[1] for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients.

PAXLOVID™ contains nirmatrelvir oral tablets that are co-packaged with ritonavir oral tablets. Nirmatrelvir targets the SARS-CoV-2 main protease, also known as 3C-like protease, preventing viral replication. The co-administration with a low dose of ritonavir inhibits the metabolism of nirmatrelvir, leading to an increased plasma concentration of nirmatrelvir for a longer period of time.[2]

The emergency use of PAXLOVID™ is for the treatment of mild-to-moderate COVID-19 in patients ≥ 12 years of age, weighing at least 40 kg, who are within 5 days of symptom onset, and are at high risk of progressing to severe COVID-19. PAXLOVID™ is not authorized for the treatment of hospitalized patients or for pre- or post-exposure prophylaxis for COVID-19. It is not recommended in patients with severe hepatic impairment and cannot be used longer than 5 consecutive days.

The recommended dose of nirmatrelvir and ritonavir is as follows:

- eGFR ≥ 60 mL/min: Nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg twice daily.
- eGFR between 30-60ml/minute: Nirmatrelvir 150 mg and ritonavir 100 mg twice daily.
- eGFR < 30ml/minute: use not recommended at this time.

Important note for dispensing pharmacists

- PAXLOVID™ is supplied in a carton holding five blister cards that contain the daily morning and evening doses for patients with normal renal function and mild renal impairment.
- For patients requiring dose reduction, the EUA directs pharmacists to remove one of the nirmatrelvir tablets for both the morning and evening doses from each blister card before dispensing for proper dose reduction (refer to figure 1). After removing the tablets, the empty blisters on the cards should be covered with manufacturer-supplied stickers.

