

March/April 2022

The Journal

of the Pharmacy Society of Wisconsin

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UpFront: 2021-2022 Legislative Review

by Danielle Womack, MPH, Daniel Funk, 2022 PharmD Candidate



Over the last year, PSW has made significant progress in advocating for patient-centered care and the pharmacy profession. Several legal updates that impact pharmacy practice were passed and signed into law. Bills impacting the pharmacy profession are summarized below, including the next steps necessary for implementation.

2021 Wisconsin Act 3 *Pharmacy Technician and Pharmacy Student Immunizations* Effective February 21, 2021

- Allows all pharmacy students to administer immunizations under the supervision of any healthcare provider who is also authorized to administer immunizations.
- Allows trained pharmacy technicians to provide immunizations under the supervision of a pharmacist. Required training includes at least 2 hours of training on injection technique and management of adverse events, BLS or CPR certification, and technician certification by PTCB or NHA.
- Allows any person authorized to immunize (pharmacist, pharmacy technician, or student pharmacist) to administer injectable epinephrine or diphenhydramine to treat adverse vaccine reactions without completing a separate non-vaccine injection training.

Are you interested in getting your technicians trained in immunization? Visit the PSW website for [training courses](#) that meet the law's requirements!

2021 Wisconsin Act 9 *Comprehensive PBM Reform*

Fully effective January 1, 2022; some provisions effective as early as March 28, 2021

- Requires pharmacy benefit managers (PBMs) to be licensed by the Office of the Commissioner of Insurance (OCI), giving OCI the authority to audit PBMs and revoke, suspend, or limit their licenses for certain offenses.
- Requires PBMs to report to OCI any rebates from pharmaceutical manufacturers that are not passed on to their health plan.
- Requires PBMs to provide written notice to enrollees 30 days in advance of formulary changes that impact the cost or coverage of their prescriptions.
- Prohibits "gag clauses," in which PBMs restrict pharmacies' ability to notify patients when they could save money by paying out of pocket for a prescription rather than with insurance.
- Limits the frequency that PBMs may change network requirements to once annually and requires PBMs to provide pharmacies with at least 30 days' notice when changes are made.
- Regulates a PBM's ability to audit pharmacies, recoup funds, and report discrepancies to pharmacies.
- Prohibits "clawbacks" in which PBMs retroactively deny or reduce a pharmacy's claim after the adjudication of the claim.

Do you have experiences with a PBM violating the new laws? Check out this [infographic](#) for information on filing a complaint with OCI.

2021 Wisconsin Act 98

Medicaid Provider Status

- Requires the Department of Health Services (DHS) to provide reimbursement under the Medicaid program to pharmacists for providing any reimbursable services within their scope of practice or as delegated by a physician.

DHS is currently working on its State Plan Amendment and necessary rule and policy changes to enact this legislation. We anticipate pharmacists' ability to bill for services will begin in early 2023.

2021 Wisconsin Act 100

Pharmacy Technician Registration

Effective January 1, 2023

- Requires pharmacy technicians to be registered with the Wisconsin Pharmacy Examining Board (PEB).
- Directs PEB to outline activities that define the practice of a pharmacy technician for registration requirement purposes.
- Provides PEB the authority to reprimand, fine, deny, revoke, suspend, or limit the license of pharmacy technicians for certain offenses.
- Allows a pharmacy technician to begin work as a technician once they have applied for registration until and unless the PEB denies their application. Technicians do not need to wait for approval of their registration application to begin work.

The Pharmacy Examining Board is working on rule changes and implementation materials for technician registration. All technicians need to have applied for registration by January 1, 2023. PSW will continue to update members with application materials as they are made available.

2021 Wisconsin Act 101

Remote Dispensing

Effective July 1, 2022

- Requires remote dispensing sites to become licensed by the Pharmacy Examining Board (PEB).
- Permits remote dispensing sites to be supervised by a pharmacist remotely. Previously, on-site pharmacist supervision was required for all licensed pharmacies.
- Allows pharmacies to switch between operating as a remote dispensing site (remotely supervised by a pharmacist) or a pharmacy (pharmacist on site).

The Pharmacy Examining Board is working on rule changes and implementation materials for licensure of remote dispensing sites. PSW will continue to update members with application materials as they are made available.

Looking Forward

As PSW celebrates these accomplishments, we thank the efforts of the pharmacist, pharmacy technician, and student pharmacist members who helped develop the legislative language and advocated for these changes. These accomplishments were made possible in large part by the members who have participated in legislator office visits, testified at committee hearings, and emailed legislators through PSW's [Pharmacy Legislative Action Network \(PLAN\)](#).

Although the changes we have witnessed are encouraging, there is always more advocacy work to be done to enhance pharmacy practice and provide opportunities for pharmacy professionals to better meet the needs of the patients they serve. As the 2021-2022 legislative session comes to a close, we are already preparing for the 2023 legislative session with a renewed sense of optimism. Learn more about how members can contribute to PSW's advocacy efforts at pswi.org/advocacy.



**Pharmacy Society
of Wisconsin**

2022 PSW Conference on Advanced Medication Management for the Elderly

**Tuesday-Wednesday, May 17-18, 2022
Milwaukee Marriott West, Waukesha**



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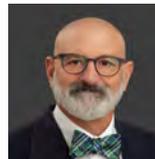
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The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA History Hall located in Washington, DC.

PHARMACIST & TECHNICIAN CE:

Uncomfortable Conversations: Improving Dialogue Regarding Sexual Health

by Amber Patt, 2022 PharmD Candidate, Sean LaBodda 2022 Pharm D Candidate, Hailey Keeser, PharmD, AAHIVP



Sexual health is an essential component of overall health, and foundational to the social and economic development of a community.¹ Sex is part of our natural biologic behavior, but it can be difficult to talk about because of cultural factors, upbringing, religion and spirituality, and social environments that shape us to believe that talking openly about sex is taboo, and therefore, private.² Sexual health can feel awkward for many pharmacists and pharmacy technicians to discuss. This discomfort might manifest as feeling flustered, stumbling over words, or simply not knowing what to say, especially when talking to patients.

Sexual and reproductive health encompasses a wide scope of topics. The list of related topics is constantly expanding, and ranges from sexual orientation and gender identity to sexually transmitted infections (STIs), unintended pregnancy, sexual dysfunction, and sexual violence. Throughout the world, sexual health care gaps are plentiful. More than 120 million couples have an unmet need for

CE FOR PHARMACISTS & TECHNICIANS

COMPLETE ARTICLE AND CE EXAM
AVAILABLE ONLINE: WWW.PSWI.ORG

Learning Objectives

- Describe the importance of improving sexual health dialogue with patients.
- Recognize potential opportunities to improve sexual health dialogue with patients.
- Identify actions pharmacists and pharmacy technicians can take to build patient trust during sexual health dialogue with patients.
- Recognize the importance of identifying biases and knowledge gaps regarding sexual health topics.
- Practice implementing strategies to improve sexual health dialogue with patients.

contraception annually. Globally, 376 million people become infected with new gonorrhea, syphilis, chlamydia, or trichomonas infections each year.³ Additionally, sexual assault and gender-based violence are still common.⁴ In the United States, erectile dysfunction (ED) incidence among men at age 50 is approximately 50%, increasing to as high as 70% at age 70.^{5,6}

Although sexual health has been acknowledged as an important part of

medical care, it has historically received little to no attention in health profession education. Limited training exists, and pharmacists and pharmacy technicians may be underequipped to address patient needs regarding sex and sexual health medication therapies. As the pharmacy landscape continues to grow and change, we can expect that pharmacists will participate in more sexual and reproductive health services.⁷

Pharmacists and pharmacy technicians

are at the forefront of the demand for medications related to sexual health needs. Pharmacies are a direct connection to care and can improve patient access to sexual health services. While ready access to primary care providers continues to prove challenging, pharmacists are frequently seen as the most accessible member of the health care team.⁸ As pharmacy practice grows, the role of the pharmacist and pharmacy technician continues to evolve. Pharmacists and technicians must prepare in order to possess the tools and confidence to address sexual health needs in their communities through conversation.⁹

Take a moment to reflect on the following potentially uncomfortable scenarios that could be encountered in pharmacy practice:

- A new patient walks into your pharmacy with a new prescription for Cialis® (tadalafil). How do you feel telling them to seek medical attention if they have an erection lasting longer than four hours?
- You are the pharmacist at a community hospital and call a patient to discuss the results of an STI test. You tell them they tested positive for chlamydia. Their first question is, “How did I get chlamydia?” How would you respond?
- You are a pharmacy technician speaking with a transgender patient and are unsure which gender pronoun to use. How do you go about asking the patient how they would like to be addressed?

These situations are common and are not limited to community pharmacies. Although these are just a few examples of sexual and reproductive health scenarios, the underlying goal remains the same: pharmacists and pharmacy technicians should feel comfortable and confident when addressing patient sexual health needs and concerns.

Dr. Debby Herbenick, director at the Center for Sexual Health Promotion at the Indiana University School of Public Health, has summarized well the difficulty of discussing sex.⁹ In her TED talk “Making Sex Normal,” she states, “Too many of us don’t know how to talk about sex and sexual health...as a result, relationships and health can suffer and important information doesn’t get to the people who need it.” Herbenick adds, “We need to make sure

that people, especially young people, have access to good, accurate information, and we need to promote tolerant, inclusive attitudes towards everyone regardless of their sexual preference or orientation.” She encourages talking about sex as if it is “no big deal.” In order to achieve this quality of dialogue with patients, pharmacists and pharmacy technicians must be prepared and confident.

Improving pharmacist confidence with sexual and reproductive health conversations begins with health profession training. Training workshops about sexual health provided in existing curricula have been shown to improve students’ attitudes and behavior, as well as their confidence and competency approaching the subject.¹⁰ It may be difficult to work within time constraints when designing curricula, but even brief education can provide impactful changes to student attitudes. Students who receive specific topic education regarding transgender health have shown improvement in competency in providing care and talking to patients who identify as LGBTQ, even when the topic is only briefly covered.¹¹ Further incorporation of sexual health topics into pharmacist training will improve confidence in new practitioners.

Increased pharmacist confidence and comfort with sexual health will increase patient trust. Studies have shown that low trust in providers and poor patient-provider relationships correlate with decreased patient satisfaction and poor retention in care.^{12,13} New patients in particular are more vulnerable to developing mistrust in providers. For example, patients living with HIV who were establishing care have reported significant anxiety about their HIV status and building a relationship with their new providers. This same hesitancy can also appear for patients who are establishing care at a new pharmacy. It is possible to avoid this onset of mistrust through actions that build patient trust and rapport. Pharmacists and technicians can:

1. Reassure the patient.
2. Remind patients that it is okay to ask questions, and encourage it!
3. Help patients interpret any lab results.
4. Avoid judgmental language and behaviors.
5. Ask the patient what their treatment goals are and find out what is important to them.

Reassure the Patient

The need for reassurance is important, particularly for patients who may not understand a new diagnosis or who may have questions about medications related to their sexual health. Pharmacists and pharmacy technicians have the power to strengthen the patient-provider relationship during potentially frightening or uncertain situations by simply providing reassurance to the patient. Even during a routine clinical visit or medication pick-up, the pharmacist can help provide a sense of security about the patient’s health.

It can be difficult to devote much time and attention to individual patients if the counter lines are long, phones are endlessly ringing, and/or there are many cars in the drive-thru. In an ideal pharmacist-patient situation, time would not be an issue. However, it is still possible to provide the patient with this same support when there is only a moment or two to talk. Sometimes something as simple as coming face-to-face with a patient can reassure patients you are available to them.

Remind Patients That it is Okay to Ask Questions

Encourage it!

Pharmacists, pharmacy technicians, and patients may feel uncomfortable discussing sexual health topics. Patients take cues from the health care provider; by normalizing sexual and reproductive health discussions, pharmacists and patients will help to remove the stigma present in these areas. Patients may not always feel comfortable bringing up their sexual health, and most patients prefer when their health care provider approaches them with the subject. Many patients want to discuss their sexual health but most do not want to bring it up on their own.^{14,15}

Pharmacies often have a large patient population. Given the sheer volume of patients coming through the door, some community pharmacists and pharmacy technicians may feel overwhelmed and that they do not have adequate time to answer questions. The approach to developing trust with patients and encouraging them to ask questions must be tailored to your specific practice site. Patients might be afraid of taking up too much of the pharmacist’s time, and do not want to feel like a burden by asking many questions. Sexual health and

medications involving sexual health can be particularly confusing, so allowing a patient the opportunity to ask questions is helpful.

Although time constraints are often a reality, it has been demonstrated that patients enjoy the opportunity to ask questions, and not just at the end of the conversation, but multiple times during the dialogue. Additionally, repeated invitations to do so increases patient comfort and trust.¹³ With sexual and reproductive health topics in particular, patients may be too embarrassed to bring up questions or to admit that they are confused. By encouraging questions, you are facilitating shared decision-making. This may improve adherence and patient satisfaction, and patients may be more likely to receive care aligned with their values and preferences.¹⁶

Offer Expertise Interpreting Lab Results

Medical appointments are often brief. Diagnoses and lab results are not always reviewed in language that matches the patient’s health literacy level. Even in clinical scenarios where lab results are stable or within normal limits, being told that labs “look good” is likely not enough to provide patients reassurance. This also does not empower patients to participate in their own care. Though pharmacists may not always be involved in ordering or interpreting lab results, they should be aware that patients may have ongoing questions. Of course, not every patient will be interested in this information and not every lab result can be interpreted without knowing the full clinical picture. However, for patients who are interested and may want clarification, pharmacists have the knowledge, resources, and training to interpret many lab results. They can provide insight about a diagnosis or treatment course to help open dialogue for questions they may be too nervous to ask. Patients then leave reassured by understanding specifics regarding their lab work and learning how labs relate to them.¹³

Avoid Judgmental Language and Behaviors

Pharmacies are well positioned to improve access to sexual and reproductive health care. Pharmacists and pharmacy technicians should identify gaps in their

TABLE 1. Mindful Use of Language Examples

<i>Try This</i>	<i>Instead of</i>
Establish rapport before asking sensitive questions	
<i>I'm going to ask you a few questions about your sexual history. Before I begin, do you have any questions or concerns you'd like to discuss?</i>	<i>You should get screened for syphilis.</i>
Avoid heteronormative* and cisnormative** assumptions	
<i>Tell me about your partner or partners.</i>	<i>Do you have a girlfriend/boyfriend?</i>
<i>Hi Alex – what are your pronouns? I'll make note of them in our system.</i>	<i>I'm going to counsel Alex on his medication.</i>
Avoid judgmental language	
<i>Have you had any new partners in the past six months?</i>	<i>You're married, so you don't need STI testing, right?</i>
<i>Tell me about the strategies you use to prevent STIs.</i>	<i>You always use condoms, right?</i>
Avoid judgmental language	
<i>Do you have preferred language that you use to refer to your body?</i>	<i>Slang, non-preferred terms</i>
Don't avoid sensitive topics	
<i>This medication may cause issues with sexual function, such as decreased sexual desire or erection problems.</i>	<i>This medication has a few uncommon side effects that you can read about in this paperwork.</i>
Use ubiquity statements	
<i>Lots of my patients have questions about sexual side effects – I'm happy to go into more detail with you on this.</i>	<i>You don't need to worry about that.</i>
<small>*Heteronormative refers to the assumption of opposite-sex attraction as the default sexuality. **Cisnormative refers to the assumption that people identify as the sex they were assigned at birth.</small>	

own knowledge and take steps to fill in these gaps. Pharmacy staff can work to foster a welcoming and inclusive environment once these gaps are filled, despite known practice setting challenges and limitations.

Pharmacists and pharmacy technicians should identify their own biases with various patient populations and topics. If health care providers are uncomfortable talking about sex and sexuality, their patients will be also. Pharmacists and pharmacy technicians can begin by assessing their patient and what makes them most comfortable. They should avoid assumptions, by working to identify the patient’s pronouns, and using neutral terms such as “partner” instead of gender-specific terms, like husband/wife. If an error is made, try not to overreact or draw attention to the error and instead rephrase the question or statement.

Patients need their health care providers to accept them for who they are and not feel judged for their identities or behaviors. To foster a trusting relationship with a patient, pharmacists and pharmacy technicians

must be supportive and learn about each patient as an individual. This will allow care to be provided to the patient in a way that best meets their needs. Pharmacists and pharmacy technicians must be mindful of the language they choose when speaking with patients. This is important when setting the stage to discuss sexual and reproductive health. Best practices are continually evolving, and we all should work to remain up to date on the most respectful and patient-centered strategies for discussing these topics.

Incorporate Shared Decision-Making

Patients are essential members of their own care teams and are interested in a two-way dialogue with their health care providers.¹³ Although most patients value their health care providers’ opinions and clinical recommendations, many patients want the opportunity to weigh in on treatment decisions. It is important to ask

patients what their goals are and provide support in achieving their goals.

There are advantages and disadvantages to incorporating patients into the care team in this manner, particularly in a community pharmacy environment. Patients can visit pharmacies quickly and without an appointment, removing some access barriers. However, the scope of pharmacy practice does not always provide access to the most tests and/or treatments appropriate for the clinical scenario. There are also potential concerns with privacy; one study demonstrated high levels of patient satisfaction with clinic privacy versus lower levels of satisfaction with privacy in a pharmacy setting. Pharmacists and pharmacy technicians should be sensitive to potential patient discomfort and use private spaces when possible.¹⁷

Each patient's desire to discuss these topics will be different, as will be their preferred communication style. Therefore, each dialogue should be individualized. Some patients may prefer in-depth discussion, while others may prefer to-the-point information. Some patients may prefer printed copies of information, while others may prefer to access health care information using technology. Overcoming these potential challenges to incorporate patients into the care process will improve provider-patient dialogue and relationships, thereby improving patient comfort and clinical outcomes.

Conclusion

Sexual health dialogue can be difficult without practice. Much like medication counseling, it is important to identify and fill knowledge gaps, and practice to improve the conversational flow. Sexual and reproductive health topics often lead to patient discomfort as well. In these potentially uncomfortable scenarios, patients look to trusted experts, like pharmacists and pharmacy technicians, for reassurance. Reassurance can take many forms based on an individual patient's needs: emotional support, clinical information, motivational interviewing, and more. In order to assess the needs of each patient, pharmacists and pharmacy technicians must ensure that patients feel empowered to ask questions. Patients are often aware of time constraints present for health care workers and may not bring forward their

TABLE 2. Actions to Build Patient Trust with Example Questions and Statements

<i>Actions to build patient trust</i>	<i>Example questions and statements</i>
Remind the patient that your practice is a safe environment.	<ul style="list-style-type: none"> • <i>I want to let you know that you are in a safe space and what you tell me is confidential.</i> • <i>I encourage you to come by and ask me questions at any time.</i> • <i>We can speak more about this in the consultation room. Otherwise, I am happy to call you later to discuss this further.</i>
Provide reassurance to the patient.	<ul style="list-style-type: none"> • <i>I understand that this information can be overwhelming, but we are here to answer any questions you might have.</i> • <i>I encourage you to ask me questions about this. I want to make sure you have all your questions answered before you leave today.</i> • <i>If I do not know the answer, I will look into it and/or provide the resources to someone who may.</i>
Ask open-ended questions to promote dialogue.	<ul style="list-style-type: none"> • <i>What have you heard about this medication?</i> • <i>What are your thoughts on what we just talked about?</i> • <i>What can I do to help you better understand this medication?</i>
Offer expertise.	<ul style="list-style-type: none"> • <i>I have printed off additional information for you and highlighted the most important sections. Please call me with any questions you have.</i> • <i>I'd be happy to help you gain a better understanding of your lab results. I can explain the importance of the lab and the value.</i> • <i>I know that this can be confusing. Can I walk you through a few more details to help you understand this better?</i>
Consider the patient perspective.	<ul style="list-style-type: none"> • <i>I understand that this might be uncomfortable to talk about, but please know that I am happy to discuss this at your comfort level.</i> • <i>What method works best for you to learn the information about this new drug?</i> • <i>I understand that this information is overwhelming, but there are resources to help. Can I gather those resources for you so we can talk through them together?</i>

questions without being explicitly invited to. Pharmacists should invite questions, not only at the point of initial counseling but on an ongoing basis. They should also take opportunities to improve patients' understanding of lab results in terms individualized to their health literacy level. They should also take opportunities to improve patients' understanding of lab result in terms individualized to their health literacy level, if appropriate. This dialogue should be non-judgmental and incorporate patients into clinical-decision making.

Take a moment to reflect on these potentially uncomfortable scenarios again, and consider the following strategies:

- A new patient walks into your pharmacy with a new prescription for Cialis®. How do you feel telling them to seek medical attention if they have an erection lasting longer than four hours?
 - » Don't avoid sensitive topics – be

sure to cover this important point in the counseling process.

- » Consider the patient's perspective – this is a sensitive topic that they may prefer to discuss in a more private space such as a counseling room.
- » Provide multiple opportunities for the patient to ask questions – the patient likely has questions but may not bring them up unless given the opportunity by the pharmacist.
- You are the pharmacist at a community hospital and call a patient to discuss results of an STI test. You tell them they tested positive for chlamydia. Their first question is, "How did I get chlamydia?" How would you respond?
 - » Establish rapport before asking sensitive questions – be sure that the patient is comfortable discussing details with you before you jump

into this dialogue.

- » Avoid assumptions – choose language carefully to ensure inclusivity and avoid alienating the patient.
- » Provide reassurance – this is a potentially distressing situation for the patient and the pharmacist's reaction to this question will set the tone for the dialogue.
- You are a pharmacy technician speaking with a transgender patient and are unsure which gender pronoun to use. How do you go about asking the patient how they would like to be addressed?
 - » Avoid assumptions – respectfully ask the patient for their pronouns and document them for future interactions.
 - » Foster an inclusive environment – remind the patient that your practice is a safe space.

Scenarios like these will come up regularly across all practice environments. Pharmacists and pharmacy technicians must recognize the importance of effective and respectful sexual health dialogue with patients and identify opportunities to improve current practice. The strategies described in this article can be widely deployed across a range of topics to build trust with patients on sensitive topics.

