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Patient Perceptions of Access to Chronic Pain Medications

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This is to certify that the doctoral dissertation by

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Walden University
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Abstract

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BS, Charter Oak State College, 2010

Dissertation Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Philosophy
Public Health

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Abstract

The 2014 Drug Enforcement Administration's reclassification of hydrocodone combination products caused significant unintentional consequences to patients with chronic pain. Although a few researchers have looked at the problems that resulted immediately following the reclassification, none have as yet repeated their studies, creating a knowledge gap. Additionally, previous researchers have shown that most of the current opioid restricting policies in place today were not created using a strong evidence-based or ethically inclusive approach. The purpose of this study was to assess whether common factors identified as issues impacting care for these patients immediately following the reclassification continue to affect care standards. The study also addressed the need for evidence-based and ethical approaches to the creation of opioid policies. Using a qualitative, phenomenological approach, 12 individual interviews were conducted and analyzed using Giorgi's phenomenological method, interpretive constructionism, and narrative-based bioethics. Results indicated that new restrictions and heightened provider vigilance associated with the reclassification made appropriate care more difficult to access and subjected participants to shame, stigma, and a reduced quality of life. This study promotes positive social change by providing crucial evidentiary data that may be used in the development of opioid policies that are both more effective and ethically responsible.

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Dedication

This work is dedicated to my loving husband, Chris, and my beautiful, intelligent, and funny children, Walker, Davis, and Berit. Thank you for all of your patience and understanding during this process. May you all achieve the goals you set for yourself and may you only expect the best things out of life.

Acknowledgments

I would like to personally acknowledge all of the unique individuals who came forth and chose to share their experiences for this study. Patients with chronic pain have been identified as a marginalized population and are often subjected to public scrutiny and social stigma. The participants in this study showed true bravery by taking part in frank and honest discussions about how current opioid policies have affected their lives. It is my sincere hope that future legislative efforts will make note these experiences to formulate more effective opioid policies.

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Chapter 1: Introduction to the Study

Inaccurate depictions of opioid use, abuse, and overdose have directly impacted both public opinion and policy. The vast majority of the research related to opioids and opioid policies has centered on death rates due to opioid overdose. Most opioid overdose deaths have not been attributed to the use of valid opioid prescriptions despite the prevalence of this belief among the general public (Bailey & Vowles, 2015; Scholten & Henningfield, 2016). These deaths have been ascribed to medications obtained illegally (often from family or friends) or to the use of street drugs such as heroin (Webster et al., 2011). Despite evidence refuting the use of valid prescriptions in most opioid overdoses, U.S. policies have continued to focus on the generalized restriction of access to these medications.

Policies designed to combat opioid overdose, including the Drug Enforcement Administration's (DEA's) reclassification of hydrocodone containing products (HCPs) in 2014, have little evidence to support the effectiveness of their chosen methods (Coleman, 2015; Seago et al., 2016). Current public health policies focus on the following primary areas: milligram morphine equivalents (MMEs), prescribed days of therapy, and pill targets. However, these measures have no substantiated data demonstrating their effectiveness at reducing addiction rates or that they are otherwise beneficial to patients in any way (Mundkur et al., 2017). The arbitrary selection of these measures in opioid policies have simply been an attempt by policy makers to "do something."

The lack of an evidence-based approach to opioid policy development has led to the institution of measures that have inadvertently harmed patients with chronic pain. By understanding the experiences of these patients and the difficulties they have encountered, new, more effective opioid policies can be instituted. If better opioid policies are not put in place, there is no hope of improving access to care for patients or reducing rates of overdose death.

Background of the Study

In 2010, at the International Pain Summit, representatives from 130 different countries proclaimed that governments are obligated to promote, and specifically not to inhibit, access to appropriate pain management as a basic human right (International Association for the Study of Pain, 2018). The 2014 DEA reclassification measures have obstructed access to appropriate pain management therapies for many patients with chronic pain. These strict, generalized regulations prohibiting the prescription of opioids to arbitrary time periods also violate current Centers for Disease Control and Prevention (CDC) guidelines recommending an individualized risk/benefit assessment for the treatment of patients with chronic pain (CDC, 2019).

The Unites States DEA classifies medications and other substances into five categories based on acceptable use and the potential for abuse and dependency. In October of 2014, the DEA reclassified products containing hydrocodone in combination with other agents from schedule III (low to moderate risk of dependence) to schedule II (dangerous with high potential for dependence/abuse). The intent behind this action was to increase the regulation of HCPs in an effort to decrease deaths from opioid misuse and overdose.

A review of the literature revealed that, for many patients in the United States, the 2014 DEA reclassification of HCPs dramatically impacted their access to appropriate pain medications (Chambers et al., 2016). In response to the reclassification of HCPs and other state-initiated policies related to opioids, many health care clinicians and researchers expressed concern at the apparent misapplication of daily dosage limits and limited dose coverages by legislators and insurance carriers (Kroenke et al., 2019). It is the opinion of these professionals that these policies violate patients' basic rights to the alleviation of pain.

The literature review illustrated that patients with chronic pain experienced unintended negative outcomes immediately following the reclassification of HCPs. The primary impediments to access identified by previous researchers include a change in provider prescribing habits, inadequate pain management, the inability to fill valid prescriptions related to pharmacy quotas, damage to the patient/physician and patient/pharmacist relationships, and increased health care costs. No studies, however, have thus far investigated the prevalence of these occurrences or if patients continue to perceive continued, long-term barriers to their pain management. While many studies have addressed opioid misuse and overdose, few have delved into access barriers created by opioid restricting policies. However, the impediment of access to appropriate pain medications is considered a global human rights violation. In this study, I evaluated the experiences of patients with various chronic pain conditions to determine not only what barriers were experienced immediately after the reclassification of HCPs but what issues related to opioid policies continue to affect pain management treatments and access to medications.

This study has the potential to contribute to public health knowledge by exploring patient experiences at a time point further from the instigating event. Many previous studies have been conducted on how the number of opioid prescriptions written has changed after the 2014 legislation, but few have addressed patients' experiences with trying to fill these prescriptions. The data provided in this study advances the knowledge of public health by highlighting where barriers to care exist and where improvement in access to care is still needed.

Problem Statement

The abuse of prescription opioids is a rampant but often misunderstood public health problem in the United States. A significant problem with current federal opioid policy in the United States is that in their quest to show that something was being done to address the opioid crisis, federal policy makers inadvertently instituted measures that can harm patients with chronic pain. Insurance companies also initiated limited dose coverages related to the misapplication of daily dose limits (Kroenke et al., 2019).

Chambers et al. (2016) conducted an online, cross-sectional survey of patients with chronic pain to explore their experiences in the first 100 days after the 2014 reclassification. Of participants who had been taken off hydrocodone completely, 52% reported their current medication to be less effective. For the participants remaining on hydrocodone, reductions in fill quantity or difficulty filling prescriptions led to the borrowing of narcotic pain medications, the use of marijuana or alcohol, or the use of illicit drugs (including heroin) in approximately 60% of that group. However, there have been no studies performed evaluating the long-term effects of these policies. This demonstrates a clear gap in the available literature and the need to reassess current patient experiences with obtaining and filling opioid prescriptions.

Additionally, current opioid restrictive policies have no evidence-based data to support their measures. Researchers in the United States, Poland, and Canada have asserted that opioid restricting regulations impede appropriate access to pain management medications for patients and should be reformed using evidence-based methods (Cleary & Maurer, 2018; Covvey et al., 2015; Curtiss, 2016; Dzierżanowski & Ciałkowska-Rysz, 2017; Vogel, 2017). Future legislation must be approached in an evidence-based manner to effectively combat opioid overdose while preserving patient rights. Gathering this evidential data requires scrutiny of the impact of these regulations on patients requiring long-term treatment with opioids. This study addresses the current lack of research available on the experiences of patients with chronic pain in accessing appropriate pain treatments.

Purpose of the Study

Future opioid policy interventions cannot strictly focus on restricting the supply of prescription medications. Austere, generalized regulations prohibiting the prescription of opioids to arbitrary time periods violate current CDC guidelines. The CDC (2016) recommends an individualized risk/benefit assessment for the treatment of patients with chronic pain. The purpose of this phenomenological study was to understand how the DEA reclassification of HCPs has affected patients with chronic pain. This includes patients’ perceptions on access to appropriate pain management, the impact of these regulations on patients’ health care costs, and how the regulations may have altered relationships with patients’ medical providers. Personal interviews guided by interpretive constructionism and narrative-based bioethics provided the primary method of inquiry for this study.

Research Questions

Research Question (RQ)1 Qualitative: How do patients with chronic pain describe their perceptions of their pain management treatment before and after the 2014 DEA reclassification of products containing hydrocodone?

RQ-2 Qualitative: What common themes related to the treatment of chronic pain and opioid restricting policies are present among the study participants?

Conceptual Framework

I used a phenomenological approach utilizing interpretive constructionism and guided by bioethical theory to explore the experiences of patients with chronic pain. Interpretive constructionism concentrates on how people interpret and allot meaning to life events (Rubin & Rubin, 2011). Constructionism examines the shared perceptions of an event, or cultural lens, within a group. Determining the shared thematic elements of these perceptions allowed me to answer the research questions posed in this study.

Integral to developing a balanced conceptual framework for this study was the incorporation of narrative-based bioethics. Narrative-based bioethical theory was relevant to the experiences of patients with chronic pain because it contests detachment and impartiality (see Carvalho et al., 2018). Narrative-based bioethical theory focuses on the total picture of the narrative of the person with pain, documenting their fears, doubts, worries, and other psychological effects of living with pain to inform the treatment plan of each person as an individual. (Carvalho et al., 2018). These concepts are further discussed in detail in Chapter 2.

Nature of the Study

Qualitative methods were the most appropriate to answer the research questions for this study because they address the common perceptions of a group by exploring individual and shared experiences in a natural setting (see Ravitch & Carl, 2015). Qualitative research uses dynamic processes in which concepts cyclically interact and build upon each other (Ravitch & Carl, 2015). The research questions for this study were developed from an interest in identifying barriers to care for patients with chronic pain. After reviewing the literature, I identified a research gap concerning the long-term effects of opioid restricting policies on access to care, and relevant theory was investigated to formulate a research plan.

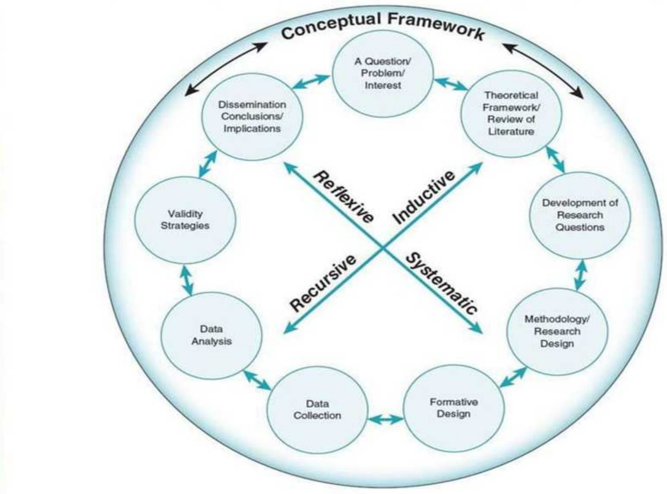
The concepts of phenomenology and bioethical theory guided me through each step of the research process. The literature review was revisited during data analysis so that a results comparison could be conducted. Figure 1 offers a graphic representation of this dynamic process. The arrows demonstrate the multidirectional, dynamic interaction of the qualitative processes.

Phenomenology is an appropriate construct for qualitative research used to understand the shared experiences of individuals related to a specific event. Exploring these experiences allows the researcher to develop a deep, rich understanding of the phenomenon (Giorgi & Giorgi, 2003). In this study, I qualitatively examined the individual and shared experiences of patients with chronic pain relative to opioid restricting policies. The individuals' experiences are vital to a shared understanding and are fundamentally important for the future development of opioid policies because of the subjective nature of pain.

A phenomenological approach using interpretive constructionism and bioethics was used to explore the experiences of patients with chronic pain. I specifically investigated both the individual experiences of these patients relative to opioid restricting policies, including the 2014 DEA reclassification of HCPs, and I explored the common thematic elements of these experiences.

Figure 1

The Dynamic Elements of Qualitative Research



Note. From *Qualitative Research: Bridging the Conceptual, Theoretical, and Methodological* (p. 2), by S. M. Ravitch and N. M. Carl, 2015, Sage Publications, Copyright 2015 by Sage Publications, Inc. Reprinted with permission.

Purposive sampling was used for participant recruitment. Purposive sampling promotes the development of trust between the researcher and the participants. This encourages the sharing of details about the phenomenon of interest. For consideration as a study participant, candidates had to meet the following criteria: be diagnosed with a condition causing chronic pain, be currently managed by an interventional pain specialist, received treatment with prescription opioids for least 6 consecutive months in 2014 prior to the DEA reclassification of HCPs and in 2015 following the reclassification, and be 18 years of age or older at the time of the study. Participants were recruited from the offices of local pain management physicians and online support groups for sufferers of chronic pain. A wide variety of chronic pain conditions was desired.

Responsive interviewing was used to identify a comprehensive representation of thematic elements. Participants were given the option of a conducting the interview via the telephone or the use of a web-based service, such as Skype. All participants chose the telephone format. I completed a demographic questionnaire (Appendix A) at the beginning of the interview session and prior to the interview questions. The interview tool (Appendix B) used Patton’s six areas of qualitative questioning to ensure the discussion of topics relevant to this study. The topics addressed previously identified themes related to the physical, psychological, and existential management of pain by focusing on experiences of social stigma and barriers to care. Questions were formulated for each topic as the individual conversations progressed. The formulation of these questions and my ability to elicit follow-up discussions yielded rich information. At the conclusion of the session, the interview tool was used as a checklist to ensure all relevant themes had been discussed.

