

Factors affecting pharmacists' opioid risk and safety counseling behaviors

By

Tanvee Thakur

A dissertation submitted in partial fulfillment of  
the requirements for the degree of

Doctor of Philosophy

(Health Services Research in Pharmacy)

at the

UNIVERSITY OF WISCONSIN-MADISON

2020

Date of final oral examination: 05/15/20

The dissertation is approved by the following members of the Final Oral Committee:

Betty Chewning, Professor, Social and Administrative Sciences in Pharmacy

Kevin Look, Assistant Professor, Social and Administrative Sciences in Pharmacy

Olufunmilola Abraham, Assistant Professor, Social and Administrative Sciences in Pharmacy

Randall Brown, Associate Professor, Department of Family Medicine and Community Health

©Copyright by Tanvee Thakur 2020

All Rights Reserved

*Dedicated to  
my past, present and future self*

## ACKNOWLEDGEMENTS

This dissertation is the culmination of three years of my time as a PhD student. The journey was one of its kind- difficult and seemingly never-ending but at the same time fruitful, life changing and worth all the sleepless nights because it has made me the researcher and person I am today. I would like to acknowledge some people who made this journey possible.

First and foremost, I would like to express my gratitude towards my advisor, Dr. Betty Chewning. She is an epitome of kindness and generosity. She was there to support me in every instance, be it professional or personal. She gave me the freedom to explore, make mistakes and find my true calling as a researcher. She believed in me more than I ever did. I cannot thank her enough for making me the independent research scientist that I am today.

A huge thanks to my committee members- Dr. Abraham, Dr Look and Dr. Brown for their support and guidance during my PhD. Dr. Abraham was there for me as a mentor throughout my PhD, involved me in her research projects and provided excellent advice whenever needed. Dr. Look was always there to help me navigate graduate school logistics and career trajectories right from the beginning. Dr. Brown has been a very involved external committee member whose advice and expertise have contributed a lot to this dissertation.

I would like to acknowledge the Sonderreger Research Center for funding this project and Joseph Wiederholdt fellowship for the scholarship to work on the dissertation. A special thanks to Dale Wilson in Sonderreger Research Center for helping me with budgeting and ordering supplies for my project.

Another set of people who endlessly supported me in this journey were my colleagues at the UW-Madison School of Pharmacy. I would especially like to thank Taylor Watterson for being the best desk-mate and a caring friend, Daniel Ricci for patiently helping me with

statistical softwares and graduate school logistics and, Marwa Rawy and Arveen Kaur for being great friends and support systems. I cannot imagine doing my PhD any other way or at any other place because of the amazing people at UW-Madison School of Pharmacy.

Most important of all, I would like to thank my parents, Dr. Mahesh and Mrs. Priti Thakur for their never-ending love and support, and for always believing in me. They were there to motivate me in the toughest times. Words are not enough to express my love and gratitude for them. I would also like to thank my extended family, who understood how important this journey was for me and supported me all along.

Last but not the least, I could not have made it through last three years without the support of my close friends. They were there to lift me every time I lost hope. Drs. Apoorva Herwadkar, Rucha Gadgil, Anagha Kulkarni and Aditi Patankar for being constant source of motivation from across the globe; Dr. Akash Patil and Susmita Bose for bearing with my sob stories, frustration and anxiety attacks every time the slightest thing went wrong. I cannot imagine what I would ever do without you all.

This dissertation marks the end of a life-changing journey and a long-chased dream for me. This journey has prepared me to face the world and give back to the community as a health services researcher. I look forward to venturing in the real world now with the support of all these phenomenal people who make life a little easier and so much more beautiful!

## TABLE OF CONTENTS

ACKNOWLEDGEMENTS	i
TABLE OF CONTENTS	iii
LIST OF TABLES	vi
LIST OF FIGURES	vi
ABSTRACT	vii
CHAPTER ONE: INTRODUCTION	1
CHAPTER TWO: LITERATURE REVIEW	
Communication between Health Care Professionals and Patients about Opioid Medications: A Systematic review	
Introduction	7
Methods	9
Results	11
Discussion	16
Conclusion	20
Pharmacists Services in the Opioid Crisis: Current Practices and Scope in the United States	
Introduction	29
Methods	31
Results	32
Discussion	37
Conclusion	40
Summary of Literature about Opioid and Safety Counseling	40
Theory of Planned Behavior	
Background and Constructs	41
Use in Pharmacy Literature	42
Rationale for Using Theory of Planned Behavior in this study	43
CHAPTER THREE: USING THE THEORY OF PLANNED BEHAVIOR TO UNDERSTAND FACTORS AFFECTING PHARMACISTS' OPIOID RISK AND SAFETY COUNSELING BEHAVIOR	
Abstract	44
Introduction	45
Methods	
Sampling	48
Data Collection	48
Interview Guide	49
Analysis	50
Results	51
Discussion	58
Conclusion	61

CHAPTER FOUR: PHARMACISTS OPIOID RISK AND SAFETY COUNSELING PRACTICES ACROSS WISCONSIN: A LATENT CLASS ANALYSIS APPROACH	
Abstract	62
Introduction	63
Methods	64
Results	66
Discussion	70
Conclusion	73
CHAPTER FIVE: UNDERLYING FACTORS AFFECTING PHARMACISTS OPIOID RISK AND SAFETY COUNSELING BEHAVIORS: AN EXPLORATORY FACTOR ANALYSIS	
Abstract	74
Introduction	75
Methods	
Study Design	78
Instrument Design and Refinement	78
Developmental pre-test interviews	78
Instrument refining	79
Cognitive Interviews	79
Pilot testing of the final instrument	80
Sampling	80
Data Collection	80
Data Analysis	81
Results	81
Principal Component Analysis	82
Exploratory Factor Analysis	84
Discussion	86
Conclusion	90
CHAPTER SIX: PREDICTING FACTORS FOR PHARMACISTS OPIOID RISK AND SAFETY COUNSELING	
Abstract	91
Introduction	93
Methods	
Study Design	93
Setting and Participants	95
Measures	95
Data Analysis	97
Results	98
Regression model for opioid risk counseling	98
Regression model for opioid safe measures counseling	99
Discussion	100
Conclusion	102
CHAPTER SEVEN: DISCUSSION	
General Discussion	104
Strengths	108

Limitations	108
Implications	109
CHAPTER EIGHT: CONCLUSION	111
BIBLIOGRAPHY	113
APPENDICES	
Appendix A: Interview Guide for Qualitative Section	120
Appendix B: First draft of survey instrument	122
Appendix C: Final draft of survey instrument	124
Appendix D: QUAID analysis report	126
Appendix E: Cognitive Interviews Script	128

### LIST OF TABLES

<b>Table Number</b>	<b>Title</b>	<b>Page</b>
2.1	Provider-patient communication about opioid medications	20
3.1	Interview guide applying the Theory of Planned Behavior	50
3.2	The TPB domains and verbatim quotes	58
4.2	Percentage Distribution per Class in Three-class model	70
5.1	Demographic characteristics of respondents	83
5.2	Survey items	83
5.3	Principal Component Analysis	84
5.4	Exploratory Factor Analysis: loadings, commonality, uniqueness	86
6.1	Items used for dependent variable	98
6.2	Opioid risk counseling regression model	100
6.3	Opioid safety counseling regression model	100

### LIST OF FIGURES

<b>Figure number</b>	<b>Title</b>	<b>Page</b>
4.1	The three-class model	69
5.1	Plot for eigen values based on Principal Component Analysis	85
5.2	Exploratory Factor Analysis three-factor model	87

## ABSTRACT

### Background

Midst the opioid crisis in the United States, pharmacists are especially well-positioned to contribute to safe opioid use due to their role in dispensing opioid prescriptions and easy accessibility to patients. As suggested by the Centers for Disease Control and Prevention, opioid risks consist of dependency, addiction, and overdose from opioids. Opioid safety consists of measures taken to reduce opioid risks and misuse. While pharmacists understand their responsibility as opioid risk and safety educators, they also report barriers to it. This dissertation aimed to explore and understand factors that affect pharmacists' opioid risk and safety counseling behaviors. The specific aims of this dissertation are as follows:

1. To qualitatively explore pharmacists' opioid risk communication behavior based on theory of planned behavior (TPB)
2. To develop a survey scale TO MEASURE Factors affecting Opioid Risks and Safety Counseling (*FORSC*) and explore the underlying factor structure associated with pharmacists' opioid risk communication behavior
3. To understand how different factors affect pharmacists' opioid risk and safety counseling practices

### Methods

This study was conducted as an exploratory mixed methods study. Interviews informed by the Theory of Planned Behavior (TPB) were conducted with 16 pharmacists from a variety of settings to explore factors that affect pharmacists' opioid risk and safety communication behaviors. Interview transcripts were analyzed using content analysis. Interview data were used

to inform survey development. Surveys were developed and refined using an iterative three step process. Surveys were then mailed to a statewide sample of pharmacists. Descriptive statistics, Latent Class Analysis (LCA), Principal Component Analysis (PCA), Exploratory Factor Analysis (EFA) and multiple linear regression analysis were conducted on the survey data.

## **Results**

### *Qualitative phase*

The following themes emerged based on domains of the TPB:

Theme 1: Pharmacists recognized that it was necessary and critical for them to counsel on opioid risks and safety but were not sure how and if it benefitted the patient. (Behavioral attitudes)

Theme 2: Pharmacists were motivated to comply with expectations and the need for them to be opioid risk educators, but their counseling behavior was affected by varying and unclear patient, prescriber and pharmacy owners' expectations and perspectives. (Subjective norms)

Theme 3: Pharmacists reported factors like busyness of the pharmacy, patients' time, privacy, relationship with the patient and patient history as factors that impact their opioid risk counseling behavior. (Behavioral Control)

Theme 4: Pharmacists reported the need for standardized resources and training to have this conversation with patients. (Behavioral Control)

### *Quantitative phase*

Out of 700 surveys distributed, 346 (48.8%) were returned after two mailing rounds. In the three-class model which was deemed the best fit in latent class analysis, the first class shows a profile of pharmacists who counsel on almost all opioid risk and safety topics, the second class shows a

profile of pharmacists who hardly counsel on any opioid risks and safety topics and the third class shows a profile of pharmacists counseling on opioid risk and safety topics mostly for new or long-term prescriptions but not for refill or short-term prescriptions.

A 13-item FORSC scale for measuring factors affecting pharmacists' counseling practices and a three-factor model were obtained from Principal Component Analysis and Exploratory Factor Analysis. . These three factors named Behavioral Attitudes, Subjective Norms and Behavioral Control were also seen to closely align with the three constructs of TPB. The "behavioral attitude" factor contained five items: assessment of patients need for counseling, patient questions, patients' prior knowledge about this medication, existing relationship with the patient and patients' time for counseling. The "subjective norm" factor also contained five items: direction from pharmacy administrators or owners, training and education received about opioid risk counseling, availability of resources to refer patients to, availability of resources for pharmacists, and recommendations by the CDC for counseling.

Predictive model using multiple linear regression for the 'risk counseling' as outcome variable had an adjusted R-squared of 0.22 and the most robust predictor was "Subjective Norm". The 'safety counseling' model had an adjusted R-squared of 0.13 and the most robust predictor was again "Subjective Norm" followed by "Behavioral Control".

## **Conclusion**

This study used a mixed-methods design to explore factors affecting pharmacists' opioid risk and safety counseling practices and developed a novel scale (*FORSC*) aligning with the Theory of Planned Behavior to measure them. These findings need to be tested in descriptive studies with diverse sample to validate and confirm them for generalizability.

## CHAPTER ONE

### INTRODUCTION

*This chapter introduces the need for this research, research objectives and significance of this dissertation. This is followed by brief overview of chapters 2-8 in this dissertation to orient the readers to the structure and flow of material in this dissertation.*

On average, 116 Americans die each day from opioid overdose.<sup>1</sup> Five times more overdose deaths involving opioids occurred in 2016 compared to 1999.<sup>2</sup> More than 40% of all opioid overdose deaths in the United States in 2016 involved a prescription opioid, with more than 46 people dying every day from overdoses involving prescription opioids.<sup>3</sup> It is evident that deaths related to opioid overdose have increased exponentially. Center for Disease Control and Prevention (CDC) describes opioid risks as addiction, dependency and overdose.<sup>2</sup> Opioid safety refers to reducing these risks and potential opioid misuse.

While the nation is trying to combat the opioid epidemic, health care professionals are deemed responsible for prescribing the appropriate amount and promoting safe use of prescription opioids.<sup>4</sup> Pharmacists are on the front line for managing the opioid crisis as they dispense medications and are easily accessible to patients.<sup>5</sup> Pharmacists are recognized as gatekeepers for dispensing opioid medications.<sup>6</sup> The potential of pharmacists to make a positive impact is significant in educating patients about opioid risks such as dependency and overdose, and safety measures to reduce risks and misuse of opioids.<sup>7</sup> They can use prescription drug monitoring programs (PDMP) to help prevent diversion of opioids, can be alert for signs of opioid misuse by patients, and detect inappropriate prescribing.<sup>5</sup> They can also counsel patients with information on risks of opioids, proper storage and disposal of medications, and the harms

of sharing medications with other people.<sup>8</sup> Pharmacists can also be a resource for information on addiction treatment options in the community.<sup>5</sup> While pharmacists are expected to adopt these roles and responsibilities to help mitigate the epidemic, literature lacks evidence of the current communication practices of pharmacists about opioid risk and safety counselling, facilitators and barriers that they face and scope for improvement. Studies state that pharmacists report many barriers such as lack of time, privacy, training and resources when providing opioid risk and safety services to patients, but there is limited evidence about their current risk and safety communication practices and factors that influence these counselling behavior when they dispense an opioid medication.<sup>9-11</sup>

Among pharmacists, counseling is generally limited to alerting patients to potential side effects.<sup>12</sup> Pharmacists reported limited self-efficacy to communicate opioid risks and safety to patients regarding prescription drug abuse and misuse. They have cited communication barriers such as lack of confidence, training, and time.<sup>13</sup> Other barriers to communicating with patients on opioid therapy were lack of communication between healthcare providers and pharmacists, difficulties discussing pain with patients, and inadequate access to health information.<sup>7</sup> Uncertainty exists among pharmacists and patients regarding pharmacists' roles in opioid medication counseling. Patients and pharmacists perceived pharmacists to be responsible for medication safety, yet pharmacists were uncomfortable dispensing high-risk opioids and policing opioid prescriptions.<sup>11</sup>

Literature also lacks studies using theoretical models and frameworks to understand counseling behaviors of pharmacists about opioid risks and safety behaviors. Behavioral theories can be used to better understand behaviors of people and are becoming more widely used in pharmacy literature. In this case, behavioral theories and frameworks can be used to understand

pharmacists' opioid risk and safety behaviors and also develop interventions to enhance counseling by pharmacists based on these frameworks.

### **Significance of this study**

There are only a few studies about current counselling practices about opioid medication risks and safety and factors affecting these counseling behaviors of pharmacists. These tend to be qualitative studies involving interviews, focus groups with a small convenience sample or exploratory studies analyzing audio recorded patient provider interactions.<sup>14-19</sup> While the majority of pharmacists and providers reported barriers for communicating about opioids, few studies report underlying factors that affect pharmacists' risk and safety communication practices regarding opioids. To the investigator's knowledge, a scale or survey instrument has yet to be developed that captures current opioid risk communication practices of pharmacists or prescribers and the factors affecting them. This study will be important in developing a survey instrument for measuring opioid risk and safety counselling practices and underlying factors.

- ✓ To our knowledge, this study is the first to assess current opioid risk practices and factors affecting risk communication behavior of pharmacists across a wide population.
- ✓ This study is the first study to use the Theory of Planned Behavior to understand factors affecting pharmacists' opioid risk and safety behaviors when dispensing an opioid medication
- ✓ The proposed survey instrument can be adapted for use in other states, health systems and populations to understand underlying factors affecting health professional's prescription medication risk counselling practices. Identifying underlying barriers has the potential to help design interventions to educate and train pharmacists and create guidelines for risk counselling across various populations.

## **Research objectives**

This study was conducted as an exploratory mixed methods study. Information obtained from the interviews was used to develop the survey instrument. The first phase involved qualitatively exploring pharmacists' perceptions of their role as opioid risk communicators, their current risk communication practices and factors that affect their risk counselling and communication behavior using the Theory of Planned Behavior. The second phase involved developing and administering a survey instrument to a statewide sample of pharmacists. Survey responses were analyzed to explore if they align with the Theory of Planned Behavior. Survey responses were also analyzed for predicting how different constructs of Theory of Planned Behavior affect pharmacists' opioid risks and safety counseling practices.

The research aims for this study are:

1. To qualitatively explore pharmacists' opioid risk communication behavior based on theory of planned behavior (Chapter 3)
2. To develop a survey scale and explore the underlying factor structure associated with pharmacists' opioid risk communication behavior (Chapter 5)
3. To understand how different factors affect pharmacists' opioid risk and safety counseling practices (Chapter 6)

This dissertation is divided into the following chapters-

Chapter 2: Literature review

This chapter has three parts- a systematic literature review of health care professionals' counseling about opioid medications; a narrative literature review of pharmacists' roles in combating the opioid crisis; and a brief review of Theory of Planned Behavior which is the theoretical framework used in this dissertation.

### Chapter 3: Qualitative study

This study addresses the first specific aim of this dissertation. It is a qualitative study about understanding factors affecting pharmacists' opioid risk and safety behaviors using the Theory of Planned Behavior.

### Chapter 4: Categorizing pharmacists based on their risk and safety practices

The need for understanding factors affecting pharmacists' opioid risk and safety counseling was thought to be better justified if pharmacists' practices based on opioid risks and safety were understood. This study uses a Latent Class Analysis approach to categorize respondent pharmacists into classes based on their opioid risk and safety counseling practices. This approach helps identify latent classes and distribution of respondents into these classes. The results from this study reinforce the need to develop an instrument and understand factors affecting pharmacists counseling practices about opioid risks and safety.

### Chapter 5: Using Exploratory Factor Analysis to develop and refine a measurement scale

This chapter addresses the second aim of this dissertation. It describes the process and outcome of developing the survey scale for measuring factors affecting opioid risk and safety counseling (*FORSC*) behaviors in pharmacists. Exploratory Factor Analysis is used to refine the survey instrument and explore the underlying construct structure based on survey responses.

### Chapter 6: Using regression to predict pharmacists' opioid risk and safety counseling practices

This chapter addresses the third aim of the dissertation. Multiple regression is used in this chapter using the *FORSC* to predict how the constructs of Theory of Planned Behavior predict pharmacists' opioid risk and safety communication practices.

### Chapter 7: Discussion

This chapter provides a comprehensive interpretation of the results of this dissertation study, limitations, and strengths of the study, and examines implications for practice and research.

### Chapter 8: Conclusion

This chapter provides a comprehensive conclusion regarding results from the studies conducted for this dissertation and provides an overview of broader agendas based on the findings of this study.

## CHAPTER TWO

### LITERATURE REVIEW

*This chapter is divided into four sections, two of which are presented in manuscript form:*

- *A systematic review of the communication between patients and Health Care Professionals (HCPs) about opioid medications*

*A Narrative Review of Pharmacists' Roles in Opioid Risk and Safety in the US*

- *A Brief Summary of Literature About Opioid Risk and Safety Counseling by Pharmacists*
- *A Review of the Theory of Planned Behavior*

*The systematic review demonstrates research in overall patient-health care professional communication about opioid medication. The narrative review is specific to pharmacists' roles in mitigating the opioid crisis in general which includes counseling about opioid risks and safety. The summary of literature review which follows provides a quick overview of literature about pharmacists' opioid counseling behaviors. This is followed by a brief review and description of the Theory of Planned Behavior.*

### **Communication Between Patients and Health Care Professionals About Opioid Medication**

#### **Use: A Systematic Review**

Tanvee Thakur, Meredith Frey, Betty Chewning

#### **Introduction**

Prescription opioids continue to contribute to the opioid epidemic in the United States, with more than 40% of all opioid overdose deaths in 2016 involving a prescription opioid, and

more than 46 people dying every day from overdoses involving prescription opioids.<sup>20</sup> From 1999-2016, more than 200,000 people died from an overdose related to prescription opioids alone.<sup>2</sup> Approximately 1,000 individuals are treated in emergency departments (ED) each day for prescription opioid misuse.<sup>21</sup> Deaths related to opioid overdose have increased exponentially and will likely continue to grow.

Although many individuals and organizations are involved in combating the opioid epidemic nationwide, health care professionals (HCP) are primarily responsible for appropriate opioid prescribing and promoting safe opioid use.<sup>4</sup> HCP can promote safe opioid use by counseling patients on the risks of opioid medications, safety measures to reduce risks and misuse, encouraging appropriate use through prescription drug monitoring programs (PDMP) and tapering or deprescribing when opioids are not needed.<sup>4, 5, 8</sup> Pharmacists and other HCP involved in prescribing and dispensing opioids are responsible for effectively communicating medication information.

Opioids can also make people feel very relaxed and "high" - which is why they are sometimes used for non-medical reasons. An opioid overdose occurs when a person uses enough of the drug to produce life-threatening symptoms or death. Prescription opioid use, even when used as prescribed by a doctor can lead to a substance use disorder, which takes the form of addiction in severe cases.<sup>20</sup> Due to increased risks for dependence, addiction, and possible overdose with opioid use, the Centers for Disease Control and Prevention (CDC) recommends that HCP talk to patients about dependency and overdose risks of opioids when they are prescribed an opioid medication.<sup>22</sup> The CDC also recommends discussing pain management and treatment goals with patients to ensure safe use of opioids.<sup>22</sup> Communicating this information is

essential to promote safe use of opioids, but it is a sensitive topic that can be difficult for HCP and patients to discuss.<sup>23</sup>

Existing literature summarizes information regarding opioid abuse and opioid use disorder. While counseling on side effects is a crucial aspect of patient communication for all medications, opioids especially have increased risks associated with use compared to non-opioid analgesics.<sup>3</sup> For this reason, counseling patients about potential risks associated with opioids, such as dependence, addiction, and overdose, is crucial to ensure patient safety and appropriate use. However, there is very limited evidence about communicating risks of opioids to patients. There is also limited research on barriers and facilitators to discussing opioid-related information from the perspectives of patients and HCP.

### *Objective*

The objective of this systematic review was to examine and summarize content covered in opioid consults, patient and HCP perceptions regarding opioid communication, and barriers and facilitators to opioid risk communication. Recommendations are suggested to improve communication and counseling practices about opioid risks and mechanisms to improve patient education based on the findings of this systematic review.

## **Methods**

### *Search strategy*

A literature search was conducted using PubMed, Cinahl plus, and Cochrane Review Library. Search terms used included opioid AND patient AND (pharmacist\* OR provider\*) AND (counseling OR communication). Search results from each database were exported to

Microsoft Excel, merged, and sorted for removal of duplicate articles. The number of duplicate articles is summarized in Figure 1.

### *Study selection*

The Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines were used to guide study selection.<sup>24</sup> Initial screening of all abstracts and titles was conducted independently by the authors to determine article inclusion based on predetermined inclusion criteria. Included studies were original, peer-reviewed research studies published in English, addressing at least one of the following topics: content covered in opioid risk counseling, HCP and patient perceptions about opioid risk and safety counseling, and barriers and facilitators to provision of opioid risk and safety counseling. Center for Disease Control and Prevention (CDC) describes opioid risks as addiction, dependency and overdose.<sup>2</sup> Opioid safety is reducing these risks and potential opioid misuse. These inclusion criteria were agreed upon during the abstract and title screening phase. Any disagreements regarding article inclusion were reconciled through discussion by the authors prior to full text review. Full text articles were reviewed and assessed for inclusion. Reasons for any study exclusion during full text review were documented and discussed by the authors. The inclusion of studies at each phase is summarized in Figure 1.

### *Data extraction*

A standardized data extraction form was used to collect study authors, article title, year published, journal title, study design, brief description of methods, primary outcome measures, and conclusions.

## Results

A total of 24 studies were identified that addressed content covered in opioid risk counseling, HCP and patient perceptions about opioid risk counseling, or barriers and facilitators to provision of opioid risk counseling.

### *Communication content*

Discussion of drug name, purpose, and side effects were commonly discussed by HCP. In one study about opioid-induced constipation (OIC), a common side effect of prescription opioids, conversations were initiated by patients. HCP inquired about constipation, but patients perceived the severity of constipation was higher than did the HCP.<sup>25</sup> Few patients with OIC discussed the burden of OIC with their HCP, and among patients who discussed OIC with their HCP, no specific action was recommended for 33.8% of patients.<sup>26</sup> In a single study comparing counseling practices among HCP in the emergency department (ED) for opioid analgesic medication versus non-opioid analgesic medications, patients were counseled equally about the drug name and purpose. In this case, counseling for patients on opioids compared to non-opioids more often included discussion of common adverse effects and duration of medication use.<sup>16</sup> Overall, the majority of the counseling conversation was spent discussing administration and common adverse effects.