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Assessment Questions

1. Pharmacists and pharmacy technicians may encounter potentially sensitive sexual health topics in which of the following practice settings?
 - a. Community pharmacy
 - b. Ambulatory clinic
 - c. Hospital pharmacy
 - d. All of the above
2. **True or False:** Dialogue regarding sexual health topics should be individualized to each patient.
 - a. True
 - b. False
3. Which of the following is not an action that pharmacists and pharmacy technicians could take to build patient trust in a sexual health dialogue?
 - a. Reassure the patient
 - b. Encourage questions at the beginning and throughout
 - c. Refer to another health care provider for explanation of lab results
 - d. Avoid judgmental language
4. **True or False:** Pharmacists and pharmacy technicians should rely on required company trainings to refresh their knowledge on sexual health topics.
 - a. True
 - b. False
5. Which of the following is false regarding sexual health dialogue?
 - a. Patients may not feel comfortable bringing up questions on their own
 - b. Patients are often interested in gaining deeper understanding of their lab results
 - c. It is not important to establish rapport before asking sensitive questions
 - d. Patients should participate in their care team whenever possible
6. **True or False:** Pharmacists and pharmacy technicians should avoid assumptions by using neutral terms such as "partner."
 - a. True
 - b. False
7. Which of the following is an action that pharmacists and pharmacy technicians could take to improve patient comfort in the pharmacy?
 - a. Offer to speak to patients privately—either in a consultation room or via phone call

- b. Speak loudly so others can hear what you are saying to the patient
 - c. Avoid “embarrassing” or “awkward” sexual health terms when consulting a patient about a new medication
 - d. None of the above
8. **True or False:** Sexual health training workshops in have shown to improve student’s attitudes and confidence about sex
- a. True
 - b. False
9. Did the activity meet the stated learning objectives? (if you answer no, please email sarahs@pswi.org to explain)
- a. Yes
 - b. No
10. On a scale of 1 – 10 (1-no impact; 10-strong impact), please rate how this program will impact the medication therapy management outcomes or safety of your patients.
11. On a scale of 1 – 10 (1-did not enhance; 10-greatly enhanced), please rate how this program enhanced your competence in the clinical areas covered.
12. On a scale of 1 – 10 (1-did not help; 10-great help), please rate how this program helped to build your management and leadership skills.
13. How useful was the educational material?
- a. Very useful
 - b. Somewhat useful
 - c. Not useful
14. How effective were the learning methods used for this activity?
- a. Very effective
 - b. Somewhat effective
 - c. Not effective
15. Learning assessment questions were appropriate.
- a. Yes
 - b. No
16. Were the authors free from bias?
- a. Yes
 - b. No
17. If you answered “no” to question 16, please comment (email info@pswi.org).
18. Please indicate the amount of time it took you to read the article and complete the assessment questions.

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- | | |
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| 2) a b | 11) _____ |
| 3) a b c d | 12) _____ |
| 4) a b | 13) a b c |
| 5) a b c d | 14) a b c |
| 6) a b | 15) a b |
| 7) a b c d | 16) a b |
| 8) a b | 17) _____ |
| 9) a b | 18) _____ |

March/April 2022

Uncomfortable Conversations: Improving Dialogue Regarding Sexual Health

ACPE Universal Activity Number:
0175-0000-22-067-H04-RT

Target Audience: Pharmacists & Technicians

Activity Type: Knowledge-based

Release Date: March 1, 2022

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ID CORNER

Antimicrobial Management of a *Nocardia farcinica* Brain Abscess

by Lucas Grabowski, PharmD

A patient, whom we'll call LP, is a 64-year-old male who presented to the emergency department with left-sided weakness; new neuropathic symptoms predominantly in his right leg; a history of recent falls; nausea; confusion; low-grade fever; and chills. He had a past medical history of cocaine and alcohol use, and of sarcoidosis, for which he was currently being treated with hydroxychloroquine, etanercept, and low-dose prednisone.

An initial head CT showed a probable ill-defined mass lesion, 2 to 3 centimeters, centered in the right temporal lobe, "with mass effect as described and associated white matter edema." LP was started empirically on intravenous (IV) meropenem and vancomycin. An MRI of the brain revealed a 3-centimeter ring-enhancing lesion in the anterior right temporal lobe and a 6-millimeter ring-enhancing lesion in the anterior medial right occipital lobe. LP experienced a seizure and was subsequently started on levetiracetam for seizure prophylaxis.

The next day, LP underwent a right temporal craniotomy during which the team cultured purulent material and evaluated the abscess. The result of the gram stain of the brain abscess specimen initially showed few gram-positive branching bacilli. Because there were some gram-positive branching bacilli identified, an infectious disease (ID) consultant suspected the microbe was part of the *Nocardia* species and recommended high dose trimethoprim-sulfamethoxazole (TMP-SMX). The microbe was later identified as *Nocardia farcinica*. ID switched the patient's meropenem to imipenem-cilastatin for increased activity against *Nocardia farcinica*. The lab sent the culture to a national reference laboratory for susceptibility testing, to provide guidance

for antimicrobial therapy. A few days later, LP was discharged to home on imipenem-cilastatin and trimethoprim-sulfamethoxazole, with the plan to complete 6 to 12 weeks of IV antibiotics, guided by MRI findings, followed by a year-long oral regimen.

LP returned to the hospital that same evening with concerns about completing the complex antibiotic regimen at home. He was readmitted to the hospital pending a plan for possible short-term facility placement. A few days later, susceptibilities returned from the national lab, showing the *Nocardia farcinica* was susceptible to TMP-SMX, but resistant to imipenem (Table 1). ID switched the patient from imipenem-cilastatin to linezolid, a susceptible alternative, and then discharged LP on an oral regimen of linezolid and TMP-SMX.

At a follow-up visit, the patient's MRI showed a new ring-enhancing lesion of the lateral right temporal lobe, and the previous abscess was shown to be almost fully resolved. The patient reported no additional seizures, but did note that he was experiencing intractable nausea and vomiting. His lab work showed severe anemia requiring a transfusion. LP was ultimately switched from linezolid to oral ciprofloxacin, which he has tolerated much better. Subsequent MRIs have shown continued improvement in the right temporal lobe with decreased area enhancement. He continues to have appointments with ID every 6 weeks.

Pathogenesis

Nocardia species are found in soil, organic matter, and water, and are often associated with decomposition of plant material.¹ They are aerobic, gram-positive, branching, rod-shaped bacteria (Figure 1 and 2). *Nocardia* infections are not typically transmitted from one person to another, but

rather through inhalation. Nocardiosis is most often characterized as an opportunistic infection, but has been seen occasionally in immunocompetent patients.² Patients who are often at risk of nocardiosis include HIV patients with low CD4 counts, solid organ transplant patients, and patients with malignancy. LP was at risk of nocardiosis due to his immunosuppressant medications.

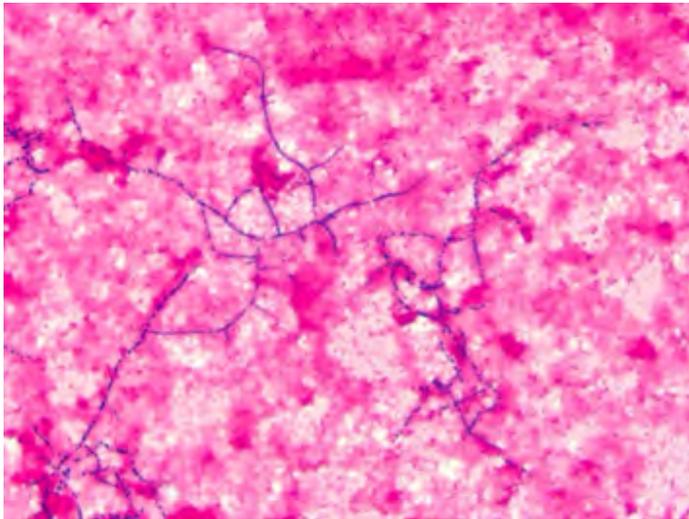
Nocardiosis is sometimes a localized infection, but also has the ability to disseminate.³ It also has a tendency to relapse and progress despite appropriate therapy. To reduce the risk of treatment failure and progression, comprehensive susceptibility testing should ideally be completed for each *Nocardia* isolate.

There have been up to 54 *Nocardia* species shown to cause disease in humans.²

TABLE 1. LP's *Nocardia farcinica* Susceptibility Results

TMP-SMX	Susceptible
Ciprofloxacin	Susceptible
Moxifloxacin	Susceptible
Amikacin	Susceptible
Doxycycline	Intermediate
Clarithromycin	Resistant
Linezolid	Susceptible
Imipenem	Resistant
Amoxicillin/Clavulanate	Susceptible
Ceftriaxone	Resistant
Minocycline	Intermediate
Tobramycin	Resistant

FIGURE 1. *Nocardia farcinica* Growing in a Blood Culture Bottle



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FIGURE 2. *Nocardia farcinica* Subculture on Blood Agar Plate



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Geographical regions play a role in the frequency of occurrence of different species. Some of the most common *Nocardia* species in the United States include *Nocardia nova* complex, *Nocardia brasiliensis*, and *Nocardia farcinica*. Disease manifestations can range from cutaneous infections to severe pulmonary or central nervous system (CNS) infections. Different *Nocardia* species are associated with different types of infections and different extents of disease. For example, *Nocardia brasiliensis* is more commonly associated with a cutaneous skin disease, whereas *Nocardia farcinica* is more often associated with pulmonary and CNS infections.

Nocardia species have a propensity to grow in neural tissue and cause neural disease.³ Most cases of neural disease occur due to dissemination and can sometimes occur even after the eradication of the infection from the primary site. Infection in the lungs appears to be the most common site that leads to dissemination to the CNS. Nocardiosis in the CNS tends to lead to the formation of parenchymal abscesses in the brain. Abscesses can form in any area of the brain, leading to a wide variety of signs and symptoms. Some common symptoms of a CNS nocardiosis include focal neurological deficits, headaches, and seizures.⁴ A patient may start with no symptoms, but, over the course of months to years, begin to show neurological deficits, while remaining asymptomatic from a systemic bacterial infection standpoint.

Treatment

Empiric antibiotic coverage with multiple agents is typically required to treat a severe *Nocardia* infection, because *Nocardia* species have a variability in their resistance to antibiotics. Monotherapy is occasionally used for patients who have a mild to moderate pulmonary disease. With severe infections, patients are often started on empiric combination therapy, and are continued on it until they show clinical improvement, and identification and susceptibilities result.⁵ Given its lower risk of relapse or death, trimethoprim-sulfamethoxazole is frequently used as an empiric therapy for suspected *Nocardia* infections.⁶ Additionally, TMP-SMX has the ability to penetrate the lungs, brain, skin, and bone, leading to high tissue concentrations in those areas.⁷ The recommended dosing varies based on the indication and presence of an immunocompromising condition (Table 2). Other antibiotics that have activity against

Nocardia species include minocycline, amikacin, meropenem, dapson, ceftriaxone, cefotaxime, imipenem, linezolid, and fluoroquinolones. The turnaround time for susceptibilities can take longer than for typical culture results, given that *Nocardia* is a slower growing pathogen, and this culture is often sent to a reference lab for susceptibilities. A common empiric therapy regimen for CNS disease is TMP-SMX and imipenem.

Evidence has shown there can be variability among antibiotic classes. Carbapenems specifically have shown different activity against *Nocardia* infections. One study showed that *Nocardia nova* complex was the only *Nocardia* species to have a MIC90 that was shown to be susceptible to imipenem, meropenem, and ertapenem.⁸ For *Nocardia farcinica*, imipenem is typically the most active carbapenem, but LP was unable to use this, given the *Nocardia farcinica* he was growing was shown to be resistant to imipenem.

TABLE 2. Example Trimethoprim-Sulfamethoxazole Dosing Recommendations Based off *Nocardia* Indication³

Indication	Dose
Cutaneous Infection	Oral: 5 -10 mg/kg/day (TMP component) in 2 divided doses
Pulmonary Infection-Immunocompetent	Oral: 5 -10 mg/kg/day (TMP component) in 2 divided doses
Severe Pulmonary Infection, Central Nervous System Infection, or Disseminated Infection	IV: 15 mg/kg/day (TMP component) in 3 to 4 divided doses
Pulmonary Infection-Immunocompromised	Oral: 15 mg/kg/day (TMP component) in 3 to 4 divided doses

Initial treatment for severe infections should be administered intravenously for four to six weeks.⁹ A transition to oral therapy and de-escalation to monotherapy can occur in patients who have documented clinical improvement. The duration of therapy depends on each clinical case and the sites of infection.¹⁰ Immunocompromised patients or patients with CNS involvement require a minimum of six months of therapy, with most receiving a year of antibiotic therapy. Frequent check-ins should be completed to monitor for risks of resistance or recurrence of infection. Follow-up imaging can help guide decision making to ensure de-escalation or discontinuation of therapy isn't premature.

Key Takeaways

Providers should suspect a possible *Nocardia* infection when a culture is growing gram-positive, rod-shaped branching bacteria. TMP-SMX is frequently used as an empiric option, given its activity against *Nocardia* species and its ability to penetrate multiple tissues. Patients with a severe *Nocardia* infection or who are immunocompromised should initially be on empiric combination therapy.

Susceptibilities, imaging, and the patient's clinical improvement should help guide providers in determining the appropriate time to both de-escalate antibiotics and transition to an oral regimen. Frequent patient follow-up should occur to monitor for relapsing or recurrent infection.

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COVID-19 Vaccination Clinic Experience: Reflections and Lessons Learned from a School of Pharmacy Perspective at a Health Sciences University

by Michael Keeney, BS, 2022 PharmD Candidate, Kristin Busse, PharmD, Lisa Henk, MS, Karen MacKinnon, BS, RPh, Ann B. Nattinger, MD, MPH

Pfizer-BioNTech published phase I/II clinical trial data for its COVID vaccine in August 2020 and received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on December 11, 2020.^{1,2} On December 12, the Advisory Committee on Immunization Practices of the Centers for Disease Control (CDC) convened to issue interim guidance for the use of the Pfizer-BioNTech COVID-19 vaccine.^{3,4}

As initial vaccine access focused on the healthcare workforce, those tasked with providing such vaccine access had to mobilize very quickly. Medical College of Wisconsin's (MCW's) COVID-19 vaccination clinic was created at a health science university as a workplace clinic with no existing clinic infrastructure. Preparatory meetings began on November 12, 2020 to plan for clinic workflow; storage and handling of vaccine shipments; recruitment of volunteers; development of training materials; and prioritization of vaccine recipients. The clinic opened on December 22, 2020, one day after receipt of the first shipment of vaccine. After the vaccination clinic opened, additional changes were made to clinic workflows based on feedback from volunteers. As interim CDC guidance developed, the clinic adjusted to operate using best practices per expert advice. An all-volunteer workforce, primarily from internal research, educational, and administration backgrounds, served as staff for the vaccine clinic.

The Pfizer-BioNTech COVID-19 vaccine storage, handling, and administration requirements created unique challenges for the operation of the clinic. Ultra-cold storage, temperature excursion

Abstract

Introduction: The quick development cycle of COVID-19 vaccines led to the rapid implementation of workplace vaccine clinics with little guidance from experts on how to design and launch COVID-19 vaccine clinics.

Objectives: The primary objective of this project was to review strategies employed by the Medical College of Wisconsin's (MCW) COVID-19 vaccination clinic to provide recommendations for guidance on future vaccination clinics.

Methods: MCW opened a workplace clinic for COVID-19 vaccination shortly after the Pfizer-BioNTech COVID-19 vaccine received FDA Emergency Use Authorization on December 11, 2020. The clinic was led by faculty and staff from the School of Pharmacy and Office of Research. Few guidelines existed at the time to inform the design of the clinic. A team was assembled to implement the clinic, and tasks included patient outreach and scheduling, vaccinator and clinic workflow training, vaccine dose preparation, post-vaccination observation, and dose administration documentation. Semi-structured interviews were conducted with the clinic team leads to identify themes for improvement of the COVID-19 clinic. All volunteers were surveyed to provide input on the safety and efficiency of clinic.

Results: Common themes from team leaders include gratitude and burnout. Respondents contributed unique perspectives on areas of improvement. Most respondents to the all-volunteer survey found the clinic to be safe for patients and volunteers (94% and 93%, respectively). The clinic was perceived to be efficient, with 85% of respondents saying that patient workflow was very efficient. Literature was reviewed to identify best practice guidelines developed after the implementation of the MCW COVID-19 vaccination clinic.

Conclusion: Despite the theme of burnout, team leaders and volunteers reported gratitude for the opportunity to participate in a COVID-19 vaccination clinic. Given the quick development of COVID-19 vaccines and little guidance, experiences at our workplace clinic can be used to help frame future pandemic clinic responses.

monitoring, inventory management, and dose preparation posed unique challenges for clinic management. Initial limited supply of the vaccine required enhanced security protocols to transport vaccine from storage to clinic. Larger demand for COVID-19 vaccines and the rollout of priority groups caused increased demand for COVID-19 vaccines as well as increased stress for volunteer staff. Staff directed patients through the clinic and ensured patient safety during post-vaccination monitoring. Vaccine administration was required to be reported to the Wisconsin Immunization Registry (WIR) within 24 hours. The two-dose series necessitated scheduling follow-up appointments at appropriate intervals and inventory management for second doses.

Clinic workflows were developed for several different aspects of clinic operations, such as vaccine shipment receipt, storage, and distribution to clinic; patient scheduling; vaccine administration; documentation of administration in WIR; and patient monitoring. Due to initial high demand for vaccine and limited supply, a prioritization scheme was created to randomly select healthcare personnel from various hospital departments who were considered front-line healthcare workers. Staff checked in individuals for their appointments to confirm eligibility. Vaccine administrators followed EUA guidelines on reviewing the vaccine waiver with each individual, and then directed individuals to a post-immunization monitoring area once the vaccination was completed. Clinic space was structured to be COVID-19 compliant, placing adjacent vaccination stations 6 feet apart. Volunteers sanitized all surfaces contacted by the individual after each vaccine recipient exited the administration area. The vaccine waivers were used to manually input vaccination administration information into WIR.

A review of current guidelines from the American Society of Health-System Pharmacists (ASHP), Centers for Disease Control and Prevention (CDC), United States Pharmacopeia (USP), and Department of Health services (DHS) provides us with more robust guidance than was available at the time of initial vaccine deployment and clinic development.⁵⁻⁹

ASHP provides guidance on several topics: initial planning and development of

COVID-19 vaccination clinics; a readiness checklist for COVID-19 vaccination clinics; appropriate syringes and needles to maximize doses per vial; principles for vaccine distribution; allocations; mass immunization; optimization of COVID-19 vaccine preparation and safety; monographs for each vaccine by manufacturer; patient and physician information for each vaccine by manufacturer; and a table comparing the efficacy and candidacy of available COVID-19 vaccines by manufacturer.^{5,6} Additionally, ASHP has links to CDC guidelines, manufacturer information on their vaccine, and the Vaccine Adverse Event Reporting System (VAERS).^{7,8}

USP offers brief guidance regarding the handling, storage, and transportation of COVID-19 vaccines and issues minimal guidance on coverage of operational considerations in preparation of, and during, a COVID-19 clinic.⁷ The CDC provides information about vaccine storage, handling, and preparation; temperature monitoring; inventory management; and staff training protocols. Additionally, the CDC vaccine toolkit contains template worksheets that clinicians may find useful for documentation.⁸ DHS provides information pertinent to Wisconsin immunizers and patients, in the form of information on vaccines by brand and links to information on the EUA and FDA clinical trial data. Additionally, DHS provides helpful resources for patients regarding information about finding a vaccination appointment, expectations for vaccine appointments, expectations for patients after immunizations, and information for parents and guardians.

DHS also provides vaccine partner resources for community outreach.⁹

While most of the guidelines mentioned above were not available while clinic workflow was under development, it is also notable to recall previous pandemics in recent history. Just over a decade ago was the H1N1 pandemic. During this pandemic, there were also issues with vaccine distribution, production timelines, and medical supply shortages.¹⁰ However, clinical practice guidelines are still slow to develop. The Infectious Diseases Society of America (IDSA) clinical practice guidelines on management of seasonal influenza were only just updated in 2018, while its previous publication on the topic was prior to the H1N1 outbreak in 2009.¹¹ Furthermore, COVID-19 is the third coronavirus that has seen rapid spread in the past two decades.¹² SARS emerged in Asia in 2003 and MERS became widespread in the Middle East in 2012.¹³ Clinical practice guidelines remain largely unchanged to date, and similar practices are still being used to manage these conditions.^{14,15} However, vaccine clinic protocols have not been developed in lieu of these outbreaks, as no licensed vaccines were available for human use for prevention of MERS or SARS.

To better prepare for future pandemics and to quickly organize vaccination clinics, it is imperative that we document our findings and clinical practices now so that, if needed, we can quickly organize vaccination clinics again in the future. Though general advice from the CDC and World Health Organization (WHO) exists, no reports currently exist from practicing workplace clinics that document the results or

TABLE 1. Semi-structured Interview Questions

<i>Interview Questions</i>
What role did you perform in the clinic? <i>Describe your duties</i>
How did your role change over the course of the clinic?
What allowed you to perform your duties more effectively?
What detracted from your ability to perform your role?
What improvements could have been made to improve the efficiency of the clinic?
What changes would you find most beneficial?
What experiences do you have working in previous vaccination clinics? <i>What differences did you notice between previous clinics and the MCW COVID-19 vaccination clinic?</i>

procedures of COVID-19 vaccination clinic efforts.¹⁶⁻²⁰ Since COVID-19 vaccination clinic protocols are limited, the methods MCW used to successfully establish and run this clinic should be analyzed and documented so we can be prepared for future outbreaks.

Methods

Semi-structured Interviews

This study conducted targeted semi-structured interviews with team leaders from the MCW COVID-19 vaccination clinic. Investigators developed the interview questions so the interviewee could offer additional details about their clinic experience outside of the specific questions. Table 1 includes the questions asked during the interview. Interviews were conducted and recorded via an electronic teleconference platform, and then transcribed to identify common themes. All 10 team leaders were interviewed by a pharmacy student who was not part of clinic operations. The clinic operations team leadership consisted of three pharmacists, one nurse, one physician, two administrative associates, and three research support personnel who were all selected by executive leadership to manage the clinic.

