AN EXAMINATION OF OPIOID PRESCRIBING POLICY AND CLINICAL PRACTICE IN THE CONTEXT OF THE UNITED STATES OPIOID CRISIS

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Elizabeth Caitlin Anne Danielson

AN EXAMINATION OF OPIOID PRESCRIBING POLICY AND CLINICAL PRACTICE IN THE CONTEXT OF THE UNITED STATES OPIOID CRISIS

In 2017, the United States government declared that the opioid epidemic was a public health emergency. Among responses to address the epidemic, the Centers for Disease Control and Prevention released a set of opioid prescribing guidelines for primary care clinicians. Since their release, federal agencies and experts have been interested and concerned about their application in policy and clinical practice.

This dissertation examines how some of these federal recommendations were implemented in clinic practice and state law, as well as the effects of related prescribing laws. This dissertation includes three studies 1) a qualitative analysis of clinician and patient discussions about opioid-related risks, benefits, and treatment goals, 2) a policy surveillance study of state tapering laws and their consistency with the CDC guideline's opioid tapering recommendations, and 3) an empirical study of the effects of morphine milligram equivalent daily dose laws and acute opioid prescribing laws on pain medication prescribing for patients with Medicaid. Overall, this dissertation attempts to understand the translation of national opioid prescribing guidelines into policy and their effects on healthcare delivery.

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CHAPTER ONE

Pain Care in the United States

"To have pain is to have *certainty*; to hear about pain is to have *doubt*."(1)

– Elaine Scarry

Pain is a subjective experience but provides meaningful information to the individual. In the United States, an estimated 50 million American adults experience chronic pain which is defined as daily pain lasting at least six months (2). As an unavoidable part of life and healthcare delivery, pain was expected and often only addressed in acute situations (3). Prior to the 1990's, opioids were infrequently prescribed for chronic pain (3). Opioids including Percocet and Vicodin were accepted as too risky for pain treatment and highly addictive (4). However, much of that sentiment started to change in the late 1990's when the Joint Commission was funded by the Robert Wood Johnson Foundation to develop pain standards (5). The Joint Commission, the American Pain Society, and other medical groups began promoting pain as the fifth vital sign and suggesting that opioids were a safe way to manage it (5, 6). As a result, opioid prescribing jumped from 2 to 8 million prescriptions from the early 1990's to 1996 (7). This number continued to climb until 2012 with a staggering 259 million prescriptions (8).

Due to high prescribing rates (8), by 2017 nearly 218,000 people had an overdose related to a prescription opioid (9). Further, an estimated 1.9 million were abusing or dependent on opioids based on the DSM-IV diagnosis criteria (10). From 1999-2013, opioid use disorder alone accounted for an estimated $72.4 billion in economic burden (11).

The United States' Response to the Opioid Crisis

Policies and Overdose

In 2016 the Centers for Disease Control and Prevention (CDC) released a set of opioid prescribing recommendations for managing chronic, noncancer pain in primary care. The CDC Guideline sought to help primary care clinicians make informed decisions related to opioid prescribing for chronic pain and acute pain episodes.

Since the CDC Guideline was published, many states have implemented laws and policies to curb opioid prescribing rates. These laws include prior authorizations, pill mill laws, prescription drug monitor program use, morphine milligram equivalent limits, and daily opioid prescribing limits for acute pain (12-15).

After acknowledgment as a public health crisis by the United States government, opioid prescribing rates fell after 2012 (16). Some state policies have been effective at reducing prescribing rates (12, 17, 18). However, as prescribing rates fell, the overdose death rates from all opioids did not fall with them (16). According to the CDC, overdose deaths from heroin and synthetic opioid have risen since 2010 and 2013, respectively (16).

Clinical Practice

As a result of national interest in treating pain, an estimated 10 million patients are prescribed long-term opioid therapy (LTOT) (19). Although chronic pain has been managed over the last few decades with opioid therapy, there is little evidence supporting the benefits of long-term therapy and several risks associated with its use (20). In response to recent evidence and the CDC guideline, clinicians have been encouraged to

prescribe when medically appropriate and continue opioid therapy when the benefits outweigh the risks. However, if benefits do not outweigh risks, clinicians should consider slowly lowering a patient's opioid medication through a tapering process. Opioid tapering and discontinuation happen for a variety of reasons. The majority of discontinuations result from aberrant behaviors (21); however, discontinuations also occur for pain resolution, inadequate analgesia, adverse effects, and for unknown reasons (22).

And on average, pain does not get worse after discontinuation of LTOT and may actually improve pain scores (23, 24). However, experts are also concerned that inappropriate discontinuation of LTOT might be contributing to rising illicit drug use. The CDC, Federal Drug Administration, and clinical experts believe clinicians and policymakers may be misapplying aspects of the CDC guideline in clinical practice (25). Their concerns center around opioid tapering, populations targeted for tapering, and hard opioid prescribing policy limits driving medical decision making. Some of the CDC recommendations have been criticized for potentially discouraging clinicians from prescribing opioids when medically appropriate and inadvertently influencing clinicians to abruptly taper prescribing for patients receiving opioids (26). Abrupt tapering places patients at risk of experiencing serious withdrawal, psychological distress, uncontrolled pain, and potentially, suicide (26, 27). To address whether misapplication occurs, I will examine how clinicians and policymakers' actions compare to the expected actions of the CDC guideline.

Overview of Dissertation

This dissertation addresses how clinicians and policymakers are incorporating the CDC guideline recommendations into practice to deliver safer pain care. I will explore three relationships to address different aspects of how the CDC guideline has been translated into practice. Specifically, I evaluate how pain care recommendations effect healthcare delivery in office visits, in state law and policy, and pain medication prescribing rates. The chapters will focus on five of the CDC guideline recommendations: 1) clinicians should establish treatment goals with all patients, including realistic goals for pain and function, 2) before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy, 3) if benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids, 4) clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day, and 5) when opioids are used for acute pain, clinicians should prescribe the lowest effective dose…three days or less will often be sufficient; more than seven days will rarely be needed.

Chapter two will describe how clinicians discuss risks, benefits, and goals around opioid-related pain care. Chapter three will describe how accurately tapering recommendations were translated into state policy. Chapter four will evaluate the effect of hard limit laws on opioid prescribing rates.

More specifically, chapter two will provide context for how clinicians incorporate aspects of the CDC guideline in their discussions with patients. I will use qualitative methods to identify emerging themes from primary care visits with clinicians and their patients receiving opioid therapy. I will focus on how clinicians and patients discuss setting goals and the risks and benefits of opioid therapy. I will also identify the ways in which these recommendations come about and how clinicians and patients discuss them.

Chapter three will examine opioid tapering state policies and compare them to the recommendations set by the CDC guideline. To do so, I will use policy surveillance methods to capture and code these policies. I will code policy characteristics and compare these relative to recommended tapering guideline attributes. This chapter will describe policy variation across states and identify ways in which policies do or do not match recommended practices.

Chapter four will evaluate the effect of recent state policies on pain medication prescribing rates. I will use a quasi-experimental design to estimate the effect of morphine equivalent daily dose (MEDD) and acute pain limit policies on opioid prescribing for Medicaid patients. This chapter will provide a rigorous evaluation of these two opioid prescribing policies on opioid and nonopioid medication rates. The results will assist future researchers in addressing whether these policies reduce opioid prescribing rates and how these types of policies may influence nonopioid medical treatments prescribed in vulnerable populations.

CHAPTER TWO

An analysis of primary care clinician communication about risk, benefits, and goals related to chronic opioid therapy

Introduction

Chronic pain and opioid use disorder present enormous public health challenges to the United States (US) healthcare system. Estimates of chronic pain prevalence range from 25 to 100 million US adults (28, 29). Pain contributes an estimated $600 billion in healthcare costs and lost worker productivity annually (29). Between 1999 and 2015, healthcare providers quadrupled their prescribing of opioid pain relievers, while overdose deaths increased dramatically (30). In 2017, over 47,000 people died in the US from opioid overdoses (31). Importantly, primary care clinicians prescribe nearly half of all dispensed opioid prescriptions (32). To help combat opioid-related risks, the Centers for Disease Control and Prevention (CDC) published the 2016 Guideline for Prescribing Opioids for Chronic Pain that targets primary care treatment of chronic noncancer pain (33).

Reflected in the CDC Guideline and other opioid prescribing best practices is the need for clinicians to regularly assess, and talk with their patients about, opioid-related risks, benefits, and treatment goals when considering or managing chronic opioid therapy. However, because primary care clinicians are often caring for multiple patient conditions during short clinic visits (34-36), it is unclear how accurately or comprehensively clinicians discuss opioid-related risks, benefits, and goals with their patients. At the same time, accurate and comprehensive communication is important to

ensure that patients understand opioid-related health risks and benefits, and that clinicians and patients have a common understanding of appropriate treatment goals. Indeed, prior research has found that patients may have inaccurate perceptions of opioid-related risks and benefits (35, 37), and patients and clinicians may not share the same outcome goals (38).

Given the importance of effective primary care communication to achieve safe and guideline-concordant opioid prescribing, the purpose of this study was to describe how clinicians communicate about risks, benefits, and goals of opioid therapy during primary care visits. This knowledge may help identify communication deficits in patient-clinician interactions about opioid-related risks, benefits, and goals of opioid therapy. This knowledge may also aid in developing policy, education, and other interventions that increase safe and patient-centered pain care.

Methods

We conducted an observational study that analyzed audio recordings of clinic visits between primary care clinicians and patients with chronic noncancer musculoskeletal pain who were receiving opioids. This study, which focuses on patients receiving opioids, is part of a larger study to understand clinical decision making for chronic pain care, including care that does not involve opioids. We analyzed clinic visits occurring between May 2016 and May 2017. The Indiana University Institutional Review Board approved this study.

Population and Sample

We recruited primary care clinicians from 3 healthcare systems in Indiana and Illinois. Eligible clinicians included physicians, physician assistants, and nurse practitioners who prescribe opioids. We purposefully recruited participants to obtain a sample that was diverse in practice type and location, clinician age, race/ethnicity, and sex. We also sought to have a diverse representation among the patients, including variations in age, race/ethnicity, sex, and complexity of pain condition. We recruited clinicians using e-mail invitations, in-person presentations at clinic staff meetings, and word-of-mouth. Next, we identified patient participants based on medical record review and recommendations from recruited clinicians. We deliberately sought patient diversity by recruiting from health clinics that serve diverse patient populations. Eligible patients were required to speak English, have a current chronic musculoskeletal pain condition, have no history of cancer in the 3 years before their visit, and currently receiving opioids. Because the larger study also recruited patients not currently receiving opioids, we identified patients with current opioid prescriptions by reviewing transcripts of their clinic visits.

Before we approached the patients, their primary care clinician confirmed their eligibility as a patient with chronic noncancer musculoskeletal pain. Both clinician and patient participants provided written informed consent to participate in the study. Patient participants were compensated with a $25 gift card for their time in the study.

Procedure

After notifying their primary care providers, a member of the research team approached eligible patients in clinic waiting areas or the exam room before scheduled visits. Patients were given sufficient time to read the consent form and ask any clarifying questions of the recruiter. After obtaining informed consent, the researcher placed an audio recorder in the exam room to capture all auditory interactions between the patient and primary care clinician. After the visit, the audio recorder was removed, and the audio file was transferred to a secure computer server. Next, a professional transcriptionist transcribed the audio recordings. Research team members de-identified each of the transcripts before analysis.

Analysis

We used a combination of deductive and inductive analytical approaches to explore patterns and themes related to clinicians' descriptions of risks, benefits and goals of opioid therapy during visits with patients (39, 40). First, to ground the analysis in established clinical practice recommendations, we used a deductive or "top-down" approach to develop a codebook based on a subset of CDC Guideline recommendations that focus on communication about opioid-related risks, benefits, and goals of opioid therapy (6). Specifically, the Guideline recommends *"… clinicians should establish treatment goals with all patients, including realistic goals for pain and function…*" (Recommendation 1) and *"… clinicians should discuss with patients known risks and realistic benefits of opioid therapy …*" (Recommendation 2). The codebook included the following codes: (i) risks – utterances about current or potential for negative health

effects of opioids; (ii) benefits – utterances about current or potential positive health effects of opioids; and (iii) goals – utterances about desired changes to pain therapy being utilized and/or utterances about the intended health effects of using opioids.

Second, two experienced and trained coders (ED and OM) individually applied the initial codes to each clinic visit transcript in Dedoose qualitative analysis software Version 7.7.6. The coders then met to discuss the fit of the codebook and adjusted codes as needed, resulting in a revised coding template. During this process, we also used an inductive or "bottom up" approach to describe new categories of meaningful data and make modifications to the codebook (40). For example, during this process, we divided the benefits code into two parts. The first code captured utterances about the positive health effects of opioids. The second code captured utterances about the lack of positive health effects of opioids.

Next, the two coders independently applied the codes from the modified codebook. The codes were applied at the utterance level, and codes were not mutually exclusive (39). The coders met after the first transcript and periodically thereafter to discuss coding differences and reach consensus. After coding all transcripts, each coder individually analyzed the coded text for patterns and themes, using the overarching research questions as a guide (41). During analysis, the coders met periodically to review emerging themes and reconcile any disagreements. We finished collecting and analyzing additional transcripts after two rounds of coding. Initially, we included and coded 24 transcripts. Next, we included 6 additional transcripts to determine whether any new themes emerged and if the emerging themes were consistent in the new transcripts. When no new themes emerged in the second round of coding, we concluded data collection.

Finally, to ensure the analysis captured patients' responses and interactions with their clinicians, we further examined the transcript excerpts within each theme. This process generated additional codes focused on patients' responses. Two coders individually identified patient response-related codes, met to compare codes and reach consensus, and then applied these codes to all transcripts. The coders met and reviewed each excerpt until they reached consensus.

Throughout data analysis, we used several established qualitative methodology procedures to ensure rigor and validity of our findings. Specifically, we practiced reflexivity by continually questioning interpretations of data and becoming aware of one's own preconceptions and biases. We also actively sought out the depth of description (seeking out rich, particular details of participants' words), and searched for alternative explanations of the data (42-44).

Results

Overview of Patients, Clinicians, and Visits

We analyzed 30 clinic visits across 3 health systems, 2 not-for-profit and 1 academic. The clinic visits took place across 6 clinics, with 21 visits at urban clinics and 9 at rural clinics. The clinic visits involved 11 physicians and 1 family nurse practitioner. Clinicians' specialty included family medicine (n = 8), internal medicine (n = 3), and general medicine (n = 1). Clinicians' experience ranged from 2 to 30 years of practice. Half of the clinicians were female; 9 identified as white, 2 identified as African American, and 1 identified as Asian.