Some studies went beyond discussion of side effects to assess if communication included discussion or counseling about risks associated with opioids. In the McCarthy et al ED study, risks associated with medication use were not as frequently discussed as side effects.<sup>17</sup> In another study conducted in the ED setting, patients were interviewed about conversations with HCP regarding pain and opioids.<sup>27</sup> Patients reported that providers rarely discussed pain

management options or risks of opioid dependence. One study specific to patients with human immunodeficiency virus (HIV) found that many HCP did not discuss risks of opioid medications.<sup>18</sup> Audio consults between HCP and patients receiving opioids were analyzed for communication about pain and opioids and found that the minority of encounters included any discussion about opioids risks. The majority of these conversations were initiated by patients and ended by HCP. An additional study found that conversations about opioid safety occurred more often if the patient reported being anxious about the medication or had close relations with the HCP (Shields et al citation 20).<sup>28</sup> Barriers to obtaining this information were reported by patients. They feared the HCP would infer that the patient was misusing opioids if the patient asked for a naloxone prescription or inquired about opioid tapering. Additionally, HCP associated high overdose risk with medication misuse, regardless of other patient factors.<sup>29</sup> Facilitators to the acceptance of naloxone in case of accidental overdose included the HCP using empowering and non-judgmental communication practices.<sup>29</sup>

In scenarios where opioid tapering was discussed as a strategy to minimize risks associated with opioid use, one study suggested explaining the need for tapering to ensure patient understanding, negotiating with patients, managing difficult conversations, and emphasizing non-abandonment as factors to facilitate opioid tapering with patients.<sup>30</sup>

#### *Patient preferences, perceptions, and relationships with HCP*

Several studies assessed how HCP addressed or acknowledged pain, and how these discussions were perceived by patients and HCP. In the study by McCarthy et al, patient requests or statements related to chronic pain and goal setting for pain management were infrequently discussed.<sup>16</sup> Patients and HCP perceptions differed in patient desire to be included in treatment decision-making, misunderstanding the diagnosis, and care fragmentation. Factors that

facilitated communication included providers' empathy and pain management.<sup>27</sup> Overall, patients perceived providers as dominating these conversations.<sup>27</sup> In another study, opioid use and pain management was discussed more frequently with patients when they had more perceived pain.<sup>28</sup> In the Hughes et al study of patients with HIV, fewer than half of providers acknowledged the patient's pain, and some conversations contained dialogue that indicated conflict. Among the included studies, HCP were seen to have lower odds of positive regard for the patient when opioids were discussed and HCP with negative attitudes towards opioids were less likely to discuss opioid safety with patients.<sup>18, 28</sup>

In a study assessing communication and relationships between patients and providers, patients had variable opinions regarding similar HCP treatment decisions.<sup>15</sup> Crucial facilitators to building rapport and effective communication included tailoring conversation to the individual patient's needs, perspectives, and knowledge. Barriers to individualizing pain management may be due to different perceptions of care priorities, beliefs regarding pain management, and uncertainty associated with opioid therapy.<sup>31</sup> Understanding ethnic and racial perspectives is another consideration in tailoring consults to individual patients. Racial and ethnic disparities exist in accessing effective pain treatment as evidenced by numerous studies reporting that minority patients are more likely to have pain underestimated by providers, less likely to have documented pain scores, and more likely to have undertreated pain compared to white patients. Improved and transparent communication between patients and providers can facilitate better pain management among these patient groups.<sup>32</sup> In another study assessing pain management in black older adults, pain management barriers were related to communication about side effects with providers, fear of addiction, and provider mistrust. These barriers highlight a

communication gap between providers and patients in discussing patient preferences, treatment information, and pain management follow up.<sup>33</sup>

In response to uncertainties about opioid use for chronic pain, patients and HCP often discussed reassurance for opioid use, minimizing opioid use, or gathering additional information prior to the decision to initiate opioid medications. Acknowledging these uncertainties and discussing collaboratively was deemed important for effective communication among patients and physicians about opioids.<sup>14</sup> Reframing conversations about benefits and risks of opioid use was also discussed as a strategy to improve opioid-related communication.<sup>15</sup>

#### *Improving HCP-patient communication*

Various strategies can promote effective communication about opioid risks. One strategy includes guidelines that describe appropriate opioid prescribing. For example, a single study in the ED setting assessing use of guidelines reported that they were often used as a tool to support communication with patients about therapy decisions regarding opioids, rather than as a decision-making tool.<sup>34</sup> Other strategies used by nurse case managers to facilitate communication about long term opioid use for chronic conditions included developing a relationship with the patient, encouraging adherence to pain monitoring, inquiring into discrepancies between patient interview and objective data, assessing patient medication use and pain to determine risk of opioid misuse, and providing patient education for appropriate opioid use.<sup>35</sup> Prescription drug monitoring programs (PDMP) can be also be used as a tool for identifying a patient's current and previous opioid use, can help facilitate decisions about opioid prescribing, and can facilitate communication between providers or with patients regarding risks of opioid use.<sup>27</sup>

Given public transparency of the opioid epidemic, patients may be familiar with harmful effects of opioids and may be more likely to under use prescribed opioids to avoid potential risks, resulting in undertreated pain. In a study involving veterans underusing opioids for chronic pain, improved patient-provider communication about the need for opioids was suggested to avoid the underuse of opioids when pain is not optimally managed and opioids are clinically appropriate.<sup>12</sup>

Pharmacists play an important role in counseling patients about opioid medications at the point of medication dispensing. However, uncertainty exists among pharmacists and patients regarding pharmacists' roles in opioid safety. Patients and pharmacists perceived pharmacists to be responsible for medication safety, yet pharmacists were uncomfortable dispensing and counseling about opioids, due to the perception of "policing" opioid prescriptions and the lack of clinical information available to support dispensing high-risk medications. Additionally, pharmacists desired training about communication techniques to facilitate conversations with patients regarding opioids.<sup>11</sup> The most prevalent behavioral belief was the disadvantage associated with patient confrontations.<sup>36</sup> Pharmacists believed that engaging patients may cause loss of customers, but also believed it may help patients receive appropriate counseling. For normative beliefs, pharmacists identified regulatory agencies and family or friends of patients as groups of individuals who influence their willingness to refer to addiction therapy. Time required for counseling was found to be the most commonly cited control belief.<sup>36</sup>

Additionally, many current and future strategies emphasize the utility of training and education to lessen the communication gap between patients and HCP. For example, one study included in this review assessed a web module developed for faculty physicians regarding opioid prescribing communication for non-malignant chronic pain. Participants reported improved

comfort in pain management, opioid prescribing, and facilitating conversations about discontinuing opioids after completion of the module. Communication knowledge, attitudes, and skills for pain management can be developed and improved through HCP training using web modules or lectures.<sup>37</sup>

## **Discussion**

Discussion of drug name, purpose, and side effects are often considered minimum expectations for counseling by HCP, especially pharmacists.<sup>38</sup> Some studies found that discussion of side effects was commonly included in communication content by health care professionals.<sup>16, 17, 19, 29, 33</sup> However, some HCP do not consistently provide this information in discussions with patients as evidenced by the study of patients with OIC.<sup>25, 26</sup> Additionally, although consequences of side effects were sometimes discussed by the patient or HCP, several patients did not receive information regarding mitigation strategies or further options for managing bothersome side effects.<sup>19, 25, 29</sup> Consequences of unaddressed side effects may result in over or undertreated pain, or inappropriate prescribing.<sup>39</sup>

While counseling on side effects is a crucial aspect of patient communication for all medications, opioids especially have increased risks associated with use compared to non-opioid analgesics.<sup>21</sup> For this reason, counseling patients about potential risks associated with opioids, such as dependence, addiction, and overdose, is crucial to ensure patient safety and appropriate use.<sup>22</sup> Based on the findings of this systematic review, these risks were discussed less frequently than side effects and discussion was more often initiated by the patient compared to the HCP.<sup>11, 18</sup> Patients have frequent exposure to information regarding opioids and risks associated with opioid use, when educating patients about risks of opioids is warranted for patient safety.<sup>15, 29, 33,</sup>

<sup>40</sup> Based on these findings, HCP may feel uncomfortable discussing sensitive issues with patients or may lack training to provide information regarding safe opioid use.<sup>7, 11, 13, 18, 31, 36</sup> Additionally, patients may feel uncomfortable asking questions out of fear of judgement. Regardless of factors in the patient-HCP relationship, HCP have a professional responsibility to provide this information to all patients using an opioid medication. Safe storage and disposal of opioid medications is also an important discussion point, yet none of the included studies assessed if this topic was discussed with patients.

In considering discussions of opioid risks, HCP, mainly prescribers, reported higher rates of burnout following conversations about opioids and any negative opinions about opioids resulted in less discussion of opioid risks and safety with patients.<sup>28</sup> These factors suggest that HCP are not consistently discussing opioid risks with patients, and that educational interventions should focus on minimizing provider burnout by involving other members of the health care team to share information and provide education, such as pharmacists, and should help to reframe the negative opinions of opioid use to a positive regard for effective pain management strategies.

Regarding patient and HCP perceptions of pain management, this review highlighted many discrepancies between both parties.<sup>15, 19, 25, 29</sup> Such discrepancies had negative consequences for communication between the patient and HCP, and often result in non-optimal pain management. Some studies reinforce that HCP had negative associations with opioid use, which resulted in less discussion of opioid safety with patients.<sup>28, 32</sup> Aside from differing patient and HCP perceptions, one of the most commonly mentioned barriers to pain treatment was due to patient-centered treatment.<sup>12, 15, 33</sup> According to studies included in this review, lack of patient-centered treatment is implicated by ethnic and racial disparities in addition to differing

perceptions of pain among HCP and patients.<sup>32, 33</sup> The impact of these factors further impacts communication, and therefore, negatively affects the relationship between the patient and HCP.

Beyond assessment of and description of some of the barriers and facilitators to effective patient-HCP communication, studies included in this review provided some strategies to improve communication. These include the use of tools, such as guidelines and PDMP, and focus on developing strong patient relationships that foster nonjudgmental and unbiased discussions regarding opioid use.<sup>34, 35, 40</sup> Another strategy includes the use of training and education to further increase HCP knowledge about opioid risks and confidence discussing sensitive issues with patients.<sup>37</sup> The following recommendations are suggested to improve communication and counseling practices about opioid risks and mechanisms to improve patient education based on the findings of this systematic review.

1. Standardize content of HCP counseling for opioid medications to include drug name, purpose, side effects, potential risks, and safe storage and disposal
2. Encourage consistent use of opioid prescribing guidelines and PDMP to identify patient's experiences with opioids and to inform discussions with patients about opioids
3. Conduct additional interventional studies to better assess current HCP-patient communication strategies and barriers and facilitators to provision of effective counseling
4. Develop education and training for pharmacy students and pharmacists specific to discussing risks associated with opioid use

This study points out several research avenues. Eighteen of the 24 studies included in this review (75%) are exploratory studies which are qualitative in nature. These studies include a convenience sample and are limited in their generalizability. While exploratory studies are

important to understand the cause and underlying factors, they must be followed by larger studies encompassing larger sample sizes through survey studies or secondary dataset analyses. Studies that use the evidence available from exploratory studies to design and develop interventions are essential to convert research to practice. This demonstrates a need for more intervention studies to train and educate health providers regarding communication about opioid risks and structured guidelines and resources that they can use to make this communication easier. Patients play an important role in communication that occurs between them and health providers which can be described by role theory, and patients must be trained to ask questions and communicate well with the health care providers as well.<sup>41, 42</sup>

### *Limitations*

This systematic review has a few limitations to acknowledge. First, there are limited number of researchers publishing evidence in this area of patient-provider communication. Three of the included authors are responsible for majority of the studies included in this systematic review. Therefore, a specific patient population or certain geographic area may be over-represented in the findings presented in this review. However, the barriers and facilitators suggested in these studies are likely generalizable to many different patient populations and settings, and findings are reinforced by other studies included in this review. Many of the included studies were observational or retrospective conversation analysis studies. Interventional studies are needed within this area of research to further assess current communication and identify optimal strategies to improve discussion between patients and HCP regarding opioids.

## Conclusion

This systematic review provides an assessment and summary of content covered in opioid consults, patient and HCP perceptions regarding opioid communication, and barriers and facilitators to opioid risk communication. The findings from this review emphasize the gap between HCP and patient perceptions and communication regarding pain. Certain strategies have helped to improve effective communication, such as using prescribing guidelines and PDMP, and developing rapport with patients. Recommendations are suggested to improve communication and counseling practices about opioid risks between HCP and patients. Additional interventional research is needed to further assess barriers and facilitators, and to inform implementation of recommendations and strategies to improve communication regarding opioids.

Table 1. Included studies regarding patient-HCP communication (n=28).

Author, year, Ref no	Study title	Study design, sample and Country	Study objective	Methods	Outcome
Bergman et al. (2013)	Contrasting tensions between patients and PCPs in chronic pain management: a qualitative study	Qualitative study/14 PCPs & 26 patients receiving 6 or more opioid prescriptions in previous year/ USA	To understand experiences, perceptions, and challenges of communication between patients with chronic pain and primary care providers.	Thematic analysis of in-depth interviews with providers and patients receiving 6 or more opioid prescriptions in previous year.	Main themes- discussing pain compared to other primary care concerns, acknowledging pain, identifying objective evidence, and recognition of patient individuality. Barriers may be due to different perceptions of care priorities, beliefs regarding pain management, and uncertainty associated with opioid therapy.
Cintron et al. (2006)	Pain and ethnicity in the United States: a systematic review	Systematic review/ 35 journal articles/ USA	To review racial and ethnic disparities in accessing pain treatment, provider	Systematic review	Minority patients are more likely to have pain underestimated by providers and have undertreated pain compared to whites,

			recommendations for care, and areas for future research.		and less likely to have documented pain scores, and more likely to
Donovan et al. (2016)	Faculty communication knowledge, attitudes, and skills around chronic non-malignant pain improve with online training	Intervention study/ 33 clinical-practitioner faculty members USA	To improve faculty communication skills, knowledge, confidence, use of skills in clinical practice, and communication skills through use a web module.	Created and implemented an educational module for faculty development.	Knowledge-based test scores improved with curriculum completion (75% vs. 90%; $P < 0.001$ ). improved comfort in managing patients with chronic non-malignant, improvements in prescribing opioids (3.3 vs. 3.8 vs. 3.9, $P = 0.01$ ) and conducting conversations about discontinuing opioids (2.8 vs. 3.5 vs. 3.9, $P < 0.001$ ) and improved communication skills were reported (mean 67% vs. 79%, $P = 0.03$ ).
Fleming et al. (2018)	Using the theory of planned behavior to investigate community pharmacists' beliefs regarding engaging patients about prescription drug misuse.	Qualitative study/ 31 community pharmacists/ USA	To elicit modal salient beliefs of community pharmacists regarding their willingness to engage patients with suspected controlled substance misuse as identified from reviewing PDMP data.	Focus groups conducted among Texas community pharmacists using the theory of planned behavior as a theoretical framework.	The most prevalent behavioral belief was the disadvantage associated with patient confrontations. Pharmacists believed that engaging patients may cause loss of customers/business but may help patients receive appropriate counseling. For normative beliefs, pharmacists identified regulatory agencies and family/friends of patients as groups of individuals who influence their willingness to refer. Time required for counseling was found to be the most commonly cited control belief.
Hagemeier et al. (2014)	Theoretical exploration of Tennessee community pharmacists' perceptions	Survey study/ 887 community pharmacists/ USA	To explore community pharmacists' perceptions and barriers regarding opioid	Survey administered to Tennessee pharmacists.	Pharmacists had limited self-efficacy in communication with patients regarding prescription drug abuse and misuse, and

	regarding opioid pain reliever abuse communication		prescribing, self-efficacy regarding prescription drug abuse and misuse communication.		cited barriers to communication as lack of confidence, training, and time.
Hartung et al. (2018)	Pharmacists' role in opioid safety: a focus group investigation	Qualitative study/ 19 pharmacists & 18 patients with current experience dispensing or receiving opioid medications/ USA	To explore pharmacists' roles in opioid safety from pharmacist and patient perspectives.	Focus groups conducted with patients and pharmacists to assess pharmacist perceived barriers and facilitators and patient perceived experiences accessing care, medications and safety information.	Patients and pharmacists perceived pharmacists to be responsible for medication safety, yet pharmacists were uncomfortable dispensing high-risk opioids, and policing opioid prescriptions. Patients worried that pharmacists may overstep clinical responsibilities by interfering with prescriber clinical decisions.
Henry et al. (2018)	Communication about chronic pain and opioids in primary care: impact on patient and physician visit experience	Qualitative study/ 49 PCPs and 86 patients taking long-term opioids for chronic musculoskeletal pain/ USA	To explore if patient-physician communication about pain affects patient and physician visit experience	Conversation analysis of 86 PCP-patient video recordings	Patient desire for increased pain medicine, greater pain severity and more patient questions was positively associated greater physician-reported visit difficulty. The association between patient requests for opioids and patient experience ratings was driven intense conflict with patients demanding opioids.
Henry et al. (2018)	Patient-Clinician Communication About Pain: A Conceptual Model and Narrative Review.	Narrative review/ 39 studies/ USA	To create a conceptual model of patient-clinician communication about noncancer pain	CINAHL, EMBASE, and PubMed were searched to find studies reporting empirical data on patient-clinician communication about noncancer pain; Studies were categorized and analyzed to identify crosscutting themes and	The conceptual model comprised the following components: contextual factors, clinical interaction, attitudes and beliefs, and outcomes. Conclusions identified: discussions about analgesics are most frequently characterized by patient-clinician agreement, and self-presentation during patient-clinician interactions plays an

				inform model development.	important role in communication about pain and opioids.
Hughes et al. (2015)	A mixed-methods study of patient-provider communication about opioid analgesics	Mixed methods study/ 45 providers & 423 patients using opioids for HIV pain/ USA	To describe patient-provider communication about opioids and how communication impacts provider attitudes towards patients.	Qualitative analysis of audio recorded encounters between providers and patients with HIV, followed by post-visit questionnaire completed by providers.	A small percent of encounters contained discussion regarding opioids. Majority of these conversations were initiated by patients and some conversations contained dialog indicated conflict. Additionally, providers had a lower odd of positive regard for the patient when opioids were discussed.
Kennedy et al. (2018)	Those Conversations in My Experience Don't Go Well": A Qualitative Study of Primary Care Provider Experiences Tapering Long-term Opioid Medications.	Qualitative study/ 40 PCPs/ USA	To explore primary care providers' experiences discussing and implementing opioid tapering with patients on long-term opioid therapy.	6 in-person focus groups conducted, audio-recorded, transcribed, and analyzed using a mixed inductive-deductive approach in ATLAS.ti. Emergent themes were identified through an iterative, multidisciplinary team-based process.	Barriers in communication included the providers' emotional burden, inadequate resources, and a lack of trust between patient and provider. Facilitators of opioid tapering included empathizing with the patient's experience, preparing patients for opioid tapering, individualizing implementation of opioid tapering, and supportive guidelines and policies.
Kilaru et al. (2014)	How do physicians adopt and apply opioid prescription guidelines in the emergency department? A qualitative study	Qualitative study/ 61 emergency physicians/ USA	To describe themes among emergency department physicians' definition, awareness, use, and opinions of opioid prescribing guidelines.	Semi-structured interviews conducted with emergency department physicians.	Guidelines were often used as a tool to support communication with patients about therapy decisions regarding opioids, rather than as a decision-making tool.
Lewis et al. (2010)	Reasons for under-use of prescribed opioid medications by patients for pain	Qualitative study/ 191 veteran patients who received an opioid prescription for pain / USA	To identify prevalence, reasons for, and implications of opioid under use.	Interviews conducted with veterans who received an opioid prescription for pain and were categorized as	Opioid under-use was more common than overuse. Improved patient-provider communication may better facilitate pain management and opioid diversion

				under-using the medication.	
Liebschutz et al. (2018)	Communication between nurse care managers and patients who take opioids for chronic pain: strategies for exploring aberrant behavior	Observational study/ 2 nurse-care managers and 41 patients in primary care setting/ USA	To describe strategies nurse care-managers use to discuss aberrances with patients on opioid therapy.	Observational study of nurse care manager interactions with patients in the primary care setting.	Five main strategies were used by nurse case managers to facilitate communication: developing a relationship with the patient, encouraging adherence to monitoring, inquiring into discrepancies between patient interview and objective data, assessing patient medication use and pain to determine risk of opioid misuse, and providing patient education for appropriate opioid use.
LoCasale et al. (2016)	The burden of opioid-induced constipation: discordance between patient and health care provider reports	Chart reviews+ Surveys/ 489 patients receiving daily opioid therapy and presence of opioid induced constipation/ USA, Canada, Germany, UK	To describe health care provider's understanding of patient experience with opioid induced constipation and evaluate provider and patient perspectives regarding impact of opioid induced constipation on patient outcomes.	Longitudinal, prospective, observational cohort study for patients receiving daily opioid therapy and presence of opioid induced constipation. Data collected from retrospective chart reviews, health care professional questionnaires, and patient surveys.	However, the importance and severity of opioid induced constipation was perceived differently by patients and providers. Additional communication may improve this discordance.
Matthias et al. (2013)	"I'm not abusing or anything": patient-physician communication about opioid treatment in chronic pain	Qualitative study/ 30 patients using opioids for chronic pain/ USA	To characterize clinical communication about opioids.	Analysis of audio-recorded clinic visits and in-depth interviews with patients regarding their pain care and relationship with their physician.	In response to uncertainties about opioid use for chronic pain, patients and physicians often discussed reassurance, avoiding opioids, or gathering additional information. Acknowledging these uncertainties and discussing collaboratively is

					important for effective communication among patients and physicians about opioids.
Matthias et al. (2014)	Communicating about opioids for chronic pain: a qualitative study of patient attributes and the influence of patient-physician relationship	Qualitative study/40 patients prescribed opioids for chronic pain/ USA	To improve understanding of communication about opioids among providers and patients and how patient-provider relationships impact communication.	Analysis of recorded primary care appointments for patients with chronic pain and patient interviews regarding pain, treatment, and relationships with providers.	Patients had variable responses to similar provider treatment decisions regarding opioid use. Improving communication could include reframing discussions about opioids in terms of benefits and risks.
Matthais et al. (2017)	“I’m not gonna pull the rug out from under you”: patient-provider communication about opioid tapering	Qualitative study/ 9 PCPs prescribing opioids for chronic pain & 37 patients with chronic musculoskeletal pain/ USA	To identify communication best practices and opportunities for improving opioid tapering.	Qualitative study of audio-recorded clinic visits and individual interviews conducted with patients and providers.	Opioid communication facilitators tapering included explaining need for tapering to ensure patient understanding, negotiating with patients, managing difficult conversations, and emphasizing non-abandonment during tapering process.
McCarthy et al (2014)	Patient recall of health care provider counseling for opioid-acetaminophen prescriptions.	Qualitative study/ 149 patients receiving new opioid prescriptions/ USA	To determine the frequency and nature of physician, nurse, and pharmacist verbal counseling at the time of a new prescription for an opioid acetaminophen containing medication as recalled by patients.	Patient recall of counseling they received from their physician, nurse, and pharmacist upon receiving the new prescription	Patients recalled- (1) details of administration from physician/nurse only 44.3%, pharmacist only 5.4%, both providers 12.8%); (2) activities to avoid and side effects (36.2%, 4.7%, 8.7%); (3) medication indication (32.9%, 4%, 4%); and (4) addictive potential (9.3%, 1.3%, 0%) (5) being referred to print informational material accompanying the prescription (MD/RN only 7.4%, pharmacist only 20.1%, both providers 2.7%); (6) having questions solicited (0%, 11.4%, 0%);

					(7) having no interaction relating to medication counseling (3.4%, 32.2%, 1.3%).
McCarthy et al. (2015)	Communication about opioid versus nonopioid analgesics in the emergency department	Conversation analysis/ 41 patients with ankle sprain, back pain, head injury, and laceration/ USA	To compare counseling about opioids to nonopioids in the emergency department setting.	Analysis of audio recorded patient visits in the emergency department.	Patients were counseled equally about name (nonopioid 100 percent, opioid 96.6 percent, $p=0.34$ ) and purpose (88.9 percent, 89.7 percent, $p=0.93$ ). Patients receiving opioids were counseled more frequently about duration of use (nonopioid 40.7 percent, opioid 69.0 percent, $p=0.03$ ) and adverse effects (18.5 percent, 93.1 percent, $p<0.001$ ). In multivariable analysis, opioids ( $\beta=0.54$ , $p=0.04$ ), number of medications prescribed ( $\beta=-0.49$ , $p=0.05$ ), and time spent in the ED ( $\beta=0.007$ , $p=0.006$ ) were all predictors of total Medication Communication Index score.
McCarthy et al. (2016)	Conversations about analgesics in the emergency department: a qualitative study	Conversation analysis/ 47 patients in ED/ USA	To characterize conversations about analgesics in the emergency department.	Analysis of audio recorded patient visits in the emergency department.	Majority of the conversation was spent discussing administration, forecasting, side effects, and past history. Patient requests, statements related to chronic pain, and contentious conversations were infrequently discussed. Providers dominated conversations compared to patients and did not discuss risks of opioid medications.
Mueller et al. (2017)	Attitudes Toward Naloxone Prescribing in	Qualitative study/24 adults prescribed high-dose ( $\geq 100$ )	To assess knowledge and attitudes toward naloxone	Semi-structured interviews with adults prescribed high-dose ( $\geq 100$ )	Patients reported receiving limited education about opioid medication risks from

	Clinical Settings: A Qualitative Study of Patients Prescribed High Dose Opioids for Chronic Non-Cancer Pain.	morphine mg equivalent daily dose) chronic opioid therapy in eight primary care internal medicine, family medicine and HIV practices / USA	prescribing among non-cancer patients prescribed opioids in primary care.	morphine mg equivalent daily dose) chronic opioid therapy in eight primary care internal medicine, family medicine and HIV practices in three large Colorado health systems.	providers. Barriers included the perception that overdose risk stems from medication misuse and that providers might infer that they were misusing their opioid medication if they accepted a naloxone prescription. Facilitators included medical providers' using empowering, non-judgmental communication practices, framing naloxone for use in "worst case scenarios" and providing education and training about opioids and naloxone.
Riley, Alemagno (2019)	Pharmacist utilization of prescription opioid misuse interventions: Acceptability among pharmacists and patients.	Survey study/ Ohio pharmacists/ USA	To evaluate pharmacist and patient acceptance of pharmacy-based opioid interventions	Two surveys were simultaneously administered to Ohio Pharmacists and patients in treatment for substance use disorders, to compare pharmacist and patient acceptance of five pharmacy-based opioid misuse interventions	Both pharmacists and patients view the use of patient counseling and Prescription Drug Monitoring Program-based validation of prescriptions as acceptable prescription misuse interventions
Robinson-Lane et al. (2018)	Pain treatment practices of community-dwelling black older adults	Qualitative study/ 20 community-dwelling black older adults/ USA	To assess pain management experiences of black older adults.	Structured qualitative interviews conducted with patients regarding pain prevalence, treatment, and barriers.	Pain management barriers were related to communication about side effects, fear of addiction, and provider mistrust. These barriers highlight a communication gap between providers and patients in discussing patient preferences, treatment information, and pain management.