Quantitative Survey

A quantitative Likert-scale survey developed by the investigators was emailed to all volunteers who participated in the MCW COVID-19 vaccination clinic. Table 2 includes questions from the quantitative survey. A single email was sent to all 506 individuals who volunteered in the clinic. This study was reviewed and approved by the MCW IRB and informed consent was obtained from all participants.

Results

Semi-structured Interview Findings

Interviews with team leaders from the MCW COVID-19 clinic generally focused on perceived obstacles or improvements that were either present during the initial formation of the clinic or evolved as the clinic grew. Common statements about perceived obstacles were separated thematically into eight groups, and common statements about perceived improvements were separated into four groups. See Table 3 for the list of themes. Comments occasionally had multiple themes but were assigned based on their perceived primary focus. All interviews were captured in analysis by identifying themes with no

TABLE 2. Quantitative Survey Questions

<p>1. Prioritize the following reminder options that are important to you (1=very important, 5=not important)</p> <ul style="list-style-type: none"> b. Confirmation Email c. Confirmation Text message d. Outlook Calendar Reminder e. Option of cancelling appointment via email or text f. An appointment reminder sent 24 hours in advance
<p>2. The MCW COVID clinic was offered at convenient days and times.</p> <ul style="list-style-type: none"> a. Yes/No b. No, please comment.
<p>3. An informational video, handout, email, or orientation session regarding my role and the clinic workflow would be beneficial to review prior to my clinic shift.</p> <ul style="list-style-type: none"> a. Yes/No b. No, please comment
<p>4. Prior to the MCW COVID clinics, were you aware that pharmacists could vaccinate?</p> <ul style="list-style-type: none"> a. Yes/no
<p>5. Prior to the MCW COVID clinics, were you aware that pharmacy students could vaccinate?</p> <ul style="list-style-type: none"> a. Yes/no
<p>6. Prior to the MCW COVID clinics, were you aware that medical students could vaccinate?</p> <ul style="list-style-type: none"> a. Yes/no
<p>7. Given your experience volunteering in MCW's COVID Clinic, how efficiently do you feel the workflow was established from a patient's perspective?</p> <ul style="list-style-type: none"> a. 1-Not efficient 2-somewhat efficient 3-very efficient
<p>8. Given your experience volunteering in MCW's COVID Clinic, how efficiently do you feel the workflow was established for you?</p> <ul style="list-style-type: none"> a. 1-Not efficient 2-somewhat efficient 3-very efficient
<p>9. Given your experience volunteering in MCW's COVID Clinic, how safe did you perceive the clinic experience was for each patient?</p> <ul style="list-style-type: none"> a. 1-Not safe 2-somewhat safe 3-very safe
<p>10. Given your experience volunteering in MCW's COVID Clinic, how safe did you perceive the clinic experience was for each volunteer?</p> <ul style="list-style-type: none"> a. 1-Not safe 2-somewhat safe 3-very safe
<p>11. Given your experience volunteering in MCW's COVID Clinic, how safe did you perceive the clinic experience was for yourself?</p> <ul style="list-style-type: none"> a. 1-Not safe 2-somewhat safe 3-very safe
<p>12. Given your experience volunteering in MCW's COVID Clinic, do you feel you had a lasting impact on MCW and the surrounding community and the COVID-19 pandemic?</p> <ul style="list-style-type: none"> a. Yes or No
<p>13. Provide any additional feedback you may have that could have improved the efficiency or safety during your clinic volunteer experience.</p>
<p>1. Demographics:</p> <ul style="list-style-type: none"> a. Approximately how many total hours did you volunteer in clinic? b. In what area did you provide volunteer time? <ul style="list-style-type: none"> i. Check-in ii. Sanitizing between patients iii. Dose preparation iv. Vaccine administration <ul style="list-style-type: none"> 1. How many years of experience have you had vaccinating patients? <ul style="list-style-type: none"> a. Less than 1 year b. 2-5 years c. 6-10 years d. 11-15+ years e. My primary licensure's responsibility does not include vaccinations on a routine basis v. Vaccine administration supervisor <ul style="list-style-type: none"> 1. How many students do you feel comfortable supervising at one time slot? <ul style="list-style-type: none"> a. 1 b. 2-3 c. 4-5 d. 5 or more vi. Data entry vii. Post-immunization monitoring viii. Select all that apply c. Are you an MCW employee? <ul style="list-style-type: none"> i. Yes/ no d. Are you an MCW student? <ul style="list-style-type: none"> i. Yes/ No

TABLE 3. Themes Identified from Semi-structured Interviews

<i>Obstacles</i>	<i>Perceived Improvements</i>
Patient issues	Workflow improvements
Burnout	Tool development
Data entry issues	Experiential improvements
Initial clinic protocol creation	Operational improvements
Communication	
Clinic location	
Volunteer issues	
Miscellaneous comments unable to classify	

rank order to the frequency of common statements.

Patient issues - Comments focused on patient efficiency issues identified a lack of predictability with patients. For example, patients would occasionally skip their appointment slot without notifying the clinic of the cancellation. Some patients made appointments within multiple systems to obtain the vaccine as quickly as possible. Prior to firm guidance from the CDC on the required time between doses, a few patients were scheduled earlier than the recommended interval. There were minor instances of patients leaving with vaccine administration paperwork, filling out paperwork incorrectly, or having their access to WIR locked, which slowed MCW’s submission of data to the WIR. As vaccine eligibility widened to the general public, more time was spent per patient on anxiety, health literacy, or simply to speak about gratitude. While these discussions are not inherently negative and are part of providing health care, they do add to the workload per patient.

Burnout - Statements focused on burnout primarily centered around volunteers who performed regular nonclinical duties in addition to clinic duties. Interviewees mentioned working much longer than their typical work week. Team leaders frequently arrived an hour before clinic and stayed over an hour after clinic ended. Additional comments mentioned the difficulty of maintaining the momentum of the clinic over time, feeling fatigue due to repetitive motions, missing meetings due to clinic duties, and not having adequate footwear to support

frequent walking or standing for long durations.

Data entry issues - The theme regarding data entry focused on the lack of electronic scanning ability and having to manually submit information to the WIR. The MCW clinic did not have access to an electronic health record (EHR) or badge or barcode scanning, as healthcare operations are normally carried out by the clinical partners. One such EHR submits information to the WIR automatically. Additionally, vaccine administration records for affiliated hospital staff and MCW employees were submitted to occupational health. However, there was no easy method to separate affiliated employees from other community patients, meaning this paperwork had to be accounted for manually.

Initial clinic protocol creation - Comments centered around initial clinic protocol creation mentioned the difficulty of applying to become a vaccination site. This is in part due to MCW’s complex organizational structure: the application to become an immunizing body had to be submitted under the correct unit. Additionally, there were decisions to be made about how and whether the clinic should proceed. For example, there was some deliberation about whether the health science university should operationalize its own clinic, or solely depend upon clinical partners. This deliberation may have slowed initial planning efforts.

Communication - Responses focused on communication largely noted the need for the immediate establishment of team lead positions upon creation of the clinic. One of the interviewees remarked that

formal roles were not established until early January. It could have been beneficial to have a formalized role for vaccination education. Certified vaccinating pharmacy students were initially invited to assist with immunizations. Medical students were also interested in assisting with vaccine administration; however, it was initially unclear who would lead the vaccination training for medical students. Formalized roles and training could correct this.

Clinic location - Statements surrounding clinic location noted the need for enhanced wayfinding and signage, especially once community members were invited for vaccinations, as these individuals were less familiar with the health sciences campus.

Volunteer issues - Statements about volunteer issues were the most varied in response. Volunteer no-shows were infrequent but created difficulty in accommodating the schedule. It was sometimes difficult to find an appropriate number of vaccinators for each shift.

Miscellaneous comments unable to classify - Miscellaneous comments about obstacles included some initial issues with available syringes, which were shipped with the vaccine product. Some of the needles provided had more dead space volume and caused some vials to only produce five doses while other needles allowed for six doses. Some early syringes were too small and made it difficult to remove large air bubbles from the syringe space. Having an independent source of syringes mitigated this issue.

Workflow improvements - Comments regarding workflow improvements discussed changes that were made to improve efficiency. Interviewees discussed alphabetizing and scanning WIR documents throughout the workday; matching doses with forms by the end of the workday; and preparing multiple batches of vaccines simultaneously. Interviewees described how having dedicated workspaces added to the efficiency of the clinic. Additionally, one interviewee noted that there was improvement in patient response rates when the MCW clinic switched from a lottery system to a voucher system for possible extra doses at the end of the day. Essentially, a limited number of patients could pick up a voucher at the start of the clinic day and return towards the end of the clinic day to

receive an available dose, if any remained. Additionally, this reduced the burden on volunteer staff who would otherwise need to reach out to potential vaccine recipients to avoid wasting doses.

Tool development - Most perceived improvements were related to tool development. Specifically, the development of a spreadsheet that allowed for scheduling appointments and tracking inventory helped improve end-of-day dose preparation management to reduce the number of remaining doses. This tool was also used to calculate the number of doses needed by the end of day based on the current schedule as well as how many doses would be needed for the following clinic day. The initial scheduling software allowed appointment registration and cancellation window to remain open up to two hours before the appointment time, which caused an excess of variability in patient count. Switching to a different scheduling software allowed for clinician staff to better understand patient demand for the day. Regarding the software utilized for volunteers to sign up for specific clinic shifts and roles, it was found that deleting previous signup dates on this software helped prospective volunteers navigate the program more easily.

Operational improvements - Common statements about operational improvements centered around using the flu clinic as a trial to create the initial operational protocols for the COVID-19 clinic; the ability to integrate students as vaccinators; and creating formal roles for necessary tasks at the clinic. Recent legislation allowed first-year pharmacy students to help in the COVID-19 clinic, expanding the number of available immunizers. Additionally, creating roles with redundancies, or an additional person assisting with the role, proved useful. As time went on, volunteer staff became more efficient at their tasks. As expected, repeat volunteers were desirable since they were already trained.

Volunteer Survey

Among the 213 respondents to the volunteer survey, 76% were MCW employees and 19% were MCW students. Volunteers primarily from the research and education missions of MCW comprised the largest group of clinic staff. Volunteer roles included check-in; sanitizing between patients; dose

preparation; vaccine administration; vaccine administration supervisor; data entry; and post-immunization monitoring. The largest group responding to the survey was vaccine administration (26%), followed by sanitizing between patients (23%). Forty percent of vaccinators had less than one year of experience administering vaccinations. Most vaccine administration supervisors (61%) preferred to supervise two to three students at one time. Prior to volunteering in clinic, 58% of volunteers were unaware that pharmacy students were able to vaccinate and 51% were unaware that medical students could vaccinate.

The vast majority of respondents found the clinic to be safe for patients and volunteers, 94% and 93% respectively. The clinic was perceived to be efficient with 85% responding that the workflow for patients was very efficient, and 77% indicating that volunteer workflow was very efficient.

Information from the volunteer survey supported some themes identified in the semi-structured interview. One potential tool for communication identified in the volunteers' survey was the addition of an informational handout to educate volunteers about their clinic workflow prior to their shift. This workflow training request was in addition to the required CDC education reviewed by all prior to volunteering. Seventy-five percent of respondents agreed that this form of communication would have been beneficial to review. One volunteer highlighted this need with the following statement: "I think having a handout for volunteers before they started their shift would have been helpful. I tried to volunteer at least once a week and when changes occurred in the way we were supposed to document, they were not always communicated." Difficulty balancing the appropriate number of staff required

for each clinic schedule was reinforced by comments from the volunteer survey. Several comments noted that several clinic days had over-staffed vaccinators resulting in vaccinators sitting idly without individuals to vaccinate. However, most respondents (94%) felt their time in clinic had a lasting impact on MCW and the surrounding community during the COVID-19 pandemic. One comment highlights the sentiment of several volunteers who responded to the survey: "I had a really positive experience volunteering at that clinic and honestly wish I could have given more time because it was a really rewarding experience. I witnessed so much positivity from the community. I didn't hear one bad thing! Kudos to everyone involved!"

Discussion

In this clinic, which was staffed mostly by internal volunteers with primarily research or education positions, most volunteers found working in the clinic to be a rewarding experience and were gratified by its lasting impact on the organization and the community. Despite the very rapid deployment, lack of external guidance for clinic operations, and initial concern on the part of the (initially unvaccinated) volunteer workforce, the clinic operations were widely perceived to be safe and efficient. Although a lead group was assembled early on, those leaders felt that earlier creation of specific leadership roles was an opportunity for improvement. Several factors led to stress for the volunteers and leaders, including unpredictability in patient attendance; the fact that some volunteers were not relieved from all other duties; and that, even when relieved of other responsibilities, managing this unusual operation required long hours. Survey respondents identified that additional communication, such

TABLE 4. Key Lessons Learned from MCW's COVID-19 Clinic Experience

Early identification and delineation of operational leadership roles.
Development of a tool and workflow to efficiently schedule patients.
Inventory management tool development.
Process development to identify eligible persons who can receive extra doses at the end of the day.
Development of a communication tool to describe clinic workflow for vaccinator volunteers with updates to this document to provide clear information on changes to workflow.
Efficient workflow for reporting administered doses to DHS.

as a handout or video describing clinic workflow, would have been beneficial prior to the start of their shifts. Improvements over time included the creation of more efficient scheduling and inventory management software, better processes for reporting vaccinations to the state's registry, and a better system for identifying eligible persons for receiving extra doses at the end of the day. These end-of-day activities were a crucial marker of success for our clinic, at a time when vaccine availability was limited, and a great emphasis was placed on not wasting any doses. With the processes implemented in our MCW clinic, we were fortunate to not waste any doses due to over-preparation at the end of the day. See Table 4 for key lessons learned from MCW's COVID-19 Clinic experience.

Many hospitals and healthcare organizations faced similar difficulties in the quick ramp-up to operationalizing COVID-19 vaccination clinics after the EUA approvals by the FDA. Our experience was slightly different than these settings because we did not have the underlying healthcare infrastructure to build from. Health systems had pool nursing staff who could be assigned to vaccination clinics and pharmacy departments who were able to prepare vaccine doses with qualified staff. Initial clinic staffing primarily came from the School of Pharmacy and Office of Research volunteers, and then expanded to include other research personnel and School of Medicine students and faculty. Affiliated clinical staff volunteered countless hours in clinic to administer vaccinations and monitor patients post-immunization. A true multidisciplinary effort created the volunteer workforce for the day-to-day operations of clinic. This report is the first to describe an evaluation of a COVID-19 clinic in this setting.

Conclusion

It is likely that future clinics will encounter similar issues unless steps are taken to prevent their occurrence. We recommend that future clinic organizers reflect upon the obstacles observed during the MCW COVID-19 vaccination clinic and implement strategies to prevent or reduce their occurrence. Additionally, we recommend that improvements made during the MCW clinic receive recognition and implementation in future clinics. For organizations to show appreciation for the

volunteers' hard work, it is recommended that future clinics incorporate the findings of this study into their design in order to promote the best environment for their healthcare team and, subsequently, provide the best possible patient care experience.

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Student Pharmacist Integration in an Ambulatory Service at a Rural Veterans Affairs Clinic

by Anna Lattos, PharmD, Erica Wagner, PharmD, BCACP, Mara Kieser, RPh, Stephanie Gruber, PharmD, BCACP, Edward Portillo, PharmD

Abstract

Background: Proton pump inhibitors (PPIs) are commonly used for the management of gastroesophageal reflux disease (GERD) and heartburn; prophylaxis and treatment of gastrointestinal (GI) ulcers and bleeds; and in combination with antibiotics for treatment of *Helicobacter pylori*.^{1,2} The Food and Drug Administration (FDA) and the American Gastroenterology Association (AGA) advise short-term length of therapy for these indications.³ However, it has been found that PPI prescriptions are often renewed for long-term therapy without clear or appropriate indications. Risks of long-term PPI use have been described in the literature, such as bone fracture, infection (*Clostridium difficile* and community acquired pneumonia), and micronutrient deficiencies of calcium, vitamin B12, iron and magnesium, all of which have been shown to affect patient health outcomes; and yet these medications are often overprescribed.^{1,2,4,7} Therefore, the opportunity exists to explore innovative models to ensure patients on PPIs are appropriately assessed for continued use. The primary objectives of this project were developed to reflect the integration of a student pharmacist into a PPI de-prescribing service. These objectives included (1) the development of tools and resources required to guide the student pharmacist, (2) processes completed by the student pharmacist to achieve service initiatives in a rural setting, and (3) evaluation of clinical pharmacist practitioner (CPP) time saved through incorporating the student pharmacist.

Methods: Tools were developed to pilot the PPI de-prescribing service in September 2019 by a third-year (P3) pharmacy student and reviewed by the CPP. Processes for chart review and phone call outreach were outlined by the CPP using a standardized decision support tool to determine appropriate PPI use. A chart review was performed by the student on 92 patients currently on long-term PPI therapy and receiving care at a rural outpatient clinic affiliated with the William S. Middleton Veterans Affairs (VA) Hospital. Patients were contacted by the P3 student between November 2019 and February 2020 under the supervision of the CPP. Project deliverables included the templates created by the student pharmacist, the use of these tools and other resources to complete service initiatives, and the time saved by the CPP per patient taper trial. The CPP time saved was determined by documenting student and CPP encounter time to complete service initiatives and taking the difference of the average time of these units.

Results: Note templates for this service were developed by the student and revised by the CPP. The student process of performing a baseline chart review demonstrated that 58% (53/92) of patients were on long-term PPI therapy for an inappropriate indication. Of the 9 patients that enrolled in the service, 2 patients completed a PPI taper, 4 patients were still in progress, and 3 patients stopped the taper trial due to return of GERD symptoms. The average time for patients who completed a PPI taper was 8-9 weeks (4-5 encounters). It is estimated that the integration of a student pharmacist in this service saved the pharmacist an average of 45 minutes per taper trial.

Conclusion: This project described and implemented the resources and processes needed to integrate a student pharmacist into the workflow of a PPI de-prescribing service. The project has demonstrated the potential benefit of using a student pharmacist to complete service initiatives in reaching rural patients. Student pharmacist outreach to eligible rural patients with pharmacist oversight provides a unique opportunity to achieve de-prescribing therapy in an effective and efficient manner in the ambulatory care setting. Future directions of this project are to package this service into other pharmacists' and clinics' workflows to help reach more patients through pharmacy services while also facilitating student learning.

Proton pump inhibitors (PPIs) are universally used agents to assist in acid suppression for a variety of gastrointestinal acid-related disease states.

PPIs are best known for the management of gastroesophageal reflux disease (GERD), in the treatment of *Helicobacter pylori* (*H. pylori*) infections in combination with antibiotics, and in minimizing the risk for gastrointestinal (GI) bleeds.^{1,2} Currently, the Food and Drug Administration (FDA) defines length of therapy of an over-the-counter (OTC) PPI for 14 days up to three times per year.³ Many patients use PPIs for much longer than this period of time because of the readily available OTC agents and the symptomatic relief they experience. For certain disease states, such as Barrett's esophagus, Zollinger-Ellison syndrome, adenocarcinoma, and GI bleeding prophylaxis, PPIs are considered essential in order to prevent acid from causing progression of the disease and/or harm to the GI tract; therefore, patients with these conditions are recommended to be on life-long therapy at the lowest tolerated dose of PPI.² While for GERD management and treatment the practice guidelines suggest that PPI therapy should not exceed eight weeks, the literature has demonstrated that this practice is not commonly followed.⁴

The overuse of PPI therapy is problematic, and negative consequences of prolonged PPI use are well described in the literature. PPI use has demonstrated a 44% significant increased risk of incident dementia in the aging population on PPI therapy compared to no PPI use.⁵ In addition, a study of United States Veterans showed a 15% increase in mortality for patients taking a long-term PPI compared to alternative therapy and a 23% increase in mortality compared to patients on no acid suppression therapy.⁶ The results of this study also showed a greater association between the duration of therapy and risk of death. Furthermore, long-term use has been associated with relative risk increases in bone fracture and infection (*Clostridium difficile* and community acquired pneumonia), and micronutrient deficiencies of calcium, vitamin B12, iron and magnesium while on long-term PPI therapy; all of which have been shown to affect patient health outcomes.^{1,2,4,7} Concerns have been raised around the overprescribing of PPIs and the

appropriateness of PPI therapy.^{7,8}

In response to these consequences of inappropriate PPI use, innovative approaches have been considered to de-prescribe PPIs. One interdisciplinary group assessed the value of PPI therapy in older adults and stratified use based on short-term and long-term indications.⁹ It was found that 1 in 8 older adults were prescribed a PPI, and over one-third of prescriptions lacked a guideline indication. Within a major academic medical center in Ohio, a pharmacist-led intervention identified older adults on PPI therapy through a population health management process, evaluated their appropriateness, and informed patients of the risks of inappropriate PPI use.¹⁰ In this intervention, 81.6% of patients who started the taper process were successfully tapered off of PPI therapy.

While these services have been shown to be effective, barriers exist to implementing these programs on a large scale across health systems. Similar to other population management models, PPI de-prescribing requires additional staffing resources, documentation time, and patient outreach that may not be feasible in primary care clinics with limited resources available. Even with the integration of a pharmacist within the primary care setting, additional disease state management initiatives may limit available time for PPI de-prescribing initiatives.

This evaluation explores a novel approach to care delivery by incorporating students as integral components of the care delivery model. This evaluation primarily considers the approach taken to integrate the student within the primary care clinic, and the tools, resources, and processes required to effectively design this new model of care delivery. Specific metrics include (1) the development of tools and resources required to guide the student pharmacist, (2) processes completed by the student pharmacist to achieve service initiatives, and (3) evaluation of pharmacist time saved through incorporating the student pharmacist.

This service pairs a student pharmacist with a clinical pharmacist practitioner (CPP) to assess patient PPI therapy appropriateness and call patients who are eligible to begin de-prescribing. The student pharmacist specifically is engaged with patients from patient service enrollment

through PPI discontinuation.

Methods

This project occurred within the Department of Veterans Affairs at a rural community-based outpatient clinic (CBOC) in Beaver Dam, Wisconsin. Resources required for integration of the student pharmacist within the service were developed in September 2019 through discussion with a CPP and the third-year pharmacy (P3) student, with the goal of designing resources that could be scalable to incorporate additional students within the service. The specific requirements of the program, including inputs, outputs, and service outcomes, were determined and integrated with a logic model designed by the student learner. Methods for each aim are included below.

