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**Designing a Patient-Centered Opioid Misuse Screening and Brief Intervention for the Community Pharmacy**

By

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# CHAPTER 8

## SUMMARY FOR A GENERAL AUDIENCE

I have written this chapter to explain my research to a broad, non-scientific audience. All scientific research is done with the goal of being useful to many people. As a health researcher, my goal is to not only improve the health of the patients, but also center their needs in all that I do. I also focus on putting my research into actual practice and creating change through my work. These goals are impossible without communicating my findings with the public. Thanks to the Wisconsin Initiative for Science Literacy at UW-Madison for providing this platform, and for sponsoring and supporting the creation of this chapter. I also appreciate the efforts of Dr. Bassam Shakhashiri in leading this initiative and Elizabeth Reynolds for editing this chapter.

# BALANCING OPIOID SAFETY AND PAIN MANAGEMENT: HOW CAN PHARMACISTS HELP?

Before the COVID-19 pandemic, researchers, clinicians, and public health officials in the United States were focused on another epidemic – the opioid overdose epidemic. While most of the research was concentrated on patients with opioid use disorders, I chose to focus on another group of patients - those who take opioids regularly and do not have opioid use disorders, but may be at risk of developing them. To explain why studying this patient group is important, I will first discuss opioid risks and give you a brief history on attempts made to reduce opioid risks for these patients. I will then describe how my dissertation project fits into the work that has been done already and what I found. My hope is that with this chapter, you will gain insights into this understudied patient population's needs and how my research attempts to help them.

## Opioid risks and chronic pain

More than 142 million opioid prescriptions are dispensed every year in the United States. Opioids are a type of pain medication that help improve the quality of life for many patients who suffer from pain from a variety of sources, including after an operation, from a new injury, or a chronic condition. However, opioids have some inherent safety risks that need to be considered when being prescribed by doctors, dispensed by pharmacists, and taken by patients. These medications can be safe if used at an appropriate and prescribed dose and frequency, the patient is monitored for side effects, and care is taken to avoid mixing the medications with other substances such as alcohol. However, even on their own, long term use of opioids can lead patients to developing tolerance, meaning the same dose of medication becomes less effective.

Some patients who become tolerant are at risk of eventually becoming dependent on their medications, and when that dependence takes over their lives or leads them to harming themselves or someone else, they may even develop an opioid use disorder. If the patient develops an opioid use disorder, they need additional treatment to manage it well and avoid emergency situations such as an opioid overdose. Therefore, at every step of the process, opioids must be handled carefully, to ensure safe and appropriate pain relief without causing undue harm.

While the use of opioids for pain in the United States is over two hundred years old, and regulation of opioids to promote safety is over 100 years old, our understanding of their effect on patients continues to grow. It was not until the late 1990's that the medical community began to understand that opioids even when prescribed and taken correctly, can still lead to tolerance and dependence. However, by then, patients who had been prescribed opioids for long term treatment without careful monitoring had not only developed tolerance, dependence, and even opioid use disorders, but were also dying at unprecedented rates due to opioid overdoses. Overdose deaths have continued to increase in the past twenty years. In 2020, over 100,000 Americans died due to a drug overdose, most of them involving an opioid.

**Restricting opioid prescriptions: Effective solution to the overdose epidemic?**

In response to the opioid overdose epidemic, the Centers for Disease Control and Prevention (CDC) has taken some measures to limit the potential risks of opioids. This included creating prescription monitoring programs: state level systems that healthcare professionals use to check a patient's history with controlled substances, including opioids. The CDC also made state-level recommendations about the maximum dose of opioids per day that should be prescribed. However, these steps have not been sufficient and have opened the doors to new

issues. For example, these new regulations and a culture that was more aware of potential harms of opioids put prescribers of opioids in a difficult place. If their prescriptions were too high, their patients overdosed, or they were accused of being a “pill mill” (an office that provides excessive prescriptions for controlled substances), they could lose their practice, their license, or even face legal consequences. However, without access to opioids, or if forced to stop their medications suddenly, patients were at risk for uncontrolled pain, poor quality of life, and even severe withdrawal symptoms, which can be disabling. Many prescribers, perceiving a difficult choice with their livelihood and their patient’s safety in the balance, opted to limit their opioid prescribing, sometimes more drastically than even recommended by the CDC. Some prescribers simply stopped their patients’ opioid prescriptions, giving them little notice to find alternative pain treatment or another prescriber. Many of these patients could have benefitted from slower adjustments of their medications, or referral to resources or treatment if their healthcare providers felt they were at risk of tolerance, dependence, or an opioid use disorder. Prescribers were not the only ones who acted in what they saw as the patients’ best interests while trying to protect themselves. Some pharmacists refused to fill prescriptions at the pharmacy counter for patients who had “red flags” in the prescription monitoring programs.