Saifan et al. (2019)	Exploring factors among healthcare professionals that inhibit effective pain management in cancer patients.	Survey study/ 472 physicians, nurses and pharmacists/ Jordan	To investigate differences in the barriers to good cancer pain management between physicians, nurses, and pharmacists in Jordan	A group of 473 participants completed the study questionnaires (Barriers Questionnaire -- II and Nurses' Knowledge and Attitudes Survey).	Fears related to analgesic use, fears related to opioid side effects, communication, cultural beliefs, and lack of knowledge were the most clearly identified barriers to cancer pain management
Shields et al. (2018)	Patient and provider characteristics associated with communication about opioids: an observational study	Conversation analysis/ 8 PCPs & 30 patients prescribed an opioid for chronic musculoskeletal pain/ USA	To examine patient-provider communication about chronic non-cancer pain and opioid management.	Analysis of audio-recorded primary care appointments and self-assessments of providers and patients.	Opioids and pain management was discussed more often when patients had greater perceived pain. Communication of mental health and opioid safety was more common with patients with anxiety, close relationships with providers, or higher self-reported provider burnout. Providers with negative attitudes about opioids were less likely to discuss mental health or opioid safety with patients.
Smith et al. (2015)	How, why, and for whom do emergency medicine providers use prescription drug monitoring programs?	Qualitative study/ 61 ED physicians/ USA	To summarize PDMP use among ED physicians.	Analysis of semi-structured interviews conducted with emergency department physicians.	PDMPs are used as tool for identifying opioid misuse and support patient-provider communication.
Smith et al. (2015)	Patient perspectives of acute pain management in the era of the opioid epidemic	Qualitative study/ 23 patients discharged from the emergency department who had presented with acute pain. / USA	To examine patient perspectives and experiences of pain treatment in the emergency department.	Analysis of semi-structured interviews conducted with patients discharged from the emergency department who had presented with acute pain.	Patients reported that providers rarely discussed pain management options or risks of opioid dependence. Communication barriers between patients and providers included diagnosis misunderstanding, care fragmentation, and patient desire to be included in treatment decision-making. Facilitators include communication

					included pain management and empathy of providers.
Vallerand et al. (2018)	Analysis of patient-provider interactions regarding the burden and treatment of opioid-induced constipation in adults with chronic noncancer pain	Database analysis/ 216 patients taking opioids/ USA	To analyze patient-health care provider discussions of opioid-induced constipation (OIC), identify communication gaps, and assess the functional burden of opioid-induced constipation on patients' lives.	Retrospective analysis of a Health Insurance Portability and Accountability Act-compliant database of patient-provider conversations.	HCPs indicated that symptoms of constipation could be caused by opioid use for 75.5% of patients with constipation. In 82.4% of cases, providers did not probe about specific constipation symptoms. Few patients with OIC (11.5%) discussed the burden of OIC with their providers, such as included emergency room visits and reduced food or fluid intake. No specific action was recommended for 33.8% of patients with constipation.

## **Pharmacist Services in the Opioid Crisis: Current Practices and Scope in the United States\*\*\***

Tanvee Thakur, Meredith Frey, Betty Chewning

### **Introduction**

Opioid medications have the potential to cause dependence characterized by a strong desire to take opioids, persistent opioid use despite harmful consequences, increased tolerance, a physical withdrawal reaction when opioids are discontinued, and potential fatal overdose.<sup>21</sup>

\*\*\*This paper has been published in the journal *Pharmacy in their special issue for pharmacist services*. The journal *Pharmacy* holds copyrights for this work. Full text can be accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6632048/>

In 2016, 34 million people globally reported using opioids consistently and about 19 million people used opioids at least once.<sup>43</sup> Deaths attributed to opioid overdose contribute up to half of all drug-related deaths globally.<sup>43</sup> There are effective treatments for opioid use disorders, and yet less than 10% of people who would benefit from treatment are receiving it.<sup>43</sup> In the United States (U.S.), prescription opioids specifically contribute largely to the current opioid crisis, with more than 40% of all opioid overdose deaths in 2016 involving a prescription opioid, and more than 46 people dying every day from overdoses involving prescription opioids.<sup>1</sup> From 1999–2016, more than 200,000 people died from overdose related to prescription opioids alone.<sup>2</sup> Approximately 1000 individuals are treated in emergency departments (ED) each day for prescription opioid misuse.<sup>3</sup> Deaths related to opioid overdose have increased exponentially and will likely continue to grow, making this an important national issue in the U.S. and the focus of this commentary. Although many individuals and organizations are involved in combating the opioid crisis nationwide, healthcare professionals are primarily responsible for appropriate opioid prescribing and promoting safe opioid use.<sup>4</sup> Pharmacists are especially well-positioned to contribute to safe opioid use due to their role dispensing opioid prescriptions and accessibility to patients.<sup>5, 7</sup> Pharmacists utilize prescription drug monitoring programs (PDMP) to help prevent diversion of opioids and detect inappropriate prescribing, and can monitor and recognize signs of opioid misuse.<sup>5</sup> PDMP is a state-based electronic database accessed by prescribers and pharmacists to track controlled substance prescribing and dispensing.<sup>44</sup> Specific information collected from the pharmacy includes what controlled substances were dispensed, how much, to whom, and by whom.<sup>44</sup> Pharmacists can extend patient counseling responsibilities by educating patients on risks associated with opioid use, proper storage and disposal of medication, and the consequences of sharing medications with another person.<sup>8</sup> Additionally, many pharmacists can

distribute naloxone, an opioid antagonist effective in reversing respiratory depression from opioid use, enabling a family member, friend, or potential bystander to prevent death associated with opioid overdose.<sup>45</sup> Pharmacists are knowledgeable about addiction treatment options and can connect patients to resources within the community.<sup>5</sup> Although pharmacists are equipped to provide these services to help mitigate the opioid crises, current literature documents that pharmacists' breadth of opportunities for services is far from fully realized. Underlying factors need to be considered to help pharmacist meet their potential to provide services related to opioid use.

### *Objectives*

This paper seeks to describe current and potential roles for pharmacists to reduce the opioid crisis, identify key factors affecting service provision, and suggest strategies for improvement.

### **Methods**

An exhaustive search of PubMed and Cinhal databases was conducted to identify evidence-based studies describing current pharmacist roles and services, factors affecting service implementation, and strategies to further pharmacist roles and services related to promoting safe opioid use for patients. The following search terms and combinations were used: opioids, pharmacy, pharmacist, safety, counseling, disposal, naloxone, PDMP, and deprescribing. Only studies conducted in the United States were included. The available evidence was summarized into six main categories based on pharmacist roles: counseling on opioid risks, naloxone dispensing, opioid storage, and disposal, PDMP utilization, opioid deprescribing, and addiction treatment resources.

## Results

### *Counseling on Opioid Risks and Safety*

A nationally distributed case vignette survey of primary care physicians (PCPs), pain specialists, and pharmacists, along with nested chart reviews and surveys of patients with chronic pain revealed that prescribers and pharmacists often omit key messages during patient counseling regarding safe opioid use.<sup>46</sup> Among pharmacists, safety counseling is generally limited to informing patients of potential side effects.<sup>46</sup> The omission of information provided may be due to limited self-efficacy among pharmacists in communicating with patients regarding prescription drug abuse and misuse. Pharmacists cited common barriers to communication as lack of confidence, training, and time.<sup>13</sup> Barriers to discussing opioid therapy were similar to those cited for discussing drug abuse and pain with patients, including lack of confidence, training and inadequate access to health information.<sup>7</sup> These barriers are compounded by uncertainty among pharmacists and patients regarding pharmacists' roles in opioid safety. Patients and pharmacists perceived pharmacists to be responsible for medication safety, yet the majority of pharmacists were uncomfortable dispensing opioids and felt they were "policing" opioid prescriptions.<sup>11</sup> Overall, there is a paucity of literature describing current counseling practices pharmacists use to educate patients about opioid risks, such as dependence and overdose, or mechanisms to promote safe opioid use.

### *Naloxone Dispensing*

Increased state and national legislative and regulatory initiatives are partly due to greater recognition and acceptance of naloxone use by the general public, people who use drugs (PWUD), and healthcare professionals such as pharmacists. About half of states have increased

funding to expand patient access to naloxone, pharmacologic treatment options for PWUD, and guidelines for safe opioid prescribing.<sup>47</sup> Standing orders have been implemented on a national level, and allow for naloxone dispensing by pharmacists or other healthcare professionals without a patient-specific prescription.<sup>48</sup> Pharmacists have successfully utilized standing orders to increase patient access to and distribution of naloxone in many pharmacy settings.<sup>49</sup> State and national policies have facilitated the expansion of pharmacist roles, enabling pharmacist to be a key resource in opioid overdose prevention.<sup>50</sup> Pharmacists utilize these policies and standing orders to identify patients who are at risk of overdose and would benefit from naloxone given their medication regimens, medical history, and comorbidities.<sup>45, 51, 52</sup> In two surveys about pharmacist roles in naloxone dispensing and education, simultaneously administered to patients receiving treatment for substance use disorders and pharmacists in Ohio, patients expressed interest in naloxone-based interventions.<sup>53</sup> Meanwhile, many pharmacists were opposed to facilitating naloxone-based interventions.<sup>53</sup> Some of the same concerns were raised for naloxone consultations as had been identified for consultation with patients about opioid safety and risks. Pharmacists identified barriers to delivering these interventions or services as a lack of training to identify eligible patients, and challenges communicating with patients about the need for naloxone. Pharmacists also identified lack of time, reimbursement, and lack of support from management as barriers to implementing naloxone services.<sup>54, 55</sup> Institution-specific guidelines and protocols addressing pharmacist roles, criteria for screening for eligibility, and flowcharts for education and dissemination of naloxone have facilitated identification of patients at risk of overdose, and serve as important resources for pharmacists and other healthcare professionals.<sup>54,</sup>  
<sup>55</sup> These resources along with structured programs regarding naloxone use have helped pharmacists successfully dispense naloxone to patients at risk of overdose.<sup>50, 56, 57</sup>

### *Opioid Storage and Disposal*

Pharmacists have a unique opportunity to educate patients on the importance of proper medication disposal and storage and disposal programs available in the community.<sup>5, 58, 59</sup> Student pharmacists can partner with community officials and businesses to provide safe and appropriate medication disposal.<sup>60</sup> While it is widely understood that medications such as opioids and other controlled substances contribute to environmental pollution when improperly disposed, it has proven hazardous to the population and community health as well.<sup>60</sup> Drug take-back programs have been popular across schools and pharmacies in the country and drug take-back days are helpful in facilitating these activities. Some community pharmacy chains, such as CVS, have installed drug take-back boxes in the pharmacies for patients to dispose of unused or expired prescription medications.<sup>61</sup>

### *PDMP Utilization*

Statewide prescription drug monitoring programs (PDMP) are a useful tool for healthcare professionals to track and monitor controlled substance prescriptions.<sup>44</sup> Specific legislative initiatives that support safe opioid prescribing and naloxone use include the 2016 21st Century Cures Act, which awarded funding to improve state PDMPs.<sup>62</sup> The PDMP can serve as a resource for pharmacists to identify patients that might be misusing opioids or those at risk of overdose. Additionally, the SUPPORT for Patients and Communities Act requires checking the PDMP for Medicare beneficiaries prior to controlled substance prescription. This may prompt further conversations with patients regarding opioid safety.<sup>63</sup> States have varying requirements for PDMP use among pharmacists and prescribers, ranging from voluntary to mandated use.<sup>44</sup> The majority of pharmacists have viewed the PDMP as an objective resource to support clinical decisions, make professional judgements, and prevent diversion and drug abuse [9,32–34].<sup>44, 64-66</sup>

Pharmacists also felt the PDMP helped support patient and prescriber communication regarding suspected drug abuse and helped provide patient education about opioid-specific risks and controlled substance abuse.<sup>44, 64, 67</sup> While the majority of pharmacists agreed that the PDMP was important in the prescribing and dispensing process, some pharmacists reported barriers to using the PDMP.<sup>68</sup> Pharmacists were less likely to use the PDMP if use was not mandated, if they were unfamiliar with it, didn't like the user interface, or if no training was provided on using the PDMP platform.<sup>44, 68</sup> Some pharmacists also reported challenges in working with prescribers or patients in response to PDMP reports.<sup>44</sup> Factors that facilitated regular use of the PDMP included providing training and education on PDMP use. Integrating the PDMP interface into dispensing software and electronic health records was shown to be particularly powerful, along with mandating use for pharmacists and prescribers at the point of prescribing and dispensing, and the ability to contact the prescriber directly through the PDMP.<sup>44, 64, 68</sup>

### *Opioid Deprescribing*

Deprescribing is a necessary mechanism to reduce the use of inappropriate medications, including medications that cause patient harm or unnecessary adverse effects, medications not providing benefit, or medications with no indication.<sup>69</sup> Deprescribing programs initiated by pharmacists, or that included pharmacists in a multidisciplinary team, have measured successful outcomes such as decreased pill burden or decreased use of inappropriate medications.<sup>70-75</sup> However, few guidelines have been developed to guide healthcare professionals in a systematic process to deprescribe or taper inappropriate medications. Systematic processes for deprescribing or tapering inappropriate medications are limited to a few specific classes of medications, and no guidelines exist for opioid discontinuation or tapering.<sup>76-78</sup> Further barriers exist to deprescribing practices in general. Prescribers cite barriers related to lack of time, limited resources to support

deprescribing, patient fear, patient withdrawal symptoms, or patient criticism among deprescribing programs involving pharmacists.<sup>79,80</sup> Pharmacists report barriers related to pressures to focus on productivity, rather than clinical interactions or decision-making with patients. Other barriers identified by pharmacists and prescribers include challenges working with patients and caregivers, lack of policies or guidelines specific to deprescribing, and difficulty partnering inter-professionally across health care settings due to lack of shared health information and patients visiting multiple pharmacies.<sup>80</sup> Factors cited by pharmacists and prescribers that would facilitate deprescribing include further involvement of patients and caregivers, staff education, financial incentives, and involvement in initiatives that expand evidence supporting deprescribing practices.<sup>80</sup>

#### *Providing Resources for Opioid Misuse and Addiction Treatment*

Pharmacists play a key role in recognizing opioid toxicity and preventing diversion of opioids.<sup>58</sup> Compared to prescriber colleagues, pharmacists perceived a larger percentage of patients to be abusing opioids (17% prescribers and 41% pharmacists, respectively).<sup>81</sup> Pharmacists understand the importance of providing appropriate counseling and resources to such patients but believed that engaging with patients potentially abusing opioids may cause loss of customers. Pharmacists identified regulatory agencies and patients' family or friends as most likely to influence their willingness to refer patients to resources for opioid misuse.<sup>52</sup> As with the earlier topics, pharmacists cited many of the same barriers to effectively communicating with patients such as lack of confidence, training, and time. Time required for counseling was found to be the most commonly cited control belief.<sup>81</sup> Pharmacists who had greater amounts of addiction-specific education had a higher likelihood of substance abuse counseling and felt more confident about counseling; however, the majority of pharmacists received no addiction

education.<sup>82</sup> This suggests that the neurobiological basis for addiction, standards of care, and pain management guidelines are likely not understood by a subset of pharmacists.

## **Discussion**

Pharmacists are considered gatekeepers for dispensing opioid medications by other health care professionals and in the literature.<sup>6</sup> They are well positioned to facilitate safe opioid use through counseling patients on opioid risks, educating about safe storage and disposal, providing naloxone, participating in deprescribing initiatives, utilizing the PDMP, and connecting patients to resources for addiction treatment.<sup>5</sup> Although these roles for pharmacist services exist, there are opportunities for broader implementation. Pharmacists are interested in providing these services and have identified mechanisms to support safe opioid use among patients as well as barriers to service implementation. Lack of confidence, training and resources, structured guidelines, and limited time were the most commonly cited barriers by pharmacists for providing all the services addressed in this commentary.<sup>5, 7, 13, 54, 55, 64, 80</sup>

### *Counseling on Opioid Risks and Safety*

Although pharmacists are expected by the Centers For Disease Control and Prevention (CDC) to communicate dependency, overdose, and other opioid risks during patient counseling, pharmacists reported barriers such as lack of confidence, training, and time.<sup>7, 11, 83</sup> Pharmacists would benefit from additional training and resources in pharmacy school curricula and in practice to facilitate effective counseling for opioid medications. Due to the paucity of research and few initiatives focusing on pharmacist communication for opioid medications, additional research is needed to inform effective training strategies.

### *Naloxone Dispensing*

Pharmacists are recognized as stewards of naloxone dispensing and often stock naloxone in the outpatient setting, but do not necessarily dispense naloxone regularly.<sup>54</sup> Pharmacists expressed a lack of training and confidence to detect patients who would benefit from naloxone and to provide education about the necessity and use of naloxone.<sup>54, 83</sup> Targeted training and resources about naloxone dispensing and communication techniques will facilitate further pharmacist involvement in naloxone dispensing and education.<sup>50, 56</sup>

#### *Education on Opioid Storage and Disposal*

Pharmacists recognize their role in informing patients about safe storage and disposal of opioids, yet few initiatives have measured pharmacist improvement, facilitators and barriers to providing such services.<sup>59</sup> There is a need for more evidence-based intervention research about how to help pharmacists offer services to promote safe disposal of opioids.<sup>61</sup>

#### *Guidelines and Protocols for PDMP Use and Opioid Deprescribing*

Most pharmacists agreed that PDMP was a useful tool, especially when linked to the electronic health record and utilized as a platform to contact prescribers. However, pharmacists also reported challenges when working with patients and prescribers about issues detected in PDMP reports.<sup>44, 64, 68</sup> Policies and procedures highlighting pharmacists' roles within the PDMP can help promote more frequent PDMP use and help involve pharmacists in the monitoring process. Beyond the monitoring of prescribed opioids, pharmacists also play an important role in eliminating unnecessary medication when it is inappropriate or no longer needed. Specific algorithms and guidelines would facilitate opioid deprescribing practices in a variety of pharmacy settings. Integrating these into electronic health records would strengthen the intervention even further.

### *Providing Resources for Addiction Treatment*

Pharmacists recognized and valued their role in detecting and communicating with patients potentially misusing prescription opioids.<sup>81</sup> They also expressed lacking confidence and time when talking to patients about opioid abuse.<sup>13, 84</sup> Training and resources about addiction treatment should be offered by schools of pharmacy and continuing education programs to facilitate better understanding and identification of resources available to patients in the community. Overall, training, education, and guidelines for pharmacist roles specific to increasing their readiness to deliver services regarding prescription opioids is warranted for ensuring that pharmacists participate in services that promote safe opioid use among patients. This commentary summarizes services that pharmacists currently offer, assesses factors that affect pharmacists providing these services, suggests strategies for improvement, including areas that should be augmented with education or advocacy in order to ensure enhanced pharmacist services that promote safe opioid use. This commentary has limitations to acknowledge. The scope of this commentary focuses on the opioid crisis and pharmacist services within the U.S., reducing generalizability to other countries. The methodology does not follow a rigorous data extraction and data analysis procedure, but rather includes articles which the authors deemed most applicable and appropriate to include. This paper points to a lack of evidence demonstrating that pharmacist services are directly impacting patient outcomes. All of these services in theory have beneficial effects but it is difficult to find evidence of direct effect of pharmacist services in the literature. Thus, there is need for future research about the impact of pharmacist services in mitigating the opioid crisis.

### **Conclusions**

This commentary paper is one of its kind to describe current practices and roles of pharmacists and factors that affect pharmacists' behaviors and attitudes dispensing these services. Pharmacists successfully recognize the importance of their involvement in services to promote safe opioid use. While pharmacists are expected to participate in service provision to mitigate the opioid crisis, it is evident that pharmacists need more targeted training, education, resources, and structured guidelines to increase confidence and self-efficacy in delivering such services.

### **Summary of Literature About Opioid Risk and Safety Counseling**

Health care professionals (HCP) are primarily responsible for appropriate opioid prescribing and promoting safe opioid use.<sup>4</sup> HCPs do not cover opioid medication risks and safety with patients in most cases.<sup>15, 85, 86</sup> Risks include dependency and overdose risks of opioid medications.<sup>2</sup> Safety includes precautionary measures to reduce risk and misuse by patients and people associated with patients. HCPs have reported facing barriers such as lack of clarity about roles, time constraints and lack of education and resources to guide them in this conversation with patients.<sup>14, 30, 87</sup>

Among the HCPs, pharmacists are considered the most accessible healthcare providers for patients.<sup>7</sup> They are the last health care provider that a patient sees before they start using their medications.<sup>5</sup> Pharmacists are also well informed about medications and their effects which makes them fit for educating patients about medications. Pharmacists can also check patients' history using PDMPs, dispense naloxone and refer them to resources in case of intended misuse

on patients' part.<sup>88</sup> Pharmacists have been deemed important by both prescriber and patients as opioid risks and safety educators.<sup>86</sup>

Pharmacists have been reported to not expand their role as opioid educators.<sup>88</sup> Similar to other HCP, they have reported barriers like lack of training, unclear role expectations, insufficient resources and time to educate patients on opioid risks and safety.<sup>11, 13, 86</sup> There is limited quantitative research about factors affecting pharmacists' opioid risk and safety counseling practices especially when they dispense an opioid medication. Importantly, none of the studies in literature have addressed this issue using a behavioral or health theory. Nor has a scale been developed to measure pharmacist counseling behaviors and factors affecting these behaviors.

### **The Theory of Planned Behavior (TPB)**

The TPB will be used in this study to explore and understand pharmacists' opioid risk and safety counseling behaviors

#### *Background and Constructs*

The Theory of Planned Behavior (TPB) is derived from the Theory of Reasoned Action (TRA). The TRA postulates that individuals act in a situation only after carefully considering all the information they have at their disposal.<sup>89, 90</sup> According to the TRA, if people assess a behavior and its outcomes as positive (attitude), and if they think that people they care about think of that behavior as positive (subjective norm), this results in stronger intentions to practice certain behaviors.<sup>90</sup> The TPB adds a third construct of 'behavioral control' to the existing two constructs of 'attitudes' and 'subjective norm'. Behavioral control addresses how a person

perceives the control they have on a particular behavior. In summary, according to TPB, attitudes (feelings about a behavior), subjective norms (perception of whether important people perform and approve the behavior) and perceived behavioral control (perception of feasibility to participate in a behavior) determine the individual's behavioral intention (willingness to perform certain behavior) and consequently determine how likely an individual is to carry out that specific behavior.<sup>91</sup> The TPB has been widely used to explain health behaviors in patients as well as in providers such as doctors, nurses and pharmacists.<sup>92</sup>

### *The TPB in Pharmacy Related Research*

The TPB is an excellent framework in explaining behaviors of healthcare providers. The three main constructs of the TPB have been used to understand factors that influence pharmacists' behavioral intention towards performing various activities like providing counseling, pharmacy services and patient education. The TPB has been used to explore factors influencing community pharmacists' counseling of asthmatic pediatric patients. Intention to provide counseling to pediatric patients was significantly associated with the subjective norm and perceived ease of counseling which is a control belief; intention to counsel pediatric patient caregivers was significantly associated with perceived ease of counseling.<sup>93</sup>

In another instance, the TPB was used to predict behavioral intentions of pharmacists to provide medication therapy management services.<sup>94</sup> All three constructs of TPB were found to be significant predictors of pharmacists' intent. The TPB has also been used in predicting Texas pharmacists' intention to report adverse drug events to the FDA.<sup>95</sup> Attitudes and subjective norms significantly predicted intent to report ADEs; however, perceived behavioral control did not.

TPB has been also used internationally in pharmacy research. It was used to investigate intentions of Thai community pharmacists to dispense antibiotics without a prescription for upper respiratory infections.<sup>96</sup> Pharmacists' attitudes in this case was the strongest predictor among all TPB constructs. In Scotland, the TPB was used to explore variables that influence community pharmacists' intentions to provide over the counter antifungals for the treatment of vulvovaginal candidiasis.<sup>97</sup> Attitude was the best predictor of intention in this case.

The TPB can be used to inform behavioral intention and behaviors of individuals, applied in this case to the opioid risk consultations of pharmacists dispensing prescription opioids. Pharmacist behavior in relation to opioid risk counselling can be explained as follows by three domains of the TPB.

Attitudes towards behavior: This is informed by the two sub-domains- behavioral belief and evaluation of behavioral belief. With respect to opioid risk consultation, this refers to pharmacist beliefs about what topics they should counsel patients when dispensing an opioid medication and how pharmacists perceive the benefits of their behavior.

Subjective norm: This is informed by the two sub-domains- normative belief and motivation to comply. In this case, it refers to what other people and entities important to their profession like patients, prescribers and laws feel their counseling behavior should be for opioid medications dispensed and how essential they think it is to comply with these beliefs.

Perceived behavioral control: This is informed by two sub-domains- control beliefs and perceived power. In this case, it refers to what factors pharmacists believe impact their behavior to counsel patients on their opioid medication risks and if they perceive they have the power to counsel in spite of these controlling factors.

## CHAPTER THREE

### APPLYING THEORY OF PLANNED BEHAVIOR TO IDENTIFY FACTORS AFFECTING PHARMACISTS' OPIOID SAFETY COUNSELING BEHAVIORS

Tanvee Thakur, Betty Chewning, Mercedes Kile

*This study addresses the first specific aim of this dissertation. It is a qualitative study involving 16 pharmacist interviews about understanding factors affecting pharmacists' opioid risk and safety behaviors using the Theory of Planned Behavior (TPB). The results from this study help understand how different factors under the TPB constructs affect pharmacists' counseling behaviors when dispensing an opioid medication, a previously unexplored area in research.*

#### **Abstract**

**Background:** The US is experiencing an opioid epidemic, and deaths due to prescription opioid overdose continue to rise. US health authorities have recognized the critical role that pharmacists can play through patient education on opioid safety. However, studies have also shown that many pharmacists do not educate patients about opioid safety. Previous research has not examined factors that could affect pharmacists' counseling behaviors using a behavioral theory.

**Objectives:** This study aims to explore factors that affect pharmacist opioid safety counseling behaviors when dispensing opioid prescriptions based on three domains of the Theory of Planned Behavior (TPB) – (1) Behavioral attitudes (2) Subjective norms, and (3) Perceived behavioral control.

**Methods:** In-depth interviews were conducted with pharmacists practicing in rural or urban community pharmacies, clinic outpatient or ambulatory care, and hospital in-patient-pharmacy

settings in Wisconsin using convenience and snowball sampling. Interviews were audio recorded and transcribed verbatim. Qualitative data were analyzed using deductive content analysis.

**Results:** Four themes emerged based on domains of the Theory of Planned Behavior related to key constructs which included behavioral attitudes, subjective norms, perceived behavioral control respectively. 1) Pharmacists recognized that it was necessary and critical for them to counsel on opioid risks and safety but were not sure of how and if it benefitted the patient (behavioral attitudes). 2) Pharmacists were motivated to comply with expectations and the need for them to be opioid risk educators, but their counseling behavior was affected by varying and unclear patient, prescriber and pharmacy owners' expectations and perspectives (subjective norms). 3) Pharmacists reported factors like busyness of the pharmacy, patients' time, privacy, relationship with the patient and patient history as factors that impact their opioid safety counseling behavior (perceived behavioral control).

4) Pharmacists also reported need for resources and training (perceived behavioral control)

**Conclusions:** This study is a first step toward identifying factors affecting pharmacists' opioid safety counseling behaviors using Theory of Planned Behavior. It is essential to combat these barriers to help pharmacists become more responsive to patient expectations and to develop training and resources needed to prepare them to communicate information clearly and with confidence.