Twenty of the 30 patient participants identified as female. Several patients had multiple pain diagnoses (as reported by their clinician following the visit), with the most common diagnoses being osteoarthritis (n = 10), spondylosis (n = 6), low back pain (n = 5), radiculopathy (n = 5), and spinal stenosis (n = 4). Additional information about study participants is located in Table 1.

Nearly all clinicians had discussions related to risk, benefits, or goals of opioid therapy. Discussions included five themes in clinician communication about risks, benefits, and goals of chronic opioid therapy. Patient responses to clinician utterances generally fell into three main categories: listening, agreeing, and providing or asking for more information about a topic.

Communication About Individual-Level and Population-Level Risks

Clinicians varied in their opioid-related risk utterances, sometimes describing individual (i.e., patient-specific) risk factors and/or sometimes describing population-level risk statistics. A few clinicians described individual-level risk factors and negative outcomes associated with opioid use (e.g., comorbid disease or fall risk) specific to the patient. In some instances, clinicians described individual-level risk factors as rationale for recommending reduction or discontinuation of opioids. In this example, a clinician described how a patient's comorbid condition, chronic obstructive pulmonary disease (COPD), when combined with opioids, may increase the severity of respiratory suppression:

> Clinician 3: . . . we do not want you on the narcotics a long time. The thing that you are getting is one of the side effects is that it can suppress breathing. So you already have COPD you have enough trouble breathing just with your COPD.

Patient 5: I breathe a lot better now that I quit smoking though.

Some clinicians also described opioid-related risks at the population level. For example, clinicians referenced current rates of opioid addiction or overdose. These risks referred to someone other than the patient. For example, this clinician communicated opioid-related mortality statistics:

> Clinician 6: . . . when people are on long-term pain medicine, and things are getting tighter and tighter as you know, it is hard because people are dying. We have almost 100 people a day dying of narcotic overdose every day. It is actually, I have not been able to talk to _____ at the school today . . . for years and years, the number one cause of death in teenagers has always been car crashes. In the last 6 years, opioid overdose. So teenagers in America today are more likely to die of an opioid overdose than a car crash.
>
> Patient 18: I do understand that.

In response to individual and population-level risk comments, some patients listened to the information provided through short responses to the clinician, similar to the quote above. We also saw some patients agreeing and/or requesting additional information about the risks as well as providing some of their own information to the risk discussion like Patient 5 who has COPD. Patient 5 provides more information about how her recent lifestyle change has made it easier for her to breathe.

Communication About Policies or New Practices Related to Opioids

Some clinicians also described current opioid policies or changes to prescribing to their patients. Most of these clinicians worked in the same health care system. In nearly all cases, this discussion occurred in the context of opioid dose reduction or

discontinuation. For example, this clinician described the CDC Guideline for Prescribing Opioids for Chronic Pain and suggested that the patient's current dose was too high6 :

> Clinician 6: . . . Cause we're kind of . . . I think I showed you before, the CDC came out with some guidelines and we're kind of exceeding those. We've got dose . . . of course you're a big guy and everything like that.

Another clinician described her health system's policy that recommends limiting opioid prescriptions:

> Clinician 3: Now at HEALTH SYSTEM really doesn't want us writing more than 2 pain pills a day. If we said we were going to reduce these from 4 to 3, do you think you would still manage or how would that be for you?
>
> Patient 5: No that wouldn't work. That just wouldn't work. I know we talked about that last time.

In most circumstances, clinicians referenced policies or changes in common practice to introduce the topic of tapering or as support for the decision to taper. Many patients listened to clinicians' explanations about opioid policies and practices and were occasionally not given a chance to respond or confirmed with short responses, such as ''I'm listening'' and ''I understand.''

Communication About the Limited Effectiveness of Opioids for Chronic Pain Conditions

Some clinicians described opioids as medications that can reduce pain in the short-term but not provide long-term benefit for patients' underlying pain conditions. These utterances often occurred in the context of discussion about nonopioid treatment options and/or about identifying the underlying cause of the patients' pain. For example,

> Clinician 5: The challenge here is making sure we are treating your pain with the right medication. Yea the Norco (hydrocodone and paracetamol) will make the pain go away, but it will not necessarily treat the cause of

> the pain, and if we treat the cause of the pain then maybe long term you will not have to take [opioids] . . .
>
> Patient 17: Well I'm thinking I might have hurt it lifting her. I still do a lot of lifting and she's [granddaughter] gotten heavier . . .

Similarly, another clinician focused on the importance of understanding the underlying cause of pain rather than relying on opioids:

> Clinician 7: You know as far as the pain medication. We need to figure out what's going on. That way we can kind of get at the root cause and you know just throwing pills at you is not a good, long-term plan here . . .

Most patients listened or agreed with clinicians' discussions of limited benefits from opioids and in a couple instances mentioned their acceptance that their pain may always linger.

> Clinician 8: There's certain things I'm just not going to be able to fix for you and I'm glad that you have that, you know, mind set about it, it certainly makes our job a lot easier.
>
> Patient 20: Especially I have a lot of arthritis all over my body and that's the same thing with the fibromyalgia, you just have a lot of pain. I've had it for 17 years. I guess I just learned to deal with it and pray that I can at least stay on the tramadol to help my legs.

Communication About Nonopioid Treatment Options for Chronic Pain

Many clinicians discussed using nonopioid therapies (e.g., nonsteroidal anti-inflammatory drugs, topical lidocaine, or physical therapy) as potentially better approaches to treating patients' pain. In the example below, one clinician suggested several non-opioid treatment options in addition to not increasing the opioid dose:

> Clinician 7: Instead of just upping what we are already doing actually keeping the Norco (hydrocodone and paracetamol) where we are but help attack the pain in another way. . . . Lyrica (pregabalin) and gabapentin. Physical therapy would be great . . .

Some clinicians also suggested additional assessments and consultations to identify the root cause of the patients' pain condition (e.g., imaging or referral to surgery).

The majority of the patients agreed with or discussed additional information during nonopioid treatment discussions. Patients were often onboard with trying new medications to treat the pain and sometimes wanted clarification of medication administration, logistic information about tapering/receiving these new treatments such as transportation, or to share other relevant information. For example, Patient 26 agrees with the new treatment plan with the expectation that it will better control her pain.

> Clinician 10: I would be interested to see how a combination of the Cymbalta and low dose Lyrica help with things and if that allows us to continue our efforts and kind of wean down that Oxycodone.
>
> Patient 26: Yeah, if I can have an alternative that worked better, hey I'm in.

In the context of a couple physical therapy discussions, clinicians emphasized the importance of pursuing physical therapy to avoid falls and improve physical function. Beyond these, functional discussions varied from a short statement at the beginning or end of a visit to patients setting goals such as playing with grandkids or going upstairs.

Communication About the Goal of the Opioid Tapering

Some of the clinicians had discussions about tapering the opioid medications that patients were currently taking. Tapering-related utterances ranged from clinicians expressing discomfort with a current opioid dose to clinicians directly recommending dose reduction. Some of these communications were suggestive of ongoing discussions about opioid tapering across several visits. For example, one clinician responded to a

patient's request for an increase in an opioid dose by suggesting opioid tapering and her discomfort with the current dose:

> Patient 1: Really I need something better for pain. I really do. If you could up my milligram.
>
> Clinician 1: I won't be able to do that, actually we're working on decreasing it, because you're on more than I'm really comfortable prescribing.

In this example, the clinician recommended nonopioids for pain in support of the tapering process:

> Patient 26, Clinician 10: I would be interested to see how a combination of the Cymbalta (duloxetine) and low dose Lyrica (pregabalin) help with things and if that allows us to continue our efforts and kind of wean down that oxycodone.

Most patients agreed with tapering discussions while a couple requested more information about the tapering process such as how much they would be going down.

> Clinician 5: So instead of like taking away the 7s and going straight to the 5s you take them away incrementally.
>
> Patient 11: What are you thinking of this?
>
> Clinician 5: It is a little bit slower, but I think you will feel less of a change.

Additional illustrative quotes related to each of the five themes can be found in Table 2.

Discussion

Currently, the United States is facing a public health crisis related to opioid use disorder and overdose deaths (30, 45). A significant driver of this crisis has been widespread opioid prescribing for pain, a prevalent symptom that affects millions of

Americans. Primary care clinicians prescribe more opioids than any other provider type (32). Yet primary care clinicians are time constrained during visits (34, 36) and report limited pain management knowledge (46). Therefore, this study aimed to describe how primary care clinicians communicate with patients about opioid-related risks, benefits, and goals. This is an important step in ensuring clinician communication is consistent with current clinical guidelines, and in supporting safe prescribing and effective clinician-patient relationships.

The primary finding of this study is that clinicians actively communicated about opioid-related risks in multiple ways. We observed clinicians explaining to patients that increased opioid doses could cause sedation and other adverse effects (20, 47). In some cases, clinicians articulated these risks in terms of individual risk factors, such as increased risk of respiratory problems in a patient with COPD (48). More often, clinicians described population-level risk information, such as opioid-related mortality statistics. Clinicians also referenced policies or current practices that recommended caution in opioid dosing, which could be interpreted as indirect discussions about risks. Similar to prior research, we found that clinicians referenced policies as a facilitator in tapering discussions to avoid blame and discomfort when communicating with the patient (49). Given that clinical guidelines recommend clinicians actively assess and discuss risks, this finding is generally encouraging; however, with recent attention to guideline misapplication, this discussion type may be a concern for patients whose risks do not outweigh the benefits (25, 50). At the same time, it is unclear if and how different approaches to communicating opioid related risks differentially affect patients. The use of different risk communication approaches may have implications for clinician satisfaction

as well as patient satisfaction, treatment adherence, and health behavior (51, 52). Evidence shows that clinicians who tailor their risk communication to a specific patient's case might better inform patients (51-54). For example, a recent study revealed that patients preferred to know how opioids may affect their health based on their unique medical history, as opposed to population-level concerns (51). Furthermore, more accurate patient risk perceptions may aid conversations about therapy changes, such as opioid tapering (51). At the same time, when discussing concerns about risks and aiming to reduce opioids, a conversation that can be fraught (52, 55-58), clinicians may feel more comfortable deferring to a third party policy or rule, which cannot be directly negotiated.

When examining utterances about opioid-related risks from the patient perspective, we observed that most of the patients listened to clinicians discussing risks without commenting. Some of the patients wanted to have clarifying discussions about risks of opioids. Thus, similar to prior research these findings suggest that patients may not fully understand or agree that opioid-related risks apply to them (51). Additional research is needed to identify barriers that preclude patients from being more actively engaged in communication about opioid-related risks with their primary care provider.

We also found that clinicians communicated about the limited effectiveness of opioids in treating chronic noncancer pain, especially for improving general outcomes like physical function (20, 59). Such discussions are encouraging given the limited evidence for the benefit of long-term opioids in treating chronic noncancer pain (60).

We also found that many clinicians discussed the use of nonopioid therapies for patients' pain. In some cases, using nonopioid therapies was described in the context of

clinicians' goals to maintain or decrease patients' opioid doses. While we saw patients often agree or listen to the proposed changes to their treatment plan, previous literature suggests patients are not confident about managing pain without opioid medication (35). This incongruence between patient preferences and utterances during clinic visits has the potential to harm patient-clinician relationship and should be explored further.

Limitations

Although we reached thematic saturation in the analysis, having a larger and/or more diverse sample of clinicians might have elicited a wider range of communication themes. It is also plausible that patients or clinicians who declined to participate may engage in different discussions about opioids than those who volunteered to be observed; consequently, we may have missed some aspects of clinical communication and perspectives related to risks, benefits, and goals of opioid therapy. Additionally, we did not assess the dose, type, duration of opioid therapy, or history of substance use disorder, all of which might influence communication about opioid therapy. Also, this study occurred in the Midwestern United States, and results may not be transferable to other settings. With that said, this region of the country has been particularly affected by opioid use disorder, making it an important area to study. We also recognized that clinician discussions could have been affected by being audio recorded. However, we believe that by using a discreetly placed audio-only recorder, such effects were minimal. Finally, because we captured a single visit in an ongoing patient-clinician relationship, we may have missed other relevant communication about risks, benefits, and goals of opioid therapy. With that said, given the risks and regulations currently surrounding chronic

opioid therapy, we believe it is reasonable to expect that some meaningful opioid-related communication occurs at all primary care visits.

Conclusion

This study provides timely understanding of how clinicians communicate with patients about common chronic pain conditions and the medications often used in their treatment. These findings add to recent literature that aims to conceptually describe factors affecting patient-clinician interactions (61) and clinical decision making for chronic pain care. (62) Building on this work, future studies might examine larger samples of patients and clinicians to estimate the prevalence of the types of communication we observed as well as the relative effectiveness of different communication strategies. Finally, educational efforts and decision support tools could be designed to help clinicians communicate with patients in ways that support safe and guideline concordant opioid prescribing while minimizing poor patient experiences.

Table 1. Description of the Clinician (N=12) and Patient Samples (N=30)

	Urban Clinic	Rural Clinic
Clinicians n=12		
Sex		
Female	5	1
Male	4	2
Race		
White	6	3
African-American	2	0
Asian	1	0
Specialty		
Family Medicine	5	3
Internal Medicine	3	0
General Medicine	1	0
Years of practice		
<10	2	2
10 - 20	6	0
>20	1	1
System Type		
Not-for-profit	8	3
Academic	1	0
Patients n=30		
Sex		
Female	17	3
Male	4	6
Race		
White	13	9
African-American	8	0
Age		
18-30	0	1
31-40	4	1
41-50	3	0
51-60	6	4
61-70	6	2
71+	2	1
Pain Diagnoses*		
Osteoarthritis	7	3
Spondylosis	6	0
Low back pain	2	3
Radiculopathy	2	3
Spinal Stenosis	4	0
Fibromyalgia	2	1
Rheumatoid arthritis	2	0
Pain Locations*		
Spine	16	2

Knee	6	1
Shoulder	2	2
Hip	2	1

*Some patients had multiple pain diagnoses and pain locations. As a result, totals are more than the number of patients.