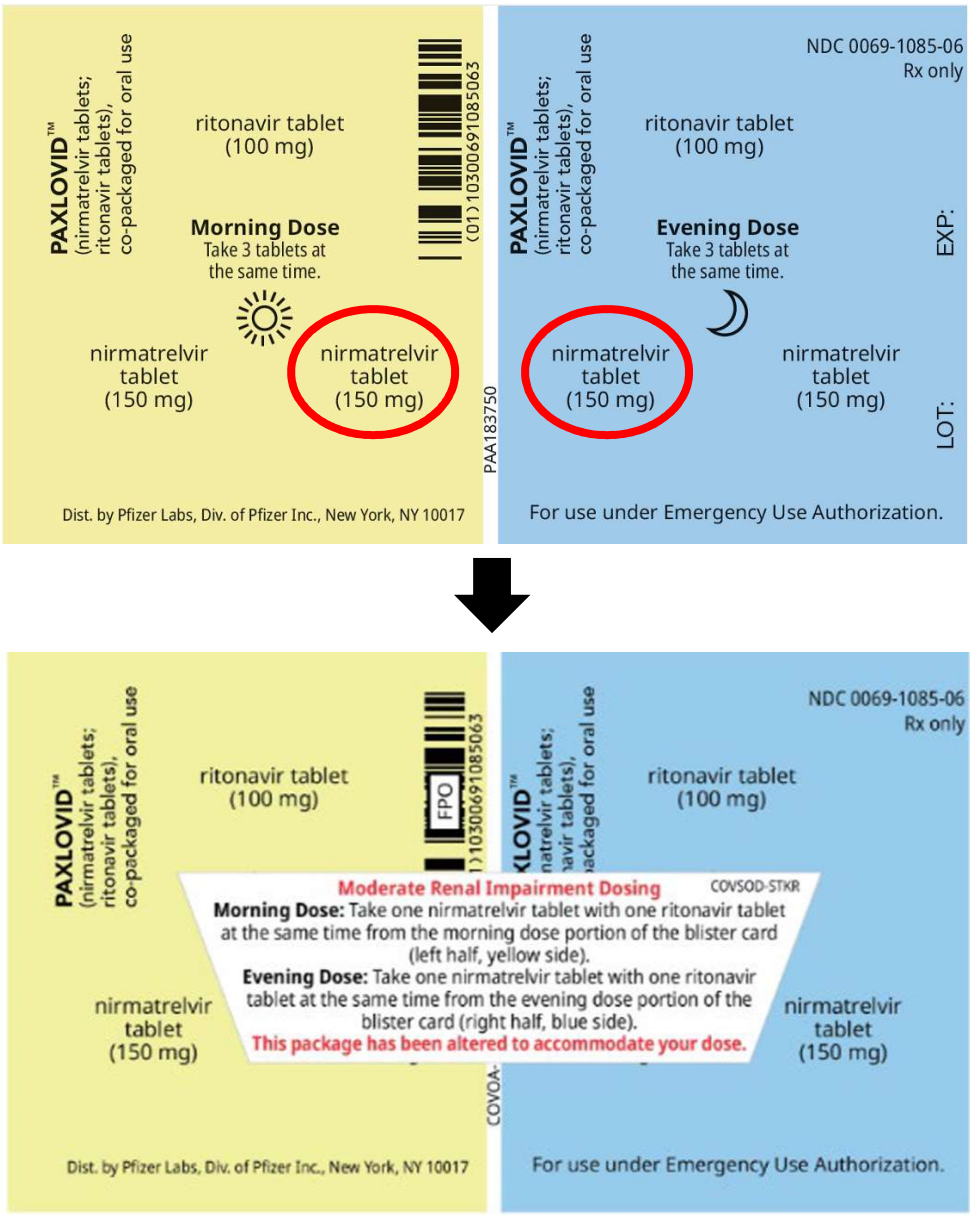

Figure 1. The red ovals in the image are where the nirmatrelvir tablets should be removed prior to dispensing PAXLOVID™ to patients with moderate renal impairment; then, a preprinted sticker with dosing instructions, should be placed over the empty blisters.[1]

Safety Concerns and Recommendations

Safety Concern	Recommendation
Challenges with prescribing the dose	• Electronic prescribing systems should include alerts to remind providers about dose adjustments for PAXLOVID™. • Prescriptions should specify the numeric dose of each active ingredient to minimize potential for dosing errors.
Drug-Drug Interactions	• A review of drug-drug interactions should be performed prior to prescribing PAXLOVID™. Ritonavir is a potent CYP3A inhibitor. This can cause an increase in the plasma concentrations of CYP3A substrates. Since nirmatrelvir and ritonavir are CYP3A substrates, drugs that induce CYP3A can decrease their plasma concentrations and reduce their therapeutic effects.
Failure to remove tablets and cover empty blisters	• Ensure pharmacies have a process to prevent dispensing errors for patients requiring dose reduction related to the removal of one nirmatrelvir tablet from the morning and evening dose of the blister card and to ensure the opened blister is covered with a sticker.
Failure to take the tablets together	• Pharmacists have an important role counseling patients to take both the nirmatrelvir and ritonavir tablets together in the morning and evening. • For patients with moderate renal impairment, pharmacists should explain that the package has been altered to provide proper dose.

All serious adverse events or medication errors related to PAXLOVID™ should be reported to the FDA MedWatch reporting program.

References:

1. Medication Safety Issues with Newly Authorized Paxlovid. ISMP Medication Safety Alert. https://www.ismp.org/alerts/medication-safety-issues-newly-authorized-paxlovid. Published January 3, 2022. Accessed January 11, 2022.
2. FDA EUA Letter. FDA Website. https://www.fda.gov/media/155049/download. Published December 22, 2021. Accessed January 11, 2022.

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Medication Safety Committee

ISMP Updates: 2022-2023 Targeted Medication Safety Best Practice for Hospitals

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The Institute of Safe Medication Practices (ISMP) Targeted Medication Safety Best Practice for Hospitals (TMSBP) was developed to draw the attention of hospitals and other health settings to medications errors that can cause harm to patients and even death. The initiative was launched in 2014 and is updated every two years, as needed. The new updated TMSBP contains nineteen best practices. The update added three new best practices and archived three best practices joining another previously archived best practice. Archived best practices are still considered best practices and maintain their original best practice number.