The interview tool was examined for appropriate content by the Walden University Department of Health Sciences. Walden University also conducted an institutional review board (IRB). Each participant was interviewed individually. Giorgi's phenomenological approach guided the analysis of the data obtained in interviews. This is discussed further in Chapters 2 and 3.

Definitions

Definitions of appropriate opioid access are crucial to the study of the experiences of patients with chronic pain. This includes definitions of appropriate opioid use, opioid misuse, and opioid abuse. The literature establishes access to pain management as a basic human right. The literature also identifies the need to individually assess patients using a risk/benefit analysis to determine when opioid therapies are appropriate. Understanding the meaning and impact of barriers to appropriately prescribe opioid therapies, therefore, must derive from the individual. To achieve this, the individual's interpretation of events and experiences must be respected as truth (Munhall, 1994). This is an essential element of phenomenological study. The following definitions of opioid access and use have been defined for application in study interviews and in the evaluation of participant responses.

Appropriate opioid access: The unimpeded access to opioid medications prescribed by a physician or other health care provider after an individualized cost/benefit analysis (IASP, 2018).

Appropriate opioid use: Patient use of an opioid medication using the defined dosages and dosing schedule noted on the prescription.

Chronic pain: Pain lasting more than 3 months (CDC, 2020).

Illicit drugs: A variety of drugs prohibited by law, including heroin, amphetamines, cannabis, ecstasy, and illegally produced fentanyl (CDC, 2020).

Morphine milligram equivalents (MME): The amount of morphine, in milligrams, that an opioid dose is equal to when prescribed (CDC, 2020).

Opioid: Natural or synthetic chemicals that interact with receptors on nerve cells in the brain and body reducing the intensity of pain signals (CDC, 2020).

Opioid abuse: The use of an opioid medication for reasons other than pain management; opioid use causing distress or impairment; the inability to reduce or control opioid use resulting in social repercussions (CDC, 2020).

Opioid dependence: An adjustment in the body's normal functioning related to the regular use of opioid medications and resulting in physical withdrawal symptoms if opioids are abruptly discontinued (CDC, 2020).

Opioid misuse: The use of a prescribed opioid medication in a manner other than indicated on the prescription; the use of someone else's opioid prescription; the use of illicit opioids (CDC, 2020).

Opioid overdose: A fatal or nonfatal injury to the body that occurs when excessive amounts of opioids are ingested (CDC, 2020).

Opioid tolerance: The body's reduced response to opioid medications requiring larger dosages to achieve the same results (CDC, 2020).

Controlled Substance Act: Instituted in 1971, this legislation classifies all substances regulated by federal law into one of five schedules based on medical use, potential for abuse, and risk of dependence (Drug Enforcement Administration, n.d.).

Assumptions

The use of qualitative research methods requires the identification of key assumptions prior to the initiation of the study (Yin, 2014). Firstly, qualitative methods focus on the perceptions of the target population and may, therefore, be perceived as less rigorous than quantitative methods (McCusker & Gunaydin, 2015). Questions of validity may also arise due to the subjective nature of qualitative methods (Trafimow, 2014).

For this study, I assumed that participants would provide honest answers to direct questions and would relate truthful renditions of their experiences. It is also a phenomenological assumption that qualified participants are experts in their own experiences and therefore the phenomenon of interest. I used a reflexive journal to record and classify assumptions that developed during the research process.

Scope and Delimitations

Delimitations outline the margins of a research study, including the inclusion and exclusion of specific elements (Simon & Goes, 2013). Participants for this study included patients with diverse chronic pain diagnoses. These patients used prescription opioids, including HCP therapies, for pain management for at least 6 consecutive months in 2014 prior to the DEA reclassification of HCPs and for at least 6 consecutive months in 2015 following the reclassification. These participants continued to require some form of opioid therapy to adequately manage their pain although most have encountered barriers to receiving these medications. I specifically focused on this population's perception of long-term barriers to care related to the reclassification of HCPs. The use of purposive sampling increases the scope of available data and patient perceptions (Rudestam & Newton, 2014). This promotes a deeper understanding of the research questions for this study (Rudestam & Newton, 2014). Participants' answers to interview questions were not time restricted. To provide a thick description, participants were encouraged to share detailed stories and experiences of how they were affected by the reclassification of HCPs.

Limitations

Restrictions on the transferability of research findings are known as study limitations (Yin, 2014). Limitations of this study included an exclusively qualitative design, sampling methods, and the interviewing process. Although the study implements have been carefully designed, the potential for interpretive error remains (see Rubin & Rubin, 2011).

To reduce this type of error, multiple sources were used to validate findings. This included the verification and validation of the results by the study participants. I also worked closely with my research committee to apply their expertise in qualitative methods to this study.

Qualitative researchers adopt a neutral approach to data collection and openly recognize known biases. This included addressing personal biases, motivated perception, and the use of a nonrandom sample population. Cyclical data review and attention to conflicting evidence helped mediate these issues. The use of reflective journaling and a topical interview tool further reduced bias by clarifying participant responses and ensuring that participants answered questions about each topic. Limitations from the interview process centered around the need to tailor the questions to each participant. I used the qualitative interviewing techniques of Rubin and Rubin (2011). An empathetic approach was used to build trust between me and the participants. I hoped that this would facilitate an open and honest discussion of the participants' experiences. Methods to reduce bias are further discussed in Chapter 3.

Significance of the Study

The 2014 DEA reclassification was never meant to affect the ability of physicians to appropriately manage the treatment of patients with chronic pain. It was also not intended to hinder access to appropriate pain relief medications or to increase the cost of treating chronic pain conditions. However, researchers who looked at patient experiences during the first 100 days post reclassification established that all of these unforeseen barriers had been encountered (Chambers et al., 2016). This study aims to fill the gap in the available literature by examining the long-term effects of HCP reclassification for patients with chronic pain.

Significance to Practice

New, effective policies that promote access to appropriate pain management treatments while reducing opioid overdose rates may only be created by assessing the ongoing experiences of patients with chronic pain and their perceived barriers to care. This study has the potential to contribute to public health knowledge by exploring patient experiences at a time point further from the instigating event. Many previous studies have been conducted on how the number and type of opioid prescriptions written changed after the 2014 reclassification. However, few have addressed patients' experiences with trying to fill these prescriptions, whether or not they are able to effectively manage their pain under the restrictions of the current policies, and how these changes have impacted their financial and psychosocial security. The lack of evidence-based strategies in current opioid policies has led to direct patient harm.

Significance to Theory

Access to appropriate pain management has been established as a basic human right. In this study, I sought to advance the understanding of the bioethical impact of policies that impede this access. In designing this study, I considered the lack of evidence-based research in the development of current opioid policies and the lack of sufficient data on how these policies affect patients with chronic pain. A paradigm shift that approaches opioid management from the subjective interpretation of patient perceptions is needed to effectively combat the opioid crisis in the United States while preserving patient rights.

Significance to Social Change

The data provided in this study may advance positive social change by influencing the development of more effective opioid legislation, thereby increasing access to care for patients with chronic pain. This is accomplished by providing direct patient accounts of how opioid restricting policies affect appropriate access to care and by highlighting where barriers to care continue to exist. I anticipated that study participants would also offer valid insights on how access to appropriate pain management might be improved. This presented the opportunity for participants to assume an educational role and to develop a sense of community.

Summary and Transition

In Chapter 1, I focused on understanding the problem identified for this research study. The topic of interest was explored in an introduction to the study and statements of the study’s problem, purpose, and nature. Discussion was further continued presenting the formulated research questions. My approach to the study was presented through discussions of the conceptual framework and the assumptions, scope, delimitations, limitations, and significance of the study.

Chapter 2 provides a brief restatement of the study’s problem and purpose. This is followed by discussion of the literature search strategy and application of the conceptual framework. It concludes with an exhaustive review of the available relevant literature.

Chapter 2: Literature Review

A significant gap exists in the literature concerning how opioid restricting policies affect the ongoing ability of patients with chronic pain to access appropriate opioid medications. While a few researchers have examined the immediate effects of the 2014 DEA reclassification of HCPs, none have thus far repeated their studies to see if previously identified barriers continue to affect patient access to care. In this study, I evaluated current patient perceptions of access to appropriate opioid medications.

In this review, I explore the barriers identified immediately following the 2014 DEA reclassification of HCPs. These include changes in physician prescribing habits, increasing illicit drug use as a negative outcome of public health policies, and other unintended negative outcomes experienced by physicians and patients. This exploration is vital in identifying commonly experienced perceptions, related behaviors, and interpersonal relationship difficulties involved in the management of chronic pain conditions. The understanding of how these changes affect access to care and treatment options is of great significance for patients with chronic pain. The planning of future public health initiatives related to pain management and the creation of new, more effective opioid legislation must take into consideration these evidential data if it is to be effective.

Literature Search Strategy

The literature was scanned to evaluate the presence of research on the effects of opioid restricting policies and patient access to care. The purpose of this search was to establish background information and to identify research gaps. The search was further narrowed to patient experiences after the 2014 DEA reclassification of HCPs, as this was a federally instituted policy affecting all 50 states.

The review revealed that little research had been conducted to assess the effect of opioid restricting policies on patients requiring long-term opioid therapy. The bulk of opioid research continues to center on rates of opioid misuse, abuse, and overdose. Social factors, including social attitudes and stigma related to opioid use, have also been significantly studied.

A computerized search was initiated using the following terms: *narcotics, opiates, opioids, regulations, policies, legislation, laws, public health, community health, population health, pain, DEA,* and *Drug Enforcement Administration*. The search used the terms both individually and in combination in the following databases: Academic Search Complete, Business Source Complete, Complementary Index, Computers & Applied Sciences Complete, Cumulative Index of Nursing and Allied health Literature (Cinahl), Cinhal Plus, Education Source, Directory of Open Access Journals, Embase, Gale Academic OneFile Select, Library, Information Science & Technology Abstracts, Medline, ProQuest Health and Medical Collection, Political Science Complete, ProQuest Nursing and Allied health Source, PsychINFO, PubMed, Science Citation Index, Science Direct, Social Sciences Citation Index, SocIndex, and Trip database. The search was restricted to peer-reviewed scholarly journals.

Between 2015 and 2020, 1,023 articles, identified using this search string, had some focus on opioid use, abuse, and policy. Seventy-one of these articles were relevant to my specific research topic. Thirty articles provided background on opioid use, social attitudes related to opioids, and opioid policy development in the United States. Twenty-seven articles described the effects of opioid restricting policies on physicians and other health care providers. Four articles investigated the link between current opioid policies and the increased use of illicit drugs. Finally, 10 articles examined other unintended negative outcomes of opioid restricting policies. Only one of these, however, Chambers et al. (2016), specifically explored the experiences of patients with chronic pain during the immediate period following the 2014 DEA reclassification of HCPs. This study employed a similar approach to investigate the long-term effects of this policy change.

A Google Scholar search using the same terms yielded 2,450 results. The primary topics in approximately 75% if these results were related to (a) the "opioid crisis" and (b) rates of opioid abuse, misuse, and overdose in the United States. The remaining 25% of the research centered on (a) the management of substance abuse, (b) the effectiveness of prescription drug monitoring programs, (c) the use of buprenorphine in treating opioid use disorder, (d) the use of cannaboids in pain management, and (e) the use of illicit opioids. One book was identified examining the need to balance the risks and benefits of prescription opioids at both the individual and societal levels.

Conceptual Framework

The intent of this research study was to understand the perceptions of patients with chronic pain and their experiences related to opioid restricting policies. A qualitative, phenomenological approach was used, guided by bioethical theory. This method allowed the subjective experiences of participants to be explored while maintaining patient rights and ethical standards.

Phenomenology was developed in 1900 by Husseri as a form of descriptive psychology. Psychology was defined at the time as the study of consciousness. Husseri defined the primary points of phenomenology; however, a variety of interpretations have since followed. I chose to use Giorgi’s (2009) phenomenological approach for data analysis because of its straightforward design.

Giorgi’s descriptive phenomenological method was developed in the early 1970s. Giorgi was an early promoter of the use of qualitative methods for psychological research and pioneered the humanistic psychology movement and the use of phenomenology. These approaches minimize reductionism and encourage researchers to bracket their assumptions related to the phenomenon of interest. This curtails the development of a singular reality for both the researcher and the study participants. The lack of a singular, predefined reality allows the researcher to record participant perceptions without having to force them into preset categories.

The steps involved in Giorgi’s method include adopting a phenomenological attitude, reviewing an entire account to develop a sense of the whole, reviewing the account again to highlight meaning units, converting meaning units into psychologically responsive statements of meaning, and synthesizing generalized, thematic elements related to an experience (Giorgi & Giorgi, 2003). Findings were derived from the participant narratives indicating how the reclassification of HCPs affected their lives in general and their specific pain management treatments. Similar responses were grouped for thematic analysis. The use of phenomenological methods increased the richness and depth of information for analysis on the effects of opioid restricting policies on patients with chronic pain. I used these phenomenological methods using narrative-based bioethics as a guide to both protect and promote the interests of the participants.

Narrative-based bioethics, as put forth by Carvalho et al. (2018), shifts the focus away from a curative oriented approach and centers on treating the whole of the psychological effects and related health issues that arise as a result of pain. Patients are given the space to share their thoughts, worries, and doubts while receiving various types of support, including but not limited to psychological, psychiatric, and psychosocial. The central theme of narrative-based bioethics explores the narratives and stories of the patients themselves (Carvalho et al., 2018),

Bioethical researchers have been exploring narrative-based approaches for some time now (Haker, 2006) as a means of gaining further information to inform the definition of the nature of research problems and potential solutions. Dubiel (2011) discussed the role that narrative-based approaches have in practicing medicine well and ensuring best practices as well as ensuring the humanity and wishes of the person are being considered. For these reasons, I selected this framework to guide the investigation into patients' perceptions of access to pain medications.

