PHARMACIST UTILIZATION OF OPIOID MISUSE AND ABUSE INTERVENTIONS: ACCEPTABILITY AMONG PHARMACISTS AND PATIENTS IN DETOX

A dissertation submitted to Kent State University in partial fulfillment of the requirements for the degree of Doctor of Philosophy

by

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LIST OF ABBREVIATIONS

AACP- American Association of Colleges of Pharmacy
APhA- American Pharmacist’s Association
ASHP- American Society of Health-System Pharmacists
CDC- Centers for Disease Control and Prevention
CPD- Controlled Prescription Drugs
CSA- Controlled Substances Act
DAWN- Deaths Avoided With Naloxone
FDA- Food and Drug Administration
HB- House Bill
IR- Immediate Release
NIAAA- National Institute for Alcoholism and Alcohol Abuse
NIDA- National Institute on Drug Abuse
OAC- Ohio Administrative Code
OARRS- Ohio Automated Rx Reporting System
OBRA-90- Omnibus Budget Reconciliation Act of 1990
ODH- Ohio Department of Health
ORC- Ohio Revised Code
OUD- Opioid Use Disorder
PDA/M- Prescription Drug Abuse/ Misuse
PDMP- Prescription Drug Monitoring Program

ProDUR- Prospective Drug Utilization Review

REMS- Risk Evaluation and Mitigation Strategies

SAMHSA- Substance Abuse and Mental Health Services Administration

WHO- World Health Organization
ACKNOWLEDGEMENTS

I have always found congratulations rather strange, particularly following graduation, publication, or completion of a similarly complex project. These accomplishments are treated as the product of individual effort, but I’ve found that the opposite is true: success is almost always a team effort. Failure, on the other hand, is something we are all quite capable of on our own.

Thankfully, I did not face the dissertation process alone. I was supported, by a team of skilled and enthusiastic public health professionals, a network of intelligent and loving friends, a resilient and eternally patient family, and a husband who found me in the midst of a chaotic research process and made the irrational decision to leap into the fray.

First and foremost, I have to thank my committee. The team that ushered me through the dissertation process showed incredible willingness to collaborate, flexibility in the face of an almost comical series of setbacks, and enthusiastic interest in my research topic. Their patience, attention to detail, and extensive network of professional contacts saved me from becoming the Sisyphus of dissertations. I mention them as a group because so many friends who have completed a PhD have encountered interpersonal conflicts and incompatibility in their own committees. In contrast, my committee worked together beautifully, a testament to the healthy professional culture within the College of Public Health.
In addition to their synergy as a group, each member of my committee lent their professional and personal strengths to the research process. Dr. Kenne offered excellent insight into the staggering complexity and wrenching world of substance abuse. In spite of the weight of the topics we discussed, he reminded me of the creative solutions that helped in the battle against substance abuse in the past, and the need for similar innovation in the future. He was pragmatic when he discussed addiction, but never callous. He was hopeful, but never diminished the gravity of this epidemic. I sincerely hope I can emulate his blend of practicality, compassion, and cautious optimism as I begin my career.

Dr. VanGeest offered expertise in interdisciplinary research. His experience in both research and medical settings, as well as his capacity to understand emerging issues from the perspective of public health professionals, policymakers, and clinicians made him as much a mentor as an advisor. Given my interest in serving as an intermediary between legislators, researchers, and medical practitioners, his insights have been indispensable. His extensive knowledge of the peculiarities of surveying clinicians proved critical in administering the pharmacist survey, while his understanding of the competing demands of medical professionals lent clarity to their response to the survey. Beyond his professional capacities, Dr. VanGeest offered his personal wisdom and insight freely, and provided critical support as I balanced the competing demands of personal and professional life.

Dr. Phillips, in turn, lent tremendous methodological skill to the team. Her understanding of statistical procedures and her ability to discuss their application in layman’s terms expanded my understanding of methodology considerably. This skill set

Dr. VanGeest offered expertise in interdisciplinary research. His experience in both research and medical settings, as well as his capacity to understand emerging issues from the perspective of public health professionals, policymakers, and clinicians made him as much a mentor as an advisor. Given my interest in serving as an intermediary between legislators, researchers, and medical practitioners, his insights have been indispensable. His extensive knowledge of the peculiarities of surveying clinicians proved critical in administering the pharmacist survey, while his understanding of the competing demands of medical professionals lent clarity to their response to the survey. Beyond his professional capacities, Dr. VanGeest offered his personal wisdom and insight freely, and provided critical support as I balanced the competing demands of personal and professional life.
was all the more essential as I used a method that was entirely new to me in this study. In addition to her skill in statistics and her ability to convert complex mathematical procedures into plain language (a rare and valuable skill in a methodologist), Dr. Phillips discussed the dissertation process and the discipline in general with a wry, easygoing humor. Individuals who are personally engaging and intellectually gifted are rare, and I will always appreciate her ability to laugh at academia’s strange insularity, her skill in differentiating battles worth fighting and battles worth shrugging off, her passionate response to the former and bemused response to the latter. Her sense of humor made the inevitable setbacks of the dissertation process manageable, and relieved some of the uncertainty when I first proposed comparing two laughably incongruent populations.

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and flexible, pragmatic and empathetic is what makes her an effective leader, and a valued friend.

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Finally, I must thank my family. This paper belongs to them.

First, my mother, the strongest, toughest, most generous soul I’ve ever encountered. In her life, she has faced innumerable struggles. She lost her father as a child. She fought through economic struggle. She obtained her master’s degree in an era where women were still shut out of many academic institutions. Eight months before I was born, she buried her first daughter, Norah. Four years later, she watched her son struggle with the same genetic defect that killed her daughter. A year ago, she lost her husband. Through all of this, she turned to compassion rather than callousness. Although these struggles made her a bit more aloof, and although she found it harder to open herself to affectionate gestures, she showed love in countless ways. She volunteered, delivering meals to home-bound seniors. She transcribed braille. She learned to play instruments to perform in assisted living communities. In spite of terrible personal loss, she gave nothing but love to the rest of the world. She taught me that personal struggle is
never an excuse for cruelty or selfishness. That generosity does not require very much in terms of personal sacrifice, because the people who need help usually have so little to begin with that even the smallest gift of time or energy can make a difference. That the value of our work is not measured in the money we make or the titles with take on, but in the people we help. She is the reason I entered this field.

I want to thank my father as well. Although dementia made it impossible for him to understand the doctoral program when I entered it, the life he lived prior to his illness drove my interest in public service. He was a generous, kind, hard-working man. Just like my mother, he was no stranger to adversity. He lost his father in a PA coal mine as a boy. To earn money to support his widowed mother, he dropped out of highschool at 16 and joined the Navy in the final months of World War II. In spite of this struggle and uncertainty, he used the GI bill to obtain an engineering degree, and provided a good life for my family. His story, all on its own, taught me the power of good public policy, and the suffering that can occur when we overlook the needs of our most vulnerable citizens. The way he carried himself taught me far more, though. He was quiet, gentle, imaginative and thoughtful, and though I never developed his gift for silence, I try to emulate his other qualities. As a girl, he taught me how to rehabilitate injured birds and orphaned squirrels. He taught me how to draw flowers, and paint landscapes. He explained the complexities of the medical devices he designed, and transitioned smoothly to the intricacies of rendering the delicate light that passes through the petal of an iris. He taught me that we are not limited by any one characteristic- an artist can be a scientist, an analyst can be a poet, a man can be profoundly gentle and nurturing, and a woman can be a strong leader. In a world that constantly tries to define who we are based on what we
are, I will always treasure that lesson. Not only because of the tireless curiosity it fostered, but also because of the way it shaped my approach to others: look for who they truly are, not who you want them to be.

I have to thank my sister as well. Although I never knew her, I saw the impact that her death had on my family. Growing up in a grieving home teaches the importance of circumstance and context from an early age. It also teaches the importance of forgiveness. I realized, long ago, that rude comments and sudden arguments are not worth holding on to, because they are very rarely about you. There is always a constellation of personal experience, perception, psychology and physiology driving our emotional response, and it is simply not worth taking personally. The scars left by my sister’s death, as well as the beautiful memories inexorably tied to them, taught me that stories matter. The past explains the present, at least in part. This lesson came to mind time and again as I worked with detox patients. Remembering that they had a past made their present easier to understand, and made tolerating their bad days and mood shifts far easier.

I must thank my brother, Kerwin, as well. He has inspired me through his resilience and positive outlook, as well as his teasing and dry brand of humor. His struggle with congenital heart disease as a boy made our whole family intimately familiar with hospitals and the medical system. Without the support of a particularly reliable insurance plan and a team of brilliant cardiologists, he would not have survived. I learned about the importance of access to healthcare before I learned to read, and saw firsthand the difference that insurance made in the treatment of patients in that hospital, though I did not understand the role that it played in who received transplants and who received palliative care. In addition to seeing the importance of healthcare access firsthand, I saw
proof of what we stand to gain when we support those in need: connected communities, families that escape the cycle of grief, and citizens who live their lives with gratitude and purpose.

In addition to my biological relatives, I want to thank my mother and father in-law, Shirley and Jim Riley, for being incredibly loving and enthusiastically supportive. They have added so much to my life, and have become as close as my own mother. Not a day goes by that I am not grateful for their kindness and energetic support for the work I hope to do.

Most of all, I want to thank my husband, Brian. Initially, I had to pique his interest in my topic by connecting the opioid epidemic to botany (opioids are, after all, synthetic parallels of compounds produced by the opium poppy). Though he quickly realized that my work had no real relationship with his beloved flora, he took my interest in the grisly business of substance abuse and addiction in stride. Throughout this process, he has been the sweetest, most supportive bundle of love, strength, and confidence I could have asked for. He has been my sanity during insanity, my soft landing when I stumble, my home, and my heart.
CHAPTER 1

Introduction

1.1 Problem Description

In 2009, 7 million Americans, or 2.8% of the total United States population, reported non-medical use of prescription drugs, including pain relievers, stimulants, and antidepressants (Medline, 2011). While the misuse of any prescription medication is troubling, misuse and abuse of prescription opioids such as Vicodin, Dilaudid, and OxyContin is particularly common, with 1.9 million Americans who use prescription opioids meeting the criteria for opioid use disorder (SAMHSA, 2016). Unfortunately, prescription opioids are not only a frequently misused and abused class of medications, they are also particularly dangerous to misuse and abuse compared to many other prescription medications. This is due in large part to the high risk of overdose associated with opioids, and the serious consequences of opioid overdose, including respiratory depression, hypoxic brain injury, and death (CDC, 2016; Mehmeti, 2016). In light of the particularly lethal effects of opioid overdose, it is, perhaps, unsurprising that roughly 74% of prescription drug overdose deaths are caused by prescription opioids (Mehmeti, 2016). Each day, more than 1,000 people in the United States are admitted to hospital emergency rooms for treatment related to prescription opioid misuse and abuse, and in 2015, prescription opioid overdose lead to more than 15,000 deaths (CDC, 2016). This mortality rate is all the more striking when compared to other causes of injury related
death. In the last decade, prescription overdose has emerged as the leading cause of injury-related mortality, surpassing overdose rates of all illicit substances, while opioid overdose has overtaken motor vehicle accidents as the primary cause of accidental death (Drug Policy Alliance, 2015).

The consequences of prescription opioid misuse and abuse are not limited to overdose from prescription opioids, however. Misuse and abuse of prescription opioids is also associated with an increased risk of illicit opioid misuse and abuse. While only 4% of substance users who misuse and abuse prescription opioids transition to using heroin, 80% of heroin users were introduced to opioids through prescription drugs (Compton et al, 2015). In spite of these correspondent increases in heroin use, however, roughly half of all opioid overdose deaths are associated with prescription opioids (Bulloch, 2016).

The full scope of the problem extends well beyond fatalities. For every one opioid-related death, there are an estimated ten admissions for treatment of opioid use disorders, 32 emergency department visits associated with opioid misuse and abuse, 130 persons that misuse and abuse or are dependent on opioids, and 825 non-medical users of opioids (Fudin, 2014). When both the mortality and morbidity associated with opioid misuse and abuse are considered, the sheer size and scope of the opioid crisis is staggering. At the epicenter of this epidemic is the state of Ohio. In 2014 and 2015, Ohio lead the nation in opioid overdose deaths, with 2,106 fatalities in 2014 and 2,698 fatalities in 2015 (Burke, 2017; Kaiser, 2017). This translates to 24.6 deaths per 100,000, placing Ohio fifth in the nation in opioid deaths per capita (Ross, 2016).

Given that the majority of prescription opioids that are currently in circulation are obtained through consultation with medical professionals, medical practitioners including
doctors, nurse practitioners, and pharmacists are uniquely positioned to contend with this emerging threat. Pharmacists, in particular, serve as the final gatekeepers, ensuring that prescriptions are safe, effective, medically appropriate, and that patients understand their appropriate use. This gatekeeping role has been codified within a complex system of established legal, medical and economic standards and practices (Brushwood, 2017). Failure to fulfill the obligations and expectations associated with gatekeeping can result in profound professional consequences; indeed, within the context of the opioid crisis, courts have ruled that the gatekeeping role of pharmacists may translate to legal accountability for harmful outcomes such as overdose and addiction (Raby, 2015; Brushwood, 2017).

Pharmacists, as a profession, are now faced with increasing pressure to directly address this crisis. Due to their professional and organizational position, rapid implementation of a variety of opioid misuse and abuse interventions is possible. Pharmacists throughout the country have explored a variety of approaches to managing the opioid crisis, including patient education through counseling, prescription drug monitoring programs (PDMPs), referral to treatment programs, and provision of medications used to treat overdose such as naloxone (Termini, 2012).

1.2 Purpose of This Study

To determine whether pharmacy-based opioid misuse and abuse interventions are practical, however, several issues must be addressed. First, it is critical to determine whether pharmacists believe that the prevention, identification, and management of prescription misuse, abuse and addiction are acceptable components of professional practice. Second, it is important to determine whether patients are receptive to pharmacist
involvement in the discussion, identification, and treatment of opioid misuse and abuse.

Third, it is useful to identify any inconsistencies between pharmacist and patient acceptance of opioid misuse and abuse interventions.

This study evaluates the acceptability of pharmacy based opioid misuse and abuse interventions by surveying practicing pharmacists and patients in treatment for substance use disorders. The survey instrument examines five specific pharmacy-based interventions using a Likert scale to measure acceptability: (1) Pharmacists counseling patients on the risks associated with opioid misuse and abuse, (2) pharmacists referring patients to drug treatment programs within the community, (3) pharmacists utilizing Prescription Drug Monitoring Programs (PDMPs) to validate prescriptions, (4) pharmacists providing emergency opioid overdose treatments such as naloxone with opioid prescriptions, and (5) pharmacists providing naloxone without a prescription.

The goal of this study is to answer three research questions: which interventions are most acceptable to pharmacists, which interventions are most acceptable to patients, and which interventions produce statistically significant agreement on acceptability when both pharmacist and patient attitudes are compared. These data are used to identify a subset of interventions with high acceptability within and across the two groups. These findings are, in turn, used as an indication of professional and patient receptivity to specific interventions. The interventions with the greatest acceptability within each group and the strongest agreement across groups are identified, and changes to State regulations, organizational policy, and professional training that foster these interventions, as supported by the literature, are proposed.
CHAPTER 2

Review of Literature

2.1 Prescription Opioid Misuse and Abuse: An Introduction

Prescription opioid misuse and abuse is a mounting threat to public health, with millions of Americans struggling with prescription opioid use disorders, and thousands losing their lives to prescription opioid overdose annually. In contrast to the heroin epidemic that captured the attention of policymakers and public health professionals in the latter half of the 20th century, the vast majority of prescription opioids fueling this epidemic are legally obtained from medical professionals, either directly, or indirectly through the prescriptions of close social contacts (SAMHSA, 2016). Because of the critical role medical professionals play in obtaining these medications, medical practitioners must be involved in combatting this epidemic. Pharmacists, who primarily function as gatekeepers to medication, play a particularly essential role. Given that pharmacists have an established role in evaluating the safety and suitability of medication regimens, and given the tremendous amount of information on patient history at their disposal, pharmacists are uniquely equipped to aid in the prevention of prescription opioid misuse and abuse, the identification of patients struggling with opioid use disorders, and the initiation of addiction management.

To understand this epidemic and the role that pharmacists can play in confronting it, it is important to consider the following. First, what are opioids, and why are they so
addictive? Second, how did changes in the medical use of opioids influence the current epidemic? Third, who is most at risk of prescription opioid misuse, abuse and addiction? Fourth, what regulations govern access to prescription opioids? Fifth, what role do pharmacists play in controlling access to prescription opioids, and how do these differ from the role of prescribers? Sixth, what role do pharmacists play in preventing prescription drug misuse and abuse? Seventh, what role do pharmacists play in monitoring and managing misuse and abuse? Finally, how do pharmacist and patient attitudes impact the success of these interventions? Before exploring these questions, Table 2.1 provides definitions for several important terms that will appear throughout this paper.

Table 2.1: Terminology Related to Opioid Misuse and Abuse (APhA 2, 2014)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abuse</td>
<td>Self-administration of medications to alter one's state of consciousness (i.e., &quot;get high&quot;). This is an intentional, maladaptive pattern of use of a medication (whether legitimately prescribed or not) leading to major impairment or distress (e.g., repeated failure to fulfill role obligations, recurrent use in situations in which it is physically hazardous, multiple legal problems, recurrent social and interpersonal problems) occurring during a 12-month period.</td>
</tr>
<tr>
<td>Addiction</td>
<td>Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.</td>
</tr>
<tr>
<td>Diversion</td>
<td>Redirection of a prescription drug from its lawful purpose to illicit use; can be done with criminal intent.</td>
</tr>
<tr>
<td>Misuse</td>
<td>The intentional or unintentional use of a prescribed medication in a manner that is contrary to directions, regardless of whether a harmful outcome occurs.</td>
</tr>
<tr>
<td>Physical dependence</td>
<td>Physical dependence is a state of adaptation that often includes tolerance and is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.</td>
</tr>
<tr>
<td>Pseudoaddiction</td>
<td>Patients with pseudoaddiction exhibit behaviors of addiction (frequently asking for more analgesics or higher doses) that resolve when pain is adequately treated. Patients often are coined as &quot;drug seeking.&quot; The cause is inadequate analgesic management, and the treatment for pseudoaddiction is adequate analgesic management. Pseudoaddiction results in a crisis of mistrust between the patient and staff and threatens the ability to provide analgesic management.</td>
</tr>
<tr>
<td>Tolerance</td>
<td>Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug’s effects over time.</td>
</tr>
</tbody>
</table>

2.2 The Chemistry of Addiction: What Are Opioids, and Why Are They So Addictive?

When there is damage to tissue (such as from trauma or inflammation), nerves sense this damage and send a signal to the brain, which is interpreted as pain. While pain is important because it tells us to react to potentially damaging external stimuli, severe
pain can negatively affect our ability to think clearly and move freely. As illustrated in Figure 2.1, opioid receptors help to mediate pain signaling, an essential function when we face an immediate threat (Throm et al., 2005; NIAAA, 2007).

**Figure 2.1: Pain Signal Modification Via Endogenous and Exogenous Opioids, as well as Opioid Antagonists Such as Naltrexone (NIAAA, 2007)**

Endogenous opioids, such as endorphin, are produced in response to acute stress, primarily to reduce the sensation of pain by binding to opioid receptors. Unfortunately, while endogenous opioids can reduce pain sensation, they are generally produced for short periods, in response to severe stress. For individuals with inflammatory conditions, post-operative pain, or pain associated with aggressive treatments such as chemotherapy, prolonged pain can significantly reduce their quality of life. Because endorphin cannot be relied upon as a long-term solution to chronic pain, medical professionals have long sought alternative approaches to pain management. The discovery of exogenous opioids, first in the form of naturally produced derivatives of the opium poppy (such as
morphine), and later in the form of synthetic chemicals including oxycodone and fentanyl, provided an effective approach to pain relief (Lu, 2017). Exogenous opioids bind with the same pain receptors that endogenous opioids bind to (NIAAA, 2007). While exogenous opioids are often more effective at pain management than their naturally produced counterparts, and while many of the side effects such as euphoria and relaxation mimic the pleasant side effects of endogenous opioids, many exogenous opioids differ dramatically in their impact on the nervous system (NIAAA, 2007). At higher doses, many exogenous opioids depress respiration, leading to unconsciousness, coma, hypoxic brain injury, and death. Exogenous opioids are thus particularly dangerous for five reasons.