Best Practice Updates

1. **Best Practice 17: Safeguard against errors with oxytocin use**. To prevent errors associated with improper administration of oxytocin, ISMP recommends using order sets to prescribe oxytocin for antepartum and postpartum use as well as standardizing to a single concentration and bag size. It is also recommended that the dose, concentration, and rate, be expressed clearly and standardized to align with the smart infusion pump dose error-reduction system (DERS). Oxytocin bags should be provided from the pharmacy in a ready-to-use form and should be labelled on both sides to differentiate from other hydration solutions. Oxytocin infusion bags should not be brought to the patient's bedside until the medication is prescribed and needed.
2. **Best Practice 18: Barcode verification to care areas beyond inpatient care units.** Implementation of barcode medication administration (BCMA) is a well-known error mitigation strategy that is designed to catch medication errors at the point of administration when used correctly. There is reported gap in the use and adoption of this technology in procedural settings and other clinical areas where there is short or limited patient stay. This best practice outlines the importance of expanding BCMA to these areas in an effort to maximize the use of barcode verification prior to administration of medications and/or vaccines to help eliminate errors. Assessing utilization and effectiveness of the safety technology as well as reviewing compliance are added benefits that would reinforce and sustain the implementation of this safety initiative.

3. **Best Practice 19: Improve safety of high alert medications**: High alert medications are drugs that can cause significant harm to patients when they are used in error. ISMP continues to encourage the use of robust set of processes for the management of high alert medications to help mitigate potential errors. Hospitals should reassess their list of high-alert medications and ensure error-prevention strategies throughout the medication-use process while establishing outcome and process measures to routinely assess effectiveness and reduce the risk of harm with these medications. Management of risks should include strategies that address system vulnerabilities that apply to all practitioners who are involved in the medication-use system. Furthermore, organizations should limit attempts to prevent errors with low-leverage risk reductions strategies and reliance on staff vigilance. Instead emphasis should be made on mid- and high-leverage risk-reduction strategies to heighten the error prevention. Sole reliance on independent double checks should be avoided and the use should be limited to select high-alert medications.

The full list of updated ISMP best practices can be found on https://www.ismp.org/guidelines/best-practices-hospitals

References:

1. Institute for Safe Medication Practices (ISMP). *ISMP Targeted Medication Safety Best Practices for Hospitals*; 2022. https://www.ismp.org/guidelines/best-practices-hospitals (Accessed 2022 April 24)

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Membership Committee

Community service event

Kisha Dunkley, PharmD, BCPS
Membership Committee Chair

On September 22nd, MSHP members participated in a volunteer event to support Moveable Feast. Several MSHP members volunteered for the in-person kitchen duties that involved food preparation and packing. The virtual fundraiser allowed individuals to contribute by monetary donation. MSHP members contributed a total of $1505.75 to Moveable Feast! In addition, members dined-in or ordered take-out from local restaurants that were donated a portion of the night's proceeds to Moveable Feast. The generous donation will go toward supporting food insecurity in our community. Thank you all for your generosity!

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Legislative Committee

Electronic prescriptions for controlled substances

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Effective January 1, 2022, Senate Bill 0166 (CH0299)/House Bill 0512 (CH0230) (2020) Drugs and Devices – Electronic Prescriptions – Controlled Dangerous Substances requires licensed health care practitioners to electronically prescribe prescriptions for controlled dangerous substances (CDS), unless an exception exists.[1] A provider who is unable to electronically transmit CDS prescriptions must request a waiver from the electronic prescribing requirement.[2] For a complete list of exceptions, please review Md. Code Ann., Health General Article, §§ 21-220(c)(2).[1]

Originally, the effective date of the state law aligned with the comparable federal law (Section 2003 of the SUPPORT Act). However, in response to stakeholder feedback, CMS announced they are delaying the start date for compliance actions to January 1, 2023.[3] In order to maintain alignment with the federal government, the Maryland Department of Health is also delaying compliance actions to January 1, 2023. The Maryland Board of Pharmacy has issued the following guidance to its licensees: A pharmacist may dispense a drug on a written or oral prescription for a CDS that meets the exception requirements, hence allowing to continue to accept a paper prescription to dispense CDS. In addition, at this time, a pharmacist is not required to verify that the prescription is an authorized exception to the electronic prescription requirement.