Literature Review

Opium was first legally introduced in the United States in 1775. In the 1860s, it was used to treat the wounded soldiers of the Civil War (Foundation Recovery Network, 2020). It was at this time that references to addiction and morphinism are first found in the literature (FRN, 2020). In 1914, the United States began regulating access to opioids with the Harrison Narcotics Act and, by the 1970s, the social stigma attached to the use of opioids had intensified to the point that many physicians would no longer prescribe them (FRN, 2020). In 2001, however, it became a requirement for medical centers to examine the pain level of patients. Pain became known as the fifth vital sign. Opioids increased in use as practitioners were required to implement graduated interventions aimed at improving pain levels.

As more and more patients received opioid prescriptions for acute pain, the potential for opioid misuse and abuse increased exponentially. By the mid-2000s, teen abuse of parental opioid prescriptions had developed as a distinct phenomenon (FRN, 2020). Overdose and addiction rates continued to climb ultimately resulting in the declaration of an “opioid crisis” in the United States.

The U.S. opioid crisis is a rampant but often misunderstood public health issue in the United States. Inaccurate depictions of opioid use, abuse, and overdose have directly impacted both public opinion and policy. Most opioid overdose deaths are, in fact, not attributed to the use of valid opioid prescriptions (Bailey & Vowles, 2015; Scholten & Henningfield, 2016). Instead, these deaths are ascribed to medications obtained illegally (often from family or friends) or to the use of street drugs such as heroin (Webster et al., 2011). These misconceptions create a public health conundrum in which there is a need to both mitigate deaths related to opioid overdose and to facilitate access to opioids for patients with chronic pain.

Policy makers have attempted to combat this crisis with stricter regulation of opioids. However, policies have been enacted that lack an evidentiary basis. Evaluations of current policies have shown them to be both of little effect in combating opioid abuse as a whole and inadvertently harmful to patients who require long-term opioid therapy.

In 2010, at the International Pain Summit, representatives from 130 different countries proclaimed that governments are obligated to promote, and specifically not to inhibit, access to appropriate pain management as a basic human right (IASP, 2018). For many patients in the United States, the 2014 DEA reclassification of HCPs dramatically impacted their access to appropriate pain medications (Chambers et al., 2016). Future legislation must be approached in an evidence-based manner to be effective while preserving patient rights. Gathering this evidential data requires scrutiny of the impact of these regulations on patients requiring long-term treatment with opioids.

In this review, I explored changes in physician prescribing habits, the connections between increasing illicit drug use and public health policies, and the unintended negative outcomes experienced by physicians and patients post the 2014 DEA reclassification of HCPs. This exploration was vital in identifying commonly experienced perceptions, related behaviors, and interpersonal relationships involved in the management of chronic pain conditions. The understanding of how access to care and treatment options were affected by these changes is of great significance for patients with chronic noncancer pain. The planning of future public health initiatives related to pain management and in the creation of new, more effective legislation must take into consideration these evidential data and be approached in an ethical manner.

Changes in Provider Prescribing Habits

One significant factor in assessing the effects of the HCP reclassification is how it affected provider prescribing habits. The primary finding by researchers across the board was that the reclassification of HCPs resulted in a dramatic decrease in HCP prescriptions (Bernhardt et al., 2017; Chumpitazi et al., 2017; Coleman, 2015; Gibson et al., 2020; Hatfield et al., 2016; Northrup et al., 2019; Seago et al., 2016; Raji et al., 2018). Jones et al. (2016) found that prescriptions for HCPs dispensed by pharmacies fell 22% in the twelve months following reclassification.

It is the consensus of many researchers that, after the reclassification, overall prescriptions for opioids in general dramatically declined across almost all health care settings (Bernhardt et al., 2017; Gibson et al., 2020; Jones et al., 2016, Mack, 2018). Alarmingly, Gibson et al. (2020) found that the prescription of opioids, in general, was so much reduced after the reclassification, that women having mastectomies and breast-conserving surgeries as cancer treatments, often did not receive even a one-day provision of opioid pain medication. A few studies, however, present conflicting results. While Northrup et al. (2019) determined that overall opioid prescriptions increased by a third after the reclassification, they also reported a minimal decrease in prescribed MMEs. Conversely, both Liaw et al. (2020) and Raji et al. (2018) found minimal increases in overall MME prescription after the reclassification. To help bring these issues into focus, it is imperative to assess what prescription pain medications increased in use after the reclassification.

Two primary opioid pain relievers saw remarkable increases in prescription rates after the HCP reclassification: Tylenol with codeine and Ultram (Bernhardt et al., 2017; Flemming et al., 2016; Hatfield et al., 2016; Northrup et al., 2019; Oehler et al., 2016; Raji et al., 2018). Several factors contributed to the increased prescription of these two medications. First, both medications are designated as Schedule III compounds by the DEA. The DEA judges Schedule III compounds to be less likely to be abused or to cause addiction. Schedule III medications are also easier for providers to write. They do not require the high level of administrative oversight or the use of special prescription pads like Schedule II medications do. Schedule III medications also allow refills without costly and redundant office visits. Finally, many practitioners now have no choice but to write for Schedule III pain medications. Many states prohibit resident physicians, Physician's Assistants, and Nurse Practitioners from prescribing Schedule II medications (Golembiewski, 2015; Mack, 2018). Because these providers were unable to write prescriptions for HCPs, other, often less effective, medications were utilized resulting in inadequately managed pain.

Primary care physicians also found themselves in difficult positions. Dineen and DuBois (2016) report that physician fear of medical board discipline, increased malpractice liability, legal sanctions, and even criminal convictions related to opioid prescribing have severely impacted the physicians' abilities to fulfill their obligations to treat pain. The reclassification of HCPs has forced these practitioners to either change how they manage their patients' pain or to refer their patients to a pain management specialist.

These changes in provider prescribing habits are significant in that they demonstrate how policies intended to reduce opioid misuse, have inadvertently removed legitimate and effective pain treatments from provider scopes of practice. The proposed study will examine patient experiences related to the medications prescribed to them for pain before and after the DEA schedule change. It will also investigate the extent to which these patients continued to receive pain management from their regular primary care providers or required referrals to pain management specialists.

Increasing Illicit Drug Use and Public Health Policy

The misuse and abuse of prescription medications is an undeniable problem in the United States. Policies designed to combat this issue and imposed at the state and federal levels (including the DEA reclassification of HCPs), however, have little evidence to support their effectiveness (Coleman, 2015; Seago et al., 2016). Even so, current public health policies focus on these primary areas: MMEs, prescribed days of therapy, and pill targets. These arbitrary measures have no legitimate data demonstrating that limits on MMEs or days of therapy reduce addiction rates or are otherwise beneficial to patients (Mundkur et al., 2017). In their quest to show that something was being done to address the opioid crisis, policy makers may have inadvertently instituted measures that harm patients with chronic pain.

The evidence that researchers have been able to collect shows that, for 2014-2015, after the introduction of opioid restrictions, overdose deaths from heroin increased by 21%, and deaths from illicit fentanyl increased by a whopping 72% (Kertesz et al., 2017). Looking specifically at the period directly following the DEA reclassification, Haynes et al. (2016) further supports a demonstrated rise in heroin use. Concurrently, deaths related to cocaine increased by 250% from 2010 to 2015. Heroin or synthetic opioids, combined with cocaine, contributed to 81.5 % of these deaths (McCall et al., 2017). Heroin and illicitly manufactured fentanyl now dominate the opioid crisis but have received little attention from policymakers (Mundkur et al., 2017). Patients who become desperate to obtain some level of pain relief, and who are unable to access prescribed opioids due to restrictions, may turn to illicit substances.

These results demonstrate how policies developed without evidence-based knowledge can inadvertently cause public harm. Future opioid policy interventions cannot strictly focus on restricting the supply of prescription medications. There have been increasing anecdotal accounts that restrictions cause harm to patients (Mundkur et al., 2017). One vector found to be harmful to patients with chronic pain is the stigmatizing language frequently used in opioid research papers and subsequently in opioid policies (Broyles et al., 2014). These terms cause patients with chronic pain to feel stigmatized while also deterring people with opioid use disorder from seeking treatment (Mundkur et al., 2017). Strict, generalized regulations prohibiting the prescription of opioids to arbitrary time periods also violate current CDC guidelines which instead recommend the individualized assessment of risks and benefits. The proposed research study delves into these patients’ experiences to determine how their lives were affected by the DEA reclassification. Determining the long-term effects of these regulations may help legislators to initiate evidence-based policy reform.

Other Unintended Negative Outcomes

As previously discussed, the DEA reclassification of HCPs led to a dramatic increase in the prescription of Tylenol with codeine and Ultram. As designated Schedule III compounds, these medications are believed to carry a reduced risk of misuse and addiction. Unfortunately, prescribing practitioners have been found to be less knowledgeable about the side-effects, dosage limitations, and interactions of these medications (Mack, 2018). During the twelve months following the DEA reclassification, Texas Poison Control reported that the number of therapeutic errors related to codeine and Ultram doubled while adverse medication reactions quadrupled (Haynes et al., 2016). The substitution of lesser-known Schedule III medications for HCPs has increased the risk of adverse events for patients.

Other unintended negative outcomes related to restrictions on opioid prescribing include inadequately managed pain, increased health care costs, damage to physician-patient and pharmacists-patient relationships, and barriers to medication access. LeBaron et al. (2019) found that pain was considerably undertreated in 60-90% of patients with cancer. The authors went on to note that, as regulations had intensified at the end of their project, the percentage of patients with undertreated cancer pain was most likely now higher. Both patients with cancer and those with other chronic pain conditions have significant difficulty accessing appropriate opioid pain medications (LeBaron et al., 2019; Page & Blanchard, 2019; Chambers et al., 2016). Researchers in the United States, Poland, and Canada believe that opioid restricting regulations impede appropriate access to pain management medications for patients and should be reformed using evidence-based methods. (Cleary & Maurer, 2018; Covvey et al., 2015; Curtiss, 2016; Dzieržanowski, T. & Ciałkowska-Rysz; Vogel, 2017).

In a meta-analysis of 122 studies assessing the prevalence of pain, more than one-third of patients with cancer and cancer survivors stated difficulty filling prescriptions for opioids, a percentage that significantly increased after 2016 (Page & Blanchard, 2019). In the 2017 oncology practice census performed by the American Society of Clinical Oncologists, 40% of practices reported that their patients were actively encountering impediments to filling opioid prescriptions related to pill caps, dosing limits, and the need for insurance authorization of prescriptions (Page & Blanchard, 2019). It is significant to note that these are patients with active cancer diagnoses and those with chronic pain conditions attributable to previous cancer diagnoses.

The HCP reclassification has similarly affected other patient populations. Chambers et al. (2016) specifically explored the experiences of patients with fibromyalgia immediately following the schedule change. The reclassification policy was found to be a significant disruption of established pain management therapies for 61% of respondents. Patients reported a loss of trust between themselves and their providers and/or pharmacists, increased financial burdens related to the need for an office visit each month to obtain new prescriptions, and poorly managed pain related to medication substitutions or the inability to access prescribed HCPs. The authors encouraged future research to explore the experiences of additional patient populations to determine if similar themes exist.

This literature illustrates that multiple patient populations have experienced unintended negative outcomes related to the reclassification of HCPs. While many studies have examined opioid misuse and overdose, few have delved into access barriers created by opioid restricting policies. These findings are particularly shocking, considering that the impediment of access to appropriate pain medications would be considered a global human rights violation. This study evaluates the experiences of patients with various chronic pain conditions to determine, not only what barriers were experienced immediately after the reclassification of HCPs, but what issues related to opioid policies continue to affect pain management treatments and access to medications.

Summary and Conclusions

The review of the literature demonstrates a clear need for additional research on how opioid restricting policies affect patients with chronic pain. Rates of opioid misuse, abuse and overdose have been extensively studied. This research highlights the fact that current opioid policies lack an evidential foundation. These policies often prevent individuals from seeking treatment for opioid addiction and, in many cases, actually worsen rates of illicit drug use and overdose.

Both medical providers and patients experienced unintended negative consequences related to the 2014 DEA reclassification of HCPs. The reclassification impacted physicians, physician assistants, and nurse practitioners by altering their abilities to treat patients with chronic pain and to prescribe effective opioid therapies. Studies also identified the fear of legal sanctions related to opioid limiting policies as a negative influence on physicians’ ability to practice.

Other negative consequences involve the ability of patients with chronic pain to access appropriate opioid medications. Immediately after the 2014 DEA reclassification of HCPs, this population experienced difficulty obtaining and filling their regular opioid prescriptions, the substitution of less effective medications for the treatment of their pain, increased health care costs, and damage to physician-patient and pharmacists-patient relationships. Examining the individual experiences of these patients and commonly shared themes within this population is vital to the effective treatment of chronic pain and the development of more effective, evidence-based opioid policies. This study addresses the gap in the available literature by utilizing a qualitative, phenomenological approach as described in Chapter 3, to gather rich information on the perceptions of these patients.

Chapter 3: Research Method

In this study, I explored how the unintended consequences of the 2014 DEA reclassification of HCPs continued to affect patients with chronic pain. The goal was to assess whether common factors including increased health care costs, the efficacy of nonopioid treatments, and the ability to access appropriately prescribed opioid medications (all identified as issues impacting care for patients with chronic pain immediately following the reclassification) continue to affect patients' management of their pain. This chapter expands upon the qualitative, phenomenological approach utilizing interpretive constructionism and bioethics used to explore the experiences of patients with chronic pain. I specifically investigated both the individual experiences of these patients relative to opioid restricting policies, including the 2014 DEA reclassification of HCPs, and explored the common thematic elements of these experiences.