Aim 1: Development of tools and resources required to guide the student pharmacist

Student training for the service was conducted by a PGY-2 pharmacy resident over a three-hour period in September 2019. The resident and the student designed the resources required for the program, including a series of templates. These tools were reviewed by the CPP and faculty mentor and then finalized before patient outreach began. The resident and the student reviewed the application of a PPI de-prescribing algorithm to guide the student learner in clinical decision making and de-prescribing based on indication and duration of PPI use. An additional resource used by the student was a PPI de-prescribing protocol developed by the local facilities' Pharmacy and Therapeutics committee (see Figure 1). This protocol incorporated the concerns for rebound acid hypersecretion, which could lead to more telephone encounters but may also improve PPI tapering attempts.¹¹ Patient outcomes were tracked through a patient de-identified tracking mechanism and outlined using Microsoft Excel. This spreadsheet included baseline characteristics and details relating to patient progress throughout the PPI taper trial. Materials were designed for the student to complete population management initiatives, patient telephone outreach, and staffing.

Aim 2: Determination of processes completed by the student pharmacist to achieve service initiatives in a rural setting

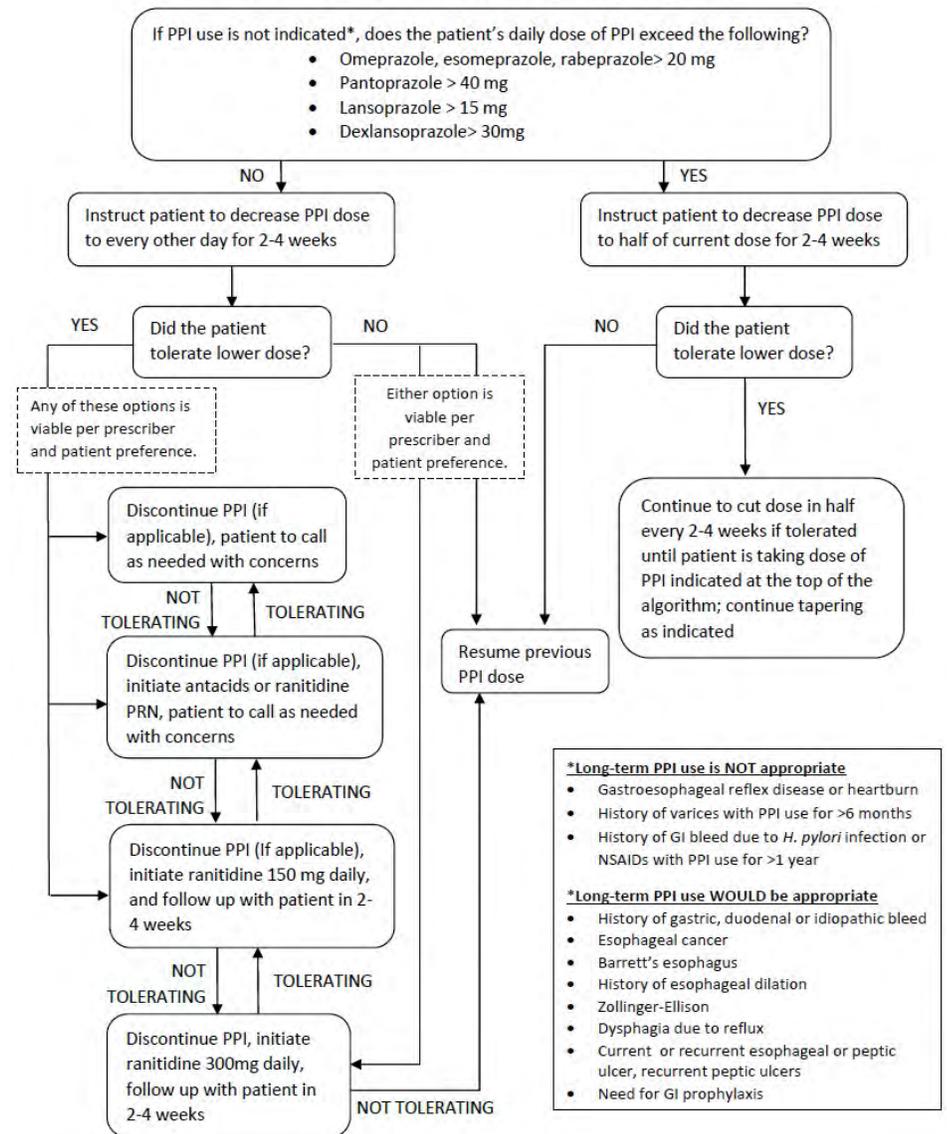
To support the student pharmacist in completing this project, the student was enrolled in a weekly project management course, Practice Innovations, from the project start to completion. In this course, the student received mentorship from faculty at the University of Wisconsin-Madison School of Pharmacy to guide them in developing project processes.

To identify patients eligible for a PPI de-prescribing, the student pharmacist received a patient panel list of 92 patients to screen for eligibility, from the Beaver Dam VA clinic. These patients were identified in a report with inclusion criteria of patients who had an active prescription of a PPI for greater than 30 days with more than 2 refills, and patients living in a community defined as either rural or highly rural.

The VA stratifies rurality as urban, rural, and highly rural, using the Rural-Urban Commuting Area (RUCA) system based on information from the U.S. Census Bureau.¹² Determining potential eligibility for the taper process was completed by the student, who accessed the electronic health record (EHR) of each patient. The student went into clinic, once a week for three hours, for a total of four weeks to complete the baseline chart review assessing eligibility for PPI de-prescribing. The student used objective information from the EHR and primary care notes to determine if patients required long-term PPI therapy. The protocol's eligibility for long-term therapy was used for screening. Additional risk factors were documented for GERD and consequent labs associated with long-term PPI use for baseline characteristics; this included BMI, smoking status, and available labs (calcium, albumin, vitamin D, vitamin B12, magnesium, serum creatinine, and eGFR). Exclusion criteria indications were included in the de-prescribing protocol. Patients who received primary care outside of the VA clinic or were followed by a GI specialist outside of the VA were also excluded.

The student pharmacist telephone outreach began in November of 2019 and finished in February 2020. The process for student outreach included: (1) initial enrollment phone call to the patient using

FIGURE 1. Madison Veterans Hospital Proton Pump Inhibitor (PPI) De-prescribing Algorithm



**famotidine used due to ranitidine recall of 2019
GI= gastrointestinal; NSAIDs= non-steroidal anti-inflammatory drugs; PPI= proton pump inhibitor; PRN= as needed

a standardized script, (2) screening for exclusion criteria with the patient to double check eligibility, (3) design of a plan for PPI tapering regimen using the protocol, (4) consult with CPP to discuss findings and plan, (5) document and communicate plan to the patient, and (6) use of initial phone call template to document the encounter notes and (7) send to CPP for verification and final sign off.

In addition to documenting and communicating the plan, the student performed education on rebound hypersecretion and lifestyle modifications. Lifestyle modifications discussed included weight loss if warranted; elevating the head

of the bed; and/or eating 2-3 hours before sleep.

A follow-up phone call was made by the student pharmacist 2-4 weeks later, to assess patient progress in the taper process. During the follow-up phone call, the student confirmed and documented current dose and adherence to taper trial; assessed if symptoms had shown improvement, stayed stable, or worsened; and asked for the patient to describe symptoms they had experienced within their taper trial. This information was collected and documented to help the student use the protocol for the patient. If prior issues regarding the taper process were discussed in previous

visits, the student reviewed this with the patient as well. The student discussed the information with the CPP and together they developed a new plan based on the PPI de-prescribing protocol and the pharmacist's clinical judgment. Next, the student called the patient back and reported the updated plan and discussed the outreach for another unscheduled follow-up phone call in 2-4 weeks. This follow-up process continued until the patient had completely discontinued therapy or had achieved their lowest tolerated dose.

Aim 3: Evaluation of pharmacist time saved through incorporating the student pharmacist

Pharmacist time saved was determined by considering the activities performed by the student pharmacist that would have otherwise been conducted by the clinical pharmacist practitioner. In each note, the student documented how long each encounter took in minutes. Then, the CPP documented the amount of time each review took in minutes. The CPP time saved was determined by documenting student and CPP encounter time to complete service initiatives, and taking the difference of the average time of these units.

This project did not require IRB approval, because it was deemed quality improvement using the UW-Madison QI/ Program Evaluation Self-Certification Tool.

Results

The tools developed by this project included a telephone call script template and three note documentation templates for initial outreach, follow-up, and no-answer encounters. The templates developed by the student and finalized with reviews by the CPP and faculty mentor for patient phone calls and documentation are included below.

The process of the baseline chart review conducted by the student found that 58% (53/92) of patients were on long-term PPI therapy for an inappropriate indication and were deemed eligible for outreach and enrollment in the PPI de-prescribing service. From the baseline chart review, it was identified that most patients in this panel were overweight (average BMI = 30.78 kg/m²), which is a risk factor for GERD/heartburn.⁴ Additional baseline characteristics can be found in Table 1 and descriptions of appropriate PPI use can

be found in Table 2. The most common inappropriate indication for long-term therapy PPI use was GERD/heartburn, which applied to 44 out of the 53 patients (83%). Additional inappropriate indications can be found in Table 3.

During the process of phone call outreach, the student pharmacist called 17 patients out of the total 53 patients eligible. Of those, 12 patients answered the phone calls, and of those, 9 patients opted in to trial PPI de-prescribing. Of the 9 patients who enrolled in the PPI de-prescribing service, 2 patients completely tapered off PPI therapy, 2 patients stopped the service due to rebound symptoms, and 5 patients were still in the taper trial process at the time of project completion.

In regard to pharmacist time saved, preliminarily, based on the 2 patients who completely tapered off therapy, this intervention took the patient 4-5 encounters (8-9 weeks) total. This took the student 20 minutes per patient telephone contact, which resulted in a range of 60-100 minutes total to completely de-prescribe per patient. As for the pharmacist time, it took the pharmacist 5-10 minutes per encounter to review and sign off on the student's note (20 to 50 minutes total to de-prescribe a patient). Therefore, by integrating a student pharmacist into the workflow, the preliminary results of the average pharmacist time saved was on average 45 minutes per de-prescribing intervention per patient.

TABLE 1. Baseline Characteristics (n=92)

Average Age	72
Sex % Male (number)	96% (88/92)
Average BMI (kg/m²)	30.78
% Rurality^A	71.2%
<i>BMI= body mass index A = See Aim 2 for definition</i>	

TABLE 2. Stratification of Appropriate Proton Pump Inhibitor (PPI) Use Per Baseline Chart Review

Appropriate PPI Usage	42% (39/92)
History of gastric, duodenal, or idiopathic bleed	7% (6/92)
Esophageal cancer	1% (1/92)
Barrett's esophagus	8% (7/92)
History of esophageal dilation	2% (2/92)
Zollinger-Ellison syndrome	0% (0/92)
Dysphagia due to reflux	1% (1/92)
Current/recurrent esophageal or peptic ulcer(s)	4% (4/92)
Need for GI prophylaxis	13% (12/92)
Seen by GI specialist	2% (2/92)
Other appropriate documented indication A	4% (4/92)
<i>GI= gastrointestinal; PPI= proton pump inhibitor A= gastritis, duodenitis, erosive esophagitis, long-term use of anticoagulant</i>	

TABLE 3. Stratification of Inappropriate Proton Pump Inhibitor (PPI) Use Per Baseline Chart Review

Inappropriate PPI Usage	58% (53/92)
Disease	
GERD or heartburn	83% (44/53)
History of varices with PPI use for > 6 months	0% (0/53)
History of GI bleed due to H. pylori infection or NSAIDs with PPI use for > 1 year	2% (1/53)
Other inappropriate documented indication ^B	15% (8/53)
PPI Use	
PPI duration greater than 8 weeks (recommended duration for GERD)	91% (48/53)
Length of therapy	Average DOT = 2,038 days Average years = 5.58 years
<i>DOT= duration of therapy; GERD= gastroesophageal reflux disease; GI= gastrointestinal; NSAIDs= non-steroidal anti-inflammatory drugs; PPI= proton pump inhibitor B = patient off NSAID and still on PPI for prophylaxis, no indication documented, history esophageal, duodenal or peptic ulcer > 1 year ago, intermittent dysphagia not due to reflux, esophageal stricture, history of bariatric surgery, ulcerative colitis, hiatal hernia</i>	

Discussion

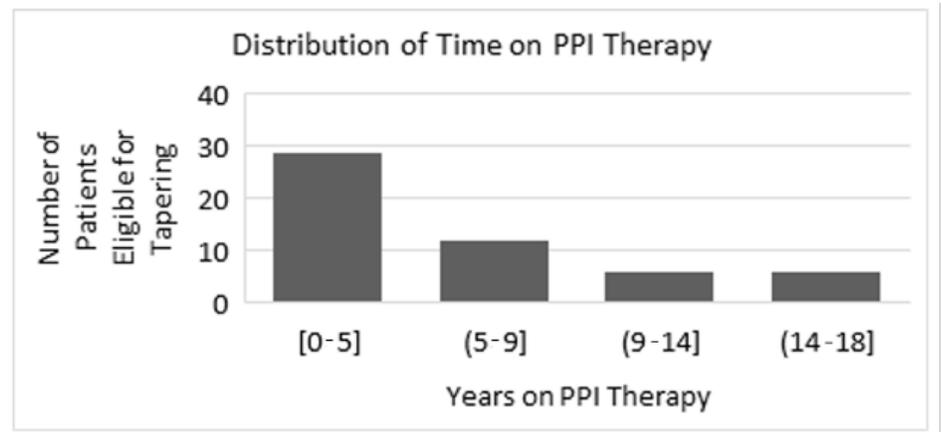
Within the VA primary care model, clinical pharmacist practitioners are integrated within primary care teams and have a scope of practice to independently prescribe medications and directly adjust medication therapy. This project described the feasibility of integrating a student pharmacist into a PPI de-prescribing service and the impact it could potentially have on expanding patient services. The tools developed were innovative in their ability to guide a student pharmacist in the primary ambulatory care setting. These tools and additional resources were utilized during the processes of baseline chart review and patient outreach. The tools and processes proved helpful in guiding the student pharmacist; the CPP rarely had to intervene to make corrections to the student's assessment and recommendations to complete service initiatives. The addition of a student pharmacist to this service shows the potential of having students assist the CPP to reach more patients and offer appropriate interventions. Furthermore, this project specifically increases the experience and competence of a student pharmacist in the ambulatory care clinic setting for future practice.

The incorporation of a student pharmacist within this service provides a rich learning environment for students to engage with rural patients through telephone communications, and to serve patients with direct oversight and mentorship by a CPP. Furthermore, the program provides students with the opportunity to apply clinical guidance on PPI de-prescribing directly to patient care opportunities for rural patients. Rural Veterans are good candidates for this service, given the prevalence of inappropriate PPI use in previous assessments, the increased risk factors among this under-resourced population, and the distance from access to healthcare.¹³

This layered approach to care delivery was intentional, to increase access to this service for a rural patient population. Telephonic appointments are used for rural patients who are, on average, older, who have more chronic conditions, and who have limited access to healthcare resources compared to their urban counterparts.¹⁴

Integrating student pharmacists in this process can be considered an innovative

FIGURE 2. Patients Eligible for PPI De-prescribing by Years on Therapy (n=53)



approach to expanding patient services, improving health outcomes, and providing a unique opportunity for student learning. This evaluation is a case study example of academically, non-experientially, integrating a student into an ambulatory clinic workflow through a PPI de-prescribing initiative.

This project adds to the literature about the process of transitioning from student pharmacist to professional pharmacist. A study organized with students from St. John's University in New York measured the acceptance rates of APPE pharmacy students' recommendations to primary care providers in a family medicine clinic.¹⁵ The study reported that 77% of recommended interventions were accepted by providers. This project is similar to other literature about involving pharmacy students in educating patients as part of the clinic workflow. A study completed by faculty from the University of Minnesota College of Pharmacy and the University of Utah College of Pharmacy evaluated the roles of pharmacy students in student-run free clinics across the United States.¹⁶ The surveys they conducted found that the two most defined and practiced roles by pharmacy students were within medication education and administration/leadership. The current project's structured approach of developing tools and processes to assist the student in completing service initiatives helped the workflow for the PPI de-prescribing service. This project provides a framework for student pharmacists to become more engaged in patient care outreach activities in the ambulatory care setting.

Factors that contributed to the success

of this project included access to an integrated system and the clinical scope of the CPP. The VA EHR is a closed system that encompasses nearly all medical information for each patient. A CPP practicing within the VA healthcare system is uniquely empowered to start, change, or stop pharmacologic treatment and provide follow-up care to patients to assess safety and efficacy of pharmacotherapy.

Opportunities exist across the private sector to similarly consider drafting collaborative practice agreements with local primary care providers and develop communication strategies with clinicians to make assessments and recommendations for therapy changes. An additional support for the student in this project included enrollment in a weekly project management course, Practice Innovations, throughout the project, which provided the student pharmacist with mentorship from faculty from the UW-Madison School of Pharmacy. Practice sites could consider forming partnerships with schools and colleges of pharmacy to expose students to real-world applicable work through experiential and didactic course work.

Additionally, this project echoes the benefits of having PPI de-prescribing services led by pharmacists. A Canadian interdisciplinary group published an evidence-based clinical practice PPI de-prescribing algorithm and specified that having a pharmacist on the team reduced the inappropriate use of PPIs.¹⁷ The results of this project mirror the prevalence of inappropriate use found in similar studies. An assessment completed at a VA health system in Michigan found that 48.6% of a group of patients were on long-term

PPI therapy and lacked reassessment of symptom management.¹⁸ Of that same group, a majority of patients did not have a documented indication for PPI therapy. At a VA clinic in New York, pharmacists identified that 68.4% of patients were not indicated for PPI use and a majority of these patients were able to taper off therapy.¹⁹

While this project demonstrated the potential for pharmacists and student pharmacists to serve as key members of the healthcare team in PPI de-prescribing, there were limitations to this project. All interventions for patients were made over telephone encounters, and while this form of communication was effective, not all patients could be reached. Phone contact and interaction may not be feasible for all patients for a variety of reasons, and may even lead to suboptimal care if, for example, a patient has difficulty understanding instructions delivered by phone. In the future, opportunities exist to conduct "plan, do, study, act" (PDSA) cycles of this project to consider the effectiveness of the PPI de-prescribing algorithm itself. This PDSA process would be completed by documenting when deviations were made from the de-prescribing protocol and considering modifications to better tailor the algorithm to the VA patient population.

Ultimately, the tools and processes outlined and developed by the student and CPP suggest that this service can be expanded to other sites across the VA and other interested healthcare settings interested in running a similar program. This service could be expanded to include other populations as well, including both female and urban patients. Other potential areas of investigation include assessing prescribing habits of PPIs prospectively by placing end dates in prescriptions and routine follow-up with pharmacists..

Conclusion

This project described and implemented the resources and processes needed to integrate a student pharmacist into the workflow of a PPI de-prescribing service. The project has demonstrated the potential benefit of using a student pharmacist to complete service initiatives in reaching rural patients. Student pharmacist outreach to eligible rural patients with pharmacist oversight provides a unique opportunity to achieve de-prescribing therapy in an

effective and efficient manner in the ambulatory care setting. Future directions of this project are to package and integrate this service into other pharmacists' and clinics' workflows to create a widespread awareness of retrospectively being able to assess need and implement PPI de-prescribing for improved patient outcomes. Furthermore, the opportunity presents itself to identify and educate on the appropriate use of PPI therapy prospectively and assess prescribing habits. Finally, this project contributes to the literature of increasing student pharmacist experience to increase their patient interaction and documentation skillset.

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PR This article has been peer-reviewed.
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Initial Phone Call Script

“Good Morning! My name is _____ (student name) and I’m a pharmacy intern calling from the VA. I work with your primary care pharmacist, Dr. _____ (pharmacist name) who works with your primary care provider, Dr. _____ (primary care provider name). How are you doing this morning?”

[Patient response]

“Currently we are evaluating _____ (whichever PPI they use). Research over the past 10 years has identified several possible, harmful side effects if _____ (PPI name) is used for longer than it should be; especially when you may not need the medication. Deficiencies of vitamin B12 (brain/memory function), magnesium (energy), vitamin D and calcium (bone health/fracture risk) have been associated with long-term PPI use. Also, the risk of infection has been found to be associated with long-term PPI use. This is why I am reaching out to patients, like yourself, who may qualify for potential decreases of their _____ (PPI name). Before I talk further, I want to emphasize that I am not forcing you to stop your _____ (PPI name) if you do not want to. I am here to make patients aware of the potential harms and help with lifestyle modifications to help you succeed in your overall health. And, if you are interested in decreasing the medication or switching to another medication for the stomach acid, then as a pharmacy intern in partnership with your pharmacist and doctor, I can help you do that. Let me pause here. I have talked for quite a bit, what are your thoughts on this?”

[Patient response] – student documents

If patient is interested, student is to go through the exclusion criteria with the patient.

“Before we can start to lower or change acid suppression therapy, I have to make sure you do not have any medical conditions that would make it unsafe to decrease your _____ (PPI name). Therefore, I am going to through a list of conditions and you will answer yes or no if you have them, okay?”

[Patient agrees]

“Do you have a history of gastric, duodenal or idiopathic (GI or other) bleeds? Do you have a history of esophageal cancer? Do you have a history of esophageal dilation? Have you ever been diagnosed with Zollinger-Ellison syndrome or Barrett’s esophagus? Do you have trouble swallowing due to stomach acid reflux? Do you currently have or do you have a history of recurrent esophageal or peptic ulcers? Finally, has a doctor or other provider ever told you that you need your _____ (PPI name) for GI prophylaxis (stomach lining/gastrointestinal protection)?”

[Patient answers question – if all no’s, patient is eligible for PPI dose reduction]

“You qualify for a dose reduction of your _____ (PPI name). I am going to talk with the pharmacist to come up with a plan to reduce your medication and call you back in a few minutes. Thank you for your time.”