References:

1. Senate Bill 0166 (CH0299)/House Bill 0512 (CH0230) (2020) Drugs and Devices – Electronic Prescriptions – Controlled Dangerous Substances. https://mgaleg.maryland.gov/2020RS/bills/sb/sb0166T.pdf. Accessed February 12, 2022.
2. Electronic Prescribing Waiver Request. Maryland Department of Health. https://health.maryland.gov/ocsa/Pages/Electronic-Prescribing-Waiver-Request-form.aspx. Accessed February 12, 2022.
3. Calendar Year (CY) 2022 Medicare Physician Fee Schedule Final Rule. Centers of Medicare & Medicaid Services (CMS). https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2022-medicare-physician-fee-schedule-final-rule. Published November 2, 2021. Accessed February 12, 2022.

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Legislative Committee

Pharmacist administration of maintenance injectable medications

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In response to the enactment of the Christopher King Access to Treatment Act in 2021, the Maryland Board of Pharmacy promulgated new regulations that allow for pharmacist administration of maintenance injectable medications – COMAR 10.34.41: Administration of a Maintenance Injectable Medication. The regulations permit administration of a maintenance injectable (other than IV) to include the treatment of psychiatric disorders, substance use disorders, contraception, and vitamins. The 2022 Administration of Injectable Medications for Treatment of Sexually Transmitted Infections Act specifically included sexually transmitted infections in the category of conditions that a pharmacist can treat with a maintenance injectable, and mandated that the COMAR 10.34.41 would immediately apply to the new category. This legislation expands the scope of clinical services provided by pharmacists, reduces patient barriers to care and has the potential to improve the health of Marylanders.

The requirements to administer a maintenance injectable medication are defined in the Board-approved procedure as detailed in the regulations. With receipt of a written order from an authorized prescriber, and documentation of informed patient consent, a pharmacist shall review the indication, and screen for precautions, contraindications, and allergies. Note, a pharmacist is not permitted to administer a patient's initial dose of a medication, unless the patient's record contains documented approval from the authorized prescriber. Upon administration, the pharmacist provides medication counseling, documents the encounter, provides the visit summary, and notifies the prescriber of the administration as well as any relevant information about the patient's condition.

Prior to initiating services for the administration of maintenance injectable medications, a pharmacist shall complete a Board-approved training program. The training program requirement is waived for pharmacists who have undergone training as part of a formal education program. Content areas of the training must include administration of a maintenance injectable medication, management of the patient population, knowledge of the specific maintenance injectable medications to be administered as well as current clinical guidelines related to the patient populations or medications. Training programs should be submitted to the Board of Pharmacy for review.

A pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern, who has successfully completed a Board-approved certification course, may administer a maintenance injectable medication under the direct supervision of a licensed pharmacist who meets the requirements for administering maintenance injectable medications. Pharmacists are not required to complete specific ongoing continuing education credits, as is required to administer vaccinations, but a pharmacist is independently responsible for maintaining competence after receiving initial training. Practice sites must have a standard procedure that is signed annually by pharmacists administering injectables and made available for inspection by the Board. This document should be updated as needed and may be included as an additional element of the training program.

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Please note that this article provides a general summary of the Board's regulations. Please reference the regulations, COMAR 10.34.41, in order to review the full requirements necessary for pharmacist administration of injectable medications.