First, because these substances closely mimic naturally occurring chemicals produced in our own bodies, and because they bind to receptors present in the nervous system of every human being, all people are, to a degree, responsive to their effects (NIAAA, 2007). Put another way, opioid misuse and abuse is driven by “risky drugs, not risky patients” (Dowell et al, 2013). Second, because they are taken orally or intravenously rather than naturally produced in relatively small amounts, it is not only possible, but relatively easy, to overdose (NIAAA, 2007). Third, scientific innovation has lead to the production of increasingly powerful synthetic exogenous opioids, which are, in turn, more likely to lead to overdose. Fourth, exogenous opioids produce pleasurable side effects such as euphoria. Fifth, regular users of exogenous opioids experienced diminished reaction over time, resulting in a need to increase dosage to elicit the same effects. When these characteristics are considered in combination, the risk of dependency, misuse and abuse that accompanies prolonged use is unsurprising (NIAAA, 2007).
Given the tremendous value of pain relief in medical practice, as well as the risks of opioid use outlined above, it is no surprise that the history of opioid use in the medical system is largely a story of extremes (Lu, 2017). From the advent of morphine in the midst of a bloody war, to the aggressive marketing of heroin in the early 1900s, to its illegalization in 1924 and the subsequent effort to develop opioids exclusively for medical applications, the history of opioid use in the United States is based upon a cycle of hope and fear (Lu, 2017). In each era, the promise of pain relief seized the imagination of doctors and patients alike, and in each era, ineffective regulation of access to opioids resulted in misuse, abuse and addiction. The current opioid epidemic repeated this same cycle of hope and fear, with three dangerous additions: conflation of the risk of addiction in short and long-term opioid use, intentionally misleading marketing, and scientific innovation that lead to the creation of staggeringly powerful opioids (Zee, 2009). Familiarity with this history is critical to understanding the role that the medical system played in the inception of the opioid epidemic.

2.3: History: How Did Changes in the Medical Use of Opioids Influence the Current Epidemic?

When opioids were first introduced to the United States medical system in the mid-19th Century, they were greeted as a miraculous means of pain management (Lu, 2017). As the nation’s doctors struggled with the gruesome wounds and subsequent amputations associated with the use of explosives and firearms in the American Civil War, opioids provided a vital method of controlling patient pain (Lu, 2017). In the decades that followed, however, medical practitioners rapidly came to recognize the risk of misuse and abuse associated with opioids. The public came to recognize the addictive
potential of heroin and other commonly available opioids as well, and in 1924, use of opioids outside of a medical setting was formally illegalized (Lu, 2017).

2.3.1: Conservative Use: Caution in the Utilization of Prescription Opioids for Pain Management

Following the recognition of opioid misuse and abuse and subsequent ban on the sale of heroin in 1924, medical practitioners treated opioids with cautious respect (Lu, 2017). The heroin epidemic in the latter half of the 20th century reinforced the medical establishment’s assumption that medical use of opioids carried the same risk of misuse, abuse and addiction as heroin (Zee, 2009). This assumption lead medical practitioners to use a conservative approach to opioid use in the hospital setting, and extreme caution in the use of opioids as a tool for outpatient pain management (Lu, 2017). In the early 1980s, several physicians concerned that the medical system could better manage patient pain, challenged the assumption that any form of opioid use carried the risk of addiction.

2.3.2: Challenging Convention: Encouraging Expanded Use of Opioids in Pain Management

The first, a paragraph-long letter written to the New England Journal of Medicine in 1980, consisted of an assessment of the rate of opioid addiction in 39,946 hospital inpatients. In this letter, the authors, Porter and Jick, reported that 11,882 patients received at least one opioid preparation, while only 4 cases of well-documented addiction developed (Porter & Jick, 1980). The letter did not include detailed information on methodology, nor a description of how patients were categorized as experiencing addiction, the duration of opioid treatment, or the duration of hospitalization.

The second publication that challenged the under-utilization of opioids in pain management came in the form of an article that appeared in the journal Pain in 1982. In
this article, authors Perry and Heidrich examined the rate of opioid addiction among 10,000 burn patients undergoing wound debridement (Perry & Heidrich, 1982). The authors found no evidence of addiction in the entire patient population, and suggested, as a result, that the risk of addiction to opioids was small (Perry & Heidrich, 1982). While this study was more methodologically robust than the study by Porter and Jick, the two publications shared one critical feature: they assessed the development of opioid addiction in patients receiving opioids in a controlled medical setting, for the treatment of acute medical conditions. For patients in treatment for acute medical conditions, opioids are often used in smaller doses for far shorter periods, with greater medical supervision (Zee, 2009). While the findings of the two publications rightfully encouraged a review of the risks and benefits of opioid use in patients with acute pain, the studies did not provide any insight into the addictive potential of opioids when used for extended periods, in increasing doses, without consistent medical supervision (Zee, 2009).

2.3.3: Misleading Marketing: Conflating Risk of Addiction in Acute and Chronic Pain Management

To pharmaceutical companies interested in increasing the consumption of their product, however, these publications offered findings that were easy to mischaracterize in the name of profit (FDA, 2001). One company in particular, Purdue, heavily relied upon these two specific publications following the 1996 release of an extended-release formulation of oxycodone, OxyContin (Zee, 2009). Purdue trained sales representatives to downplay the risk of opioid addiction while marketing OxyContin, and to specifically describe the risk of addiction of OxyContin as “Less than one percent” based upon the results of the two aforementioned studies (FDA, 2001).
Still more troubling, Purdue and competing pharmaceutical companies made little effort to distinguish between the use of opioids in the treatment of acute pain and their use in the treatment of chronic pain. While Porter and Jick’s letter and the later study by Perry and Heidrich demonstrated that there is a low rate of opioid misuse and abuse among patients treated for acute pain in a hospital setting, a number of other studies provided ample evidence of the risk of addiction associated with opioid use in the treatment of chronic pain (Zee, 2009; Ross, 2015). A 1992 literature review of studies exploring drug misuse and abuse, dependence, and addiction in chronic pain patients found that between 3.2-18.9% of chronic pain patients received a diagnosis of dependency, opioid use disorder, or addiction (Fishbain et al, 1992). Another study, published in the International Journal of Addiction in 1995, found that in a group of 414 chronic pain patients, 12.6% met the criteria for analgesic dependency (Hoffman et al, 1995). A third study, published in 1997, found that 27.6% of pain clinic patients using opioids for chronic pain met three or more criteria for opioid use disorder, and that a history of drug or alcohol misuse and abuse did not appear to predict any significant difference between those who used opioids to manage chronic pain without incident and those who misused or abused them (Chabal et al, 1997). Still more troubling, researchers have found little evidence of functional pain relief when opioids are used to manage pain in extended periods (Ross, 2015; Holle, 2017).

There is ample evidence that Purdue was well aware of the increased risk of addiction in long-term use of opioids (Zee, 2009). In light of mounting evidence that Purdue misrepresented the risk of addiction associated with OxyContin, Purdue Frederick Company and 3 company executives pled guilty to criminal charges of misbranding in
2007, facing $634 million in fines (Zee, 2009). Unfortunately, by the time these fines were assessed, aggressive marketing and mischaracterization of the risk of addiction had already brought about a staggering change in opioid prescribing practices.

It is important to note that in addition to misleading marketing practices, research suggests that the increase in prescription drug utilization in general, and prescription opioid utilization in particular, may also be partially attributable to pharmaceutical advertising practices unique to the United States (Fain & Alexander, 2014). In 1997, the U.S. Food and Drug Administration (FDA) loosened pharmaceutical advertising regulations, expanding opportunities for pharmaceutical manufacturers to advertise medications directly to consumers (Fain & Alexander, 2014).

Direct-to-consumer advertising expenditures increased by roughly 20% annually since the 1997 regulatory decision, with particular emphasis placed on “elective medications” designed to improve the perceived quality of life of customers rather than those designed to treat life-threatening conditions (Macdonald, 2010). Direct-to-consumer marketing has been identified as a driving force behind increasing medication use and subsequent overutilization (Emanuel & Fuchs, 2008). Overutilization has, in turn, been implicated as a critical factor in prescription misuse and abuse (Emanuel & Fuchs, 2008). Such claims of pharmaceutical manufacturer responsibility for overutilization, misuse, and abuse are not limited to academic publications and medical journals (Mello et al, 2003). Legal experts and judges throughout the country have suggested that the introduction of direct-to-consumer advertising has altered the role that physicians traditionally play in evaluating the risks and benefits of medical therapy, transferring at
least part of the responsibility to communicate risks and benefits to the manufacturers advertising their product (Mello et al, 2003).

2.3.4: Birth of an Epidemic: More Prescriptions, More Addiction, More Overdoses

As a result of misrepresentation of medical research and direct-to-consumer advertising practices, the number of opioid prescriptions increased threefold, from roughly 76 million in 1991, to 219 million in 2011 (Compton et al, 2011). In addition to an increase in the number of opioid prescriptions written, the quantity of pills in each individual prescription increased (CDC 3, 2014). These increases in prescribing and dosage emerged without a concurrent increase in the amount of pain reported by Americans (National Vital Statistics, 2013).

Figure 2.2: A Comparison of the Amount of Opioid Pain Relievers Sold Per 10,000 Residents, Contrasted With the Drug Overdose Death Rate Per 100,000 Residents (National Vital Statistics, 2013)

Instead, this increase is largely attributed to the growing use of opioids in the management of chronic pain (Zee, 2009). This proved critical, as roughly 1 in every 4 patients given prescription opioids for the management of non-malignant, chronic pain
develop some form of opioid use disorder, wherein repeated opioid use results in drug-seeking behavior, compulsive use, and even physiological dependence (SAMHSA, 2015; CDC, 2016).

Evidence of the relationship between increases in opioid prescriptions and increases in opioid misuse and abuse is reflected in overdose death data. Trends in prescription opioid misuse and abuse are heavily influenced by state and local prescribing practices. While nation-level data suggests the number of opioid prescriptions and the drug overdose death rate are unrelated, **Figure 2.2** shows that geographically detailed data tells a different story (National Vital Statistics, 2013). When examined at the county level, as in **Figure 2.3**, the relationship between higher rates of prescription opioid sales and higher rates of drug overdose becomes even clearer (Bernstein et al, 2016). In counties that dispense more doses of opioid medication per capita, overdose rates are markedly higher (Bernstein et al, 2016). This trend can be attributed, in large part, in changes in opioid prescribing practices, and an associated increase in the availability of prescription opioids.
Figure 2.3: Where the Most Opioids Are Prescribed, the Most Drug Overdoses Happen (Bernstein et al., 2016)
While the average quantity of prescription opioids delivered per capita varies regionally, overdose rates vary in a strikingly similar pattern (Bernstein et al, 2016). Midwestern states such as Indiana, Kentucky, and Ohio have remarkably high painkiller prescription rates, with between 96 and 143 painkiller prescriptions written per 100 people, or roughly 1 painkiller prescription per capita (CDC, 2014). In many states, high volume for-profit pain clinics colloquially referred to as “pill mills” have emerged as a major enabler of opioid misuse and abuse, prescribing and dispensing large quantities of opioid medications regardless of established medical need of individual patients (CDC, 2014). Drug dealers often take advantage of lax prescribing practices, obtaining prescription medications through “pill mills” and selling the medication illegally.

**Figure 2.4: Sources of Prescription Opioids Reported by Individuals Abusing Prescription Opioids (SAMHSA, 2016)**

![Pie chart showing the sources of prescription opioids]

- 50% directly from friends or family
- 22.20% from prescriptions of friends or family
- 28% from medical professionals
- 10% from drug dealers

These changes in prescribing practices have had a critical impact on how individuals are introduced to opioids, and how those who have an opioid use disorder generally obtain prescription opioids. While individuals with opioid use disorders have historically been introduced to opioids through illicit drugs like heroin, individuals with
opioid use disorders are now more likely to be introduced to opioids through prescriptions. As demonstrated in Figure 2.4, 22.2% of individuals who have a prescription opioid use disorder obtained their medication from doctors (SAMHSA, 2016). The availability of prescription opioids has expanded indirect access as well, with roughly 50% of people who misuse and abuse prescription opioids reporting that they obtained opioids through friends or relatives (SAMHSA, 2016). Illegal trade of prescription painkillers provides additional access to opioids, with 28% people who misuse and abuse prescription opioids reporting that they purchased from a dealer (SAMHSA, 2016).

Figure 2.5 provides more detailed data on the ways individuals obtain prescription pain medications for misuse and abuse (SAMHSA, 2017). While prescription pain relievers are somewhat broader category of medication, the vast majority of prescription pain relievers that are misused and abused are classified as opioids; as a result, this data provides essential insight into the weaknesses within the medical system that allow diversion of prescription pain relievers (SAMHSA, 2017). This updated data reveals several troubling trends. First, the majority of individuals who misuse and abuse prescription pain relievers (53.7%) obtain these medications from a friend or relative, with 40.5% of individuals reporting that they obtained these drugs for free (SAMHSA, 2017). This suggests that patients are not properly disposing of unused medication (Maeng et al, 2016).
Figure 2.5: Sources Where Pain Relievers Were Obtained for Most Recent Misuse and Abuse Among Individuals Aged 12 or Older Who Misused or Abused Prescription Pain Relievers in the Past Year (SAMHSA, 2017)
Second, about one in three individuals (36.4%) who misuse and abuse prescription pain relievers obtain these medications through a prescription or a health care provider (SAMHSA, 2017). Taken together, roughly 90.1% of individuals who misuse and abuse prescription pain medications obtain the drugs they misuse and abuse either directly from a health care provider, or indirectly through friends and family. This suggests that prescribers and dispensers alike play a critical role in the prescription opioid epidemic (SAMHSA, 2017).

The consequences of the prescription opioid misuse and abuse epidemic are far-reaching. It is estimated that, as of 2013, prescription opioid misuse and abuse cost roughly $26 billion in health care costs, and more than $78.5 billion when costs associated with criminal justice and lost work productivity are accounted for (NIDA, 2017). While the cost of responding to this epidemic is felt nationwide, the consequences of misuse, abuse and overdose are felt far more acutely in some communities than in others. Demographics, geography, and economic status appear to play an important role in individual susceptibility to opioid use disorders. Exploring the demographic and economic characteristics that place an individual at increased risk of opioid misuse and abuse is, as a result, critical to targeting preventive initiatives and distributing resources that support treatment programs.

2.4: Demographics: Who is Most At Risk of Prescription Opioid Misuse and Abuse?

Limited public understanding of the demographic characteristics of individuals who misuse and abuse prescription opioids has inhibited the implementation of misuse and abuse prevention and treatment in the very communities most at risk for prescription opioid misuse and abuse (ODH, 2014). This is due in large part to profound
misconceptions surrounding the demographics of prescription opioid addicts. While there is an assumption that drug users are generally younger, and that they generally live in urban areas, these assumptions are derived from the media portrayal of heroin users (ODH, 2014). The population of individuals who misuse and abuse opioids is distinct, however, from groups that misuse and abuse pharmacologically similar illicit substances such as heroin. Broadly speaking, individuals who misuse and abuse opioids tend to live in rural areas, and are generally much older than heroin users, who tend to live in urban areas (ODH, 2014).

**Figure 2.6: Opioid Overdose Deaths by Gender (Kaiser Family Foundation, 2017)**

![Pie chart showing the gender distribution of opioid overdose deaths]

Another characteristic of the current opioid epidemic that differs dramatically from the heroin epidemic of the later half of the 20th century is the age distribution of overdose victims. Unintentional opioid overdose deaths are more common among adults between the ages of 45-64, unlike heroin overdose deaths, which are generally more common among younger adults between the ages of 25 and 34 (Paulozzi, 2012). As noted in **Figure 2.7**, due in large part to prescription opioid overdose deaths overtaking heroin
overdose fatalities, adults between the ages of 25 and 34 account for only 26% of opioid overdose deaths, while adults 45 and older account for 42% of opioid overdose deaths (Kaiser Family Foundation, 2017).

**Figure 2.7: Opioid Overdose Deaths by Age Group (Kaiser Family Foundation, 2017)**

The overdose death rates of all age groups have increased significantly, as noted in **Figure 2.8**, with overdose deaths among individuals over the age of 55 offering the most striking increase, from roughly 500 opioid overdose deaths in 1999, to more than 6,000 in 2015 (Kaiser Family Foundation, 2017). Although overdose death rates in 25-34 year olds overtook death rates among 45-54 year olds once again in 2014, this followed a 10-year period where opioid overdose mortality in 45-54 year olds exceeded the overdose death rate of all other groups (Kaiser Family Foundation, 2017). Given that heroin users are generally younger, this data emphasizes the clear distinctions between individuals who misuse and abuse prescription opioids and those who misuse and abuse illicit opioids (Kaiser Family Foundation, 2017).
A considerable portion of the increase in opioid overdose fatalities among older individuals can be attributed to increases in opioid prescribing rates. Opioid prescriptions are prescribed to older adults at strikingly high rates; while there are only .3 opioid prescriptions per capita among 10-29 year olds, there are 1.1 opioid prescriptions per capita among 40-59 year olds, and nearly 2 opioid prescriptions per capita among those over the age of 60 (Paulozzi, 2012). The harmful effects of increasing prescription opioid utilization are compounded by unrealistic pain management expectations on the part of patients. As highlighted in Figure 2.9, over 62% of individuals who misuse and abuse prescription pain relievers misuse and abuse these medications in an effort to relieve physical pain, suggesting either tolerance or physical dependence (SAMHSA, 2017).

Economics also play a major role in the opioid epidemic, both directly and indirectly. Income has a profound impact on the type of medical coverage an individual
has access to. For economically depressed communities, Medicaid is often the only source of insurance available. Unfortunately, Medicaid patients are at particular risk for developing opioid misuse and abuse behaviors due to inappropriate prescribing practices, simultaneous prescription of painkillers and benzodiazepine, and use of high dosage prescriptions (CDC, 2015). Consequently, states with higher numbers of Medicaid beneficiaries such as Ohio, Indiana, Michigan, Tennessee and Kentucky have experienced a particularly high rate of opioid overdose (ODH, 2014). This high rate is due in large part to a combination of high poverty rates, an aging population, a large number of economically depressed rural communities, and high rates of chronic medical conditions associated with pain (ODH, 2014).

In addition to the unusual age distribution of opioid overdose deaths, and the unique economic characteristics of individuals who become addicted to opioids, there are clear trends in the racial and ethnic makeup of opioid overdose victims, as demonstrated in Figure 2.10. Opioid overdose deaths are most common among non-Hispanic whites, with 6.3 opioid overdose fatalities per 100,000 non-Hispanic white Americans, though the opioid overdose mortality rate of white Americans is comparable to that of American Indians and Alaskan Natives (Paulozzi, 2012). As noted in Figure 2.11, non-Hispanic whites account for 82% of overdose fatalities, compared with non-Hispanic black (8%), and Hispanic victims (8%), with all other racial and ethnic groups accounting for just 2% of overdose fatalities (Kaiser Family Foundation, 2017).
Figure 2.9: Main Reasons for Prescription Pain Reliever Misuse and Abuse Among Individuals Aged 12 or Older in the United States Who Misused Prescription Pain Relievers in the Past Year (SAMHSA, 2017)
Racial and ethnic variations in opioid fatalities can be attributed, in part, to differences in opioid prescribing rates for black, Hispanic, and non-Hispanic white patients (Singhal et al, 2016). Researchers have found marked disparities in the rate at which non-Hispanic black emergency department patients receive opioid prescriptions for non-definitive pain when compared to non-Hispanic whites (Singhal et al, 2016). Another, similar study in a primary care setting found that, even when black patients reported higher pain scores compared to their white counterparts, white patients were more likely to obtain and use prescription opioids than black patients. A total of 45.7% of white patients reporting the use of prescription opioids while 32.2% of black patients reported the same (Chen et al, 2017). Critically, there were no similar differences in the use of other forms of pain management, including physical therapy or non-steroidal anti-inflammatory drugs (Chen et al, 2017). This suggests that racial differences in opioid prescribing practices may play a role in racial disparities in opioid misuse and abuse.
Geography also appears to play an important role in opioid overdose fatality trends. Rural counties tend to have higher dosage opioid prescriptions, with higher numbers of opioid prescriptions per capita, and a correspondently high rate of opioid overdose fatalities (Bernstein et al, 2013). Consider, for instance, the map of average opioid dosage and overdose death rates previously noted. Rural communities along the California-Oregon border, in Arizona, in Kansas, in Pennsylvania, and perhaps most strikingly, in Appalachia, tend to prescribe more opioids, and to suffer correspondingly high opioid overdose deaths (Bernstein et al, 2013; Burke, 2017). Overdose of opioids is far more common in non-metropolitan areas, in contrast to heroin overdose, which is far more common in large metropolitan areas (Paulozzi, 2012).