## **Introduction**

According to Center for Disease Control and Prevention (CDC), deaths due to opioid overdose are a leading cause of accidental deaths in the US. An average of 130 Americans die

from opioid overdose everyday.<sup>1</sup> In 2017, 68% of the 70,200 drug overdose deaths was attributed to an opioid, including both prescription and illicit opioids.<sup>1</sup> There were 17,087 deaths in 2016 due to a prescription opioid.<sup>2</sup> To combat this epidemic, there has been efforts by US health authorities like the CDC to regulate the prescribing of opioids through the use of Prescription Drug Monitoring Programs (PDMPs) and to increase prevention efforts through patient education of opioid risks and the use of opioid-reversal medications like naloxone. While the PDMPs have helped to decrease the opioid prescribing rate, it has not shown an association in reduced opioid abuse and overdoses, and the evidence surrounding the impact of the PDMPs is mixed overall.<sup>3-6</sup> Furthermore, there is a gap in prevention efforts through patient education of opioid risks and safety.<sup>7,8</sup>

Pharmacists are particularly useful when addressing this gap of educating and informing patients about opioid safety risks when dispensing an opioid medication.<sup>9</sup> Pharmacists are viewed as one of the most trusted professions, and they play a major role in appropriate dispensing of opioid medications.<sup>10,11</sup> Health authorities have recognized the critical role that pharmacists play in combatting the opioid epidemic.<sup>12-14</sup> Pharmacists are usually the last point of contact between a patient and their medications, and patients see the value of this when questions arise regarding medication use.<sup>9</sup> This is especially true in rural communities where pharmacists may be more accessible than a primary care provider.<sup>15</sup> While pharmacists have the knowledge base to counsel patients about opioid medications, studies have shown that pharmacists are not confident to provide education on opioid safety risks.<sup>12,9</sup> Some studies speculate that it could be due to a need for continuing education or a need for a standardized resource.<sup>11,16-18</sup> However, limited empirical literature directly examines factors affecting pharmacists' opioid safety counseling behaviors.

This study aims to explore factors that affect pharmacist opioid risk and safety counseling behaviors based on domains of the Theory of Planned Behavior- 1) Attitudes 2) Subjective norms, and 3) Perceived behavioral control

*Using the TPB to understand factors affecting pharmacist opioid risk counseling behavior*

The TPB has been widely used in the pharmacy practice literature to explain pharmacist behaviors, including vaccination, medication therapy management, disease state management, and medication administration.<sup>20</sup> Based on the TPB model, behavior is informed by behavioral intentions which are in turn informed by subjective norms, perceived behavioral control and attitudes towards behavior.<sup>19</sup> Pharmacist behavior in relation to opioid risk counselling can be explained as follows by three domains of the TPB.

Attitudes towards behavior: This is informed by the two sub-domains- behavioral belief and evaluation of behavioral belief. With respect to opioid risk consultation, this refers to pharmacist beliefs about what topics they should counsel patients when dispensing an opioid medication and how pharmacists perceive the benefits of their behavior.

Subjective norm: This is informed by the two sub-domains- normative belief and motivation to comply. In this case, it refers to what other people and entities important to their profession like patients, prescribers and laws feel their counseling behavior should be for opioid medications dispensed and how essential they think it is to comply with these beliefs.

Perceived behavioral control: This is informed by two sub-domains- control beliefs and perceived power. In this case, it refers to what factors' pharmacists perceived impact their behavior to counsel patients on their opioid medication risks and if they perceive they have the power to counsel in spite of these controlling factors.

These three domains of the TPB inform behavioral intention and behaviors of individuals, applied in this case to the opioid risk consultations of pharmacists dispensing prescription opioids. This qualitative study uses sub-domains of the TPB framework to inform interview questions and explore pharmacists' opioid risk and safety counseling behaviors.

## **Methods**

### *Sampling*

To gain insights of pharmacists from varied settings, we initially used a convenience sample to identify a sample of rural and urban community pharmacists, clinic outpatient, and hospital in-patient pharmacists. This convenience sampling was achieved by reaching out to pharmacists known to the research team. Both urban and rural settings were chosen as rural Wisconsin has reported more opioid misuse than urban regions.<sup>98</sup> Snowball sampling was then used where participants from the convenience sample connected the principal investigator to other participants to interview for this study. Pharmacists from Wisconsin who dispensed opioids and communicated with patients about opioid medications were included. A request was emailed to identify pharmacists to participate in the study outlining the purpose of the study and eligibility criteria which was that the pharmacist should be dispensing opioid medications and communicating with patients about them to qualify for the interview. This approach recruited the convenience sample and then was used for the snowball sample.

### *Data Collection*

Semi-structured interviews were conducted with 16 participants (4 urban community, 4 rural community, 4 clinic outpatient or ambulatory care, 4 hospital in-patient pharmacists). Interviews were conducted until content saturation was achieved, that is when no new or relevant

information emerged with respect to the question of interest.<sup>20</sup> The lead researcher conducted semi-structured interviews between July and September 2019 either in person or by phone by the lead researcher (TT). The interviewer was a female doctoral candidate in health services research conducting this research as a part of her dissertation. Pharmacists geographically closer to the research team within one-hour radius were interviewed in person and those located at a distance were interviewed on the phone. The in-person and phone interviews were similar in format and duration. Only the interviewer and the participant were present at the time of the interview. Oral consent was obtained from each participant. Participants were informed that this study was a part of the interviewers' doctoral dissertation. The audio recordings were deidentified such that they could not be linked back to the participants following protocols approved by the Health Sciences Institutional Review Board.

### *Interview Guide*

Consistent with the aims of this study, the interview guide explored pharmacists' counseling behaviors in terms of information covered and expected to be covered in opioid consultations based on domains of the TPB. Questions used to guide the interviews had the same domains for all four categories of participants (See table 1). The semi-structured interviews were conducted in person or on the phone by the lead author (TT), lasted anywhere between 20 minutes to one hour, and were audio recorded and transcribed verbatim.<sup>21</sup>

Table 1. Interview Guide Applying the Theory of Planned Behavior

<p><b>Attitudes towards Behaviors</b></p> <p><u>Behavioral Belief</u> As a practicing pharmacist, how necessary is it for you to tell the patients about opioid risks and safety? Why?</p> <p><u>Evaluation of Behavioral Belief</u></p>
--

How do you think your counseling practice affects patients' knowledge and attitude towards opioid risks and safety?

### **Subjective norms**

#### Normative Belief

How would you describe what the patients expect to be covered in opioid consults?

What do the prescriber expect you to cover in opioid medication consults?

What training have you received from state or organization that makes opioid risk discussion easier?

What resources do you have or wish you had for this topic?

#### Motivation to Comply

How feasible is opioid risk counseling for every opioid prescription dispensed?

How feasible is it to abide by CDC recommendations for patient education?

### **Perceived Behavioral Control**

#### Control Beliefs

What common barriers do you face about opioid risk communication with patients?

How often is time a factor when discussing opioid risks? (control beliefs)

How would you say privacy affects your intention to counsel patients about opioid risks and safety?

#### Perceived Power

How do you initiate opioid risk discussion?

What factors do you think facilitate opioid risk counselling?

### *Data Analysis*

A deductive content analysis informed by the TPB was performed. In this approach, salient beliefs raised by participants were systematically coded into categories based on the constructs of the theory: 'attitude', 'subjective norm', and 'perceived behavioral control'.<sup>19</sup> NVivo version 14 was used for coding.<sup>22</sup> To accomplish this, two researchers (TT, MK) separately read and reread the data, collected and compiled lists of words, ideas, and quotations representing the sub-domains of the Theory of Planned Behavior.<sup>19</sup> Differences between the two researchers were reconciled until consensus was reached. The researchers (TT, MK) then independently analyzed the data to identify themes within these pre-specified categories.<sup>23</sup> Themes were finalized after discussion and consensus between the two researchers was

achieved. Discussion between the two researchers helped to generate a comprehensive and holistic account of the perspectives of all the participants.

## **Results**

Interviews were conducted with pharmacists situated in five counties. Pharmacists had an experience of  $9 \pm 1.3$  years on average. 6 of the interviewed pharmacists were males and 10 were females. All pharmacists reported counseling on dosage and common side effects for short term opioid prescriptions, and almost a third reported telling patients to take medication only for extreme pain. For refill medication consults, all respondents reported asking follow-up questions about effectiveness and side effects of medications followed by asking if patients had any questions. Only 2 out of 16 pharmacists reported that they counsel to patients about dependency and/or overdose risk of opioids. Two primary reasons were reported for not discussing dependency and risk of overdose for new and refill opioid prescriptions. Firstly, most pharmacists reported that the new prescriptions are for two-three weeks only which is a short duration to develop dependency. Secondly, for refill prescriptions they expected patients would already have had this information explained since they had been taking the medication for a long time and did not counsel them on risks and safety of opioid medications. Seven of 16 pharmacists reported talking to patients about accidental overdose if the patients' dose had increased over time for opioid prescriptions.

Investigators identified the following themes related to domains and sub- domains of the TPB. Each of these are discussed with examples. Additional representative quotes under each TPB domain and theme are presented in Table 2.

### The TPB Domain: Attitudes towards behavior

Theme 1: Pharmacists recognized that it was necessary and critical for them to counsel on opioid risks and safety but were not sure of how and if it was benefitting the patient.

a. Behavioral beliefs:

Pharmacists recognized the need and responsibility on their part to counsel patients on opioid safety for new opioid medications especially for chronic conditions. They stated that it is very necessary and critical that they talk to patients about severe side effects and opioid safety as they are the last healthcare professional that the patients see before they start taking the opioid medication.

*“It's always our job to make sure patients are safe using these medications”*—Hospital

Inpatient Pharmacist 1

They mentioned that with the need to combat the current ongoing opioid epidemic, it is essential that they prioritize opioid risk and safety counseling.

‘I think it's one of our most like important things that we have to do right now in terms of dispensing opioids’- Urban Community Pharmacist 2

b. Evaluation of behavioral beliefs

Most pharmacists hoped their counseling benefited the patients and if were not sure if the patients wanted them to counsel about side effects and risks of opioid medications.

*‘I hope it makes people smarter, about how they use the medications’* -Urban

Community Pharmacist 1

Although all the pharmacists mentioned being hopeful and liking to think that their counseling benefits the patients, they also expressed thinking that patients were not listening to their counseling efforts.

*'They (patients) are not really listening to you (when counseled on medications). So perhaps, you know, saying this out loud to you now says to me, maybe in a day or two we should be calling these people back, doing a call back and reinforcing even at an early stage and not trusting that it's going to get relayed the same well, the same way'* -Rural Community Pharmacist 4

#### The TPB Domain: Subjective Norms

Theme 2: Pharmacists were motivated to comply with expectations and need for them to be opioid risk educators, but their counseling behavior was negatively affected by varying and unclear patient, prescriber and pharmacy owners' expectations and perspectives.

##### a. Normative beliefs

Normative beliefs were categorized into pharmacists' beliefs about patients, prescribers and employers' perceptions and expectations of their counseling behaviors. For patient perceptions and expectations, pharmacists recognized the social stigma about opioid use among patients and limited time on patients' side.

*'Some people are like, give me my pills, and let me get out of here'* - Urban Community Pharmacist 3

They mentioned that there is a wide range of patients they encounter based on what they expect from pharmacists. While some patients want them to go in depth about the medication, they

perceived that majority of the patients were not interested in being counseled about the medication.

*'Some patients really don't want you (pharmacist) to go into extreme detail, they just want the prescription, others are very much interested in the details...'- Clinic outpatient pharmacist 2*

For expectations and perceptions of prescribers about pharmacist opioid risk and safety counseling behavior, most pharmacists reported that they had no idea about what prescribers wanted them to cover with patients and if they expect pharmacists to be opioid safety educators for patients.

*'I have no idea (about what prescriber expects me to cover in opioid medication consult) '- Rural Community Pharmacist 3*

Pharmacists also mentioned that there was lack of direction, resources and training from the state, pharmacy organizations and owners about standardized practices to follow.

*'I wish that there was probably better training as far as how to deal with that, or also too how to deal with, you know, if the patient were to become violent '- Urban Community Pharmacist 4*

Pharmacists reported that Wisconsin State laws expect them to provide a complete consult on both new and refill medication prescriptions. Most of them reported that they were not aware of any specific opioid medication consult requirements from their pharmacy owners and that they were supposed to make a judgement call on what should be covered about risks and safety in these consults.

b. Motivation to comply

Pharmacists reported that they were motivated to comply with state laws and their public health role as opioid risk and safety educators but depended also on job demands. Study participants were aware of the CDC recommendations for topics to cover in consultations and recognized their important role in mitigating prescription opioid misuse. According to participants, these consultations would be feasible in ideal conditions, but the busyness of the pharmacy and lack of time makes it difficult.

*'So, it's very important to follow the guidelines in the current situation with the epidemic-*

*Hospital Pharmacist 1*

*'It would be possible depending on the pharmacy site, the other demands of the job, how*

*busy the pharmacy is' - Rural Community Pharmacist 1*

The TPB Domain: Perceived Control

a. Control beliefs

Theme 3: Lack of time, privacy and negative patient attitudes impact pharmacists' opioid risk counseling beliefs

All pharmacists perceived their time and patients' lack of time as major barriers followed by patient attitudes and someone other than the patient picking up the prescription. Especially community pharmacists (7/8) were seen to report lack of time as a barrier followed by clinic outpatients and then hospital pharmacists.

*'Pharmacy being busy, if you're doing a consult, and you've got a lot of other things to*

*check' - Clinic outpatient pharmacist 4*

*'Time and stigma are definitely two major barriers' - Rural community pharmacist 4*

*'they're in a hurry, or they're hurting, or they really just don't necessarily want to have that conversation' - Rural Community Pharmacist 2*

Pharmacists considered patient attitudes as a major controlling barrier affecting their intention to counsel patients on opioid risks and safety.

*'Sometimes they get very defensive. You can't get too much out of them' - Rural Community Pharmacist 4*

Finally, four pharmacists reported that it becomes difficult to counsel patient caregivers on opioid risk symptoms and pain management as pharmacists are not sure the caregivers understand it and if they would convey it to the patient.

*'One barrier that we do run across with a lot is our opioid patients aren't the ones actually picking up the prescription' - Clinic Outpatient Pharmacist 2*

b. Perceived power

Theme 4: Need for formal training and standardized resources

Pharmacists reported not receiving any formal training in communication with patients after pharmacy school especially about opioid risk communication. They reported not having a standardized protocol or resource to use and direct patients to.

*'So, it's been more experience and more professional reading, and just reading the news, nothing formal' - Urban Community Pharmacist 4*

*'I think the training that we had in school was open-ended questions help' - Clinic Outpatient Pharmacist 4*

*'Some training on, you know, situations and how to handle them would be good'* - Clinic  
Outpatient Pharmacist 3

Table 2. TPB Domains and Verbatim Quotes.

The TPB domain	The TPB sub-domain	Representative quotes
<i>Theme 1: Pharmacists recognized that it was necessary and critical for them to counsel on opioid risks and safety but were not sure of how and if it was benefitting the patient.</i>		
Attitude towards behavior	Behavioral Belief	<p>"I think I have to tell them as it helps them and gives them a better awareness" -Rural Community Pharmacist 3</p> <p>"I think it (counseling about opioid medications) is beneficial. I think we (pharmacists) can do a good job at it" -Clinic Outpatient Pharmacist 4</p>
	Evaluation of Behavioral Belief	<p>"Oh, gosh. I like to think that it makes a difference. I'm not sure if it does. I think a lot of people tend to have opinions already set..." -Clinic Outpatient Pharmacist 3</p> <p>"I think it's a good like frank discussion to have with patients..."-Hospital Pharmacist 4</p>
<i>Theme 2: Pharmacists were motivated to comply with expectations and need for them to be opioid risk educators, but their counseling behavior was negatively affected by varying and unclear patient, prescriber and pharmacy owners' expectations and perspectives.</i>		
Subjective norm	Normative belief	<p>"Honestly, it would be nice to go to, to get something from the organization, you know, one place that maybe everyone is kind of adopting, so we can all be kind of sharing the same message"- Rural Community Pharmacist 1</p> <p>"I never really had a prescriber tell me anything"- Urban Community pharmacist 4</p>
	Motivation to comply	<p>"I think it's very feasible (to comply with CDC guidelines). I mean, it's not, you know, it's not something that you can do without effort..."-Clinic Outpatient 2</p> <p>"Sometimes, I'm going to be quite frank with you, with the volume that we run, you know, and staffing, it's not feasible 100% of the time. But I wish there was some way that it was..."</p> <p>-Urban community Pharmacist 4</p>
<i>Theme 3: Lack of time, privacy, and negative patient attitudes impact pharmacists' opioid risk counseling beliefs</i>		
<i>Theme 4: Need for formal training and standardized resources</i>		
Perceived Behavioral Control	Control Beliefs	<p>"Privacy does in the fact that there are, you know, some shared rooms where there will be two patients in a room." -Hospital Pharmacist 1</p>

		“I think they feel judged if I talk about risks”- Urban Community Pharmacist 3
	Perceived Power	“I think it just depends, again patient-dependent on, you know, how willing they are to engage in like counseling, and ask questions, and bring up their concerns so...”- Hospital Pharmacist 1 “Uniform and uhh..just more resources and maybe CE (continuing education) would be helpful...” -Rural Community Pharmacist 4

## Discussion

This study aimed to explore factors that affect pharmacist opioid risk and safety counseling behaviors based on the TPB domains which include attitudes, subjective norms, and perceived behavioral control. Interviews were conducted with pharmacists in urban community, rural community, ambulatory/clinic outpatient, and hospital inpatient pharmacy settings. Overall, pharmacists reported they discussed side effects with opioid medications, but they usually do not approach the subject of opioid risks with patients for both short- and long-term prescriptions. Pharmacists do recognize the importance of opioid risk and safety counseling and are motivated to comply with expectations to be opioid risk educators. However, the interviewed pharmacists were unsure of how to approach and initiate the conversation about opioid risks and safety. Pharmacist behavior was influenced by factors such as lack of time and training. Also, they perceived varied expectations from patients, providers, and pharmacy owners for pharmacist opioid consultations. Additionally, they reported a need for directions, structured training, and written standardized handouts and resources for effective opioid risk and safety consultations.

The TPB was useful to explore the aforementioned factors affecting pharmacist opioid risk and safety counseling. From this perspective, the intention to perform a behavior is influenced by attitudes, subjective norms, and perceived behavioral control, and these 3 domains

are also influenced by each other. Interviewed pharmacists saw the benefit of opioid risk and safety counseling and they wanted to perform this action (attitude). They were also aware of the importance of opioid risk and safety counseling and their duty to comply.<sup>13,14</sup> But pharmacists did not know if patients want to receive this information. They reported they are unaware of patient expectations (subjective norm), and most pharmacists perceived that most patients are not interested, affecting their control over the situation (i.e. they may believe the patient has the control over this situation). Furthermore, not knowing the expectations of the prescriber or the pharmacy owner affected their attitude toward and perceived control of the situation.

Pharmacists are unsure of how to initiate the opioid risk and safety conversation also because they do not know what has been covered by the prescriber. Study participants reported having no policies set by the pharmacy owner for topics of discussion, which further added to their concern or confusion as to whether their conversation would benefit the patient. Therefore, pharmacists may not be aware of the control they have in this situation. Time also affects opioid risk and safety conversations. If pharmacists do not believe they have enough time (perceived control), then they may not believe in the need for consultations about opioid risks as feasible. This would reduce motivation to comply (subjective norm), even though they continue to recognize the importance of this conversation (attitude).

This study has several implications. First, standardized resources and training are needed to help pharmacists about know what is expected of them and how to consult patients effectively during both initial and refill consults for acute and chronic pain. The lack of clear expectations from the employers, organizations, prescribers, and patients seems to confuse the pharmacists. These findings are consistent with a previous study which identified that pharmacists wanted more education in handling patients who are misusing opioid medications and who are at high

risk for addiction, and that there was a lack of continuing education for risk assessment tools.<sup>20</sup> The same study reported that pharmacists face a lack of confidence in dealing with risky opioid prescriptions, which affects their perceived control over the situation. Training and continuing education do improve pharmacist attitudes towards approaching opioid risk counseling. One study delivered a 3-hour training program about opioid misuse and overdose prevention to community pharmacists to assess how pharmacist attitudes could change. The study found that pharmacists understood the value of counseling for at risk patients and the value of screening tools.<sup>25</sup> Therefore, pharmacists would benefit from further education on opioid risk counseling and screening tools in order to assist themselves and patients with safe opioid use.

As mentioned previously, the interviewed pharmacists expressed an interest in having a standardized handout or resource to integrate into their opioid risk counseling. A standardized resource could possibly save time by being integrated into the workflow and it could improve pharmacist confidence by having a resource on hand. There is a gap in the literature to test this approach to save time and improve pharmacist confidence. Potentially each patient could receive the same information. Opioid risk handouts are available through the CDC.<sup>26,27</sup> Given pharmacists confusion regarding expectations for opioid consultations, priority topics with the assistance of these handouts can be conveyed to patients in consults. There is also a need for policies in place at either the company, state, or federal level to ensure that pharmacies provide patients with educational handouts with information prescription opioid safety.

Overall, pharmacists are motivated to comply with and see the benefit of opioid safety counseling, but there are factors that affect their intention and perceived ability to perform this action.

### *Limitations*

This study has the limitations of an exploratory, qualitative study. The study used convenience sampling and sampled pharmacists from a limited geographical region. The sample size used for this study was not large which reduces generalizability. Additionally, different disease states, provider types and individual patient characteristics may change communication offered and reported. Similarly, demographics, practice site of pharmacists, gender, experience, training etc. may affect the responses. Larger descriptive studies with diverse pharmacy settings and broader geographic areas are needed to explore this communication gap further.

## **Conclusion**

This study was a first step toward identifying factors affecting pharmacists' opioid safety counseling behaviors using a validated social behavioral theory- the Theory of Planned Behavior. It is essential to combat these barriers to help pharmacists become more responsive to patient expectations and to develop training needed to prepare them to communicate information clearly and with confidence. There is a need for organizational support and structured guidelines for roles and pamphlet tools for prescribers and pharmacists to support opioid safety communication with patients. Future descriptive and intervention research is needed to develop effective interventions consistent with the TPB to overcome apparent role conflicts regarding expectations of patients, prescribers, and pharmacists.

**CHAPTER FOUR**  
**PHARMACISTS OPIOID RISK AND SAFETY COUNSELING PRACTICES:**  
**A LATENT CLASS ANALYSIS APPROACH**

Tanvee Thakur, Betty Chewning, Kevin Look, David Kaplan

*This study uses a Latent Class Analysis approach to categorize respondent pharmacists into class profiles based on their opioid risk and safety counseling practices. This approach helps identify latent classes and distribution of respondents into these classes and provides a rationale for aims 2 and 3 which focus on understanding factors that affect opioid risk and safety counseling behaviors. The results from this study reinforce the need to develop an instrument and understand factors affecting pharmacists counseling practices about opioid risks and safety.*

**Abstract**

**Background**

Over the last two decades, the US has been affected by an opioid crisis. Limited research addresses pharmacists' opioid medication counseling practices and risk and safety topics that the pharmacists cover in general. . This exploratory study helps to address this gap through latent class analysis to understand different classes that the pharmacists in Wisconsin fall into based on their counseling practices for opioid medication risks and safety. The objective of this paper is to categorize pharmacists based on their opioid risk and safety counseling practices to inform future interventions and research to improve practice. The percent of pharmacists falling into each of these underlying, unobservable subgroups is identified.

**Methods**

This study was conducted as a statewide survey of pharmacists using the modified Dilman technique. The survey consisted of ten items about pharmacists' opioid risk and safety practices when dispensing an opioid medication. Descriptive statistics were conducted followed by latent class analysis. This approach categorized pharmacists based on their responses to the survey items.

## **Results**

In the three-class model which was deemed the best fit, the first class shows a profile of pharmacists who counsel on *almost all* opioid risk and safety topics and comprised 16.75% of the total respondent population. The second class shows a profile of pharmacists who *hardly counsel on any* opioid risks and safety topics and comprised of 39.80% of the respondent population. The third class shows a profile of 'pharmacists counseling on opioid risk and safety topics mostly for *new or long-term prescriptions, but not for refill or short-term prescriptions* which constituted 43.45% of respondent population.

## **Conclusion**

It is essential to understand gaps in practice and specific areas for improvement based on the results of this study. Interventions targeting these gaps in practice can be developed for pharmacists to make them adept opioid risk and safety educators.

## **Introduction**

The Midwestern region of the United States (U.S.) experienced a 70% increase in opioid overdose cases from July 2016 through September 2017.<sup>1</sup> In 2017, 47,600 individuals in the U.S.

died of overdoses associated with opioids. Every day, on average of 130 people in the US die after overdose on opioids and more than 46 people die from an overdose of prescription opioids.<sup>4</sup> In 2016, 15.8 deaths per 100,000 persons occurred in Wisconsin compared to 13.3 deaths per 100,000 nationally.<sup>99</sup> Deaths attributed to prescription opioids increased from 285 to 382 deaths in 2016.<sup>99</sup> The rate of opioid use disorder has more than tripled from 2005 to 2016 in Wisconsin.<sup>99</sup>

Healthcare professionals are deemed important to educate and counsel patients on opioid risks and safety when the patients are prescribed or dispensed an opioid prescription. Pharmacists are recognized as gatekeepers for dispensing opioid medications.<sup>6</sup> They are well positioned to counsel patients on opioid risks, safe storage and disposal, misuse and abuse and to dispense naloxone.<sup>5</sup> Pharmacists have expressed an interest in offering opioid risk counseling services; however, they have also reported facing barriers like lack of time, resources and training when dispensing these services. Given the current opioid crisis in the state of Wisconsin, pharmacists can play an important role as opioid risk and safety educators for patients.

There is scarce literature available about pharmacists' opioid medication counseling practices in general and there is little published evidence about it in the state of Wisconsin. Understanding this gap in the literature, this exploratory study aims to understand different classes that the pharmacists in Wisconsin fall into based on their counseling practices for opioid medication risks and safety. The goal is to identify a set of underlying, unobservable subgroups along with the percent of pharmacists falling into each subgroup to help inform future interventions and research to improve practice.

## **Methods**

This study was conducted as a statewide survey study where pharmacists were asked if they counseled patients on dependency and overdose risks for opioid medications for new short-term and long-term prescriptions as well for refill prescriptions. Additionally, they were asked if they counseled patients on safe opioid storage and disposal, self-monitoring of pain, common side effects, said the term opioid during a consult and initiated conversation about naloxone for overdose risk. This survey underwent revisions for content, formatting and wording through 12 pretest interviews with 3 urban community, 3 rural community, 3 clinic outpatient and 3 hospital in-patient pharmacists. This process helped in refining and validating the survey instrument.

