

Student Clinical Digest

Presented by the Student College of Clinical Pharmacy
University of Georgia Student Chapter

Table of Contents

Clinical Pharmacist
Spotlight

New Drug Update

Clinical Pharmacy
Benefits Review

OTC Drug Update

Hypertension
Guideline Update



Clinical Pharmacist Spotlight

Dr. Amber Mayo, Pharm. D.

**Clinical Pharmacist at Charlie Norwood Veterans Affairs
Medical Center**

By: Zoe Krenz, Pharm.D. Candidate

Where did you go to school and did you know what you wanted to do when you graduated? What positions have you held since graduating and how has that gotten you to where you are today?

I took my pre-requisite courses at Mercer University in Macon, Georgia. Interestingly enough, I went on to attend pharmacy school at the University of Georgia College of Pharmacy, and I like to joke that I graduated from the program soon after the turn of the century (in 2002).

My graduating class was the first class that did not have a choice between the Bachelor of Science or doctoral degree in pharmacy. This lack of choice was an unrecognized blessing since I originally had planned to be married to my high school sweetheart and go back to my hometown to work in retail pharmacy, and retail pharmacists at the time generally did not go on to get their doctorates in pharmacy. The field of pharmacy was thriving with demand when I graduated, and I honestly was confused in which direction I wanted to proceed. I was interested in many more fields of pharmacy than I had been interested in when I started pharmacy school, and I believe those varied interests should reflect well for the UGA College of Pharmacy's program for having such a talented pool of preceptors who helped generate so much interest for me. Recognizing my struggle and knowing that I had decided not to complete a residency, a professor suggested I consider part-time employment in a hospital setting so that I could explore both hospital and retail pharmacy more.

Dr. Chisholm was able to facilitate a discussion between the clinical manager of pharmacy at University Hospital in Augusta, GA (now Piedmont Hospital) and me. I was able to arrange a scenario in which I worked a part-time evening shift at the hospital to obtain more hospital experience while also working part-time for an independent pharmacy in my hometown of Sandersville, GA, to expand my interests in independent pharmacy and compounding.

New Drug Update

By: Jamie Le, Pharm.D. Candidate

Momelotinib (OJJAARA®)

Indication:

For the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis or secondary myelofibrosis (post-polycythemia vera and post-essential thrombocythemia) in adults with anemia (Hb <12.0 g/dL in women and <13.0 g/dL in men) regardless of prior myelofibrosis therapy.¹

Dosage & Administration:

- Available as tablets: 100 mg, 150 mg, 200 mg
- Recommended dosage: 200 mg orally once daily with or without food.
- For patients with severe hepatic impairment (Child-Pugh Class C), the starting dose is reduced to 150 mg orally once daily.¹

Clinical Manifestations:

Myelofibrosis (MF) clinical manifestations typically include anemia, thrombocytopenia (low platelet count), splenomegaly, hepatomegaly coupled with symptoms of fatigue, abdominal pain and discomfort, night sweats, bone pain, and pruritus.¹

Relevance in Current Therapy:

MF is a rare blood cancer caused by dysregulation of JAK-signal transducer and activator of transcription protein signaling characterized by splenomegaly, cytopenia, and shortened life expectancy with a median overall survival rate of 5-7 years.^{2,3} Anemia is a deficiency in red blood cells and can be defined as a marked reduction in hemoglobin or hematocrit.⁴

I continued this path for approximately two years before being presented with the opportunity to train with a clinical pharmacy specialist in the emergency room. I enjoyed learning more about her role and experiences when working evenings with her, so I jumped at the opportunity when she and the clinical pharmacy director approached me about taking over her position in the ED. I was able to train for a few months with her before she left, and I worked in the ER for approximately eight years before going back part-time when my daughter was almost one year old. I was a part-time staff pharmacist at University Hospital for almost seven years, during which I was able to float in most areas of the hospital, for a total of 17 years at University Hospital in Augusta, Georgia.