Table 2. Emergent Themes with Illustrative Quotes

Theme	Illustrative Quote
Communication about individual-level risks a	Clinician: The problem is how do we get your pain better without putting you on medicines that are going to make you feel more groggy and also that won't have other long-term side effects and make you more likely to fall (Patient 15, Clinician 7) Now on this pain medicine, like I said, I'm going to give you #20 just in case you take them and they loop you out, I don't want to give you a ton. So you're probably going to want to call me the end of this week, to let me know whether it is working or not (Patient 23, Clinician 9)
Communication about population-level risks b	Clinician: So it can cause lots of side effects, and I can give you a whole handout about this, there's the constipation, possible to get addictive, confusion, causes people to fall, it can change how your body feels pain so actually you have more pain as time goes on... so all that stuff. (Patient 15, Clinician 7) Patient: That's fine, but here's the way I understand opiates for people who take them recreationally, they work as a. Clinician: A stimulant. Patient: A stimulant, yeah. So it works like cocaine or methamphetamine or something like that. Clinician: ___ actually a lot of people just want to be numb. They want to not feel anything. They want to be sedated. That is why trazodone, sertraline and Zoloft (Sertraline), seroquel, all of these ___ can be abused. Some people just want to be knocked out, you know? I'm not saying that is what you want, you know, but that's what we have to be careful of. (Patient 3, Clinician 1)
Communication about policies and practice	Clinician: The ___ policy wants us to cut down on your Norco (hydrocodone and paracetamol) / to 2 a day but I'm just gonna say you know what, you need your 4 a day." (Patient 6, Clinician 3) Clinician: I think the tough thing about chronic pain is that it's very easy to slip out of control, so I'm not someone to write large quantities for long periods of time because, you know, if you get a big bottle, it's very easy to just take a lot of them initially and then _____ problems, so that's kind of what we're doing. (Patient 3, Clinician 1)

Communication about the limited effectiveness of opioids	Clinician: So it's important to me that you try again to see if it will help your back, because that's really / the underlying thing that will help your back. The pain medicine isn't going to help, it's just going to make the pain go away, but it will always be there, unless we do something to help. (Patient 1, Clinician 1) Clinician: "The reason why I'm pushing the ibuprofen is because you have some inflammation, you saw it on your MRI right? And this is a medicine that is actually going to help decrease the inflammation. I think that's more helpful, to me, than the Percocet (Oxycodone-Acetaminophen)." (Patient 3, Clinician 1)
Communication about non-opioid therapies	Clinician: for your back pain, although you had that for a year, we're going to put you right back on your gabapentin which you're out of, back on your Flexeril (cyclobenzaprine), ___ pain. We will keep your pain pills where they are right now." (Patient 8, Clinician 3) Clinician: Okay. So let's tell you what ___, so a couple of things, one for your back pain, although you had that for a year, we're going to put you right back on your gabapentin which you're out of, back on your Flexeril (cyclobenzaprine), ___ pain. We will keep your pain pills where they are right now. I (Patient 8, Clinician 3)
Communication about opioid tapering goals	Clinician: Later on in the month, if things are going well with adding the Mobic (meloxicam) and your exercises, maybe you could try a half of one [MS Contin] (morphine). Break it in half and see what happens. Because our goal eventually is to try to get you off completely. (Patient 12, Clinician 6) So one of the things I wanted to talk to you because in the meantime we talked about this the last time. I would like to talk about, even though we are talking about this new identified pain, cutting back on our pain medications. (Patient 11, Clinician 5)

Note:
a Individualized risk discussions occur when a clinician addresses risks specific to that patient.
b Population risk discussions occur when a clinician addresses risks about the general population rather than the patient.

CHAPTER THREE

Assessing variation in state opioid tapering laws: How do state laws compare with the CDC prescribing guidelines?

Introduction

In 2017, the United States government declared the opioid crisis a public health emergency, identifying prescription opioids as a major contributor (63). During 2017, over 47,000 people died from an opioid-related overdose (64) while an estimated $78.5 billion in economic burden has accrued from prescription opioid overdose, abuse, and dependence (65). As one approach to curb these outcomes, the Centers for Disease Control and Prevention (CDC) released a set of opioid prescribing recommendations for primary care (33, 66). These recommendations sought to provide guidance on when and how to prescribe opioids to patients with chronic nonmalignant pain in the primary care setting. However, since their release federal agencies have voiced concerns of abrupt tapering (26) and caution that misapplication of the guidelines may be occurring in clinical practice (25, 50). When patients are discontinued from opioids too abruptly, they can experience serious withdrawal, psychological distress, uncontrolled pain, and in some cases suicide (26). As a result, abrupt tapering and discontinuation of opioids may place patients at risk of having inadequately controlled pain (26, 60) which could result in seeking illicit opioids (67). Given states have enacted recent policies in response to the opioid crisis (14, 15), states may also have attempted to address inappropriate tapering.

Recently, clinical experts identified three components of the CDC guideline that could be misapplied by clinicians and thus could contribute to abrupt tapering and

inappropriate discontinuation of opioids (25) Specifically, clinical experts raised concerns about 1) setting a hard morphine equivalent daily dose threshold (MEDD), 2) setting prescription duration limits for acute pain management, and 3) determining when and how to taper opioids (25, 50). Since the guideline was released, some states enacted new opioid prescribing laws to control prescribing rates and promote safer prescribing practices (14, 15, 17, 68). Researchers have examined state policies pertaining to MEDD (14) thresholds and those pertaining to prescription duration limits for acute pain (15) and generally report variation across states with respect to dose thresholds, duration, and, flexibility of clinical judgment to override the policies. No research has examined state variability in laws regulating when and how to taper opioids, but some federal (69-71), state (72, 73), and provider organizations (74) have published tapering policies and guidelines with varying instructional detail and information (69, 70, 72-74). Although the CDC guidelines may influence prescribing behavior, clinicians are also likely to be influenced by state laws. Thus, an assessment of state laws pertaining to when and how to taper opioids is necessary to address rising concerns about guideline misapplication in clinical practice.

The purpose of the current study is to examine state laws that address when and how to taper prescription opioids, determine the extent to which such laws vary across states, and describe the extent to which such laws are concordant with the CDC guideline and the CDC tapering pocket guide. Further, I will examine how the variability in state tapering laws is associated with state characteristics including opioid-related outcomes. In order to accomplish these goals, I will use policy surveillance methods (75-77) to extract and code tapering laws in each of the 50 US states and the District of Columbia.

This assessment will be beneficial to researchers interested in advancing the ongoing discussion of guideline misapplication in clinical practice and to policymakers interested in understanding how states adopt guidelines in law.

Methods

Overview

In this study, I systematically searched state statutes and regulations (heretofore state laws) related to when and how to taper opioid prescriptions for chronic, noncancer pain in primary care. To identify state laws, I used LexisNexis, an online library database comprised of historical records of state laws and cases (78). With LexisNexis, I conducted a comprehensive legal search to identify state statutes and regulations related to opioid tapering for all 50 states and the District of Columbia implemented prior to January 1, 2020. Once identified, I coded these laws for specific attributes to describe and compare them to the CDC guideline and the opioid tapering pocket guide. These attributes characterize specific aspects of the laws and determine whether they contain information recommended in opioid guidelines. Lastly, I evaluated the relationship between law attributes and various state characteristics including geographical region, population size, political leaning of the governor when the law was enacted, opioid prescribing rate, and opioid-overdose rate. I included governor political leaning to understand the relationship between enacted policies and political affiliation (79).

Scope

I defined opioid tapering laws as those pertaining to the reduction and/or discontinuation of opioid therapy for patients with chronic pain or receiving long-term opioid therapy. I was only interested in laws that targeted chronic pain management in primary care, the intended audience of the CDC guideline (33). As a result, to be included in the study, three things needed to be true 1) the law could be or was specifically applicable to primary care prescribers, 2) the law applied to chronic pain prescribing, and 3) the law mentions anything related to controlled substance tapering.

Search Strategy

I conducted a comprehensive review in LexisNexis to capture statutes and regulations related to opioid tapering using the following search strategy: (taper* OR discont* OR wean*) and prescri* and (opioid* OR controlled substance OR narco*). All polices were reviewed by a trained qualitative researcher (ED), who erred on the side of inclusion during this process. The researcher reviewed each state statute and regulation identified in the search for inclusion based on the scope set above. Laws pertaining to tapering but inconsistent with the intended audience of the CDC guideline were excluded. These excluded laws often focused on addiction treatment (e.g., medication assisted treatment, opioid treatment programs, office-based addiction treatment, substance abuse treatment programs, and addiction co-prescribing), scope of practice, or non-primary care settings such as pain clinics, hospice organizations, and skilled nursing facilities. Eight states also passed duplicate laws, or laws that use nearly if not identical language. These laws would either apply to different prescriber groups or in the treatment of different

kinds of pain such as fibromyalgia and lower extremity pain. These duplicate laws were recorded but counted as a single law in the sample.

Law Attributes Coded

I collected standard law attributes based on recently published opioid prescribing legal review studies to be consistent with prior policy surveillance work (14, 15). I reviewed these papers to identify common characteristics used to describe state laws. They included: the state, the type of law, the effective date, contributing authors of the law (e.g. state medical board, Medicaid agency, health department, state legislature, medical board, pharmacy board, etc.), the number of laws per state, patient and prescriber populations included or exempt from the law, and whether the law identifies a penalty for noncompliance.

To measure concordance between states laws and the CDC guideline, I created a list of concordance attributes. Concordance attributes were constructed based on tapering recommendations from the CDC's opioid tapering pocket guide and a recently published article, from a group of clinical experts in pain and opioids (25, 33, 70). The experts identified three tapering behaviors to consider in clinical application: management of inherited patients with a full reevaluation, cautions of abrupt opioid discontinuation, and exemption of patient populations beyond the scope of the CDC guideline (25).

Analysis

A single researcher reviewed and coded states in batches of five to address emerging questions with coauthors about inclusion and review code application with a

law librarian. For example, the researcher coded a law and reviewed the coded attributes with a law librarian for input. This process was repeated until all 50 states and the District of Columbia were coded. All state data was recorded in an Excel spreadsheet.

To further understand the variability in state law attributes, I evaluated the relationship between state characteristics and law attributes. I examined five state characteristics: geographic region, population size, political leaning of the governor at the time the law was enacted, current opioid prescribing rate, and current rate of opioid-related overdose deaths. Geographic region and population estimates were obtained from the US Census Bureau Classifications and Data (80). Political leaning was based on the state governor's political party at the time the law was enacted and was collected from the National Governor's Association (81). Opioid prescribing and opioid-related overdose data were collected from the CDC's National Center for Injury Prevention and Control data from 2006 to 2018 and 1999-2018, respectively (66). I categorized state population based on percentage of the national population. States with less than 1 percent of the US population were small (<3.5 million) and states with 3 or more percent were large (≥9 million). Opioid prescribing and opioid-related overdose rates were measured annually. To evaluate the relationship between these state characteristics and law attributes, I used Chi-square for categorical variables and t-tests for continuous variables.

Results

As of December 31, 2019, twenty-seven states and the District of Columbia enacted 61 laws that mention tapering controlled substances for chronic pain and applied to primary care. Nearly half of taper laws were enacted between 2016 and 2019 (n=30

laws, see Figure 1). Table 3 presents the frequencies of each law attribute and the states that have enacted them. Most laws were regulations (85.2%) and authored by medical boards (31.1%), workers' compensation boards (21.3%), or state health departments (14.7%). Sixteen states (31.4%) enacted a law with a penalty for noncompliance including lack of reimbursement (n=10 states), disciplinary action (n=5 states), and criminal offense (n=1 state). State laws applied to multiple provider types (states=22), physicians or medical directors (states=7), and advanced practice registered nurses (states=6). Figure 2 displays a US map of all the states with a taper law. Most states with taper laws are in the southern and northeastern regions of the US.

In Table 4, state and law frequencies are listed by CDC tapering recommendation. Few states have tapering policies that capture recommendations from the CDC's opioid tapering pocket guide. The CDC taper recommendation that is most often represented in a state law was for prescribers to *weigh the benefits and risks of opioids to make a decision about whether to continue, reduce, or discontinue use* (67.9% of states with laws). The second most common CDC taper recommendation was to taper *when the patient shows signs of substance use disorder (e.g. work or family problems related to opioid use, difficulty controlling use)* (28.6% of states with laws). Approximately one-third of states with a taper law (35.7%) included at least 1 recommendation about when to taper an opioid prescription. And only four states with a taper law (14.3%) included at least 1 recommendation about how to taper.

Table 3 and Table 4 above also include items pertaining to the critical recommendations from the expert panel (25). Specifically, three states (10.7% of states with laws) included information about inheriting patients and two states (7.1% of states

with laws) cautioned about abruptly discontinuing opioid therapy. Over half of states (64.3% of states with laws) identified exempt patient groups, patients for whom the law does not apply; however, the patient groups identified varied across states and laws, see Table 3. Some states (39.3% of states with laws) excluded more than one patient population. Whereas a few states only excluded patients with cancer pain (14.3% of states with laws) or palliative care (10.7%). Variation also occurred across laws, some states with more than one taper law (35.7% of states with laws) enacted laws with different exemption groups.

In Table 5, I display the bivariate relationships between the presence of taper laws and penalties and various state characteristics. States with higher drug-related overdose deaths were significantly more likely to enact a taper law ($p<.001$). These states were also more likely to enact a taper law with penalties ($p=.007$). I observed no relationship between taper laws and the Governor's political affiliation nor with state population size or geographical location.

Discussion

This was the first study to systematically review state tapering laws within the context of controlled substance prescribing for chronic pain. I found that over half of US states enacted at least one law that addressed opioid tapering and were frequently mentioned in the context of treatment agreements (data not shown). In the agreement, the prescriber often must include reasons for discontinuing or tapering an opioid prescription. For some states, the law might include an example such as violation of the contract. However, these laws often did not elaborate on what those violations were nor how to

taper the patient. Lack of instruction can be particularly problematic when laws are becoming instrumental in how we address the opioid epidemic (12, 82, 83). Without explicit instructions for prescribers during a period of heavy scrutiny via prescription drug monitoring checks and morphine milligram equivalent limits, policymakers are limiting aspects of clinical judgment but not detailing the expected ways to transition patients into safer treatment options. Prior research suggests that lack of instruction regarding how clinicians should interpret guidelines could result in less useful interpretations that do not always benefit patients (84, 85). Additionally, lack of instruction further exacerbates a challenging situation for primary care providers. Providers often have insufficient time to address health concerns in a visit (36) but are now also expected to engage in an emotionally demanding conversation about beginning to taper and then how to safely continue (86).