Research Design and Rationale

RQ1 Qualitative: How do patients with chronic pain describe their perceptions of their pain management treatment before and after the 2014 DEA reclassification of products containing hydrocodone?

RQ-2 Qualitative: What common themes related to the treatment of chronic pain are present among the study participants?

Qualitative methods were most appropriate to answer these research questions. A phenomenological approach using interpretive constructionism and bioethics was used to explore the experiences of patients with chronic pain. I specifically investigated both the individual experiences of these patients, relative to the 2014 DEA reclassification of HCPs, and explored the common thematic elements of these experiences.

Phenomenology was an appropriate construct for this study because it is used to understand shared experiences related to a specific event. Exploring these experiences allows the researcher to develop a deep, rich understanding of the phenomenon (Giorgi & Giorgi, 2003). The addition of interpretive constructionism allows the researcher to understand how the participants interpret and allot meaning to life events (Rubin & Rubin, 2011). Constructionism also examines the shared perceptions of an event, otherwise known as the cultural lens, of a group.

The sample population for this study consisted of patients with varying chronic pain diagnoses who used prescription opioids for 6 consecutive months pre- and post- the reclassification of HCPs. These individuals also stated that they had persistent, intractable pain that severely impacted their functionality and was not adequately controlled without the use of opioid medications. This is a marginalized population highly at risk of social stigma. Integral to the development of a conceptual framework, and to protect the rights of this population, was the incorporation of narrative-based bioethics. Narrative-based bioethical theory is relevant to the experiences of patients with chronic pain because it contests detachment and impartiality by bringing the stories and experiences of patients into the focus of the care and development of continuing treatment plans (Carvalho et al., 2018).

Due to the subjective nature of pain, the individual’s experience becomes vital to a shared understanding and is fundamentally important. After careful consideration of the goals and purpose of this study, I precluded strict quantitative measures as being unable to provide experiential understanding of the phenomenon. Future studies may expand on the findings of this study by using a mixed methods approach; however, the purpose of this study did not require that level of complexity.

Role of the Researcher

As the primary research instrument, I conducted personal interviews for data collection. I verified the participation criteria of potential participants via the telephone. Once interest and participation criteria were confirmed, a copy of the informed consent form was emailed to the participants. The informed consent form contained detailed information about the study. Participants replied, via email, with the words, “I consent,” prior to data collection, to verify willingness of study participation. I also verified verbal consent at the time of the interview. Interviews were transcribed for data analysis.

Personal interviews create a flexible research environment, allowing participants greater opportunity to respond (Abutalibov & Guliyev, 2013; Yin, 2014). A private, intimate interview session increases the likelihood that participants will give frank, honest responses (Trier-Bieniek, 2012). The use of social media platforms in the virtual environment allows the researcher to overcome some of the difficulties traditionally noted in patient populations with diverse geographic locations. I conducted 12 interviews until saturation was reached, with participants having diverse chronic pain diagnoses. The purpose of the interviews was to increase understanding of the barriers to care faced by these patients as related to the 2014 DEA reclassification of HCPs.

Both telephone and social-media platform options were offered to participants as interview methods. All participants chose to complete their interviews via the telephone. I was available before, during, and after the study to answer participant questions. Participants received a $20 thank you gift at the conclusion of the study. This incentive was appropriate and within ethical guidelines given the current health and financial states of the country.

Actions were taken to manage researcher bias brought on by personal beliefs and expectations. Morse (2015) identified two forms of researcher bias: the use of a nonrandom sample population and motivated perception. To combat researcher bias, Morse and Yin (2014) suggested that the data review be cyclical in nature, that data and thematic elements be checked throughout the course of the interview, and that conflicting evidence be given ample consideration. To manage my personal bias, I approached the interviews in an open, nonjudgmental fashion.

As a registered nurse, I have a history of direct experience caring for patients with chronic pain. I currently have no direct relationship with any of the study participants. I have a professional acquaintance with some of the local pain specialists.

Methodology

Qualitative research methods were first introduced by Lazarsfeld in 1925. By 1945, the package components of phenomenology had been established as motivations research, depth interviewing, group discussion formats, the use of expert practitioners, the vitality of interpretation, and the use of “why” questions (Bailey, 2014). Qualitative methods are thus appropriate when the researcher wishes to focus on the who, why, and how of a topic of interest (Yin, 2014). These methods have now been successfully incorporated into both scholarly and market research.

Phenomenology is a philosophical construct that attempts to define how individuals assign meaning to an event. Without understanding the interpretive process of the individual, it is impossible to attribute meaning to a lived experience. Through these interpretive processes, meaning is attached to a lived experience and perceptions established. Researchers must respect individual perceptions as truth. Guided by these concepts, I implemented a phenomenological study design.

This approach encouraged the active participation of participants in the exposition of meaning using their own perceptions. To understand the experiences of patients with chronic pain related to opioid restricting policies, I interacted with the study participants. To understand the social and financial implications of these experiences, I was attentive to the participants' responses and interactions. Participants were treated as equal partners in a quest for discovery as outlined by Colaizzi (1978). Interview questions used an open-ended design to engage the participants and to promote personal reflection on their perceptions of access to chronic pain medications and barriers to care.

Participant Selection Logic

Purposive sampling was used for participant recruitment. Purposive sampling promotes the development of trust between the researcher and the participants. This encourages the sharing of details about the phenomenon of interest. For consideration as a study participant, candidates met the following criteria: diagnosed with a condition causing chronic pain, currently managed by an interventional pain specialist, received treatment with prescription narcotics for least 6 consecutive months in both 2014 (before the DEA reclassification of HCPs) and in 2015 (after the reclassification), and be 18 years of age or older at the time of the study. Participants were recruited from the offices of local pain management physicians and online social media support groups for people with chronic pain. A wide variety of chronic pain conditions present in 12 participants aligned with the phenomenological approach and represented data saturation.

The sampling procedure began with the distribution of a flyer soliciting patients with chronic pain as study participants. Flyers were placed in the offices of local pain management physicians and outlined participation criteria. Ten participants were sought to meet the saturation needs of this phenomenological study. I spoke to the respondents via telephone to confirm eligibility criteria. Interviews continued until saturation was reached as evidenced by a lack of the introduction of new information and the presence of no unexplained phenomena (see Burkholder et al., 2016).

Instrumentation

Responsive interviewing was used to identify a comprehensive representation of thematic elements. Participants had the choice of being interviewed either via the telephone or via web-based services (such as Skype), per the participant’s preference. The interview tool was researcher produced and focused on Patton’s six areas of qualitative questioning. All data collection instruments were examined for appropriate content by the Walden University Department of Health Sciences. Walden University also conducted an IRB.

The intended purpose, and the appropriate use of a research instrument for that purpose, affects the validity of any data collection tool (Burkholder et al., 2016). The collection of demographic information on study participants has previously been used successfully to enrich study data. The researcher-developed interview tool and demographic questionnaire expanded on the thematic elements identified by Chambers et al. (2016). The responses given in these interviews directly address the research questions of this study.

Procedures for Recruitment, Participation, and Data Collection

Recruitment flyers were posted in the offices of local pain management physicians and on social media support sites for people with chronic pain. The flyers detailed the expectations and requirements of the study, participants' rights, procedures for data collection, and how the information would be used and stored. I contacted respondents via telephone to confirm eligibility. Participation in this study was voluntary, and participants could elect to leave the project at any time.

Data collection began after receiving confirmation of consent. To indicate consent, participants replied to the informed consent email with the words, "I consent." The information stated in the informed consent form supported a process that promoted open communication with participants while minimizing bias. Participants were assigned a six-digit number on a Name Page. Only I, the researcher, had access to this information. Apart from the Name Page, all information that could personally identify participants will remain confidential. Other than the Name Page, names were not recorded on any paper questionnaire response forms, or in any digital computer files.

Data were first collected using a demographic questionnaire. I collected this information during the first few minutes of the interview, and prior to the asking of open-ended responses questions. Responses were number coded for anonymity and entered into an Excel spreadsheet.

A guided interview tool focusing on previously identified barriers to pain management was utilized to conduct personal interviews with participants. The average interview time was 85 minutes. Interviews were audio recorded and transcribed either by me or by a reputable transcription service. I also utilized a reflective journal to record personal insights and perceptions during the interviews. The use of this type of journal is suggested by Irvine et al. (2012) as a method of controlling bias and clarifying participant responses. Baškarada (2014) and Snyder (2012) proposed that participants answer the same set of questions to reduce bias. The semi-structured nature of these interviews and the need for personalized follow-up questions prevented the use of a strict interview script. The interview tool, however, was utilized as a checklist to ensure each relevant topic was discussed with each participant. Member checking of transcribed responses was utilized to increase the validity of the study.

Data Analysis Plan

Data analysis was conducted in parallel with data collection to enhance the research process and permit coding adjustments (Baškarda,2014; Ingham-Broomfield, 2015; Snyder, 2012). Initial codes based on the literature review were developed prior to data collection as recommended by Ingham-Broomfield (2015).

Data coding and analysis was cyclical allowing codes to be updated to reflect emerging themes and outliers (Baškarada, 2014). Coded interview transcripts were stored in a password protected file on a password protected computer. Transcripts were read multiple times to identify thematic elements. Further analysis was conducted using the qualitative software program, NVivo.

Issues of Trustworthiness

Credibility

Credibility is a qualitative measure of a study's internal validity (Ravitch & Carl, 2015). The researcher must examine and consider the plethora of information presented during data collection and manage aberrant themes (Guba & Lincoln, 1981). The foundation of credibility is demonstrating that the people you are interviewing are informed about the phenomenon of interest. After all, you would not gain much insight on perceptions of chronic pain from individuals who had never experienced it. With this in mind, the data collection tools and participation criteria were developed in a manner that promoted only the most qualified candidates. Being able to demonstrate that the participants were well informed on the topic of interest by being able to recount detailed descriptions of identified themes increased the overall credibility of the study. (Rubin & Rubin, 2011). This involved politely checking the interviewees' responses for recall, frankness, and uniformity. Credibility was also increased through the use thick description, member checking, and triangulation. Because this study explored the use of illicit drugs for pain management, it was necessary to allow participants to initially answer an indirect question and then expand with personal experiences.

Transferability

Transferability is the extent to which sample population study findings are generalizable to the larger population of interest (Burkholder et al., 2016). This is not the purpose of qualitative research but instead a way to establish the continued meaning of the study. The use of participants with varied pain diagnoses increases variation and supports transferability (Merriam, 2009)

Dependability

Qualitative researchers explore phenomena through multiple data sources and in a natural setting (Houghton et al., 2013). To create reliability, Lincoln and Guba (1985) suggest the use of the following criteria: credibility, transferability, dependability, and transferability. Houghton et al. (2013) further discussed methods of establishing rigor to include member-checking, triangulation, and an audit trail.

I developed an interview tool based on the themes identified in the research of Chambers et al. (2016). This allowed me to answer the study's research questions by fully exploring the experiences of patients with chronic pain and to determine if those themes are still present within this population. The demographic assessment tool allowed me the ability to separate responses into groups and subgroups providing a method of analytical data triangulation. I worked with my committee to further develop my data analysis plan.

Confirmability

Qualitative researchers make no claims of objectivity. Instead, they attempt to approach data collection in a neutral manner, free from unknown biases and clearly recognizing known biases (Ravitch & Carl, 2015). Despite a lack of objectivity, the confirmability of findings is greatly desired. Confirmability is used to identify and record researcher bias while analyzing its effect on data interpretation. Confirmability may be achieved through the initiation of triangulation strategies and researcher reflexivity. Researcher positionality and bias must be scrutinized as the researcher is the primary instrument in a qualitative approach (Ravitch & Carl, 2015).

Ethical Procedures

Participation in this qualitative, phenomenological study was on a voluntary basis. Recruitment flyers were posted in the offices of local pain management physicians and on social media support sites for people with chronic pain. The flyers detailed the expectations and requirements of the study, participants' rights, procedures for data collection, and how the information would be used and stored.

Data collection began after the receipt of the acknowledgement of the informed consent form. This was performed at the beginning of the personal interview. The information stated in the informed consent form supported a process that promoted open communication with participants while minimizing bias. Apart from the Name Page, all information that could personally identify participants will remain confidential. Other than the Name Page, names were not recorded on any paper questionnaire response forms, or in any digital computer files.

Numeric codes were utilized to protect the identity of participants. These codes are stored in a secure location and are only accessible by me, the researcher. None of the paper forms or electronic data files (e.g., database, spreadsheet, etc.), other than the Name

Page contain any information that would allow individual participants' identities to be identifiable. Protecting participant confidentiality maintains ethical compliance and promotes public trust (Beskow et al., 2012).

Participants had the right to withdraw from the study at any time. They also had the right to refuse to answer any of the interview questions. At the conclusion of the interview data analysis, participants were notified of the primary themes identified. I will publish the study findings in fulfillment of PhD candidacy requirements at Walden University. Participants will not be identified in any publications or presentations.

All documents related to this study will be destroyed 5 years after the close of the study. All computer files will be password protected and all computers hosting such files will also have password protection to prevent access by unauthorized users. Only I, the researcher, will have access to the passwords.