In 2018, I decided to apply for a full-time position at the Charlie Norwood VA Medical Center (now also called the VA Augusta Health Care System) that would allow for a more consistent work schedule, and I have been working there for over 4 years. I specifically work as a clinical pharmacist helping process prescriptions for veterans who have met certain criteria to be referred for care outside of the VA.

I believe my time working for a retail pharmacy in a rural town along with my experience in a hospital and ER setting paved the way for me to serve my veteran patients well in my current position, and I can expound upon some of those.

I know the financial burdens that some medications can place on veterans with limited budgets, and I enjoy being able to work for veterans to determine what clinical information is needed from their community providers to be able to get the medications approved. If the medications are unable to be approved, I can explain the formulary steps that are remaining before the patients meet criteria for approval. In the Community Care area, my colleagues and I reach out to providers for the veterans. Likewise, my years of experience in the ER and inpatient settings allowed me to know the pitfalls that can occur during transitions of care with multiple providers that do not all have access to the same health records. There are opportunities to recognize when there are “too many hands in the pot” and help prevent duplicate therapy and provide the necessary counseling for those veterans.

Another previous experience that helps with my current position is formulary management. I had the (often-frustrating) experience in retail pharmacy of various PBMs having different formularies and requiring prior authorizations. I was also able to observe how a regional hospital managed its massive drug budget with formulary protocols. These prior experiences now allow me to balance the therapy needs of the patients better with the costs to the healthcare system to ensure patients get safe and cost-effective care.

What is your current position and what are your day-to-day tasks?

I am currently a clinical pharmacist in the Community Care Pharmacy area. I deal with all medications related to the **MISSION Act**, an act which was signed into federal law in 2018 to improve and expand the then-existing program that had a quick and rocky start in 2014 (called the CHOICE program). While many were concerned the MISSION Act would lead towards privatization of the VA system, privatization has not been the case. The Augusta program has grown from 1 to 4 pharmacists with one pharmacy technician hired to start soon. We service all the veterans using the Augusta VA system, including community clinics in Athens, Statesboro, and Aiken, SC. Our roles involve processing prescriptions ranging from ER and urgent care visits (2019) and inpatient hospital stays to patients in rural areas seeing local providers for primary care. There are also many prescriptions coming from specialty clinics such as cardiology, urology, nephrology, OB GYN/IVF, oncology, etc. We also get into processing prescriptions for specialty medications such as ambrisentan, mixed salt oxybate, tadalafil, etc.

While our section does not physically dispense medications, we do all the background work to verify which prescriptions are eligible to be filled by inputting the prescriptions from faxes and hard copies of prescriptions to review and process the prescriptions received electronically. Our system is set up such that our outpatient pharmacies (2 locations in Augusta) process prescriptions for veterans who present to the window with prescriptions and wish to wait for a supply of medications that are routinely stocked. If the veterans are amenable to having the prescriptions mailed from our

New Drug Update, Continued

Almost all patients with MF will eventually develop anemia.² Of the primary prevention population, 40%² are already anemic at diagnosis of MF. Of the secondary prevention population already treated for MF, a large proportion of the patients developed anemia, and patients who develop MF- or therapy-related anemia have a reduced survival rate.² Anemia is most consistently associated with a poor MF prognosis.² Presently, there are no curative treatments for MF other than allogeneic hematopoietic stem cell transplantation (allo-SCT), a complex, costly, and invasive procedure that depends on the availability of suitable donors and thus, can only be utilized for a small portion of patients.⁵ Consequently, therapy primarily focuses on palliative care, aiming to manage disease symptoms while enhancing overall patient well-being.⁵ Current treatments approved for MF include Janus kinase (JAK) inhibitors: ruxolitinib (Jakafi), fedratinib (Inrebic), and pacritinib (Vonjo) as well as Danazol (Danocrine).^{6,7,8} These treatments address MF symptoms and reduce spleen size effectively, but induce myelosuppression causing worsening anemia. Overall, MF patients with anemia represent a significant unmet medical need, as they often require frequent red blood cell transfusions with more than 30% of patients discontinuing their treatment as a result.^{2,9}

What is the most satisfying part of your job? What is the most challenging part of your job?