I also found that among states with taper laws only two states cautioned against abruptly discontinuing. Currently, state laws provide little protection for patients when they need to be tapered off of a controlled substance. This gap leaves an already vulnerable population at the discretion of their healthcare provider who may or may not have the ability to provide tapering support or transition to a substance use specialist (86). Providers have identified several ways to facilitate tapering including supportive guidelines and policies, but there is little evidence that state laws are facilitating that need (86). Given these findings, policymakers should consider addressing this gap to minimize the risk of withdrawal, untreated pain, and suicide (26, 60).

Finally, I found that states with higher overdose death rates, as opposed to other state characteristics like political affiliation or geographic locations, were more likely to

enact a taper law and for their law to have a penalty. States with high opioid-related overdose death rates have more motivation to enact a policy that will decrease the number of opioids prescribed. However, states enacting these laws and those with penalties may place patients at a greater risk of abrupt tapering. Since these state laws mention tapering but generally lack patient protection from inappropriate ways or instances to taper, prescribers, in these states, may be more motivated to quickly reduce the number of opioids prescribed. Additionally, stopping opioids may further contribute to overdose and suicide rates (87). These concerns warrant further investigation to understand the relationship between opioid prescribing and these preventable deaths.

Limitations

The current study has several limitations. First, the cross-sectional nature of these analyses is not suitable for casual inference, thus the findings can be interpreted as associations only. Second, the way I determined state policy concordance to the CDC guideline may not be comprehensive. I included twenty-four concepts from the CDC tapering pocket guide; however, the tapering pocket guide does not numerically label concepts. To the best of my ability, I worked to minimize interpretation and pull concepts nearly word for word from the guideline. Third, only one researcher was able to code the policies. As a result, the analysis could be subject to coding bias. However, I explain in detail how I generated the codes and make the definitions simple to reduce error. Last, although I attempt to capture all tapering laws, I may have missed some. To minimize missed laws, I completed a systematic search of all state laws that mention tapering a controlled substance and erred on the side of inclusion.

Conclusion

As of December 2019, most states have a law that mentions tapering but few address the bulk of the CDC's tapering recommendations. Related to experts' concerns (25), less than half of states with taper laws excluded more than one patient group and very few states cautioned against abrupt tapers or addressed how to handle inherited patients. Overall, most states do not address recommended tapering practices. This gap is concerning given our national goals to reduce opioid prescribing for those roughly 60 million Americans with chronic pain (2). As this patient population transitions into other types of pain management, future research should explore what relationship if any tapering laws have on the health outcomes and cost implications for this population. Researchers should also explore what happens to patients once they are discontinued from opioid therapy and how policy might help bridge the treatment gap between opioid therapy and nonopioid therapies for chronic pain management.

Table 3: Frequency of Opioid Taper Law Attributes in the United States

Variable	Number of States including DC with a tapering law N = 28 (100%)[1]	Number of Individual Laws Across States N = 61 (100%)	States with this attribute
Law Type			
Regulation (written by entities granted this authority by legislative action)	25 (89.2)	52 (85.2)	AL, AZ, AR, DC, DE, IN, KY, LA, ME, MI, MN, MS, MO, NH, NJ, NM, OH, OK, PA, RI, TX, VT, VI, WA, WV
Statutes (written by legislative bodies)	9 (32.1)	9 (14.8)	AZ, CT, FL, ME, NH, NJ, OK, PA, NV
Organization Author			
Medical boards	13 (46.4)	19 (31.1)	AL, DE, IN, KY, ME, MS, NH, NJ, OH, OK, PA, TX, VA, WA
Workers' compensation	8 (28.5)	13 (21.3)	AZ, AR, DE, LA, MI, OH, VT, WV
Health department	4 (14.3)	9 (14.7)	AZ, RI, VT, WA
Occupational and professional board	8 (28.5)	8 (13.1)	CT, DC, FL, LA, NV, NH, NM, WA
Department of Labor and Industry	2 (7.1)	4 (6.5)	MN, WA
Medicaid Agency	2 (7.1)	3 (4.9)	ME, MO
State legislature	2 (7.1)	2 (3.3)	PA, OK
Other[2]	3 (10.7)	3 (4.9)	DE, OK, NJ
Penalty for noncompliance			
Yes	16 (57.1)	20 (32.8)	AZ, AR, DE, ME, MI, MN, MO, NH, NM, OH, OK, RI, VT, WA, WV
No	21 (75.0)	41 (67.2)	AL, AZ, CT, DC, DE, FL, IN, LA, ME, MS, NV, NH, NJ, OH, OK, PA, TX, VT, VI, WA, WV
Of state laws with penalties			
Reimbursement (claim denial, prior authorization)	10 (62.5)	13 (65.0)	AZ, AR, ME, MI, MN, MO, OH, VT, WA, WV
Disciplinary action (revoke license, fine)	5 (31.3)	6 (30.0)	DE, KY, NH, NM, RI
Criminal offense	1 (6.2)	1 (5.0)	OK
To whom the law applies			
Multiple provider types	22 (78.6)	Not applicable	AZ, CT, DC, DE, FL, IN, KY, ME, MN, MS, MO, NV, NH, NJ, OH, OK, PA, RI, VT, VI, WA, WV
Nonspecific	8 (28.6)	Not applicable	AR, DE, LA, ME, OH, VT, WA, WV

Physicians or medical directors	7 (25.0)	Not applicable	AL, AZ, LA, MI, OK, TX, WV
Advanced practice registered nurse	6 (21.4)	Not applicable	KY, NH, NM, TX, VI, WA
Excluded Patient Groups			
No exclusions	21 (75.0)	37 (60.6)	AL, AZ, AR, CT, DC, DE, IN, KY, LA, ME, MI, MN, MO, NV, NH, OK, PA, TX, VT, WA, WV
More than one group excluded[3]	11 (39.2)	16 (26.2)	AZ, DE, KY, ME, NH, NJ, OH, OK, PA, VT, VI
Cancer pain only	4 (14.2)	5 (8.2)	FL, LA, NM, WV
Palliative care only	3 (10.7)	3 (3.4)	MS, OH, RI

Note: This table does not include tapering policies related to substance use disorder treatment (i.e., medication assisted treatment, opioid treatment programs, office-based addiction treatment, substance abuse treatment programs, and addition co-prescribing). This table also excludes tapering policies related to scope of practice, pain clinics, hospice organizations, and skilled nursing facilities.

[1] States were often counted more than once per category because they had more than one tapering law.

[2] Other committees include the state bureau of narcotics and dangerous drugs control, controlled substance advisory committee, and dangerous substances and narcotic drugs.

[3] Excluded groups included some combination of the following: patients in long-term care facilities, receiving treatment for cancer, receiving hospice care, receiving palliative care, receiving pain treatment for sickle cell, receiving treatment in a clinical trial, receiving care as part of normal care at a hospital, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

Figure 1. State Opioid Tapering Laws Enacted by Year

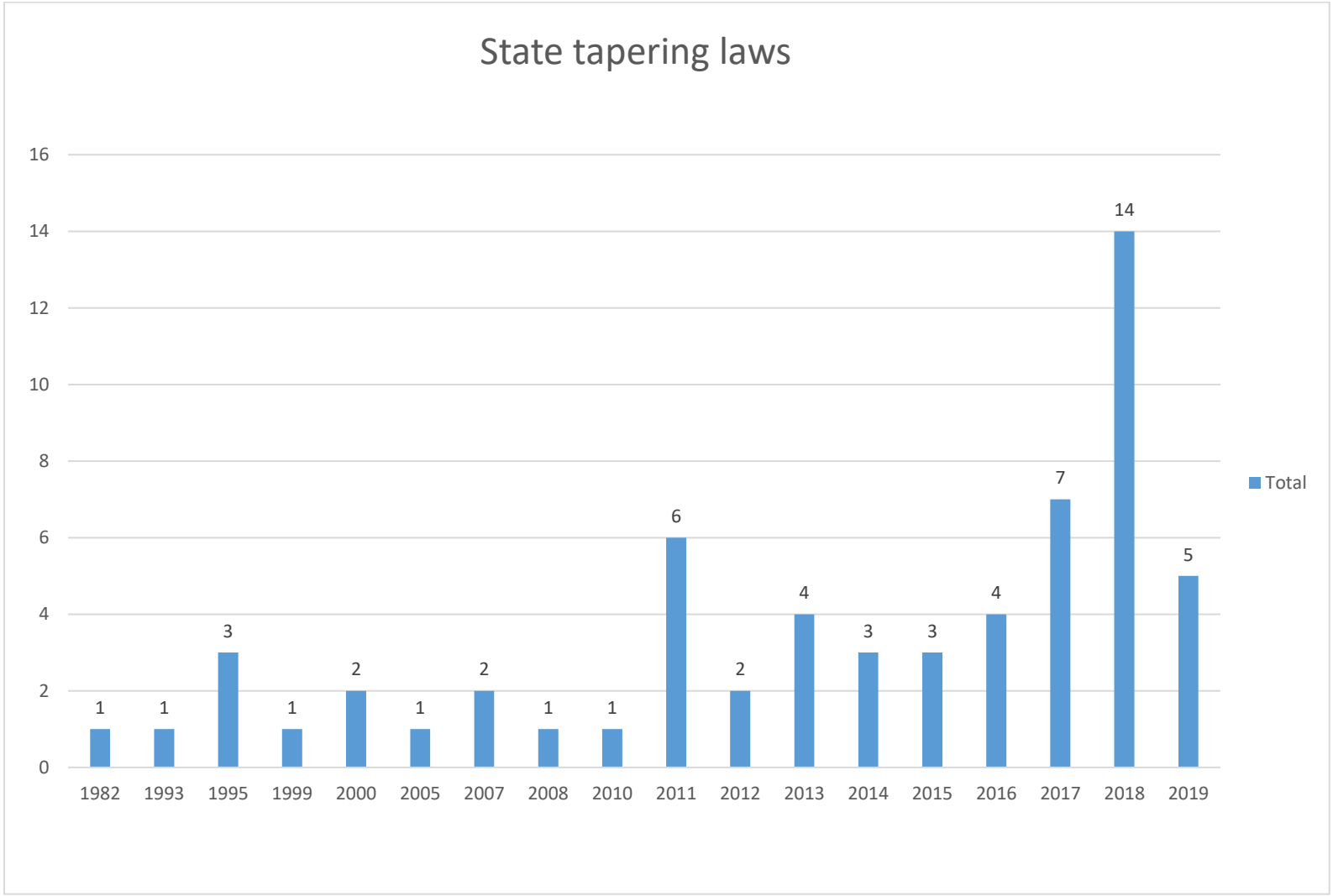


Figure 2. States with a Taper Law

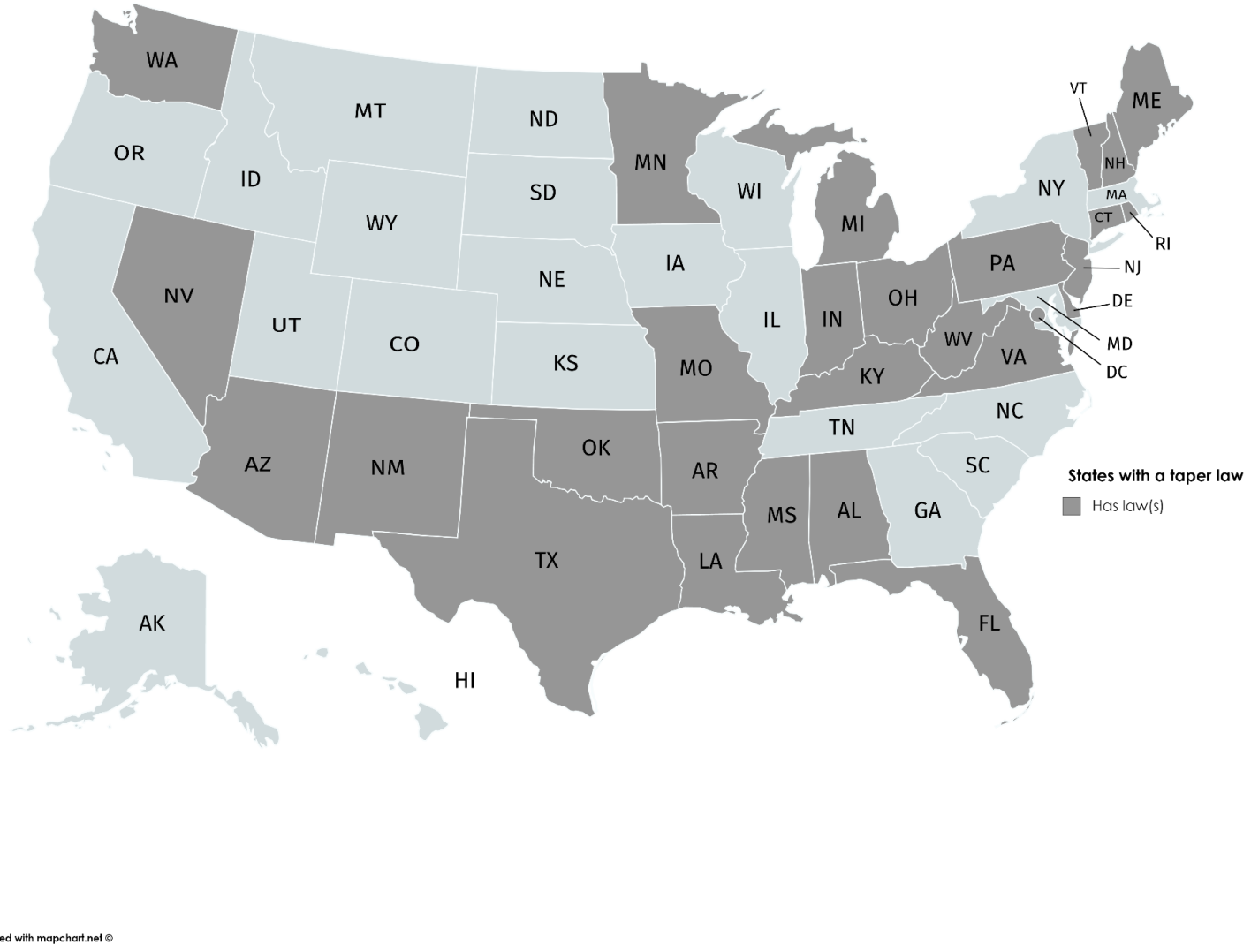


Table 4. State with Laws that Are Concordant with CDC Taper Recommendation

CDC Taper Recommendation	State with Any Opioid Taper Laws N=28 (100%)	Number of Individual Laws Across States that Address Opioid Tapering N=61 (100%)	States with this attribute
Suggested instances to taper			
1. When the patient requests a dosage reduction	1 (3.6)	2 (3.3)	WA
2. When the patient does not have clinically meaningful improvement in pain and function	7 (25.0)	12 (19.7)	DE, LA, ME, OH, RI, WA, WV
3. When on dosages ≥ 50 MME per day without benefit	1 (3.6)	1 (1.6)	KY
4. When opioids are combined with benzodiazepines	1 (3.6)	1 (1.6)	KY
5. When the patient shows signs of substance use disorder (e.g. work or family problems related to opioid use, difficulty controlling use)	8 (28.6)	10 (16.4)	DE, KY, LA, MN, RI, VT, WA, WV
6. When the patient experiences overdose or other serious adverse event	4 (14.3)	6 (9.8)	KY, VT, WA, WV
7. When the patient shows early warning signs for overdose risk such as confusion, sedation, or slurred speech	0 (0.0)	0 (0.0)	-
Suggested ways to taper			
8. Develop an individualized tapering plan with the patient	2 (7.1)	2 (3.3)	MN, MO
9. Minimize symptoms of opioid withdrawal while maximizing pain	3 (10.7)	3 (4.9)	KY, MN, OH