My study requires observance of the requirements stipulated by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission) and the National Research Act regarding researcher interaction with human study participants. These guidelines were put in pace to promote ethical responsibility in research. In 1979, the Commission further established these ethical principles and guidelines involving human subjects in the Belmont Report (U.S. Department of Health and Human Services, 2018). My study was conducted utilizing these guidelines The Walden University Institutional Review Board (IRB) ensured that the study was in regulatory and ethical compliance. IRB approval number: 01-07-21-0626086.

Summary

Chapter 3 addressed the methodology and credibility of this research study. The methodology section outlined participant selection, instrumentation, recruitment procedures, and the data analysis plan. The credibility section established the methods in which transferability, dependability, confirmability, and ethical procedures were ensured. After obtaining IRB approval, I began data collection with participant acknowledgment of the informed consent form. Data analysis was conducted using Giorgi's phenomenological method. This included both manual coding of the data and the use of the qualitative assessment software, NVivo. These results will be presented in Chapter 4.

Chapter 4: Results

The purpose of this phenomenological study was to understand how the U.S. DEA's 2014 reclassification of HCPs affected patients with chronic pain. This included patients' perceptions of access to appropriate pain management, the impact of these regulations on patients' healthcare costs, and how the regulations may have altered relationships with patients' medical providers. The following two research questions were used to guide this study:

> RQ-1 Qualitative: How do patients with chronic pain describe their perceptions of their pain management treatment before and after the 2014 DEA reclassification of products containing hydrocodone?
>
> RQ2 Qualitative: What common themes related to the treatment of chronic pain and opioid restricting policies are present among the study participants?

The following section of this chapter is a description of the setting of data collection. Next, I include a description of the study participants, followed by descriptions of the data collection and data analysis procedures. I then continue with a discussion of the evidence of the trustworthiness of the study findings, followed by a presentation of the study results, which are organized by research question. This chapter concludes with a summary of the findings.

Setting

The 12 participants were interviewed by telephone. Telephone interviews were conducted to protect the safety of the participants and myself by adhering to social-distancing guidelines associated with the COVID-19 pandemic, and because most participants did not live within a feasible traveling distance of me. The interviews were conducted on dates and at times of participants' choice to ensure they had adequate time to provide full and detailed responses to the interview questions. Participants were asked to answer the interview questions from a safe, quiet place where they would have privacy and minimal distractions to ensure they were able to focus on the interview and to protect the confidentiality of their identities. No unanticipated conditions arose during data collection that influenced the interpretation of the results.

Demographics

The purposive sample included 12 adults, at least 18 years of age, who were diagnosed with a condition causing chronic pain, were managed at time of study by an interventional pain specialist and had received treatment with prescription narcotics for least 6 consecutive months in both 2014 (before the DEA reclassification of HCPs) and in 2015 (after the reclassification). Table 1 indicates participants' individual demographic characteristics. Participants' histories of chronic pain and prescription opioid use are found in Table 2 and Table 3 indicates participants' employment status before and after the 2014 DEA reclassification of HCPs.

Table 1

Participant Demographics

Participant	Age	Gender	Ethnicity	State	Marital Status	Education	Other members of household
P1	62	F	White	WV	Divorced	Bachelor's	Alone
P2	41	F	White	NY	Married	High School	Spouse, (2) children
P3	65	M	-	AL	Divorced	Associate's	Alone
P4	37	M	White	OH	Married	Associate's	Spouse
P5	38	F	White	TX	Married	Master's	Spouse
P6	59	F	-	IL	Married	College	Spouse
P7	49	F	White	LA	Married	Master's	Spouse
P8	53	F	White	CA	Divorced	Bachelor's	Adult daughter
P9	58	F	-	VA	Married	High School	Spouse
P10	55	F	White	IN	Married	Some College	Spouse
P11	47	M	-	KS	Married	Bachelor's	Spouse, (2) children
P12	53	F	White	CA	Married	Some College	Spouse, (2) children, father

Note. A dash (“-”) in the ethnicity field indicates that the participant preferred not to disclose.

Table 2

Participant Chronic Pain and Prescription Opioid Use Histories

Participant	Current health insurance	Part of the body affected most by pain	Time using hydrocodone prior to rescheduling	Total number of years using opioids
P1	State-sponsored health program	Low back, left hip	15 years	18 years
P2	Medicare, Medicaid, Aetna	Global	10 years	18 years
P3	Cigna	Low back	10+ years	10+ years
P4	Worker's Comp, cash pay	Left hand, left arm	4 years	8 years
P5	Marketplace, cash pay	Back	12 years	19 years
P6	Cigna, Aetna, Medicare	Global	5 years	11 years
P7	Aetna	Global	15 years	22 years
P8	Blue Cross Blue Shield	Chest	2 years	9 years
P9	Medicare and supplement	Back	9 years	15 years
P10	Medicare	Back, bilateral legs	14 years	21 years
P11	Medicare, Private insurance, Workers Comp	Back, bilateral legs	15 years	20 years
P12	None, cash pay	Abdomen	3 years	14 years

Table 3

Participants' Employment Status Before and After 2014 Reclassification of HCPs

Participant	Employment prior to 2014 HCP reclassification	Employment status at time of study	Reason for change, if applicable
P1	Full time	Retired/Disabled	Reduced pain management efficacy
P2	Full time	Disabled/Part time	Reduced pain management efficacy
P3	Part time	Disabled	Reduced pain management efficacy
P4	Unemployed	Disabled	Reduced pain management efficacy
P5	Full time	Part time	Reduced pain management efficacy
P6	Disabled	Disabled	N/A
P7	Full time	Full time	N/A, but misses work for pain management appointments
P8	Disabled	Disabled	N/A
P9	Full time	Disabled	Reduced pain management efficacy
P10	Disabled	Disabled	N/A
P11	Full time	Retired/Disabled	Reduced pain management efficacy
P12	Unemployed	Unemployed	N/A

Data Collection

Data were collected through a single, one-to-one, semistructured interview with each participant. The interviews were conducted by telephone from January 28 through March 18 of 2021. The average duration of the interviews was 85 minutes. All interviews were audio recorded with participants' permission using a digital recording device. No unanticipated circumstances were encountered during data collection, and there were no deviations from the data collection procedure described in Chapter 3.

Data Analysis

I transcribed the audio-recorded interviews verbatim (P1 through P5) and the professional transcription service REV.com (P6 through P12). The data were analyzed using the descriptive phenomenological method as described by Giorgi (2009). In the first step of the analysis, I assumed the phenomenological attitude by bracketing everyday knowledge. Bracketing knowledge involved setting aside or mindfully suspending cultural, theoretical, and experiential preconceptions to see the data as they were, without positing or doubting their validity. The purpose of assuming the phenomenological attitude by bracketing researcher preconceptions was to see the phenomenon from participants' perspectives.

After assuming the phenomenological attitude, I read and reread the data (see Giorgi, 2009). In undertaking these readings, I attempted to maintain a naïve perspective by continuing to bracket preconceptions. I reflected on the data to understand how participants experienced the phenomena they described in their interview responses.

The third step of data analysis involved breaking the data down into meaning units, which were phrases or groups of consecutive phrases that expressed a single meaning relevant to describing the phenomenon of interest (see Giorgi, 2009). Meaning units were demarcated by rereading the transcripts and noting where participants shifted between meanings in providing their responses. By breaking down the data into meaning units, the data were separated into manageable portions for further analysis. A total of 265 meaning units were identified across the 12 transcripts.

In the fourth step of the analysis, the meaning units were translated into psychologically sensitive descriptions of the phenomenon (see Giorgi, 2009). This translation process involved rephrasing each meaning unit in the third person, maintaining an experiential, psychological perspective rather than attempting to express transcendental or experience-independent truths. During this step, the meaning units were grouped by applying the same psychologically sensitive description to different meanings units that expressed the same meaning. To assist in this process, imaginative variation was used. Imaginative variation involved imagining changes to participants' descriptions of the phenomena to determine which qualities were essential and which were accidental (i.e., they could be altered without changing the essence of the phenomenon). The third person, psychologically sensitive descriptions were developed to refer to the essential properties of the phenomenon. The meaning units were clustered into 25 psychologically sensitive descriptions of the phenomenon during this step of the analysis. These descriptions were identified as the interdependent constituents of the phenomenon, and they represented convergent meanings in participants' responses. Table 4 indicates the constituents of the phenomenon as they were represented in psychologically sensitive descriptions in Step 4 of the analysis.

Table 4

Psychologically Sensitive Descriptions of the Constituents of the Phenomenon

Description of constituent	*n* of participants contributing (*N*=12)	*n* of meaning units included
Accommodating care associated with patient compliance	5	5
Arduous administrative requirements	8	11
Complications from withdrawal and drug interactions	7	12
Doctors readily prescribed appropriate pain medication	10	14
Doctor-shopping as a red flag	4	4
Emotional distress	6	9
Financial struggles	4	6
Forgoing ER treatment	5	7
Frustration with doctors' reluctance to prescribe	7	8
Increased costs	11	17
Increased functional impairment	9	14
Intolerable pain as a suicide risk factor	8	10
Medication did not eliminate pain	5	6
Number and dosage of opioids are restricted	6	9
Partly discrepant data - Barriers to obtaining workers compensation	1	1
Partly discrepant data - Challenges in finding a doctor who would prescribe HCPs	1	2
Pharmacies refusing to fill opioid prescriptions	8	13
Pressure to try ineffective alternatives	7	10
Providers declining to prescribe opioids	9	14
Providers shame patients by suspecting addition	10	26
Required appointments as a burden	3	5
Required to see a pain management specialist	12	12
Shame and anxiety	9	22
Stigmatization of chronic pain sufferers	10	19
Suspicion of abuse resulting in patient mistreatment	6	9

The fifth and last step of the analysis consisted of a synthesis of the general psychological structure of the phenomenon out of the interdependent constituents identified in Step 4 (see Giorgi, 2009). The interdependent constituents were clustered as parts of whole descriptions, or themes, that indicated the psychological essence of the phenomenon. Table 5 indicates how the constituents were grouped to form the themes that described the psychological structure of the phenomenon of how the DEA's 2014 reclassification of HCPs affected patients with chronic pain.

Table 5

Clustering of Constituents Into Themes

Theme	Constituent grouped to form theme	*n* of participants contributing (*N*=12)	*n* of meaning units included
Theme 1. Chronic pain was manageable before the DEA reclassification		12	30
	Accommodating care associated with patient compliance		
	Doctors readily prescribed appropriate pain medication		
	Medication did not eliminate pain		
	Partly discrepant data - Barriers to obtaining workers compensation		
	Partly discrepant data - Challenges in finding a doctor who would prescribe HCPs		
Theme 2. New restrictions associated with the reclassification made appropriate care more difficult to access		12	70
	Arduous administrative requirements		
	Complications from withdrawal and drug interactions		
	Financial struggles		
	Increased costs		
	Number and dosage of opioids are restricted		
	Pressure to try ineffective alternatives		
	Required appointments as a burden		
Theme 3. Heightened provider vigilance about opioid abuse after the reclassification made appropriate care more difficult to access		12	67
	Doctor-shopping as a red flag		
	Forgoing ER treatment		
	Frustration with doctors' reluctance to prescribe		
	Pharmacies refusing to fill opioid prescriptions		
	Providers declining to prescribe opioids		
	Required to see a pain management specialist		
	Suspicion of abuse resulting in patient mistreatment		
Theme 4. Shame and stigma		12	67
	Providers shame patients by suspecting addition		
	Shame and anxiety		
	Stigmatization of chronic pain sufferers		
Theme 5. Reduced quality of life		12	33
	Emotional distress		
	Increased functional impairment		
	Social and/or geographic isolation		
	Intolerable pain as a suicide risk factor		

Evidence of Trustworthiness

Credibility

Credibility is a qualitative measure of a study’s internal validity (Ravitch & Carl, 2015). Credibility was strengthened through demonstrating that the participants were well informed on the topic of interest, as indicated by their ability to recount detailed descriptions of identified themes increased the overall credibility of the study (Rubin & Rubin, 2011). This involved politely checking the interviewees’ responses for recall, frankness, and uniformity. Credibility was also increased through the use thick description and member checking. Member checking was conducted by emailing participants a report of my initial interpretations of their responses and asking them to respond with confirmation or recommended corrections.

Transferability

Transferability is the extent to which sample population study findings are generalizable to the larger population of interest (Burkholder et al., 2016). This is not the purpose of qualitative research but instead a way to establish the continued meaning of the study. The use of participants with varied pain diagnoses increased variation and will support transferability (Merriam, 2009). To the extent compatible with confidentiality, detailed descriptions of the participants and their circumstances have also been provided to assist readers in assessing transferability. The use of thick descriptions in reporting the results, by presenting the findings with evidence in the form of participants’ own words, will also assist readers in assessing transferability by indicating the contexts and perspectives in which the findings are grounded.

Dependability

Dependability is the qualitative analogue of the quantitative construct of reliability (Lincoln & Guba, 1985). Dependability is strengthened by providing descriptions of study procedures that are thorough and clear enough to allow readers to reproduce the study if desired. Such descriptions allow readers to verify the integrity of the study procedures. The use of a semi-structured interview guide contributed to the clear description and reproducibility of the data collection procedure. The use and description of a sourced data analysis procedure, the descriptive phenomenological method as indicated in Giorgi (2009), also contributed to the integrity of the study procedures.

Confirmability

Qualitative researchers make no claims of objectivity. Instead, they attempt to approach data collection in a neutral manner, free from unknown biases and clearly recognizing known biases (Ravitch & Carl, 2015). Confirmability is used to identify and record researcher bias while analyzing its effect on data interpretation. Member checking strengthened confirmability in this study by enabling participants to validate that my interpretations of their responses reflected their intended meanings rather than researcher bias. The bracketing procedure implemented during the first step of data analysis to facilitate mindful suspension of researcher preconceptions also contributed to confirmability. Inclusion of evidence for the findings in the form of direct quotations from the data will enable the reader to make an independent assessment of confirmability.