I have really enjoyed the expansion of my clinical knowledge in this position. I get to read lots of progress notes from specialists when reviewing non-formulary medications, so I've learned more about so many different areas of pharmacy. I've also learned the optimal use of technology to disseminate clinical information and guideline updates among each other within the profession. The VA has a massive pool of talented and knowledgeable pharmacy practitioners, and I can absorb bits and pieces every day through access to these national resources! I regret when veterans sometimes must wait longer than I would like to get their medications for them. Factors are usually out of my control and can include delays in getting outside records or delays due to the mail or work volume, but I have still had to learn to cope better with these issues that can be associated with a larger health system.

What was one of the most important lessons you've learned in your career?

Not all patients were raised to be polite. Sometimes, you must be firm yet respectful to make patients realize that you are really trying to help them. Other times, you have to take a deep breath and really try to dig in and listen to what the patients' biggest concerns are. Then, you can perform service recovery so that they are more likely to feel heard and absorb the appropriate education you need to provide. Being truthful to patients and acknowledging their concerns goes far to help produce better outcomes.

centralized mail-out facility (CMOP), then those prescriptions are passed along to the Community Care Pharmacy group for processing. We also call ourselves the Non-VA Care Pharmacy sometimes to avoid confusion with the Care in the Community area of the VA system dealing with evaluating veteran eligibility and appointment scheduling for Community Care patients (among many other tasks).

Once we receive a non-formulary medication, we obtain outside progress notes to review the medications for approval and denial. Upon determination of coverage, we inform the provider and veteran if the medication is not approved and why. If approved, we complete processing of the prescriptions. If any outside contracts are utilized to fulfill medications such as specialty medications, we coordinate with our procurement pharmacy staff.

We also have quite a few veterans who have heard from others about their improved experiences with the VA system, so they have their providers send us their prescriptions, as well. Unfortunately, we are not able to fill every outside prescription received because there are certain eligibility requirements, so we must notify those providers that we are unable to fill the prescriptions.

We also interface with our pharmacy call center to help veterans who may be calling with questions about their community care prescriptions.

Mechanism of Action:

OJJAARA has an inhibitory action along 3 key signaling pathways: Janus kinase (JAK) 1, JAK2, and activin A receptor Type I (ACVR1). Inhibition along the JAK1/JAK2 pathways may control the ability to reduce the size of the spleen, thus improving splenomegaly. The off-target mechanism inhibiting activin A receptor Type I (ACVR1) decreases circulating hepcidin, a peptide hormone elevated in MF that blocks iron absorption, contributing to the drug's additional benefits in controlling anemia.^{4,10}

Side effects:

Overall, OJJAARA has side effects similar to other MF treatments such as thrombocytopenia, hemorrhage, risk of bacterial infection and Hepatitis B reactivation, fatigue, dizziness, diarrhea, and nausea.^{1,6}

Lab monitoring:

Complete blood count (CBC) with platelets & hepatic panels should be obtained prior to starting treatment with OJJAARA and periodically during treatment. AST and ALT levels should be monitored at baseline, every month for 6 months while on the treatment.⁵

Major warnings and precautions:

Prior to administration of OJJAARA, the patient must be monitored for signs and symptoms of active infection, including reactivation of hepatitis B as hepatitis B viral

Why should a person choose to go into clinical pharmacy, and what advice would you give to them to achieve this career goal?

Clinical pharmacy keeps life interesting, and there are so many choices of patient populations! Just within our VA location in Augusta, we have skilled pharmacists focusing on women's health, anticoagulation, infectious disease, emergency care, oncology, acute care, home-based care, CLC (community living centers) care, mental health, informatics, pharmacist education, pain management, and more!

Soak up every minute of this time in pharmacy school and network to meet as many contacts as you can. Ask the graduates what they felt the most unprepared for with their curriculum. Based on those answers, think about whether you want to request any rotations that target those subjects. Ask similar questions you have asked me to your preceptors and professors. While on rotations, set up periodic meetings with your fellow students. Share the valuable resources among yourselves that make life easier. Whether or not you decide to do a residency or match with a residency site, you will have resources that will make you a better pharmacist when you get in the "real world." It is not a competition, but, rather, a collaboration that leads to better outcomes with patients. . . and, shouldn't that be our biggest goal?