Pharmacists were sampled using stratified random sampling. A list of practicing pharmacists obtained from the Department of Safety and Professional Services was used in this study. Pharmacists from this list were stratified based on rural or urban setting and into five geographical areas defined by DHS Wisconsin.<sup>98</sup> An equal number of pharmacists was randomly picked from each stratum resulting in 700 surveys in total. The mail survey was administered using the modified Dilman technique. The first round was mailed to the entire sample, which was followed by a reminder post card in a week. To help incentivize responses \$2 were included as a small thank you in the first round of surveys. The non-respondents from the first round of mailing were sent the survey again two weeks after the first reminder postcard was sent. The second round of reminder postcards was sent within a week to recipients of the second round of surveys. Data were entered into an excel spread sheet by the lead author. Fifteen percent of the entered responses were checked for quality assurance. The data analyses were completed using R version 3.4.3.

Descriptive statistics were conducted on the data followed by latent class analysis. Latent class analysis (LCA) aims to identify subgroups of people who share common characteristics in

such a way that people within the subgroups have a similar scoring pattern on the measured variables, while the difference in scoring patterns between the subgroups are as distinctly different as possible.<sup>100, 101</sup> LCA helps create or characterize a multidimensional discrete latent variable based on a cross-classification of two or more categorical variables.<sup>100</sup> Latent class analysis would help classify pharmacists into latent classes based on their opioid risk and safety counseling practices, which was deemed an important contribution to existing literature. Typically, four parameters are used in these analyses: Bayesian Information Criterion (BIC), chi-square goodness of fit, likelihood ratio chi-square ( $G^2$ ) and entropy of the model to decide model fit.<sup>102, 103</sup> Entropy is a measure of the unpredictability, in this case it is the state of average information content.<sup>101</sup> The final model is selected based on 1) having lowest values of each of the parameters and 2) how clearly the model describes or responds to the research question.<sup>100,</sup>

103

## Results

Out of 700 surveys administered, 346 (48.8%) were returned from both the mailing rounds. Out of this, 33% were returned back from the first round and 15.8% from the second round. A criterion for inclusion was that the pharmacist counseled patients on opioid medications. Out of the 346 surveys, 216 met this criterion. Demographic characteristics for respondents are presented in Table 4. About a quarter (24.3%) of the pharmacies dispensed less than 1000 prescriptions a day, 37.5% dispensed 1000-5000 prescription a day and 2.5% dispensed more than 5000 prescriptions a day.

Latent class analysis was conducted on responses obtained from the statewide sample of pharmacists on 10 items on a four-point scale. The items used for exploring the unmeasured class membership in this case are presented in Table 1.

For the purpose of latent class analysis which can be conducted only with dichotomous data, *never* and *sometimes* were considered as one category where pharmacists hardly consulted on these topics (0) and *most times* and *always* were considered as the second category where pharmacists mostly consulted on these topics (1). The results obtained for one, two, three and four class analysis after conducting latent class analysis are as follows.

#### One class model

The likelihood ratio Chi- square ( $G^2$ ) for this one class model was 751.718 ( $p=1.315808e^{-63}$ ) and the Pearson Chi- square ( $X^2$ ) was 12735.79. The BIC for this model was 2582.445.

Entropy for this model was 5.91

#### Two- class model

The likelihood ratio Chi- square ( $G^2$ ) for this two-class model was 394.4487 ( $p=6.998052e^{-16}$ ) and the Pearson Chi- square ( $X^2$ ) was 1653.214. The BIC for this model was 2284.201. Entropy for this model was 5.11.

#### Three class model

The likelihood ratio Chi- square ( $G^2$ ) for this three-class model was 322.3308 ( $p=7.401104e^{-10}$ ) and the Pearson Chi- square ( $X^2$ ) was 3072.385. The BIC for this model was 2271.11. Entropy for this model was 4.92. The three-class model is also graphically represented in a plot in Figure 1. It depicts the above discussed results graphically.

#### Four class model

The likelihood ratio Chi- square ( $G^2$ ) for this three-class model was 276.07 ( $p=8.474727e^{-06}$ ) and the Pearson Chi- square ( $X^2$ ) was 2504.04. The BIC for this model was 2284.083 which is

higher than the three- class model which can suggest overfitting in the four-class model. Entropy for this model was 4.79 which was just a little lower than the three-class model.

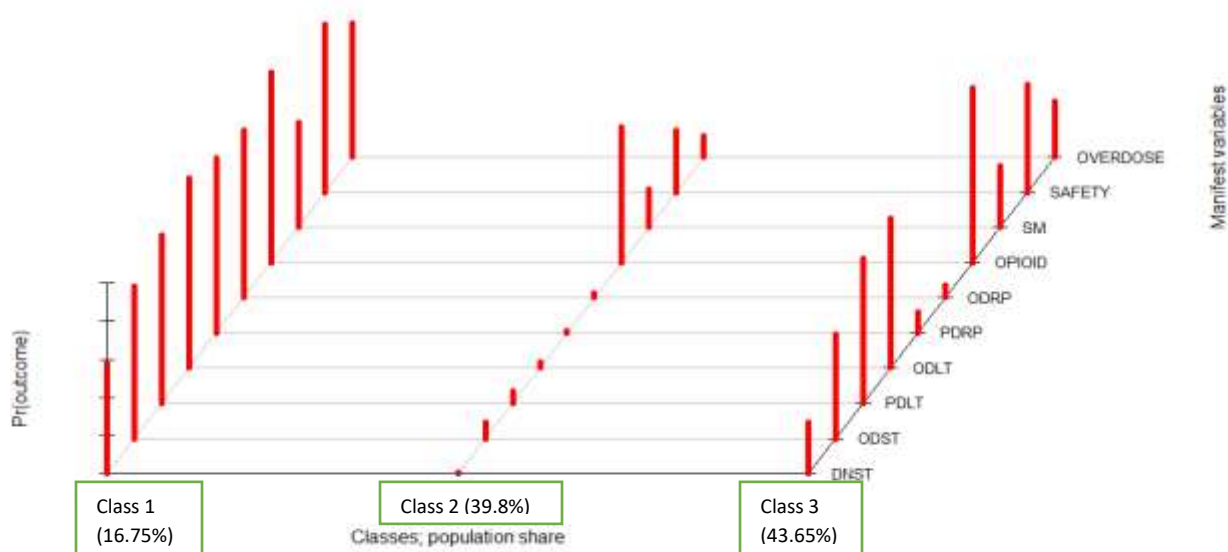


Figure 1. The Three class model

Based on goodness of fit parameters and logical distribution of classes, the three-class model was used for this study. The statistical parameters for the three-class model and four class model were very close. Even if the four-class model had slightly lower values for chi-squares statistics, it had higher BIC than the three-class model. The three-class model made logical sense and was simpler to explain in this descriptive study as well. This the three-class model was considered the best fit in this case.

In this three-class model, the first class shows a profile of pharmacists who counsel on almost all opioid risk and safety topics and comprises 16.75% of the total respondent population. The second class shows a profile of pharmacists who hardly counseling on any opioid risks and safety topics and comprises of 39.8% of the respondent population. The third class shows a

profile of ‘pharmacists counseling on opioid risk and safety topics mostly for new or long-term prescriptions but not for refill or short-term prescriptions which constitutes 43.45% of respondent population. (see figure 1)

Table 2. Percentage distribution for discussion topic per class in three-class model (denominators for percentages in parenthesis)

Item code	% of Class 1 (n=37)	% of Class 2 (n=87)	% of Class 3 (n=92)
Dependency risk- short term prescription	58	0.4	27
Overdose risk- short term prescription	80	9	55
Dependency risk- long term prescription	88	7	76
Overdose risk- long term prescription	100	3	79
Dependency risk refill prescription	92	1	11
Overdose risk- refill prescription	88	2	7
Tell the patient medication is an opioid	100	71	92
Self-monitoring of pain	55	20	32
Safe storage and disposal	88	33	57
Discuss naloxone for overdose	70	11	29

Table 2 demonstrates item-wise distribution of each class. Interpretation of this table can be explained by the following examples. Fifty-eight percent of pharmacists in Class 1, 0.4% in Class 2 and 27% in Class 3 counsel patients on dependency risks for short-term opioid prescriptions. All the pharmacists in Class 1, 3% of pharmacists in class two and 79% in class 3 counsel patients on overdose risks for long-term opioid prescriptions. Figure 1 is a graphical representation of item-wise distribution of the three classes reported in Table 2.

The type of prescription was also seen to play a role in pharmacists deciding if they should talk to patients about opioid risk and safety in class three obtained in this study. Pharmacists were seen to not counsel patients as much on opioid risks for short term and refill prescriptions (See table 2).

## Discussion

Latent class analysis proved useful in efficiently identifying three underlying classes of pharmacists on the basis of their counseling behaviors. This approach was useful in exploring unobservable class distribution using observable variables which were the survey items.<sup>101</sup> Based on the class structure obtained, this study shows that only a small percentage of pharmacists engaged in counseling patients about opioid risks and safety. Forty percent of the respondents hardly engaged in counseling about opioid risks and safety with patients. Around 43% engaged in counseling for long term prescriptions but not as much for short term and refill prescriptions. The counseling practices of pharmacists are seen to be widely distributed across the three classes.

Empirical literature lacks evidence about measuring opioid risk and safety counseling practices of pharmacists using a survey measure in large sample sizes. Studies conducted so far use qualitative measures such as interviews and focus groups to understand pharmacists' counseling practices.<sup>11, 15</sup> This study contributes to the literature by using latent class analysis to understand gaps in practice areas of pharmacists. This instrument can be used to assess counseling practices of pharmacists in other states, health systems and practice areas. It also demonstrates actual counseling practice of pharmacists in Wisconsin in the current opioid crisis faced by the state.<sup>99</sup> The class breakdown of pharmacist practices are likely to be generalizable around the country or globally. The exact percentage distribution of pharmacists within those subgroups will likely differ from state to state in the United States, but this survey instrument and analytical method provide a starting point to understanding these distributions of pharmacists.

Discussion about opioid risks and safety is a sensitive topic and is associated with stigma in the society.<sup>14, 87</sup> At the same time, given the current opioid crisis, it is necessary that patients

are informed about opioid risks and safety.<sup>88</sup> Pharmacists are easily accessible to patients especially as opioid risk educators.<sup>5,7</sup> Patients have expressed wanting to know about opioid risks and safety especially from the pharmacists. Prescribers and patients have recognized pharmacists as opioid risk and safety educators.<sup>86</sup> On the other hand, pharmacists are seen to not expand their opioid risks and safety counseling services and have reported facing barriers like lack of time, standardized resources, training, education and direction about opioid medication counseling.<sup>7,36,86</sup> (cite dissertation paper 1)

The type of prescription also played a role in pharmacists deciding if they should talk to patients about opioid risk and safety in class three obtained in this study. Pharmacists did not counsel patients as much on opioid risks for short term and refill prescriptions. Opioids usually do not show dependency risks in first two weeks of use and that can justify pharmacists not informing patients about it.<sup>104</sup> Opioid overdose can occur if patients use a higher quantity of opioid medication for pain relief.<sup>2</sup> Overdose can also occur if the opioid medication happens to be misused or diverted by some other member of the family like teenagers or children.<sup>2</sup> Thus, informing patients about the potential signs and symptoms of overdose may be beneficial even in case of short-term opioid prescriptions which is not a practice in majority of pharmacists in this study sample.

It has been previously reported that pharmacists usually do not counsel patients for a refill prescription.<sup>105</sup> This may be assuming that the patients already know the side-effects and risks of the medication and asking them if they have any questions may suffice and is also dependent on varying counseling laws in each state in the United States.<sup>105</sup> In case of opioid medications, it might help if pharmacists quickly go through the risks of opioid medications and check if patients have any symptoms of dependency and overdose. Patients may not be open to

spending time on information they already know and would not be receptive to in-depth counseling by pharmacists for refill prescriptions. (see chapter 3) At other times, pharmacists would not have the time to counsel patients due to busyness of pharmacy which also comes with lack of privacy for such sensitive conversations.<sup>88</sup> Lack of patients' time, pharmacists' time and privacy have been reported by pharmacists as barriers to opioid risks and safety communication.(see chapter 3)

Given the class distribution found in this study, pharmacist services as opioid risk and safety educators need to be enhanced and expanded in the state of Wisconsin especially with the opioid crisis in the state. Clear directions from the state, pharmacy owners and organization about expectations from staff pharmacists in these roles can help pharmacists at adopting their role as opioid risk and safety educators. Structured training and guidance from the state in form of continuing education modules or face to face workshops about best practices and techniques for communication can help pharmacists feel more comfortable and ready to offer opioid risk and safety counseling. Having standardized resources such as handouts, pamphlets or toolkits that can be used as patient education tools and given out with the medication can help pharmacists spend less time on counseling patients with refill or short term prescriptions, where long in-depth consults may seem unwarranted by pharmacists.

Limitations: This study has some limitations. These data were collected from Wisconsin alone and may not be generalizable outside of the state. More research is needed with this instrument to test the generalizability across the country. The measurement scale can be used in other clinical settings e.g. opioid medication prescribers; however, the instrument would need to be revised and validated based on characteristics of other clinicians.

## **Conclusion**

This latent class analysis identified clear subgroups of pharmacists on the basis of their opioid counseling behavior, with only a very small percentage of pharmacists counseling patients on almost all topics for opioid risks and safety. It is essential to understand gaps in practice and specific areas for improvement which analyses with this survey identified. Interventions targeting these gaps in practice can be developed for pharmacists to make them adept opioid risk and safety educators.

**CHAPTER FIVE**  
**UNDERLYING FACTORS AFFECTING PHARMACISTS OPIOID RISK AND SAFETY**  
**COUNSELING BEHAVIORS: AN EXPLORATORY FACTOR ANALYSIS**

Tanvee Thakur, Betty Chewning, Kevin Look, Olufunmilola Abraham

*Building on previous chapters and addressing the second aim of this dissertation, this chapter describes the three-step process of developing and refining the survey scale for measuring factors affecting opioid risk and safety counseling (FORSC) behaviors in pharmacists and the outcome after administering this survey. Exploratory factor analysis is used to refine the survey instrument and explore the underlying construct structure based on survey responses.*

**Abstract**

**Background:** Pharmacists are responsible for educating patients about safe and efficacious use of prescription opioids, which is particularly important in the current opioid epidemic in the United States. However, pharmacists have expressed low self-efficacy and confidence in initiating consults about opioid risks and safety. There is scarce evidence in literature on underlying factors that affect pharmacists' behavior to counsel patients about opioid risks and safety.

**Objectives:** The goals of this study were to:

1. develop a measurement scale in a survey instrument to understand underlying factors that pharmacists perceive affect their opioid risk counseling behaviors, and
2. assess the underlying domains for factors affecting pharmacists' opioid risk and safety counseling behavior and see if they fit the Theory of Planned Behavior constructs

**Methods:** This study involved developing, refining, and administering a survey to a sample of pharmacists to understand their counseling behaviors when dispensing opioid medications. The design and refinement of the survey instrument involved an iterative 3 step process: pre-test interviews, QU Aid analysis and cognitive interviews. Principal Components Analysis and Exploratory Factor Analysis were conducted to further refine the measurement scale and understand the underlying factor structure that affected pharmacists' behavior to counsel about opioid risks and safety.

**Results:** Three items from the 16 initial items were dropped resulting in a 13-item scale. The three-factor model yielded a simple structure with all items having a loading greater than 0.40 on only one factor and was a good fit based on statistical parameters. The three factors that arose from this model were- behavioral attitudes, subjective norms and behavioral control which also closely aligned with the TPB.

**Conclusion:** The resulting scale is a promising and psychometrically validated tool for assessing factors affecting opioid risk and safety counseling practices. The scale is informed by the TPB and an intensive development process. Using this scale in research can help understand and target specific factors in future descriptive and intervention research.

## **Introduction:**

In the midst of the nation trying to combat the opioid crisis, health care professionals are deemed responsible for safe and efficacious use of prescription opioids.<sup>22</sup> Pharmacists are at the frontline for educating patients about risks and safe use of opioids when they dispense opioid prescriptions.<sup>7</sup> Pharmacists are recognized as gatekeepers for dispensing opioid medications.<sup>6</sup>

They are well positioned to counsel patients on opioid risks, safe storage and disposal, misuse and abuse and to dispense naloxone.<sup>5</sup> However, pharmacists have reported barriers to communication about opioid risks. Among pharmacists, risk counseling is generally limited to alerting patients to potential side effects.<sup>12</sup> Pharmacists reported limited self-efficacy to communicate with patients regarding prescription drug abuse and misuse.

Uncertainty exists among pharmacists and patients regarding pharmacists' roles in opioid safety.<sup>86</sup> Patients and pharmacists perceived pharmacists to be responsible for medication safety, yet pharmacists were uncomfortable dispensing high-risk opioids and policing opioid prescriptions.<sup>11, 86</sup> Pharmacists have expressed an interest in offering opioid risk and safety counseling services; however, they have also reported facing barriers when dispensing these services.<sup>88, 106</sup> The lack of confidence, training and resources, structured guidelines and limited time for counselling were the commonly expressed barriers by pharmacist for providing all the services.<sup>7, 11, 44, 54-57, 64, 80, 81, 107</sup> To carry out their services to the fullest in order to effectively combat the opioid crisis will require addressing these barriers.

There is scarce evidence in literature on underlying factors that affect pharmacists' behavior to counsel patients about opioid risks and safety when dispensing an opioid medication. Studies about pharmacists' opioid risk counseling when dispensing the medication are qualitative exploratory studies.<sup>11, 86</sup> Survey studies involving larger samples of pharmacists have not yet been reported in this area. Survey studies are more representative than qualitative studies as they are representative of a broader population of pharmacists, cover more practice settings and ask objective questions to get accurate information. Therefore, there is a need to develop a measurement scale to identify pharmacists' perspectives on what are significant factors that influence their consultation using a structured survey and assess whether these factors align with

an existing theoretical framework such as the Theory of Planned Behavior (TPB). This scale will be called Factors affecting Opioid Risk and Safety Counseling (*FORSC*).

The characteristics and their supporting rationale for developing the *FORSC* with certain important characteristics can be summarized as follows:

(1) the scale would be rooted in previous evidence and studies using the TPB, such that it

incorporated existing scientific knowledge and theoretical constructs

(2) the scale would be usable across various practice settings including pharmacists and other providers

(4) the scale can help identify specific factors affecting counseling practices which can help in developing targeted interventions for those groups

(5) the scale would demonstrate strong psychometric validation

#### *The Theory of Planned Behavior (TPB)*

The TPB is originally derived from the Theory of Reasoned Action (TRA).<sup>92</sup> According to the TPB, individuals carefully consider the available information and existing perceptions to guide their behavior. According to TPB, attitudes towards a behavior (feelings about a behavior), subjective norms (perception of whether important people perform and approve the behavior or not) and perceived behavioral control (perception of the difficulty of performing a behavior) determine the individual's behavioral intention (plan to perform behavior) and consequently determine the likelihood of the individual carrying out that specific behavior.<sup>92</sup> The TPB has been used to explain health behaviors in patients as well as in providers such as doctors, nurses and pharmacists.<sup>36, 92, 108</sup> This study builds on previous qualitative work by the research team

which had used the TPB to understand factors that affect pharmacists' opioid risks and safety behaviors. (see Chapter 3)

Given this gap in the literature, the goals of this study were to--

1. Develop a measurement scale in a survey instrument to understand underlying factors that pharmacists perceive affect their opioid risk and safety counseling behaviors
2. Assess the underlying domains for factors affecting pharmacists' opioid risk and safety counseling behavior guided by the TPB

## **Methods:**

### *Study design*

This study involved developing, refining, and administering a survey to a sample of pharmacists to understand their counseling behaviors when dispensing opioid medications. An initial draft of survey with 16 items about factors affecting pharmacists' opioid risks and safety counseling behaviors was initially prepared based on authors' previous work. (refer chapter 3) These items were measured on a scale of 1-5 (not at all, a little, some, quite a bit, a great deal).<sup>109</sup>

### *Instrument design and refinement*

The refinement of the survey scale involved an iterative three step process.

Developmental pre-test interviews: The initial items were informed by the scientific literature and previous interviews conducted by the author. (chapter 3) Four interviews were conducted with pharmacists from different settings (urban community rural community, clinic out-patient and hospital). Pharmacists completed a draft survey and were asked open-ended questions to help understand jargon and words that pharmacists used to describe their current

practices, and barriers and facilitators for opioid risk communication. They were also asked open-ended questions to identify underlying factors affecting their opioid risk and safety counseling practices that could be added to the survey. Time required for the respondents to answer questions and questions that required clarification were noted.<sup>110</sup> Respondents were asked questions about why they answered a certain way and how the questions could be revised. A debrief at the end of the interview gave respondents a further chance to provide comments and suggestions on the instrument.<sup>109</sup>

Instrument refining: The revised version of the survey instrument (after the developmental interview phase) underwent analysis using Question Understanding Aid (QUAID) for problems and discrepancies in wording.<sup>111</sup> QUAID is software offered by the University of Memphis for public use which assists in survey questions evaluation. It analyzes questions to assess problematic questions for terms and design and provides a summary of problems detected.<sup>111</sup> The instrument was revised for the problems detected by QUAID.

Cognitive interviews: Four cognitive interviews with pharmacists from different settings (urban community, rural community, clinic out-patient and hospital in-patient pharmacy) were conducted to understand how respondents perceived and interpreted questions and to identify potential problems that may arise in prospective survey questionnaires.<sup>112</sup> Cognitive interviews included thinking aloud by respondents about the process of analyzing the questions when thinking of an answer and use of pre-defined probes by the researcher following the think aloud process to understand how participants were thinking about unclear questions.<sup>113, 114</sup>

The survey was then revised based on problems detected in cognitive interviewing. The initial draft was revised and reviewed by survey design and research consultants at the University of Wisconsin-Madison Survey Center. The new survey draft was pilot tested.

Pilot testing of final instrument: Four in-person interviews with pharmacists from different settings (urban community, rural community, clinic out-patient and hospital in-patient pharmacy) were conducted in this phase. Respondents completed a paper survey followed by a debrief about survey design and questions.<sup>110</sup> This phase was focused on understanding formatting issues, question wording and time taken for completion. The survey was revised based on the feedback and became the final survey instrument administered to a statewide sample in this study (see table 2).

### *Sampling*

The survey was sent to a statewide sample of pharmacists. The sample was identified from a list of pharmacists registered in Wisconsin obtained from the Department of Safety and Professional Services. A stratified random sampling of pharmacists was created based on how the Wisconsin Department of Health Services divides the state into five geographical regions,<sup>98</sup> and based on urban and rural classification. An equal number of pharmacists were randomly sampled from each of these regions. A total of 700 pharmacists were used as a final sample.

### *Data collection*

Mail surveys were sent using the modified Dilman technique where surveys were mailed in three rounds.<sup>115</sup> The first round was mailed to the entire sample, which was followed by a reminder post card in a week. To help incentivize responses, a \$2 bill was included as a small thank you in the first round of surveys. Providing a \$2 incentive increased the response rate by 11% in previous studies.<sup>116</sup> The non-respondents from the first round of mailing were sent the survey again two weeks after the first reminder postcard was sent. The second round of reminder postcards were sent within a week to the recipients of the second round of surveys.

### *Data analysis*

The paper surveys were entered into an electronic database by the lead researcher. Data entry verification was conducted by verifying 15% of the total responses. Principal Components Analysis (PCA) and Exploratory Factor Analysis (EFA) were conducted to understand the underlying factor structure that affected pharmacists' behavior to counsel about opioid risks and safety. PCA is a variance maximizing mathematical procedure that provides insight into the number of principal components that accounted for a majority of the variance in the data and informed the number of factors to test in an EFA. The EFA was conducted to assess the underlying factor structure that affected pharmacists' behaviors to counsel patients about opioid risks and safety. The EFA analysis utilized Maximum Likelihood estimation and Promax oblique rotation. An EFA factor loading of 0.4 was chosen as a conservative cutoff and items with a factor loading less than 0.4 were removed from the dataset and the analysis was run again.<sup>117, 118</sup> The survey went through two iterations of item reduction before reaching acceptable factor loadings (all items greater than 0.4), goodness-of-fit statistics (significant chi-square and p-value > 0.05, Tucker Lewis Index (TLI) > 95%, Root mean square of approximation (RMSEA) < 0.05), and internal consistency of items within the domains (Chronbach's Alpha > 0.70).<sup>117</sup> The data analyses were completed using R version 3.4.3.

### **Results**

Out of 700 surveys distributed, 346 (48.8%) were returned after both the mailing rounds. Out of this, 33% were returned back from the first round and 16% from the second round. A criterion for inclusion in the study was that the pharmacist counseled patients on opioid medications in their daily practice. Out of the 346 surveys, 216 were met this criterion. About a

quarter (24.3%) of the pharmacies dispensed less than 1000 prescriptions a day, 37.5% dispensed 1000-5000 prescription a day and 2.5% dispensed more than 5000 prescriptions a day.

Table 1. Demographic characteristics of respondents (n=216)

Demographic characteristic	Percentage frequency
Sex	
Male	50
Female	50
Years of practice	24.8 years (SD: $\pm 15.2$ )
Practice setting	
Community	
Independent	22.1
Chain	43.2
Clinic outpatient/ hospital out-patient	30
Hospital in-patient	5.7
Work time	
Full time	73
Part time	27

### *Principal Components Analysis*

The scree plot and eigenvalues of the complete 16-item data set suggested three components to be considered. The eigen values and standard deviations for all 16 items are presented in Table 3. Principal component and exploratory factor analyses were conducted for all 16.