Results

This presentation of the results is organized by research question. Under the heading for each research question, the findings are organized by theme. The themes are the major findings used in this study to address the research questions.

Research Question 1

RQ1 was as follows: How do patients with chronic pain describe their perceptions of their pain management treatment before and after the 2014 DEA reclassification of products containing hydrocodone? Three of the themes identified during data analysis were used to address this question. The themes were (a) chronic pain was manageable before the DEA reclassification, (b) new restrictions associated with the reclassification made appropriate care more difficult to access, and (c) heightened provider vigilance about opioid abuse after the reclassification made appropriate care more difficult to access.

Theme 1: Chronic Pain Was Manageable Before the DEA Reclassification

All 12 participants contributed to this theme. The finding indicated that participants considered their chronic pain to be manageable using prescribed opioids before the 2014 reclassification of HCPs by the DEA. Participants' descriptions of successful pain management varied. For six out of 12 participants, successful pain management enabled them to work full-time. One additional participant was able to work part-time. Two participants were unemployed but were able to work. Three out of 12 participants were classified as disabled prior to 2014 because of the conditions that caused their chronic pain, but they described their pain management as moderately successful in making their pain level tolerable.

Most participants reported that successful pain management enabled them to function in their normal, day-to-day activities prior to the 2014 reclassification. P11 suffered slip-and-fall injuries on the job, but his pain management was successful enough before 2014 that he was able to work full-time. He stated, “I had treatment, I had shots, I had a lot of things, and they all worked. I had some pain pills that kind of got me through, and usually I bounced back pretty quick from slips and falls.” P1, who suffered a back injury at work, reported that her opioid prescription did not eliminate her chronic pain, but that it made the pain manageable and allowed her to function: “I called him [my doctor] one day from work, and I was just crying in pain, so he put me on a fentanyl patch. It didn’t take all the pain away, but it made it manageable.” Asked if her pain management allowed her to function prior to 2014, P6 answered, “It did. I used to joke about it. I'd say, ‘I wake up 99 years old, but on a good day, I can get [down] to 66 by bedtime [after treatments for pain].’” P5 stated that her pain was not eliminated by HCPs, but that it was manageable enough for her to engage in day-to-day activities: “[Hydrocodone] doesn’t make me feel high or anything like that. It really just makes me feel better enough to clean house or whatever for a little bit.” P2 stated that when her pain was being managed successfully with HCPs, “If I was working, I was fine.”

Ten out of 12 participants reported that they had no trouble receiving prescriptions for HCPs or other opioids from their doctors or filling those prescriptions at their pharmacies prior to 2014. One additional participant (P4) reported that challenges in obtaining prescriptions were associated with bureaucratic obstacles to receiving workers compensation rather than provider reluctance. One participant (P2) attributed her physician's reluctance to prescribe HCPs for her chronic pain to her young age at the time she first sought assistance. P2 indicated that doctors were skeptical that a person under 30 years of age was experiencing potentially disabling chronic pain. She was eventually diagnosed with Ehlers-Danlos Syndrome stating,

> Well, what happened was, I had broken my back. There was no reason why. It's just I was walking, it snapped and I fell to the ground. My doctor, the surgeon, was kind of like, "Oh, sometimes it happens." It took me about five years before I finally broke down and got surgery. But the surgery, it was not fixed, it still hurts. My doctor kind of called me a baby about it. My incision was ripping. It didn't go as well as I thought it would.
>
> So I still was dependent on pain medication. I've tried many different things, injections and stuff like that. And, after a couple years, I went to go get surgery for my back because my whole body was just starting to break down like my joints were popping, my wrist was popping, bones were breaking, and nobody could understand why. So, I wanted to get neck surgery. My doctor was like, "No, I can't do this for you. You need a specialist." Then that's what set off genetic testing which led to my diagnosis of Ehlers-Danlos syndrome.
>
> [It] took me 10 years for a doctor to finally listen and look at me and say, "No, this isn't right" like you have the body of somebody that's been in like a tractor-trailer accident and a linebacker and for no reason. Like I was never in any

> accident, nothing ever happened to me.

P7 reported that obtaining pain medication was not burdensome to her before the 2014 reclassification:

> They [doctors] had no problems giving me pain medication. I would go to the doctor once every 90 days to get a refill. And then of course at my pharmacy, I could get refilled every month, and I didn't have an issue. There were no problems, no judgments.

P11 described experiences similar to P7's in stating, "Back early in 2000, when I was injured off and on throughout my career, my regular doctor would write me hydrocodone. It wasn't any big deal." Prior to the reclassification, P12 associated appropriate access to pain medication, without undue hardship, with her doctor's trust in her:

> My doctor used to have me come in one month, and he would write me that month's scripts and then the following month's scripts, so I didn't have to go in every month. I only had to go in every other month. He did that to make it more convenient for me. I was a trusted patient. He knew I wasn't going to abuse it.

P3 described accessing appropriate prescription HCPs prior to 2014 in stating, "You didn't feel embarrassed about being there . . . And you see [doctors], they check you out, if everything's okay, they'll refill everything, and you go about your business." P6 described herself as a model patient who knew which medication regimen was most successful in managing her pain and had no trouble receiving the necessary prescriptions: "I'm the kind of pain patient you want to have. I've done all of the [available medications]. I know what works for me. And I come in, and you give me my pills, and I go away."

P4 described utter desperation regarding his pain management after the reclassification:

> I'm damned if I do, damned if I don't. I'm literally stuck in this never-ending cycle of pain, sorrow, misery, you know. And that doesn't even get into the extent of my worst fear when the accident happened, was losing my finger. And then I had to live with it, not being able to use it for 4 years before it finally got cut off. After I took a knife and tried to saw it off myself.

Theme 2: New Restrictions Associated With the Reclassification Made Appropriate Care More Difficult to Access

All 12 participants contributed to this theme. Regardless of the level of success with which participants were able to manage their pain before the 2014 DEA reclassification of HCPs, pain management became significantly more challenging after the reclassification. One new set of challenges consisted of the new administrative requirements that were imposed as safeguards to prevent abuse of HCPs and other opioids.

Some of the post-reclassification safeguards against HCP abuse required patients to meet arduous administrative requirements, a factor reported by eight out of 10 participants. P1 described the challenge of having regularly recurring urinalyses to screen for opioid levels, particularly after the COVID-19 pandemic caused many doctors' offices to close temporarily:

> Now I just had one [urinalysis] done in February and March, and my doctor’s office told them, said look, “we don’t have anybody here in the office to do urine tests because of the pandemic.” My insurance company demanded that I have a urinalysis done . . . So, they basically forced me to go to the hospital, exposing myself to corona, and have a urine test that came back with “tangents” [adulterants] or something in it. Which means, basically, it had toilet cleaner in it. And they tried to deny me on that. My doctor’s office had to have the lab write a letter that if the urine sits too long before being tested, that that can happen.

P2 was required to complete a questionnaire before receiving her prescription to assess risk of opioid abuse according to a point system. P2 described the test as disadvantaging her because of her gender: “They make you fill out a questionnaire . . . Just being female, you get like four points added to it. Once you hit a certain level of points, they deem it as possible opioid addiction and will not prescribe your medication.”

P9 was also required to fill out assessment questionnaires prior to treatment for her chronic pain. P9 illustrated additional areas of discrimination present in the assessment forms:

> Oh, this is on a piece of paper that they give you. You have to answer these questions, and they score you. It's like zero to three for each question. God forbid you tell them you were a victim of sexual abuse in your younger years. That's like a three. You can only get four. And if you have a four, then your chances of being an addict are high, so they won't prescribe. So, God forbid you had trauma in your

> childhood. It has nothing to do with your pain. It automatically makes you more susceptible to be an addict to pain meds.

P4 reported a number of administrative requirements that made obtaining the prescriptions he needed both difficult and embarrassing:

> I had to do drug testing. I had to do injections. I had to do physical therapy five times a week. If I missed any rule, I was questioned. You know, like, "hey, why didn't you go?" Probably because I hurt too damn bad, and I couldn't move that day. It was always about the next surgery, the next injection. We had to drug test. Every time we went in there, it didn't matter. To me that felt like, because I never dropped a dirty urine ever, and the pill counts. It makes you feel like you're a damn criminal.

P5 reported undergoing quarterly urinalysis and random pill counts: "They can call you within three hours' notice to come in and count your pills. They drug test quarterly. If they find anything in your urine, you're discharged." P9 also reported undergoing regular urinalysis and random pill counting:

> I can have random drug tests, random pill counts. They can call at any time. I have 24 hours to go bring them my medication.

Six out of 12 participants reported that post-reclassification limits on the number of opioids they could take at one time, and on the dosages they could take of any single opioid, increased the level of impairment they experienced as a result of their chronic pain. P1 reported that dosage limits on Percocet made the drug ineffective (she was limited to 30 pills per month), and that the requirement in her state that she could only be on one opioid at a time caused her to choose fentanyl. Prior to the reclassification, she was on 75mcg of Fentanyl with Percocet for breakthrough pain. However, post reclassification dosage restrictions on fentanyl made P1 unable to manage her pain effectively enough to continue her employment:

> I walked in one day and they said, "did so and so talk to you last month?". And I said, "No, they didn't". Well, the new regulations are that you can only have one opiate in this state, and you need to choose. [After the reclassification] I was on [25mcg fentanyl patches] for a few months, and then I went back [to my doctor], and I said, "Look, you need to raise it up to the 50[mcg] because it's just not controlling [my pain]." Well, he of course, he got a little bit upset, but he did it. He said, "This is the last raise I can do. I cannot go any higher because of the DEA ruling [regarding MME per day]." So, I'm at 50mg fentanyl . . . I tried to stay working but my body just broke down. It just couldn't do it anymore. [On 75mcg of Fentanyl with Percocet for breakthrough pain] I could function. I was a tax paying citizen. I worked every day. Every day. I created the (name redacted) program, from start to finish, for the State of West Virginia, on drugs. Yeah, it puts too much pain in my body, on my body. It's just. I'm fighting the tears right now because, I used to take my grandkids camping. Uh, we climbed Seneca Rock Mountain, five/six years ago, which is a five mile hike up a mountain, and I had no problems on my pain meds.

P9 described the reduction in her pain medication that caused her to move from full-time employment to disability status because of dosage restrictions:

> Well, in 2016 is when they cut my prescriptions down…They took my Oxycontin and said I was going over the guidelines and needed to watch what I took. Well, 30 milligrams isn't equivalent to the 90 [MMEs] that they were talking about, but he just cut it… I went on disability at the end of 2016 and beginning of 2017 because I was an assistant manager on my feet nine hours a day. So, when they took that, I couldn't do it. I ended up having two strokes in February from being undermedicated and my blood pressure being out of control. Yeah, he cut my prescription in December. February, I had two strokes within two weeks, and every time, my blood pressure was sky-high…It took me until 2018 to get my Oxycontin back, and I only got one a day.

P8 reported that when her doctor reduced her dosage enough that her pain became unmanageable, he appeared indignant about the new restrictions and described them as nonsensical from a medical point of view:

> My doctor was telling me, he says, “We're just getting hounded by the DEA.” And he goes, “I have three daughters that I have to pay for probably weddings. I cannot lose my job because somebody has decided that chronic pain patients should have this magical 90[MME] number.” And he was really upset by the whole thing, and he goes, “I just don't understand.” He says, “That [MME conversion] chart is so off, it's ridiculous.” He says, “They're basically saying that your oxycodone would be the same as if I were to give you…so many milligrams of morphine in a day.” And he goes, “If you took that much morphine, it would kill you almost immediately.”

Eleven out of 12 participants reported that the cost of obtaining their medications under post-reclassification requirements was financially burdensome. Costs included quarterly urinalysis, monthly doctor visits, and medications not covered by insurance. P5 stated that her husband owned his business and therefore did not have employer-sponsored health insurance. P5 did not qualify for Medicaid and needed to obtain coverage through the government marketplace. P5 could not find a general practitioner who was comfortable prescribing opioids after the 2014 reclassification. She tried to make appointments with more than 100 specialists, but none of them would accept marketplace coverage, an aversion she attributed to heightened DEA scrutiny of opioid use under government-sponsored plans. P5 therefore needed to pay for her doctors' visits out of pocket, a situation she described in stating,

> I cash pay $155 a month [for a specialist visit]. And then I have a $90 quarterly for drug tests . . . And of course, I'm paying $400 a month for [marketplace] insurance that doesn't cover anything. Yes, it is an incredible financial burden, having to go to your doctor every 30 days.

P12 reported that her doctor was willing to prescribe her two opioids if she agreed to take two non-opioid painkillers in addition. P12 could not afford the out-of-pocket costs of all four medications, though, and her pharmacist would not fill the opioid prescriptions unless the non-opioids were filled as well: "I didn't have enough money to afford the $400 for all four medications at the time. And she [the pharmacist] told the cashier do not give me the opioids if I could only afford some of the medications." P4 described the out-of-pocket costs of his medications after 2014 as, "An outrageous price that we couldn't afford." P7 offered a comparison in stating, "Before the reclassification, my medications and the doctor visit, my out-of-pocket a year would probably be three or four hundred dollars. My out-of-pocket now is probably $5,000 a year."

In summary, all 12 participants reported that the 2014 DEA reclassification of HCPs made the care they needed to manage their pain more difficult to obtain. Dosage restrictions and limits on the number of different opioids that could be prescribed to one patient made pain more difficult to manage. Administrative requirements like quarterly urinalysis, questionnaire screenings, random pill counting, and monthly specialist visits were arduous for most participants. The increased costs associated with the new administrative requirements were excessively burdensome for almost all participants.