Lastly, keep the profession well-represented by maintaining your integrity and conscientious work ethic. Don't be afraid to let your professors, other students, preceptors, or co-workers know when you are struggling and ask for help.

load (HBV-DNA titer) increases have been reported in patients with chronic hepatitis B virus infection on JAK inhibitors. Taking OJJAARA can increase the risk of life-threatening medical problems including serious infections. In the event of an active infection in patients with chronic infections, OJJAARA should be delayed until infections are resolved. Additionally, thrombocytopenia and neutropenia are possible exacerbations of taking a JAK inhibitor and should be managed with dose reduction or therapy interruption.¹

References

1. OJJAARA package insert. (2023). https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Ojjaara/pdf/OJJAARA-PI-PIL.PDF
2. Naymagon, L., & Mascarenhas, J. (2017). Myelofibrosis-Related Anemia. *HemaSphere*, 1(1), e1. <https://doi.org/10.1097/hs9.0000000000000001>
3. Masarova, L., Bose, P., Pemmaraju, N., Daver, N. G., Sasaki, K., Chifotides, H. T., Zhou, L., Kantarjian, H. M., Estrov, Z., & Verstovsek, S. (2022). Improved survival of patients with myelofibrosis in the last decade: Single-center experience. *Cancer*, 128(8), 1658–1665. <https://doi.org/10.1002/cncr.34103>
4. Pagani, A., Nai, A., Silvestri, L., & Camaschella, C. (2019). Hepcidin and Anemia: A Tight Relationship. *Frontiers in Physiology*, 10. <https://doi.org/10.3389/fphys.2019.01294>
5. Cervantes, F. (2014). How I treat myelofibrosis. *Blood*, 124(17), 2635–2642. <https://doi.org/10.1182/blood-2014-07-575373>
6. Loguidice, C. T. (2022). New JAK Inhibitors and Emerging Novel Agents Expand Myelofibrosis Treatment Arsenal. *www.onclive.com*, 23(17). <https://www.onclive.com/view/new-jak-inhibitors-and-emerging-novel-agents-expand-myelofibrosis-treatment-arsenal>
7. Robinson, K. (2022). Momelotinib Bests Danazol in Symptomatic Patients With Anemic Myelofibrosis. *Ashpublications.org*. <https://ashpublications.org/ashclinicalnews/news/6295/Momelotinib-Bests-Danazol-in-Symptomatic-Patients>
8. Verstovsek, S., Gerds, A. T., Vannucchi, A. M., Al-Ali, H. K., Lavie, D., Kuykendall, A. T., Grosicki, S., Iurlo, A., Goh, Y. T., Lazarou, M. C., Egyed, M., Fox, M. L., McLornan, D., Perkins, A., Yoon, S.-S., Gupta, V., Kiladjian, J.-J., Granacher, N., Lee, S.-E., & Ocroteala, L. (2023). Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis (MOMENTUM): results from an international, double-blind study.
9. Oh, S. T., Talpaz, M., Gerds, A. T., Gupta, V., Verstovsek, S., Mesa, R., Miller, C. B., Rivera, C. E., Fleischman, A. G., Goel, S., Heaney, M. L., O'Connell, C., Arcasoy, M. O., Zhang, Y., Kawashima, J., Ganz, T., Kowalski, M., & Brachmann, C. B. (2020). ACVR1/JAK1/JAK2 inhibitor momelotinib reverses transfusion dependency and suppresses hepcidin in myelofibrosis phase 2 trial. *Blood Advances*, 4(18), 4282–4291. <https://doi.org/10.1182/bloodadvances.202000266>
10. Bassiony, S., Harrison, C. N., & McLornan, D. P. (2020). Evaluating the Safety, Efficacy, and Therapeutic Potential of Momelotinib in the Treatment of Intermediate/High-Risk Myelofibrosis: Evidence to Date. *Therapeutics and Clinical Risk Management*, Volume 16(889-901), 889–901. <https://doi.org/10.2147/tcrm.s258704>



Dr. Amber Mayo



Charlie Norwood VA Medical Center

What was the moment that you knew you chose the right profession?