Table 2. Items in the Factors affecting Opioid Risk and Safety Counseling Scale (*FORSC*)

How much do the following factors affect your (pharmacists') intent to counsel patients on opioid risks and safety? (not at all, a little, some, quite a bit, a great deal)	
Item code	Item
a	Amount of time you have for counseling
b	Busyness of pharmacy
c	Privacy during counseling
d	Direction from pharmacy administration or owners
e	Your assessment of individual's need for risk counseling
f	Type of prescription they have e.g. acute, chronic

g	Training and education, you received about opioid risk communication
h	Availability of resources to refer patients to e.g. online, written
i	Availability of professional resources to help you in this conversation
j	Knowledge of patient friendly terms to use in opioid risk counseling
k	Recommendations by CDC for opioid counseling
l	Patient's questions
m	How much patient already knows about this medication
n	Patient's time for counseling
o	Existing relationship with the patient
p	Patient's medication and pain history

Table 3. Principal Component Analysis

Number of components	Eigen value	Standard deviation
1	11.91	3.83
2	0.98	2.24
3	0.67	1.81
4	0.46	1.41
5	0.34	1.27
6	0.26	1.09
7	0.22	1.02
8	0.20	0.97
9	0.19	0.95
10	0.14	0.91
11	0.13	0.85
12	0.12	0.79
13	0.09	0.75
14	0.088	0.73
15	0.089	0.69
16	0.05	0.57

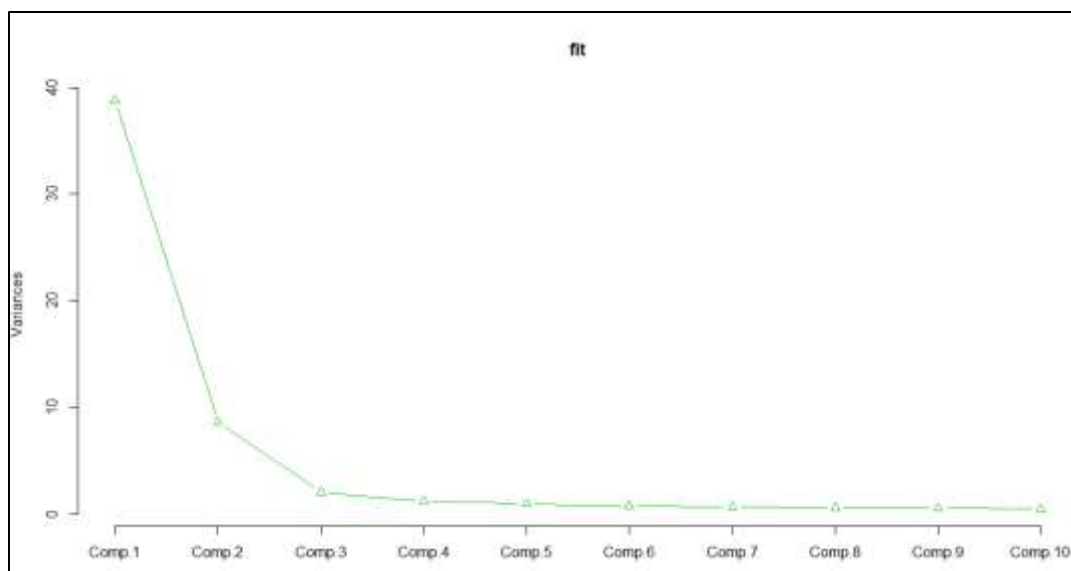


Figure 1: Plot for eigen values based on Principal Component Analyses

### *Exploratory Factor Analysis*

The factor loadings for a 3-factor structure are presented in Table 4 with the factor associations highlighted. Three rounds of EFA and item reduction were conducted, removing three items from the original 16. Item reduction concluded when the structure fit-statistics indicated a statistically significant model fit.

The three-factor model yielded a simple structure with all items having a loading greater than 0.40 on only one factor with low cross-loadings. No secondary loadings were greater than 0.20). The TLI indicated that the three-factor model fit better than no model at all (97.7%). When considering approximate fit, the RMSEA suggested that the four-factor model fit the data well (0.078). The Cronbach's Alpha for the three factors indicated fair item correlation within each factor (0.79 for factor 1, 0.77 for factor 2 and 0.60 for factor 3). The final 3-factor model is visually depicted in Figure 2. The exploratory factor analysis provided insight into the underlying factors affecting pharmacists' opioid risks and safety counseling behavior.

As depicted in Figure 2, the factors in the three-factor structure were named “behavioral attitude”, “subjective norm” and “behavioral control”. The “behavioral attitude” factor contained five items: assessment of patients need for counseling, patient questions, patients’ prior knowledge about this medication, existing relationship with the patient and patient’s time for counseling. The “subjective norm” factor contained also contained five items: direction from pharmacy administrators or owners, training and education received about opioid risk counseling, availability of resources to refer patients to, availability of resources for pharmacists, recommendations by CDC for counseling. The ‘behavioral control’ factor contained three items: amount of time pharmacists had for counseling, busyness of pharmacy and privacy during counseling.

Table 4: Exploratory factor analysis- loadings, commonality, and uniqueness

Item	Factor1	Factor2	Factor3	Commonality	Uniqueness
a	0.12	0.00	0.75	0.45	0.554
b	0.37	0.01	0.62	0.86	0.138
c	0.28	0.10	0.56	0.75	0.246
d	0.19	0.45	0.16	0.53	0.466
e	0.70	0.23	0.03	0.85	0.153
g	0.50	0.53	0.10	0.82	0.184
h	0.09	0.99	0.04	0.90	0.103
i	0.04	0.95	0.04	0.87	0.129
k	0.29	0.65	0.07	0.74	0.263
l	0.97	0.04	0.07	0.91	0.090
m	0.98	0.02	0.03	0.94	0.058
n	0.67	0.03	0.30	0.88	0.120
o	0.78	0.06	0.10	0.83	0.170

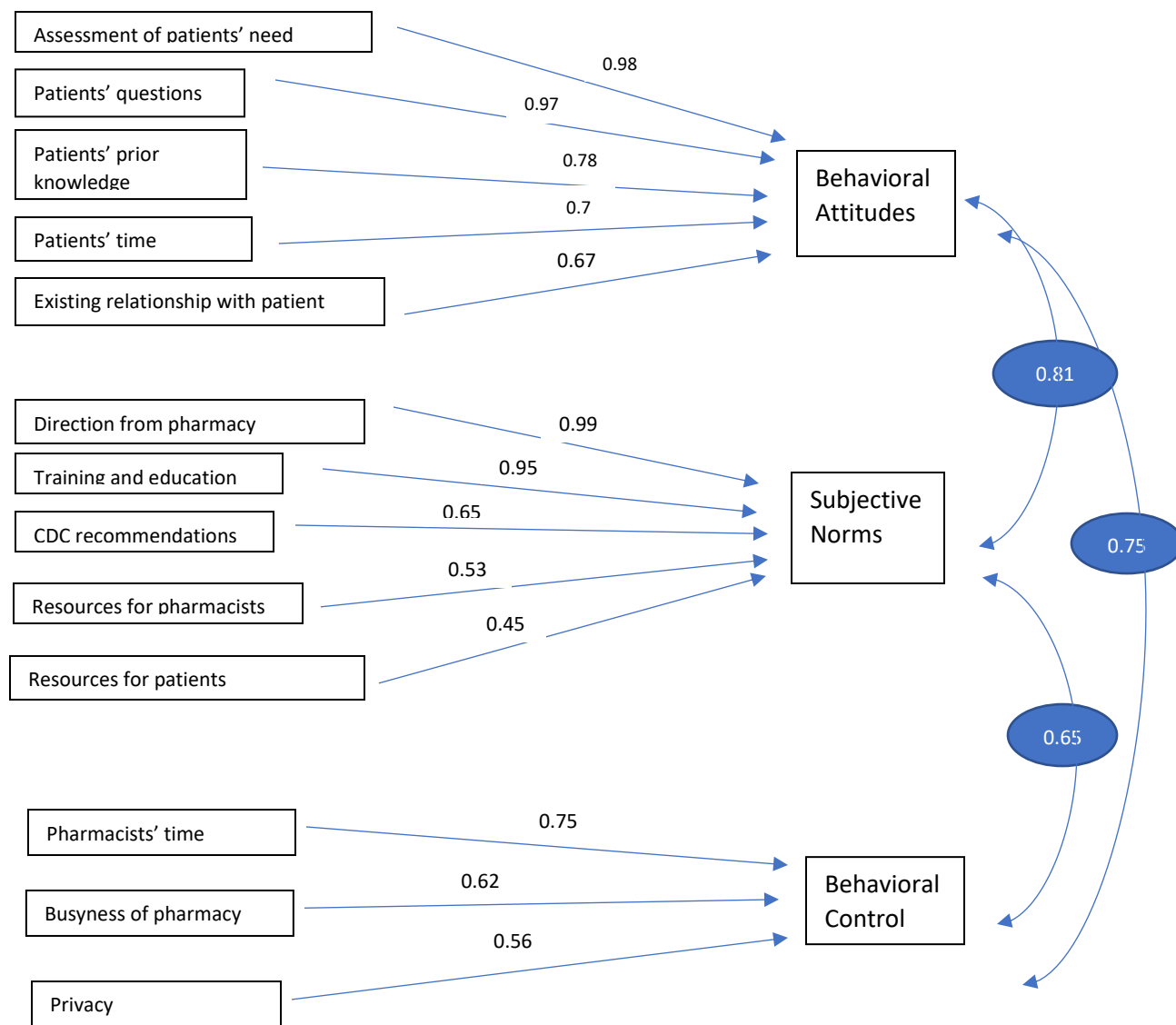


Figure 2. Exploratory Factor Analysis model

## Discussion

This study contributes a new validated tool, the *FORSC* to measure factors affecting pharmacists' opioid risk and safety counseling behaviors. The *FORSC* was developed using a rigorous three step process with preliminary construct validity. The three-factor solution was

finalized based on the PCA plot, eigen values and the best model fit based on statistical parameters like TLI and RMSEA aligns with the constructs of the TPB as well.<sup>117, 92</sup>

Individuals' barriers to opioid consultation can be explained by the TPB. The factors that emerged from the three-factor model in this study broadly fit the three constructs of Theory of Planned Behavior well.<sup>92</sup> Even though the TPB was used to inform the survey instrument partially, statistical analysis of the responses actually showed that the survey responses aligned with the domains of the TPB. Based on the TPB model, behavior is informed by subjective norms, perceived behavioral control and attitudes towards behavior.<sup>92</sup> The items that fell under each of the three buckets in this study, together explain the construct of TPB that they represented for the TPB. The alignment of the domains emerging in this study and the corresponding TPB constructs is as explained below.

Applying the TPB to pharmacist opioid consultation with patients, an attitude towards behavior refers to pharmacist beliefs about what topics they should counsel patients when dispensing an opioid medication, which patients they decide to educate about opioid risks and safety, and how pharmacists perceive the benefits of their behavior. The first factor generated in this study, 'behavioral attitudes', consists of items which influence pharmacists' attitudes towards counseling about opioid risks and safety. While pharmacists have reported understanding their importance and responsibility as opioid educators, they have also mentioned being uncertain about patient expectations about their role as opioid safety educators.<sup>11, 86</sup> (cite paper 1) This lack of clarity may lead to the pharmacists to base their decision to counsel patients on variety of factors like their relationship with patient and if the patient asks questions, which may help them gauge patients' interest and reaction to this consultation better.

From the perspective of the TPB, a second factor is subjective norm. In this context it would refer to what other people and entities important to pharmacists think pharmacists should do regarding opioid consultation. This could include what patients, prescribers, schools of pharmacy and laws expect from them about opioid risk and safety counseling behavior and how essential pharmacists think it is to comply with these beliefs. The items falling under the ‘subjective norm’ domain in our results align with these factors. The CDC has guidelines for health professionals to counsel on opioids but does not mention what is expected specifically from pharmacists.<sup>22</sup> National pharmacy organization and state pharmacy boards should have clear instructions and expectations from pharmacists about their role as opioid safety educators as well as provide pharmacists with standardized training and resources to facilitate these conversations.

The third construct of the TPB is perceived behavioral control which refers to factors that the pharmacists believe control their behavior to counsel patients on their opioid medication. These factors can be personal factors or workplace-related factors. The third factor generated from this analysis, which we named ‘perceived behavioral control’, includes items addressing time, busyness and privacy for opioid risks and safety consults, all of which could influence pharmacists’ behavior to counsel patients in the pharmacy which have been previously reported by pharmacists as barriers.<sup>88</sup>

These findings add to the existing empirical evidence about pharmacists’ opioid risk and safety counseling behaviors. Previous research has used the TPB to understand pharmacists’ behaviors in communicating with patients suffering from opioid use disorder or patients diverting or misusing opioids.<sup>36</sup> However, there is scarce literature about pharmacists’ counseling practices about opioid medications when dispensing an opioid prescription.<sup>88</sup> This study adds to the literature a scale derived from earlier pharmacist interviews and literature that measures

pharmacist views of factors affecting their opioid risks and safety behaviors and also tests how well the factors used in the instrument fit a well-known validated theory. There are several ways in which the *FORSC* scale can be used in future research. First, this scale helps understand specific factors, both personal and societal which affect pharmacists' counseling behaviors. This validated scale can be used across diverse pharmacy settings in states or health systems in the future to understand factors affecting pharmacists. This scale can be adopted to explore factors affecting counseling practice of other healthcare professionals such as prescribers and nurses who communicate with patients about opioid medications as well. The *FORSC* scale may need some revisions to validate it for a different population, but the basic content and framework will remain the same.

The 3 domains that emerged from the Exploratory Factor Analysis have utility for future studies to understand whether certain domains affect pharmacists' counseling behaviors more than others. Ample evidence of interventions developed for other health conditions using the TPB domains is available.<sup>92</sup> Education and training materials following the validated interventions developed for other conditions and based on the TPB could be developed to prepare pharmacists to communicate with patients about opioid risks and safety when they dispense an opioid prescription. This aligns with our earlier research which suggested that handouts, guidelines and toolkits must be made available to pharmacists to support their verbal counseling practices. These types of resources could help increase the opioid counseling self-efficacy of pharmacists and may indirectly facilitate addressing other barriers.

Study findings suggest that patient factors influence pharmacists' counseling behaviors.<sup>41, 42</sup> Pharmacists may provide patients with information on opioid safety based on their perception of patients desire for medication counseling. Patient questions are powerful in

motivating pharmacists to provide more information and counseling.<sup>41</sup> In addition to providing pharmacists with key resources and training, patients should be trained to ask questions to make their interaction more fruitful.<sup>41</sup>

### *Limitations*

This study has a few limitations. The respondent pool in this study is representative of the five geographical regions of Wisconsin. However, data were collected from only one state which may not be generalizable outside of this region. Future research may involve administration of the survey instrument to more states across the country to assess generalizability of the questionnaire. The measurement scale can be used in other clinical populations such as prescribers; however, the instrument would need to be revised and validated based on characteristics of other clinicians. This study used EFA approach to categorize items into different factors which fit the TPB. Another study using confirmatory factor analysis on a different sample of pharmacists would help validate the findings of this study and support confirmation of the factor structure.

### **Conclusion**

This study used a three-step intensive method to develop the *FORSC* instrument to measure factors affecting pharmacists' opioid risk and safety counseling behaviors and used exploratory factor analysis to refine and validate the instrument as well as explore the nature of underlying factors. Attitudes, subjective norms, and perceived control emerged as important factors which is consistent with the TPB. Interventions consistent with the TPB should be designed to increase pharmacists' sense of control over their ability to offer opioid consultations. Further confirmatory studies to validate these results and the factor structure are warranted

## CHAPTER SIX

### PREDICTING FACTORS FOR PHARMACISTS OPIOID RISK AND SAFETY COUNSELING

*Building on the FORSC scale and domains obtained in chapter 5, this chapter addresses the third aim of the dissertation which is to understand how the factors in FORSC affect pharmacists' opioid risk and safety counseling behaviors. Multiple linear regression is used in this chapter using the FORSC to predict how the constructs of Theory of Planned Behavior predict pharmacists' opioid risk and safety communication practices.*

#### **Abstract**

#### **Background**

Different factors affect pharmacists' opioid risk counseling practices when dispensing an opioid medication. These factors can hinder pharmacists' counseling about opioid safety even if pharmacists want to be opioid safety educators. These factors can be explained based on constructs of the Theory of Planned Behavior. This paper aims to understand what factors based on Theory of Planned Behavior (TPB) affect pharmacists' opioid risk and safety counseling practices.

#### **Methods**

Surveys were mailed to a statewide sample of pharmacists using stratified random sampling. Descriptive statistics were used to describe population characteristics and demographics. Multiple linear regression analyses were used to examine the impact of independent variables on

dependent variables. Composite scores of pharmacists reported opioid risk and opioid medication safe practices counseling were dependent variables and factors affecting pharmacists' opioid risk and safety counseling behaviors were used as independent variables in the multiple regression models.

## **Results**

Out of 700 surveys distributed, 346 (48.8%) were returned from both of the mailing rounds. The 'risk counseling' model had an adjusted R-squared of 0.22 and the most robust predictor was "Subjective Norm" followed by "number of years of practice as registered pharmacist". The 'safe practices counseling' model had an adjusted R-squared of 0.13 and the most robust predictor was "Subjective Norm" followed by "Behavioral Control". The domain subjective norm consisted of factors like availability of clear instructions, training and resources from the pharmacy owners, organizations and states about opioid risk and safe practices counseling for pharmacists. Behavioral control consisted of factors like time of pharmacist, busyness, and privacy in the pharmacy. Thus, both pharmacists' opioid risk and safe practices counseling were strongly predicted subjective norms in this study.

## **Conclusion**

This study generates a predictive model for understanding how different factors based on the Theory of Planned Behavior affect pharmacists' opioid risks and safety behaviors. More descriptive and intervention studies addressing these factors must be conducted to enhance pharmacists' delivery of opioid risk and safe practices counseling.

## Introduction

Opioid medications carry potential risk for the development of opioid use disorder (or “addiction”) characterized by a strong desire to take opioids, persistent opioid use despite harmful consequences, increased tolerance, a physical withdrawal reaction when opioids are discontinued, and potential fatal overdose.<sup>21</sup> In the United States (U.S.), prescription opioids specifically contribute largely to the current opioid crisis, with more than 40% of all opioid overdose deaths in 2016 involving a prescription opioid, and more than 46 people dying every day from overdoses involving prescription opioids.<sup>1</sup>

Although many individuals and organizations are involved in combating the opioid crisis nationwide, healthcare professionals are primarily responsible for appropriate opioid prescribing and promoting safe opioid use.<sup>4</sup> Pharmacists are especially well-positioned to contribute to safe opioid use due to their role dispensing opioid prescriptions and accessibility to patients.<sup>5, 7</sup> Pharmacists can extend patient counseling responsibilities by educating patients on risks associated with opioid use, proper storage and disposal of medication, and the consequences of sharing medications with another person.<sup>8</sup> Although pharmacists are equipped to provide these services to help mitigate the opioid crises, current literature documents that pharmacists’ breadth of opportunities for services is far from fully utilized. Pharmacists reported limited self-efficacy to communicate with patients regarding prescription drug misuse. They have cited barriers to communication including lack of confidence, training, and time.<sup>13</sup> Other barriers to communicating with patients on opioid therapy were difficulties discussing pain with patients, and inadequate access to health information.<sup>7</sup>

There is scarce evidence in the literature about pharmacists’ practices about counseling patients on opioid risks and safety when they dispense an opioid medication and factors that

affect these counseling practices. However, previous research has explored and understood factors affecting pharmacists' opioid risks and safety behaviors using both interview and survey data. (See Chapter 3 and 5) For the purposes of this paper, consultation about risk is differentiated from consultation about safety. Specifically, based on CDC's definition, opioid risk consists of physical dependence, addiction, and overdose. In this context, opioid risk counseling addresses issues of physical dependence and overdose for a new or refill prescription both for short-term and long-term opioid treatment. In contrast, opioid medication safe practice is described as reducing opioid risks and misuse. Consultation on opioid safety addresses issues such as self—monitoring pain, safe storage and disposal which aim to reduce misusing the medication and combating the risks. Each is important for different reasons and the literature is equally silent on what influences pharmacist counseling about each. It may be that such predictive models differ.

Given this gap in the literature, and based on previous research using the TPB to develop factors affecting opioid risk and safety counseling behaviors (FORSC), this study now applies the FORSC in a predictive model of pharmacist self-reported opioid patient consultation practices about opioid medication risks and safe practices. The overall goal is to explore which factors are most robust in predicting pharmacists' opioid risk and safe practices counseling practices with patients.

## **Methods**

### *Study Design*

This descriptive study was approved by the University of Wisconsin-Madison's Institutional Review Board (IRB) prior to data collection. This research administered a mail survey using the modified Dilman technique to a state-wide sample of pharmacists.<sup>115</sup>

### *Setting and Participants*

The survey sample was selected from a list of pharmacists registered in Wisconsin provided by Department of Safety and Professional Services (DSPS). Stratified random sampling was used where pharmacists were stratified by the five geographical regions used by the DHS and based on rural/ urban location of the site.<sup>98</sup> An equal number of pharmacists were randomly picked from each of these regions. A total of 700 pharmacists were selected for the final sample. The DSPS does not indicate the type of pharmacy site (community pharmacy, clinic, in-patient hospital, etc.) This information was collected by the survey. Criteria for inclusion in the study was that pharmacists communicate with patients about opioid medications in their daily practice.

The first round of surveys was mailed to the entire sample and was followed by a reminder post card in a week. To help incentivize responses, a \$2 bill was included as a small thank you in the first round of surveys. The non-respondents from the first round of mailing were sent the survey again two weeks after the first reminder postcard was sent. The second round of reminder postcards were sent within a week to the recipients of second round of surveys.

### *Measures*

The survey measure provided three types of data needed for this paper's analyses (1) pharmacist opioid risk counseling behaviors, (2) factors affecting pharmacist opioid risk counseling behaviors and (3) pharmacist demographics. The two-page survey consisted of 27 items. The items were based on literature and authors previous work about opioid risks and

safety practices of pharmacists and factors affecting them.<sup>86</sup> (cite chapter 3) The initial survey draft went through an iterative process which included multiple pre-test, cognitive and pilot test interviews for developing and refining the survey instrument with respect to question wording, formatting and missing content. Exploratory factor analyses identified 3 factors aligned with the Theory of Planned of Planned Behavior. Cronbach's Alpha for the total Factor scale was strong at 0.72. The subscales of Attitude, "Behavioral Control" and "Subjective Norm" had acceptable Cronbach's alphas of 0.79, 0.77, 0.60. More detailed information about the instrument design and refinement can be found in paper about instrument design and exploratory factor analysis (cite chapter 5).

These factors form the key independent variables in the predictive model and were tested in this paper's analyses. The "Behavioral Attitude" factor contained the items: assessment of patients need for counseling, patient questions, patients' prior knowledge about this medication, existing relationship with the patient and patient's time for counseling. The "Subjective Norm" factor contained the items: direction from pharmacy administrators or owners, training and education received about opioid risk counseling, availability of resources to refer patients to, availability of resources for pharmacists, recommendations by CDC for counseling. The "Behavioral Control" factor contained the items: amount of time pharmacists have for counseling, busyness of pharmacy and privacy during counseling (cite paper 2). In addition to these three variables, an additional variable which was 'number of years of practice as a registered pharmacist' was used as an independent variable.

Two dependent variables were used in these analyses and each of these variables were composite scores of scales composed of multiple items. To measure the dependent variables to be used in this analysis, the survey asked pharmacists how often they counselled patients on (1)

opioid risk topics and (2) opioid medication safe measures topics when dispensing an opioid medication. A four-point scale was used. For each measure, a composite average score was calculated. The two resulting dependent measures of each dependent variable were strong with Cronbach's alphas of 0.89 and 0.90 respectively. (See items in Table 1)

Table 1. Items used for dependent variable

How often do you counsel patients when you dispense an opioid medication on (on a four-point scale: never, sometimes, most times, always)	
<b>Opioid Risk Counseling</b>	
a)	Physical dependence for new short-term prescriptions? i.e. $\leq 14$ days?
b)	Overdose risk for new short-term prescriptions? i.e. $\leq 14$ days?
c)	Physical dependence for new long-term prescriptions? i.e. $\geq 14$ days?
d)	Overdose risk for new long-term prescriptions i.e. $\geq 14$ days?
e)	Physical dependence for refill prescriptions familiar to patients?
f)	Overdose risk for refill prescriptions familiar to patients?
<b>Opioid Medication Safe Measures Counseling</b>	
The variable 'opioid medication safe counseling' was generated as an averaged composite score of the following survey items:	
How often do you counsel patients when you dispense an opioid medication for (on a four-point scale from not at all to all the time)	
a)	Tell them that the medication is an opioid or narcotic?
b)	Appropriate ways to self-monitor pain?
c)	Safe opioid storage and disposal?
d)	Naloxone for an opioid overdose

In addition, number of years of practice as a registered pharmacist was also included in the predictive model analyses as it was assumed that pharmacists with more years of practice may be more versed in communicating with patients about opioid risks and safety.

### *Data Analysis*

Data were entered by the lead author in an excel spreadsheet. Fifteen percent of the entered responses were checked for the purposes of quality assurance. Descriptive statistics were conducted initially. Multiple linear regression analyses were conducted to understand the

correlation between opioid risk counseling practice and factors affecting it. As described earlier, FORSC domains were used as independent variables and pharmacists' opioid risk and safety counseling practices were used as dependent variables in the multiple regression model. The data analyses were completed using R version 3.4.3. The following regression equation was used for both outcome variables.

$$Y_i = \alpha + \beta_1 \text{attitude} + \beta_2 \text{SubjectiveNorm} - \beta_3 \text{BehavioralControl} - \beta_4 \text{PracticeYears} + \varepsilon_i$$

## Results

Out of 700 surveys distributed, 346 (48.8%) were returned from both of the mailing rounds. Out of this, 33% were returned back from the first round and 15.8% from the second round. Out of the 346 surveys, 216 were usable as these respondents counseled patients on opioid medications which was required for the study. Fifty percent of the respondents were male and 50% were females. Average years of practice as a registered pharmacist among respondents was 24.8 years (SD:  $\pm 15.2$ ). Sixty five percent of the respondents were community pharmacists (43.2% chain and 22.1% independent), 5.7% were hospital inpatient, 13.7% were hospital outpatient and 1% worked in clinic outpatient settings. Seventy three percent of respondents worked as full-time pharmacists and 37% worked as part-time pharmacists. Slightly less than a quarter (24.3%) of the pharmacies where respondents worked dispensed less than 1000 prescriptions a day, 37.5% dispensed 1000-5000 prescription a day and 2.5% dispensed more than 5000 prescriptions a day.

*Regression model for 'opioid risk counseling'*

The ‘risk counseling’ model had an adjusted R-squared of 0.22 (see table 2). The most robust predictor was “‘Subjective Norm’” followed by years of practice as a pharmacist. ‘Attitude’ was weakly positively related to opioid risk counseling.

Table 2. Opioid risk counseling regression model

Variable	Slope
Intercept	1.02
Attitude	0.12*
“‘Subjective Norm’”	0.27***
“‘Behavioral Control’”	-0.05
Years of practice as registered pharmacist	0.008**
R- squared:0.23 Adjusted R-squared:0.22	p-value: 2.858e-11 Alpha: 0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05

*Regression model for ‘opioid medication safe practice counseling’*

The ‘opioid medication safe measures counseling’ model had an adjusted R-squared of 0.13 (see table 3). However, again, the most robust predictor was “‘Subjective Norm’” followed by “‘Behavioral Control’”.

Table 3. Opioid medication safe counseling regression model

Variable	Slope
Intercept	1.9
Attitude	0.06
“‘Subjective Norm’”	0.23***
“‘Behavioral Control’”	-0.06*
Years of practice as registered pharmacist	0.0009
R- squared:0.14 Adjusted R-squared:0.13	p-value: 1.779e-06 Alpha: 0 ‘***’ 0.001 ‘**’ 0.01 ‘*’ 0.05

## Discussion

TPB has been widely used in previous pharmacy practice literature to explain pharmacist behaviors in educating patients on various health conditions. Based on the TPB model, behavior is informed by “Subjective Norm”, perceived “Behavioral Control” and attitudes towards behavior.<sup>92</sup> Pharmacist behavior about opioid risk counselling has been seen to follow the three domains of TPB (see chapter 5). This study showed that pharmacists reported opioid risk and safe practices counseling behavior was affected most by their “Subjective Norm” domain of the TPB.