[discuss findings and plan with pharmacist, come up with a finalized plan for the patient and document this. Call patient back and communicate the plan, address lifestyle modifications and discuss rebound hypersecretion]

Initial Phone Call Documentation Template

IPATIENT NAME| is a IPATIENT AGE| y.o. IPATIENT SEX| contacted by phone for a pharmacy intern PPI tapering project to optimize patient safety through pharmacy and therapeutics approved protocol.

S:

TODAY, patient called to discuss PPI tapering. Patient states ____ (insert what patient told writer about their thoughts on PPI risks and tapering or switching to a different acid suppressing agent)

PMH:

IACTIVE PROBLEMS|

IACTIVE MEDICATIONS|

1. PPI USE

Medication:

PPI dose:

PPI duration:

Indication for PPI use:

Adherence: Last fill:

Dosing frequency (per patient):

Reviewed the following with the patient: (if patient reports any of these indications, change denies to reports and patient is indicated for long-term use)

- denies history of gastric, duodenal or idiopathic bleed
- denies history of esophageal cancer
- denies history of esophageal dilation
- denies Zollinger-Ellison syndrome diagnosis
- denies Barrett's esophagus diagnosis
- denies dysphagia due to reflux
- denies current/recurrent esophageal or peptic ulcer(s)
- denies need for GI prophylaxis

O:

LABS:

ICREATININE|

leGFR|

IALBUMINI

ICALCIUMI

IMAGNESIUMI

IVITAMIN DI

IVITAMIN B12|

ASSESSMENT:

1. PPI Use

- Patient currently on inappropriate therapy for PPI use. The recommended length of therapy for ____ (indication) treatment is ____ (length). Based on VA de-prescribing protocol, patient is eligible to trial PPI dose reduction. After discussion with patient, shared-decision was made to _____. (plan that was agreed upon). Patient agreeable to this plan and was informed to call with questions/concerns.

PLAN:

- Med Changes

DECREASE/CHANGE/DISCONTINUE:

F/U:

- Any referrals
- Phone pharmacy intern: unscheduled phone call in 2-4 weeks

Pt Education:

- call with questions/concerns as needed
- discussed harmful SEs of chronic PPI use (B12, D, and Magnesium deficiency, increased fracture/infection/memory challenge risks)
- lifestyle changes: avoid meals 2-3 hours before bedtime, elevating the head of the bed, regular exercise to achieve weight loss, and the possibility of rebound symptoms

Time ~ __ min

Follow-up Phone Call Documentation Template

IPATIENT NAMEI is a IPATIENT AGEI y.o. IPATIENT SEXI contacted by phone for a pharmacy intern PPI tapering project to optimize patient safety. Previously identified as eligible for PPI tapering through pharmacy and therapeutics approved protocol.

HPI: Patient last assessed by PACT PharmD on ___ (date), where ___ (shortly describe what happened with patient's acid suppression therapy).

S: TODAY, patient called to follow-up on PPI dose reduction. Patient reported ___ (write what was discussed – How is it going? Have they been adherent? What symptoms are they experiencing? Have symptoms improved, worsened or remained stable? What lifestyle modifications have they been able to try? Did they help? Did they experience rebound acid hypersecretion? Did antacids help with this? Etc.)

PMH:

IACTIVE PROBLEMSI

IACTIVE MEDICATIONSI

O:

1. PPI Use

Current PPI regimen: (dose and directions) – patient confirms dose and adherence

Rate of symptoms: (improved, worsened or stable)

Lifestyle modifications attained since last encounter:

LABS:

ICREATININEI

IeGFR I

IALBUMINI

ICALCIUMI

IMAGNESIUMI

IVITAMIN DI

IVITAMIN B12I

ASSESSMENT:

1. PPI Use

-Patient currently tolerating/or not PPI dose reduction. Patient previously identified eligible for PPI dose reduction. After discussion with patient, shared-decision was made to ____. (plan that was agreed upon). Patient agreeable to this plan and was informed to call with questions/concerns.

PLAN:

- - Med Changes

DECREASE/CHANGE/DISCONTINUE:

F/U:

- Any referrals
- Phone pharmacy intern: unscheduled phone call in 2-4 weeks

Pt Education:

- call with questions/concerns as needed
- discussed harmful SEs of chronic PPI use (B12, D, and Magnesium deficiency, increased fracture/infection/memory challenge risks)
- lifestyle changes: avoid meals 2-3 hours before bedtime, elevating the head of the bed, regular exercise to achieve weight loss, and the possibility of rebound symptoms

Time ~ __ min

No Answer Documentation Template

IPATIENT NAMEI is a IPATIENT AGEI y.o. IPATIENT SEXI contacted by phone for a pharmacy intern PPI tapering project to optimize patient safety. Previously identified as eligible for PPI tapering. Unable to reach patient today, will attempt in ~___ week(s).

Pharmacy Efforts to Dismantle Health Disparities

by Emily A. LaMonte, 2023 PharmD Candidate, Hope E. Schier, 2024 PharmD Candidate, Kane G. Carstens, 2024 PharmD Candidate, Marissa L. Hakala, 2023 PharmD Candidate, Eva M. Vivian, PharmD, MS, PhD

According to the 2019 National Healthcare Quality and Disparities Report, Blacks, American Indians, Alaska Natives, and Hispanics receive worse care than Whites.¹ This adds to existing evidence that certain racial and ethnic groups have limited access to healthcare. These limitations contribute to health disparities. The Office of Disease Control and Prevention and Health Promotion's Healthy People 2020 initiative defines a health disparity as "a particular type of health difference that is closely linked with social, economic, and/or environmental disadvantage. Health disparities adversely affect people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."²⁻⁴

Pharmacists play an active role in patient care and are accessible healthcare professionals. "Data shows that patients see their pharmacists 8 times more often than primary care providers, making pharmacists uniquely influential in health care."⁵ Pharmacists in the community setting provide a wide range of services (e.g., blood pressure screenings and immunizations) that help ensure patient wellness and adequate disease management. Pharmacists not only offer these services to their patients, but they also serve as a bridge between the patient and the provider. The availability of pharmacists allows for better access to healthcare for those individuals who may not have the opportunity and resources to visit their primary care physician. For instance, "...community pharmacists have a role to play in a collaborative care model as evidence shows pharmacists are capable of screening for depression and referring patients for assessment and appropriate

management."⁶ Though pharmacists provide a plethora of services to ensure positive health outcomes for their patients, health disparities are still seen in all healthcare settings, including pharmacies.

Health disparities have been an issue for many years. Unfortunately, health disparities exist in most disadvantaged, low-income communities. For example, "in 2017, the rate of hospital admissions for short-term complications of diabetes was three times as high for adults in the lowest income group (101.0 per 100,000 population) compared with adults in the highest income group (32.9 per 100,000 population)."⁷ Pharmacies already have many procedures and services in place to help those who may be affected by health disparities. In particular, pharmacists can administer vaccines, counsel patients on medications, provide education about disease management, and help with referrals through outreach programs.⁵ What may seem like "small" gestures like these in pharmacies have made a huge impact on those with limited healthcare access, by creating a welcoming environment and showing community members that pharmacists are there to provide accessible patient-centered care.

While much effort has been put into narrowing the care gap, there is still a lot of work to be done. This article offers guidelines for pharmacists to learn about existing health disparities and how they can develop strategies to reduce them. It is important to note that not every program will work in every case, as each community has its own subset of health disparities. Our goal is to examine current practice strategies addressing health disparities in under-resourced communities.

Methods

We identified a pharmacist from three different pharmacies located in underserved communities in Madison, Wisconsin. The pharmacists were asked to share their

accounts of health disparities within the patient populations they serve. Pharmacists and their respective pharmacies are referred to as A, B, and C. Pharmacists A, B, and C were selected due to their locations in the city of Madison and the variability among their patient populations and pharmacy services. Pharmacy A operates in conjunction with a community health center located in south/central Madison. The patient population is primarily low-income and non-English speaking. Pharmacy B is a charitable pharmacy located in south Madison, and it was established for provision of medications to individuals who are uninsured. This pharmacy serves patients that are at or below 200% the federal poverty level, and the demographic is ethnically diverse. Pharmacy C is a worker cooperative aimed at promoting better health in the Madison community. The patient demographic has economic variability and includes many students, working class adults, and older adults.

We asked the pharmacists these questions:

1. Can you tell me about the patient demographics seen at your pharmacy?
2. How would you define a health disparity?
3. How were these disparities identified?
4. What services do you currently offer in your pharmacy, and do you have any programs that address specific health disparities?
5. Have you seen any direct benefits of these programs, and what are they?
6. What advice do you have for pharmacies who want to start programs to help individuals facing health disparities?

The interviews were conducted and recorded through Zoom, due to COVID-19 limitations. The authors interviewed the pharmacists and transcribed the conversations. Authors LaMonte, Schier, Carstens, and Hakala authorized Pharmacists A, B, and C to review their

TABLE 1. Services Provided by Pharmacy A, Pharmacy B, and Pharmacy C

Pharmacy A	Pharmacy B	Pharmacy C
<ul style="list-style-type: none"> • 340B • Diabetes education • Blood pressure & cholesterol screenings • Interpreter services • Retrospective screening* • Vaccinations 	<ul style="list-style-type: none"> • Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver • Diabetes education • Blood pressure & cholesterol screenings • Vaccine clinics • Closely connected to a food pantry • Medication repository** 	<ul style="list-style-type: none"> • Medication repository** • Connection with the Acquired immunodeficiency syndrome (AIDS) Resource Center of WI—Free needle distribution • Vaccinations
<p>*Retrospective Screening (Pharmacist A's definition): "Our retrospective screening is screening patients who were seen in clinic 6 weeks prior and gauging if they need follow up from the pharmacy team. [It] is to ensure that patients aren't falling through the cracks with blood pressure management. The screening process is as follows:</p> <ol style="list-style-type: none"> 1. Screen patients who were seen in the family medicine clinic 6 weeks prior. 2. Look at patients who have elevated blood pressures and then were either lost to follow up or blood pressures remain uncontrolled. (Specific at-risk populations are prioritized: those of African American descent, diabetes history, past MI, stroke, etc) 3. Schedule patients with an in person visit with the pharmacy team to address medication management, adherence, and lifestyle, and to recheck blood pressure." <p>**Medication repository definition: A repository is a drug donation program where people can donate unused and unexpired medications for redistribution to uninsured patients who would otherwise be unable to afford the medication.</p>		

interview transcripts.

LaMonte, Schier, Carstens, Hakala, and Dr. Eva Vivian summarized the transcribed interviews provided by Pharmacists A, B, and C. Distinctions among demographics, pharmacy services, patient health benefits, and pharmacy resources were prevalent. Pharmacists A, B, and C provided different pharmacy perspectives within a relatively small geographic location. The goal of the interview was to identify current pharmacy efforts toward tackling health disparities.

Results

The pharmacist's responses related to our questions are presented below:

Question 1: Can you tell me about your patient demographics seen at your pharmacy?

Pharmacist A: "The main demographics are those of lower income and the underserved... a certain income requirement. A lot of them are low health literacy, low income, and a lot of them are... non-English speaking patients."

Pharmacist B: "The patients that we take care of are at or below 200% of the federal poverty level; so that means for a household of one person, they are making about \$2,000 a month, or \$24,000 a year on an annual basis. And you can figure about \$600 extra per additional family member. So a lot of our patients are working poor. They may have a part time job or maybe a couple of part time jobs that don't

provide benefits. A third of our patients are [native Spanish speakers] and in terms of ethnic distribution, we have Black, White, Korean, Tibetan, and Filipino patients."

Pharmacist C: "We have quite the variety... We have students, we have people that work downtown, we have transgender patients—not so much families with children... There are elderly, and there are people that live downtown."

Question 2: How would you define a health disparity?

Pharmacist A: "To me, a healthcare disparity is when there is something wrong with the system and as a result there are certain people or individuals who have lack of access to care, either due to their income, their background, or their race. Unfortunately, these factors can predispose individuals to higher risk of certain diseases such as hypertension, heart failure, and stroke.

"I see populations who are non-White, LatinX, African American, Hmong—those are the people who usually don't have access to care, regardless of income levels or where they grew up. Having a lower income, or not being born in this country predisposes people to not being healthcare literate, as well as not having access to care."

Pharmacist B: "I really liked the CDC definition of health disparity. The CDC defines health disparities as 'preventable differences in the burden of disease, injury, violence or opportunities to achieve optimal

health, that are experienced by socially disadvantaged populations.' So, because of the environments that folks are living in, their life expectancy and their health outcomes can vary greatly."

Pharmacist C: Pharmacist C did not provide a clear definition of what a health disparity was.

Question 3: How were these disparities identified?

Pharmacist A: "There are two ways that we receive patients on our panel. One way is that the pharmacist retrospectively screens them. We look back at the clinic's patient panel over maybe six to eight weeks and see where there are gaps in care, specifically looking at blood pressure or cholesterol medicine use. The other way is that the provider refers a patient to us."

Pharmacist B: "We actually did a needs assessment survey every year where we see around 1000 families a month. They were all surveyed to...help identify things they were struggling with and what things they need help with.

"We have a diabetes wellness program that is in conjunction with the food pantry, where we actually have identified folks that have diabetes"

Pharmacist C: "On a daily basis we have conversations with our patients, and I can tell how thankful they are... for example the transgender community. They feel safe coming here and know that we're here to take care of them and not judge them for

what they're picking up at the pharmacy.”

Question 4: What services do you currently offer in your pharmacy, and do you have any programs that address specific health disparities?

Please see Table 1 for a cumulative list of pharmacy services offered at Pharmacy A, B, and C.

Pharmacist A: “What's really convenient with our clinic is that we're currently funded and have a 340B account. So we're allowed to purchase medicines that are usually really high costs to the patient and pharmacies at a lower cost. In doing so, we're able to provide medications at a really discounted rate. We also offer free diabetes education and teaching... We are able to set up consultations, to go through diabetes testing, how to administer insulin and discuss other related care. In our pharmacy, another way we address healthcare disparities is by doing retrospective screening, targeting those patients who are at highest risk for hypertension, hyperlipidemia and stroke.”

Pharmacist B: “We do actually have a CLIA Certificate. So we are able to do point of care testing...that's one of the areas we want to move into to help provide quantitative measures to help folks assess where they are with their health.

“We do immunize patients... and we offer the flu vaccine to the clients from the food pantry as well as our own pharmacy patients.

“In addition to that, we have a diabetes wellness program that is in conjunction with the food pantry, where we actually have identified folks that have diabetes.... And we had hoped to pair that with some education or training.”

Pharmacist C: “We have a repository; people can donate their unused, unexpired medications. Not pills, usually, unless it's in their stock bottle sealed. So it's usually inhalers, eyedrops, things like that. They can donate them and then we can give them out to our customers who can't afford medications or who don't have insurance, for free.

“We provide needles to help prevent the spread of disease. We used to be paired with the AIDS Resource Center of Wisconsin, and they provided us with those needles, at no charge to dispense to people.”

TABLE 2. Resources/Recommendations to Aid in Service Implementation

Financial Resources	<ul style="list-style-type: none"> • Apply for grants. Though grants are often limited in number, it is worthwhile to apply to any grants a service/pharmacy is eligible for. Below are a few grants for which community pharmacies can apply based on certain eligibility requirements: <ul style="list-style-type: none"> » American Pharmacists Association (APhA) Foundation Incentive Grants » Community Pharmacy Foundation • Reimbursement: Find additional ways to get reimbursement. For example, medication therapy management (MTM) and comprehensive medication reviews (CMR) are great ways to increase a pharmacy's revenue. If workflow allows, implementing additional patient-centered services that insurance companies reimburse can add to a pharmacy's fund. • Apply for 340B. Applying for 340B should be considered if permitted by the pharmacy/institution. 340B allows pharmacies/institutions to buy medication(s) at a lower cost and to sell their medication(s) to their patients at an affordable price. • Apply for a CLIA Certificate of Waiver. This certification allows pharmacies to have point-of-care testing, under the regulations of the CLIA Certificate of Waiver, accessible to patients.
Additional Resources	<ul style="list-style-type: none"> • Pharmacy students. Students are a valuable resource as they are motivated to advance the pharmacy profession. Students are always looking for new ways to get involved. Utilizing students to help with the start or expansion of a service/project may be beneficial. • Volunteers, community members, and/or community organizations. Volunteers can help with simple tasks in the pharmacy to reduce the workload. Community organizations can advertise pharmacy events/services such as promoting vaccine clinics. • Technicians are significant assets to a pharmacy team. Technicians are a great resource to utilize when looking into new opportunities for a pharmacy.
Recommendations	<ul style="list-style-type: none"> • Pharmacy partners: Find other pharmacies to partner with to expand access to healthcare or establish new services. Making connections with other pharmacies, or strengthening that connection, can be a start to lessening health disparities. If pharmacies within a community work together and are knowledgeable about what each other offers, pharmacists, technicians, and other staff members will be adequately informed on which pharmacy to refer their patients when in need of a specific service or medication. • Volunteers: When utilizing volunteers, the longevity of volunteers is important. Try implementing a volunteer program that has specific requirements, such as requiring a certain number of volunteer hours per week. A volunteer program may be necessary to ensure volunteers are there regularly to avoid pharmacy staff being unproductive by constantly training new volunteers. Also, a volunteer program will help to set volunteer standards and expectations. • Pharmacy staff buy-in. It is critical that the pharmacy staff understands the importance of implementing a new service. Listening to feedback from team members and having ways to decrease staff resistance to the new or changed service should be considered. • Advertising. A new service needs to be advertised to patients and the community. If patients don't know about the service, they can't utilize it. It is important that all members of the pharmacy staff understand the goal of the service to ensure they can describe the importance and the goal of the service to patients.

Question 5: Have you seen any direct benefits of these programs, and what are they?

Pharmacist A: “Yes. I think that one of the most wonderful things working in [my pharmacy] is seeing patients who weren't able to afford their medications...finally seeing their A1C or diabetes blood sugar

levels improve just because they have access to medications.

“Witnessing patients' increased comfort levels in our clinic is important as well. A lot of our patients are Spanish-speaking...a lot of our providers are Spanish-speaking doctors, and we have interpreters on site. That also helps bridge the gap of care.”

Pharmacist B: “We had one patient who was motivated and came to us with an elevated blood pressure...we worked with him and the doctors and got him on a regimen and now his blood pressure is perfect. And there are times where he would come in just to get his blood pressure taken, because he saw the results, and he was motivated to keep them that way. So, it was truly a partnership.”

Pharmacist C: “As far as the repository, I have definitely seen people be very thankful for us providing these medications. A lot of these medications are very expensive, such as inhalers or eyedrops. I’ve seen the benefit of...people’s reactions to what we can do for them.”

Question 6: What advice do you have for pharmacies who want to start programs to help individuals facing health disparities?

Pharmacist A: “[Find] government programs to fund you because the biggest barrier to trying to provide the access that we have is funding. So I would probably start by seeing how you can receive grants, how to become an access point, and how to have that 340B. We’re trying our best to eliminate costs for patients...”

“Our clinic wouldn’t be possible without all the health care providers that are involved. From pharmacists to social workers to doctors to [medical assistants] to [physician assistants], so I would say having a good interprofessional team, who have the same overarching goal of providing access to care to those unable to afford it.”

Pharmacist B: “I would say that as community pharmacists we’re the most accessible health care team member... Oftentimes, and traditionally, this has been the case that the community pharmacist has really been kind of the pillar of information and [a] trusted resource in the community.

“You don’t have to have all the answers but just really being able to refer [patients]... is really a good thing to be aware of and know.”

Pharmacist C: “Never give up, because it can become overwhelming and frustrating sometimes to start something up and to continue with it, especially if you don’t know the results or the benefits necessarily, but we’re helping the community and our patients, and I think not giving up on something like that is the key.”

Discussion

Spectrum of Health Disparity Knowledge

In order to address health disparities in their communities, pharmacists must first recognize that those disparities exist. This involves knowing what a health disparity is and having the ability to recognize what disparities are present in the communities they serve. Among the pharmacists we interviewed, we found that there is a spectrum of health disparity knowledge. One pharmacist was unable to provide a clear definition of health disparities, but all three were able to identify needs within their community. In one study of New Zealand pharmacists, Aspden and colleagues found that anywhere from 24% to 67% of pharmacists had knowledge regarding specific health disparities.⁸

Various opportunities exist for pharmacists wanting to learn more about health disparities. Aspden et al found that 80% of pharmacists surveyed wanted to learn more about health disparities.⁸ Those with limited knowledge may want to start with basic research on what health disparities are and ways to identify those disparities within their communities. It is also important to acknowledge the social and economic determinants of health that predispose patients to health disparities. In some communities, public records can describe the disparities present. However, pharmacists may need to develop formal surveys for patients, such as the annual needs assessment performed by Pharmacy B. Community needs and demographics can be collected and assessed through conversations and relationships with patients—this approach is utilized by Pharmacy C. Understanding the patient population and health disparities that exist within a community is an important step before implementing change into practice. Even with increased knowledge of health disparities and self-awareness of biases, pharmacists’ comfort in cross-cultural encounters is not necessarily increased.⁹ Pharmacists must be comfortable in these encounters in order to best serve their patients.

Pharmacy Structures and Origin

Each pharmacy in our study had a different structure that influenced its impact on health disparities. Pharmacy A utilizes the government 340B program to

TABLE 3. Educational Resources for Pharmacists and Pharmacies Regarding Health Disparities

- The American College of Surgeons Committee on Health Care Disparities—Health Care Disparities Resources
- Centers for Disease Control and Prevention—Racial and Ethnic Approaches to Community Health
- Healthy People 2020—Disparities
- U.S. Department of Health and Human Services—Health Disparities Resources

reduce prescription costs. Additionally, the pharmacist could consult each patient up to an hour to assess understanding and overall well-being of the patient. Pharmacy B is a charitable pharmacy where government aid, donations, and volunteers make it possible to provide patients with little- to no-cost prescriptions and counseling. Pharmacy C is a retail community practice that does not have a specific focus on providing care to low-income patients.