References:

1. Code of Maryland Regulations 10.34.41. Administration of a Maintenance Injectable Medication. http://www.dsd.state.md.us/COMAR/SubtitleSearch.aspx?search=10.34.41.* Accessed September 27, 2022.
2. Title 10 Maryland Department of Health. Subtitle 34 Board of Pharmacy. Chapter 41 Administration of a Maintenance Injectable Medication. http://www.dsd.state.md.us/comar/searchall.aspx Accessed September 1, 2022.
3. Senate Bill 0084/House Bill 0135 (2021) Pharmacists – Administration of Self–Administered Medications and Maintenance Injectable Medications (Christopher King Access to Treatment Act). https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0084/?ys=2021rs Accessed September 1, 2022.
4. Senate Bill 0019/House Bill 0229 (2022) Pharmacists – Administration of Maintenance Injectable Medications – Treatment of Sexually Transmitted Infections. https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/sb0019?ys=2022RS Accessed September 1, 2022.

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Education and Programming Committee

Events and opportunities

Crystal Lu, PharmD, BCOP
Terri Jorgenson, RPh BCPS
Ann Zhou, PharmD BCPS

We are SO excited to reconnect with you all in person at the upcoming MSHP Fall Seminar and Residency Showcase! The robust continuing education (CE) programming will be held at the Sheraton Baltimore North Hotel in Towson, MD on October 28, 2022. The Fall Seminar will run from 7:30AM to 4:30PM and is followed by the Residency Showcase from 4:30PM to 6:30PM. Speakers will be engaging attendees with active learning techniques on a variety of exciting and emerging hot topics such as workplace well-being and resilience, use of SGLT2 inhibitors, atypical antipsychotics, and toxicology. A unique addition this year will be a didactic and interactive session focusing on strategies for equity, diversity, and inclusion. We will also be holding the MSHP annual member business meeting. Member technicians can register and attend at no cost!

The residency showcase will feature pharmacy residency programs throughout Maryland. It is a great opportunity for students to network and learn more about post-graduate training opportunities and some pearls of wisdom for ASHP midyear and beyond.

Registration and schedule for the Fall Seminar can be found using the link below:
https://mshp.site-ym.com/events/EventDetails.aspx?id=1635439&group=

We want to hear from you! Want to get involved? Have ideas for future seminar topics? Interested in serving as faculty? Reach out the MSHP EPC now!

- To inquire about joining our committee, please reach out to Crystal Lu (Crystal.Lu@nih.gov), Terri Jorgensen (Terri.Jorgenson@va.gov), or Ann Zhou (xzhou38@jhmi.edu)
- To submit topics for future educational presentations, fill out the form here: https://forms.gle/VSB2r5kqesQjbxKm8
- If you're interested in speaking at an upcoming seminar, fill out the form here: https://forms.gle/wKizj6K2RL7hocKH8

SAVE THE DATE for our 2023 MSHP Spring Seminar! It is scheduled for April 21st, 2023, at The Hotel at Arundel Preserve in Hanover, MD. The event will be hybrid in-person/online event with CE programming for both pharmacists and technicians.

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Antimicrobial Stewardship Committee

Pnew pneumococcal conjugate vaccines!

Jonathan Ford PharmD, MBA, BCIDP
Clinical Pharmacy Specialist, Infectious Diseases and Antimicrobial Stewardship, LifeBridge Health

Vaccines save lives. This is well known. However, vaccines also play a critical role in preserving our antimicrobial armamentarium through infection prevention. This impact has been especially prominent with vaccines targeting common serotypes of *Streptococcus pneumoniae*.