The “Subjective Norm” was a composite score of the following items- resources made available to the pharmacists and patients, training and education about opioid risk counseling available to the pharmacists, directions from pharmacy owners and organizations and recommendations from the CDC (see chapter 5). While variety of resources are made available by different organizations for pharmacists to use, pharmacists are not provided with guidance about intended use of these resources. Pharmacists have reported better use of resources when trained about their use.<sup>119</sup> Opioid risk and safety communication is a sensitive topic that is associated with stigma in the society.<sup>11, 120</sup> Educating patients on this topic requires skills that can be developed by providing pharmacists with training and education about opioid risks and safety communication. While there is ample evidence in literature about training programs for pharmacists and providers about talking to patients with opioid use disorder or patients misusing opioids about the risks of opioid medications<sup>52, 121</sup>, there is scarce evidence about communicating with patients about opioid risks and safe practices when dispensing the medication. There is also uncertainty among pharmacists about what topics to educate patients on in opioid medication consultations.<sup>88, 86</sup> The CDC has recommendations for pharmacists and providers about what they are expected to cover and provides online training about the same.<sup>22</sup> Covering topics like

opioid risks and safety as expected by CDC and patients requires more time than a normal consult. Pharmacists require clear directions from their owners and pharmacy organizations about their role as opioid risks and safety educators (see chapter 3). This includes clear expectations on topics to be covered and time spent on opioid consultations in addition to provision of resources to use and training and education about the same.<sup>88, 86</sup>

Attitude towards behavior which is another domain of the TPB was a weaker but significant predictor of pharmacists 'opioid risk counseling'. Risk counseling refers to counseling and informing patients about dependency and overdose risk of opioid medications for new and refill prescriptions for short and long-term opioid treatment. Attitude towards behaviors includes factors which affect pharmacists' decisions towards providing education to patients. This includes from the lens of the pharmacist- patients' time, relationship with the patient, knowledge of patients about opioids and type of prescription (long term or short term) (see chapter 5). These factors have been seen to affect pharmacists' counseling practices in empirical literature.<sup>36, 41</sup>

It was interesting that for the Safety Counseling dependent variable, "Behavioral Control" which is the third domain of TPB was seen to affect pharmacists' counseling about opioid safe practices, though still weaker than "Subjective Norm". This contains the items- pharmacists' time, busyness, and privacy in the pharmacy. These factors are closely related to each other and can deter pharmacists from counseling patients about opioid medication safety as these consultations require more time and are sensitive in nature, warranting the need for privacy. Patients on opioid therapy have previously mentioned discomfort in conversations with pharmacists due to lack of privacy especially in community pharmacies.<sup>122</sup> Finally, number of years that the pharmacist has practiced was seen to positively correlate with pharmacists' opioid

risk counseling practices. The more experienced the pharmacist in talking to patients and fostering patient relations, the more comfortable the pharmacist may be at talking about opioid safety measures.

This study has several implications. First, pharmacists need training and resources to enhance both opioid risks and safety communication with patients. This training can be provided by pharmacy schools, organizations, federal bodies and/or pharmacy owners.<sup>57, 60, 88, 123</sup> Trainings in pharmacy school curriculum not only provide needed skills but reinforce expectations and norms for pharmacist roles. Second, more clarity from pharmacy owners and organizations about expectations about pharmacist roles as opioid educators is essential. Clearer expectations about roles of pharmacists are needed.<sup>86</sup> Third, patients must be made aware of the important role of pharmacists in medication safety and risk education, and patients should be motivated to ask questions and raise concerns when at the pharmacy.<sup>41</sup>

*Limitations:* This study has a few limitations. The respondent pool in this study is representative of the five geographical regions of Wisconsin, but the sample size is smaller which makes it difficult to generalize the results broadly. These data were collected from only Wisconsin and cannot be generalized to pharmacists across the country. Similar statewide surveys should be conducted using this instrument to generalize the findings across different states as well as validate the instrument. The measurement scale can be used with other clinical providers e.g. opioid medication prescribers as well but will have to be revised and validated based on characteristics of other clinicians.

## **Conclusions**

This study identifies subjective norm construct of the TPB to be the most impactful predictor of pharmacists' opioid risks and safe practices counseling behaviors. Based

on this finding, it is important that pharmacy owners, organizations, and the state provide pharmacists with better training, resources, clarity, role expectations and direction. Future descriptive and intervention research is needed to develop effective training and resources consistent with the TPB to overcome the gaps suggested by this study.

## CHAPTER SEVEN

### DISCUSSION

*This chapter provides a comprehensive interpretation of the results of this dissertation study, limitations, and strengths of the study, and examines implications for practice and research. It takes the readers through a brief discussion for each chapter followed by broader implications, limitations, and strengths of the study.*

**Overview.** The study conducted for this dissertation aimed to understand pharmacists' opioid risks and safety counseling practices and factors affecting them using the Theory of Planned Behavior. A mixed methods approach was used for this study. This study consisted of two distinct phases: a qualitative interviews phase and a quantitative surveys phase. One on one interviews were conducted with pharmacists in the first qualitative phase. This phase was used to inform the survey development in the second phase. The second quantitative phase consisted of developing, refining, administering a survey instrument to pharmacists and analyzing the survey responses. Three phases were involved in developing, refining, and administering a new survey instrument developed to explore influences on pharmacists' opioid consultations. This entire study was divided into four sub-studies based on specific aims, results, and analysis. The four sub-studies in this work were: 1) a qualitative interview study using the TPB to understand factors affecting pharmacists' opioid risk and safety behaviors. 2) categorizing pharmacists into classes based on their opioid risk and safety counseling practices. 3) developing and refining a scale named the *FORSC* scale to measure factors affecting pharmacists' opioid risk and safety counseling and exploring underlying structure of the factors 4) testing the ability of the new instrument to predict their opioid consultation and the factors affecting it.

### *Qualitative Study*

The aim of the qualitative study, conducted before the survey phase, explored factors that affect pharmacist opioid risk and safety counseling behaviors based on the TPB domains of 1) attitudes, 2) subjective norms, and 3) perceived behavioral control. Interviews were conducted with pharmacists in urban community, rural community, ambulatory/clinic outpatient, and hospital inpatient pharmacy settings. In general respondents reported discussing side effects of opioid medications with patients, but they usually did not discuss opioid risks for both short- and long-term prescriptions. Pharmacists reported recognizing the importance of opioid risk and safety counseling and were motivated to comply with expectations of patients and society as opioid risk educators. The interviewed pharmacists were however unsure of how to initiate the conversation about opioid risks and safety. Pharmacists reported their behavior was influenced by workplace factors such as lack of time and training. Also, they perceived varied expectations from patients, providers, and pharmacy owners for pharmacist opioid consultations. Additionally, they reported a need for clear directions, structured training, and written standardized handouts and resources for effective opioid risk and safety consultations.

### *Classes of pharmacists based on counseling practices*

Latent class analysis proved useful in efficiently identifying three underlying classes of pharmacists on the basis of their counseling behaviors. This approach was useful in exploring unobservable class distribution using observable variables which were the survey items.<sup>101</sup> Based on the class structure obtained, this study shows that only a small percentage of pharmacists engaged in counseling patients about most opioid risks and safety issues for both short term and refill prescriptions. 40% of the respondents hardly engaged in counseling about opioid risks and safety with patients. Around 43% engaged in some counseling for long term prescriptions but not

as much for short term and refill prescriptions. This study contributes to the literature by using latent class analysis to understand gaps in practice areas of pharmacists. This instrument can be used to assess counseling practices of pharmacists in other states, health systems and practice areas. It also demonstrates actual counseling practice of pharmacists in Wisconsin in the current opioid crisis faced by the state.<sup>99</sup>

### *Instrument Development and Exploratory Factor Analysis*

This research successfully designed an instrument called the *FORSC* to measure factors affecting pharmacist opioid risk and safety consultations to address a gap in the literature. Drawing on the findings from our qualitative interviews, literature and the TPB, items were generated and tested to create a 16-item new instrument to measure factors affecting pharmacists' opioid risk and safety counseling practices. Exploratory factor analysis helped reduce the number of items and refine the survey instrument. Three items were dropped based on low item loadings. In addition, exploratory factor analysis categorized the remaining 13 items regarding factors affecting pharmacists' opioid risk and safety counseling into three domains. The three domains generated from this analysis fit the domains in Theory of Planned Behavior (TPB).<sup>92</sup> This psychometric measure was strong based on Cronbach's alpha of 0.88.

This *FORSC* is the first to measure factors affecting pharmacists' opioid risk and safety counseling behaviors when pharmacists dispense an opioid medication. This measurement scale can be used in different states, health systems and pharmacies to understand factors affecting pharmacists' counseling practices. The gaps found through the use of this instrument can then help inform specific interventions.

### *Developing Predictive Model and Applying TPB*

In this research, the domains that emerged from exploratory factor analyses in the previous study were tested for their effect on pharmacists' opioid risks and safety counseling practices in regression analyses.

The domain 'subjective norms' was seen to strongly predict both opioid risk counseling as well as safe opioid use counseling practices of pharmacists. This factor consisted of items such as directions, clarity, and expectations for pharmacists from state, pharmacy owners, organizations, and patients. Educating patients on opioid risks and safety requires skills due to its sensitive nature and these can be developed only by providing pharmacists with structured training and education about opioid risks and safety communication by the state, pharmacy organization and owners.<sup>11, 120</sup> There is also uncertainty among pharmacists about what topics to educate patients regarding opioid medication consultations.<sup>88, 86</sup> The CDC has recommendations for pharmacists about topics to cover for opioid risks and safety.<sup>22</sup>

The 'behavioral attitudes' domain consists of items which influence pharmacists' attitudes towards counseling about opioid risks and safety. From the lens of the pharmacist this includes patients' time for consultation, relationship with the patient, perceived patient knowledge about opioids and type of prescription (long term or short term) and weakly predicted pharmacists' opioid risk counseling behavior. These factors affected pharmacists' counseling practices in empirical literature where pharmacists decide to counsel patients based on patient attitudes and other related factors.<sup>36, 41</sup> Behavioral control domain contains items like pharmacists' time, busyness and privacy in the pharmacy was seen to weakly predict pharmacists' opioid safety counseling behaviors.<sup>88</sup>

## **Strengths**

These findings contribute and add to the existing evidence in the literature about pharmacists' opioid risk and safety counseling behaviors. Previous research has used the TPB to understand pharmacists' behaviors in communicating with patients suffering from opioid use disorder or patients diverting or misusing opioids.<sup>36</sup> There is scarce literature available about pharmacists counseling practices about risks and safety measures when dispensing an opioid prescription.<sup>88</sup> This study adds to the literature a measurement scale based on a well-respected health behavior theory (the TPB) to measure factors that affect pharmacists' opioid risks and safety behaviors, as well as a measurement scale for studying opioid risk and safety counseling practices. There is growing evidence in the literature about interventions based on the TPB developed for other health conditions.<sup>92</sup> Education and training materials following the validated interventions developed for other conditions and based on the TPB could be adapted to prepare pharmacists to communicate with patients about opioid risks and safety when they dispense an opioid prescription. Resources like handouts, guidelines and toolkits could support pharmacists verbal counseling practices.<sup>86</sup>

## **Study limitations**

The first phase qualitative study has the limitation of using convenience sampling and sampled pharmacists from a limited geographical region. The sample size used for this study was not large which reduces generalizability. Additionally, different disease states, provider types and individual patient characteristics may change communication offered and reported. Similarly, demographics, practice site of pharmacists, gender, experience, training etc. may affect the responses. Larger descriptive studies with diverse pharmacy settings and broader geographic areas are needed to explore the communication gaps further.

This second quantitative phase of this study also has a few limitations. The respondent pool in this study is representative of the five geographical regions of Wisconsin but the sample size is small which makes it difficult to generalize the results across the country. Similar national surveys should be conducted using this instrument to generalize the findings in pharmacists across different states as well as validate the instrument. The measurement scale can be used in other clinical settings but will have to be revised and validated based on characteristics of other clinicians. Another study using similar sampling strategy, but different sample of pharmacists from Wisconsin should be conducted to confirm this factor structure using confirmatory factor analysis. This will help in validating the results of this study.

### **Implications**

This study has several implications. First, standardized resources and training are needed to help pharmacists about know what is expected of them and how to consult patients effectively during both initial and refill consults for acute and chronic pain. The lack of clear expectations from the employers, organizations, prescribers and patients seems to confuse the pharmacists. These findings are consistent with a previous study which identified that pharmacists wanted more education in handling patients who are misusing opioid medications and who are at high risk for addiction, and that there was a lack of continuing education for risk assessment tools.<sup>20</sup> This study also reported that pharmacists face a lack of confidence in dealing with risky opioid prescriptions, which affects their perceived control over the situation. Training and continuing education do improve pharmacist attitudes towards approaching opioid risk counseling. One study delivered a 3-hour training program about opioid misuse and overdose prevention to community pharmacists to assess how pharmacist attitudes could change. The study found that

pharmacists understood the value of counseling for at risk patients and the value of screening tools.<sup>25</sup>

The interviewed pharmacists expressed an interest in having a standardized handout or resource to integrate into their opioid risk counseling and the surveyed pharmacists reported not having enough resources like handouts for their and patients' use. A standardized resource could possibly save time by being integrated into the workflow and it could improve pharmacists' confidence by having a resource on hand. There is a gap in the literature to test this approach to save time and improve pharmacist confidence. Potentially each patient could receive the same information. Opioid risk handouts are available through the CDC which can be used or resources for patients and pharmacists.<sup>26,27</sup> Given pharmacists' confusion regarding expectations for opioid consultations, priority topics with the assistance of these handouts can be conveyed to patients in consults. There is also a need for policies in place at either the company, state, or federal level to ensure that pharmacies are in know of their responsibilities and are supported for dispensing their counseling services. Clear directions, resources and training about opioid risks and safety counseling provided by the state, organizations and owners to the pharmacists can enhance pharmacists' delivery of opioid risk and safety counseling services.

## CHAPTER EIGHT

### CONCLUSION

*This chapter provides comprehensive conclusions regarding results from the studies conducted for this dissertation and provides an overview of broader agendas based on findings of this study.*

This study is the first of its kind to explore and understand factors that affect pharmacists' opioid risks and safety counseling behaviors when they dispense an opioid medication using a behavioral theory. The qualitative phase of this study used constructs from the widely acclaimed behavioral theory TPB towards identifying factors affecting pharmacists' opioid risks and safety counseling behaviors. Pharmacists identified a number of factors, both facilitators and barriers, which affect their counseling behavior. It is essential to address these barriers to help pharmacists become more responsive to patient expectations and needs. This includes developing training and resources needed to prepare them to communicate information clearly and with confidence. This study pointed to a need for descriptive studies with larger sample to validate and further explore these qualitative findings.

The second phase of this study involved developing and administering a survey instrument to explore the underlying structure of the factors. This study added a new validated scale (*FORSC*) to the literature to measure factors affecting pharmacists' behaviors. Latent Class Analysis categorized pharmacists into three classes based on the underlying latent structure of responses. Exploratory factor analysis examined the nature of factors that pharmacists believe influence their opioid risk and safety counseling practices when dispensing prescription opioids. Behavioral attitudes, subjective norms, and perceived control emerged as factors through Exploratory Factor Analysis which is consistent with the TPB. A need to develop interventions

consistent with the TPB to increase pharmacists' sense of control over their ability to offer opioid consultations was suggested by this study. Further confirmatory studies using a different sample of pharmacists to validate these results and the factor structure are needed.

In the third phase of this study, the survey responses were also used to identify how the TPB factors affected pharmacists' opioid risks and safety counseling behaviors. Based on the results, subjective norm, which includes clarity and resources from organizations important to pharmacists, was strongly related to pharmacists' intention to counsel on opioid risks as well as safety. It is thus essential to provide pharmacists with better training, resources, clarity and direction from owners, organizations, patients, and state policy makers. This can help pharmacists become more responsive to expectations and needs about their opioid risk and safety patient consultations. Future descriptive and intervention research is needed to develop effective interventions consistent with the TPB to overcome the barriers suggested in this study.

Overall, this study used a well validated theory to qualitatively explore pharmacists' opioid risk and safety counseling behavior. The *FORSC*, building on findings from the qualitative phase, further aligned with the TPB. This scale had reasonably strong psychometric characteristics. A distribution of pharmacists into classes based on their counseling practices was also achieved using latent class analysis. A predictive model of pharmacist opioid consultations using the *PORSC* identified subjective norm as a key factor influencing pharmacist consultation behaviors. Both of these reinforces the importance of future intervention research to address the most robust predictive factors to mitigate communication barriers faced by pharmacists.

## BIBLIOGRAPHY

1. National Institute of Health. Opioid overdose crisis. 2018. <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>. Accessed on April 29, 2020.
2. Center for Disease Control and Prevention. Opioid overdose- Understanding the epidemic. 2018. <https://www.cdc.gov/drugoverdose/index.html>. Accessed on April 29, 2020.
3. Seth P, Scholl r, Rudd A R, Bacon S. Increases and Geographic Variations in Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants with Abuse Potential – United States, 2015-2016. *MMWR Morb Mortal Wkly Rep*. 2018.
4. Woodard D, Van Demark RE, Jr. The Opioid Epidemic in 2017: Are We Making Progress? *S D Med*. 2017;70:467-471.
5. Compton WM, Jones CM, Stein JB, Wargo EM. Promising roles for pharmacists in addressing the U.S. opioid crisis. *Res Social Adm Pharm*. 2017.
6. Shimane T. [The Pharmacist as Gatekeeper of Prescription Drug Abuse: Return to "Community Scientists"]. *Yakugaku Zasshi*. 2016;136:79-87.
7. Marlowe KF, Geiler R. Pharmacist's role in dispensing opioids for acute and chronic pain. *J Pharm Pract*. 2012;25:497-502.
8. Compton WM, Boyle M, Wargo E. Prescription opioid abuse: Problems and responses. *Prev Med*. 2015;80:5-9.
9. Bakhireva LN, Bautista A, Cano S, Shrestha S, Bachyrycz AM, Cruz TH. Barriers and facilitators to dispensing of intranasal naloxone by pharmacists. *Subst Abus*. 2017:1-11.
10. Countey H, Steinbronn C, Grady SE. Changing student attitudes and perceptions toward opioid use disorder. *Ment Health Clin*. 2018;8:222-226.
11. Hartung DM, Hall J, Haverly SN, et al. Pharmacists' Role in Opioid Safety: A Focus Group Investigation. *Pain Med*. 2018;19:1799-1806.
12. Lewis ET, Combs A, Trafton JA. Reasons for under-use of prescribed opioid medications by patients in pain. *Pain Med*. 2010;11:861-871.
13. Hagemeyer NE, Murawski MM, Lopez NC, Alamian A, Pack RP. Theoretical exploration of Tennessee community pharmacists' perceptions regarding opioid pain reliever abuse communication. *Res Social Adm Pharm*. 2014;10:562-575.
14. Matthias MS, Krebs EE, Collins LA, Bergman AA, Coffing J, Bair MJ. "I'm not abusing or anything": patient-physician communication about opioid treatment in chronic pain. *Patient Educ Couns*. 2013;93:197-202.
15. Matthias MS, Krebs EE, Bergman AA, Coffing JM, Bair MJ. Communicating about opioids for chronic pain: a qualitative study of patient attributions and the influence of the patient-physician relationship. *Eur J Pain*. 2014;18:835-843.
16. McCarthy DM, Cameron KA, Courtney DM, Adams JG, Engel KG. Communication about opioid versus nonopioid analgesics in the emergency department. *J Opioid Manag*. 2015;11:229-236.
17. McCarthy DM, Engel KG, Cameron KA. Conversations about analgesics in the emergency department: A qualitative study. *Patient Educ Couns*. 2016;99:1130-1137.
18. Hughes HK, Korthuis PT, Saha S, et al. A mixed methods study of patient-provider communication about opioid analgesics. *Patient Educ Couns*. 2015;98:453-461.

19. McCarthy DM, Cameron KA, King JP, et al. Patient recall of health care provider counseling for opioid-acetaminophen prescriptions. *Pain Med.* 2014;15:1750-1756.
20. Misuse of prescription opioids. National Institute of Drug Abuse. 2018. <https://www.drugabuse.gov/publications/misuse-prescription-drugs/overview>. Accessed April 29, 2020.
21. Opioid overdose. 2018. Centers for disease control and prevention. <https://www.cdc.gov/drugoverdose/index.html>. Accessed on April 29, 2020
22. Opioid overdose- communicating with patients. Centers for Disease Control and Prevention; 2017. <https://www.cdc.gov/drugoverdose/training/communicating/index.html>. Accessed on April 29, 2020.
23. Haug NA, Bielenberg J, Linder SH, Lembke A. Assessment of provider attitudes toward #naloxone on Twitter. *Subst Abus.* 2016;37:35-41.
24. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev.* 2015;4:1.
25. LoCasale RJ, Datto C, Wilson H, Yeomans K, Coyne KS. The Burden of Opioid-Induced Constipation: Discordance Between Patient and Health Care Provider Reports. *J Manag Care Spec Pharm.* 2016;22:236-245.
26. Vallerand AH, Hendry S, Baldys E, Hu Y, Datto C. Analysis of Patient-Provider Interactions Regarding the Burden and Treatment of Opioid-Induced Constipation in Adults with Chronic Noncancer Pain. *Pain Med.* 2018.
27. Smith RJ, Rhodes K, Paciotti B, Kelly S, Perrone J, Meisel ZF. Patient Perspectives of Acute Pain Management in the Era of the Opioid Epidemic. *Ann Emerg Med.* 2015;66:246-252.e241.
28. Shields CG, Fuzzell LN, Christ SL, Matthias MS. Patient and provider characteristics associated with communication about opioids: An observational study. *Patient Educ Couns.* 2018.
29. Mueller SR, Koester S, Glanz JM, Gardner EM, Binswanger IA. Attitudes Toward Naloxone Prescribing in Clinical Settings: A Qualitative Study of Patients Prescribed High Dose Opioids for Chronic Non-Cancer Pain. *J Gen Intern Med.* 2017;32:277-283.
30. Matthias MS, Johnson NL, Shields CG, et al. "I'm Not Gonna Pull the Rug out From Under You": Patient-Provider Communication About Opioid Tapering. *J Pain.* 2017;18:1365-1373.
31. Bergman AA, Matthias MS, Coffing JM, Krebs EE. Contrasting tensions between patients and PCPs in chronic pain management: a qualitative study. *Pain Med.* 2013;14:1689-1697.
32. Cintron A, Morrison RS. Pain and ethnicity in the United States: A systematic review. *J Palliat Med.* 2006;9:1454-1473.
33. Robinson-Lane SG, Vallerand AH. Pain Treatment Practices of Community-Dwelling Black Older Adults. *Pain Manag Nurs.* 2018;19:46-53.
34. Kilaru AS, Gadsden SM, Perrone J, Paciotti B, Barg FK, Meisel ZF. How do physicians adopt and apply opioid prescription guidelines in the emergency department? A qualitative study. *Ann Emerg Med.* 2014;64:482-489.e481.
35. Liebschutz JM, Lange AV, Heymann OD, et al. Communication between nurse care managers and patients who take opioids for chronic pain: Strategies for exploring aberrant behavior. *J Opioid Manag.* 2018;14:191-202.

36. Fleming ML, Bapat SS, Varisco TJ. Using the theory of planned behavior to investigate community pharmacists' beliefs regarding engaging patients about prescription drug misuse. *Res Social Adm Pharm*. 2018.
37. Donovan AK, Wood GJ, Rubio DM, Day HD, Spagnoletti CL. Faculty Communication Knowledge, Attitudes, and Skills Around Chronic Non-Malignant Pain Improve with Online Training. *Pain Med*. 2016;17:1985-1992.
38. Kimberlin CL, Jamison AN, Linden S, Winterstein AG. Patient counseling practices in U.S. pharmacies: effects of having pharmacists hand the medication to the patient and state regulations on pharmacist counseling. *J Am Pharm Assoc (2003)*. 2011;51:527-534.
39. Rochon PA, Gurwitz JH. The prescribing cascade revisited. *Lancet*. 2017;389:1778-1780.
40. Smith RJ, Kilaru AS, Perrone J, et al. How, why, and for whom do emergency medicine providers use prescription drug monitoring programs? *Pain Med*. 2015;16:1121-1131.
41. Peters J, Desai K, Ricci D, Chen D, Singh M, Chewing B. The power of the patient question: A secret shopper study. *Patient Educ Couns*. 2016;99:1526-1533.
42. Guirguis LM, Chewing BA. Role theory: literature review and implications for patient-pharmacist interactions. *Res Social Adm Pharm*. 2005;1:483-507.
43. Management of substance abuse. World Health Organization. 2018. [https://www.who.int/substance\\_abuse/en/](https://www.who.int/substance_abuse/en/). Accessed April 29, 2020.
44. Johnston K, Alley L, Novak K, Haverly S, Irwin A, Hartung D. Pharmacists' attitudes, knowledge, utilization, and outcomes involving prescription drug monitoring programs: A brief scoping review. *J Am Pharm Assoc (2003)*. 2018;58:568-576.
45. Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. *Ann Pharmacother*. 2016;50:778-784.
46. Salinas GD, Susalka D, Burton BS, et al. Risk assessment and counseling behaviors of healthcare professionals managing patients with chronic pain: a national multifaceted assessment of physicians, pharmacists, and their patients. *J Opioid Manag*. 2012;8:273-284.
47. Wickramatilake S, Zur J, Mulvaney-Day N, Klimo MC, Selmi E, Harwood H. How States Are Tackling the Opioid Crisis. *Public Health Rep*. 2017;132:171-179.
48. Naloxoneinfo.org Case Studies. [(accessed on 23 July 2018)]; Available online: <http://naloxoneinfo.org/case-studies/standing-orders>.
49. The Network for Public Health Law Using Law to Support Pharmacy Naloxone Distribution. [(accessed on 23 July 2018)]; Available online: [networkforphl.org/\\_asset/qdkn97/Pharmacy-Naloxone-Distributions.pdf](http://networkforphl.org/_asset/qdkn97/Pharmacy-Naloxone-Distributions.pdf).
50. Penm J, MacKinnon NJ, Boone JM, Ciaccia A, McNamee C, Winstanley EL. Strategies and policies to address the opioid epidemic: A case study of Ohio. *J Am Pharm Assoc (2003)*. 2017;57:S148-s153.
51. Bailey AM, Wermeling DP. Naloxone for opioid overdose prevention: pharmacists' role in community-based practice settings. *Ann Pharmacother*. 2014;48:601-606.
52. Cochran G, Hruschak V, DeFosse B, Hohmeier KC. Prescription opioid abuse: pharmacists' perspective and response. *Integr Pharm Res Pract*. 2016;5:65-73.
53. Riley TB, Alemagno S. Pharmacist utilization of prescription opioid misuse interventions: Acceptability among pharmacists and patients. *Res Social Adm Pharm*. 2019.
54. Nielsen S, Van Hout MC. What is known about community pharmacy supply of naloxone? A scoping review. *Int J Drug Policy*. 2016;32:24-33.