The structures of these pharmacies can create limitations in implementing strategies to address health disparities. For example, not all pharmacies fit the criteria to apply for a 340B program. Additionally, it can be difficult to allot enough time for consultation for adequate information collection. It can be challenging for pharmacies that do not have these attributes or resources to attend to the needs of the community. However, these limitations should not be an excuse to eliminate opportunities to offer helpful services. The nature of the pharmacist is to provide patient-centered care, which includes providing patients who have difficulty accessing or acquiring the medications they need.

Services

Community pharmacists are in an ideal position to address health disparities. Pharmacy services can target specific health disparities or provide general support. Pharmacies A, B, and C have a combination of services that provide specific and general assistance to their patient populations.

Pharmacy A believes medical interpreters are a valuable resource for both patients and healthcare professionals. Low health literacy disproportionately affects those who speak English as a second language.¹⁰ Patients possessing reduced health literacy perceive poorer communication

with their pharmacists.¹¹ Furthermore, there is an increased risk of improper use and consumption of medications by patients with limited health literacy.¹² Medical interpreters can help close the communication gap between pharmacists and patients with different primary languages. At Pharmacy A, the interpreter service has helped bridge the gap of care and increased comfort levels for Spanish-speaking patients. If a pharmacy is unable to provide an interpreter service, multilingual education materials can provide a supplemental source of information. Pharmacists should be aware of the primary languages within the pharmacy's patient population to implement this service or similar services appropriately.

Pharmacy C services a needle exchange program, which directly benefits the population of people who use injectable drugs through the provision of harm reduction. This program decreases transmission rates for diseases like human immunodeficiency virus (HIV) and hepatitis C.¹³ Harm reduction services support health equity and address disparities by serving vulnerable populations like injection drug users.¹⁴

Many pharmacy services can still have a significant impact on health disparities in their community without specifically targeting a single patient population. The goal of these services is to increase general medication and service access. For example, Pharmacy B and C both offer a repository service. Pharmacist C hopes awareness of repository programs expands and partnership between pharmacies improves to allow for easier referral of patients, which will increase medication access. Other programs, like the 340B program and the CLIA Certificate of Waiver provide low-income and uninsured patients with medications and pharmacy services at a discounted cost. Pharmacy A is enrolled in the 340B program, which uses limited federal resources to reduce the price of outpatient medications. Furthermore, Pharmacy B has a CLIA Certificate of Waiver, which allows for the pharmacy to provide immunizations and on-site point of care testing. These programs put the pharmacies in a favorable position to provide care for low-income populations.

Pharmacy immunization services support preventative care and are often

cost-effective.¹⁵ Increased vaccine access and equitable administration mitigates disproportionate negative health impacts and reduces the risk of disease. Pharmacy students have been used as a resource in vaccination efforts throughout the COVID-19 pandemic. Students have been helpful in administering vaccines, organizing clinics, and registering vaccinations. Having additional immunizers, like pharmacy students, increases vaccine access within a pharmacy without significantly impacting pharmacist workflow.

Educational programs on various disease states that are prevalent within a certain ethnic/racial group in the community and partnerships with local food pantries are additional services that pharmacies can offer to benefit patients burdened by health disparities. Pharmacies A and B offer diabetes wellness and education programs. Diabetes education programs have been shown to increase knowledge about the disease state and improve self-care behaviors and self-efficacy for patients with adequate and inadequate levels of health literacy.¹⁰

Pharmacy B is directly partnered with a local food pantry. The partnership has increased medication and food access for all its patients. Adults and children who are food insecure are at a greater risk for negative health outcomes.¹⁶ Diabetes and cardiovascular programs in conjunction with a food pantry can help patients obtain healthy food options. The ability to refer patients to local food pantries can be easily emulated by all pharmacies. Pharmacies can also provide patients with an affordable "healthy grocery list" or healthy recipes to support higher quality diets for low-income individuals.¹⁷

Pharmacy B provides a needs assessment survey annually, and Pharmacy A has retrospective screening of patients. The needs assessment survey provides the pharmacy with a better understanding of the different adversities being faced within the community. Pharmacy A, B, and C use consultation and the patient-pharmacist relationship to stay up-to-date with current patient needs. Pharmacist B regarded a pharmacist-patient relationship as a "partnership," which increased patient adherence and motivation. Statements from Pharmacist A, B, and C suggest that communication with patients is at the center of providing excellent patient care.

Limitations

The pharmacists and pharmacies examined for this article were restricted to Madison, Wisconsin. As the patient population changes, so does the burden of health disparities. Rural communities and more urban areas would provide additional insight to the interpretation of health disparities and pharmacy services within Wisconsin. This paper only references three pharmacists from three different pharmacies. Examining different pharmacists' understanding of health disparities within the same pharmacy setting may provide greater information about the spectrum of knowledge. This paper would benefit from interviewing more pharmacists from different areas in Wisconsin to better understand variability of health disparities and services available within Wisconsin. Information from a greater sample size would allow for more accurate interpretation of pharmacy action toward addressing health disparities

Resources and Recommendations for Pharmacy Services

Finding ways to implement and adapt new and existing services can be challenging with limited resources. Table 2 provides a non-exhaustive list of resources for expanding monetary assets and additional proposals to establish services within a pharmacy or institution. These resources and recommendations can help to reduce costs, increase workflow efficiency, provide better access to patients, promote pharmacy services, and help to relieve pharmacists' stress from being overworked.

What you can do right now

There are many propositions for lessening health disparities in our communities and making healthcare more accessible for patients, but the process needs to be taken in an incremental fashion. Instead of trying to carry out new ideas right away, it is crucial to self-educate to ensure the implementation of the most supportive services. Reading this article was a great way to learn more about health disparities, but that is just the start. It is recommended to read additional articles, watch videos/documentaries, or learn from patients' stories to continuously stay up to date on the topic of health disparities. Table

3 provides additional educational resources that address the topic of health disparities. Continue to ask: What is a health disparity? Who do health disparities affect? In what ways are health disparities being addressed in different healthcare settings? What can I do to help address and lessen health disparities in my community? Health disparities are not going to be the same in every region, so education on the specific patient population being served is key. Once comfortable with the patient population and health disparities that exist in a specific location, it becomes easier to implement pharmacy services that target the prevalent inequities. Look into different resources and ask for help when needed. Pharmacists have a responsibility to train, educate, and ensure equitable patient care.

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Health Disparities

by Eva M. Vivian, PharmD, MS, PhD

Health disparities in racial, ethnic, and socioeconomic populations are well documented and have a negative impact on the health of many residents in underserved communities. While structural inequalities in health care have existed for decades, the COVID-19 pandemic has brought these inequalities to the forefront of public consciousness.¹ The differences in COVID-19 death rates by race are not due to biological differences, but social and economic inequalities that are directly associated with health disparities. It should be no surprise that Black Americans who have faced disparities in the US healthcare systems for decades are disproportionately impacted by coronavirus disease (COVID-19).² Blacks represent 14.8% of all COVID-19 mortalities in the United States, which is greater than the proportion of Black individuals in the U.S. population (13.4%). This disparate outcome can be attributed to the influence of structural racism on institutions, laws, and social policies that gave rise to an uneven distribution of the social determinants of health.^{2,3}

While the availability of COVID-19 vaccines is positioned to change health inequalities, decades of institutional distrust coupled with crowded living conditions, overrepresentation in high-risk occupations (e.g., essential workers), inadequate access to health care, lack of private transportation, lower health knowledge, and chronic health conditions leave Black communities at a severe disadvantage.²⁻⁴ Historically, the health care system has been one of the most segregated systems in our nation, but recently pharmacists have been mitigating the damaging impact of structural racism through health care services, such as administering vaccines, medication counseling, blood pressure screenings, and other community outreach programs.^{2,4}

The article titled “Pharmacy Efforts to Dismantle Health Disparities,” which appears on page 29 of this issue of *JPSW*, describes how pharmacists are in a unique

position to address disparities since they are the most accessible health care professional.⁵ The authors elaborate on the importance of pharmacists being aware of the most salient disparities in the communities they serve and the factors driving these disparities that result in medication nonadherence and other poor health outcomes. Gaining an understanding of the social and environmental factors that influence the health of a patient provides a realistic view of the challenges a patient may face when attempting to lead a healthy lifestyle, and allows the pharmacist to work with the patient to develop a realistic medication plan.⁶⁻⁸ For example, many uninsured and underinsured patients from low-income communities are forced to choose between feeding themselves and their children or refilling their medications. A pharmacist who has insight into the challenges that patients living in poverty face can identify patient assistance programs that will assist the patient in obtaining medications at little to no cost.

Pharmacists can learn more about the community they serve by volunteering at local community centers, churches, or schools and attending community events. Active engagement in the community will provide an opportunity to learn who are the community leaders and where the power resides within the community. It is important to learn how health care agencies that provide services in the community are perceived and identify past or current periods of marginalization and mistrust. Pharmacists should build on the community's strengths and knowledge to learn what services and programs are needed and work with the community to develop sustainable disease prevention and health promotion programs.⁶⁻⁸

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MEDICAL COLLEGE OF WISCONSIN SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Expanding the Role of the Pharmacist with Pharmacist-Prescribed Contraception

by Jillian Allen, 2022 PharmD Candidate, Andrea Modlin, 2022 PharmD Candidate, Olivia Osielski, 2022 PharmD Candidate

The role of the pharmacist continues to expand beyond dispensing medications. Pharmacists in Wisconsin may soon prescribe hormonal contraceptives for patients, as pharmacists do in other states. Legislation that promotes pharmacist prescribing, if passed, would permit patients over the age of 18 to visit a pharmacist, complete a blood pressure screening, fill out a health screening questionnaire, and obtain a prescription for a contraceptive method if deemed appropriate by the pharmacist. More than 20 other states have successfully implemented laws or collaborative practice agreements allowing pharmacists to prescribe hormonal contraception. The clinical privilege to prescribe contraceptives for patients who menstruate would improve access to hormonal contraceptives, allowing more patients to play an active role in family planning. Successes in other states that permit pharmacist-prescribed contraception can provide guidance and prove the utility of the pharmacist in family planning. Comparing legislation in Wisconsin to implemented laws in other states will help pharmacists in Wisconsin prepare for future opportunities to prescribe for their patients.

Pharmacist-Prescribed Contraceptives

As the role of a pharmacist continually evolves, pharmacists are no longer solely dispensing medications. They can gather vitals, administer immunizations, and complete other tasks by collaborating with a physician.¹ Pharmacists are accessible, skilled providers with the expertise in pharmacology to help patients make informed decisions regarding their reproductive health. Nearly 99% of women will use a form of contraception during their lifetime.² These forms include condoms, sterilization, oral hormone tablets, injectable

hormones, hormone patches, or intrauterine devices. As of October 27, 2021, the Wisconsin State Assembly passed legislation allowing pharmacists to independently prescribe oral and patch contraceptive products. The bill now moves to the State Senate for a vote.

Pharmacists have been highly trusted members of the healthcare team for decades and have proven success with other prescribing protocols in Wisconsin, such as the statewide naloxone prescribing initiative. The most current legislation in the Wisconsin State Assembly is Assembly Bill 36, with a corresponding Senate Bill 30. This bill allows pharmacists to prescribe and administer select hormonal contraception medications.³ This would be the first time that pharmacists in Wisconsin would have independent prescriptive power without using a collaborative practice agreement with a physician. In other states, pharmacists have had the authority to prescribe certain medications for years. With this new opportunity for prescribing hormonal contraceptives, it is important to understand the specific details of the bill and, thus, the implications of the legislation.

Based on Assembly Bill 36 (or Senate Bill 30), for a pharmacist in Wisconsin to prescribe and dispense hormonal contraception, the pharmacist must provide a self-screening risk assessment tool, perform a blood pressure screening, and provide the patient with a written prescription record. The pharmacist must report a record of the prescription to the patient's primary care practitioner after dispensing. Some pharmacists may delegate the blood pressure measurement or questionnaire to a qualified pharmacy employee, like an intern; however, the pharmacist must be the clinical decision-maker based on the results of the reading and assessment. Patients must be 18 or older to obtain this service.³ Pharmacists must provide contraceptive products promptly and inform the patient that hormonal forms

of contraception do not protect against sexually transmitted infections.

The bill also ensures reimbursement for pharmacist services and products provided for patients with Medicaid. With the recent passage of Provider Status in Wisconsin, there will be fewer reimbursement barriers for pharmacists who choose to provide patient care services going forward. Completing a blood pressure check in a pharmacy requires valuable time and resources, so this stipulation in legislation and the Provider Status laws help ensure that services provided will be financially sustainable. In this scenario, specifying reimbursement is essential to compensate for a pharmacist's clinical services. Is it also important to note that the Patient Protection and Affordable Care Act ensures prescription coverage for most patients, as there are very limited situations in which employer-sponsored plans choose not to cover contraceptive products.

Pharmacists who decide to pursue prescribing authority will follow rules determined by the Pharmacy Examining Board (PEB). These rules will include aspects outlined in the bill and must refer pharmacists to guidelines set for hormonal contraceptive prescribing from the American College of Obstetricians and Gynecologists (ACOG), the Wisconsin Board of Medicine, the Wisconsin Board of Nursing, and the Department of Health Services (DHS). As an example, the proposed legislation in Wisconsin does not require a pregnancy test before a pharmacist prescribes a contraceptive agent to a patient. Ruling out pregnancy is generally a standard of practice before implementing hormonal contraceptives and would be addressed by the PEB if the legislation passes as written. Most states' PEBs rule out pregnancy through their patient questionnaires. As another example, Wisconsin legislation does not require additional education for pharmacists to begin prescribing

contraceptives. Based on the precedent set by other states, it is likely that the PEB will also require additional training or education for pharmacists before they may prescribe contraceptive products.

The Benefits of Birth Control

In the United States, approximately 65% of women aged 15-49 were using contraception in 2017-2019.⁴ Currently, intrauterine devices are the most effective contraceptive method, followed by oral hormone tablets, injectable hormones, hormone patches, and rings.⁵ Although birth control medications are widely used to prevent pregnancy, they can also be used for various other health-related issues. The benefits of birth control include relieving physical symptoms associated with the menstrual cycle like irregular periods, menstrual cramps, acne, cysts in breasts or ovaries, and premenstrual syndrome (PMS).^{4,6} Due to the benefits of hormonal contraceptives, increasing access to them is essential for a patient's reproductive health. Because this legislation does not specify any particular indication for the drugs, pharmacists may end up prescribing contraceptives for reasons like severe menstrual cramps or acne, not just as family planning methods.

Potential for Patient Impact

As more states allow pharmacists to prescribe hormonal contraceptives, pharmacists must ensure that patients at risk for serious adverse effects avoid contraceptives. Adverse effects, like mood changes, weight gain, and acne, should not be underestimated. The most serious and life-threatening side effect of hormonal contraceptives is thromboembolism. In one study performed on women taking oral hormone tablets, nearly 57% of the group discontinued taking their medication due to side effects like weight change, headaches, moodiness, and decreased sexual satisfaction.⁷ Despite this percentage, hormonal birth control tablets remain one of the most prevalent methods of contraception, representing 21% of contraceptive users, or nearly 10 million patients.⁸

Accessible hormonal contraceptives are essential for patients who menstruate. Regarding patients' interest in over-the-counter contraceptives, one study revealed

more than 60% of participants were strongly or somewhat in favor of the agents becoming available without a prescription. What is even more staggering is that of the 50% of patients who did not use contraception or only used condoms, 37% reported they would use oral hormonal contraceptives if available over the counter.⁹ Current laws that allow pharmacists to prescribe do not permit the drugs to be over the counter, but pharmacist-prescribed contraceptives do increase patient accessibility. Researchers discovered that in Oregon, nearly 10% of all prescriptions for hormonal contraceptives were from a pharmacist after legislation allowing pharmacists to prescribe was passed.¹⁰

Oregon Leading the Way

Oregon was the first state to expand contraceptive prescribing to pharmacists. Under legislation proposed and adopted in 2015, pharmacists can prescribe and dispense hormonal tablets, patches, and injections to patients over 18 years of age. Patients under the age of 18 must have already taken a form of hormonal contraception in the past.¹¹ However, unlike the new Wisconsin legislation, in Oregon, once given the initial prescription, the patient has three years to complete a clinical visit with a physician regarding reproductive health.

In Oregon, before prescribing the contraceptive method, a pharmacist must follow procedures outlined in the Standard Procedures Algorithm for Oregon RPh Prescribing Contraceptives, created by the Oregon Board of Pharmacy, to obtain the background knowledge needed to prescribe safely and effectively. This process requires the pharmacist to collect a medical history, medication history, pregnancy status, and a blood pressure screening. It is the pharmacist's responsibility to determine whether the patient can start taking hormonal contraceptives safely. When hormonal contraceptives are contraindicated for patients, the pharmacist can refer them to a physician to discuss further reproductive-health options.¹² Once the patient is determined to be eligible for a hormonal contraceptive prescription, the pharmacist chooses a contraceptive method and counsels the patient.

According to proponents of Oregon's 2015 legislation, the main objective

of pharmacist-prescribed hormonal contraceptives is to increase access to self-administered birth control. Within the first two months of the program, pharmacists issued over 200 prescriptions, meaning 200 patients had better access to care.¹² Oregon set a strong example of a safe and effective practice for pharmacists to follow when prescribing and dispensing contraceptives.¹³

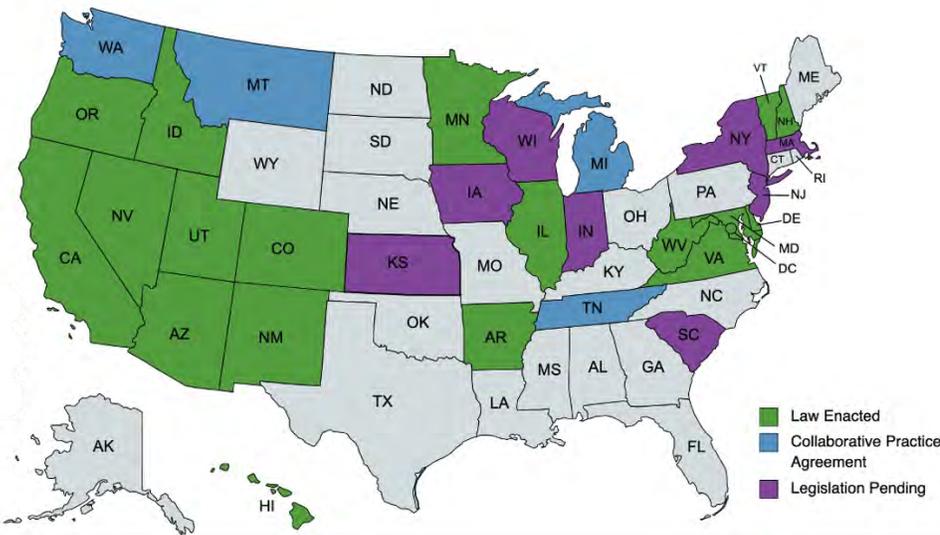
States Following in Oregon's Footsteps

There are currently more than 20 states that have passed and implemented similar allowances expanding hormonal contraception prescribing to the pharmacist, all following the 2015 Oregon law.^{14,15} Some states allow pharmacist-prescribed contraception through law, and some states allow it through collaborative practice agreements. Michigan, Montana, Tennessee, and Washington operate through collaborative practice agreements, while 19 other states operate through statutory authority. Iowa, Indiana, Kansas, Massachusetts, New Jersey, New York, and South Carolina have legislation in the works.¹⁵ See Figure 1 for a visual representation. A full comparison of the laws from state to state, including Wisconsin's, can be reviewed below in Table 1.

In states that permit pharmacist-prescribed contraceptives, laws vary widely in detail but contain similar general principles. One overarching similarity from state to state is the requirement for patients to complete a health screening. Nearly every state with pharmacist prescribing authority for contraceptives requires patients to complete a health screening. The two states that do not specify health screenings are Idaho and New Hampshire.^{23,28} The health screening helps determine whether a patient is eligible to obtain a prescription for contraceptives. The questionnaires include questions about blood pressure, medication history, pregnancy history, and smoking history.³⁵

Another aspect comparable among states is the obligation to provide timely access to prescriptions. To assure that contraception is accessed promptly, states like Colorado, Hawaii, and Oregon forbid pharmacists from requiring patients to schedule an appointment to receive contraception.^{19,22,30}

FIGURE 1. States with Pharmacist Prescriptive Authority for Contraceptives



Some states advertise specific times the pharmacist is available for consultation by displaying the information outside the pharmacy.³⁵ By eliminating the need for an appointment, the patient can access self-administered contraception at a time convenient for them.

While most state laws are very similar, there are a few specific differences in the patient populations permitted to obtain prescriptions. Of the states allowing pharmacist prescribing, eight (Arizona¹⁶, Arkansas¹⁷, Colorado¹⁹, Minnesota²⁶, Oregon³⁰, Utah³¹, Virginia³³, and West Virginia³⁴) enforce an age restriction of 18 years or older. Other states, such as California, Minnesota, and New Mexico, allow prescriptions to minors if they fit other requirements, such as providing evidence of a previous contraception prescription.^{18,26,29} The requirements for minors vary from state to state.

States also vary in the types of contraceptives that pharmacists are permitted to prescribe. Most states allow pharmacists to prescribe oral hormone tablets and hormonal patches. One outlier is Arkansas, which permits pharmacists to prescribe only oral hormone tablets.¹⁷ Eight states (California¹⁸, Delaware²⁰, Hawaii²², Idaho²³, Illinois²⁴, Minnesota²⁶, New Mexico²⁹, and Virginia³³) allow pharmacists to prescribe hormone injections. Based upon proposed legislation, pharmacists in Wisconsin could prescribe only hormonal patches and tablets. They would not be able to dispense vaginal rings or hormonal injections.³

Ten states require some form of provider referral once a patient is prescribed contraceptives. The idea behind the patient referral is that patients continue to obtain necessary testing, like a pap smear, essential to reproductive health. However, each state has its own guidance on the timeline in which a patient must see a provider. Arkansas requires patients to have an appointment with a provider within six months (before or after) when a pharmacist prescribes hormonal contraceptives. A pharmacist can only dispense six months' worth of drugs if the patient has not met with a provider.¹⁷ West Virginia requires patients to visit their physician within the first year of the initial prescription.³⁴ In Utah, a prescription is only valid for two years before a physician visit is required.³¹ In states that do not require provider referral, there is often language in the law that requires a pharmacist to promote regular provider visits. For example, Maryland requires pharmacists to mention obtaining annual screenings, but there is no formal time frame for the patient to see a provider.²⁵ It is in the patient's best interest for the pharmacist to advocate for visiting primary care or reproductive health providers after prescribing, even if it is not required by law.