In summary, the portrait of individuals who misuse and abuse opioids differs markedly from that of heroin users, suggesting that effective interventions must be tailored to the groups most at risk for opioid misuse and abuse and overdose.
Interventions should also take into account the most common means by which individuals obtain prescription opioids. Medical professionals, either directly or indirectly through family and friends, are providing 72.2% of the prescription opioids misused/abused in the United States. To reduce the rate of prescription opioid misuse and abuse and overdose, policymakers must use every tool at their disposal, by refining systems that regulate the availability of opioids, rethinking the way medical practitioners work with patients treated with prescription opioids, and redefining the role that all members of the medical system play in misuse and abuse prevention and management.

2.5: Misuse and Abuse Prevention Through Regulation: What Regulations Govern Access to Prescription Opioids?

In light of the significant power of prescription opioids, as well as their potential for misuse and abuse, the structure of and force behind Federal and State level laws that regulate the prescription and distribution of prescription opioids is vitally important. While a profoundly complex constellation of laws govern the use of prescription opioids throughout the medical system, this particular study focuses on pharmacy-based opioid interventions and the management of prescription opioid misuse and abuse in the pharmacy setting. As a result, we focused on Federal laws that specifically govern how pharmacists handle prescription opioids.

In light of their long history of use in the United States, Federal regulation of the medical use of opioids has evolved over time. The Comprehensive Drug abuse Prevention and Control Act of 1970, commonly referred to as the Controlled Substances Act or CSA, created a system of regulations designed to govern the production, storage, and use of controlled substances, including both medications and illicit substances (Plank, 2011). As Table 2.2 illustrates, the CSA had a significant impact on how
substances with the potential for misuse and abuse are handled, and particularly how they are prescribed, dispensed, stored, and disposed of (Van Dusen et al, 2006; Plank, 2011). The impact of the CSA on prescription medications fell into four broad categories: Scheduling, Records Keeping Standards, Inventory Management, and Computerization of Prescription Information (Van Dusen et al, 2006).

Under the CSA, substances with potential for misuse and abuse were placed into five categories, known as Schedules. Schedule I substances include drugs and other chemicals that are simultaneously (1) known to have a great potential for misuse and abuse, and (2) known to have no proven medical applications (Van Dusen et al, 2006). Schedule II drugs (such as prescription opioids) are also prone to misuse and abuse, but drugs within this category have accepted medical applications (Van Dusen et al, 2006). Schedule III and Schedule IV drugs range in their potential for misuse and abuse, though the risk they present is significantly lower than substances included in Schedule I and II. Schedule V drugs present the least concern, and are thus subject to less scrutiny (Van Dusen et al, 2006).

While relatively uncommon, the CSA specifically described the process by which medical practitioners should handle substances that transition from Schedules II-V to Schedule I (For example, Methaqualone, or ‘Quaaludes’, transitioned from Schedule II to Schedule I in 1984) (Van Dusen et al, 2006). When the Schedule of a substance changes, all organizations in possession of said substance, such as pharmacies, should dispose of the drug properly (Van Dusen et al, 2006).
Table 2.2: Federal Laws That Regulate How Controlled Substances Are Dispensed: The Controlled Substances Act (Van Dusen et al, 2006)

<table>
<thead>
<tr>
<th>The Controlled Substances Act, or CSA, provided a legal framework for the management of substances with the potential for abuse or misuse. The CSA has had one of the most marked, direct impacts on pharmacy practice of any federal regulation to date.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Scheduling- Under the controlled substances act, controlled substances are placed in one of 5 categories.</td>
</tr>
<tr>
<td>1) Schedule I drugs cannot be handled by pharmacies. These substances have a great potential for abuse and currently have no recognized medical applications. When a substance is moved to Schedule I from another category, pharmacies must properly dispose of the drug or face penalties under the CSA.</td>
</tr>
<tr>
<td>2) Schedule II drugs, while exhibiting a high potential for abuse, have accepted medical applications. The CSA requires that Schedule II prescriptions must be written and signed by individual practitioners. Schedule II prescriptions cannot include refills.</td>
</tr>
<tr>
<td>3) The strength and addictive potential of Schedule III, IV, and V drugs vary, though considerable oversight and careful documentation of prescriptions filled for Schedule III, IV, and V drugs is still required. The principle difference between schedule III and IV drugs, compared to Schedule II, is that refills are allowed.</td>
</tr>
<tr>
<td>(B) Record Keeping- One of the most important components of the CSA involves record keeping. Every pharmacy must maintain complete, accurate, and up-to-date records for each controlled substance purchased, received, distributed, dispensed, or disposed of. All records must be retained for at least 2 years. The CSA also requires that records for Scheduled drugs must be maintained separately from other records, or in a form that is easily isolated and extracted from other records.</td>
</tr>
<tr>
<td>(C) Inventory- Pharmacies must take an inventory of controlled substances every 2 years.</td>
</tr>
<tr>
<td>(D) Computerization of Prescription Information- The CSA introduced the era of computerization of pharmacy records, establishing standard protocol for storage of prescription order information, distinct standards for management of refill orders for more addictive Schedule II drugs and less addiction Schedule III and IV drugs, and developing a standard set of information that must be included in computer based prescription records for Scheduled drugs (Full name and address of the patient, prescriber’s name and address, DEA registration number, the name of the prescription in question, the strength of the prescription, the dosage prescribed, the quantity of medication provided in the prescription, and the total number of refills authorized by the prescriber).</td>
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Failure to appropriately dispose of a re-Scheduled substance may result in financial penalties. It is important to note that these fines are relatively unique in the CSA, as they represent one of the few instances where the CSA explicitly called for financial or criminal penalties medical for practitioners rather than individuals caught illegally selling controlled substances or using Schedule I substances (Van Dusen et al, 2006). As a result of the explicit threat of financial consequences, or the “teeth” of this
portion of the legislation, practitioners have been particularly careful to comply with disposal related regulations (Van Dusen et al, 2006).

In addition to the categorization of controlled substances based upon their combined potential for misuse and abuse and their medical value, the CSA established clear record-keeping requirements for individuals tasked with prescribing, dispensing, and producing said substances. The CSA required that organizations that stock controlled substances, such as pharmacies, must maintain detailed, accurate, up-to-date records for every controlled substance purchased, received, distributed, dispensed, or disposed of within their organization (Van Dusen et al, 2006). The CSA mandated that pharmacies retain such records for at least 2 years. Furthermore, the CSA established explicit standards for the process by which pharmacies review inventory, requiring that a full review of the inventory of all Scheduled substances should occur at least once every two years (Van Dusen et al, 2006).

The CSA also developed the first Federal-level framework for the computerization of prescription information. First, the CSA established protocol for digitally documenting refill requests for Schedule III and IV substances, while explicitly prohibiting refill orders for Schedule II substances, instead requiring a new prescription for each round of treatment (Van Dusen et al, 2006). Second, the CSA provided a detailed summary of the information that must be included in computer-based prescription records for Scheduled drugs, including: The full name and address of the patient; the prescriber’s full name and address; the DEA registration number; the brand name, strength, dosage, and quantity of medication in each prescription; and the total number of refills authorized by the prescriber (Van Dusen et al, 2006). The standard for
computerized prescription information established by the CSA provided a framework for later record-keeping initiatives and Prescription Drug Monitoring Programs, or PDMPs.

2.6: The Importance of Professional Role: What Role Do Pharmacists Play in Controlling Access to Prescription Opioid Medications?

As a result of the opioid epidemic, the medical profession has undergone an enormous internal debate, challenging the traditional role of prescribers and dispensers in the prevention, identification, and treatment of prescription opioid misuse and abuse. As a result of this debate, medical institutions and pharmacy retailers have explored a broad variety of interventions designed to integrate misuse and abuse prevention, identification, and management into day-to-day practice. Through interventions such as urine screening, single-source prescriber and pharmacy partnerships, Prescription Drug Monitoring Programs (PDMPs), and increased availability of opioid overdose medications such as naloxone, medical institutions and retailers have made an effort to create a medical system that actively prevents, identifies, and treats prescription opioid misuse and abuse (Volkow & McLellan, 2011; Ross, 2016).

Interventions differ based on the role of the practitioner in question. In terms of prescription medication, medical professionals generally take on one of two roles: prescribers, or individuals involved in the identification of patient medical needs and the selection of a corresponding medication used to treat the condition in question, and dispensers, or individuals involved in reviewing and accurately filling the prescription requested by the prescriber (AACP, 2009). The first category, prescribers, includes individuals that prescribe medications, such as physicians and, in some states, nurse practitioners. The second category, dispensers, includes pharmacists, and in certain clinical settings, physicians with direct access to medications.
The responsibilities of prescribers and dispensers differ, as illustrated in Table 2.3, both in terms of professional duties and regulatory oversight. Prescribers serve a dual function, simultaneously identifying the medical needs of a patient, and, in instances where medication would be useful, selecting an over-the-counter or prescription medication that would effectively meet the medical needs of a patient. When selecting a medication, prescribers must consider a number of factors, including the patient’s pre-existing medical conditions, the other medications or supplements a patient is taking, and the potential risks associated with a particular medication.

Table 2.3: Contrast Between Prescriber and Dispenser Responsibilities (ASHP, 1999)

<table>
<thead>
<tr>
<th>Prescriber Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify patient condition</td>
</tr>
<tr>
<td>• Consider a variety of treatments for condition, weighing options based on the patient’s needs and medical history</td>
</tr>
<tr>
<td>• Inform patient of risks associated with various treatments</td>
</tr>
<tr>
<td>• Help patient choose treatment</td>
</tr>
<tr>
<td>• Write a prescription for medication or referral for other medical professional</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dispenser Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identify appropriate medication, or equivalent medication if not available</td>
</tr>
<tr>
<td>• Identify unusual or potentially dangerous dosages, and discuss with prescriber</td>
</tr>
<tr>
<td>• Fill medication based on the prescriber’s instructions</td>
</tr>
<tr>
<td>• Provide patients with instructions regarding dosage and safe use</td>
</tr>
<tr>
<td>• Provide patients with a warning of potential side effects and interactions</td>
</tr>
</tbody>
</table>

Dispensers, on the other hand, review of the medication and dosage requested by the prescriber. This is particularly critical, as research has shown that many opioid prescriptions are written without specific medical justification (Hagemeier et al, 2014). When a prescription appears medically inappropriate or otherwise questionable, pharmacists are expected to consult with the prescriber to review the prescription.
In addition to reviewing medication safety, pharmacists are expected to warn patients of the risks associated with each medication dispensed, including side effects, impaired reaction time, risk of overdose, and interactions with food, drink, or other medications (AACP, 2009). While patient counseling is an established component of pharmacy practice, the topics covered during counseling remain the subject of lively debate among pharmacy professionals. Risk of misuse and abuse is not generally included in counseling, as substance misuse, abuse and addiction are relatively new issues in pharmacy practice (Bartels, 2015). Within the profession, there is considerable debate surrounding the role pharmacists should play prevention, identification, and management of misuse and abuse. Differences of opinion are due, at least in part, to professional setting, which can be divided into two major categories: community (or retail) pharmacists, and hospital pharmacists, as illustrated on Table 2.4.

When working in a retail setting, pharmacists serve a specific community, providing care to a diverse array of patients with a variety of needs, ranging from general advice regarding the use of over-the-counter medications, to filling prescriptions (AACP, 2015). When operating in a hospital setting, pharmacists provide specialized care to patients with severe, often life-threatening conditions (ASHP, 1999).
Table 2.4: Characteristics of Community and Hospital Pharmacists (ASHP, 1997; AACP, 2009)

<table>
<thead>
<tr>
<th>Community/ Retail Pharmacists</th>
<th>Hospital/ Institutional Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Serve patients from a specific community</td>
<td>• Serve any patients obtaining care from their institution</td>
</tr>
<tr>
<td>• Provide advice to patients seeking OTC medications</td>
<td>• Provide advice to physicians regarding medication</td>
</tr>
<tr>
<td>• Provide advice to patients filling prescriptions</td>
<td>• Provide care to patients that are sick</td>
</tr>
<tr>
<td>• Work with patients that are healthy and those that are sick</td>
<td>• Provide care to patients with more serious conditions</td>
</tr>
<tr>
<td>• Provide care to patients with both mild and severe conditions</td>
<td>• Sometimes compound and customize medication formulations</td>
</tr>
<tr>
<td>• Generally dispense medications that are pre-formulated</td>
<td>• Ongoing monitoring and testing of patient use of medication</td>
</tr>
<tr>
<td>• Limited ability to monitor the outcome of patient medication use</td>
<td></td>
</tr>
</tbody>
</table>

Due to the specialized needs of the patients served by hospitals and other health care institutions, hospital pharmacists serve a limited advisory role, focusing instead on preparing or compounding patient medication regimens, monitoring patients for adverse responses to therapeutic interventions, and engaging in differential diagnosis in situations where medication is suspected as a complicating factor (ASHP, 1999). Due to their location, community pharmacists assist patients with the management of chronic conditions and treatment of mild intermittent conditions, in contrast with hospital pharmacists, who serve patients struggling with acute injury and illness.

2.7: Misuse and Abuse Prevention Through Professional Practice: What Strategies Can Pharmacists Use to PREVENT Misuse and Abuse?

Although the roles of community and hospital pharmacists differ, all pharmacists have unique opportunities to identify and assist patients struggling with misuse and abuse. The American Pharmacists Association (APhA) has helped to define the general
role that pharmacists might play in preventing, identifying and treating misuse and abuse (APhA, 2014; Cobaugh, 2017). Organizations specifically tailored to hospital pharmacists such as the American Society of Health System Pharmacists (ASHP) have developed specific steps that pharmacists operating in health care institutions might take to prevent and mitigate misuse and abuse as well (ASHP, 1997; AACP, 2009; Cobaugh, 2014).

As illustrated in Table 2.5, professional organizations such as ASHP and APhA have also attempted to encourage the use of interventions designed to prevent and treat substance misuse and abuse, including interventions specifically tailored to opioid misuse and abuse. Additionally, many pharmacies have integrated some aspects of substance misuse and abuse prevention and mitigation into organizational policy (CVS Health, 2015). As a result of differing institutional policies, integration and utilization of pharmacist-based substance misuse and abuse interventions varies, and compliance with Federal and state recommendations designed to curtail opioid misuse and abuse is inconsistent (Twillman et al, 2014). In spite of these limitations, pharmacist involvement in the prevention, identification, and management of patient misuse and abuse remains critical in combatting the opioid epidemic.
Table 2.5: A Comparison of APhA and ASHP Recommended Interventions for Substance Misuse and abuse (APhA, 2014; ASHP, 1997; AACP, 2009)

2.7.1: Patient Counseling: Counseling Patients on the Risks Associated With Prescription Misuse and Abuse

**APhA Recommended Substance Misuse and Abuse Interventions for All Pharmacists** *(APhA, 2014)*

1. Communicate health care professional roles and expectations, encouraging partnership between health care practitioners and law enforcement
2. Leverage the use of health IT through electronic prescribing of controlled substances and improvements to pharmacy data infrastructure
3. Strengthen Prescription Drug Monitoring Programs (PDMPs) through real-time PDMP uploads, integration of the use of PDMPs into workflow, and improvements of the interoperability of PDMP systems across states
4. Enhance provider education on prescription drug misuse and abuse
5. Increase patient education on prescription drug misuse and abuse awareness
6. Increase prescription drug take-back sites
7. Increase access to opioid reversal agents such as naloxone

**ASHP Recommended Substance Misuse and Abuse Interventions for Hospital Pharmacists** *(ASHP, 2015)*

1. Contribute to developing substance misuse and abuse prevention and assistance programs in health care organizations
2. Participate in public substance misuse and abuse education and prevention programs
3. Oppose the sale of alcohol and tobacco products by pharmacies
4. Improve systems designed to track controlled substance inventories
5. Partner with law enforcement to control substance misuse and abuse
6. Utilize PDMPs
7. Document new substance misuse and abuse behaviors and report emerging trends
8. Discourage prescribing practices that enable or encourage substance misuse and abuse
9. Collaborate with other health care providers to monitor patient substance use following discharge
10. Refer patients exhibiting substance misuse and abuse symptoms to rehabilitative care
11. Foster the development of substance misuse and abuse curriculum for pharmacists and educate peers
12. Assist substance misuse and abuse counselors by providing information on substance pharmacology
13. Conduct substance misuse and abuse research
14. Educate patients on storage, use, handling, and disposal of prescriptions
15. Assist in identifying individuals exhibiting substance misuse and abuse behaviors
16. Participate in interdisciplinary efforts to support health organization employees recovering from substance misuse and abuse and dependency
17. Support and encourage the recovery of peers with substance use disorders
18. Assist in the development of medication assisted drug detoxification
19. Provide continued pharmaceutical care for patients in treatment for substance misuse and abuse
20. Refuse to allow colleagues, students, or employees, including other health professionals, to work or practice while impaired by drugs
Patient education, provided through counseling, is a cornerstone of all pharmacy practice. In the process of filling any prescription, pharmacists are expected to offer patients counseling regarding the side effects, risks, and interactions associated with each medication (Schell, 2016). While many pharmacists repeat the information contained on the label of a medication during counseling, research suggests that providing patients with additional information improves patient outcomes, and prevents dangerous misuse (Lutz, 2015 Rickles et al, 2016). Counseling may include discussion of the role of medication in the patient’s treatment plan, establishment of reasonable treatment expectations, development of a timeline for transition from use of a particular medication, description of behaviors and activities that should be avoided for the duration of treatment, and the signs and consequences of misuse and abuse (Lutz, 2015; Genord et al, 2017).

Organizations such as the American Pharmacists Association (APhA) have encouraged the integration of substance misuse and abuse education into the counseling offered while dispensing many medications, particularly opioids (APhA, 2014). Additionally, regulatory agencies, including the Food and Drug Administration (FDA), regularly provide Risk Evaluation and Mitigation Strategies (REMS) for substances associated with misuse and abuse, overdose, or severe side effects. The purpose of REMS is to establish that the therapeutic benefits associated with a medication outweighs the risks associated with the drug (Stanos, 2012). In addition to the evaluation of risks and benefits, REMS provide clear direction to prescribers and dispensers on safe medication use (Stanos, 2012). Research has shown that without explicit instruction on appropriate use of medications, between 30% and 50% will misuse or abuse prescriptions, with
misuse and abuse resulting in an increased risk of overdose-related mortality and morbidity (Cameron et al, 2010; McDonough, 2013). By providing patients with clear directions on appropriate use of prescriptions, and by providing a warning regarding the addictive potential of each individual medication, pharmacists have a critical opportunity to empower patients to make healthier decisions while using medications (Termini, 1998; NIDA, 2016).

Pharmacists are also able to provide patients with passive warnings regarding the risks associated with a particular medication. Patient counseling provides particularly valuable opportunities for reinforcing counseling efforts with print material. Providing supplemental literature is a particularly important component of counseling considering patients absorb information in a variety of ways (Kear, 2011; Wick, 2015). Print materials cover counseling topics in greater depth, providing detailed information on side effects and risks associated with misuse and abuse (Gilchrist & Eder, 2016).