According to the Centers for Disease Control and Prevention, invasive pneumococcal disease (IPD) incidence in the United States has dropped by 50-90% across all age groups following the introduction of pneumococcal conjugate vaccines (PCVs). The California PCV7 licensure trial provides a glimpse of the antimicrobial stewardship impact of these vaccines. In this trial, PCV7 prevented 35 antibiotic prescriptions per 100 children vaccinated. Extrapolated nationwide, this would translate into 1.4 million avoided antibiotic courses in pediatric patients alone.[1]

PCVs are different from unconjugated pneumococcal polysaccharide vaccines (e.g. PPSV23) in that the capsular polysaccharides are linked (conjugated) to an immunogenic protein. This elicits a T-cell dependent response with establishment of B-cell memory and an extended duration of immunity relative to PPSV23.

Historically PCVs have been administered first to elicit this robust immune response and PPSV23 is administered a year later in high risk patients and those over 65 years of age. The reduction in IPD caused by *S. pneumoniae* serotypes covered by PCV7 and PCV13 was so dramatic that in 2019, the Advisory Committee on Immunization Practices (ACIP) softened PCV13 vaccination recommendations in adults 65 years and older. Rather than being recommended for all patients in this cohort, PCV13 prescribing was made optional based on a "shared clinical decision-making process." Under this framework, high-risk conditions were the guiding force for PCV13 prescribing, independent of patient age. PPSV23 was still recommended in patients 65 years and older though given its protection versus an additional 11 serotypes that are not covered by PCV13. These 11 serotypes accounted for 32-37% of IPD in this elderly cohort at that time.[2]

Recently two new PCVs have received FDA approval: PCV15 (brand name Vaxneuvance) and PCV20 (brand name Prevnar 20). PCV15 is approved for patients 6 weeks and older whereas PCV20 is only approved for patients 18 and older. Clinical trials of PCV20 in infants are ongoing.

The expansion of serotype coverage offered by these new PCVs has led ACIP to revise pneumococcal vaccine recommendations again. The following table provides a summary of updated CDC pneumococcal vaccine recommendations. For full recommendations, please visit Pneumococcal Vaccination: Who and When to Vaccinate | CDC.

Infants	• PCV13 or PCV15 as a series of 4 doses at 2 months, 4 months, 6 months and 12-15 months
Patients 2-18 Years of Age with Certain Medical Conditions*	• PCV13 or PCV15 dose(s) if patient has not received full PCV series • One dose of PPSV23 following PCV dose(s) • An additional PPSV23 dose 5 years later for specific immunocompromising conditions**
Adults 19-64 with High Risk Conditions* **	• **PCV20** OR **PCV15 followed by a dose of PPSV23 one year later** • For those who have received PPSV23: **PCV20** OR **PCV15** (note no need for an additional PPSV23 before the age of 65 if giving PCV15) • If PCV13 already given: PPSV23 x 2 doses spaced at 5 year intervals before the age of 65 with a final dose of PPSV23 after the age of 65
Adults ≥ 65 Years-Old	• If patient has received PCV20 previously OR if patient has received PCV13 or PCV15 previously with a PPSV23 dose after the age of 65: **No further vaccination needed** • If none of the above or if vaccination status unknown: **PCV20** OR **PCV15 followed by a dose of PPSV23 one year later**

*CSF leak, cochlear implant, chronic heart disease, chronic lung disease, cochlear implant, diabetes mellitus.
**chronic renal failure, congenital immunodeficiency, congenital or acquired asplenia, diseases associated with treatment of immunosuppressive drugs or radiation therapy, HIV infection, sickle cell disease or other hemoglobinopathies.
***Alcoholism, Cerebrospinal fluid leak, Chronic heart disease, Chronic liver disease, Chronic lung disease, Chronic renal failure, Cigarette smoking, Cochlear implant, Congenital or acquired asplenia, Congenital or acquired immunodeficiency (B- (humoral) or T-lymphocyte deficiency, Complement deficiency, Phagocytic disorder, excluding chronic granulomatous disease, Diabetes mellitus, Generalized malignancy, HIV infection, Hodgkin disease, Iatrogenic immunosuppression, including long-term systemic corticosteroids and radiation therapy, Leukemia, Lymphoma, Multiple myeloma, Nephrotic syndrome, Sickle cell disease or other hemoglobinopathies, Solid organ transplant

If PCV20 receives FDA approval for pediatric patients, PPSV23 may become further relegated to increasingly unique scenarios. And this may simplify pneumococcal vaccine recommendations to an even greater extent. Only time will tell if the more robust immune response achieved through additional serotype coverage with these new conjugate vaccines will result in lower rates of IPD caused by these serotypes; and in turn fewer antibiotic prescriptions for IPD.