treatment with nonpharmacologic therapies and nonopioid medications			
10. Taper slowly	1 (3.6)	1 (1.6)	KY
11. Decrease of 10% per month if patients have taken opioids for more than a year	0 (0.0)	0 (0.0)	-
12. Decrease of 10% per week if patients have taken opioids for a less than a year	0 (0.0)	0 (0.0)	-
13. Discuss the risk of overdose if patients quickly return to a preciously prescribed higher dose	0 (0.0)	0 (0.0)	-
14. Use extra caution for pregnant women[1]	0 (0.0)	0 (0.0)	-
15. Use extra caution for patients with an opioid use disorder	0 (0.0)	0 (0.0)	-
16. Offer psychosocial support, such as mental health providers, arrange for treatment of opioid use disorder, or offer naloxone for overdose prevention[2]	0 (0.0)	0 (0.0)	-
17. Watch for signs of anxiety, depression, or opioid use disorder[3]	0 (0.0)	0 (0.0)	-
18. Encourage the patient through the tapering process	0 (0.0)	0 (0.0)	-
Taper Considerations			
19. Weigh the benefits and risks of opioid to make decision about whether to continue, reduce, or discontinue use	19 (67.9)	32 (52.4)	AL, AZ, DE, FL, KY, LA, ME, MN, MS, NH, NJ, NM, OH, OK, RI, TX, VT, WA, WV

20. Caution against abrupt tapering or sudden discontinuation	2 (7.1)	2 (3.3)	KY, LA
21. Adjust the rate and duration of the taper according to the patient's response	1 (3.6)	1 (1.6)	MO
22. Cautions against reversing a taper	0 (0.0)	0 (0.0)	-
23. Mentions that once the lowest available dose is reached the interval between doses can be extended	0 (0.0)	0 (0.0)	-
24. Mentions how to manage inherited patients on opioids	3 (10.7)	3 (4.9)	ME, RI, WA

[1] While no laws discussed pregnant patients with respect to tapering, six states had laws that identified pregnant women as a vulnerable population requiring extra attention and possibly referral for chronic opioid prescribing.

[2] No laws stated offering psychosocial support in the context of tapering, but 14 states identified ways to provide psychosocial.

[3] No laws discussed watching for anxiety, depression, or opioid use disorder with respect to tapering; however, six states had laws that suggested the psychosocial function be monitored such as anxiety, substance use disorder, and opioid use disorder.

Table 5. State Characteristics Associated with Taper Law(s) and Penalties (2014-June 2017)

	State has taper policy (Y/N)			State has a taper policy with a penalty (Y/N)		
	Yes	No	P-value	Yes	No	P-value
Opioid prescribing rate per 100 persons (mean)	73.0	77.7	0.269	77.0	77.5	0.959
Opioid-related overdose rate per 100,000 persons (mean)	21.1	16.3	<.001	23.9	16.4	.007
Geographical Region						
Northeast (n=9)	33.3%	66.7%	0.135	33.3%	66.7%	0.833
Midwest (n=12)	25.0%	75.0%		33.3%	66.7%	
South (n=17)	58.8%	41.2%		17.6%	82.4%	
West (n=13)	30.8%	69.2%		23.1%	76.9%	
Population Size						
Small (n=22)	40.9%	59.1%	0.900	27.2%	72.8%	0.952
Medium (n=19)	52.6%	47.4%		26.3%	73.7%	
Large (n=10)	50.0%	50.0%		20.0%	80.0%	
Governor's political affiliation at time of enactment						
Democrat (n=20)	53.6%[1]	N/A	--	37.5%	72.5%	0.431
Republican (n=21)	39.3%[1]			31.3%	78.7%	

[1] These percentages are out of the total number of states that have a taper policy.

CHAPTER FOUR

The impact of opioid limit policies on pain medication prescribing for patients with Medicaid

Introduction

Since the 1990s, the increased rate of opioid prescribing has contributed to thousands of opioid related overdose deaths (45, 88). In response, the Centers for Disease Control and Prevention (CDC) released a set of opioid prescribing recommendations for primary care clinicians (33). Since the release of the CDC guideline, states have continued to enact laws and policies to decrease the amount of opioids prescribed. Two recent policies are morphine equivalent daily dose (MEDD) thresholds and acute pain prescription duration limits. Between 2014-2017, nineteen states enacted MEDD policies while 15 enacted acute opioid prescribing limit laws (14, 15). As states enact policies to reduce opioid prescribing, policymakers and researchers need to evaluate the effect of these laws on their intended outcomes.

MEDD policies and laws that limit acute pain opioid prescribing both attempt to curb the amount of opioids prescribed by restricting different aspects of opioid prescriptions. MEDD policies set a limit by using a standard measurement, often referred to as milligrams morphine equivalent (MME) (89). MEDD policies determine a MME threshold at which a prescriber should stay below per day, ranging from 30-300 MEDD (14). Whereas, acute opioid limit prescribing laws focus on restricting the days supplied of an initial opioid prescription for acute pain (15).

While some state laws are believed to affect opioid prescribing (12, 90-92), recent evidence has suggested that MEDD and acute pain limit laws are not associated with changes in opioid distribution across states (93) but acute pain limit laws increase initial opioid prescribing rates for new patients (94). Importantly, experts have called for more research on specific patient populations given that a broad analysis could mask population-specific effects of these laws (93) and a need to evaluate the effect of acute pain limits for longer than 3 months (94). One population, that may be sensitive to the effect of these laws, are patients with Medicaid, who are 3 to 6 times more likely to experience an opioid overdose (95). Additionally, patients with Medicaid have fewer nonopioid treatment options covered by their plans relative to commercial plans (96), which possibly places them at higher risk of uncontrolled pain. Lastly, while patients with Medicaid have received fewer opioids from 2012-2016 (97), little is known about the effect of these newer opioid prescribing policies on prescribing rates (93).

The purpose of the current study is to determine the effect of MEDD and acute pain prescription duration limit laws on opioid prescribing rates for patients with Medicaid. Moreover, I am interested in determining whether these laws have changed clinicians' prescribing practices by examining changes in nonopioid pharmacologic treatments following enactment of state laws. To accomplish these goals, I combine and utilize several published and publicly available datasets including an MEDD policy dataset from Heins et. al (14), an acute pain prescription limit law dataset from Davis et. al (15), Medicaid enrollee data, and the State Drug Utilization dataset. Heins et. al and Davis et. al published policy surveillance datasets that include the date laws or policies were enacted and characteristics about them. The State Drug Utilization dataset includes

state-level, Medicaid prescription drug information on prescription type, number of prescriptions, and amount paid. This study will be of interest to health researchers, healthcare clinicians, and policymakers who are interested in understanding whether these laws decreased opioid prescribing and how they might have changed medications prescribed to this population.

Methods

Data

For this study, I used generalized difference-in-difference models, which includes state and quarter time fixed effects. I used three and half years (2014 – June 2017) of state-quarter prescription drug utilization and reimbursement data from the Centers for Medicare and Medicaid Services' (CMS) State Drug Utilization Dataset (SDUD). SDUD measures outpatient prescriptions, at least partially, paid for by Medicaid. Each quarter, the number of prescriptions, units reimbursed, amount paid, product name, and the national drug code number. While this does not measure all opioid prescribing to Medicaid patients, it is a good proxy for how many opioids were prescribed by clinicians and filled by patients. Specifically, this measure is a proxy measure for all prescriptions because a transaction is counted in SDUD only if a drug is dispensed and at least partially reimbursed. To calculate the number of prescriptions per enrollee, I used state Medicaid enrollee data available from CMS (98). Medicaid enrollee data is reported monthly and includes the state, expansion status, applications submitted, and total Medicaid enrollment. Two states (CA and ND) had a few quarters of enrollee data under review by Medicaid for accuracy. The data was available but identified as possibly incorrect. Since

these states did not have consecutive quarters under review and no more than 2 quarters under review in total, I imputed values for these quarters using the enrollee data in the quarter prior to and after the quarter under review.

For the opioid prescribing policies, I used two publicly available policy surveillance datasets for MEDD (14) and acute pain prescription limit laws across states (15). The MEDD policy dataset includes state laws, prior authorizations, passive alert systems, and other state-level organization guidelines. The acute pain prescription limit law data set includes enactment date of the state law, duration limit, and medications covered.

To examine the effect of the opioid prescribing policies, MEDD and acute pain limits, I controlled for other state laws or policies known to influence opioid prescribing in the analyses. These laws include 1) requirements on prescribers to access the PDMP, 2) legalized recreational marijuana, and 3) legalized medical marijuana. I obtained requirements regarding PDMP use from the National Alliance for Model State Drug Laws dataset and used in published research (94). Medical marijuana laws were obtained from ProCon.org, a nonprofit public charity in Santa Monica, California. In addition to these law or policies, I controlled for whether a given state expanded their Medicaid program using expansion dates from the Kaiser Family Foundation. Medicaid expansion is known to have increased opioid prescribing and opioid addiction therapies after expansion (97).

To control for within state time varying characteristics, I captured several state economic measures that correlate with prescription opioid use and are commonly involved similar studies (99-101). Specifically, I included unemployment rate, poverty

rate, and median household income from the US Census Bureau. I also included a variable to control for changes in prescribing across year quarters which might include seasonal patterns.

Measures

The primary outcome was the number of opioid prescriptions filled per Medicaid enrollee. I included 13 opioid medications including hydrocodone, oxycodone, codeine, buprenorphine, fentanyl, morphine, tramadol, meperidine, hydromorphone, methadone, pentazocine, tapentadol, and oxymorphone. The second outcome was prescription nonopioid medication rate per Medicaid enrollee and includes 12 nonopioid medications used to manage chronic pain: gabapentin, acetaminophen/butalbital, amitriptyline, desipramine, baclofen, duloxetine, nortriptyline, pregabalin, tylenol/butalbital, tylenol/butalbital/caffeine, amitriptyline, and celecoxib. This list was generated with the guidance of a board certified anesthesiologist and includes medications identified in previous work (100, 102-104). I used the publicly available national drug code (NDC) dataset from the Federal Drug Administration to identify these medications by their NDC number and identify these medications in the SDUD dataset.

Statistical Analysis

I used a generalized difference-in-difference design with state and quarter fixed effects to estimate the effect of MEDD and acute pain limit policies on opioid and nonopioid pain medication prescribing rates. The state fixed effects control for time invariant characteristics that might influence the outcome variable such as a states'

affinity for deciding to adopt an opioid prescribing law. Quarter fixed effects control for seasonal characteristics that might influence the outcome variable such as the national release of the CDC's opioid prescribing guideline. I also controlled for all the variables, described above, related to policies and state varying characteristics known to correlate with opioid prescribing.

All difference-in-difference model estimates were generated from negative binomial fixed effect regressions. I used this approach because the outcome, number of prescriptions per Medicaid enrollee, was discrete integers and skewed toward 0. All regressions were modeled as incident rate ratios. To estimate policy effects, I used the following expression:

$$\ln(Rx_{s,t}) = \beta_0 + \beta_1 ST_s + \beta_2 QRT_t + \beta_3 POLICY_{s,t} + \lambda COV_{s,t} + ln(enrollment_{s,t}) + \varepsilon_{s,t}$$

The coefficient for $POLICY_{s,t}$ estimates the effect of either MEDD policies or acute pain limit laws on prescribing rates. Depending on the model, I evaluated these policies separately and within the same model.

To address fixed effect model assumptions, I evaluated the parallel trends assumption by visually plotting the outcomes overtime for states with and without MEDD policies and states with and without acute pain limit laws. I saw the number of prescriptions in the treatment and control groups were running in roughly parallel over the study period. To address strict exogeneity, another fixed effect model assumption that must be true to reduce estimation bias, I regressed the MEDD policies and acute pain limit laws on the model covariates. I found no covariates were significantly associated with states that enacted an MEDD or acute pain limit policy during the study period.

In the main analysis, I estimated the effect of a new MEDD policy on the number of opioid and nonopioid prescriptions per Medicaid enrollee. A new MEDD policy is a MEDD law or guideline enacted during the observation period (2014-June 2017). Next, I estimated the effect of adding an additional new MEDD policy. For states that enacted more than one MEDD policy, I included a model to estimate the effect of one, two or more, and no MEDD policy on the number of prescriptions. Last, I estimated the effect of MEDD policy dose limits on prescribing rates. MEDD policies ranged from 30-300 morphine milligrams equivalent a day. To determine the effect of more restrictive policies, I created two MEDD dose restriction categories: less than 100 MEDD per day and greater than or equal to 100 MEDD per day. Two states (AK and NY) enacted medical marijuana laws in the same quarter as a new MEDD policy. To eliminate collinearity and meet the strict exogeneity assumption, these two states were dropped from the MEDD analysis.

I similarly estimated the effect of acute pain limit laws on the number of opioid and nonopioid prescriptions per Medicaid enrollee. For these analyses, two states (ME and PA) were dropped because they enacted recreational marijuana and expanded Medicaid in the same quarter as a new MEDD policy, respectively.

Sensitivity Testing

I conducted sensitivity tests to further explore the relationship between opioid prescribing policies and prescribing rates. First, I explored the effect of lagging the independent policy variable if the policy was enacted in the second half of a quarter. States enacted MEDD and acute pain limit policies throughout the quarter. Only 7 out of

19 MEDD policies between 2014 and June 2017 were enacted in the first month of the quarter. Similarly, only 8 out of 15 acute pain limit laws were enacted in the first month of the quarter. To better isolate the effect of these policies, I delayed the intervention quarter by 1 period when a state enacted a policy in the second half of the quarter (see Appendix A). Appendix B includes a list of the states included in the analyses.