The FDA has recently required that in addition to this supplemental literature, immediate release (IR) opioids must be clearly labeled with warnings regarding the risk of misuse, abuse and overdose (Gilchrist & Eder, 2016). While such documentation and labeling is important supplementation of patient education via counseling, however, interactive patient counseling remains critical, as it provides patients with an opportunity to directly learn about risks associated with a medication and to ask related questions (Termini, 1998; Webb et al, 2008; Kear, 2011).

Federal and state regulations heavily influence the structure and utilization of patient counseling. Patient counseling is specifically mandated in The Omnibus Budget Reconciliation Act of 1990 (Van Dusen et al, 2006). The Omnibus Budget Reconciliation
Act of 1990, otherwise known as OBRA-90, sought to improve Medicaid patient outcomes by introducing safeguards into prescription dispensing to reduce the rate of drug interaction, overdose, misuse and abuse, and allergic reaction in Medicaid patients (Van Dusen et al, 2006). While the regulations introduced in OBRA-90 applied specifically to Medicaid patients, pharmacies generally serve mixed populations, including patients with Medicaid, Medicare, private insurance, and individuals without insurance. Consequently, state-level laws that sought to enforce OBRA-90 regulations were drafted in a manner that required that pharmacists follow OBRA-90 standards when dispensing to all patients (Van Dusen et al, 2006). As outlined in Table 2.6, OBRA-90 established standards for the dispensing process that fall into three general categories: Prospective Drug Utilization Review, which sought to identify potential problems with drug therapy; standards of patient counseling; and records retention standards (Van Dusen et al, 2006).

Under the OBRA-90, pharmacists and other individuals tasked with filling prescriptions were required to use a process called Prospective Drug Utilization Review, or ProDUR, which sought to identify potential problems with drug therapy. The ProDUR process required that pharmacists should screen patients for prescription-related problems including, but not limited to prescriptions that: are redundant, are contraindicated for patients with specific medical conditions, may interact with other medications, excessively large or small in relation to the medical condition, used for an inappropriate duration, may cause allergic responses, and prescriptions that may lead to misuse or abuse (Van Dusen et al, 2006).
Table 2.6: Federal Laws That Regulate How Pharmacists Counsel Patients (Van Dusen et al, 2006)

<table>
<thead>
<tr>
<th><strong>The Omnibus Budget Reconciliation Act of 1990</strong></th>
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<tr>
<td>While most federal regulation deals with how pharmacists handle pharmaceuticals, particularly controlled substances, the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) provided explicit direction for how pharmacists should interact with patients. Although the main goal of OBRA-90 was to save money by improving health outcomes, OBRA-90 sought to achieve these cost savings by establishing explicit pharmacist counseling obligations, outlining Prospective Drug Utilization Review (ProDUR) requirements, and establishing record-keeping standards.</td>
</tr>
<tr>
<td>(A) The ProDUR requirements were specifically established for pharmacists filling prescriptions for Medicaid recipients. ProDUR (and associated state level regulations such as those described in Item 4) sought to identify potential problems with drug therapy, specifically screening for:</td>
</tr>
<tr>
<td>1) Therapeutic duplication</td>
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<tr>
<td>2) Drug-disease contraindications</td>
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<tr>
<td>3) Drug-disease interactions</td>
</tr>
<tr>
<td>4) Incorrect drug dosage</td>
</tr>
<tr>
<td>5) Incorrect duration of treatment</td>
</tr>
<tr>
<td>6) Drug-allergy interactions</td>
</tr>
<tr>
<td>7) Clinical abuse/ misuse of medication</td>
</tr>
<tr>
<td>(B) OBRA-90 also established standards for patient counseling, specifically requiring that pharmacists must offer counseling on the unique drug therapy regimen of every Medicaid recipient filling a prescription.</td>
</tr>
<tr>
<td>(C) OBRA-90 also required that pharmacists serving Medicaid patients must make reasonable efforts to obtain, record, and maintain relevant information on the treatment history of Medicaid patients.</td>
</tr>
<tr>
<td>While OBRA-90 gave directives specific to the treatment of Medicaid patients in a pharmacy setting, the overall result was that similar care should be rendered to all patients. Consequently, states generally established the same standards of practice for all patients, including ProDUR, counseling, and documentation of treatment history and outcomes.</td>
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</table>
The OBRA-90 created a standard for patient counseling, introducing consistency to a system previously governed by a variety of state level regulation and pharmacy board standards. Patient counseling requirements established by OBRA-90 included: offering patient-specific counseling tailored to the unique drug therapy regimen of the patient, offering counseling every time a patient fills a prescription, counseling on proper use and potential side effects, and providing patients with supplemental material detailing the known side effects of the medication in question (Van Dusen et al, 2006). OBRA-90 also established clear records retention standards, mandating that pharmacists should make reasonable efforts to obtain any new information relevant to the patient’s treatment, record any side effects or adverse outcomes associated with treatment, and maintain this information in an organized manner (Van Dusen et al, 2006).

At the state level, OAC section 4729-5-22, summarized in Table 2.7, offers specific guidance for the process pharmacists should use to counsel patients (OAC, 2011; State of Ohio Board of Pharmacy, 2017). Pharmacists are required to offer counseling to patients or caregivers whenever a prescription is filled, though this particular regulation does not require pharmacists to provide patients with a description of what counseling might entail. While patients can refuse counseling, pharmacists are required to document said refusal in the presence of the patient or caregiver (Ohio Administrative Code. § 4729-5-22, 2011). While 4729-5-22 requires documentation of refusal, the form and retention requirements for said documentation are not explicitly described.

Under 4729-5-22, a pharmacist, or an intern operating under the supervision of a pharmacist, will provide counseling on the following topics: The name and description of the drug; the dosage, form, route of administration, and duration of drug therapy; the
intended use of the drug and expected effects; special directions and precautions for preparation, administration, and use by the patient; common adverse effects, interactions, and contraindications that might occur as well as strategies to avoid them; techniques for self-monitoring drug therapy; proper storage; prescription refill information; actions to be taken in the event of a missed dose; and the pharmacist’s comments on the patient’s specific therapeutic regimen (Ohio Administrative Code. § 4729-5-22, 2011).

Table 2.7: Ohio Laws That Regulate How Pharmacists Counsel Patients (Ohio Administrative Code. § 4729-5-22, 2011)

A) Pharmacists or designees (such as an intern) shall personally offer to counsel patients or caregivers whenever a prescription, whether new or a refill, is dispensed. Pharmacists aren’t required to counsel patients or caregivers if the offer of counseling is refused, or if there is no response to the written offer of counseling. If counseling is refused, the pharmacist must document refusal in the presence of the patient or caregiver. If the patient or caregiver is not physically present (e.g. they are picking up a prescription), the offer to counsel will be made by telephone or in writing.

B) A pharmacist, an intern under the supervision of a pharmacist, shall counsel the patient or caregiver on the following topics:

1. The name and description of the drug;
2. The dosage form, dose, route of administration, and duration of drug therapy;
3. The intended use of the drug and the expected action;
4. Special directions and precautions for preparation, administration, and use by the patient;
5. Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;
6. Techniques for self-monitoring drug therapy;
7. Proper storage;
8. Prescription refill information;
9. Action to be taken in the event of a missed dose; and
10. The pharmacist's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.
While 4729-5-22 establishes standard counseling practices, it is important to note that risk of misuse and abuse or overdose is not included as a subject of counseling. It is also important to note that pharmacists are not required to discuss appropriate disposal of unused medication. Given that roughly 50% of individuals with opioid use disorders misuse and abuse the prescriptions of family and friends, counseling patients on the risks associated with keeping and sharing unused medication and strategies for disposal may prove essential to combatting the opioid epidemic (McCauley et al, 2013; SAMHSA, 2016).

2.8: Misuse and Abuse Management Through Professional Practice: What Strategies Can Pharmacists Use to IDENTIFY and MANAGE Misuse and Abuse?

In addition to the role that pharmacists play in providing counseling, pharmacists throughout the country have used their unique position in the medical system to identify patients struggling with misuse and abuse and connect them to critical resources. Although pharmacist involvement in misuse and abuse management is a subject of ongoing debate, interventions that allow pharmacists to monitor patient behavior for signs of misuse and abuse provide an additional level of scrutiny. When paired with interventions that allow pharmacists to direct patients to treatment resources, pharmacists are empowered to respond proactively to suspected misuse and abuse. Finally, interventions that allow provision of medications that treat opioid overdose, such as naloxone, empower pharmacists to help patients take steps to prevent opioid fatalities, while introducing a powerful opportunity to discuss the serious risks associated with opioid misuse and abuse (Burke, 2011; O’Shea, 2016).
2.8.1: Referral: Connecting Patients Suspected of Misuse and Abuse to Treatment

Direct interaction with patients offers pharmacists an opportunity identify patients exhibiting behaviors associated with prescription opioid misuse and abuse through observation. When patients exhibit urgency, irritability, or anxiety, pharmacists have an opportunity to assess this behavior in relation to patient’s medication regimen (CDC 3, 2015). When a pharmacist identifies behavior associated with misuse and abuse in a patient using potentially addictive medications, they can refer patients to local detox centers, rehabilitation programs, and support groups (Islam & McRae, 2014; Hagemeier et al, 2015). Unfortunately, patients may take offense at the suggestion that they need treatment, which may introduce conflicts between pharmacists and patients that are difficult to navigate (Islam & McRae, 2014).

2.8.2: Prescription Drug Monitoring Programs (PDMPs): Monitoring Drug Seeking Behavior and Proactively Responding

In addition to the physical and psychological behaviors described above, patients struggling with opioid use disorders often exhibit a pattern of drug-seeking behavior that is far more difficult for individual practitioners to recognize. Identification is difficult, in large part, as drug-seeking behaviors occur over time, within the medical system as a whole. Drug-seeking behaviors, as outlined in Table 2.8 may include: attempts to obtain overlapping or pharmacologically similar prescriptions from multiple providers and pharmacies, taking high daily doses of prescription painkillers, attempting to fill one prescription multiple times, attempting to fill a prescription that is purportedly lost or stolen, or frequently changing medical providers (CDC, 2015).
Because drug-seeking behavior generally occurs over time, within a large and diffuse medical system, identification of such behavior is particularly difficult, and likewise, particularly essential (CDC, 2015). Prescription Drug Monitoring Programs (PDMPs), programs designed to track prescription and dispensing of controlled medications, have proven effective in identifying these drug-seeking behaviors. The goal of PDMPs is to identify illicit activities broadly known as ‘diversion’ (Deyo et al, 2013).

Traditionally, PDMP-traceable diversion is fivefold: first, PDMP users can identify substance misuse and abuse occurring through “doctor shopping” practices, including obtaining multiple prescriptions through multiple doctors; second, PDMP users can identify instances of drug theft from pharmacies; third, PDMP users can identify instances of prescription duplication or forgery; forth, PDMP users can identify the illegal sale of prescriptions; and fifth, PDMP users can identify the illegal sale of the drugs themselves (Deyo et al, 2013). PDMPs can also be used to identify legal drug-seeking behaviors, however, a subject that will be discussed in depth below.

Prescription Drug Monitoring Programs differ based upon the circumstances under which PDMPs must be consulted, and the specific medical practitioners compelled to reference PDMP systems. In general, PDMP laws either require that pharmacists
consult a PDMP when filling a prescription, or require that prescribers consult PDMPs prior to writing a prescription AND that pharmacists consult a PDMP when filling a prescription (Vestal, 2016). Typically, PDMPs involve a centralized database of dispensed medications, documenting the drug name, strength, quantity, dispensing date, prescriber name, and patient name. This information is then made available to other health care providers and law enforcement officials (Deyo et al, 2013).

The Ohio PDMP system is available to both prescribers and dispensers. As illustrated in **Table 2.9**, Section 4729-5-20 of the Ohio Administrative Code, which deals with the Ohio Automated Rx Reporting System (OARRS), provides explicit guidelines for the review process pharmacists should use when dispensing prescriptions, and particularly rigorous review standards associated with substances scheduled under the CSA.

In 4729-5-20, prior to dispensing, pharmacists are required to review the patient profile to identify incorrect dosages, therapeutic duplication, drug-disease contraindications, drug-drug interactions, drug-allergy risks, and inappropriate duration of treatment (Ohio Administrative Code. § 4729-5-20, 2017). Additionally, 4729-5-20 requires that pharmacists use OARRS to request and review the patient’s file to determine whether there are any particular warning signs of misuse and abuse (Ohio Administrative Code. § 4729-5-20, 2017).
Table 2.9: Ohio Laws That Regulate Pharmacist Use of the Ohio Prescription Drug Monitoring Program, the “Ohio Automated Rx Reporting System” (OARRS) (Ohio Administrative Code, § 4729-5-20, 2017)

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<table>
<thead>
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<tbody>
<tr>
<td>A) Prior to dispensing any prescription, a pharmacist shall review the patient profile to identify</td>
<td></td>
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<tr>
<td>(1) Over-utilization or under-utilization;</td>
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</tr>
<tr>
<td>(2) Therapeutic duplication;</td>
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</tr>
<tr>
<td>(3) Drug-disease state contraindications;</td>
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<td>(4) Drug-drug interactions;</td>
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<td>(5) Incorrect drug dosage;</td>
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<td>(6) Drug-allergy interactions;</td>
<td></td>
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<tr>
<td>(7) Abuse/misuse;</td>
<td></td>
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<td>(8) Inappropriate duration of drug treatment; and</td>
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<tr>
<td>(9) Food-nutritional supplements-drug interactions.</td>
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<tr>
<td>B) Upon identifying any of the aforementioned issues, pharmacists shall take appropriate steps to avoid or resolve the potential problem, including requesting and reviewing an OARRS report or another state’s report, and consulting with the prescriber and/or counseling the patient.</td>
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<tr>
<td>C) Review will use standards including peer-reviewed medical literature, American hospital formulary service drug information, and United States pharmacopeia drug information.</td>
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<tr>
<td>D) Prior to dispensing an outpatient prescription for drugs listed in 4729-37-02 (All Schedule II, III, IV, and V controlled substances, including prescription opioids), pharmacists shall, at minimum, request and review an OARRS report covering at least a one year time period, including a border state’s information when the pharmacist is practicing in a county bordering another state (if available), or if the patient meets any of the following criteria:</td>
<td></td>
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<tr>
<td>(1) A patient adds a different or new reported drug to their therapy</td>
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<tr>
<td>(2) An OARRS report has not been reviewed for that patient in the past year</td>
<td></td>
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<tr>
<td>(3) A prescriber is located outside the usual pharmacy geographic area;</td>
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<tr>
<td>(4) A patient is from outside the usual pharmacy geographic area;</td>
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</tr>
<tr>
<td>(5) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;</td>
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<tr>
<td>(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.</td>
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<tr>
<td>E) In the even an OARRS report isn’t available, the pharmacist shall use professional judgment to determine whether dispensing is in the patient’s best interest.</td>
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<tr>
<td>F) A pharmacist may use a delegate to request an OARRS report.</td>
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<tr>
<td>G) For prescriptions to be valid, they must be issued for legitimate medical purpose by an individual prescriber acting in the normal course of their professional practice. A pharmacist is not required to dispense a prescription of suspicious origin.</td>
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</table>
The OARRS guidance in 4729-5-20 does explicitly direct pharmacists to remain watchful for signs of substance misuse and abuse such as over-utilization, early refills, physical intoxication, or requests for medication based upon identifying marks or street name (Ohio Administrative Code, § 4729-5-20, 2017). It does not, however, differentiate between the physical symptoms of dependency such as irritability, intoxication, sedation, or urgency and systemic drug-seeking behaviors. Preferably, pharmacists should be encouraged to watch for physical signs of misuse and abuse during face-to-face interactions with a patient, and should also be encouraged to scan the OARRS report for the systemic behaviors that might indicate drug-seeking behavior.

PDMP systems have become increasingly common. As of 2013, forty-four states implemented PDMPs, and in 2016, five additional states introduced PDMP systems (Vestal, 2016). As of April 2017, Missouri introduced plans to implement a PDMP system. As illustrated in Figure 2.12, PDMP systems primarily vary based upon the practitioners required to consult the system. Sixteen states, including Ohio, require that both prescribers and dispensers consult PDMP systems, while the remaining 33 states only require pharmacists to consult PDMP systems (Vestal et al, 2016). It is important to note that this figure, created in 2015, does not account for the new PDMP law introduced in Missouri.
One of the major concerns associated with increased dependence on Prescription Drug Monitoring Programs stems from the state-specific nature of PDMP regulations and software. Given that each state generally develops a proprietary prescription drug monitoring system, many PDMPs are not technologically compatible (Bharel, 2016). This makes sharing data extremely difficult. Given that system-wide drug seeking behavior is a key characteristic of misuse and abuse, and given the additional concerns associated with illicit inter-state transportation of legally obtained prescription medications, the need for PDMP compatibility is clear (CDC, 2017). Efforts are already underway to improve compatibility and enable interconnectivity through the adoption of technologically compatible PDMP systems (Bharel, 2016).
Two specific PDMP systems have come to dominate the PDMP market: PMPi and RxCheck. As illustrated in Figure 2.13, 23 states have either RxCheck or PMPi systems, 13 states are now able to connect to the PMPi based systems through MassPAT, and 6 states are implementing PMPi based systems (Bharel, 2016). Due to a coordinated effort from both PMPi and RxCheck, both systems will soon be able to connect and effectively coordinate. Eight remaining states have legal barriers preventing data sharing, or in the case of Missouri, have no PDMP system.

In spite of these technological improvements, there are a number of the other problems associated with PDMPs. First, while physicians and a select handful of other medical professionals are uniquely endowed with the ability to write prescriptions, PDMPs introduce a level of scrutiny that physicians find disconcerting (Hoppe et al, 2018).
PDMPs that identify substance misuse and abuse and over-prescription may conflate fraudulent prescribers with physicians that simply lack the training necessary to identify and respond to medication misuse and abuse. Over 40% of physicians struggle to discuss the possibility of substance misuse and abuse with patients, and over 90% fail to identify misuse and abuse symptoms, suggesting that lack of training may heavily influence problematic prescribing practices (Islam & McRae, 2014). Second, the possibility of criminal investigation triggered by PDMPs may influence physician behavior. Given the growing number of high profile criminal prosecutions targeting fraudulent prescribers, many physicians have argued that the scrutiny associated with PDMPs may drive prescribers to underutilize controlled substances such as opioids due to fear of legal repercussions (Islam & McRae, 2014). This “chilling effect” may lead physicians to avoid using opioid medications and other controlled substances in therapeutically appropriate situations, driving physicians to use less effective medications that have more severe side effects (Hoppe et al, 2014; Islam & McRae, 2014).

Third, patients may have to contend with a number of financial and emotional impacts associated with PDMPs. If physicians are reluctant to write prescriptions with refills, patients may worry about increased costs associated with frequent office visits (Islam & McRae, 2014). Furthermore, when patients with chronic or severe conditions receive prescriptions large enough or frequent enough to prompt PDMP response, subsequent inquiries by pharmacists may be embarrassing or alienating (Islam & McRae, 2014). Fourth, PDMPs only identify prescription drug misuse and abuse already in progress. Given the considerable risks associated with even brief periods of substance
misuse and abuse, including neurological damage and overdose, prevention of substance misuse and abuse is preferable to identification and management (SAMHSA, 2014).

2.8.3: Paired Prescription of Naloxone: Providing Naloxone With Each Opioid Prescription

While interventions would ideally prevent misuse and abuse through appropriate counseling, identify addictive behavior through the effective use of PDMPs, and treat misuse and abuse through referral to local treatment resources, pharmacists also have the opportunity to prevent life-threatening overdose through the provision of medications used to treat acute opioid overdose such as naloxone, sold under the brand names Evzio and Narcan (Mehmeti, 2016). In the event of acute opioid overdose, the greatest threat to patient survival is depression of the central nervous system, resulting in reduced respiration, decreased heartbeat, and subsequent hypoxia (Edwards & Read, 2014; Mehmeti, 2016). Rapid medical treatment with naloxone can effectively treat these symptoms, significantly reducing the risk of death (Drug Policy Alliance, 2015; O’Shea, 2016). Until recently, naloxone was primarily available through first responders and emergency rooms. In the last decade, several major metropolitan areas experimented with distributing take-home naloxone kits through extant syringe exchange programs (Drug Policy Alliance, 2015). Unfortunately, provision of naloxone through syringe exchange programs only provided access to heroin users. Given that more than twice as many deaths are attributed to prescription opioids than heroin, efforts were made to expand naloxone availability to prescription opioid users (Drug Policy Alliance, 2015).