In cases where patients were already dependent on their opioid medications, they were left with an impossible choice: do they withstand their pain and withdrawal symptoms without an end in sight, or keep looking for opioids? These patients, already vulnerable due to their pain and their dependence, were at risk of seeking out illicit sources of opioids. The situation was worse for patients from underserved groups such as Black and American Indian patients, and patients without insurance. Healthcare professional bias, media portrayal of the overdose epidemic, legal systems, and double stigma towards patients with opioid use disorders who were

from marginalized groups meant that these patients had lower access to opioid medications and lower access to treatment for opioid use disorders, than non-Hispanic white patients from affluent neighborhoods. These disparities in healthcare access continue to this day. I chose to use a patient-centered lens to conduct my research to avoid worsening these disparities.

**How do we balance opioid safety and patient needs?**

Everyone in this situation, from the prescribers to the pharmacists to the patients, is looking for a balance of symptom control and safety; it is clear that neither prescription without limits, which can eventually lead to an opioid use disorder and overdoses, nor abruptly stopping or reducing medications, which lead patients to uncontrolled pain and withdrawal, is the answer.

My dissertation project sought to explore this problem from the perspective of pharmacists and patients. I conducted interviews with pharmacists and patients who were taking opioids to understand their perspectives and experiences related to opioid medications. Consider the scenario below (Fig 1). On the left, a pharmacist from my study describes his experience seeing opioid prescriptions written for patients whose pain remains uncontrolled while their opioid dosage keeps increasing. Higher doses of opioids in patients who may also be at risk for misuse because of uncontrolled pain, increases the chance of an accidental overdose death. On the right, a patient I interviewed who has been taking opioid medications for the past ten years describes her experiences of stigma from being labeled a drug abuser and having the legitimacy of her need for opioids questioned. Both sides have their own perspectives, leading to a constant tension without reaching a balance of opioid safety and acceptable pain control. So, how can we

achieve this balance?

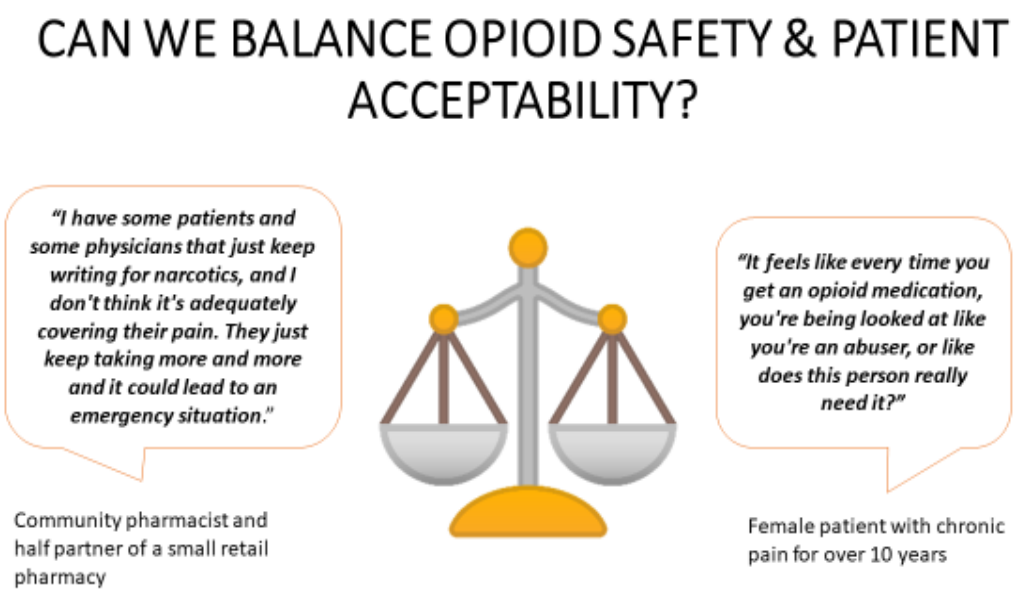


Fig 1: Quotes from pharmacist and patient study interviews

Clearly, this is a difficult balance to achieve. From my interviews, I found that while patients may be at risk for opioid-related harm, they may not fully understand this, even if they have been taking medications for years. Remember, the medical community did not fully realize even responsible opioid use could lead to tolerance and dependence until the late 1990's. Patients interpret the provider and pharmacist concern about a potential risk as being abrupt and inappropriate, stigmatizing, or not made in their best interests. Pharmacists have the training to identify inappropriate prescriptions, but don't necessarily have any tools to intervene other than refusing to fill the prescription. There is a need to develop a prevention program that addresses opioid misuse and safety in a way that is acceptable to patients and pharmacists. Instead of only checking for red flags of opioid misuse, such as the amount prescribed, there also needs to be a

'next step' or intervention so that patients who are found to be at risk for possible misuse are given appropriate resources by pharmacists, or their treatment plan is appropriately adjusted.