Thinking about the flexibility and opportunities that the pharmacy profession has provided me, I become more thankful every day that I decided on pharmacy as a career. I met my husband of almost 20 years in my pharmacy school class. When I was sleep-deprived with a one-year-old and able to go part-time for around 7 years, I was thankful for the flexibility to get through that season of life. When I recently learned that science is developing to the extent that pharmacists will contribute to patient care in the field of pharmacogenomics, I was extremely excited!

While I am not sure that there was one moment, perhaps the ER patient who came in by ambulance receiving CPR following an elective outpatient shoulder surgery ranks high on my pharmacology and toxicology nerd meter. He required a bag of lipid emulsions to be acquired quickly and bolused for local anesthetic systemic toxicity. From keeping up with the toxicology literature, I knew that the lipids would bind the lipophilic drug to keep the patient from subjecting to this particular kind of *overdose*. I especially remember all the nurses wondering why I was running to the pharmacy to get lipids for this patient and being able to explain to them why lipids should work to help the patient was very cool to me.

What is the most impactful patient encounter you've had?

I once participated in a code for a patient on hemodialysis. The attending physician properly supervised the code and exhausted all potential causes of cardiovascular collapse before "calling the code." A couple of the individuals in attendance seemed irritated that the code went on as long as it did based on the presenting rhythm. Later in the pharmacy, I overheard someone offering condolences to one of our pharmacy technicians. The hemodialysis patient was her aunt and an important member of her family structure. I was reminded that although no family may be present to advocate or speak for a certain patient-type that is chronically ill, the patient is still a human being who is loved by someone and should be regarded as such.

What are some qualities you believe a pharmacist needs to work in a clinical setting?

Clinical pharmacists must be determined, conscientious, and motivated to overcome obstacles in developing a program that provides good patient care. Yes, keeping up with new research and guidelines is important, but knowledge is just a piece of success. Persistence and communication with leadership are important and needed to be able to express ideas, concerns, and suggestions clearly to develop a program and advance and improve patient care. Analytical skills and thoroughness are needed to make sure nothing major is missed in process development and chart reviews, and resourcefulness is always a plus. For example, using my title can be helpful when calling for records! "Hi, this is Dr. Mayo calling from the Augusta VA, and I'm trying to help a veteran get 'drug XYZ' filled. I need to get records faxed so we can assist this veteran in getting his/her medication through the VA, please."

Is there anything that you wish you did differently that would've prepared you more for your role?

For my current role, I believe that I would have benefitted from a little more training on the pharmacy dispensing system and how it interfaces with our centralized mail-out facility (determining reasons for rejections, troubleshooting, etc.). I did have limited training in this area, but I am the only one on our current team that did not work in the outpatient pharmacy at the VA prior to being in this position. Fortunately, I have co-workers who have kindly assisted me along the way with questions.

Disclaimer: Responses have been edited for length and clarity.

Review of the Benefits of Clinical Pharmacists

By: Bayard Taylor II, Pharm.D. Candidate

Although the impact of COVID-19 left a historical imprint, the nation is currently facing another health crisis in the form of chronic diseases. It is reported that 60% of Americans have at least two chronic diseases while over 40% have three or more chronic diseases such as hypertension, diabetes mellitus, coagulopathy, HIV, and many others. Furthermore, this concern has evolved during one of the biggest shortages of primary care physicians ranging from more than 13,000 in 2019 with a projected shortage of over 49,000 primary care physicians by the year 2030. This deficiency in the quantity of healthcare professionals has resulted in many patients facing barriers to direct patient care. However, clinical pharmacists are well positioned to help bridge this gap in care.