Initiatives designed to distribute naloxone kits through public health departments and community-based organizations have resulted in broad increases in naloxone availability (Ross 2, 2015). In addition to the community and public health department
based distribution sites, several states have experimented with novel pharmacy-based naloxone distribution programs. New York, Rhode Island, and Washington have introduced initiatives that allowed pharmacies to partner with physicians, enabling pharmacists to directly dispense naloxone to patients filling opioid prescriptions (Drug Policy Alliance, 2015). These novel programs automatically pair opioid prescriptions with a prescription for naloxone, ensuring that individuals receiving an opioid prescription large enough to potentially result in overdose obtain an overdose reversal agent and instruction on its appropriate use as prophylaxis (Drug Policy Alliance, 2015; Fudin, 2014; Green et al, 2015).

Community-based, public health department-based, and pharmacy-based naloxone distribution initiatives have resulted in a 243% increase in the number of naloxone distribution sites between 2010 and 2015 (Ross 2, 2015). These distribution efforts have resulted in a 187% increase in the number of individuals accessing naloxone and a 160% increase in the number of reported drug overdose reversals (Ross 2, 2015). It is increasingly clear that increased naloxone availability saves lives, and with this evidence in mind, pharmacists have explored the possibility of expanding availability of naloxone from the population of individuals obtaining opioid prescriptions, to the general public.

2.8.4: Naloxone Over the Counter: Dispensing Naloxone Without a Prescription

In 2015, states such as California, New Mexico, and Vermont introduced programs that allow pharmacists to provide naloxone, particularly formulations designed to be administered intranasally, without a prescription or physician oversight (Drug Policy Alliance, 2015). This enables access to naloxone for all opioid users, including
patients with legally obtained opioid prescriptions, individuals using illegally obtained prescription opioids purchased through dealers, individuals using medication given to them freely by friends and family, and individuals using illicit substances such as heroin (Drug Policy Alliance, 2015; Editorial Board, 2017). Naloxone distribution interventions have rapidly grown in popularity, as noted in Figure 2.14.

**Figure 2.14: Map of Pharmacy-Based Availability of Naloxone (HealthPopuli, 2016)**

As of 2016, 14 states, including Ohio, have passed statewide naloxone protocol allowing OTC distribution of naloxone or prescriptive authority for pharmacists, while 21 states have established laws allowing pharmacists to dispense naloxone under a standing order from a physician (HealthPopuli, 2016). Another 6 states have introduced collaborative practice provisions that allow pharmacists to dispense naloxone based upon an ongoing agreement with a prescriber (HealthPopuli, 2016). The nine remaining states comply with Federal standards that require a prescription to obtain naloxone.

The introduction of programs designed to expand access to naloxone through paired prescription and over-the-counter designation has generated a blend of concern
and optimism among pharmacists (Green et al, 2015). On one hand, the lifesaving potential of expanded naloxone access is well-established, and expanded availability increases utilization by reducing the stigma associated with obtaining naloxone (Wermeling, 2010; Green et al, 2017). On the other hand, legal concerns regarding the accountability of individuals administering emergency naloxone, particularly those engaged in substance misuse and abuse as well as individuals rescued from overdose, have been the subject of intense legal debate (Burris et al, 2009).

In the case of emergency naloxone administration, lay individuals observing an overdose may hesitate to use the medication or contact emergency services due to a perception that they could be held criminally liable for any illegal behavior they have witnessed or participated in (Burris et al, 2009). While a number of Good Samaritan laws and legal protections have been introduced to alleviate these concerns, expanded access to naloxone must be paired with legal protections and effective public education campaigns designed to inform friends and families of opioid users of the function, effects, and legal consequences of naloxone administration (Ohio Injury Prevention Partnership, 2013). Individuals obtaining naloxone must understand the signs and symptoms of an opioid overdose, the appropriate administration of naloxone, the limitations of the medication, and the need for appropriate transition of overdose patients to emergency medical care. Pharmacists involved in any opioid misuse and abuse interventions utilizing naloxone must integrate counseling components, regardless of prescription or over-the-counter access.

In early 2016, the Federal government introduced $1 Billion in designated Federal funding designed to bolster pilot programs and evaluation of the effectiveness of various
opioid misuse and abuse mitigation strategies (Hunter, 2016). This investment has been met with broad support from advocacy organizations, medical professionals, and private entities alike (Hunter, 2016; Hove, 2016). In light of the emergence of new funding, a number of pilot programs have been introduced in states with particularly high rates of prescription opioid and heroin overdose. One of the most complex and heavily debated initiatives spurred by renewed Federal investment is an initiative introduced in February of 2016 by CVS Pharmacies.

Beginning in March of 2016, CVS pharmacies implemented a pilot program through which naloxone was made available without a prescription (Hove, 2016). While this strategy has been previously attempted in states such as California, New Mexico, and Vermont, the Ohio initiative was unique due to the particularly high rates of opioid overdose in the state, as well as the broad availability of naloxone through a private pharmacy chain rather than the more limited availability of naloxone previously offered through pharmacies directly associated with substance treatment clinics (Drug Policy Alliance, 2015; Hove, 2016). Following this pilot program, Ohio passed HB170, allowing pharmacists to dispense naloxone under ongoing authorization of a physician or a Board of Health, and establishing clear legal protections for individuals who administer naloxone in an emergency (Healthpopuli, 2016; Ohio Department of Health, 2017; Ohio Revised Code, 2017).

2.9: Categorizing These Strategies as Distinct Pharmacy-Based Opioid Misuse and Abuse Interventions

In summary, the opioid misuse and abuse interventions generally used by pharmacists fall into five major categories: (1) Pharmacists counseling patients on the risks associated with opioid misuse and abuse, including addiction and overdose, (2)
pharmacists referring patients to drug treatment programs within the community, (3) pharmacists utilizing Prescription Drug Monitoring Programs (PDMPs) to track the validity of prescriptions, (4) pharmacists providing emergency opioid overdose treatments such as naloxone with every opioid prescription through collaborative partnerships with prescribers, and (5) pharmacists providing naloxone over the counter, without a prescription. Each of these interventions, outlined in Table 2.10, have been used in select states, communities, and pharmacy chains. Prior to broader implementation, it is essential to identify barriers to implementation and develop strategies to overcome these barriers in the pharmacy setting.

Table 2.10: Categories of Opioid Misuse and Abuse Interventions Commonly Used By Pharmacists

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Pharmacists counseling clients on the risks associated with opioid</td>
<td>Pharmacists counseling clients on the risks associated with opioid misuse and abuse, including addiction and overdose.</td>
</tr>
<tr>
<td>misuse and abuse, including addiction and overdose</td>
<td></td>
</tr>
<tr>
<td>(2) Pharmacists referring clients to drug treatment programs within the</td>
<td>Pharmacists referring clients to drug treatment programs within the community.</td>
</tr>
<tr>
<td>community</td>
<td></td>
</tr>
<tr>
<td>(3) Pharmacists utilizing Prescription Drug Monitoring Programs (PDMPs)</td>
<td>Pharmacists utilizing Prescription Drug Monitoring Programs (PDMPs) to track the validity of prescriptions and identify potential drug seeking behavior.</td>
</tr>
<tr>
<td>to track the validity of prescriptions and identify potential drug</td>
<td></td>
</tr>
<tr>
<td>seeking behavior</td>
<td></td>
</tr>
<tr>
<td>(4) Pharmacists providing emergency opioid overdose treatments such as</td>
<td>Pharmacists providing emergency opioid overdose treatments such as naloxone with every opioid prescription through collaborative partnerships with prescribers.</td>
</tr>
<tr>
<td>naloxone with every opioid prescription through collaborative partnerships</td>
<td></td>
</tr>
<tr>
<td>with prescribers</td>
<td></td>
</tr>
<tr>
<td>(5) Pharmacists providing naloxone over the counter, without a prescription</td>
<td>Pharmacists providing naloxone over the counter, without a prescription.</td>
</tr>
</tbody>
</table>

2.10: Barriers to Successful Intervention Use: How Do Pharmacist and Patient Attitudes Impact the Success of These Interventions?

Several barriers inhibit the success of the aforementioned interventions. First, pharmacists must fully understand substance misuse and abuse (Blow and Barry 2012; Reidy et al, 2014). Second, pharmacists must accept that preventing and managing patient substance misuse and abuse is a relevant component of pharmacy practice, and must be willing to take the time to engage with patients on the subject of misuse and
abuse (Hagemeier et al., 2014; Murphy et al., 2016). Third, patients must be receptive to pharmacist involvement in the prevention, identification, and treatment of substance misuse and abuse (Foreman, 2013).

The quality and quantity of addiction-specific training that pharmacists receive varies widely. A recent survey of 1,000 pharmacists practicing in Pennsylvania found, for instance, that 29% of pharmacists received no formal training on misuse and abuse, while an earlier study of 484 pharmacists in Florida found that 29.2% reported the same deficits (Tomko & Giannetti, 2013; Lafferty et al., 2006). Without training in the science of addiction, pharmacists struggle to effectively identify and care for patients struggling with substance misuse and abuse (Lafferty et al., 2006; Blow and Barry, 2012; Reidy et al., 2014).

Without a strong grasp of the underlying neurochemistry and physiology of addiction, compassionate care is difficult to provide. In the same survey of Pennsylvania pharmacists, over a third reported that they felt little sympathy for patients struggling with substance misuse and abuse (Tomko & Giannetti, 2013). When pharmacists understand the medical basis of addiction, they are better able to develop compassion for patients struggling with this condition, they are far more willing to take time from a busy pharmacy practice and expend the effort necessary to handle this complex issue (Tomko & Giannetti, 2013).

Successful implementation of these programs also requires pharmacists to accept misuse and abuse identification and management as a relevant component of pharmacy practice (Cochran et al., 2013). Compliance may be hard to achieve if pharmacists believe that recommended practices designed to prevent substance misuse and abuse, educate via
counseling, and assist in patient recovery fall outside of acceptable professional conduct (Hagemeier et al, 2014). Furthermore, interventions designed to identify and treat substance misuse and abuse often involve some measure of direct confrontation. Direct inquiries regarding misuse and abuse, for instance, may lead patients to feel either embarrassed or harassed, creating discomfort for both the practitioner and the patient (Islam & McRae, 2014).

In addition to issues surrounding pharmacist training and compliance, the success of pharmacy-based interventions is heavily influenced by patient receptivity to substance misuse and abuse interventions. As regulatory oversight of potentially addictive medications increases, patients have expressed justifiable concerns regarding their continued ability to obtain necessary medications in a timely, private, and efficient manner (Anson, 2014). For individuals with a physical or neurological dependence on medication, due to either medical necessity or addiction, efforts to limit access to potentially addictive medications can result in tension between pharmacists and patients (Foreman, 2013). Due to the increasing backlash against regulatory oversight of prescription medications, additional exploration of the patient perspective on substance misuse and abuse interventions is encouraged (Goodin et al, 2011). By encouraging patient and pharmacist acceptance of interventions through educational campaigns and training, it is possible to improve both patient and practitioner adoption of interventions and expand compliance.

Previous efforts to improve pharmacist engagement with misuse and abuse prevention and identification interventions have largely focused on strategies to increase utilization of patient counseling and PDMPs (Tomko & Giannetti, 2013). Participation in
training programs specifically designed to help pharmacists identify substance misuse and abuse is generally correlated with greater acceptance of pharmacist-initiated substance misuse and abuse interventions (Tomko & Giannetti, 2013; Fleming et al, 2014). In addition to training, actual experience working with patients struggling with substance misuse and abuse increased practitioner participation in and support of substance misuse and abuse intervention use (Tomko & Giannetti, 2013). Other studies have revealed that organizational standards and professional norms increase the likelihood of practitioner utilization of drug monitoring tools (Gavaza et al, 2013).

Overall, research suggests that professional support of pharmacist-initiated substance interventions is influenced by the training pharmacists receive in substance misuse and abuse identification and treatment, the organizational policy and professional norms that support active involvement in substance misuse and abuse identification and treatment, and repeated interaction with patients struggling with substance misuse and abuse.

Given that patient receptivity and compliance is essential to the success of an intervention, patient acceptance of pharmacist involvement in substance misuse and abuse interventions may provide valuable insight into the problems and potential associated with specific interventions (NIDA 2, 2015). Due to the important role that individual medical history and substance use behavior plays in patient receptivity to substance misuse and abuse interventions, a rigorous assessment of patient acceptance of specific pharmacist based interventions should also evaluate the impact that these characteristics have on patient attitudes (NIDA 2, 2015).

While there is evidence that patient counseling and use of PDMPs are generally accepted within the pharmacist community, patient acceptance of these interventions has
received little scrutiny. Additionally, the variety of pharmacist-initiated substance misuse and abuse interventions extends well beyond patient counseling and PMPD use. Given a growing body of research that suggests the potential benefits of prophylactic provision of overdose medication and referral to treatment programs, and given that low acceptance among both pharmacists and patients can serve as a barrier to implementation, it is important to evaluate the acceptance of pharmacist-initiated substance misuse and abuse interventions among pharmacists and patients struggling with opioid use disorders alike.

To identify pharmacy-based interventions with the greatest acceptance among both pharmacists and detox patients, this study examined three research questions: which interventions are most acceptable to pharmacists, which interventions are most acceptable to patients, and which interventions produce statistically significant agreement on acceptability when both pharmacist and patient attitudes are compared.
CHAPTER 3

Methods

Given the severity of the opioid epidemic in the state of Ohio, this study focused on the attitudes of Ohio-based pharmacists and patients living with substance use disorders in Ohio, specifically exploring pharmacist and detox patient acceptance of five general pharmacy-based opioid misuse and abuse interventions: counseling patients on the addictive potential of opioids when filling opioid prescriptions, utilization of PDMP systems to identify patient drug-seeking behavior, referral of patients exhibiting opioid misuse and abuse behaviors to local support programs, paired prescription of naloxone with all opioid prescriptions, and over-the-counter provision of naloxone. The goal is to answer three essential research questions: which interventions are most acceptable to pharmacists, which interventions are most acceptable to patients, and which interventions produce statistically significant agreement on acceptability when both pharmacist and patient attitudes are compared.

3.1: Recruitment Methodology for Pharmacists

To answer the first research question, the researcher surveyed Ohio pharmacists using the Qualtrics online survey distribution system. The target population (discussed in detail below) included all board certified Ohio pharmacists with a working email address. Respondents were recruited using an email that (1) summarized the purpose of the study, (2) explicitly outlined incentives associated with the study, and (3) provided a link to the
web-based survey. All responses were entirely anonymous, and each completed survey was identified using case number associated with the chronological order of the response.

To encourage response, email recipients were offered the opportunity to register for a gift card drawing following the completion of the survey. Respondents were provided a link to a secure random drawing management website, Gleam, which would maintain the anonymity of each entrant throughout the drawing process. Each respondent profile was then assigned a random number, and on the date of the prize drawing, Gleam randomly selected winners from this pool, with no direct selection on the part of the researcher.

To reach an appropriate sample size, the researcher contacted the Ohio Board of Pharmacy and requested contact information for all Ohio pharmacists with current board certification. The Board provided a list of 14,209 email addresses, with no additional other identifying information. This email list was then uploaded to Qualtrics, as bulk actions through Qualtrics ensure that the researcher cannot trace individual survey recipients or their responses. Qualtrics assigned each email a coded hyperlink to the survey, to trace response. This was essential to maintaining anonymity. On December 19, 2016, the researcher sent out the query email via Qualtrics, included in Appendix C, with a description of the survey, a description of the incentives, and a link to the survey itself. A reminder email was sent on January 3rd, 2017, to all recipients who had not used their coded hyperlink. Of the full list of emails, 11,540 worked, while the remaining emails were returned due to either being inactive, or due to an error from the server. The survey window remained open until January 20, 2017.
3.2: Measures for Pharmacists

The pharmacist survey, attached in full in Appendix D, captured the following background information on the pharmacist: basic demographic data, information on the professional experience of the pharmacist, descriptive information on the type of pharmacy the pharmacist was employed at during the survey administration, and information on the community the pharmacist practiced in. The pharmacist survey also examined the respondent’s background in substance misuse and abuse and addiction management, including: their training in substance misuse and abuse and addiction, the misuse and abuse related programs and policies specific to their employer, their personal experience with misuse and abuse in their pharmacy, strategies they have used to identify and manage suspected misuse and abuse, and information on the frequency with which they encounter misuse and abuse in their practice. To assess the relative acceptability of the interventions described above, pharmacists were also asked to quantify their support of or opposition to each intervention using a 5 point Likert scale. Pharmacists were also given the opportunity to provide detailed qualitative descriptions of the perceived barriers to successful execution of each intervention and the potential problems associated with each intervention.

3.3: Recruitment Methodology for Patients

To identify interventions with the greatest potential to combat this deadly epidemic, information from patients is also critical. Patients dealing with misuse and abuse present a particularly challenging target for opioid misuse and abuse interventions. In light of the physiological and psychological produced by the cycle of misuse and abuse, the urgency with which individuals addicted to opioids seek their drug of choice,
and the unique perspective of patients who have completed the detox process, the researcher narrowed the patient population down to a particular group: individuals currently enrolled in a drug treatment program.

To directly answer the second research question and develop a sufficiently large sample of patients to answer the third research question, the researcher reached out to Quest Recovery and Prevention Services campus in Massillon. Located in Stark, Ohio, the Quest campus provides drug treatment services to individuals struggling with opioid misuse and abuse, alcohol dependency, and addiction to a variety of other drugs. Services fall into three broad categories: in-patient, intensive treatment in a residential setting; outpatient programs involving a combination of medication, counseling, and group based therapy; and outpatient medication maintenance, without any additional therapeutic support. Individuals in residential inpatient treatment include patients who have elected to seek treatment, and patients who were ordered to enter into drug diversion at the order of a judge.

The primary concern, when surveying this particular population, is consent. First and foremost, the researcher consulted with treatment professionals at the Quest campus to identify the standard duration of acute withdrawal. To ensure that the physical and psychological symptoms associated with withdrawal did not influence a potential respondent’s ability to consent to participate, the researcher only interacted with patients who had already completed the acute detox program. Due to the social complexities associated with substance misuse and abuse, particular care was taken when approaching patients in this group, with clear and repeated emphasis that the patient was not required
to participate, that responses would be entirely anonymous, and that neither the researcher nor the Quest campus staff would review their individual responses.

Given the sensitive nature of substance misuse and abuse, as well as addiction, the recruiting process was carefully crafted to ensure that respondents were not pressured to take the survey. While Quest campus staff facilitated the researcher’s introduction to patients at the facility, they were not involved in recruiting patient participation. This was due in large part to concerns regarding their position of power and authority over patients, particularly those involved in an inpatient program.

Administering the survey presented unique challenges as well. Just as with the pharmacists, an online survey using the Qualtrics platform was developed. Because of the secure nature of the facility, access to computers was limited. Consequently, the researcher created a small survey center using a university laptop, a table, and a privacy screen. This survey center was placed in high traffic areas in the Quest facility that were off limits to patients who had not completed the detox process.

Staff from the Quest campus noted that many patients struggle with reading comprehension. To ensure that patients could fully understood the survey, the researcher ran the entire text through a program designed to measure the average reading level of a particular document. After several rounds of editing, the researcher honed the survey instrument to a 5th grade reading level. To further facilitate comprehension, the researcher included a voice recording of each survey question, and provided prospective respondents with a set of headphones upon request.

In the Fall of 2016, the researcher began to visit the Quest campus multiple times a week. The researcher engaged patients with an open-ended, non-conditional offer of
snacks, books, and crossword puzzles. Following successful initial interaction, the researcher offered patients a brief summary of the intent of the study, as well as an opportunity to take the survey. This approach proved surprisingly effective, with the majority of patients, both inpatient and outpatient, expressing interest in the project.