Theme 3: Heightened Provider Vigilance About Opioid Abuse After the Reclassification Made Appropriate Care More Difficult to Access

All 12 participants contributed to this theme. Participants indicated that after the reclassification of HCPs in 2014, they observed increased resistance among doctors to prescribing opioids, as well as increased resistance to filling those prescriptions among pharmacists. The resistance they encountered in providers and pharmacists was associated with vigilance about the potential for opioids to be abused. Participants who felt that they received the benefit of the doubt prior to the reclassification felt pressured afterwards to demonstrate that they were not addicts engaged in drug-seeking behavior. All participants spoke of feeling (after the reclassification) that they were treated, by at least some practitioners and pharmacists, as if they were addicts or criminals whose opioid use was illegitimate.

Nine out of 12 participants reported that at least one doctor refused to prescribe the opioids they needed and were accustomed to taking. P1 said of the challenge of obtaining appropriate pain medication after the reclassification, “You can have both your breasts cut off, and you’re not getting anything but intravenous Tylenol. Tylenol destroys your liver, but that’s what they’re [doctors] going to give you.” P11 said of a practitioner from whom he received his HCP prescriptions without any trouble for the three years prior to the reclassification, “Once the insurance company started cracking down on the whole opioid thing, he bailed. He's like, ‘I'm not doing this anymore . . . You'll have to go somewhere else.’” P2 also reported that the doctor she had seen for 10 years refused to prescribe her HCPs after the reclassification:

> My doctor cut me off immediately, my primary care that would prescribe 120 Lortabs a month. He cut me off instantly. There was no ifs, ands, [or] buts. He was like, “You need to go to pain management.” There was no break structure, nothing like that. That’s when I actually experienced my first withdrawal symptoms and learned what that was.

P7 stated that her need for pain medications raised a barrier to her finding new doctors to manage her care:

> I can't find a primary care doctor to treat me as a primary care physician because I'm on pain medications. Anytime I go to any specialists, outside of my pain doctor . . . some places, they won't accept you if you're on pain medications because they don't want to be involved with it at all.

P5 offered statements that corroborated P7’s views:

> I mean, it affects us hugely. You know, for one thing, if you try to find someone…it's a full-time job trying to find a doctor. And that is not an over exaggeration. [T]rying to find someone to treat you is a 40-hour week job. But it is also really scary because, like I say, my doctor is probably in his late 60s, maybe early 70s, but no one coming out of medical school wants to do pain management. Because, why would you? Why would you want to go into a field that you might get arrested for?

All 12 participants reported that other providers required them to see pain management specialists to receive their opioid prescriptions. Participants reported that these specialists were able to prescribe the painkillers they needed but were at least as vigilant as general practitioners and other specialists. P2 described how she felt when being subjected to testing by her pain management specialist before she was discharged as a result of being unable to report for required appointments:

> I had to go into a pain management [clinic]. I was with them for a year and a half, and I had to do the whole bring in your pills and count them, go through [urine] testing, feeling like a drug addict. Unfortunately, I missed too many appointments, so they had to dismiss me . . . [I missed appointments because] I couldn't move. Like my hip would pop out and I just wasn't able to drive. My husband worked full-time, my family worked full-time, I didn't have ways to get there and that would be it. Unfortunately, there's too many times... And then after that, I went back to my primary, and he was like, "I can't help you." Then he's like, "I can't believe you missed your appointment. You will never find another

> doctor that’s going to prescribe you what he did.” Like, he was on point about that, because doctors then, just all of a sudden, nobody would prescribe you anything.

P4 said of the pain management clinic he needed to visit to receive his HCP prescriptions, “It was a 4 ½-hour trip each way.” P4 became unable to obtain the prescriptions he needed when, “I was told by my [pain management] doctor that he was no longer writing them, and he wouldn’t refer me to anyone else, but he wouldn’t release me, either.”

Eight out of 12 participants reported that some pharmacists resisted filling their HCP prescriptions. P10 stated, “Some would refuse to fill it, or they'd call [me over the PA] and try and make sure that I was actually getting that amount or whatever. And it embarrassed me to be called out.” P10 added that the violation of her privacy that occurred when a pharmacist announced her prescription over the public address system also put her in danger, because opioids were frequent targets for theft with a high resale value, and, “Anybody sitting in that area knew what I was getting, what I was walking out with . . . They can jump me. I'm by myself.” P12 said of a pharmacy she had been using “for many, many years,” that after the reclassification, “They started giving me attitude about [filling HCP prescriptions], and . . . I've been to three more who often are giving me problems.” P3 stated that when he brought an HCP prescription to his pharmacy after the reclassification,

> I’m waiting to get that filled. And I go in there [to the pharmacy’s waiting area], and [the pharmacist] comes in there, and she’s like, “Here’s your prescription, and

> I'm burning it." And she had like a fishbowl with all these ashes in it of burned-up prescriptions, you know, from people bringing them in. And she says, "You're not getting them filled, and we don't want your business anymore," and all of this. And I'm in shock because I didn't know about doctor shopping or none of that. This is brand-new.

Five out of 12 participants reported that they no longer went to emergency rooms because the doctors there regarded them as drug-seeking addicts, and it humiliated them to be treated this way. P7 said of her last experience of going to an emergency room four years prior to time of study,

> The doctor was in the room, and he was like . . . "I'm just letting you know. We don't care how you act up in here. We're not giving you pain medication." I can't tell you how that breaks you down. I'm a very honest person. I have been a hard worker. I've worked since I was 14 years old. I've raised my family. I cannot believe that people think that every single person that's in pain is automatically a drug seeking person all of a sudden.

P1 reported that during the winter, her car slid on black ice, and she ran directly into a cement wall on an interstate onramp. She did not go to the emergency room. When she saw her pain management specialist several days afterwards, he reprimanded her for not going directly to an ER after the accident, and she replied, "I told him, I am not going to go and be ridiculed." P4 provided a response that corroborated P1's and P7's in stating, "I refuse to go to the hospital because you will instantly be labeled as a drug-seeker if you even bring up the word 'pain.'" P9 had two stokes in 2017 from lack of pain control which raised blood pressure to dangerous levels. This is how she described the experience at the hospital:

> The first time I went in [to the ER] for the stroke, the doctor came in and told me he would not be giving me any pain medication. I was like, "First of all, I didn't come in here for pain medication. I had a stroke on my front lawn, and I couldn't even move." So, we got the patient advocate involved because I wasn't in there for pain. I was in there for a stroke.
>
> You're judged the minute you walk in the [ER] door. They're judging you because you want something for pain, and they treat you like you're not even human. Don't even go in there and tell them you're in pain, because they don't even want to hear it. You can be in there for something totally different. But the first thing, they're like, "You're not getting no pain meds." I was supposed to have [spinal] surgery, and they told me they would treat my pain post-surgery with Tylenol. I will never go back to the hospital.

Seven out of the 12 participants stated that they believed their ability to access appropriate levels of opioid medications was further directly limited by their physicians' offices as a result of 2016 CDC guidelines on pain. Five of the participants related that their doctor's offices specifically restricted patients from going above 90 MMEs. This is despite the fact that these guidelines were intended for application by primary care physicians, not chronic pain being managed by pain specialists. Provider confusion on how to appropriately apply CDC recommendations for the treatment of acute versus chronic pain has further influenced opioid restrictive policies.

P4 had his medications reduced after the publication of the 2016 CDC guidelines on pain stating:

> I don't have the option of going to the hospital to say "hey, I'm in a flareup… can you guys help me?" Like I said, the minute you bring up pain, you're labeled as a drug seeker and then they put you under the category of acute pain on the CDC guidelines…[T]he head of the CDC, everybody, came out and said that we, chronic pain patients do not fall under the acute guidelines. But yet, that's what doctors follow.

P5 stated that she had also been told by her physicians that her pain medication options were limited because of the 2016 CDC guidelines on pain. She expressed that she believed that these guidelines were expressly responsible for harming the chronic pain community:

> [T]he biggest thing that affected the chronic pain community is the 2016 CDC guidelines. Which I'm sure a lot has been, you know, a lot written about that. And then 90 MME equivalents is what really has completely, completely screwed us. They say you are only supposed to be on 90 [MMEs]. So, all these states made laws based on those guidelines. Which the FDA told the CDC, "you shouldn't publish these because of the effects they will have on chronic pain patients." And then since they got so much blowback, the CDC said, "oh well, we only meant that for acute care and for primary care doctors".

P7 shared that her pain management physician was disheartened about state and federal monitoring of chronic pain practitioners:

> [My doctor] said, "We're changing our processes for two reasons. One, we don't want the DEA to have any reason to come into our office, and two, the State of Louisiana, in 2017, wrote laws around the 2016 [CDC] guidelines."

In summary, experiences of reduced quality of life were a common theme related to the treatment of chronic pain and opioid-restricting policies among the study participants. Reduced quality of life took a variety of forms for participants. Most participants experienced increased functional impairments as a result of their inability after the reclassification to obtain the care they needed to manage their pain effectively. Increased functional impairments were associated with strain on relationships and decreased productivity. For most participants, intolerable pain resulting from the unavailability of needed treatment had triggered suicidal thoughts.

In summary, participants reported that after the reclassification, provider resistance to prescribing opioids, and pharmacists' reluctance to fill such prescriptions, made appropriate care more difficult for them to access. Provider reluctance for many participants took the form of an outright refusal by doctors they had seen for years before the reclassification to continue prescribing their painkillers. Some participants encountered barriers in seeking needed help from new physicians, who did not want to be involved with a patient who took opioids. Emergency room doctors were described as particularly blunt in assuming that any patient reporting pain was a drug-seeker, to such an extent that some participants were too humiliated to visit an emergency room again, regardless of their need. Some pharmacists humiliated participants and violated their privacy when refusing to fill or resisting filling opioid prescriptions. Pain management specialists were often difficult to access and had rigid administrative requirements that burdened patients, sometimes to such an extent that they could not obtain the care they needed. Access to care was further limited by policies designed around the 2016 CDC guidelines on pain. These policies were instituted at the provider and state levels. Many of these blanket policies would appear to violate the guidelines they were meant to follow by removing the physician's ability to perform an individual cost/benefit assessment.

Research Question 2

RQ2 was as follows: What common themes related to the treatment of chronic pain and opioid restricting policies are present among the study participants? Two of the themes identified during data analysis were used to address this question. The themes were (Theme 4) shame and stigma and (Theme 5) reduced quality of life.

Theme 4: Shame and Stigma

All 12 participants contributed to this theme. Experiences of shame and stigma were a common theme related to the treatment of chronic pain and opioid-restricting policies among the study participants. Participants reported that as sufferers of chronic pain, they experienced stigmatization, with physicians and loved ones frequently conflating legitimate pain management needs with drug addiction. Participants also felt that providers placed the burden of proving they weren't opioid abusers on them, and they felt shame at feeling suspected of dishonesty and drug addiction. Shame and anxiety were particularly acute when participants were afraid of being dismissed by their doctors and subsequently unable to obtain the treatment they needed, potentially resulting in their needing to acquire their medication through the black market.

Ten out of 12 participants reported feeling shamed by providers who appeared to suspect them of drug-seeking behavior. P12 reported the public humiliation she experienced when her pharmacist interrogated her before filling her prescription:

> The [pharmacist's] questions like, "Well, are you taking anything else? Well, we need to get another medication that's non-opioid or we can't continue to give you these." They always filled it, but there were several times they actually reduced me to tears, and they were doing this out-loud, in front of other customers. And it just became such a horrible situation, just mean . . . It was her attitude, treating me like an addict when I clearly wasn't.

P5 joined P12 in reporting humiliation resulting from pharmacists' suspicions: "You always get the dirty looks of the pharmacist, and people want to give you a lecture before they give you your pills. I can't even count how many times that's happened." P7 said of pharmacists, "They look at you like you're a drug addict and treat you pretty much the same way. They're rude. They tell you that you don't need to be on medication, even though they don't have a clue what's wrong." P7 described the inappropriate treatment she received at pharmacies in stating, "I've had so many instances where the pharmacist tech would berate me in front of customers, like, 'What's wrong with you? Explain why you need pain medication. You're too young,' or, 'You don't look like you're in pain.'" P2 also expressed embarrassment related to filling her opioid prescriptions at a Walgreen's Pharmacy:

> The pharmacist was like yelling at me about how long I had been on these opioid medications and "obviously they're not working, because I wouldn't be taking

> them this long.” And he is like, “you’re taking all this and you’re so young” and I felt so embarrassed, and I ended up leaving that pharmacy to go to Rite Aid.

P8 related similar experiences with pharmacists who requested, not only diagnosis codes, but copies of her medical records; a request her doctor flatly denied as baseless:

> I would go in [to the pharmacy] and introduce myself and say, "Breast cancer survivor, and I'm someone who can't have any more surgery, and I am now limited to pain medication." And that's when the pharmacist started saying things like… she wanted a copy of my medical record. And my doctor said, "Absolutely not." My pain doctor said, "That is not up to her, find another pharmacy, (name redacted). She's not getting your medical records. It's ridiculous." And so, then you're off to find another pharmacy.
>
> And so, I ended up having to search for a pharmacy that knew that doctor well enough to know that he was the real deal... So, getting my prescriptions filled has been forever a challenge in different ways, like I said, first not knowing if they were going to have it and then kind of searching around for it. And then having the pharmacist starting to become much more particular, they wanted diagnosis codes, they wanted to speak with the doctor, they wanted medical records, at one point in time, there was a form that they wanted to be filled out by the doctor stating why I was on the medication, why I've been on it so long, and how and when he was going to taper me off of it. And unless he had a plan to get me off the medications, they would not fill it. So, he's like, "Then I'll find a new pharmacy." …So yes, since after 2016, there's been, I can't even begin to tell you

> the stories of horrible pharmacists and the discrimination that happens. And you know, I have literally had pharmacists look at me and say, "You don't look sick enough to need this medication."