References:

1. Klugman KP and Black S. Impact of existing vaccines in reducing antibiotic resistance: primary and secondary effects. Proceedings of the National Academy of Sciences. 2018;115(51). 12896-12901.
2. Matanock A, Lee G, Gierke R, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: updated recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep. 2019;68(46):1069-1075

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Ambulatory Care Committee

Pharmacy burnout

Olivia Gaudreault, PharmD Candidate 2022

Burnout. A buzzword that we are constantly hearing these days, especially in the world of pharmacy. Many of us know the feeling or can recognize it in our coworkers/peers, but what specifically is causing it and how can we prevent it? By definition burnout is a state of emotional, physical, and mental exhaustion that can lead to loss of interest and motivation.[5] Typically, periods of excessive and prolonged stress as well as feeling overwhelmed contribute to the feeling. Being constantly overwhelmed, emotionally drained, or unable to meet constant demands can leave one feeling unaccomplished and unfulfilled.

The signs and symptoms of burnout are not just emotional but can become behavioral and even physical. Feeling tired and drained all the time can lower one's immunity, and constantly being stressed or tense can lead to headaches or muscle pains. The way it manifests can be different person to person, however, it can be noted that women tend to express their emotions more which can lead to more of an emotionally exhaustive state, whereas men tend to present in a more detached way.[5] Depersonalization may look like someone just doesn't care, but in reality the issue is much deeper. As a fellow coworker, and human, if you see someone self-isolating or skipping work/arriving late constantly it may be a great chance to step in and see if the person can be helped before more serious consequences happen.

This is because burnout is not just an individual's problem, but rather a problem that we as health professionals should be concerned about. It can cause dangerous health outcomes both for the healthcare provider as well as the patient. Relating to pharmacy specifically, competing demands, time constraints, and performance metrics can cause medication errors and poor patient interaction.[2] Free pizza is not enough to solve these problems! Work conditions need to be improved, and soon, for the benefit of all. Adequate staffing would be a great start. Enough help allows safe dispensing of medication, proper delivery of clinical services, and enough time to counsel patients. The Board of Pharmacy's engagement would also be extremely valuable in evaluating staffing needs, performance measures that jeopardize care, utilization of technology, and distracting administrative policies.[1]

Until these can be implemented, finding out ways to reduce the amount of stress and boost one's mood is an individual process that is highly essential. Whether that be planning time in one's week to meet up with friends or working out, having something good to look forward to can help when the pressures of work become too much. In addition, there are a ton of resources available for pharmacy staff to utilize, such as ASHP Wellbeing and You and the Pharmacy Workplace and Well-Being Reporting (PWWR). ASHP Wellbeing and You offers many resources, tools, and community connections to help members combat burnout in the workplace.[6] The PWWR is a confidential and anonymous report that is collected and analyzed by the Alliance for Patient Medication Safety. They aggregate, non-identifiable data from all the reports and use the information to influence and educate the pharmacy community and leaders on meaningful and actionable changes. [7] As much as it can be hard to control the things that happen during a day at work, take the opportunities, even if it may seem small, to take care of yourself and each other.