Clinical pharmacy is not only a growing profession, with a 46% increase in the number of certified clinical pharmacists by the National Clinical Pharmacy Specialist commission in just five years. Pharmacy is one of the most beneficial fields in terms of being responsible for positive patient outcomes because of the direct involvement to see any adverse reactions or possible interactions of medicines early on in the healthcare plan. Many of these positions focus on interdisciplinary teams that provide care to chronic disease states for patients who suffer from hypertension, diabetes mellitus, coagulopathy, HIV, tobacco cessation, and more. The National Clinical Pharmacy Specialist committee, NCPS for short, requires all their certified pharmacists to report the outcomes in patient disease states that they treat. This allows for transparency of the benefits of the clinical pharmacist position.

When it comes to anticoagulation, benefits due to pharmacist intervention reinforce why anticoagulation therapy is one of the most valuable aspects of the pharmacy profession. The data reported by the NCPS certified pharmacists indicate that the mean time in therapeutic range for patients is at about 67.6% over two years of studies conducted between 2016-2017. Regarding the Chest Guidelines' goal of 65-70% time in therapeutic range, pharmacists' impact on anticoagulation therapy is reinforced and validated by the data observed.

OTC Drug Update - Progestin-Only Hormonal Contraception

By: Alex Ruehman, Pharm.D. Candidate

What is Opill?

Opill is the first and only FDA-approved oral contraceptive available for purchase over the counter (OTC). Its active ingredient, norgestrel, a second-generation progestin, has an established record of safety and efficacy since 1973.¹ Norgestrel belongs to a class called progesterone-only pills (POPs) which thicken cervical mucus and block the luteinizing hormone surge needed for ovulation. Research indicates that roughly 9 out of every 100 women will become pregnant within one year of appropriate POP use.² However, initial trials of norgestrel show perfect-use effectiveness rates can be as high as 98%.³

Pros

There are many forms of contraception available in the United States; though, some require an injection or implantation of a device which may not be suitable for everyone due to their invasive administration. Some women may prefer shorter acting contraceptives over longer acting methods such as IUDs, the arm implant, or depot injection. Opill is an excellent alternative because it is orally available, taken once daily, and is effective after 48 hours of use. Furthermore, Opill does not contain estrogen, a hormone known to increase the risk of thrombotic events such as deep vein thrombosis (DVT) or pulmonary embolism (PE). Notably, oral contraceptives have been shown to reduce the risk of some cancers including colorectal, endometrial, and ovarian cancer.⁴ For postpartum patients seeking contraception while breastfeeding, progesterone-only pills like Opill are a safe choice.

Cons

Side effects are a possibility with any medication, and when it comes to norgestrel, some common ones to be aware of include irregular vaginal bleeding, nausea, breast tenderness, mood changes, and headaches.³ These side effects are typically mild but if they persist or become more severe, it's recommended to contact your healthcare provider. It's important to note that Opill, while effective as a contraceptive, does not offer protection against sexually transmitted infections or HIV/AIDS. Hence, it's crucial to use additional protection with a condom to safeguard against these infections. For

Data has also been reported over two of the most prominent disease states in the country right now, hypertension and diabetes mellitus. These two chronic conditions not only impact quality of life themselves, but they are also both risk factors for a vast number of more serious conditions such as stroke, cardiovascular diseases, kidney disease and much more. Thus, treating these diseases could further promote clinical pharmacy as a mainstay in healthcare professions. Data reported by the NCPS certified pharmacists in 2016-2017 demonstrated that the addition of clinical pharmacy services can reduce A_{1c} by about 1.8% on average from the patients' baseline. Pharmacists' intervention in hypertension can also result in a reduction of a patients' systolic and diastolic blood pressures by eleven and six millimeters of mercury respectively. The impact of this must be acknowledged because reducing the impact of these chronic diseases can significantly lessen the prevalence of other disease states such as stroke which will lessen the burden on hospitals resulting in better healthcare for all patients.

The data reported by the NCPS certified pharmacists helps quantify the benefits of including a clinical pharmacist in direct patient care. Expanding the role of clinical pharmacists in patient care may improve chronic disease state outcomes and become more common in a setting of primary care provider shortages.