Results

In Table 6 are the descriptive statistics of key variables including independent, dependent, and control variables. During the study period, eighteen states enacted MEDD policies and 15 states enacted acute pain limit laws. States also enacted mandatory PDMP laws (n=24), medical marijuana laws (n=31), recreational marijuana laws (n=9), and expanded their Medicaid program (n=31). During the study period, opioids were prescribed at a higher rate (13.2 per 100 enrollees) than nonopioid drugs (6.3 per 100 enrollees).

Figure 3 displays state pain medication prescribing rates in states with a MEDD or acute pain limit policy. Opioid prescribing rates decreased over time in states with a MEDD or acute pain limit law. States with MEDD policies appeared to have a slightly lower prescribing rate over time than control states, whereas states with an acute pain limit law had prescribing rates about the same as control states. For nonopioid prescribing rates, I observed an increase in the number of prescriptions per enrollee over time for both treatment and control states.

In Table 7 are the regression results for the effect of MEDD policies on pain medication prescribing. Model 1, which presents the adjusted difference-in-difference

estimate for the effects of a new MEDD policy, shows a significantly decreased incident rate of opioid prescriptions (IRR=0.92; CI=0.87, 0.98). Model 2 estimates the effect of enacting one or more MEDD policies while controlling for other variables and shows a significant decline in the incident rate of opioid prescriptions once a new MEDD policy (IRR=0.92; CI=0.86, 0.97) is enacted. In Model 3, we observe a significant decrease in the number of opioid prescriptions when a state enacts an MEDD law with a limit greater than or equal to 100 MEDD relative to control states (IRR=.91; CI=0.83, 0.99). In the sample, nine states enacted a MEDD policy equal to or above 100 MEDD while 7 enacted a MEDD policy below 100 MEDD. Models 4-6 present the difference-in-difference estimates for the effect of MEDD policies on nonopioid prescriptions. Model 4 shows no significant change in the number of nonopioid prescriptions per Medicaid enrollee. Similarly, this finding is consistent in Model 5, which estimates the effect of adding one or more MEDD policies on nonopioid prescribing. In Model 6, we also observe no significant change in nonopioid prescribing related to MEDD dose limit.

Table 8 displays the difference-in-difference regression results for the effects of acute pain limit laws on pain medication prescribing. Model 1, which includes the control variables, shows a significant decrease in the number of opioid prescriptions when an acute pain limit law is enacted (IRR=0.85; CI=0.79, 0.91). In Model 2 we observed no significant change in the number of nonopioid prescriptions.

The results of the sensitivity analyses are presented in Appendix A. Appendix A includes regression results for the estimated lagged effect of a new MEDD policy or acute pain limit law on pain medication rates. Appendix A largely supports the main findings showing a significant decrease in the number of opioid prescriptions (IRR=.91;

CI=.85, .96) for MEDD policies and acute pain limit laws (IRR=0.81; CI=0.74, 0.88). Neither policy is associated with a significant change in nonopioid pain medication prescribing.

Discussion

MEDD policies and acute pain limit laws were both associated with a decrease in the number of opioid prescriptions filled per Medicaid enrollee. These associations were consistent across all of the sensitivity tests. MEDD policies are mainly intended to focus upon decreasing the morphine milligram equivalent per day prescribed to patients with chronic pain. For chronic pain patients, these findings suggest that clinicians may be responding to the policies by tapering patients off opioid therapy, prescribing opioids less often, or no longer starting patients on long-term opioid therapy. Previous studies found MEDD policies were associated with decreases in the MEDD of opioids in a single state study and in the workers' compensation population (83, 105). However, total opioid prescriptions appear to be affected and may be problematic. One particularly difficult change may be opioid tapering which is challenging for clinicians and patients and can result in terminated care (51, 106). Without a standardize way to transition patients off opioid therapy and stronger evidence of the long-term effectiveness and accessibility of nonopioid treatments (107, 108), more research is need to understand if there is an unintended consequence of MEDD polices.

Acute pain limit laws were also associated with reductions in the number of opioid prescriptions filled by Medicaid enrollees. Acute pain limit laws focus on restricting the number of days an initial opioid prescription can last for patients with

acute pain. The results suggest that clinicians, in states with these policies, may be prescribing fewer opioids than previous when compared to control states. In previous studies, acute pain limit laws' were not associated with a change in the volume of morphine gram equivalents distributed (93), but they were associated with an increase in the number of initial prescriptions to new opioid users (94). If the number of initial prescriptions to new opioid users is increasing, then the results may not be measuring a prescribing changing for patients with acute pain. This distinction warrants further investigation to understand the effects of acute pain limit policies, especially given recent concern that clinical prescribing guidelines may be misapplied in clinical practice (25, 26, 50).

The secondary finding was that both MEDD and acute pain limit policies were not associated with a significant change in nonopioid pain medication prescribing. Most MEDD policies exclude opioid prescribing for patients with terminal, acute, and cancer pain (14), Given these policies do not exclude patients with chronic pain, these findings suggest that patients may not be receiving additional nonopioid pharmacologic prescriptions to manage their pain while the number of opioid prescriptions declines. The CDC opioid prescribing guideline and tapering guide for chronic pain suggests using nonopioid treatments to manage patients' pain while they are reduced to safer MEDD limits or are discontinued from opioid therapy (33, 70). Given declines in the number of prescriptions written and insignificant rise of nonopioid pharmacologic prescriptions, researchers should attempt to identify what alternative treatments patients are receiving.

Acute pain limit laws were also not associated with a change in nonopioid pain medication prescribing. Unlike MEDD policies which focus on individuals with chronic

pain, acute pain limit laws target patients with acute pain. And while this study did not capture all possible treatment alternatives to nonopioid prescriptions, no significant change in nonopioid prescriptions suggests that patients may not be receiving more pharmacologic nonopioid pain medications despite the observed reduction in number of opioid prescriptions. Given the constrained nonopioid treatment options patients with Medicaid face and primary care clinicians high refusal to treat patients with opioids (96, 109), further investigation is needed to understand what treatments, beyond opioids, these patients with chronic and acute pain receive.

Limitations

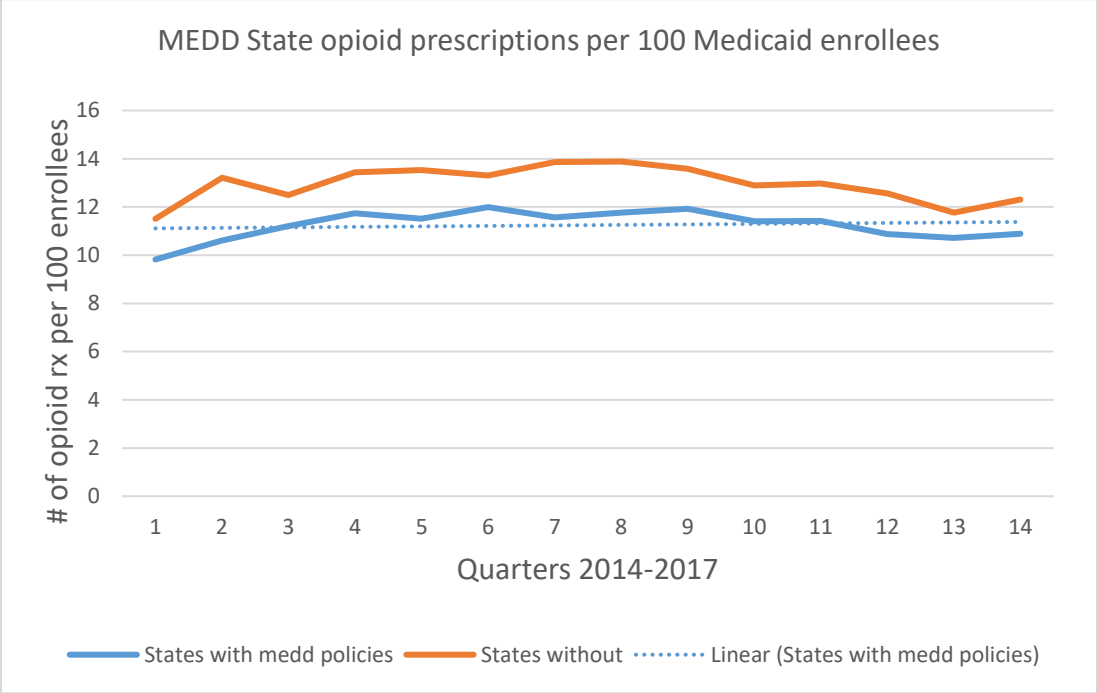
First, this study cannot differentiate opioid prescribing for acute and chronic pain. Ideally, we would want to isolate the effect of these policies on the type of pain they are expected to treat or unintentionally to influence. I recommend future research to explore the effect of these policies on acute and chronic pain individually to determine if clinical misapplication occurs. Second, I was unable to measure the effects of these laws on MEDD prescriptions or the number of days supplied. The SDUD data includes NDCs; however, NDCs do not include the number of days a prescription is to be taken. As a result, future research should attempt to understand the effect of these laws with full prescription information for patients with Medicaid. Third, I was unable to control for other factors that might influence the outcomes such as mandatory pharmaceutical PDMP checks, patients not able to fill or collect a prescription, etc. Thus, these and other omitted variables may bias the regression results. Fourth, SDUD data is suppressed when 11 or fewer prescriptions are prescribed per NDC code in a given state quarter for a specific

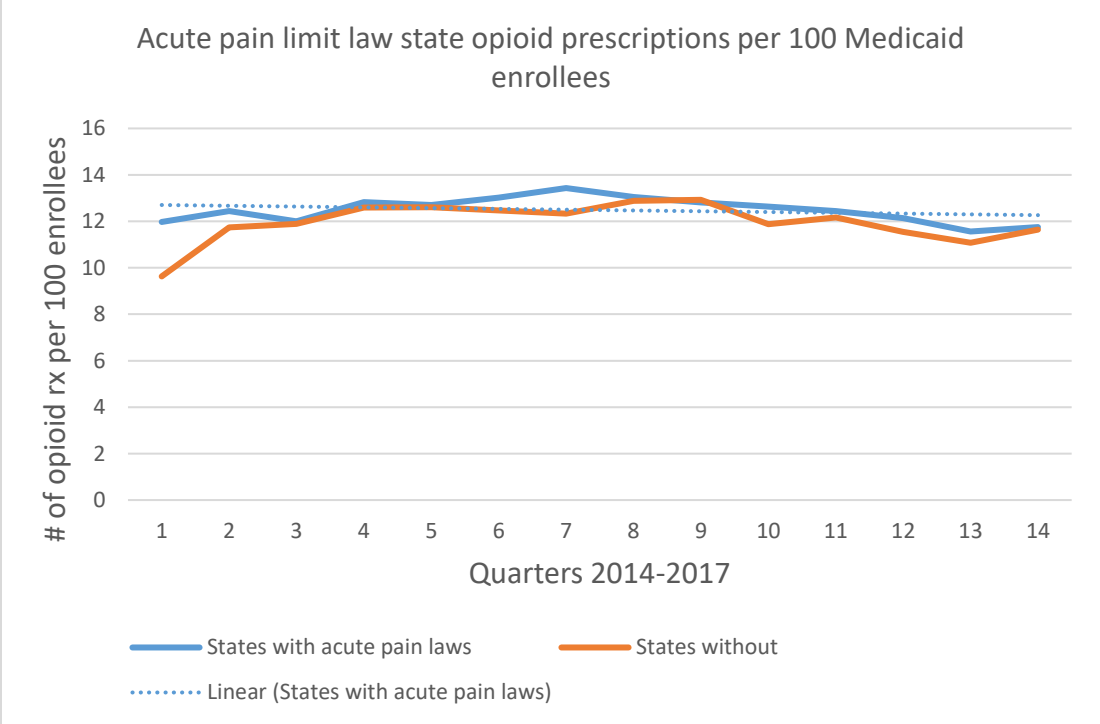
medication. For example, if only 3 prescriptions were written for meperidine in New Mexico in quarter 3 of 2014, then that medication did not have a recorded value and is blank. Although this is not a large amount of missing medications, this limitation may under count certain prescription medications. Finally, the results from this analysis are not generalizable beyond the Medicaid population.

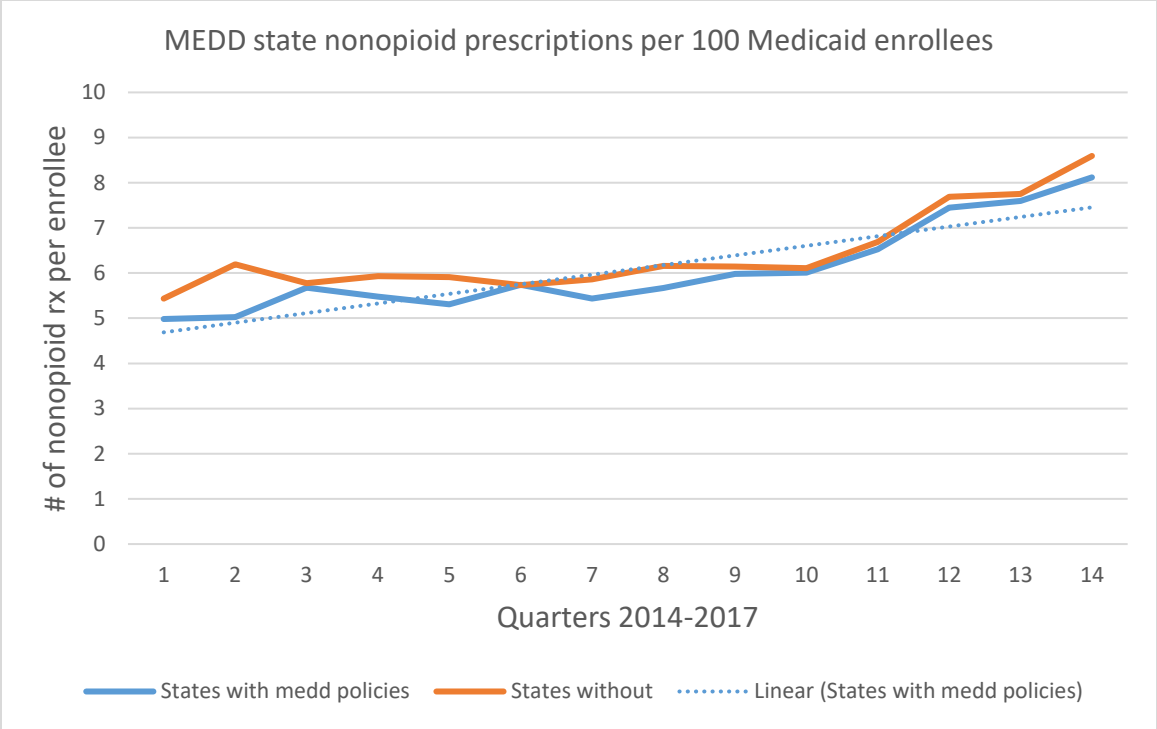
Conclusion

I found that states with either MEDD policies or acute pain limit laws reduced their opioid prescriptions per Medicaid enrollee compared to states without these policies. This suggests current policies may not be written with enough specificity to minimize unintended effects. Both of these policies target limiting a specific aspect of opioid prescribing doses, the morphine milligram equivalent daily dose and the number of days supplied. However, both policies appear to influence the number of total opioid prescriptions written and filled for patients with Medicaid. Additionally, while these policies are associated with fewer opioid prescriptions, they are not associated with increased nonopioid medications. The findings from this study suggest policy researchers do not have a complete understanding of how state policies are influencing medication prescribing and that exploring those relationships deserves further attention. These findings also encourage additional exploration about recent concerns of clinical misapplication of the CDC opioid prescribing guideline (25, 26, 50).