The computer used in the survey center was programmed to allow access to only one website: Qualtrics. When patients sat down to take the survey, they were required to read a description of the study and confirm that they agreed to take the survey. Following this consent process, the survey proceeded as follows.

3.4: Measures for Patients

The patient survey, attached in full in Appendix E, captured the following background information on the patient: basic demographic data, information on the substance use preferences and misuse and abuse history of the patient, several questions evaluating the medical consequences of said substance use, and a brief history of treatment associated with their substance use. The patient survey also examined how the patient accessed prescription medications, including questions on their source of insurance, the particular type of medical service provider they generally use, and the type of pharmacy they use to fill prescriptions. To assess the relative acceptability of the interventions described above, patients were also asked to quantify their support of or opposition to each intervention using a 5 point Likert scale, though the language in this section was simplified compared to the pharmacist survey. Patients were also given the opportunity to provide detailed qualitative descriptions of the perceived barriers to successful execution of each intervention and the potential problems associated with each intervention.
CHAPTER 4

FINDINGS

4.1: Descriptive Statistics For Pharmacists

Eight hundred and fifty-two pharmacists responded to the survey. Of these responses, 684 surveys were complete, giving a response rate of about 5.9%. Table 4.1 summarizes the descriptive statistics associated with pharmacists. In spite of the relatively low response rate, the sample size of 684 proved more than adequate for the analysis. Ultimately, 56.7% of respondents were female, and 43.2% were male. Meanwhile, roughly 55% of respondents were under the age of 40, and over 90% were under the age of 60. In terms of race and ethnicity, 94.9% of respondents were white, 1.9% were black, 2.5% were of Asian descent, and .7% identified as “other”. Only 1% of respondents identified as Hispanic.

Figure 4.1 summarizes the professional background of the respondents, an extremely important characteristic given differences in training, patient interactions, and day-to-day professional obligations. A total of 54.5% worked in a community pharmacy. Another 29.9% worked in a hospital pharmacy. The remaining 18.2% worked in another type of pharmacy, such as a compounding facility or academic institution.
Table 4.1 Descriptive Statistics for Pharmacists

<table>
<thead>
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<th>Variable</th>
<th>Subcategory</th>
<th>N</th>
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<td>50 to 59</td>
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<td>60 to 69</td>
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<td>70 to 79</td>
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<td>11</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<td><strong>Ethnicity</strong></td>
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<tr>
<td><strong>Race</strong></td>
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<tr>
<td>White</td>
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<td>Black</td>
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<td>13</td>
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<td>American Indian</td>
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<td>3</td>
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<tr>
<td>Other</td>
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<td>1</td>
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<tr>
<td><strong>Pharmacy Type</strong></td>
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<tr>
<td>Community/ Retail Pharmacy</td>
<td>373</td>
<td>54.50%</td>
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<td>Hospital Pharmacy</td>
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<td>Other (e.g. Compounding, Academic)</td>
<td>106</td>
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<tr>
<td><strong>Years in Practice</strong></td>
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<tr>
<td>0-2 Years</td>
<td></td>
<td>123</td>
<td>18.00%</td>
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<tr>
<td>3-5 Years</td>
<td></td>
<td>116</td>
<td>17.00%</td>
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<tr>
<td>6-10 Years</td>
<td></td>
<td>107</td>
<td>15.7%</td>
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</tr>
<tr>
<td>11 or More</td>
<td></td>
<td>336</td>
<td>49.3%</td>
<td></td>
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<tr>
<td><strong>Community Served (Can Serve Multiple)</strong></td>
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<tr>
<td>Rural</td>
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<td>241</td>
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<td>Suburban</td>
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</tbody>
</table>
The survey also assessed the experience of respondents, as illustrated in Figure 4.2. Around 18% of respondents were quite new to practice, with 0-2 years in practice. Another 16.9% had practiced between 3 and 5 years, 15.6% had between 6 and 10 years of experience, and the remaining 49.1% had 11 or more years in practice. The variation in experience suggests that the sample includes both practitioners who entered their field in the midst of the prescription opioid epidemic, as well as those who were in practice prior to its emergence.

Figure 4.2: Professional Experience of Pharmacist Respondents
Given that the prescription opioid epidemic has hit rural communities particularly hard, respondents were asked about the type of community their pharmacy generally serves, as described in Figure 4.3 (Burke, 2017). Because rural and urbanized areas are not always neatly delineated, pharmacists were simply asked whether their pharmacy generally serves rural, suburban, and/or urban communities.

**Figure 4.3: Types of Communities Served By Pharmacist Respondents**

![Bar chart showing percentages of pharmacists serving urban, suburban, and rural communities.]

*Note: Pharmacies May Serve Multiple Community Types*

Around 50% of pharmacists reported that their pharmacy served an urban community. Around 55.8% of pharmacists reported that they served a suburban community. At least 35% of pharmacists reported that their pharmacy served a rural community. This suggests that this sample includes perspectives from pharmacists operating in rural, suburban, and urban settings.

Pharmacists were also asked to offer a general assessment of the frequency with which they encounter patients exhibiting symptoms of prescription opioid use disorder, as shown in Figure 4.4. Only .7% of pharmacists noted that they had never encountered patients they suspected of opioid misuse and abuse in their practice. Another 14% noted
that they only ran into patients with suspected prescription opioid use disorder a few times a year. An additional 10.8% of pharmacists reported that they encountered patients misusing prescription opioids at least once a month, while 23.6% encountered prescription opioid use disorders several times a month.

**Figure 4.4: Frequency With Which Pharmacists Encountered Patients Struggling With Prescription Opioid Use Disorders**

Still more troubling, 11.5% of pharmacists reported encountering patients they suspected of prescription opioid misuse and abuse once a week, 15% reported encountering individuals struggling with prescription opioid use disorder multiple times a week, and 12.6% reported that they dealt with patients struggling with prescription opioid misuse and abuse on a daily basis. This means that 73.8% of pharmacists encounter patients they suspect of misuse and abuse at least monthly, and more than 39% of pharmacists encounter patients they suspect of misuse and abuse at least once a week.

**4.2: Descriptive Statistics For Patients**

While the descriptive data from pharmacists offers a fascinating and frightening glimpse of the profound impact that opioid misuse and abuse has had on pharmacy
practice, pharmacists represent only half of the equation. All told, a total of 127 patients took part in the sister survey, with a total of 124 complete responses. A summary of the descriptive statistics associated with patients is included in Table 4.2 below. A brief review of patient demographics and history follows, as well as an exploration of the implications of the particular composition of the sample.

Table 4.2 Descriptive Statistics for Patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Subcategory</th>
<th>N</th>
<th>% or Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>18 or 19</td>
<td>1</td>
<td>.80%</td>
</tr>
<tr>
<td></td>
<td>20 to 29</td>
<td>37</td>
<td>30.10%</td>
</tr>
<tr>
<td></td>
<td>30 to 39</td>
<td>55</td>
<td>44.70%</td>
</tr>
<tr>
<td></td>
<td>40 to 49</td>
<td>22</td>
<td>17.90%</td>
</tr>
<tr>
<td></td>
<td>50 to 59</td>
<td>7</td>
<td>5.70%</td>
</tr>
<tr>
<td></td>
<td>60 to 69</td>
<td>1</td>
<td>.80%</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>83</td>
<td>65.90%</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>41</td>
<td>32.50%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Hispanic</td>
<td>3</td>
<td>2.40%</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
<td>112</td>
<td>88.90%</td>
</tr>
<tr>
<td></td>
<td>Black</td>
<td>8</td>
<td>6.30%</td>
</tr>
<tr>
<td></td>
<td>American Indian</td>
<td>4</td>
<td>3.20%</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
<td>2</td>
<td>1.60%</td>
</tr>
<tr>
<td>Treatment Type</td>
<td>Inpatient (Elective or Court Mandated)</td>
<td>63</td>
<td>50.00%</td>
</tr>
<tr>
<td></td>
<td>Outpatient (Medication and Therapy)</td>
<td>27</td>
<td>21.40%</td>
</tr>
<tr>
<td></td>
<td>Outpatient (Medication Only)</td>
<td>34</td>
<td>27.00%</td>
</tr>
</tbody>
</table>

In total, 66% of respondents were male, while 32% were female. Roughly 30% of respondents were under the age of 30, while 44% were between the ages of 30 and 40. An additional 18% were between the ages of 40 and 50, and the remaining 6% were over 50. Given that the present prescription opioid epidemic has disproportionately impacted
individuals over the age of 30 in contrast with the heroin epidemic, wherein individuals under 30 represented the majority of individuals who misuse and abuse opioids, this age distribution suggests that the sample obtained reflects the same trends recorded in nation-wide surveillance.

In terms of race, 88.9% of respondents identified as white, 6.3% identified as black, 3.2% identified as American Indian, and only 1.6% reported that they were of Asian descent. A total of 2.4% of respondents identified as Hispanic. This closely parallels the demographic characteristics of Stark County, where the Quest campus is located, although American Indians appear to be over-represented (City-Data, 2017).

Educationally, the sample included a disproportionately low percentage of individuals with a high school diploma or only some high school education, when compared to the county as a whole (City-Data, 2017). A total of 48% of respondents reported only some high school education, a high school diploma or a GED. In contrast to the county average of 17.9%, only 2.4% of respondents reported that they had obtained a bachelor’s degree or higher, (City-Data, 2017). Precisely 50% of respondents identified as inpatients, either participating in elective on-site inpatient care or a court mandated residential drug diversion program, as illustrated in Figure 4.5. Roughly 22% of respondents reported that they were outpatients, using a combination of medication, counseling, and support group services. The remaining 27% reported that they were outpatients who used only medication maintenance services.
The substance use history of patients was particularly interesting, as the Quest campus serves individuals struggling with prescription and illicit opioid addiction, alcohol misuse and abuse, and general drug dependency. Respondents were offered the opportunity to describe all substance use characteristics that apply to them. Roughly 80% of respondents used heroin to get high at least once, while 88.9% reported abusing prescription opioids. Furthermore, 78% of respondents reported simultaneous use of multiple drugs, known as polypharmacy. A striking 79.4% of patients reported that their substance use had made them so sick on at least one occasion that they thought they might die.
In terms of treatment history, the patients generally reported relapse as a major concern. All told, over 72% of respondents reported that they were in misuse and abuse treatment on multiple occasions, while only roughly 26% reported that they were in treatment for the first time. As illustrated in Figure 4.6, a total of 30% of respondents reported that it had been less than a month since they last used their preferred drug, while 48% reported they had last used their preferred substance in the last 1-6 months. Only 11% of respondents reported that it had been between 6 months and a year since they last used, and only 7% reported that it had been longer than a year. These results reinforce the remarkable difficulty of misuse and abuse recovery, as well as the frequency of relapse.

4.3: Research Questions

This study sought to answer three research questions: which interventions are most acceptable to pharmacists, which interventions are most acceptable to patients, and which interventions produce statistically significant agreement on acceptability when both pharmacist and patient attitudes are compared. The first two research questions required a relatively straightforward analytic plan. To evaluate the level of support of each intervention within each group, the researcher simply ran a crosstab for each group and each individual intervention. With this analytic approach, respondents were broken into two groups: pharmacists and patients. The responses of each group were further divided into 5 separate cells, where the percentage of respondents who either supported or opposed each intervention was recorded.

Given the vast discrepancies in the socioeconomic background of the two respondent groups, particularly in terms of education, assessing the level of agreement across both groups proved somewhat more challenging. The researcher explored analytic
strategies specifically designed to evaluate the opinions and attitudes of two dramatically
different groups. Ultimately the use of Cohen’s Kappa provided the single best means for
quantifying the level of agreement or disagreement in the opinions of each group. Each
intervention was scored on a scale of -1 (meaning diametrically opposed attitudes) to 1
(meaning perfect agreement across the two groups). The researcher also calculated the
statistical significance of each intervention’s score, to determine whether the agreement
of disagreement between the two groups was the result of random chance or the produce
of real differences in response group attitudes.
<table>
<thead>
<tr>
<th>Group</th>
<th>Agree</th>
<th>Neither Agree Nor Disagree</th>
<th>Somewhat Agree</th>
<th>Strongly Agree</th>
<th>Somewhat Disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Neither Agree Nor Disagree</th>
<th>Somewhat Disagree</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>0.40%</td>
<td>10.00%</td>
<td>13.00%</td>
<td>31.70%</td>
<td>21.90%</td>
<td>6.00%</td>
<td>10.00%</td>
<td>1.00%</td>
<td>1.00%</td>
<td>0.10%</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>0.00%</td>
<td>11.40%</td>
<td>16.50%</td>
<td>26.40%</td>
<td>37.40%</td>
<td>9.30%</td>
<td>10.00%</td>
<td>1.00%</td>
<td>1.00%</td>
<td>0.30%</td>
</tr>
</tbody>
</table>

Table 4.3: Cross-tab Comparison of Support of Opposition of Each Intervention Within Pharmacist and Patient Group
4.3.1: Research Questions 1 and 2: Acceptability of Interventions Among Pharmacists, and Acceptability of Interventions Among Patients

In general, both pharmacists and patients were reasonably receptive to four of the five interventions. There were, however, variations in the level of support each response group expressed for each intervention. Table 4.3 offers a summary of the percentage of respondents who expressed that they strongly supported, somewhat supported, neither supported nor opposed, somewhat opposed, or strongly opposed each intervention.

The first intervention involved pharmacists providing patients with counseling on the risk of misuse, abuse, addiction and overdose associated with prescription opioids. Roughly 66% of patients expressed moderate or strong support for use of this intervention. Around 27% of patients expressed moderate or strong opposition to counseling patients on the risk of misuse, abuse, and addiction associated with prescription opioids, while around 7% neither supported nor opposed this particular approach to counseling. Only 32% of patients reported that a pharmacist had ever counseled them on the addictive potential of prescription opioids.

Pharmacists, in turn, were much more decisively in favor of pharmacists providing counseling on the addictive potential of prescription opioids. Roughly 86% of pharmacists expressed moderate or strong support for this intervention. Another 11% reported that they neither supported nor opposed use of this particular approach to counseling, and only 3% reported moderate or strong opposition to counseling patients on the risk of misuse, abuse and addiction associated with prescription opioids. In total, 84% of pharmacists reported that they had, on at least one occasion, offered patients specific counseling on the risk of misuse, abuse and addiction associated with prescription opioids.
The second intervention involved pharmacists referring patients to local substance misuse and abuse and addiction treatment resources. The crosstab demonstrates that there are clear distinctions in pharmacist and patient attitudes toward referral. A total of 67% of pharmacists reported either moderate or strong support for referral, though the majority of those supported the intervention did so with some reservations. Another 21% reported that they neither supported nor opposed this particular intervention. The remaining 12% of pharmacists expressed either mild or strong opposition to referral. Interestingly 25% of pharmacists reported that they had, at least once in their professional career, referred patients to local misuse, abuse and addiction treatment services.

Similar to pharmacists, 64% of patients expressed either moderate or strong support for referral. Fewer patients appear to be undecided when it comes to pharmacists referring patients to substance misuse and abuse treatment resources, with only 12% of patients reporting that they neither opposed nor supported this particular intervention. The remaining 24% of respondents noted that they were either moderately or strongly opposed to pharmacist referral. In contrast to the 25% of pharmacists who reported using referral at least once in their career, only 1.6% of patients reported receiving such guidance from a pharmacist.

The third intervention assessed in this study involved the use of Prescription Drug Monitoring Programs to identify patient behavior associated with misuse, abuse and addiction. Because such behaviors are often complex, the researcher focused on one of the most widely recognized and traceable drug seeking behaviors: attempting to fill an illegitimate prescription. More specifically, the researcher asked pharmacists and patients
to assess whether they supported the use of PDMPs to determine the legitimacy of a prescription.

The crosstab demonstrated that there were similarities in pharmacist and patient support for PDMP-based validation of prescriptions. Pharmacists were overwhelmingly in favor of PDMP use, with roughly 98% of respondents reporting strong or moderate support for this intervention. Of those who supported PDMPs, 90.3% expressed strong support. An additional 1% reported that they neither supported nor opposed use of PDMPs in assessing the legitimacy of prescriptions, and the remaining 1% expressed moderate to significant opposition. A correspondently high percentage of pharmacists (91.8%) reported that they had, in fact, used PDMPs to determine the legitimacy of prescriptions in the past. This inspires two observations: First, even in a state where referring to a PDMP is required when dispensing controlled substances, utilization is not universal. Second, use of PDMPs as a means of identifying drug-seeking behavior is a broadly accepted component of pharmacy practice, suggesting that there is ample opportunity to refine how professionals use Prescription Drug Monitoring Programs to detect misuse, abuse and addiction early through drug-seeking behavior.

While patient support for the use of PDMPs was not as uniform as that of pharmacists, around 71% of patients reported either moderate or strong support for PDMP use in determining the legitimacy of prescriptions. Another 12% reported that they neither supported nor opposed PDMP use. The remaining 17% of respondents reported either moderate or strong opposition to PDMP use. Given that PDMPs are utilized via computer, without direct interaction with clients, patients had no basis for
assessing whether a pharmacist had ever used a PDMP to assess the legitimacy of their prescription, and as a result, were not asked about their experience with PDMP use.

The fourth intervention assessed in this study involved provision of naloxone with every opioid prescription. Given the intense debate generated by similar paired prescription programs, as described in the literature review, the researcher anticipated relatively polarized attitudes toward this particular intervention. Only around 36% of pharmacists reported that they either somewhat agreed or strongly agreed that this particular intervention was acceptable. An additional 23% neither agreed nor disagreed, while 41% either somewhat disagreed or strongly disagreed that the use of paired prescriptions was acceptable. This represents the only instance, in either response group, of a plurality of respondents opposing an intervention rather than supporting it. Only 16.2% of pharmacists reported that they had ever dispensed naloxone while filling an opioid prescription, suggesting that in Ohio, at least, this is not a particularly common intervention.

Patients, in contrast, appeared to be more supportive of the use of paired prescriptions, though the support was somewhat more dilute than the support expressed for other interventions. Around 61% of patients reported either moderate or strong support for the use of paired prescriptions. Another 15% reported relative neutrality on the use of this intervention, while 24% either moderately or strongly opposed paired prescriptions. Interestingly, only 4% of patients had ever received naloxone when filling an opioid prescription, reinforcing that this is not a commonly used intervention.

The fifth and final intervention explored in this study involved providing naloxone over the counter. Prior to exploring the response to this particular intervention,
it is important to note that naloxone became available over the counter throughout Ohio in the midst of this study, with new guidance released in October of 2016 and broad implementation of expanded availability in early 2017. As such, this assessment of patient and pharmacist attitudes toward over the counter availability of naloxone differs somewhat from the assessment of the other four interventions. While the previous analyses have the potential to influence the formation or alteration of new policy, this assessment of patient and pharmacist attitudes toward OTC availability of naloxone is more useful in identifying potential barriers to utilization of this new resource.

Pharmacists appeared supportive of over-the-counter availability of naloxone, with 64% of pharmacists reporting moderate or strong support for this intervention. This support appears somewhat dilute, however, as a slight majority of pharmacists who back over the counter availability only offer moderate support. Another 12% of pharmacists expressed neutrality, while the remaining 24% expressed moderate or strong opposition. In total, around 22% of pharmacists had dispensed naloxone over-the-counter on at least one occasion.

Patients expressed considerable enthusiasm for over-the-counter availability of naloxone. Around 84% of respondents reported either moderate or strong support for this intervention. Another 5% reported relative neutrality toward over-the-counter sale of naloxone, while 11% reported moderate opposition. Interestingly, no patients reported strong opposition to this intervention. Furthermore, 47.6% of patients reported that they had carried naloxone in case of overdose in the past, and a larger percentage expressed interest in purchasing naloxone over the counter in the future. In total, 62.7% of patients expressed interest in purchasing naloxone without a prescription, while around 40% of
respondents reported that they would be willing to pay for said purchase out of pocket. This suggests that while there is tremendous interest in naloxone in this community, cost presents a major barrier.