Impact in Oregon and California

In a 2019 study, researchers took a closer look at the level of impact and utilization of pharmacist-prescribed birth control

in Oregon and California with the focus on a supermarket-based chain. Data was collected from prescription records and visit documentation forms to evaluate the services provided and the characteristics of the patients who took advantage of these amenities. Over six months, pharmacists conducted 2,117 visits and provided 1,970 prescriptions. The average age of patients who received the pharmacist-prescribed contraception was 27, with the majority in the 18-24 age range.³⁶

In addition, the study evaluated whether patients had an established primary care provider and/or insurance, or had used any form of hormonal contraception in the past. One of the more prevalent concerns about pharmacist-prescribed hormonal contraception is the fear that patients will no longer go to their primary care provider for regular examinations. This study does not support that assumption, with 74% of patients having an established primary care provider and 89% visiting a provider within the previous year. Another common concern about pharmacist-prescribed contraception is that it may negatively impact first-time users of hormonal contraception because they might miss out on the proper pre-screening, examination, and counseling needed. However, 91% of patients utilizing this service had previously used a form of hormonal contraception in the past.³⁶

Another study endpoint was the number of patients denied or referred to a primary care provider. As discussed in the previous sections of this article, before being prescribed any hormonal contraception, the patient must fill out a Self-Assessment Questionnaire, which assesses the patient for any possible risk factors or contraindications that would require further examination. Only 7% of patients who sought hormonal contraception were denied or referred to a PCP. Ineligibility was due to criteria like elevated blood pressure (45%), experiencing migraines with aura (14%), current smoking status with chronic kidney disease (2%), or inability to rule out pregnancy (14%). These results demonstrated the reliable clinical judgment a pharmacist can make as a healthcare provider with patients, safely expanding access to hormonal contraception to patients.³⁶

Opportunity for Pharmacy

As pharmacist-prescribed contraception

is a monumental undertaking for the pharmacy community, the implementation of this legislation will lie in the hands of working pharmacists. Pharmacists must embrace Assembly Bill 36 so that they can care for patients efficiently, impactfully, and at the top of their licenses. Not every pharmacist will use this potential law in

their day-to-day tasks, but incorporating it lays the groundwork for further expansion of the profession. While it seems that the United States continues to struggle with contraceptive barriers, more than 100 countries have expanded hormonal contraceptive access to over the counter.³⁷ As pharmacists are the most accessible

health care providers, it is only natural for the profession to address the issue of access to contraceptives by expanding prescriber authority to pharmacists.

As the pharmacist's role continues to evolve with the current legislation in Wisconsin, newly acquired provider status, the COVID-19 pandemic, and the

TABLE 1. Comparison of Pharmacist-Prescribed Contraception Laws in the US

State	Date Passed into Law	Pharmacists					Patients		Pharmacies
		Requires Additional Training	Utilizes Risk Assessment and Health Screenings	Able to Prescribe:			Must be 18 Years+	Requires Physician Referral or Contact	Prohibits Appointments
				Oral Hormone Tablets	Transdermal Hormone Patches and/or Vaginal Rings	Intramuscular Hormone Injections			
Wisconsin ³	-	-	X	X	X	-	X	X	-
Arizona ¹⁶	July, 2021	-	X	X	X	-	X	-	-
Arkansas ¹⁷	March, 2021	X	X	X	-	-	X	X	-
California ¹⁸	September, 2016	X	X	X	X	X	-	-	-
Colorado ¹⁹	June, 2016	X	X	X	X	-	X	X	X
Delaware ²⁰	October, 2021	X	X	X	X	X	-	-	-
District of Columbia ²¹	January, 2018	X	X	X	X	-	-	X	-
Hawaii ²²	July, 2017	X	X	X	X	X	-	X	X
Idaho ²³	March, 2019	-	-	X	X	X	-	-	-
Illinois ²⁴	July, 2021	X	X	X	X	X	-	-	-
Maryland ²⁵	April, 2017	-	X	X	X	-	-	X	-
Minnesota ²⁶	May, 2020	X	X	X	X	X	X	X	-
Nevada ²⁷	June, 2021	-	X	X	X	-	-	-	-
New Hampshire ²⁸	June, 2018	X	-	X	X	-	-	-	-
New Mexico ²⁹	May, 2017	X	X	X	X	X	-	-	-
Oregon ³⁰	July, 2015	X	X	X	X	-	X	X	X
Utah ³¹	March, 2018	X	X	X	X	-	X	X	-
Vermont ³²	October, 2020	X	X	X	X	-	-	-	-
Virginia ³³	April, 2020	X	X	X	X	X	X	X	-
West Virginia ³⁴	March, 2019	X	X	X	X	-	X	X	-

rapidly changing pharmacy market, they must be creative and innovative to provide quality care to those who need it most. The pharmacy community should not ignore this opportunity to expand the pharmacist's scope of practice and expand access to hormonal contraceptive methods. Embrace and advocate changes that improve patient care.

Moving forward, keep the Oath of a Pharmacist in mind: "I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow: I will consider the welfare of humanity and relief of suffering my primary concerns. I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients. I will respect and protect all personal and health information entrusted to me. I will accept the lifelong obligation to improve my professional knowledge and competence. I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct. I will embrace and advocate changes that improve patient care. I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists. I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."³⁸

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PR This article has been peer-reviewed.
The contribution in reviewing is greatly appreciated!

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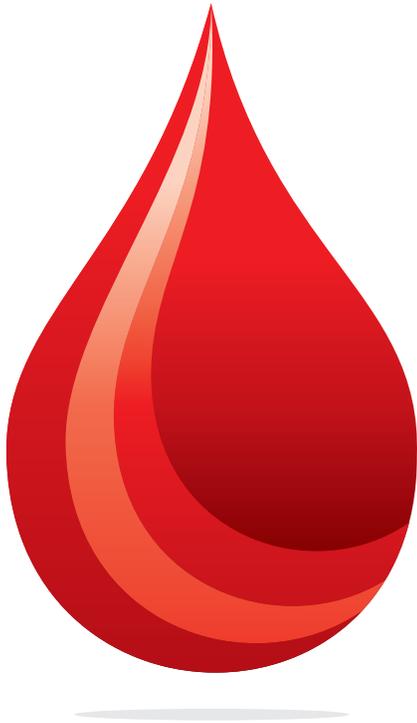
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Literature Review of Fixed and Weight-Based Dosing of 4-Factor Prothrombin Complex Concentrate in Achievement of Hemostasis in Adult Patients Taking Factor Xa Direct Oral Anticoagulants

by Ivy Cannella, 2022 PharmD Candidate, Carolyn Villareal, PharmD, BCPS

Clinical Question

How does fixed dosing of 4-factor prothrombin complex concentrate (4F-PCC) compare to traditional weight-based dosing of 4F-PCC in achieving hemostasis in adult patients taking factor Xa direct oral anticoagulants (DOACs)?

Major bleeding is an unfortunate risk of anticoagulation therapy. Currently, andexanet alfa is the only approved agent for reversal of factor Xa DOACs.¹ Other agents, including 4F-PCC, have been used off-label for the reversal of DOACs in the setting of major bleeding. Factor Xa DOACs, which include rivaroxaban, apixaban, edoxaban, and betrixaban, target Xa to block the coagulation cascade. 4F-PCC can be used as a reversal agent because it contains coagulation factors II, VII, IX, and X, as

well as proteins C and S.² An additional benefit to using 4F-PCC over other approved reversal agents is a significant cost savings. Wilsey et al. calculated the cost of a dose of andexanet alfa to be \$58,080, a 50 unit/kg dose of 4F-PCC to be \$6,885, and a 25 unit/kg dose of 4F-PCC to be \$3,443 for an 85-kg patient.³

In recent years, use of 4F-PCC for factor Xa DOAC reversal has become more common. Gundersen Health System in La Crosse, Wisconsin has a pharmacist-driven protocol to use 4F-PCC for reversal of warfarin, but still requires provider oversight for use in patients on DOACs. There is some discrepancy among some services, with some using fixed dosing of 2000 units and some using weight-based dosing of 50 units/kg. This literature review aims to provide data for pharmacists to use when providing recommendations for use of 4F-PCC for factor Xa DOAC reversal.

Literature Review

A 2020 single-center, retrospective cohort study evaluated achievement of hemostasis with fixed dosing versus weight-based dosing of 4F-PCC in patients taking direct factor Xa inhibitor

oral anticoagulants.⁴ Adult patients who were taking factor Xa inhibitor oral anticoagulation and received 4F-PCC from January 1, 2014 through December 31, 2018 at a 433-bed tertiary care hospital in central Kentucky were included in the study. This study included 72 patients, 46 of whom were taking factor Xa DOACs. The intervention was 4F-PCC, dosed at 35 units/kg for moderate bleeding, 50 units/kg for severe bleeding, or a fixed dose of 2000 units. The primary outcome was clinically effective hemostasis. In patients taking factor Xa DOACs, clinically effective hemostasis was achieved in 95% of patients who received fixed dosing and 76.9% of patients who received weight-based dosing ($p=0.091$). One limitation was the exclusion of patients who died within 24 hours of hospitalization. This may have impacted the results of this study, since the cause of death and treatment course were unknown.

A 2021 updated systematic review and meta-analysis evaluated the efficacy and safety of the use of 4F-PCC as a reversal agent in patients experiencing major bleeding who take factor Xa inhibitors.⁵ Randomized controlled trials (RCT), prospective or retrospective cohort studies,

case control, and case series studies were included if they studied adult patients taking factor Xa inhibitors who received 4F-PCC for treatment of major bleeding. Trial bias was evaluated using the Joanna Briggs Institute critical appraisal checklist and low-quality studies were removed. A total of 33 studies (n=2568 patients) were included in the systematic review, and 29 in the meta-analysis. Of note, all studies were retrospective or prospective cohort studies.

The meta-analysis showed pooled proportion outcomes for hemostasis (80%, CI 0.75-0.84), mortality (15%, CI 0.11-0.19), and thromboembolic adverse events (3%, CI 0.02-0.05).⁵ No difference was seen between high (>30 unit/kg/dose) (77%, CI 0.72-0.82) or low (<30 unit/kg/dose) (79%, CI 0.71-0.85) 4F-PCC in the efficacy of hemostasis. Publication bias was analyzed with funnel plots and the Egger's test. No publication bias was detected for thrombosis and hemostasis outcomes, but the Egger's test was positive for the mortality outcome. Moderate heterogeneity was detected between the studies ($I^2 = 61\%$, $p < 0.01$) and a sensitivity analysis to exclude outliers was performed. Presentation of dosing for each included study is a limitation of this

analysis. Specific dosing was not reported for several studies, and upon further review, the study by Schulman et al. was reported as weight-based, but fixed dosing was actually used.^{5,6} Another significant limitation is the possibility of confounders, since other hemostatic agents were likely given to these patients, but are not reported in this analysis.⁵

Given limited head-to-head data, a supplemental indirect comparison was included (Table 1). Attention was given to present comparable direct oral anticoagulants in the comparison.

Due to the nature of this topic, there are several limitations in the studies included in Table 1.^{3,6,7} Notably, these studies all are small and underpowered. Schulman et al. had 12 patients who deviated from the fixed dosing protocol, and these patients are included in the overall efficacy data without differentiation, potentially leading to inaccurate results on hemostasis data.⁶ Wilsey et al. had patients in both dosing groups who received packed red blood cells, platelets, and fresh frozen plasma along with or after their 4F-PCC.³ The percentage of patients who received packed red blood cells in the low dose group was 8.4% higher than

the high dose group and the percentage of patients who received fresh frozen plasma was 6.2% higher in the high dose group compared to the low dose group. These other agents may have affected the primary outcome of hemostasis. The study done by Majeed et al. had 3 patients who received a second dose of 500-1500 units of 4F-PCC due to inefficacy after the first dose.⁷ The dose that these patients initially received is not reported, and these patients are included in the efficacy data. In a study of this size, these patients may make a difference in overall results.

Recommendations from Others

The American College of Cardiology published a 2020 expert consensus decision pathway (ECDP) to guide practitioners in management of bleeding in patients taking oral anticoagulants.¹⁰ This consensus pathway is an update to their original ECDP that was published in 2017, and is derived from current scientific evidence and expert opinion. There is no grading system used in their summary. Regarding the use of prothrombin complex concentrate (PCC) in

TABLE 1. Effect of Weight-Based and Fixed Dosing of 4F-PCC in Patients Taking DOACs on Achievement of Hemostasis

Reference	Design	Inclusion Criteria	Number of Patients	Intervention	Results
Schulman et al (2018) ⁶	Prospective, observational, multicenter, cohort study at a Canadian hospital, July 2014 – July 2017	Patients who received 4F-PCC and were taking rivaroxaban or apixaban and did not receive other hemostatic agents	N = 66 <ul style="list-style-type: none"> • 2000 units = 54 • 1000 units = 2 • 1500 units = 3 • 2500 units = 1 • 3000 units = 4 • 3500 units = 1 • 4200 units = 1 	Fixed dose of 4F-PCC 2,000 units <ul style="list-style-type: none"> • Beriplex (10%) • Octaplex (90%) 	Achievement of clinically effective hemostasis: <ul style="list-style-type: none"> • Good: 43 (65%; 95% CI, 53-77) • Moderate: 13 (20%; 95% CI 10-30) • Poor/none: 10 (15%; 95% CI, 6-24)
Wilsey et al (2021) ³	Retrospective cohort study at a University of Kentucky level 1 trauma and stroke center, January 2015 – December 2018	Patients who experienced major bleeding and were taking apixaban or rivaroxaban and received 4F-PCC	N = 99 <ul style="list-style-type: none"> • Low dose: N=57 (57.6%) • High dose: N=42 (42.4%) 	4F-PCC (Kcentra) <ul style="list-style-type: none"> • Low dose (20-34 units/kg) (mean dose = 26.6 units/kg) • High dose (35-50 units/kg) (mean dose = 47.6 units/kg) • Dosed using actual body weight with a dose cap at 100 kg 	Oral Comparison of hemostasis between high and low doses of 4F-PCC: <ul style="list-style-type: none"> • 75.4% (low dose) • 78.6% (high dose) • p=0.715
Majeed et al (2017) ⁷	Prospective cohort study using cases from 25 hospitals in Sweden, January 1, 2014 – October 1, 2016	Patients who had taken a dose of rivaroxaban or apixaban within 24 hours and received 4F-PCC due to acute and active major bleeding	N = 84	4F-PCC (Octaplex or Confidex/Beriplex) given at a median, interquartile dose of 1500 – 2000 units with an approximate dose of 25 IU/kg <ul style="list-style-type: none"> • < 65 kg = 1500 units • > 65 kg = 2000 units 	Achievement of clinically effective hemostasis: <ul style="list-style-type: none"> • Effective: 58 (69.1%) • Ineffective: 26 (30.9%) • No p value provided by authors

4F-PCC = 4-factor prothrombin complex concentrate

the management of bleeding in patients taking direct factor Xa inhibitor oral anticoagulants, they recommend using PCC if andexanet alfa is not available, and do not recommend a particular dose of PCC. They do recognize that evidence in this area is limited and 4F-PCC is the most studied to date.

The Anticoagulation Forum, which is made up of anticoagulation providers in North America, published guidance in 2019 on the reversal of DOACs.¹¹ This guidance is based on the best available evidence and expert opinion. There is no grading system used in their executive summary. Regarding use of PCC in the management of bleeding in patients taking direct oral anticoagulants, they have separate suggestions depending on specific DOAC. In rivaroxaban or apixaban treated patients, they suggest using 2000 units of 4F-PCC if andexanet alfa is not available. In edoxaban or betrixaban treated patients, they suggest using either high dose andexanet alfa or 2000 units of 4F-PCC.

Evidence-Based Answer and Strength of Recommendation (SOR) & Rationale

Fixed dosing of 4F-PCC may be comparable to traditional weight-based dosing of 4F-PCC in adult patients taking factor Xa DOACs in regard to hemostasis. (Strength of recommendation = B based on a single head-to-head cohort study and 3 well-done cohort studies looking at a patient-oriented outcome). Results from the included studies³⁻⁷ share two common conclusions; 4F-PCC is effective in achieving hemostasis in patients taking factor Xa DOACs, but larger studies with head-to-head comparisons are needed to determine the optimal dose. As Wilsey et al pointed out, cost should also be considered, as there is approximately a 50% cost savings for using fixed dosing as opposed to weight-based dosing.⁴

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This article has been peer-reviewed. The contribution in reviewing is greatly appreciated!

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TABLE 2. Definitions of Major Bleeding and Effective Hemostasis Used in Each Study

Source	Major Bleeding Definition	Hemostatic Efficacy Definition
Kim et al (2020) ⁴	Moderate bleeding = possibly requiring blood transfusion but no hemodynamic compromise Major bleeding = intracranial hemorrhage or bleeding that causes hemodynamic compromise	Determined to be effective if: no further reports of significant bleeding in operative or procedural documentation, stabilization of bleeding noted on serial computed tomography scans, and no further significant drop in repeat hemoglobin measurements defined as a drop of > 2g/dL within 2-6 hours post PCC administration
Milioglou et al (2021) ⁵	ISTH definition (17/33 studies), ANEXXA-4 trial ⁸ criteria for hemostasis (5/33 studies), ⁹ or each study's definition following center-specific or subjective information	
Schulman et al (2018) ⁶	ISTH definition	Good = less than one hour to cessation of bleeding with no additional coagulation intervention required Moderate = one to four hours until cessation of bleeding, with no additional coagulation intervention required Poor/none = more than four hours until cessation of bleeding and/or additional coagulation required
Wilsey et al (2021) ³	Life-threatening bleeding or potentially life-threatening requiring emergent surgery or invasive procedure or bleeding requiring a blood transfusion	Effective hemostasis reflects definitions used in ANNEXA-4 and were adapted from Shulman et al to include "moderate" and "good" ratings as hemostatic success
Majeed et al (2017) ⁷	ISTH definition of major bleeding in non-surgical patients	Effective or ineffective based on criteria published by the Standardization Subcommittee on the Control of Anticoagulation of the ISTH

4F-PCC = 4-factor prothrombin complex concentrate

ISTH major bleeding in non-surgical patients is defined as having a symptomatic presentation and 1 of the following⁹:

- Fatal bleeding, and/or
- Bleeding in a critical area or organ, such as intracranial, intraspinal, intraocular, retroperitoneal, intra-articular or pericardial, or intramuscular with compartment syndrome, and/or
- Bleeding causing a fall in hemoglobin level of 20 g L⁻¹ (1.24 mmol L⁻¹) or more or leading to transfusion of two or more units of whole blood or red cells

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2022 PSW Legislative Day Recap

by Sommer Gay, 2022 PharmD Candidate

The PSW 2022 Legislative Day was a great success. PSW brought together almost 400 pharmacists, pharmacy students, and pharmacy technicians virtually for this event. Ellina Seckel, President of PSW, welcomed attendees and thanked members for their significant involvement in advocacy for the profession of pharmacy. Seckel highlighted her experience attending Governor Tony Evers's State of the State address on behalf of PSW. Governor Evers expressed sincere appreciation for what the pharmacy profession has accomplished throughout the Covid-19 pandemic, emphasizing that our voice is stronger than ever together while we are physically apart.

Throughout Legislative Day, PSW members highlighted the successful policies that were passed during the previous legislative session.

To kick off Legislative Day, a group of bipartisan legislators, who are deeply involved in healthcare policy in the state legislature, were welcomed for a panel discussion. Senator Patrick Testin, Representative Lisa Subeck, and Representative Robert Summerfield discussed the session and the current health policy issues being discussed in their chambers. To wrap up the discussion, panel members shared advice for how PSW members can become more involved, including establishing relationships with elected officials, educating elected officials about issues important to the pharmacy profession, and sharing the impact these issues have on patients and communities.

Following the panel discussion, Danielle Womack, Vice President of Public Affairs at PSW, provided an update on the 2021-2022 legislative session. Womack outlined policies that were signed into law this session, including PBM reform; provider status; pharmacy technician and student pharmacist immunization authority expansion; remote dispensing site allowances; technician registration; and penalties for criminal vaccine/drug destruction. Womack also highlighted

policies that are being considered as the session ends on March 10. Proposed legislation enabling pharmacist prescribing of contraceptives and proposed legislation prohibiting payor-mandated white-bagging were included in this update.

Next, Ellina Seckel and Melissa Theesfeld, Chairman of the Board for PSW, presented the PSW legislative awards. Recipients included three pharmacy students who are growing their skills in promoting the profession of pharmacy; 11 state legislators who have advocated for pro-pharmacy and pro-patient legislation; two past Wisconsin Pharmacy Examining Board members; and six pharmacists who served on the PSW Provider Status Core Team, acknowledging the significant contributions they made in shepherding provider status advocacy efforts forward for pharmacists in Wisconsin.

Wisconsin Pharmacy Examining Board (PEB) members John Weitekamp and Tiffany O'Hagan gave an overview of administrative rule revisions that are underway, including updates to Chapter Phar 5, 6, 7, 8, 11, 12, and 15. Board resources were also shared.

Lastly, Danielle Womack and Kari Trapskin, Vice President of Healthcare Quality Initiatives at PSW, presented on provider status, which requires Wisconsin Medicaid to pay pharmacists for any patient care service within a pharmacist's scope of practice or delegated to the pharmacist by a physician. Womack and Trapskin provided an in-depth overview of the timeline for implementation, which aims for pharmacists to be able to bill for these services at the beginning of 2023. PSW will provide implementation support to members. These resources will enable service billing on behalf of Medicaid patients. The PSW Ambulatory Care Advisory Committee (ACAC), PSW Community Pharmacy Advisory Committee (CPAC), and the Provider Status Core Team and Sounding Board work group will collaborate on the creation of a provider status implementation guide. This work will build upon prior work completed by the PSW Practice

Advancement Leadership Team. Some anticipated components of the guide include creating relationships and buy-in within organizations; Medicaid enrollment; back-end billing; coding; claims reconciliation; reimbursement models; legal considerations; internal credentialing; documentation; collaborative practice agreement (CPA) templates; and promotion.