References:

1. "APhA: Pharmacist Burnout Hits Breaking Point, Impacting Patient Safety." *American Pharmacists Association*, 17 Dec. 2021, https://www.pharmacist.com/APhA-Press-Releases/apha-pharmacist-burnout-hits-breaking-point-impacting-patient-safety#:~:text=Pharmacy%20burnout%20is%20a%20significant,pressure%20to%20meet%20performance%20metrics.
2. Elizabeth H. Padgett, PharmD Candidate 2020 Auburn University Harrison School of Pharmacy Auburn. "Pharmacist Burnout and Stress." *U.S. Pharmacist – The Leading Journal in Pharmacy*, 15 May 2020, https://www.uspharmacist.com/article/pharmacist-burnout-and-stress.
3. Flemings, Eric, and RPh Shane Desselle. "Coping with Burnout in the Pharmacy." *Pharmacy Times*, Pharmacy Times, 28 Oct. 2021, https://www.pharmacytimes.com/view/coping-with-burnout-in-the-pharmacy.
4. Johnston, Karlee, et al. "Burnout and the Challenges Facing Pharmacists during COVID-19: Results of a National Survey." *International Journal of Clinical Pharmacy*, Springer International Publishing, June 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8043093/.
5. Melinda. "Burnout Prevention and Treatment." *HelpGuide.org*, 23 Dec. 2021, https://www.helpguide.org/articles/stress/burnout-prevention-and-recovery.htm.
6. *PWWR*, APhA, https://www.pharmacist.com/Advocacy/Well-Being-and-Resiliency/pwwr.
7. "Resources - Wellbeing ASHP." *ASHP Wellbeing & You*, https://wellbeing.ashp.org/resources?loginreturnUrl=SSOCheckOnly.

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Diversity, Equity and Inclusion Steering Committee

Introducing *MSHP Diversity, Equity and Inclusion Steering Committee*!

Reemal Zaheer, PharmD
PGY-1 Community-based resident, Johns Hopkins Home Care Group

We are excited to introduce the MSHP Diversity, Equity, and Inclusion (DEI) Steering Committee, which was initially established in March 2021, and the first members started in July 2021! The purpose of this committee is to promote health care equity in pharmacy services for our patients and to develop best practices within the realms of racial, social, sexual, religious, and gender diversity. We also aim to promote training to bring awareness to DEI in the workplace when interacting with patients and other healthcare team members. The committee is also committed to developing a mentorship program for underrepresented pharmacists interested in advancing in their careers with the help of key champions from healthcare systems in Maryland. We are very excited to work with dedicated members of MSHP who are passionate about DEI and look forward to collaborative opportunities to ensure DEI initiatives are well-integrated within the organization.

Committee chair: Ifeanyi Egbunike (iegbunike@umm.edu)

Meeting time: 3rd Wednesday of the month from 5-6 pm

Goals:

- Support the needs of our membership in the areas of racial diversity, equity, and inclusion.
- Ensure diversity, equity, and inclusion within the organization.
- Eliminate racial and ethnic healthcare disparities in all practice settings and the state of Maryland.
- Promote ASHP Diversity, Equity, and Inclusion initiatives where feasible and applicable.

Highlights of our activities:

- Addressing the Elephant in the Room: Embracing our diversity in the pharmacy workplace & Preceptor development education: Creating an inclusive learning environment (Fall Seminar October 2021), Encore Presentation at Technician Seminar (January 2022)
- International Women's Day Social Media Pose Campaign: #BreakTheBias (March 8, 2022)
- The John Hopkins Hospital – Diversity, Equity, & Inclusion Presentation & CE (April 27, 2022)
- Implicit bias training – new license renewal requirement for both pharmacists and technicians (email blast, April 2022)
- Student Leadership Workshop (June 5, 2022)

Future topics plan we plan to explore:

- Path to Allyship
- Cracking the code: Why we must do it?
- Cultural Awareness in Healthcare
- Microaggression and its Macro Impact
- Health Equity
- Addressing stereotypes in the workplace
- Strategies to consider when engaging in conversation about diversity and inclusion
- Round table discussion on DEI for residents and students

Have ideas for future topics, or are you interested in joining our committee? Please feel free to reach out to our chair. We would love to have you join our group. Stay tuned for exciting updates, events, and articles coming your way very soon!