4.3.2: Research Question 3: Support of Each Intervention Across Groups

A weighted Kappa coefficient was calculated to evaluate the level of agreement or disagreement between the pharmacists’ and patients’ acceptance of each intervention. Quadratic, rather than linear weighting was used, as quadratic increases the weight of greater disagreement (i.e. separation of 1 category receives less weight than separation of 2, which receives less weight than separation of 3, and so forth). This is the standard approach to weighting when assessing agreement on a Likert scale, as it emphasizes the increasing distinction between strong agreement, slight agreement, neutrality, slight disagreement, and strong disagreement (Norman, 2010).

Table 4.4: Altman’s Kappa Benchmark Scale (Altman, 1991)

<table>
<thead>
<tr>
<th>Kappa Statistic</th>
<th>Strength of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.20</td>
<td>Poor</td>
</tr>
<tr>
<td>0.21 to 0.40</td>
<td>Fair</td>
</tr>
<tr>
<td>0.41 to 0.60</td>
<td>Moderate</td>
</tr>
<tr>
<td>0.61 to 0.80</td>
<td>Good</td>
</tr>
<tr>
<td>0.81 to 1.00</td>
<td>Very Good</td>
</tr>
</tbody>
</table>

The strength of agreement was assessed using Altman's Kappa Benchmark Scale, which standardizes the interpretation of the strength of Kappa coefficients (Altman, 1991). Altman’s Kappa Benchmark Scale is summarized in Table 4.4.
<table>
<thead>
<tr>
<th>Kappa</th>
<th>Weighted Kappa Over the Counter Prescriptions Providing Naloxone with Opioid Prescriptions Providing Naloxone Over the Counter</th>
<th>Weighted Kappa Over the Counter Prescriptions Providing Naloxone with Opioid Prescriptions Providing Naloxone Over the Counter</th>
</tr>
</thead>
<tbody>
<tr>
<td>[0.096 - 0.054]</td>
<td>100' &gt; 110' 0.75</td>
<td>100' &gt; 70 0.36</td>
</tr>
<tr>
<td>[0.259 - 0.383]</td>
<td>100' &gt; 32 0.32</td>
<td>100' &gt; 32 0.32</td>
</tr>
<tr>
<td>[0.110 - 0.442]</td>
<td>95 0.14 0.05</td>
<td>100' &gt; 42 0.15</td>
</tr>
</tbody>
</table>

Table 4.5: Weighted Kappa: Level of Agreement in Support or Opposition of Each Intervention Across Pharmacist and Patient Groups
Table 4.5 summarizes the findings of the Weighted Kappa analysis. While both pharmacists and patients expressed considerable support for counseling patients on the risks associated with prescription opioids, there was only a poor, though statistically significant level of agreement in the level of support expressed by each group. Similarly, while both pharmacists and patients expressed cautious support for pharmacists referring patients to drug treatment programs within the community, the weighted Kappa coefficient revealed poor, statistically insignificant agreement between the attitudes of the two groups. Given that both groups expressed strong support for the use of prescription drug monitoring programs, it is unsurprising that PDMP use elicited a fair and statistically significant level of agreement between pharmacists and patients. In contrast, the Kappa coefficient revealed a poor but statistically significant disagreement in patient and pharmacist attitudes toward the paired prescription of naloxone. Over-the-counter availability of naloxone produced similarly poor, but significant disagreement.
CHAPTER 5
LIMITATIONS, DISCUSSION AND IMPLICATIONS

5.1: Limitations

This study has several limitations, with the low response rate among pharmacists signifying the chief concern. Of the 11,540 emails that successfully sent, 852 recipients responded to the survey. Of these responses, 684 surveys were complete, giving a response rate of about 5.9%. While clinician surveys generally produce a response rate that is lower than that of the general population, a response rate of 25.6% is typically expected, while participation over 50% is generally considered high (Asch et al, 1997; Cummings et al. 2001; VanGeest et al. 2001). Although response rate of a survey may not be the best sole measure of data quality (Johnson & Wislar, 2012), it is a critical indicator of potential non-response bias within a study (Asch et al, 1997; Cull et al, 2005; McFarlane et al, 2007; Cho et al, 2013). As such, it is important to view the results of this study in the context of the low response rate. It is particularly important to consider some of the factors that may have contributed to the low response rate, to explore potential differences between survey respondents and the population of pharmacists as a whole, and the potential impact of these differences on the generalizability of the findings.

To explore potential differences between the general population of Ohio pharmacists and survey respondents, the researcher compared the geographic setting, professional setting, and professional experience of both groups. While 28% of the general population worked in pharmacies located in rural communities, 35% of
respondents served a rural community. 29% of Ohio pharmacists worked in hospital pharmacies, 29.9% of respondents worked in a hospital setting; 49.7% of Ohio pharmacists worked in community/retail settings; while 54.5% of respondents worked in retail pharmacies. The remaining 21.3% of Ohio pharmacists worked in settings other than hospital or retail pharmacies, compared to 18.2% of the response group. Although there were similarities in the geographic and professional service characteristics of both populations, there were pronounced differences in the professional experience of the two populations. While only 9.6% of the general population had under 3 years of experience, 18% of respondents reported they had been in practice less than 3 years. 11.6% of the general pharmacist population had 3-5 years of experience, compared to 16.9% of respondents. 15.37% of the Ohio pharmacist population had 6-10 years of experience, compared to 15.6% of respondents. Finally, while 63.7% of Ohio pharmacists had 11 or more years of experience, 49.1% of respondents reported the same.

The use of an e-mail based mode of survey distribution may have played a role in reduced responsivity, as research suggests that e-mail surveys generally produce a lower response rate (Braithwaite et al, 2003; Leece et al, 2004; Beebe et al, 2007; VanGeest et al, 2015; Hardigan et al, 2016; Agley et al, 2017). The incentive structure used in the survey may have played a role in the response rate as well. Research has confirmed that monetary incentives increase response rate (Delnovo et al, 2004; James et al, 2011; VanGeest et al, 2015; Agley et al, 2017), but that the structure of financial incentives have a marked effect on survey success. Studies that offer non-contingent financial incentives prior to filling out a survey tend to perform better than surveys that provide contingent incentives after the fact, the incentive method employed in this study.
Based on the literature, the perceived relevance of a survey subject has a particularly critical impact on response rate (Sudman, 1985; Maguire, 1991; Edwards et al, 2002; VanGeest et al, 2007). Considering that the role of pharmacists in the identification and management of misuse, abuse, and addiction are topics of ongoing debate, it is possible that the subject of the e-mail itself, “Opioid Abuse Prevention in Pharmacy,” may have not felt immediately relevant (Bartels, 2015).

The primary limitation associated with the patient study, in contrast to the pharmacist study, stems from the experimental nature of the survey. A broader sample of patients with variety of opioid use patterns would add value to the study. Similarly, a sample of patients from diverse geographic locations and socioeconomic backgrounds would improve the generalizability of the study. Despite the limitations associated with a single-site sample, this investigation emphasizes that engaging patients in the evaluation of misuse and abuse interventions can offer new insight into barriers to implementation. Further, it is important to note that, while geographically limited, the Quest campus did offer a diverse blend of both elective detox and drug diversion patients, as well as responses from patients utilizing a variety of treatment modalities.

Given that data collection required the physical presence of the researcher, and that their availability was relatively limited, it is unsurprising to note that fewer patient responses were recorded when compared to pharmacists. All told, a total of 127 patients took the survey, with a total of 124 complete responses. Unfortunately the Quest campus was unable to provide specific data on the total number of patients in inpatient detox, outpatient treatment, and medication management during the data collection period. The
researcher made an effort to speak to every patient she encountered, however, and found the vast majority of the patients were enthusiastic participants who were eager to take the survey to assist others struggling with misuse and abuse.

In total, 66% of respondents were male, while 32% were female. While this may initially suggest over-representation of men in the study, this response rate is likely an artifact of the disproportionately large number of men involved in court-mandated drug diversion relative to women.

In addition to the limitations associated with response rate and site-specific samples, it is important to note that a few specific questions used within the survey were subjective. When pharmacists were asked, for instance, to estimate the frequency with which they encounter patients exhibiting signs of misuse and abuse, pharmacists did not specify the behaviors that they used as indicators for misuse and abuse. Given the subjective nature of such questions, it is important to recognize that pharmacists may be over or under-estimating the true prevalence of misuse and abuse within their clientele, as specific methods used to assess misuse and abuse are not provided and the accuracy of each pharmacist’s method cannot be assessed. In the patient survey, patients were asked to determine whether their drug use had ever made them so sick they thought they might die. This question is also inherently subject, and as such, should not be used as an accurate reflection of the prevalence of life-threatening drug use complications within the patient population.

5.2 Discussion and Implications

While agreement between patients and pharmacists was quite mild, in the case of the two interventions with statistically significant agreement (PDMP use and counseling),
comparison of support levels within each group reinforces that these interventions have reasonably high levels of acceptance among both pharmacists and patients. This study demonstrates that certain interventions are not only readily accepted within the profession, but also accepted among patients struggling with opioid use disorders. Given that pharmacists continue to debate the role that they should play in combatting the opioid epidemic, this study indicates that some interventions may prevent fewer barriers than others, particularly in terms of professional and patient acceptance.

Because this study is exploratory, and because of the limitations described above, this study should not be used as the sole basis for any policy change or legislative proposal. The results of the study only serve as a basis for identifying the interventions with the greatest acceptance within the profession. In the discussion below, Ohio PDMP and patient counseling practices are explored. When supported by the literature and professional organizations such as the APhA and the ASHP, legislative and educational recommendations are suggested to help improve and increase utilization of patient counseling and PDMPs.

5.2.1: Patient Counseling: Active Engagement

Pharmacy-based misuse and abuse counseling produced weak, though statistically significant agreement across groups. Both groups generally supported patient counseling, with 85.8% of pharmacists and 66.2% of patients expressing strong or moderate support for patient counseling. In addition to support from both groups, counseling is already a broadly accepted component of pharmacy practice (Leuck, 2017). Given that pharmacists regularly counsel patients on risks associated with drugs known to cause specific side effects (including drowsiness and harm to a fetus), pharmacists might use a similar
approach when discussing risk of misuse, abuse and addiction (Termini, 1998; Leiderman, 2009; Leuck, 2017). Professional organizations such as the American Pharmacists Association have encouraged the use of intensive counseling when dispensing opioids and other medications with a high risk of misuse and abuse and overdose, encouraging pharmacists to educate patients on safe use and the risks of misuse and abuse (APHA, 2014; Holdworth et al., 2015).

The current regulations governing patient counseling in the state of Ohio, particularly section 4729-5-22 of the Ohio Administrative Code, outline a number of different subjects pharmacists might touch upon in counseling (Ohio Administrative Code, 2011). While the present regulation encourages pharmacists to discuss the appropriate use and potential risks associated with prescription medication, section 4729-5-22, as worded at present, does not specifically mention the risk of misuse, abuse, addiction or overdose in the patient counseling guidance. Revisions to this particular section of the Ohio Administrative code might emphasize that the state and regulatory bodies view misuse and abuse prevention as a legitimate component of pharmacy practice, and codify the essential components of counseling (Puspitasari & Aslani, 2009).

5.2.1-1: Implication: Consider Amendment of OAC Section 4729-5-22 to Include Misuse, Abuse, and Addiction as a Subject of Counseling

First and foremost, given that 85.8% of pharmacists and 63.2% of patients support counseling on the risks associated with misuse, abuse, addiction and overdose, and given broad support for misuse, abuse, and addiction specific patient counseling from both professional organizations and published research, policymakers might consider taking steps to amend current regulations to include misuse, abuse, addiction and overdose as potential subjects of patient counseling (ASHP, 1997; APhA, 2014; Hall, 2016; Leuck,
In Ohio, section 4729-5-22 of the Ohio Administrative Code could be amended to identify discussion of misuse, abuse, addiction and overdose as a legitimate component of counseling. While one could categorize misuse, abuse and addiction under the category of “appropriate use,” delineation of misuse, abuse and addiction and overdose risk and inclusion as a distinct component of counseling would help to emphasize the importance of patient education via counseling in prevention (Hall, 2016; Lecuk, 2017).

The process by which patients are offered counseling, and the frequency with which pharmacists offer counseling present challenges as well. Researchers have found that the percentage of pharmacists who actually provide counseling varies based upon the type of medication dispensed, the payment method used, and the patient’s treatment history (Puspitasari & Aslani, 2009). While section 4729-5-22 of the Ohio Administrative Code mandates that pharmacists offer counseling when dispensing, there is no explicit description of how pharmacists should phrase this offer, and this lack of clarity may result in decreased patient engagement (Kear, 2011; Bulloch, 2016; Schell, 2016). Often, pharmacists fill the obligation to offer counseling by simply asking the patient if they have any specific questions, and concluding the consultation if the patient does not have specific questions (Kear, 2011; Bulloch, 2016; Schell, 2016).

While it is important to give patients an opportunity to ask questions, it is not reasonable to assume that all patients have the familiarity with their medication regimen necessary to ask questions without an initial overview of the intended effects and potential side effects associated with a medication (Kear, 2011; Bulloch, 2016; Schell, 2016). Additionally, this approach to offering counseling assumes that patients who do not have questions do not need additional information on their medication (McCarthy et
Pharmacy research suggests that directing offering counseling on specific topics and asking more pointed questions of patients can help practitioners assess their knowledge of the appropriate use of a medication, identify gaps in a patient’s understanding of their medication regimen, and ensure patients understand instructions (Schommer, 1997; Cameron et al, 2010; Peters et al, 2016). To improve the counseling process, lawmakers might consider rewriting this particular section of the Ohio Administrative Code to specify that pharmacists should offer patients the opportunity to learn specifically about the appropriate use and potential risks associated with their medication.

5.2.1-2: Implication: Consider Amendment of OAC Section 4729-5-22 to Clarify Language Describing the Offer of Counseling

While amending counseling regulations to specifically encourage discussion of misuse, abuse, and addiction may be helpful, it is also important to provide all patients with a clear opportunity for counseling. Amendment of section 4729-5-22 could therefore also include clarification of the process pharmacists use to offer counseling to patients. In section 4729-5-22, an offer of counseling could include a clear description of the potential topics that pharmacists could offer information on, including potential side effects, interactions, and risks associated with use. While many pharmacists simply ask patients if they have any questions, this assumes that patients have the familiarity with their medication and treatment regimen necessary to identify specific questions.

Further, there is a significant distinction between a patient having questions, and a patient needing information on a medication. Though a patient may not have any questions, this does not mean that they do not need additional information on a medication (Blom & Krass, 2011; Leuck, 2015). By offering specific insight into the
proper use, potential side effects, and risks associated with a prescription, pharmacists can directly evaluate whether patients want this specific information (Leuck, 2015; Schell, 2016). Asking whether a patient has any questions can, of course, be included in the counseling process as a whole.

**5.2.1-3: Implication: Consider Amending OAC Section 4729-5-22 to Include Disposal of Unused Medication as a Subject of Counseling**

When counseling patients on the risks of misuse, abuse, and addiction associated with prescription opioids, pharmacists might use a variety of counseling-based educational strategies to address both the direct misuse and abuse of prescription medications by the patient and the risk of indirect misuse and abuse of medications that are not disposed of properly (McCauley et al, 2013; Leuck, 2015; Bratberg, 2017). Just as misuse, abuse, and addiction are not specifically listed as a standard subject of counseling in Section 4729-5-22, proper disposal of unused medication is also not included in this list. As over half of individuals who misuse and abuse prescription opioids obtain them from the prescriptions of friends and family, inclusion of this topic is critical to combatting this epidemic (Burke, 2011; SAMHSA, 2016). It is particularly important that pharmacists explain the risks associated with retaining unused medication to children in the house, to family members, and to visitors (Burke, 2011; Stanos, 2012; Leuck, 2015).

**5.2.2: Prescription Drug Monitoring Programs**

The second intervention that garnered considerable support within each group, pharmacists utilization of PDMPs, produced fair and statistically significant agreement, with 71.6% of patients and 97.9% of pharmacists expressing strong or moderate support for such interventions. As with counseling, the use of PDMPs is particularly appealing as they have already been introduced in most states, have received considerable Federal
support, and have ample support from practicing pharmacists and professional associations alike (Gilchrist, 2016; Genord et al, 2017). Given that the state of Ohio has recently introduced reforms requiring both prescribers and dispensers to consult PDMPs when handling opioid prescriptions, the next steps might involve the training pharmacists receive to specifically use PDMPs to identify drug-seeking behavior.

Patients struggling with misuse and abuse can exhibit distinct physical and psychological symptoms, including anxiety, irritability, and urgency. While these behavioral signs are helpful in identifying individuals who may have a substance misuse or abuse problem, they are not exclusive to misuse and abuse, and are associated with a broad array of physical and psychological conditions that are not associated with substance misuse and abuse. Furthermore, these behaviors tend to be more common during acute withdrawal, and may only be noticeable in an individual from time to time. Drug-seeking behaviors, on the other hand, occur over time, establishing a pattern of behavior that can be traced, identified, and with appropriate training, used to initiate care.

Prescription Drug Monitoring Programs, such as OARRS, provide a system-wide view of patient activity, allowing pharmacists to identify drug-seeking behavior (Gaines & Branham, 2016). Given the reasonably high levels of support of using PDMPs to determine the legitimacy of prescriptions expressed by both pharmacists and patients, pharmacists could reasonably extend the use of PDMPs to identify both illegal examples of drug-seeking behavior (such as falsifying a prescription or attempting to fill a prescription multiple times) and legal examples of drug-seeking behavior (such as obtaining multiple pharmacologically similar prescriptions, obtaining increasing doses
over time, frequently switching practitioners, or obtaining overlapping prescriptions of the same medication) (CDC, 2015; Eckel, 2016).

**5.2.2-1: Implication: Consider Amending OAC Section 4729-5 to Clarify Drug Seeking Behaviors to Look for in OARRS Reviews**

Given that 71.6% of patients and 97.9% of pharmacists support the use of PDMPs, and given that PDMPs are already an established component of pharmacy practice, efforts to reduce the prescription opioid misuse and abuse rate might include changes to PDMP regulations. Section 4729-5 of the Ohio Administrative Code outlines the circumstances under which pharmacists should initiate an OARRS review. Presently, pharmacists are encouraged to review a patient’s OARRS record if a patient is filling a prescription for a controlled substance designated as Schedule II, if a new medication is added to their treatment regimen, if an OARRS report has not been reviewed in the past 12 months, if the patient has obtained multiple controlled substance prescriptions from several prescribers who do not share a common practice, and if either the patient or the prescribing physician is from outside of the usual service area of the pharmacy.

While these standards offer a useful baseline for consultation of OARRS for general medication, PDMP regulations might be improved by providing instruction on the specific behaviors associated with drug seeking behaviors. This is essential, as OARRS reports are complex documents, and present guidance puts the majority of emphasis on searching patient records for illegal behavior. While it is important to monitor for falsified prescriptions, there is ample evidence that legal behaviors, including obtaining multiple pharmacologically similar prescriptions, frequently changing physicians, obtaining overlapping prescriptions, and obtaining increasing doses over time may all indicate a substance use disorder (CDC, 2015).
5.2.2-2: Implication: Consider Designing Pharmacist Training and Continuing Education Programs to Encourage Use of PDMPs to Identify Systemic Drug Seeking Behaviors

In addition to changes in Ohio Administrative Code standards for pharmacist use of OARRS, pharmacists could receive specific training designed to help them identify drug-seeking behavior through OARRS. PDMPs provide a systemic view of patient activity, allowing pharmacists to identify drug-seeking behaviors including: falsification of a prescription, obtaining multiple pharmacologically similar prescriptions at the same time, obtaining the same prescription from multiple doctors, attempting to fill one prescription at multiple pharmacies, and frequently changing medical service providers. Pharmacist training organizations, such as the American Association of Colleges of Pharmacy, have already recognized the need for improving pharmacist training in the identification and management of misuse and abuse, suggesting that there is ample opportunity to integrate identification of both legal and illegal drug seeking behaviors via PDMPs as a component of expanded training efforts (AACP, 2013). Efforts to improve pharmacist familiarity with PDMP systems and their role in reducing diversion of controlled prescription drugs (CPDs) have proven beneficial. Programs that provide pharmacists with specific information on the drug seeking behaviors that can be monitored in PDMP systems and that train pharmacists to use PDMPs efficiently and effectively have proven particularly effective (Fleming et al, 2016).
APPENDIX A

IRB APPROVAL LETTER

RE: Protocol #16-340 - entitled “Pharmacist Utilization of Opioid Abuse Interventions”

We have assigned your application the following IRB number: 16-340. Please reference this number when corresponding with our office regarding your application.