**Screening and brief interventions: Are they an acceptable solution?**

Screening and brief interventions (SBI) are a prevention strategy commonly used for identifying substance misuse behaviors and providing brief counseling to address that behavior and reduce misuse. SBI were initially developed for risky alcohol use and have been implemented in various clinical settings such as primary care offices, emergency care, and other non-substance use treatment facilities. They are also often designed as clinical interventions for prescribers, usually to be done in a clinical setting. However, pharmacists are much more accessible to patients than providers, and see patients outside of scheduled office visits. You don't need an appointment or even insurance to see a pharmacist. In rural areas, pharmacists are often the only healthcare professional for several miles. Pharmacists also have the training to identify inappropriate medications, and counsel patients regarding prescriptions. But the lack of focus on improving pharmacists' roles in clinical services has meant that the pharmacist is limited to only dispensing or refusing to dispense medications.

**What do we know about pharmacy-based SBI?**

My dissertation aimed to develop a SBI for opioid misuse to be delivered by pharmacists that was acceptable for patients. The first step was to conduct a scoping review of the literature on this topic. A scoping review is a systematic way of creating a search strategy from multiple databases of published studies and other reports. My search resulted in over 2500 studies and reports, which were screened and reviewed until 29 final reports were qualitatively analyzed. The results of the analysis informed the development of the SBI.

I found that research on pharmacist-led SBI for opioid misuse is very new (all studies conducted after 2016). Most of the research involved pharmacists surveys, and only 7 developed an SBI. Those programs involved a standardized screening tool, and resulted in pharmacists providing naloxone, commonly referred to as Narcan, an opioid overdose antidote. While such programs have been developed previously, they have not been centered on patient needs. As patients have not been involved in the development of SBI, uptake of such programs has not been high, and patients often refused the recommended naloxone. Additionally, even after rigorous design and development, few pharmacy-based interventions have actually translated into change in day-to-day practice. This was because the research was not focused on implementation and the practical realities of the setting, but was done in controlled clinical trials. Therefore, my scoping review highlighted a need for an intervention that improves opioid safety, is acceptable and useful to patients, allows the pharmacist to provide clinical services that they have been trained to provide, and can be implemented efficiently.

**Addressing limitations of existing SBI research**

In this dissertation, I addressed this gap by interviewing pharmacists and patients about what they find acceptable and feasible when it comes to such an intervention. I also identified barriers they might have with participating in this type of intervention and appropriate solutions to address those issues. Using this information, I have designed a program that includes screening for opioid misuse and a brief intervention that can be implemented in local community pharmacies in the future. The developed program includes screening using a standardized tool and offers the pharmacist a quick (<5min) way of assessing how the patient is taking their opioid medication and if they are at risk for misuse. The brief intervention (<15mins) then allows the pharmacist to intervene based on what the patient needs without causing patient harm. There are

several options for the brief intervention: this intervention will be simply providing opioid education to patients if they are not at risk, or contacting the prescriber if the prescription is inappropriate for the patient. My intervention will also include naloxone for at risk patients, but unlike previously developed programs, my program will describe naloxone in a non-stigmatizing way. For example, pharmacists will refer to it as a drug that can reverse an overdose and will compare it to an Epi-pen for allergies, and will clarify that it can be useful for patients who may be taking a high dose of opioids or are at risk of misuse. The program will also describe naloxone as helpful for patients who are older, take other medications that can lower breathing rates, live with children or teenagers who may accidently overdose, or have breathing issues like asthma. Finally, my brief intervention will involve the pharmacist referring the patient to additional treatment services if they are found to be at risk of developing an opioid use disorder. The entire SBI program has been designed from the ground up based on patient-reported needs and interests when it comes to their opioid medications.

Additionally, my dissertation also focused on what was practically possible to do and how best to implement the SBI in actual pharmacy practice. I used implementation science principles, which analyze the factors of a system that make change easier or harder, at the designing stage of this intervention to develop something that can be integrated within regular pharmacy workflow. I studied factors related to the pharmacy setting, the intervention, and pharmacists themselves to make the SBI more implementable. Pharmacists described not needing changes within the pharmacy itself, planned to use existing resources and workflow, and felt the intervention was compatible with their setting. They also believed that the SBI could be adapted for their setting, was not complicated to deliver, and had higher benefits than costs. Pharmacists had positive beliefs about the effectiveness of the SBI, and were highly motivated to

provide it within their pharmacies. Finally, the project also highlighted the implementation strategies that will be needed prior to testing the intervention, such as pharmacist training, and modifications specific to the pharmacy (such as phone-based or digital interventions for busy pharmacies). As part of the project, I also developed a tool to survey pharmacists in the future regarding the now developed intervention and its future implementation in their pharmacies. This tool will help evaluate how useful our intervention will be to larger groups of pharmacists in more diverse settings, and will serve as a way to test readiness for the SBI in new regions. This project has led to new findings about what the important factors are in a pharmacy setting and among pharmacists themselves that will help with sustaining the SBI as a clinical service offered by pharmacists in the long-term.

At the end of this study, I have systemically evaluated gaps in existing research, and developed a new way for pharmacists to screen for possible risk of harm from opioid medications and to briefly intervene to improve safety. This intervention is designed in a way that is more acceptable to patients, and can be efficiently implemented and tested. It is my hope that this project leads to a widespread patient-acceptable program for opioid safety within community pharmacies across the United States.