References

Bott, A. M., Collins, J., Daniels-Costa, S., Maves, K., Runkle, A., Simon, A., Sheffer, K., Steers, R., Finocchio, J., Stringham, L., Sutedja, G., & United States Public Health Service National Clinical Pharmacy Specialist Committee. (2019). Clinical Pharmacists Improve Patient Outcomes and Expand Access to Care. *Federal practitioner: for the health care professionals of the VA, DoD, and PHS*, 36(10), 471–475.

the optimal effectiveness of POPs, they must be taken consistently within the same 3-hour time window every day. If, by any chance, a dose is missed, it's recommended to use a condom or another barrier method for the subsequent 48 hours.

Contraindications

Opill is contraindicated for individuals with a history of breast cancer, acute liver disease, liver tumors, or cirrhosis. If you are pregnant or plan to become pregnant, stop taking Opill. Additionally, other methods of hormonal contraception should not be used while taking Opill.

Other relevant clinical information

A systematic review compared patients who were taking non-rifamycin while on oral contraception and found that concomitant antibiotic use was not associated with changes in pregnancy rates or ovulation, unscheduled uterine bleeding, or decreased progesterone levels.⁵ The only antibiotic shown to cause failure of oral contraceptives is rifampin, if a patient is prescribed rifampin and an oral contraceptive, a barrier method should be utilized for the duration of rifampin treatment and for 2 weeks after stopping the antibiotic.

References

1. Commissioner, O. of the. (2023, July 13). FDA Approves First Nonprescription Daily Oral Contraceptive. FDA. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive>
2. CDC - Progestin-Only Pills - US SPR - Reproductive Health. (2019, October 6). [Www.cdc.gov. https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/progestin.html](https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/progestin.html)
3. Research, C. for D. E. and. (2023). Opill (0.075mg Oral Norgestrel Tablet) Information. FDA. <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/opill-0075mg-oral-norgestrel-tablet-information#:~:text=Norgestrel%20is%20generally%20safe%20for>
4. Gierisch, J. M., Coeytaux, R. R., Urrutia, R. P., Havrilesky, L. J., Moorman, P. G., Lowery, W. J., Dinan, M., McBroom, A. J., Hasselblad, V., Sanders, G. D., & Myers, E. R. (2013). Oral Contraceptive Use and Risk of Breast, Cervical, Colorectal, and Endometrial Cancers: A Systematic Review. *Cancer Epidemiology Biomarkers & Prevention*, 22(11), 1931–1943. <https://doi.org/10.1158/1055-9965.epi-13-0298>
5. Simmons, K. B., Haddad, L. B., Nanda, K., & Curtis, K. M. (2018). Drug interactions between non-rifamycin antibiotics and hormonal contraception: a systematic review. *American Journal of Obstetrics and Gynecology*, 218(1), 88-97.e14. <https://doi.org/10.1016/j.ajog.2017.07.003>

Hypertension Guideline Update

By: Valery Cepeda, Pharm.D. Candidate

Hypertension (HTN) is the leading modifiable risk factor for cardiovascular disease (CVD), causing more CVD events than any other factor. In recent years, there has been an increase in HTN cases and a decline in HTN control rates. The American Heart Association (AHA) has released a new guideline for managing stage 1 HTN in adults with a low 10-year CVD risk, addressing a gap in previous recommendations.

In 2014, the AHA/American College of Cardiology (ACC) began issuing guidelines for HTN. The 2017 update notably lowered the HTN threshold to $\geq 130/\geq 80$ mmHg and reclassified "pre-HTN" as elevated blood pressure (SBP 120-129 and DBP less than 80 mmHg). This change was based on evidence showing a direct link between blood pressure and cardiovascular risk, emphasizing the benefits of intensive blood pressure control.

The 2015 Systolic Blood Pressure Intervention Trial (SPRINT) supported this by demonstrating that lower systolic blood pressure targets (<120 mm Hg) led to fewer cardiovascular events (myocardial infarction, acute coronary syndrome, stroke, acute decompensated heart failure, or cardiovascular death) and lower mortality rates compared to standard SBP targets (<140 mm Hg), particularly in high-risk individuals.