55. Green TC, Case P, Fiske H, et al. Perpetuating stigma or reducing risk? Perspectives from naloxone consumers and pharmacists on pharmacy-based naloxone in 2 states. *J Am Pharm Assoc (2003)*. 2017;57:S19-S27.e14.
56. Devries J, Rafie S, Polston G. Implementing an overdose education and naloxone distribution program in a health system. *J Am Pharm Assoc (2003)*. 2017;57:S154-s160.
57. Tewell R, Edgerton L, Kyle E. Establishment of a pharmacist-led service for patients at high risk for opioid overdose. *Am J Health Syst Pharm*. 2018;75:376-383.
58. Cobaugh DJ, Gainor C, Gaston CL, et al. The opioid abuse and misuse epidemic: implications for pharmacists in hospitals and health systems. *Am J Health Syst Pharm*. 2014;71:1539-1554.
59. Athern KM, Linnebur SA, Fabisiak G. Proper Disposal of Unused Household Medications: The Role of the Pharmacist. *Consult Pharm*. 2016;31:261-266.
60. Gray-Winnett MD, Davis CS, Yokley SG, Franks AS. From dispensing to disposal: the role of student pharmacists in medication disposal and the implementation of a take-back program. *J Am Pharm Assoc (2003)*. 2010;50:613-618.
61. CVS. Expanding access to safe and convenient drug disposal. 2018. <https://cvshealth.com/thought-leadership/expanding-access-to-safe-and-convenient-drug-disposal>. Accessed April 29, 2020.
62. H.R.34—21st Century Cures Act. Unuted States Congress. <https://www.congress.gov/bill/114th-congress/house-bill/34>. Accessed April 29, 2020.
63. H.R.6—Support for Patients and Communities Act. Unuted States Congress. <https://www.congress.gov/bill/115th-congress/house-bill/6?q=%7B%22search%22%3A%5B%22hr6-2018%22%5D%7D&s=2&r=1> . Accessed April 29, 2020.
64. Norwood CW, Wright ER. Integration of prescription drug monitoring programs (PDMP) in pharmacy practice: Improving clinical decision-making and supporting a pharmacist's professional judgment. *Res Social Adm Pharm*. 2016;12:257-266.
65. Lal A, Bai J, Basri D, Yeager KA. Pharmacists' Perspectives on Practice, Availability, and Barriers Related to Opioids in Georgia. *Am J Hosp Palliat Care*. 2018:1049909118815440.
66. Strand MA, Eukel H, Burck S. Moving opioid misuse prevention upstream: A pilot study of community pharmacists screening for opioid misuse risk. *Res Social Adm Pharm*. 2018.
67. Fendrich M, Bryan JK, Hooyer K. Prescription Drug Monitoring Programs and Pharmacist Orientation Toward Dispensing Controlled Substances. *Subst Use Misuse*. 2018;53:1324-1330.
68. Freeman PR, Curran GM, Drummond KL, et al. Utilization of prescription drug monitoring programs for prescribing and dispensing decisions: Results from a multi-site qualitative study. *Res Social Adm Pharm*. 2018.
69. Scott IA, Hilmer SN, Reeve E, et al. Reducing inappropriate polypharmacy: the process of deprescribing. *JAMA Intern Med*. 2015;175:827-834.
70. Potter K, Flicker L, Page A, Etherton-Bear C. Deprescribing in Frail Older People: A Randomised Controlled Trial. *PLoS One*. 2016;11:e0149984.
71. Kaur S, Mitchell G, Vitetta L, Roberts MS. Interventions that can reduce inappropriate prescribing in the elderly: a systematic review. *Drugs Aging*. 2009;26:1013-1028.

72. Spinewine A, Fialová D, Byrne S. The role of the pharmacist in optimizing pharmacotherapy in older people. *Drugs Aging*. 2012;29:495-510.
73. Mudge A, Radnedge K, Kasper K, et al. Effects of a pilot multidisciplinary clinic for frequent attending elderly patients on deprescribing. *Aust Health Rev*. 2016;40:86-91.
74. Martin P, Tamblyn R, Benedetti A, Ahmed S, Tannenbaum C. Effect of a Pharmacist-Led Educational Intervention on Inappropriate Medication Prescriptions in Older Adults: The D-PRESCRIBE Randomized Clinical Trial. *JAMA*. 2018;320:1889-1898.
75. Tannenbaum C, Martin P, Tamblyn R, Benedetti A, Ahmed S. Reduction of inappropriate benzodiazepine prescriptions among older adults through direct patient education: the EMPOWER cluster randomized trial. *JAMA Intern Med*. 2014;174:890-898.
76. Farrell B, Pottie K, Thompson W, et al. Deprescribing proton pump inhibitors: Evidence-based clinical practice guideline. *Can Fam Physician*. 2017;63:354-364.
77. Bjerre LM, Farrell B, Hogel M, et al. Deprescribing antipsychotics for behavioural and psychological symptoms of dementia and insomnia: Evidence-based clinical practice guideline. *Can Fam Physician*. 2018;64:17-27.
78. Pottie K, Thompson W, Davies S, et al. Deprescribing benzodiazepine receptor agonists: Evidence-based clinical practice guideline. *Can Fam Physician*. 2018;64:339-351.
79. Anderson K, Stowasser D, Freeman C, Scott I. Prescriber barriers and enablers to minimising potentially inappropriate medications in adults: a systematic review and thematic synthesis. *BMJ Open*. 2014;4:e006544.
80. Conklin J, Farrell B, Suleman S. Implementing deprescribing guidelines into frontline practice: Barriers and facilitators. *Res Social Adm Pharm*. 2018.
81. Hagemeyer NE, Gray JA, Pack RP. Prescription drug abuse: a comparison of prescriber and pharmacist perspectives. *Subst Use Misuse*. 2013;48:761-768.
82. Lafferty L, Hunter TS, Marsh WA. Knowledge, attitudes and practices of pharmacists concerning prescription drug abuse. *J Psychoactive Drugs*. 2006;38:229-232.
83. Green TC, Dauria EF, Bratberg J, Davis CS, Walley AY. Orienting patients to greater opioid safety: models of community pharmacy-based naloxone. *Harm Reduct J*. 2015;12:25.
84. Hagemeyer NE, Tudiver F, Brewster S, et al. Interprofessional prescription opioid abuse communication among prescribers and pharmacists: A qualitative analysis. *Subst Abuse*. 2018;39:89-94.
85. Matthias MS, Parpart AL, Nyland KA, et al. The patient-provider relationship in chronic pain care: providers' perspectives. *Pain Med*. 2010;11:1688-1697.
86. Thakur T, Chewing B. Using role theory to explore pharmacist role conflict in opioid risks communication. *Res Social Adm Pharm*. 2019.
87. Kennedy LC, Binswanger IA, Mueller SR, et al. "Those Conversations in My Experience Don't Go Well": A Qualitative Study of Primary Care Provider Experiences Tapering Long-term Opioid Medications. *Pain Med*. 2018;19:2201-2211.
88. Thakur T, Frey M, Chewing B. Pharmacist Services in the Opioid Crisis: Current Practices and Scope in the United States. *Pharmacy (Basel)*. 2019;7.
89. Hennessy M, Bleakley A, Ellithorpe M. Prototypes reflect normative perceptions: implications for the development of reasoned action theory. *Psychol Health Med*. 2018;23:245-258.

90. Ajzen I, Kruglanski AW. Reasoned action in the service of goal pursuit. *Psychol Rev.* 2019;126:774-786.
91. Ajzen I. The theory of planned behaviour: reactions and reflections. *Psychol Health.* 2011;26:1113-1127.
92. Godin G, Kok G. The theory of planned behavior: a review of its applications to health-related behaviors. *Am J Health Promot.* 1996;11:87-98.
93. Pradel FG, Obeidat NA, Tsoukleris MG. Factors affecting pharmacists' pediatric asthma counseling. *J Am Pharm Assoc (2003).* 2007;47:737-746.
94. Herbert KE, Urmie JM, Newland BA, Farris KB. Prediction of pharmacist intention to provide Medicare medication therapy management services using the theory of planned behavior. *Res Social Adm Pharm.* 2006;2:299-314.
95. Gavaza P, Fleming M, Barner JC. Examination of psychosocial predictors of Virginia pharmacists' intention to utilize a prescription drug monitoring program using the theory of planned behavior. *Res Social Adm Pharm.* 2014;10:448-458.
96. Saengcharoen W, Chongsuvivatwong V, Lerkiatbundit S, Wongpoowarak P. Factors influencing dispensing of antibiotics for upper respiratory infections among Southern Thai community pharmacists. *J Clin Pharm Ther.* 2008;33:122-129.
97. Walker A, Watson M, Grimshaw J, Bond C. Applying the theory of planned behaviour to pharmacists' beliefs and intentions about the treatment of vaginal candidiasis with non-prescription medicines. *Fam Pract.* 2004;21:670-676.
98. DHS regions by county. Wisconsin Department of Health. 2018. Madison, Wisconsin. <https://www.dhs.wisconsin.gov/aboutdhs/regions.html>. Accessed April 29, 2020.
99. Opioids. Wisconsin Department of Health Services. 2019. <https://www.dhs.wisconsin.gov/opioids/index.html>. Accessed April 29, 2020.
100. Kongsted A, Nielsen AM. Latent Class Analysis in health research. *J Physiother.* 2017;63:55-58.
101. Schreiber JB. Latent Class Analysis: An example for reporting results. *Res Social Adm Pharm.* 2017;13:866-1191.
102. Van den Bergh M, van Kollenburg GH, Vermunt JK. Deciding on the Starting Number of Classes of a Latent Class Tree. *Sociol Methodol.* 2018;48:303-336.
103. Gudicha DW, Schmittmann VD, Vermunt JK. Statistical power of likelihood ratio and Wald tests in latent class models with covariates. *Behav Res Methods.* 2017;49:1824-1837.
104. Just J, Mucke M, Bleckwenn M. Dependence on Prescription Opioids. *Dtsch Arztebl Int.* 2016;113:213-220.
105. Van Geffen EC, Philbert D, van Boheemen C, van Dijk L, Bos MB, Bouvy ML. Patients' satisfaction with information and experiences with counseling on cardiovascular medication received at the pharmacy. *Patient Educ Couns.* 2011;83:303-309.
106. Thakur T, Frey M, Chewing B. Pharmacist roles, training, and perceived barriers in naloxone dispensing: A systematic review. *J Am Pharm Assoc (2003).* 2019.
107. Freeman PR, Goodin A, Troske S, Strahl A, Fallin A, Green TC. Pharmacists' role in opioid overdose: Kentucky pharmacists' willingness to participate in naloxone dispensing. *J Am Pharm Assoc (2003).* 2017;57:S28-s33.
108. Amin ME, Chewing B. Pharmacists' counseling on oral contraceptives: A theory informed analysis. *Res Social Adm Pharm.* 2016;12:669-681.
109. Krosnick JA. Survey research. *Annu Rev Psychol.* 1999;50:537-567.

110. Timmins F. Surveys and questionnaires in nursing research. *Nurs Stand*. 2015;29:42-50.
111. Graesser AC, Wiemer-Hastings K, Kreuz R, Wiemer-Hastings P, Marquis K. QUAID: a questionnaire evaluation aid for survey methodologists. *Behav Res Methods Instrum Comput*. 2000;32:254-262.
112. Drennan J. Cognitive interviewing: verbal data in the design and pretesting of questionnaires. *J Adv Nurs*. 2003;42:57-63.
113. DiBenedetti DB, Price MA, Andrews EB. Cognitive interviewing in risk minimization survey development: patient and healthcare professional surveys. *Expert Rev Clin Pharmacol*. 2013;6:369-373.
114. Keim SA, Smith K, Boone KM, Oza-Frank R. Cognitive Testing of the Brief Breastfeeding and Milk Expression Recall Survey. *Breastfeed Med*. 2018;13:60-66.
115. Dilman Don SJ, Christian Leo. Mail questionnaires and implementation. In: Internet, Phone, Mail and Mixed-Mode Surveys Hoboken, NJ: Wiley; 2014:351-396.
116. Griffin JM, Simon AB, Hulbert E, et al. A comparison of small monetary incentives to convert survey non-respondents: a randomized control trial. *BMC Med Res Methodol*. 2011;11:81.
117. Finch WH. Using Fit Statistic Differences to Determine the Optimal Number of Factors to Retain in an Exploratory Factor Analysis. *Educ Psychol Meas*. 2020;80:217-241.
118. Izquierdo I, Olea J, Abad FJ. Exploratory factor analysis in validation studies: uses and recommendations. *Psicothema*. 2014;26:395-400.
119. Patwardhan PD, Amin ME, Chewning BA. Intervention research to enhance community pharmacists' cognitive services: a systematic review. *Res Social Adm Pharm*. 2014;10:475-493.
120. Paquette CE, Syvertsen JL, Pollini RA. Stigma at every turn: Health services experiences among people who inject drugs. *Int J Drug Policy*. 2018;57:104-110.
121. Pasquale MK, Sheer RL, Mardekian J, et al. Educational intervention for physicians to address the risk of opioid abuse. *Journal of opioid management*. 2017;13:303-313.
122. Le PP, Braunack-Mayer A. Perspectives on privacy in the pharmacy: The views of opioid substitution treatment clients. *Res Social Adm Pharm*. 2019;15:1021-1026.
123. Schartel A, Lardieri A, Mattingly A, Feemster AA. Implementation and assessment of a naloxone-training program for first-year student pharmacists. *Curr Pharm Teach Learn*. 2018;10:717-722.

## APPENDICES

### Appendix A: Interview Guide

Thank you for agreeing to do this interview. Now I will be asking you a few questions about your opinions, and practices about opioid risk communication. Opioid risk in this interview includes both dependency and overdose risks. This will take around 30-45 minutes. I will be audio recording this interview and later we will be transcribing this interview verbatim. Your name or any personal information will not be linked in any way to your responses. Please try to avoid saying your name, any other person's name or your pharmacy's name in your responses. During the interview feel free to ask me questions at any point or to stop answering at any point as well. Feel free to not answer any question that you feel uncomfortable answering. Do you have any questions that I can answer now? Are you still willing to continue with the interview?

1. How necessary do you think it is for you to tell the patients about opioid risks and safety when you dispense opioid prescriptions? Why?
2. What do you usually cover with a patient when dispensing a new opioid prescription?
  - a. Side effects
  - b. Risks
3. What do you usually cover with a patient when dispensing a refill opioid prescription?
  - a. Side effects
  - b. Risks
4. What do you cover with patients about opioid risks for short term prescriptions for acute conditions?
5. What do you cover with patients about opioid risks for long term prescriptions for chronic conditions?
6. How do you think your counseling practice about opioid medications affect patients' knowledge and attitude towards opioid risks and safety?
7. How would you describe what the patients expect to be covered in opioid consults?

8. What do the providers expect you to cover in opioid medication consults?
9. What topics do the pharmacy laws expect you to cover when dispensing opioid medications?
10. How feasible do you think opioid risk counseling is for every opioid prescription dispensed?
11. What common barriers do you face about opioid risk communication with patients?
12. How often is time a factor when discussing opioid risks?
13. How would you say privacy affects your intention to counsel patients about opioid risks and safety?
14. How do you initiate opioid risk discussion?
15. What terms and phrases do you usually use for describing various risks of opioids?
16. What factors do you think makes opioid risk counselling easier?
17. What training have you received that makes opioid risk discussion easier?
18. What resources do you have or wish you had for opioid risk and safety communication?
19. How do you decide when to mention basic opioid risks and safety to patients?
20. When do you dispense naloxone?
21. How do you screen patients for overdose risk?
22. How do you initiate conversation about overdose risk and naloxone?
23. What barriers do you face in naloxone dispensing and counselling?
24. What factors facilitate naloxone dispensing and counselling?

## Appendix B: First draft of survey



You are receiving this survey because the Department of Safety and Professional Services listed you as a practicing pharmacist in Wisconsin. This survey seeks to understand **practices of pharmacists about opioid risk and safety communication**. It will take about **3-5 minutes**. Your name or any personal information will not be linked to your responses and your confidentiality will be protected. This survey is a part of my PhD **dissertation project at University of Wisconsin-Madison School of Pharmacy**. You can use the enclosed envelope to send back the survey. The return mailing is already paid for by the study team. If you have any questions, please feel free to contact us at [tmthakur@wisc.edu](mailto:tmthakur@wisc.edu). Thanks so much for your time and valuable responses!

Tanvee Thakur

Betty Chewning

Does your practice involve counseling patients about opioid medications?  Yes  No

If YES, CONTINUE TO QUESTION 1

If NO, PLEASE STOP HERE

**1. Think about topics you cover with patients when counseling them on opioid medication. Do you talk to them about-**

	Yes	No
a) Side effects of opioids?	<input type="radio"/>	<input type="radio"/>
b) Dependency risk for acute pain prescription?	<input type="radio"/>	<input type="radio"/>
c) Dependency risk for chronic pain prescription?	<input type="radio"/>	<input type="radio"/>
d) Overdose risk for chronic pain prescription?	<input type="radio"/>	<input type="radio"/>
e) Overdose risk for acute pain prescription?	<input type="radio"/>	<input type="radio"/>
f) Dependency risk for new prescription?	<input type="radio"/>	<input type="radio"/>
g) Dependency risk for refill prescription?	<input type="radio"/>	<input type="radio"/>
h) Overdose risk for new prescription	<input type="radio"/>	<input type="radio"/>
i) Overdose risk for acute prescription	<input type="radio"/>	<input type="radio"/>
j) Tell them that the medication is an opioid/ narcotic?	<input type="radio"/>	<input type="radio"/>
k) Appropriate ways to self-monitor pain?	<input type="radio"/>	<input type="radio"/>
l) Safe opioid storage and disposal?	<input type="radio"/>	<input type="radio"/>
m) Naloxone to combat an overdose?	<input type="radio"/>	<input type="radio"/>

**2. How much do the following factors affect your intent to cover opioid risks?**

	Not at all	A little	Some	Quite a bit	A great deal
a) Your time for counselling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Busyness of pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Privacy during counselling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

d) Direction from pharmacy organization/ owners	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Individual's need for risk counselling felt by you	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f) Type of prescription they have (acute, chronic)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Training and education received about opioid risk communication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h) Availability of resources to refer patients to	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i) Availability of resources to help you have this conversation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j) Knowledge of terms to use in opioid risk counselling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k) Recommendations by CDC for opioid counselling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l) Questions and cues from patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m) How much patient already knows about this medication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
n) Patients time for counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
o) Existing relationship with the patient	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
p) Patient's medication and pain history	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**5. Finally, we have some demographic questions about you.**

a. How would you describe your pharmacy setting?

Chain pharmacy

Independent pharmacy

Hospital outpatient

Ambulatory clinic outpatient

Hospital inpatient

Other. Please mention-

b. Number of opioid prescriptions dispensed per week (approximately)? \_\_\_\_\_

c. Number of years of practice as registered pharmacist? \_\_\_\_\_

d. Gender:  Male  Female  Identify as other

e. City in which pharmacy is located in: \_\_\_\_\_

**THANK YOU FOR YOUR TIME. WE DEEPLY APPRECIATE IT!**

## Appendix C: Final Draft of survey after three-step survey development and refinement process



You are receiving this survey because the Department of Safety and Professional Services (DPS) listed you as a practicing pharmacist in Wisconsin. This survey seeks to understand **factors determining pharmacists' counseling practices about opioid risk and safety**. It will take about **5 minutes**. Your personal information will not be linked to your responses. This survey is a part of my **PhD dissertation project at University of Wisconsin-Madison School of Pharmacy**. You can use the enclosed envelope to send back the survey. The return mailing is already paid for by the study team. If you have any questions, please feel free to contact me at [tmthakur@wisc.edu](mailto:tmthakur@wisc.edu). Thank you so much for your time and valuable responses!

Tanvee Thakur, MS, BPharm

Betty Chewning, PhD, FAPhA

**1. Does your practice involve counseling patients about opioid medications?**  Yes  No

**If YES, CONTINUE TO QUESTION 1**

**If NO, PLEASE STOP HERE AND RETURN THE SURVEY**

**2. Think about topics you cover in opioid medications consultations with patients. How often do you cover...**

	Never	Sometimes	Most times	Always
a) Side effects of opioids?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Physical dependence for <i>new short-term</i> prescriptions? i.e. $\leq 14$ days?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Overdose risk for <i>new short-term</i> prescriptions? i.e. $\leq 14$ days?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) Physical dependence for <i>new long-term</i> prescriptions? i.e. $\geq 14$ days?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Overdose risk for new <i>long-term</i> prescriptions i.e. $\geq 14$ days?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f) Physical dependence for <i>refill</i> prescriptions familiar to patients?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Overdose risk for <i>refill</i> prescriptions familiar to patients?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h) Tell them that the medication is an opioid or narcotic?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i) Appropriate ways to self-monitor pain?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j) Safe opioid storage and disposal?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k) Naloxone for an opioid overdose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**3. Thinking about last year, how much did the following factors affect your intent to counsel on opioid risks and safety?**

	Not at all	A little	Some	Quite a bit	A great deal
a) Amount of time you have for counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Busyness of pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Privacy during counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) Direction from pharmacy administration or owners	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Your assessment of individual's need for risk counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f) Type of prescription they have e.g. acute, chronic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Training and education, you received about opioid risk communication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h) Availability of resources to refer patients to e.g. online, written	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i) Availability of professional resources to help you in this conversation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j) Knowledge of patient friendly terms to use in opioid risk counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k) Recommendations by CDC for opioid counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l) Patient's questions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m) How much patient already knows about this medication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
n) Patient's time for counseling	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
q) Existing relationship with the patient	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
r) Patient's medication and pain history	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Finally, we have some demographic questions for you.**

f. How would you describe the pharmacy setting where you work the most?

- Chain pharmacy                       Independent pharmacy                       Hospital outpatient  
 Ambulatory clinic outpatient                       Hospital inpatient                       Other. Please describe-

g. At this pharmacy, do you work...  Full-time       Part-time

h. Total number of prescriptions dispensed per week in this pharmacy (approximately)? \_\_\_\_\_

i. Number of opioid prescriptions dispensed per week (approximately)? \_\_\_\_\_

j. Number of pharmacists working per shift when pharmacy is busy? \_\_\_\_\_

k. Number of years you have practiced as a registered pharmacist.. \_\_\_\_\_

l. Gender:  Male    Female    Identify as other

m. City in which this pharmacy is located.. \_\_\_\_\_

-----THE END--

**THANK YOU FOR YOUR TIME. WE DEEPLY APPRECIATE IT!**

## Appendix D: QUAID analysis report

### Section 1

a. How often do you talk about the side effects of opioids?

**1. Unfamiliar technical terms: opioids**

The following term may be unfamiliar to some respondents: [opioids](#), in sentence 1 in the Question.

**2. Vague or imprecise relative terms: Frequency ambiguity: often**

The following terms refer implicitly to an underlying continuum or scale, but the point or value on the scale is vague or imprecise: [Frequency ambiguity: often](#), in sentence 1 in the Question.

**3. Vague or ambiguous noun-phrases: Vague noun: opioids**

The referent of the following nouns or pronouns may be vague or ambiguous to the respondent: [Vague noun: opioids](#), in sentence 1 in the Question.

**4. Unfamiliar technical terms: counseling, opioid, medication**

The following term may be unfamiliar to some respondents: [counseling, opioid, medication](#), in sentence 1 in the Context.

**5. Vague or imprecise relative terms: Frequency ambiguity: sometimes**

The following terms refer implicitly to an underlying continuum or scale, but the point or value on the scale is vague or imprecise: [Frequency ambiguity: sometimes](#), in sentence 1 in the Answer.

b. Dependency risks for short term prescriptions i.e.

**1. Unfamiliar technical terms: dependency, short-term, prescription, i.e**

The following term may be unfamiliar to some respondents: [dependency, short-term, prescription, i.e](#), in sentence 1 in the Question.

**2. Vague or ambiguous noun-phrases: Vague noun: i.e**

The referent of the following nouns or pronouns may be vague or ambiguous to the respondent: [Vague noun: i.e](#), in sentence 1 in the Question.

**3. Unfamiliar technical terms: counseling, opioid, medication**

The following term may be unfamiliar to some respondents: [counseling, opioid, medication](#), in sentence 1 in the Context.

c. Overdose risk for short term prescriptions i.e.

1. Unfamiliar technical terms: overdose, short-term, prescription, i.e

The following term may be unfamiliar to some respondents: [overdose, short-term, prescription, i.e](#), in sentence 1 in the Question.

Section 2. a. Your time for counseling

**Unfamiliar technical terms: counseling**

The following term may be unfamiliar to some respondents: [counseling](#), in sentence 1 in the Question.

**2. Unfamiliar technical terms: opioid**

The following term may be unfamiliar to some respondents: [opioid](#), in sentence 1 in the Context.

**3. Vague or imprecise relative terms: Quantification ambiguity: much**

The following terms refer implicitly to an underlying continuum or scale, but the point or value on the scale is vague or imprecise: [Quantification ambiguity: much](#), in sentence 1 in the Context.

**4. Vague or imprecise relative terms: Intensity ambiguity: very**

The following terms refer implicitly to an underlying continuum or scale, but the point or value on the scale is vague or imprecise: [Intensity ambiguity: very](#), in sentence 1 in the Answer.

How often do you dispense naloxone to the patients

**Unfamiliar technical terms: naloxone**

The following term may be unfamiliar to some respondents: [naloxone](#), in sentence 1 in the Question.

**2. Vague or imprecise relative terms: Frequency ambiguity: often**

The following terms refer implicitly to an underlying continuum or scale, but the point or value on the scale is vague or imprecise: [Frequency ambiguity: often](#), in sentence 1 in the Question.

Answer looks good to me.

**Appendix E: Questions and probes for cognitive interviewing**

Now, please read this question aloud. Then think out loud about how you analyze this question and get to the answer. Think out loud as you work through the process of getting to the answer after reading the question.

Thank you for doing that. I have a few follow-up questions on that (Choose any that applies)

Why did you pause at ....

What did you mean by ..... when you were thinking of the answer?

What part of the question seemed confusing to you?