Figure 3. State Pain Medication Prescribing Rates by Policy Type






MEDD state nonopioid prescriptions per 100 Medicaid enrollees
# of nonopioid rx per enrollee
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7
8
9
10
11
12
13
14
Quarters 2014-2017
States with medd policies
States without
Linear (States with medd policies)

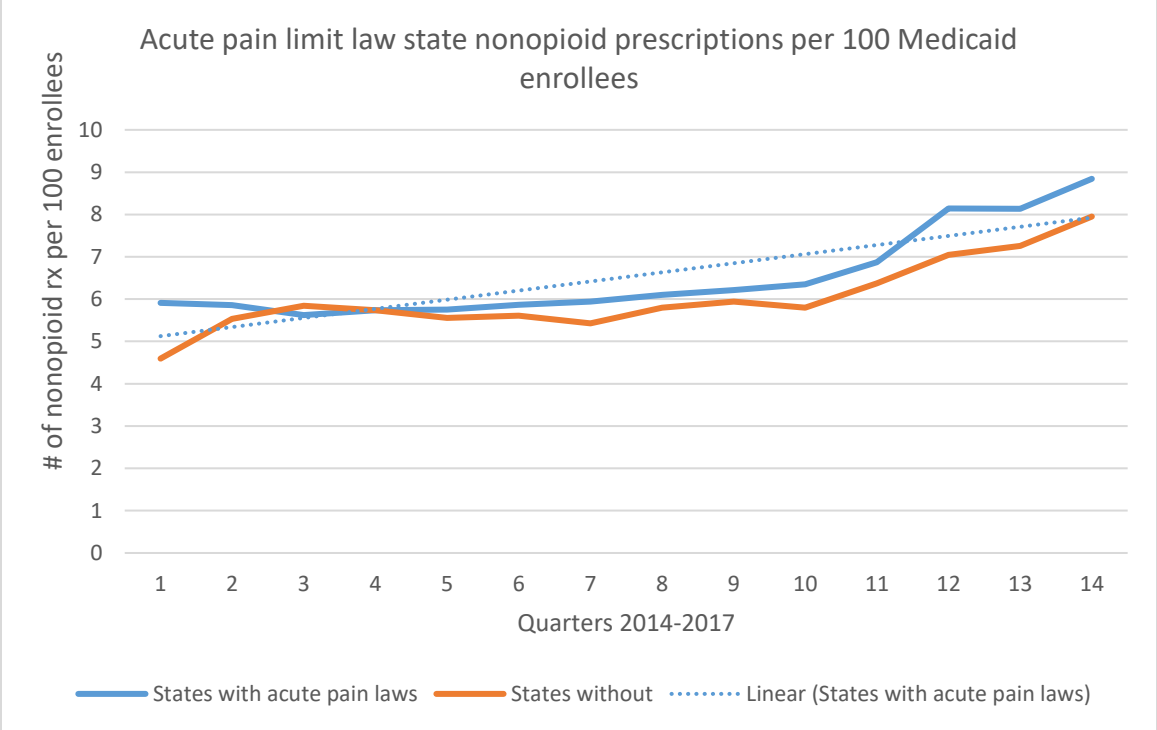

Acute pain limit law state nonopioid prescriptions per 100 Medicaid enrollees
# of nonopioid rx per 100 enrollees
0
1
2
3
4
5
6
7
8
9
10
1
2
3
4
5
6
7
8
9
10
11
12
13
14
Quarters 2014-2017
States with acute pain laws
States without
Linear (States with acute pain laws)

Table 6. State Covariates and Prescription Outcomes

	All states N=51 Mean (S.D.)	State-Quarter N=714
# of states with MEDD policies	22 (43.1%)	213 (29.8%)
# of states with acute pain laws	19 (37.3%)	91 (12.7%)
# of states with New MEDD policies during study period (2014-June 2017)[1]	16 (31.3%)	122 (17.1%)
# of New MEDD policies		
1	16 (31.3%)	94 (13.2%)
2+	3 (5.9%)	28 (3.9%)
New MEDD policies with focus on:		
>100 MEDD	7 (13.7%)	47 (6.6%)
≤100 MEDD	9 (17.6%)	75 (10.5%)
# of states with acute pain laws during study period (2014-June 2017)[2]	13 (25.5%)	31 (4.3%)
# of opioid Rx per quarter	152,972 (171,640)	NA
Opioid Rx per 100 enrollees per quarter	12.2 (4.4)	NA
# of nonopioids Rx per quarter	83,057 (99,937)	NA
Non-Opioid Rx per 100 enrollees per quarter	6.3 (2.7)	NA
Poverty rate	14.1 (3.1)	NA
Median household income	$56,898.25 ($9,670.86)	NA
Unemployment rate	5.0 (.01)	NA
PDMP law	24 (47.0%)	226 (31.7%)
Legal marijuana	9 (17.6%)	64 (8.9%)
Medical marijuana	31 (60.8%)	355 (49.7%)
Medicaid expansion	31 (60.8%)	399 (55.9%)

[1] Two states (AR and NY) were excluded from the analysis because they enacted another policy in the same quarter as the new MEDD policy.

[2] Two states (ME and PA) were excluded from the analysis because they enacted another policy in the same quarter as the acute pain law.

Table 7. Fixed Effect Negative Binomial Regression Results for the Effects of MEDD Policies on the Number of Pain Medication Prescriptions per Medicaid Enrollee: United States, 2014 – June 2017

	Dependent variable: number of opioid prescriptions per Medicaid Enrollee			**Dependent variable: number of nonopioid prescriptions per Medicaid Enrollee**		
Variable	Model 1, IRR (95% CI)	Model 2, IRR (95% CI)	Model 3, IRR (95% CI)	Model 4, IRR (95% CI)	Model 5, IRR (95% CI)	Model 6, IRR (95% CI)
New medd policy[1]	.92* (.87, .98)			.98 (.93, 1.04)		
# of new medd policies[2]						
No New MEDD		Reference			Reference	
1		.92** (.86, .97)			.98 (.93, 1.04)	
2+		1.05 (.95, 1.15)			.98 (.90, 1.06)	
New MEDD policy by dose						
No New MEDD			Reference			Reference
<100 MEDD			.93 (.96, 1.01)			.99 (.92, 1.06)
≥100 MEDD			.91* (.83, .99)			.98 (.89, 1.07)
Seasonality	1.14* (1.00, 1.03)	1.02* (1.00, 1.03)	1.16* (1.00, 1.03)	1.03*** (1.01, 1.04)	1.03*** (1.01, 1.04)	1.03*** (1.01, 1.04)
PDMP law	.89** (.83, .96)	.90** (.84, .97)	.89** (.83, 96)	1.00 (.94, 1.06)	1.00 (.93, 1.06)	.99 (.94, 1.06)
Medical marijuana law	1.00 (.94, 1.08)	1.01 (.95, 1.08)	1.01 (.95, 1.08)	1.22*** (1.14, 1.31)	1.23*** (1.14, 1.31)	1.22*** (1.14, 1.31)
Rec marijuana law	1.04 (.96, 1.12)	1.02 (.95, 1.10)	1.03 (.96, 1.11)	1.16*** (1.10, 1.22)	1.16*** (1.10, 1.22)	1.16*** (1.10, 1.22)
Medicaid expansion	1.06 (.97, 1.16)	1.06 (.97, 1.16)	1.06 (.97, 1.15)	.97 (.88, 1.07)	.97 (.87, 1.07)	.97 (.88, 1.07)
Poverty rate	.93*** (.89, .97)	.93*** (.89, .97)	.93*** (.89, .97)	.99 (.96, 1.03)	.99 (.96, 1.03)	.99 (.96, 1.03)

Median household income	.99*** (.99, .99)	.99*** (.99, .99)	.99*** (.99, .99)	1.00*** (1.00, 1.00)	1.00*** (1.00, 1.00)	1.00*** (1.00, 1.00)
Unemployment rate	.91*** (.88, .94)	.93*** (.90, .96)	.91*** (.88, .94)	.90*** (.87, .93)	.90*** (.87, .93)	.90*** (.87, .93)

* <.05
**<.01
***<.001

[1] This measure captures the effect of any new medd policy enacted during the intervention period.

[2] This measure captures the effect of enacting one or two or more new medd policies during the intervention period

Table 8. Fixed Effect Negative Binomial Regression Results for the Effects of Acute Pain Laws on the Number of Pain Medication Prescriptions per Medicaid Enrollee: United States, 2014 – June 2017

	Dependent variable: number of opioid prescriptions per Medicaid Enrollee	**Dependent variable: number of nonopioid prescriptions per Medicaid Enrollee**
Variable	Model 1, IRR (95% CI)	Model 2, IRR (95% CI)
Acute pain limit law	.85*** (.79, .91)	1.03 (.97, 1.09)
Seasonality	1.01* (1.00, 1.03)	1.03*** (1.01, 1.04)
PDMP law	.89** (.82, .96)	.94 (.88, 1.01)
Medical marijuana law	.94 (.88, 1.01)	1.01 (.93, 1.09)
Rec marijuana law	1.05 (.97, 1.14)	1.17*** (1.10, 1.24)
Medicaid expansion	1.07 (.96, 1.20)	.97 (.86, 1.10)
Poverty rate	.92*** (.88, .96)	.94*** (.91, .98)
Median household income	.99*** (.99, .99)	1.00* (1.00, 1.00)
Unemployment rate	.93*** (.30, .96)	.92*** (.89, .95)

* <.05
**<.01
***<.001

CHAPTER FIVE

Conclusion

Over the past two decades, overdoses involving opioids have taken the lives of nearly half a million Americans (110). As one response to the opioid epidemic, the CDC published a set of opioid prescribing recommendations for primary care clinicians detailing how and when to prescribe opioids for patients with chronic nonmalignant pain. Among these recommendations, the CDC guideline included topics to discuss in clinic visits and recommended prescribing thresholds at which to exercise caution.(33) The CDC also released a set of opioid prescribing considerations related to tapering a patient off of long-term opioid therapy (70).

Since the release of the CDC guideline, overdose rates involving prescription opioids have leveled off and started to decline (111). However, medical experts and federal agencies have voiced concern about their application in policy and clinical practice (25, 26, 50). To better understand whether these concerns are warranted, this dissertation examined how some of these federal recommendations were implemented in clinic practice and state law, as well as the effects of prescribing laws related to prescribing thresholds.

Overall, this dissertation attempts to understand the translation of national opioid prescribing guidelines into policy and their effects on healthcare delivery. I sought to understand how elements of the CDC guideline are adopted into clinical practice, state policy, and establish the downstream effects of two state policies on prescribing behavior. The purpose of this dissertation was to garner knowledge on how clinicians and states interpret federal guidelines, determine the accuracy and outcomes of guideline adoption,

and with these findings, inform the development of future guidelines and minimize the risk of misinterpretation across the structural and procedural aspects of healthcare delivery (112).

To address these interests, this dissertation included three studies 1) a qualitative analysis of clinician and patient discussions about opioid-related risks, benefits, and treatment goals, 2) a policy surveillance study of state tapering laws and their consistency with the CDC guideline's opioid tapering recommendations, and 3) an empirical study of the effects of morphine milligram equivalent daily dose laws and acute opioid prescribing laws on pain medication prescribing for patients with Medicaid.

Chapter two examined clinician and patient communication about opioid-related risks, benefits, and treatment goals with the intent on understanding how similarly, if at all, clinical practice mirrored the information from the CDC guideline. I observed several encouraging themes during these discussions. First, clinicians discussed opioid-related risks with their patients in two ways. Clinicians presented risks at an individual and population-level manner. The individual-level risk discussions focused on patient specific health concerns of using opioid therapy. On the other hand, population-level risk discussions referenced population statistics related to opioid overdose deaths. Second, I observed clinicians convey the limited effectiveness of opioid therapy, instructing patients that these medications were not long-term solutions to pain management and did not treat the underlying cause of the pain. Finally, I found clinicians discussed the use of nonopioid therapies as better alternatives to managing pain symptoms including within the context of tapering discussions.

These results are encouraging in that clinicians are discussing the risks and limitations of opioid therapy with their patients while introducing nonopioid therapies to control pain. However, the use of population-level risk discussions may not best serve the patient like an individualized risk discussion.(51) Given these findings, the discussions in clinical practice are generally concordant with the discussion-based aspects of the CDC guideline with one exception. The CDC guideline does not provide structured advice of how to best communicate risk to patients. As a recommendation for future policy, I suggest federal and state policymakers be more explicit about how clinicians should share information with patients given the most up-to-date evidence available. Policymakers should wield this information to ensure a less varied delivery of information to patients.

Chapter three focused on identifying and articulating the variation in state tapering policy related to opioid prescribing. I found over half of states enacted at least one law that mentioned opioid tapering, often in the context of an opioid treatment agreement. However, these laws did not provide instruction around how to taper nor consistently identify when to discontinue treatment. Importantly, I also found that only two states cautioned against abruptly discontinuing, an established concern with long-term opioid use. Last, I observed that states with high overdose death rates were more likely to enact a taper law and for those laws to have a penalty.