However, there's a lack of randomized controlled trial (RCT) data for younger, "low-risk" patients, which makes it challenging to establish guidelines for this group. The previous 2017 guidelines recommended lifestyle changes for adults with stage 1 HTN and low cardiovascular risk and repeat interval blood pressure measurement every 3 to 6 months but didn't offer guidance for intervention if blood pressure remained the above target of SBP >130 or DBP > 89 .

The recent AHA Scientific Statement addresses this gap by recommending antihypertensive medication consideration for stage 1 HTN patients who don't meet blood pressure goals after six months of lifestyle modifications. This recommendation applies especially to those with additional CVD risk factors such as family history of early CVD, a personal history of pregnancy-related HTN, or history of premature birth.

Although the short- and intermediate-term risks of hypertension and the resulting cardiovascular disease (CVD) complications and fatalities may appear to be relatively low, the risk over a span of 20 years or more can be considerably high.

Studies such as the Coronary Artery Risk Development in Young Adults (CARDIA) study, found the occurrence of hypertension between the ages of 18 and 55 ranged from 40% to 76%.² Recent observational data in this study have shown elevated rates of CVD events among individuals with untreated stage 1 HTN, even among those under 40 years old.²

In the Multi-Ethnic Study of Atherosclerosis (MESA) study, the cumulative occurrence of HTN between ages 45 and 85 ranged from 84% to 93%.¹ Whelton and colleagues conducted a study involving 1457 participants from the MESA study, all of whom had no prior history of ASCVD or risk factors.¹ The average age of this group was 58.1 years, with a standard deviation of 9.8 years. Their research revealed a notable increase in ASCVD rates for each 10 mmHg rise in SBP above 90. The hazard ratio for patients with stage 1 hypertension was 4.58 with a 95% confidence interval.

Yano and colleagues applied the most recent 2017 ACC/AHA HTN definitions to a cohort comprising 4851 adults with an average age of 35 from the CARDIA study.² Their findings revealed that individuals with elevated blood pressure, stage 1 HTN, and stage 2 HTN had significantly elevated rates of CVD events in comparison to those with normal blood pressure.

SCCP Officers

Faculty Advisors	Beth Phillips, Pharm.D., BCPS, BCACP, FCCP, FASHP
	Rebecca Stone, Pharm.D., BCPS, BCACP, FCCP
President	Mark Arthen
President-Elect	Anna Darke
Secretary	Alexandria Rakestraw
Treasurer	Isis Salmon
Education Chair	Sarah Dubin
Membership Chair	Zoe Krenz
First Year Liaison	Angel Prum

These studies illustrate the increased risk of HTN and its related complications in younger, lower-risk populations, thus forming the foundation for the new guideline recommendation.

Although the authors recognize that this new recommendation relies on observational data and intermediate endpoints, most of the existing evidence supports the idea of considering pharmacological treatment for stage 1 hypertension, even for individuals who have typically been considered low risk. This update in American guidelines aligns with the latest 2018 guidelines from the European Society of Cardiology/European Society of Hypertension guidelines.

While there are many benefits to justify starting pharmacological intervention in this patient population, it is important for clinicians to weigh the potential adverse effects of aiming for lower blood pressure targets. Some risks include hypotension, episodes of fainting and fall, electrolyte imbalances, and acute renal failure. Thus, when deciding whether or not to treat stage 1 hypertension, it is essential for clinicians to participate in clinical decision-making with patients.

References

1. Whelton SP, McEvoy JW, Shaw L, et al. Association of normal systolic blood pressure level with cardiovascular disease in the absence of risk factors. *JAMA Cardiol* 2020;5:1011-18.
2. Yano Y, Reis JP, Colangelo LA, et al. Association of blood pressure classification in young adults using the 2017 American College of Cardiology/American Heart Association Blood Pressure guideline with cardiovascular events later in life. *JAMA* 2018;320:1774-82.