Trapskin also detailed how PSW members can prepare for provider status while waiting for implementation. Some steps to take now include evaluating current services; considering CPAs and beginning conversations with partner physicians; obtaining or evaluating liability insurance; and holding internal conversations regarding credentialing/privileging departments within the health-system and billing/coding. As this work continues, PSW communicate progress and suggestions for next steps in FastFacts, through social media, and in The Journal. Following this presentation, attendees were split into virtual breakout rooms to discuss what provider status means to PSW members.

The 2021-2022 Legislative Session has been one of the most productive sessions in PSW history. Members participated in efforts to advocate for legislation that will benefit patients and practice in the years to come. This grassroots advocacy of PSW members was essential. If you are interested in continuing to advocate for the profession, PSW offers a number of opportunities to get involved at pswi.org/becomeinvolved.

Sommer Gay is a 2022 Doctor of Pharmacy Candidate at the University of Wisconsin-Madison School of Pharmacy in Madison, WI.

Friends of Pharmacy Award

For their Leadership in Authoring 2021 Wisconsin Act 9



Senator
Roger Roth



Senator
Jon Erpenbach



Senator
Mary Felzkowski



Representative
Michael Schraa

For their Leadership in Authoring
2021 Wisconsin Act 98



Senator
Julian Bradley



Representative
David Murphy

For their Leadership in Authoring
2021 Wisconsin Act 100



Senator
Kathy Bernier



Representative
Cody Horlacher

For their Leadership in Authoring
2021 Wisconsin Act 3



Senator
Dale Kooyenga



Representative
Joe Sanfelippo

Leadership in Authoring
Assembly Bill 36



Representative
Joel Kitchens

Service to the Pharmacy Examining Board



Franklin "Rockky" LaDien,
RPh



Phillip Trapskin,
PharmD, BCPS

Good Government Award

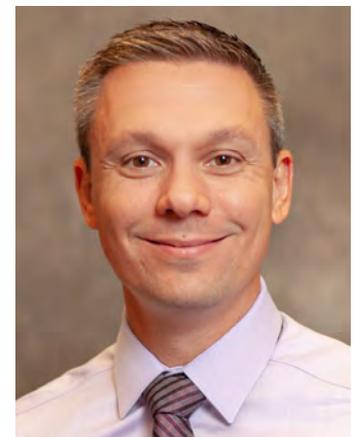
For their service on the Provider Status Core Team and work to pass
2021 Wisconsin Act 98 - Pharmacist Provider Status



Ellina Seckel,
PharmD, BCPS



Adam Gregg,
PharmD, BCPS



Nicholas Olson,
PharmD, BCACP,
AAHIVP



Julie Bartell, PharmD,
BCACP, CACP



Jordan Spillane,
PharmD



Dimmy Sokhal,
PharmD

WPQC Spotlight: David Schiek - Rhinelander Hometown Pharmacy

by Mason Brandt, 2022 PharmD Candidate

Pharmacy and health care are moving toward a more comprehensive, patient-centered approach to tackling the needs of patients across the nation. Because of this transition, care providers are increasingly looking for programs that directly focus on patient-centered care and result in measurable improvements. One program operating in Wisconsin with great success is the Wisconsin Pharmacy Quality Collaborative (WPQC). WPQC is a network of pharmacies and payers working to improve the quality of care in Wisconsin.

The WPQC program, initiated by PSW, connects payers to WPQC-certified providers for performing medication therapy management (MTM) services for patients. Services include Level I intervention-based services (medication device instruction, dose/dosage form/duration changes, adherence interventions, etc.) and Level II CMR/A services. Pharmacists benefit from the program by building stronger connections with patients, and patients receive tailored care. Providers can focus on improving medication use, patient safety, and reduced health care costs.

David Schiek, of Hometown Pharmacy

Q&A WITH DAVID SCHIEK

Can you explain the benefit this service (both for you and your patients)?

"The benefits of using this service are two-fold. First, it helps the pharmacy staff to understand limitations the patient may have that the pharmacy would typically be unaware of, such as financial, physical, or educational limitations. Second, and most importantly, it helps our patients develop a reason why they are taking medications and allows them to piece together their disease state and medication list."

What training were you and/or staff required to complete to run these programs?

"We trained for the billing side of the program (REDCAP) with a webinar-like module that took an hour or so. We also had 2-3 Zoom meetings that laid out the program expectations, goals, and best execution protocols. We followed that up with a recapping webinar that helped to train our pharmacy technicians. All educational items were easy to understand and execute."

How has WPQC accreditation impacted your pharmacy practice and helped your patients?

"I believe the WPQC accreditation has impacted my pharmacy more by helping my patients and getting them a better understanding of not only their disease states but understanding 'why' they are taking their medications. They become more involved and active in their health and less of a bystander."

What barriers did you face initiating these programs or do you face operating these programs?

"There were some barriers to the program. Not everyone wants to participate. They are either short on time or can't see the benefit of sitting down for the CMR. Some others will sit down but show little need to change. That is where we hope we made some, even if small, impact for later."

What are you particularly proud of about your practice location?

"I am very proud of my staff and how they treat our patients. We are a patient-centered team and are problem solvers for our patients. Especially in a rural area, our staff will often find themselves a link between the patient and exceptional health care. Our team anticipates the needs and expectations of our patients and clinicians and often does things before they are asked, exceeding the expectations of a typical pharmacy."



Above: Hometown Pharmacy on Brown Street in Rhinelander, Wisconsin.

in Rhinelander, Wisconsin, has been participating in programs sponsored by PSW for several years. After receiving WPQC accreditation in April of 2019, Schiek originally participated in the Flip the Pharmacy (FTP) program, a 24-month initiative designed to transform a pharmacy from a “filling prescriptions” mentality to a patient-level focus. FTP uses change packages and domains to optimize staff workflow and implement continuous quality improvement measures with a patient-centered approach. Hometown Pharmacy of Rhinelander not only offers comprehensive medication reviews (CMR) to further WPQC standards, but also offers services such as free medication delivery, durable medical equipment rentals, and blister packing that many larger chains do not offer. Schiek, with 26 years of pharmacy experience in Rhinelander, has strengthened his ties with Rhinelander and Oneida County residents by joining the WPQC through the end of 2021.

Hometown Pharmacy of Rhinelander participates in a WPQC program specializing in diabetes, hypertension, and hyperlipidemia. Patients are introduced to the pharmacy through a Medicaid program that identifies gaps in care in disease states. Each patient flagged must have two chronic conditions, take four or more medications for these conditions, and receive care from two or more physicians. When a patient qualifies, Schiek and his team are primed to intervene. The Hometown Pharmacy team meets with the patient three times over the course of several months to develop and implement a plan of care. With visits occurring every other month, Schiek performs a CMR focusing on the patient's medications and disease states. After a discussion, Schiek helps the patient set small goals to accomplish and build on. For example, if a patient struggles with high blood pressure, the patient may have a goal to measure and record blood pressure readings every morning, and then build to more robust goals as the patient learns to manage their health. Schiek and his team have found that small changes over time have led to a significant positive impact on the health of patients.

Oneida County, in northern Wisconsin, is home to around 35,000 residents and the city of Rhinelander. As a third-generation healthcare worker in Rhinelander, Schiek



Above: View of the pharmacy and education center, with materials for blood pressure, diabetes, and healthy lifestyle teachings.

has perfected the art of Northwoods hospitality, forming many relationships in the community. He says that this is what makes programs like WPQC so successful in his community. A Rhinelander native, his long history in the area helps build trust with his patients, and confidence that their care is his top priority. Like any program, this one has had occasional setbacks; Schiek explains that some patients simply refuse the service. Including some who either lack the time or cannot see the benefit of a CMR. These patients are few and far between, however, as Schiek and his team have turned many patients into success stories. Many of his patients have completed the program with substantial health improvement.

Mason Brandt is a 2022 Doctor of Pharmacy Candidate at Concordia University Wisconsin School of Pharmacy in Mequon, WI.



Above: David Schiek, a third-generation healthcare worker in Rhinelander, scheduling an appointment with a patient.

"MORTAR & PESTLE" CONCORDIA UNIVERSITY WISCONSIN SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Business Member Spotlight: Dr. Ellen Popov - Aurora Good Hope Oncology Clinic

by Kira M. Larson, 2022 PharmD Candidate

Advocate Aurora Health is a not-for-profit health system comprised of Advocate Health Care in Illinois and Aurora Health Care in Wisconsin.¹ With over 500 sites of care, Advocate Aurora Health is recognized for clinical excellence in areas like cardiovascular care, oncology, neurology, geriatrics, and trauma care. In addition to values of excellence, compassion, and respect, safety also plays a significant role in patient care.² At Aurora Good Hope Oncology Clinic in Milwaukee, Ellen Popov, PharmD, is the oncology pharmacist who works closely with other members of the oncology service line to provide the best care to patients.

Day-to-Day Practice

Aurora Good Hope Oncology Clinic is an ambulatory cancer clinic that provides services to patients receiving both oncology and non-oncology infusions. In addition to medication administration services, oncology pharmacists also participate in clinical drug monitoring, oversight of drug preparation, drug information services, drug interaction checking, and precepting students and pharmacy residents. Popov describes her work environment as fun, rewarding, challenging, engaging, and collaborative.

Pharmacists in the oncology service line at Advocate Aurora Health have unique collaboration opportunities with their department and other specialties, like oncology precision medicine, cardio-oncology, palliative care, research, clinic nursing staff, patient service representatives, medical assistants, and advance practice clinicians. As part of day-to-day services, Popov collaborates with healthcare team members to review current patient statuses and whether treatment adjustments are necessary. She communicates with other pharmacists regarding double-checks for treatment plans, overall treatment

clarifications, and coordination of product supply. Finally, Popov and her colleagues at other Aurora oncology clinics often connect to discuss complex patient cases. For example, Popov recently worked with a pharmacist in oncology precision medicine regarding a mutual patient whose disease had progressed. During their discussions, they evaluated which treatment option would be the best fit for the patient's current condition.

Popov has a lot of opportunities to give back to the community through the Sunshine Committee, which is run by the oncology pharmacy department. This committee works to foster support interdepartmentally, as well as in the community. Activities include supporting local charities through school supply drives, participating in Milwaukee River clean-

up initiatives, and joining local cancer-awareness walks. Popov also participated in advocacy through PSW by sending letters to local legislators in support of pharmacist provider status.

Raising the Bar

The oncology pharmacy department at Advocate Aurora Health has developed a collaborative workflow that fosters resource sharing and promotes discussion and learning. Popov believes this unique collaboration is a huge advantage when it comes to patient care.

Since the expansion of oncology services in the Advocate Aurora clinics, technology has been integral to the practice. With clinics from Green Bay to Kenosha, telecommunication and technology have been a large part of how pharmacists

Below: Outside Aurora Good Hope Oncology Clinic in Milwaukee, WI.



communicate throughout the department. Using telecommunications has allowed for remote checking of products, cross-coverage, and enhanced monitoring of patients. Additionally, as the practice has grown over the years, the team has implemented many enhanced safety measures to meet the organization's safety goals. Part of the practice model includes mandatory, virtual daily check-ins or safety huddles with the team to discuss safety, service, or quality issues. These meetings include pharmacy staff across many sites. Furthermore, the safety call is extended twice a week to give pharmacists time to discuss logistical or clinical issues, patient cases, or new developments in practice or guidelines. Pharmacy technicians also meet once per week to discuss logistical concerns and to collaborate as needed.

The pharmacy team also receives specialized training. They complete annual training updates via competencies, video training, and an extensive training manual that is frequently updated. Popov says a unique element of training in the oncology pharmacy service line is the extensive number of resources the team has cultivated over the years and the ongoing work to ensure that all members of the team have access to those resources. Pharmacy residents in the organization provide virtual grand rounds and forums on a broad range of healthcare topics, providing anyone an opportunity to listen in. At monthly pharmacy oncology meetings, time is set aside for pharmacists to present updates in an area of oncology practice. Lastly, board certification is supported by Advocate Aurora Health, and many of the oncology pharmacists have achieved board certification. This promotes lifelong learning in oncology practice.

Knowing that the main goal of the organization is patient safety allows the team to form clear goals towards practice advancement. For Popov, knowing that she can reach out to her team members with questions or concerns makes her feel like her opinions and ideas matter. Working together with leadership and her colleagues to solve problems helps form a strong bond of trust among department members. Popov believes the key to setting and achieving goals is to make them achievable. She works on setting small goals to learn or do one thing that will enhance her practice. Many of her goals revolve around her desire to stay

current with developments in breast cancer and gynecologic cancers. She accomplishes these goals by listening to podcasts or webinars with practice updates, which she can then apply to patient care.

Bumps in the Road

Pharmacy practice would not be where it is today without having had to overcome various challenges. At Aurora Good Hope Oncology Clinic, the most current challenges are shortages, which range from staff shortages to medication and supply shortages. The oncology service line makes a tremendous effort to work together to minimize the effects of shortages.

During the daily meetings, service challenges for the day are addressed, and the group works together to reduce the impact of these issues. Technology is an important tool. It allows the team to use remote coverage and order processing, as well as inventory reviews of other sites to enable supply sharing across the system as needed. More broadly, the oncology pharmacy team at Advocate Aurora Health has a large annual meeting that serves as an idea-generating session where the team can address current practice challenges and potential workflow enhancements for the coming year.

Popov has been a part of the oncology pharmacy team at Advocate Aurora Health for many years. A major challenge she faced was the integration of pharmacists into ambulatory cancer clinics. The practice change was a big shift from how the sites had previously operated. To overcome this challenge, the oncology pharmacy team personally met with each site and communicated proposed workflows with all clinic staff, and set the bar for how the practice has progressed over the years. Communication has been the key, including the increased use of technology. As technology has progressed, pharmacists have gained more real-time communication than ever before with other members of the health care team.

Change can be scary, but it can also be very exciting. There is always a fear that something may fail, but failures are opportunities to try again and learn from what didn't work. Originally, the shift to the current practice model was due to the need to have hospital-affiliated cancer clinics and to have a pharmacist review orders before a patient's treatment. The practice at Advocate

Aurora Health in oncology continues to be driven by a very dedicated team that strives to provide the best care to patients and continually looks to improve their practice.

Moving Forward

For future growth, Popov plans to continue her education in oncology pharmacy practice, as the field has seen tremendous growth and advancement in the last several years. Her goal is to keep pace with the changes. Professionally, Popov has supported legislative changes that would grant pharmacists provider status in the state of Wisconsin. With the recent approval of the pharmacist provider status bill in Wisconsin, Popov is excited to see the benefits she knows can be achieved with provider status, and how they will impact patient care. Specifically, she hopes to work toward a pharmacist-led program providing additional support for side-effect management of cancer patients. To other practice sites hoping to implement practice advancement initiatives, Popov says to first determine the main purpose of the service and ensure that all the steps align with that purpose. Next, communicate to the stakeholders the goal of the service and the steps needed to achieve that goal. Finally, reframe the idea of failure. If what you are trying to achieve has setbacks, use those "failures" as opportunities to learn and refocus to achieve your goal. The outcome will surely be all the stronger for it. For individuals wanting to practice in this field, Popov's advice is to trust and believe in yourself. You are capable of doing whatever you put your mind to.

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MEDICAL COLLEGE OF WISCONSIN SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Leadership Spotlight: Dr. Anita Kashyap, PharmD

by Dani K. Oelerking, 2022 PharmD Candidate



Editor's Note:

Since this article was written, Anita Kashyap has accepted a new position at the Madison VA as a Clinical Pharmacy Manager for Specialty Ambulatory Care and Investigational Drug Research and splits her time between that role and direct patient care in clinic.

Anita Kashyap, PharmD, BCACP is a clinical pharmacy specialist at the William S. Middleton Memorial Veterans Hospital (Madison VA). After graduating from the UW Madison School of Pharmacy in 2012, she accepted a post-graduate year 1 and year 2 residency in ambulatory care at the Madison VA. She originally started with the VA as a pharmacy technician in 2007 and has been building her career within the VA community since. Not only does she direct patient care as a provider, but she also works with her fellow staff as an ambulatory care clinical lead. Kashyap says that, in a typical week, she acts as a clinical pharmacist for three days and as a clinical lead for two. As a clinical pharmacist, she performs comprehensive medication services in both the primary care clinic and the heart failure clinic. As a clinical lead, she works on innovative practice changes and expansions of the ambulatory care clinical pharmacy services offered at the Madison VA. She manages program activities and provides leadership support for the ambulatory care clinical pharmacy specialists.

As an ambulatory care clinical lead, Kashyap has been working on developing local policies that meet national VA standards. She has also helped lead practice expansion efforts at the Madison VA, like integrating a pharmacist into the pulmonary clinic and restructuring the transplant pharmacy program to ensure that the pharmacists are meeting national policies. Most recently, she has been co-leading a project to increase COVID vaccinations in veterans who belong to a minority group. Her role in this population health initiative was to help train staff on how to approach

patients about receiving the vaccines and assist with the evaluation analysis. Throughout this project, Kashyap and her team have reached out to over 1,300 veterans to help them receive the COVID vaccines.

Although Kashyap states that she never expected to hold a leadership role, she gained a lot of respect for the position during one of her fourth-year experiential rotations at the Pharmacy Society of Wisconsin (PSW). While continuing her relationship with PSW as a clinical pharmacist, she has gained leadership experience by participating in conferences, speaking at various conferences, proctoring the yearly Wisconsin Pharmacy Residency Conference, and revising the heart failure toolkit. Her advice to future and current pharmacists is to “have experience yourself if you are going to manage others.” Kashyap also feels that managers should be able to give good feedback and receive it.

Along with being a PSW member, Kashyap also serves on the Ambulatory Care Advisory Committee for PSW. She is involved with multiple projects, including developing the PSW Ambulatory Care Advisory Committee Podcast. In this podcast, each episode focuses on pertinent ambulatory care pharmacy practice topics and is hosted by PSW members across the state of Wisconsin.

Accomplishments

Throughout her 14 years of work with the Madison VA, Kashyap's greatest professional achievement was being part of the team to receive the VA's first Clinical Pharmacy Practice Office (CPPO) PACT Clinical Pharmacy Platinum Practice Designation in June of 2020. The national

VA Pharmacy Benefits Management CPPO established the platinum designation to recognize the sites that have created innovative practices that maximize the impact of the PACT model, and specifically the integration of the clinical pharmacist provider. This award is presented to sites that have creative and innovative pharmacy practices with an integrated team-based care model. She says “it was truly a humbling moment” to be recognized for not only having a great team of pharmacists, but having a great team of staff working together at the Madison VA.

Kashyap is also proud of being selected to attend the PSW Pharmacy Leadership Conference in 2019 where she was able to surround herself with others who were also passionate about leadership, while developing her skills. After applying to attend this conference in 2017 and being accepted as the first alternate, she decided to make it a goal to be invited to attend in the future. Two years later, she met her goal. Her advice to others is to understand that career goals may change or not go the way you've planned, but that is okay. She feels that attending the 2019 Leadership Conference had more impact for her than it would have in 2017. She says that, even if you are not in a leadership position, you should still strive to be a leader by finding opportunities to participate and to let your voice be heard. Some of her favorite examples: volunteer to speak at a conference; volunteer to do a project within your work group; and volunteer to lead a patient care team. Kashyap believes that by stepping out of your comfort zone, you are opening the door to new opportunities. She

says challenging herself to complete tasks outside of her comfort zone gave her the biggest opportunities for growth.

Concerns Today

Kashyap is grateful for the opportunities that she has had at the Madison VA, including having a provider status, which most pharmacists within other organizations do not have. She understands that there is a definite challenge for current pharmacists being recognized as direct patient care providers. Although she does not see this challenge at the Madison VA, she observes these challenges while working with PSW. She hopes that, 10 years from now, all pharmacists will be able to work to the top of their license with provider status. She believes that all pharmacists should be using their clinical knowledge and collaborating with other healthcare professionals to offer the best health care to every patient. Under the leadership of PSW, she believes that there is a strong foundation of support for provider status from not only the organization itself, but from every Wisconsin pharmacist who is a PSW member. Kashyap says that this support should extend not only to fellow pharmacists but to other health care professionals. This will help promote awareness and support for provider status across the health care field. Kashyap knows

that it has been a challenge reaching this status, but she believes that we could make a big impact in our communities just by building relationships and collaborating with providers outside of our own profession. This practice is why she thinks that she and her pharmacy colleagues are recognized and treated as core members of the healthcare team at the Madison VA. She says, “advocacy is key!” All pharmacists must continue to advocate for themselves and encourage support from those outside of the pharmacy profession.

Advice for Future Leaders

As Kashyap reflects on her career as a clinical lead, her advice for future leaders is to set goals, find opportunities to achieve those goals, and acknowledge that your goals may evolve as you progress through your career. She wants to remind everyone not to feel discouraged if their career path changes, and to take every opportunity to establish personal and professional growth. She lists as mentors her colleagues at the Madison VA, especially her supervisor (and PSW President), Ellina Seckel, who Kashyap says is a great listener to her staff's needs, and gives them all the opportunity to succeed. Seckel has opened a lot of doors for Kashyap, specifically her leadership role as a clinical pharmacist lead. Kashyap also recalls looking up to Professor Orly Vardeny, who

always presented opportunities in an open teaching style to connect with students and encourage them to reach for the stars. When her career path started to change, Vardeny encouraged Kashyap to embrace the change.

Kashyap says that she is always trying to go above and beyond in every patient and student interaction she has, because she feels it's important to pay it forward from those mentors who have invested a lot into her. She is also a preceptor for APPE students from the UW-Madison School of Pharmacy as well as PGY1 and 2 ambulatory care residents at the Madison VA. She is very proud to be a mentor to others, as she was named residency program preceptor of the year in 2018. She says that, if she started her career all over again, she would be more confident earlier in her career to reach a leadership position sooner. Kashyap believes every pharmacist should recognize their strengths and dive into them, even if the path they indicate isn't what they had originally planned. She says she would have signed up for smaller opportunities along the way to help guide her to her current career path.

Dani Schmaus is a 2022 Doctor of Pharmacy Candidate at the Medical College of Wisconsin School of Pharmacy in Milwaukee, WI.

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