Overall, these findings suggest that policymakers may not consult with the CDC guideline to model their policy or have not yet recognized the importance of acknowledging evidence-based tapering practices. Provided the CDC guideline does not intend nor encourage tapering beyond necessary, the CDC's tapering pocket guideline

recommendations were scarcely represented across state laws. With federal and expert concerns about abrupt opioid discontinuation (25, 26, 50), my work suggests that policymakers should take notice of these discrepancies and provide more evidence-based tapering recommendations in their policy. As I expected, states with higher overdose death rates were more likely to have a taper law and a penalty. This finding is particularly worrisome, because these laws do not provide much guidance around tapering procedures and yet require compliance. Further, these states may have a greater population at risk of being incorrectly tapered from opioid therapy. Based on these findings, I recommend state policymakers take notice of the CDC's tapering pocket guide and other evidence-based tapering recommendations to ensure safer tapering for this patient population.

Chapter 4 evaluated the effect of two opioid prescription limit laws on pain medication prescriptions for patients with Medicaid. Overall, I found MEDD policies and acute opioid limit laws decreased the number of opioids prescribed. I also observed no significant change in the number of nonopioid prescriptions when a state enacted one of these policies, despite the reduction in opioid prescriptions.

These findings suggest prescribing threshold policies may be contributing to overall declines in the number of opioid prescriptions, meanwhile not increasing the number of nonopioid prescriptions. Declines in opioid prescriptions may be an unintended effect of these laws that warrants further investigation across different patient populations. The second finding, no significant change in nonopioid prescriptions, also warrants further investigation. As I learned from chapter 2, clinicians often discussed with patients the use of nonopioid prescriptions as a means of treating pain while reducing or tapering opioid therapy. Given this discrepancy, I recommend further

investigation into the potential unintended effects of these laws and study of how pain is managed, if at all. Future studies should also identify and explore how these patients are discontinued from opioid therapy and what their treatment involves.

When considered cumulatively, these findings illuminate both strengths and weaknesses of the US's reaction to federal policy from policymakers to healthcare professionals. Among those strengths, I observed clinicians convey the risks and limitations of opioid therapy, state policymakers introduce the need for treatment agreements and tapering as a consequence of not upholding those agreements, and over half of states have at least some language or guidance around opioid tapering. However, the US also has an opportunity to improve its response to federal guidelines, for the opioid epidemic and all future national crises.

In addition to the above-mentioned recommendations, I believe federal guideline authors would benefit from using more precise language to clearly articulate the intention of the guideline to address the opioid epidemic. With a clear goal and understanding in mind, policymakers, health administrators, and clinicians should be equipped to actualize the more detailed nuances of the guideline and minimize misapplication and interpretation of them. Second, I believe federal guidelines should anticipate the outcomes of their recommendations by carefully considering the future for all parties involved such as how patients with chronic pain might be treated, how policymakers might interpret the guideline, etc. Finally, I believe how the US addressed the epidemic deserves considerable attention in order to improve our ability to address future public health crises.

Appendix A. Lagged Analysis – Fixed Effect Negative Binomial Regression Results

Lagged Analysis – Fixed Effect Negative Binomial Regression Results for the Effects of MEDD Policies and Acute pain limit laws on the Number of Pain Medication Prescriptions per Medicaid Enrollee: United States, 2014 – June 2017

	Dependent variable: number of opioid prescriptions per Medicaid Enrollee		Dependent variable: number of nonopioid prescriptions per Medicaid Enrollee	
Variable	Model 1, IRR (95% CI)	Model 2, IRR (95% CI)	Model 3, IRR (95% CI)	Model 4, IRR (95% CI)
New MEDD policy[1]	.91** (.85, .96)		.97 (.92, 1.03)	
Acute pain limit law		.81*** (.74, .88)		1.01 (.95, 1.08)
Seasonality	1.01 (.99, 1.02)	1.01* (1.00, 1.03)	1.03*** (1.02, 1.04)	1.03*** (1.01, 1.04)
PDMP law	.90** (.83, .97)	.89** (.82, .96)	1.00 (.93, 1.06)	.95 (.88, 1.01)
Medical marijuana law	.97 (.91, 1.04)	.94 (.88, 1.01)	1.22*** (1.14, 1.31)	1.01 (.93, 1.09)
Rec marijuana law	1.06 (.98, 1.14)	1.05 (.98, 1.14)	1.16*** (1.10, 1.22)	1.16*** (1.09, 1.24)
Medicaid expansion	1.07 (.98, 1.17)	1.07 (.96, 1.19)	.97 (.88, 1.07)	.97 (.86, 1.10)
Poverty rate	.90***(.87, .94)	.91*** (.88, .95)	.99 (.96, 1.03)	.95** (.91, .99)
Median household income	.99*** (.99, .99)	.99*** (.99, .99)	1.00*** (1.00, 1.00)	1.00** (1.00, 1.00)
Unemployment rate	.92*** (.89, .95)	.93*** (.90, .96)	.90*** (.87, .93)	.92*** (.89, .95)

* <.05

**<.01

***<.001

[1] This measure captures the effect of any new MEDD policy enacted during the intervention period.

Appendix B. States with MEDD or Acute Pain Policies

States with MEDD or acute pain policies included in the analysis and enacted during the study period, 2014 – June 2017 respectively (Heins, et al., 2019; Davis, et al., 2019)

States with new MEDD polices **N=16**	States with acute pain laws **N=13**
Alabama	Connecticut
Alaska	Delaware
Arizona	Hawaii
California	Kentucky
Colorado	Maryland
Hawaii	Massachusetts
Indiana	Nevada
Kentucky	New Hampshire
Maine	New Jersey
Massachusetts	New York
Minnesota	Rhode Island
New Mexico	Utah
Rhode Island	Virginia
South Carolina	
Tennessee	
Wisconsin	

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Dissertation Title: "An Examination of Opioid Prescribing Policy and Clinical Practice in the Context of the United States Opioid Crisis"
Committee Members: Nir Menachemi, PhD, MPH (Co-Chair), Christopher Harle, PhD, MS (Co-Chair), Justin Blackburn, PhD, MPH, & Ross Silverman, JD, MPH

M.A., Social Sciences
Master of Arts Program in the Social Sciences — 2012
University of Chicago

B.S., Psychology with high distinction — 2011
Concentration in Neuroscience
Minor in Biology
Indiana University
Degree earned at Indiana University Bloomington (IUB)

POSITIONS HELD

Graduate Assistantship — 2020
Indiana University Fairbanks School of Public Health
Department of Global Health

Program Coordinator — 2019 – 2020
Indiana University Fairbanks School of Public Health
Department of Global Health

Research Assistant — 2015 – 2019
Indiana University Fairbanks School of Public Health
R01HS023306 Designing User-Centered Decision Support Tools for Primary Care Pain Management Agency for Healthcare Research and Quality (AHRQ), Harle PI

Hospitalist Research Coordinator — 2015
University of Chicago Medical Center

NCT00204048 A Multicenter Trial of Academic Hospitalists
National Institutes of Health (NIH), Meltzer PI

Research Intern 2014 – 2015
University of Chicago Medical Center, Center for Quality

User Experience Specialist 2012 – 2014
GfK Market Research

Research Intern 2011
St. Mary's Hospital Human Resources Internship

Research Assistant 2009 – 2011
Indiana University Neuroscience

PEER-REVIEWED PUBLICATIONS

Militello LG, Hurley RW, Cook RL, **Danielson EC**, DiIulio J, Downs SM, Anders S, Harle CA. Primary care clinicians' beliefs and strategies for managing chronic pain in an era of a national opioid epidemic. *Journal of General Internal Medicine.* 2020.

DiIulio J, Militello LG, Andraka-Christou BT, Cook RL, Hurley RW, Downs SM, Anders S, Mamlin BW, **Danielson EC**, Harle CA. Factors That Influence Changes to Existing Chronic Pain Management Plans. *Journal of the American Board of Family Medicine*. 2020.

Menachemi N, **Danielson EC**, Tilson H, Yeager VA, Sellers K, Halverson PK. Tenure & Turnover
among State Health Officials from the SHO-CASE Survey Correlates & Consequences of Changing
Leadership. *Journal of Public Health Management and Practice*. 2020.

Yeager VA, Menachemi N, Jacinto CM, Chapple-McGruder T, **Danielson EC**, Halverson PK. State Health Officials: Backgrounds and Qualifications. *Journal of Public Health Management and Practice.* 2020.

Danielson EC, Mazurenko O, Andraka-Christou B, DiIulio J, Downs S, Hurley R, Harle CA. An Analysis of Primary Care Clinician Communication about Risk, Benefits, and Goals Related to Chronic Opioid Therapy. *Medical Decision Making Policy & Practice*. 2019.

Harle CA, DiIulio J, Downs SM, **Danielson EC**, Anders S, Cook RL, Hurley RW, Mamlin BW, and Militello, LG. "Decision-Centered Design of Patient

Information Visualizations to Support Chronic Pain Care." *Applied clinical informatics*, 2019.

Harle CA, Apathy NC, Cook RL, **Danielson EC**, DiIulio J, Downs SM, Hurley RW, Mamlin BW, Militello LG. Information needs and requirements for decision support in primary care: An analysis of chronic pain care. *In AMIA Annual Symposium Proceedings 2018* (Vol. 2018, p. 527).

Militello LG, Anders S, Downs SM, DiIulio J, **Danielson EC**, Hurley RW, Harle CA. Understanding how primary care clinicians make sense of chronic pain. *Cognition, Technology & Work.* 2018.

Harle CA, **Danielson EC**, Derman W, Stuart M, Dvorak J, Smith L, Hainline B. Analgesic Management of Pain in Elite Athletes: A Systematic Review. *Clinical Journal of Sport Medicine.* 2018.

Danielson EC, Mazurenko O, Andraka-Christou BT, DiIulio J, Downs, SM, Hurley RW, & Harle CA. How do primary care clinicians and patients discuss risks, benefits, and goals in chronic opioid therapy? *The Journal of Pain.* 2018. [Abstract]

Militello LG, Anders S, Downs SM, DiIulio J, **Danielson EC**, Hurley RW, Harle CA. Using Sensemaking to Better Understand Chronic Pain Management. *Proceedings of the 13th International Conference on Naturalistic Decision Making*. Bath, UK, June 2017.

Harle C, Anders, S, Militello L, Downs S, **Danielson E**, Mamlin B, ... & Hurley R. Developing clinical decision support for chronic pain by understanding clinician information needs during primary care visits. *The Journal of Pain*, *18*(4), S50. 2017. [Abstract]

OTHER PUBLICATIONS

Danielson EC. Research Gaps in Health Care Delivery: Retail Clinics' Expansion into Chronic Condition Care, AcademyHealth Blog, 13 September 2017.

Danielson EC. Security Vs. Convenience, How Bad are the "Worst" Passwords, GFK Insights Blog, 30 January 2014.

Danielson EC. Chicago's Bean: What Art Teaches Us about the User Experience, GFK Insights Blog, 12 April 2013.

TEACHING

Teaching Assistant for:

DrPH in Global Health Leadership Program 2019-2020

Leadership in Global Health Law and Ethics
Organizational Leadership Theory and Practice
Population Perspective for Global Health
Initiating the Research Process
Financing Global Health
Fundamentals of Research Analysis

Management Science for Health Services Administration 2017

PEER-REVIEWED PRESENTATIONS

Danielson EC, Hale CA. Patient Perceptions of Missing Health Information in Outpatient Settings. Poster presentation at AMIA 2019 Annual Symposium.

Danielson EC, Wiley KK, Harle CA. Examining Factors Related to Patient Experiences of Missing Information and Repeat Testing during Healthcare Encounters. Poster presentation at AcademyHealth, 2019.

Danielson EC, Mazurenko O, Andraka-Christou BT, DiIulio J, Downs SM, Hurley RW, Harle CA. How Patients and Primary Care Clinicians Discuss the Risks, Benefits, and Goals of Opioid Treatment. Podium presentation at AcademyHealth, 2018.

Halverson, PK, Yeager, VA, Jacinto, C, Menachemi, N, **Danielson, E.** State Health Officials: Essential
Competencies for Success. Oral Presentation at American Public Health Association Annual Meeting, San Diego, CA, November 2018.

Yeager, VA, Menachemi, N, Jacinto, C, **Danielson, E**, Halverson, PK. What Do State Health Officials
Come to the Job With? Backgrounds, Qualifications, and Motivations for Serving as SHOs. Oral Presentation at AcademyHealth Annual Research Meeting: PHSR Interest Group, Seattle, WA, June 2018.

Halverson, PK, Yeager, VA, Menachemi, N, Jacinto, C, **Danielson, EC.** State Health Officials:
Perceptions of Essential Competencies and Activities Necessary for Success. Oral Presentation at
AcademyHealth Annual Research Meeting: PHSR Interest Group, Seattle, WA, June 2018

Harle, Christopher A, Ander, Shilo, Apathy, Nate, Cook, Robert L, **Danielson, EC**, DiIulio, Julie, Downs, Sarah M, Hurley, Robert W, Mamlin, Burke W, Militello, Laura G. User-centered design of an electronic health record decision support system for guideline-concordant opioid prescribing. Poster presentation at AcademyHealth, 2018. [poster]

Anders S, Militello L, Downs SM, Mamlin BW, Cook RL, Hurley RW, **Danielson EC,** Harle CA. Information technology gaps in primary care management of chronic pain. Poster presented at Human Factors and Ergonomics Society (HFES) International Symposium on Human Factors and Ergonomics in Health Care, 2018. [poster]

Anders S, Militello L, Downs SM, **Danielson EC**, Mamlin BW, Cook RL, Hurley RW, Harle CA. Primary Care Clinician Sensemaking for Managing Patients with Chronic Pain. Poster presented at Human Factors and Ergonomics Society (HFES) International Symposium on Human Factors and Ergonomics in Health Care, New Orleans, LA, March 5-8, 2017.

PROFESSIONAL ASSOCIATIONS AND SERVICE

AcademyHealth Student Chapter Vice President	2018-2019
Reviewer, American Journal of Public Health	2017
Reviewer, Pain Medicine	2017
Member, AcademyHealth	2016 – present
Member, Academy of Management	2017
Member, American Pain Society	2017
University of Chicago Committee on Campus Expression Member	2012

HONORS

American Pain Society Young Investigator Travel Award	2018
Indiana University Graduate and Professional Educational Grant	2018
AcademyHealth HSR Project Semi-Finalist	2017
GfK Team of the Year Award	2014
Indiana University Founders Scholar	2011
Incentive Scholarship from Indiana University	2011
Collins Living Learning Center Earnest Barnhart Award	2011
Collins Living Learning Center Recognition of Service Award	2008 – 2010
Collins Living Learning Center Academic Achievement	2008 – 2011