The Kent State University Institutional Review Board has reviewed and approved your Application for Approval to Use Human Research Participants as Level I/Exempt from Annual review research. Your research project involves minimal risk to human subjects and meets the criteria for the following category of exemption under federal regulations:

- Exemption 2: Educational Tests, Surveys, Interviews, Public Behavior Observation

This application was approved on June 10, 2016.

***Submission of annual review reports is not required for Level I/Exempt projects. We do NOT stamp Level I protocol consent documents.
If any modifications are made in research design, methodology, or procedures that increase the risks to subjects or includes activities that do not fall within the approved exemption category, those modifications must be submitted to and approved by the IRB before implementation. Please contact an IRB discipline specific reviewer or the Office of Research Compliance to discuss the changes and whether a new application must be submitted. Visit our website for modification forms.

Kent State University has a Federal Wide Assurance on file with the Office for Human Research Protections (OHRP); FWA Number 00001853.

If you have any questions or concerns, please contact us at Researchcompliance@kent.edu or by phone at 330-672-2704 or 330.672.8058.

Doug Delahanty | IRB Chair | 330.672.2395 | ddelahan@kent.edu
Tricia Sloan | Administrator | 330.672.2181 | psloan1@kent.edu
Kevin McCreary | Assistant Director | 330.672.8058 | kmccrea1@kent.edu
Paulette Washko | Director | 330.672.2704 | pwashko@kent.edu
APPENDIX B

IRB APPLICATION SUMMARY

i) Briefly summarize the purpose of the proposed research: The goal of this study is to compare and contrast patient and pharmacist acceptance of strategies pharmacists use to identify and assist patients struggling with opioid misuse and abuse.

ii) List the scientific or scholarly aims of the research study: The scholarly goal of this study is to compare and contrast patient and pharmacist acceptance of 5 specific strategies used to identify and assist patients struggling with opioid misuse and abuse. The 5 specific interventions include 1) providing patients with information on the risk of misuse and abuse associated with opioid medications, 2) determining the validity of a prescription through the use of Prescription Drug Monitoring Programs, 3) referring patients struggling with opioid misuse and abuse to misuse and abuse treatment programs within the community, 4) providing the opioid overdose treatment Naloxone to patients filling an opioid prescription, and 5) providing the opioid overdose treatment Naloxone over to counter to anyone seeking the medication.

iii) Identify and describe the interventions and interactions that are to be performed solely for the research study. Procedures/interventions should listed sequentially and be separated into paragraphs in the space below: An anonymous survey, offered online, through Qualtrics. A link to the survey will be provided to pharmacists via email. Meanwhile, access to a similar survey tailored to patients will be provided via a secure terminal with headphones and a privacy screen at CommQuest Services detox Center. An
opportunity to complete the anonymous patient survey will be offered to patients who have COMPLETED the detox treatment program. As patients are only admitted to the detox program if they are 18 or older and are not decisionally impaired, as participation in the survey is purely elective, as survey language has been estimated at the 5th grade reading level or below, and as the survey will be dictated to the patients via headphones as well as shown on screen, no issues with patient capacity to consent or understand survey procedures are anticipated.
APPENDIX C

PHARMACIST RECRUITMENT EMAIL

Hello!

My name is Tegan Beechey, and I am a doctoral candidate in Kent State University’s College of Public Health. I am writing to let you know about an opportunity to participate in a survey of pharmacist attitudes toward pharmacy-based opioid abuse prevention strategies.

All participants will have an opportunity to enter a drawing for one $200 gift card, two $100 gift cards, and two $50 gift cards.

This study includes a brief, anonymous online survey of Ohio pharmacists. This 10 minute survey asks participants about their experience with prescription opioid abuse in their client population and their perception of strategies used to identify and reduce prescription opioid abuse behavior. Strategies discussed include:

- Providing clients with information on the risks associated with prescription opioid abuse.
- Using Prescription Drug Monitoring Programs (PDMPs) in the identification of prescription opioid abuse behavior (e.g. attempting to fill prescriptions multiple times).
- Referring clients struggling with opioid abuse to treatment centers within the community.
- Dispensing Naloxone prophylactically to clients filling opioid prescriptions.
- Dispensing Naloxone without a prescription to clients or acquaintances of individuals struggling with prescription opioid abuse or heroin use.

If you are interested in participating, follow this link to the survey:

Take the survey

Or copy and paste the URL below into your internet browser:

https://kent.qualtrics.com/SE?Q_DL=0ANg1eh9G6ZpesZ_4GBnUME2ndKtV9X_MLRP_cHoCnR9ZuTp3F9r&Q_CHL=email

By following the link to the survey, you are consenting to participate in the study.

Best regards and happy holidays,

Tegan Beechey, M.P.A.
Doctoral Candidate
Kent State University College of Public Health
214-606-3786
APPENDIX D

PHARMACIST SURVEY

The goal of this survey is to explore pharmacist attitudes about practice related to opioid addiction. This survey will ask you about your thoughts related to possible intervention in pharmacy settings to prevent drug abuse or refer patients for treatment. The survey will take less than 10 minutes of your time. This survey is anonymous and there will be no attempt to match your responses with your identity. First, you will be asked questions about your background and experience with drug abuse. Second, we will describe the tools pharmacists use when working with patients with drug abuse problems. We will then ask you your opinion about interventions to help patients with drug abuse problems. Once we have collected answers, we will compare how patients and pharmacists feel about each tool that pharmacists use to help patients with substance abuse problems.

What is your age?
- 20-29 years (1)
- 30-39 years (2)
- 40-49 years (3)
- 50-59 years (4)
- 60-69 years (5)
- 70-79 years (6)

Are you male or female?
- Male (1)
- Female (2)

Are you Hispanic or Latino?
- Hispanic or Latino (1)
- Not Hispanic or Latino (2)

What is your race?
- Black or African American (1)
- White or Caucasian (2)
- American Indian or Alaskan Native (3)
- Native Hawaiian or Other Pacific Islander (4)
- Asian (5)
In what type of pharmacy do you work at?
- Community pharmacy (1)
- Hospital pharmacy (2)
- Other (3) ____________________

How long have you been a practicing pharmacist?
- 0-2 years (1)
- 3-5 years (2)
- 6-10 years (3)
- 11 years or more (4)

What kind of community does your pharmacy serve? (Please select all that apply)
- Urban (1)
- Suburban (2)
- Rural (3)

What type of formal substance abuse-related training have you participated in? (Please select all that apply)
- Required coursework as part of your pharmacy degree (1)
- Single session conference presentations or lectures (2)
- Workshops with direct participation in activities (3)
- Credentialed continuing education programs outside of a university (4)
- Formal coursework at a university (5)
- Volunteering for organizations involved in substance abuse prevention and treatment (6)
- Working for organizations involved in substance abuse prevention and treatment (7)
- Other (please explain) (8) ____________________

Does your workplace have any recommended strategies designed to handle patients with suspected substance abuse problems?
- Yes (1)
- No (2)
Does your workplace have any recommended strategies designed to handle patients with suspected substance abuse problems?
If yes: what specific strategies does your workplace encourage when handling patients with suspected substance abuse problems? (Please select all that apply)
- Counsel patient on the risks associated with substance abuse (1)
- Communicate with prescribing medical professional to discuss concerns (2)
- Refer to prescription drug monitoring database to ensure the requested prescription has not been filled already (3)
- Refer patient to appropriate treatment services for substance abuse (4)
- Refuse to fill prescriptions for patients exhibiting signs of substance abuse (5)
- Other (6) ________________

Does your workplace have any policies that require steps when handling patients with suspected substance abuse problems?
- Yes (1)
- No (2)

Does your workplace have any policies that require steps when handling patients with suspected substance abuse problems?
If yes: what specific strategies does your workplace encourage when handling patients with suspected substance abuse problems? (Please select all that apply)
- Counsel patient on the risks associated with substance abuse (1)
- Communicate with prescribing medical professional to discuss concerns (2)
- Refer to prescription drug monitoring database to ensure the requested prescription has not been filled already (3)
- Refer patient to appropriate treatment services for substance abuse (4)
- Refuse to fill prescriptions for patients exhibiting signs of substance abuse (5)
- Other (6) ________________

In the course of your work, have you ever suspected that one of your patients is struggling with a prescription substance abuse disorder?
- Yes (1)
- No (2)
In the course of your work, have you ever suspected that one of your patients is struggling with a prescription substance abuse disorder?

If Yes: What behaviors do you use to identify patients with a prescription substance abuse disorder? (Please select all that apply)
- Attempting to fill the same prescription multiple times (1)
- Multiple prescriptions for the same or pharmacologically similar medications (2)
- High dosages of medications (3)
- Prescriptions from multiple doctors (4)
- Erratic behavior (5)
- Irritability (6)
- Secretive behavior (7)
- Confusion or disorientation (8)
- Urgency when attempting to fill a prescription (9)
- Other (Please specify) (10)

In the course of your work, have you ever suspected that one of your patients is struggling with a substance abuse disorder?

If yes: How often would you say you encounter prescription substance abuse in the patient population you serve?
- Never (1)
- Less than Once a Month (2)
- Once a Month (3)
- 2-3 Times a Month (4)
- Once a Week (5)
- 2-3 Times a Week (6)
- Daily (7)

In the course of your work, have you ever suspected that one of your patients is struggling with prescription opioid abuse?
- Yes (1)
- No (2)
In the course of your work, have you ever suspected that one of your patients is struggling with prescription opioid abuse?

If yes: How often would you say you encounter prescription opioid abuse in the patient population you serve?

- Never (1)
- Less than Once a Month (2)
- Once a Month (3)
- 2-3 Times a Month (4)
- Once a Week (5)
- 2-3 Times a Week (6)
- Daily (7)

Do you agree that pharmacists should warn patients about the risk of addiction when filling prescriptions for drugs that could be addictive?

- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)

Do you agree that pharmacists should warn patients about the risk of addiction when filling prescriptions for drugs that could be addictive?

If you disagree, why do you believe pharmacists should not warn patients about the risk of addiction when filling prescriptions for drugs that could be addictive?

Have you ever warned patients about the risks associated with prescription opioids and addiction?

- Yes (1)
- No (2)

What are some of the barriers pharmacists might encounter when warning patients about the risk of addiction associated with prescription opioids?

Do you agree that pharmacists should refer patients to local drug treatment resources (like support groups, detox centers, and treatment centers) if they think the patient has a drug abuse problem?

- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)
Do you agree that pharmacists should refer patients to local drug treatment resources (like support groups, detox centers, and treatment centers) if they think the patient has a drug abuse problem?

If you disagree, why do you believe that pharmacists should not refer patients to drug treatment resources if they think the patient has a drug abuse problem?

Have you ever referred patients struggling with substance abuse to treatment resources?
- Yes (1)
- No (2)

What are some of the barriers that pharmacists might encounter when referring patients struggling with substance abuse to treatment programs?

Do you agree that pharmacists should use computer programs (like prescription drug monitoring programs) to make sure a prescription is legal and patients haven't tried to fill the same prescription multiple times?
- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)

Do you agree that pharmacists should use computer programs (like prescription drug monitoring programs) to make sure a prescription is legal and patients haven't tried to fill the same prescription...?

If you disagree, why do you believe that pharmacists should not use computer programs to check to see if a prescription is legal and patients haven't tried to fill a prescription multiple times?

Have you ever used prescription drug monitoring programs specifically to see if a prescription is legal OR that a patient has not attempted to fill a prescription multiple times?
- Yes (1)
- No (2)

Does your workplace require the use of prescription drug monitoring programs when filling prescriptions for controlled substances?
- Yes (1)
- No (2)
- Only in some circumstances (please specify) (3) ____________________
What are some of the barriers that pharmacists might encounter when trying to use prescription drug monitoring programs to see if a prescription and patients haven't tried to fill a prescription multiple times?

Opioids cause a growing number of overdoses in Ohio. Naloxone is a drug that safely treats acute opioid overdose. Do you agree that opioids should be sold with Naloxone to help patients get faster treatment when they overdose?
- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)

Opioids cause a growing number of overdoses in Ohio. Naloxone is a drug that safely treats acute opioid overdose. Do you agree that opioids should be sold with Naloxone to help patients get faster treatment when they overdose?
If you disagree, why do you believe that opioids should not be sold with Naloxone?

Have you ever filled a dual prescription for Naloxone and Opioids?
- Yes (1)
- No (2)

What are some of the barriers that pharmacists might encounter when filling a dual prescription of Naloxone and Opioids?

Recently, CVS announced that Naloxone will be available over the counter, without a prescription, to ensure that all patients are able to access the medication, regardless of whether the opioids they use are legally obtained. Do you believe that Naloxone should be available over the counter?
- Strongly agree (1)
- Somewhat agree (2)
- Neither agree nor disagree (3)
- Somewhat disagree (4)
- Strongly disagree (5)

Recently, CVS announced that Naloxone will be available over the counter, without a prescription, to ensure that all patients are able to access the medication, regardless of whether the opioids they use are legally obtained. Do you believe that Naloxone should be available over the counter?
If you disagree, why do you believe that Naloxone should not be made available over the counter?
Does your pharmacy offer Naloxone without a prescription/over-the-counter?
○ Yes (1)
○ No (2)

Does your pharmacy offer Naloxone without a prescription/over-the-counter?
If yes: Have you ever given a patient Naloxone without a prescription?
○ Yes (1)
○ No (2)

What are some of the barriers that pharmacists might encounter when providing Naloxone over-the-counter?

Thank you for completing the survey- Please follow this link to enter a drawing for one of 5 Gift Cards: One $200, Two $100, and Two $50!

Thank you for your time! If you think we can make this survey better, please let us know how!
Hello! Kent State University is studying how pharmacists can help people who are addicted to drugs get help. As part of this study, we are asking people who have gone through your detox program to fill out an anonymous survey. You do not have to fill out this survey. However, if you choose to fill out the survey, all of your answers will be kept completely private and your answers will help us better understand this important issue. Thanks for your time.

☑ Yes, I want to take the survey (1)
☑ No thank you (2)

What is your age?
☐ 18 or 19 years (1)
☐ 20-29 years (2)
☐ 30-39 years (3)
☐ 40-49 years (4)
☐ 50-59 years (5)
☐ 60-69 years (6)
☐ 70-79 years (7)

Are you male or female?
☐ Male (1)
☐ Female (2)

Are you Hispanic or Latino?
☐ Hispanic or Latino (1)
☐ Not Hispanic or Latino (2)

What is your race?
☐ Black or African American (1)
☐ White or Caucasian (2)
☐ American Indian or Alaskan Native (3)
☐ Native Hawaiian or Other Pacific Islander (4)
☐ Asian (5)
What is the highest level of school you have finished?
- Highschool or less (1)
- Some college (2)
- Associates degree (3)
- Bachelor's degree (4)
- Master's degree (5)
- Doctoral degree (6)

What sort of treatment program are you currently in?
- Inpatient/ resident detox (1)
- Outpatient detox (2)
- Medication maintenance (3)

How long has it been since you last used?
- Less than a month ago (1)
- Between 1 and 6 months (2)
- Between 7 months and a year ago (3)
- Over 1 year ago (4)

Have you ever used heroin (Dope) to get high?
- Yes (1)
- No (2)
- I don't remember (3)

Have you ever used prescription opioids (like OC, Oxy, Percs, Apache, China Girl, Tango) to get high?
- Yes (1)
- No (3)
- I don't remember (2)

Have you used prescription opioids or pain pills (like OC, Oxy, Percs, Apache, China Girl, Tango) to get high in the past 6 months?
- Yes (1)
- No (2)
- I don't remember (3)
What type of drug do you use most often?
- Heroin (Dope) (1)
- Opioids or Pain Pills (Like OC, Oxy, Percs, Apache, China Girl, Tango) (2)
- Cocaine or Crack (3)
- Hallucinogens (Like PCP, LSD) (4)
- Inhalents (Like Whippets) (5)
- Methamphetamines (Meth, Speed) (6)

Has your drug use ever made you so sick you thought you might die?
- Yes (1)
- No (2)
- I don't remember (3)

Do you use more than one type of drug at a time when you get high?
- Yes (1)
- No (2)

How many times have you been in treatment for drug use?
- Once (this is my first time) (1)
- More than once (2)

When you need to fill a prescription (script, RX), where do you usually go?
- Free clinic (1)
- Community health center (2)
- Hospital (3)
- Local pharmacy (like CVS or Walgreens) (4)
- Grocery Store (Acme, Giant Eagle, WalMart) (5)
- The VA (6)
- Mail order or online (7)
- Other (8) ____________________

How do you pay for medicine? (You can choose more than one answer)
- I pay out of pocket (1)
- I go to a free clinic (2)
- I have veteran benefits (3)
- I have Medicaid (4)
- I have Medicare (5)
- I have private insurance (6)
- Other (7) ____________________
Agree or Disagree: Pharmacists should warn patients about prescription drugs that cause addiction.
- I strongly agree (1)
- I somewhat agree (2)
- I neither agree nor disagree (3)
- I somewhat disagree (4)
- I strongly disagree (5)

Are there any reasons you think pharmacists SHOULDN'T warn patients about prescription drugs that cause addiction?

Has a pharmacist ever warned you about prescription drugs that cause addiction?
- Yes (1)
- No (2)

Agree or disagree: Pharmacists should help patients find drug treatment when they think a patient has a drug problem.
- I strongly agree (1)
- I somewhat agree (2)
- I neither agree nor disagree (3)
- I somewhat disagree (4)
- I strongly disagree (5)

Are there any reasons you think pharmacists SHOULDN'T help patients find drug treatment when they think a patient has a drug problem?

Has a pharmacist ever helped you find drug treatment?
- Yes (1)
- No (2)

Agree or disagree: Should pharmacists use computers to make sure that a doctor really wrote a prescription (script/ RX)?
- I strongly agree (1)
- I somewhat agree (2)
- I neither agree nor disagree (3)
- I somewhat disagree (4)
- I strongly disagree (5)
Agree or disagree: Should pharmacists use computers to make sure that a doctor really wrote a prescription?

Are there any reasons you think pharmacists SHOULDN'T use computers to make sure that a doctor really wrote a prescription?

Overdosing on heroin (dope) or prescription opioids (like OC, Oxy, Percs, Apache, China Girl, Tango) can make it hard to breathe. Naloxone is a drug that helps people breathe when they overdose on opioids. The next questions will deal with Naloxone.

Have you ever carried Naloxone or a drug like it with you just in case of overdose (OD)?
- Yes (1)
- No (2)

Agree or disagree: All opioid prescriptions should come with Naloxone so patients have Naloxone in an emergency.
- I strongly agree (1)
- I somewhat agree (2)
- I neither agree nor disagree (3)
- I somewhat disagree (4)
- I strongly disagree (5)

If Agree or disagree: All opioid prescriptions should come with Naloxone so patients have Naloxone in an emergency
Are there any reasons you can think of that opioid prescriptions SHOULDN'T come with Naloxone?

Have you ever had Naloxone come with an opioid prescription you had filled?
- Yes (1)
- No (2)

Agree or disagree: Everyone should be able to buy Naloxone without a prescription.
- I strongly agree (1)
- I somewhat agree (2)
- I neither agree nor disagree (3)
- I somewhat disagree (4)
- I strongly disagree (5)

Agree or disagree: Everyone should be able to buy Naloxone without a prescription, so even illegal drug users have Naloxone in an emergency.
Are there any reasons you could think of that people SHOULDN'T be able to buy Naloxone without a prescription?
Would you be interested in purchasing Naloxone without a prescription?
☑ Yes (1)
☑ No (2)

Would you be interested in purchasing Naloxone without a prescription?
If yes: would you be interested in purchasing Naloxone without a prescription IF you had to pay for it out of pocket?
☑ Yes (1)
☑ No (2)

Thank you for your time! Please add any comments below:
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