P4 reported feeling humiliated and shamed when prescribing physicians treated him as if they suspected him of being an opioid abuser, stating that he encountered this mistreatment frequently and from a variety of doctors:

> I feel like people on heroin get treated better than us chronic pain patients . . . I was treated like I was abusing my meds, or I was addicted. But yet, they [doctors] wouldn’t come out and say it, because they had no factual evidence to it. But I feel like we’re lower than the scum of the earth at this point. That’s how we’re treated. The minute you speak of pain, it’s instant, you’re a drug seeker.

P3 indicated that in his pain management clinic, the precautions and restrictions implemented to limit opioid abuse were demeaning: “You’re run through like a piece of cattle, and they give you these prescriptions. You get there, you keep your mouth shut, you better not talk in the waiting room. I mean, it’s just gotten ridiculously embarrassing.” P4 perceived sufferers of chronic pain as forced to make a stark choice between monthly humiliation from doctors and pharmacists or the risks associated with purchasing pain medication on the black market:

> It’s sad that that’s where it is for the [chronic pain] community now for most of us, that you’re given the option of, be treated like a criminal and hope that they’re [doctors and pharmacists] going to care and help you. Or you can play Russian

> roulette and go to the streets and hope you don’t get a pill laced with fentanyl that kills you. Just to get pain relief.

Participants’ experiences of shame when providers appeared to suspect them of drug-seeking were compounded by their perception of a pervasive, societal stigmatization of sufferers of chronic pain who used prescribed opioids to manage their pain. P1 said of the pervasive stigmatization she perceived sufferers of chronic pain as facing, “The public believes we are addicts or we have OUD [opioid use disorder].” P11 spoke of the pervasive confusion of sufferers of chronic pain with abusers of street drugs in stating, “I think 70% of the opioid crisis is from illegal drugs on the streets . . . People that really need pain meds for pain, they're not the problem, [but] we all got thrown in the same pond.” P8 said of the suspicion of drug addiction she encountered among members of the public that it was a consequence of public discourse that did not distinguish between medically necessary opioid use and addiction to street drugs: “I do not understand why people who are addicted to drugs are in the same conversation with pain patients who need medication . . . People who have legitimate pain need to be treated as the medical patients they are, not drug-seekers.” P5 attributed the stigmatization of sufferers of chronic pain in part to media coverage that associated pills with addictions and overdoses caused by fentanyl, normally found on the black market as a powder:

> I don’t remember who it was [that] published an article the other day [about] how overdose rates are continuing to go up in their county. And they published it with the stock photos of bottles of pills. And then down at the bottom, they have a tiny little mention that 95% of these overdose deaths involve fentanyl. And it’s like,

> you are leading to the misinformation when you put pictures of pills in a story and you’re talking about people who died, not from pills. These deaths are unrelated to pills.

Participants felt stigmatized not only by public discourse, but by the influence of that discourse on their own loved ones. P7 reported that two of her sisters were nurses and added,

> Before the reclassifications and the guideline changes, my sisters never cared about [P7’s and their mother’s use of HCPs for pain management]. They were very supportive of the situation with my mom and myself. But since then, I really feel a disconnect. I feel like I can't talk to them about it because I may be judged, or they probably do judge me for it. They know how hard it is for us because I bring my mom for us to get to the doctor, to get our medications every month. And they never offer any support.

When asked if his family members had reached a tipping point related to his pain, P4 stated:

> My children absolutely. And that was reached rather quickly by them after the accident. Now my wife, I believe she’s at that phase now because she was there for everything and I don’t know how she did it. I don’t know how she continued to stay by my side and take care of me and stuff. But she’s at that point that she can’t do it anymore because I’m not happy anymore. I’m not myself anymore. I don’t even know who I am anymore. I don’t know what my purpose is anymore, besides to suffer, and she sees all that. She knows how I feel, and I think she’s

> now at that point. I legitimately have nobody left and it's sad, I mean, because I truly love all of them with all my heart and I don't want to be that way towards them is. It's just I can't control it anymore because I'm so angry because of pain and I'm so angry at the way that I've been treated by the medical community when there's absolutely no reason that I… should have been treated this way.

In summary, a common theme in participants' treatment of chronic pain and opioid-restricting policies was shame and stigma. Participants felt shamed by doctors and pharmacists who presumed they were drug-seeking addicts, particularly when resistance to prescribing opioids or filling those prescriptions was associated with privacy violations, public humiliation, and implicit accusations of dishonesty and illicit behavior. Pervasive public discourse that conflated legitimate use of prescription opioids for pain management with addiction to and overdoses from street drugs further contributed to participants' shame and stigmatization. Participants described themselves as particularly frustrated and hurt when that discourse influenced their loved ones to withdraw emotional and practical support.

Theme 5: Reduced Quality of Life

All 12 participants contributed to this theme. Eleven out of 12 participants described significant functional impairment resulting from their inability, after the reclassification, to obtain the medication they needed to adequately manage their pain. P1, who worked full-time outside the home prior to the reclassification, said that as a result of her inability at time of study to manage her pain under the new restrictions, "I can't do anything. I sit on the couch all day on a heating pad. My house is a wreck. I have no life. I can’t walk my dog anymore.” Of the resulting strain on relationships, P1 added, “It took my grandkids a long time to adjust to the fact that we weren’t ever going to go do anything anymore,” citing activities they had previously enjoyed such as riding bikes, hiking, and camping. P11 said of his reduced functioning, “If I have flare-ups, which happen all the time, there's times I'm having spasms, like I can't get up or I'll be on the floor or I'll just be in bed.” P11 said of the resulting strain on his closest relationships, “There's family functions I've missed . . . I'd have a shorter fuse. I would have sleeping issues. And a lot of times my family felt the effects of that. You know, crappy dad.” P4 said that when his pain management became inadequate after the reclassification, “I couldn’t lift my arm. I couldn’t use it. I couldn’t use my hand. I couldn’t even open it. I couldn’t dress myself. I couldn’t shower myself . . . It was so humiliating.” Of the resulting strain on his relationships, P4 stated, “I was ruining all the friendships and relationships I had with everybody because I was so miserable and in so much pain.” P4 said of the consequences of these functional impairments for his quality of life, “My complete quality of life is gone. I lost my business again that I had started. I don’t work now. I’m back to square zero, basically. So yes, I’m very, very angry. I’m bitter at the world, honestly.”

Eleven out of 12 participants experienced moderate to severe emotional distress, at least monthly, related to anxiety about whether or not their doctors would continue to prescribe their needed opioid medications, whether or not their pharmacies would fill their opioid prescriptions in a timely manner or the potential for embarrassing public interactions with pharmacy staff when filling opioid prescriptions. P1 stated that she worries, “every month, and I am dead serious, I wonder if this is going to be the month they cut me off.” P7 confirmed P1’s sentiments concerning the uncertainty of access to appropriate pain management: “It's a scary feeling. You don't know what's going to happen from day to day.” P9 reported that her uncontrolled pain causes her to have panic attacks.

P5 discussed how her anxiety was linked to the extreme difficulty she had finding a doctor to manage her pain after her previous physician stopped treating patients with opioids:

> One of my doctors discharged me in August 2019 because he didn’t want to continue to cover people who were taking long-term [opioid] medication. He switched to basically just doing steroid shots. And I called over 100 doctors and none of them will take marketplace plans… I’m terrified every time I go see him that he’s going to tell me he’s retiring. Absolutely terrified because I don’t know what I will do if he retires. I can’t find someone else. And I’m sure all of us feel the same. If he got hit by a car today, I don’t know what I would do.

Two participants (P11 and P12) reported good relationships with both their doctors and with their pharmacists. Both, however, also reported anxiety related to their physicians and the continuation of their current pain management treatments. P11 admitted that he is, “worried as hell,” that his pain management physician will retire.

P12 echoed this sentiment stating:

> I know that if he [my pain management physician] ever did anything to lower my medications or taper me, cut me off, whatever, I know that it would be outside of

> his control. It happened to me when it happened with my old doctor's office and that fear has never left me. He reassures me up one side and down the other, but I just can't shake that anxiety. And the closer it gets to my appointment time; I get almost nauseous."

Nine out of 12 participants experienced social isolation, geographic isolation, or a combination of the two. These participants expressed that their feelings of sequestration were founded in the restrictions and stigma of being a patient with chronic pain requiring opioid therapy. P10 said her elevated level of functional impairment after the reclassification drastically impacted her socialization: "I don't leave the house. I've almost become a hermit because it hurts to move . . . I've lost basically my enjoyment. I only get out for doctor's appointments." P2 expressed that her lack of desire to socialize was also related to a decrease in her functional status after the reclassification: "I don't go out as much at all because I have nothing to talk about because I'm just always in pain, so I bring no value to anything . . . I can't be the mom I should and used to be." When asked how her anxiety about how her decreased pain management affected her relationships, P9 stated, "Now I stay to myself. Like [my husband will] drag me out of the house. I hate going out. I just do not like leaving my house.

Two participants (P1 and P6) expressed frustration and sadness at their inability to visit family members. P1 explained that she was unable to leave her state for more than three weeks because of restrictions on the filling of her opioid medications:

> See I live in West Virginia. I have family in Florida. I have family…in Indiana. I want to be able to travel. I can't. I'm trapped in West Virginia. See, I have to be

> here every month, to get my medication. With the telemedical, I can be anywhere. But, prescriptions, they will not fill in any other state. So that means, every three and a half weeks, I have to come back to West Virginia, no matter where I'm at, to get my medicine.

P6 stated that her lack of adequate pain management after the reclassification meant that she was unable to see her family:

> I may never see my family again because I moved over a thousand miles away and then I got sick. And I cannot airline travel without having pain care…[T]he fact is, without at least some medication to treat some of the pain, I will never see my children or my family again… I had my treatment taken away, so I don't have the strength to go see them now. So, that's probably one of the cruelest things.

Opioid restricting policies affecting when patients may refill prescriptions caused P9 to miss her mother-in-law's funeral. P9 was required to fill her opioid medication in her home state of Virginia on the 30th day of the previous prescription. Her doctor would not authorize her to fill the prescription on the 28th day. P9 would have experienced withdrawal from her opioid medication if she completed her trip without the medication refill.

Eight out of 12 participants stated that intolerable pain sometimes caused them suicidal thoughts. P4 stated that he had attempted suicide because of his chronic pain: "I tried to commit suicide and everything else over all this stuff. Sadly, my wife had to find me unresponsive and not breathing. So, I went through some dark days." P5 reported a suicidal plan for when her pain became intolerable. She said of the motive for having such a plan, “How much can anyone take? And it's not just how much pain can you take, but how much do you have to try to find another doctor, someone that will take you seriously?” Of her suicidal planning, P5 said, “I’ve always said that when [pain] gets to that point [of being intolerable], I will do it [commit suicide] in the CDC. I will do it in the offices of the CDC because they are to blame for it.” P7 said that as a result of pain, shame, and stigma, “I've contemplated suicide on several occasions.” P9 said that on occasions when her pain seemed intolerable, “I'd think of committing suicide, yes. I don't think I would because I don't want to hurt my kids. I would never put that on them. But has it crossed my mind? Absolutely.”

Summary

Two research questions were used to guide this study. RQ1 was: How do patients with chronic pain describe their perceptions of their pain management treatment before and after the 2014 DEA reclassification of products containing hydrocodone? Three of the themes identified during data analysis were used to address this question. The first RQ1 theme was: chronic pain was manageable before the DEA reclassification. All 12 participants contributed to this theme. The finding indicated that participants considered their chronic pain to be manageable using prescribed HCPs before the 2014 reclassification by the DEA. Participants’ descriptions of successful pain management varied. For six out of 12 participants, successful pain management enabled them to work full-time. One additional participant was able to work part-time. Two participants were unemployed but were able to work. Three out of 12 participants were classified as disabled prior to 2014 because of the conditions that caused their chronic pain, but they described their previous pain management as making their pain levels tolerable.

The second RQ1 theme was: new restrictions associated with the reclassification made appropriate care more difficult to access. Participants reported that the 2014 DEA reclassification of HCPs made the care they needed to manage their pain more difficult to obtain. Dosage restrictions and limits on the number of different opioids that could be prescribed to one patient made pain more difficult to manage. Administrative requirements like urine drug screening, questionnaire screenings, random pill counting, and monthly specialist visits were arduous for most participants. The increased costs associated with the new administrative requirements were excessively burdensome for almost all participants.

The third RQ1 theme was: heightened provider vigilance about opioid abuse after the reclassification made appropriate care more difficult to access. Participants reported that after the reclassification, provider resistance to prescribing opioids, and pharmacists' reluctance to fill such prescriptions, made appropriate care more difficult for them to access. Provider reluctance for many participants took the form of an outright refusal by doctors they had seen for years before the reclassification to continue prescribing their painkillers. Some participants encountered barriers in seeking needed help from new physicians, who did not want to be involved with a patient who took opioids. Emergency room doctors were described as particularly blunt in assuming that any patient reporting pain was a drug-seeker, to such an extent that some participants were too humiliated to visit an emergency room again, regardless of their need. Some pharmacists humiliated participants and violated their privacy when refusing to fill or resisting filling HCP prescriptions. Pain management specialists were often difficult to access and had rigid administrative requirements that burdened patients, sometimes to such an extent that they could not obtain the care they needed. The 2016 CDC guidelines on the treatment of pain further influenced provider vigilance and opioid restricting policies. Misapplication or misinterpretation of these guidelines at both the provider and legislative levels resulted in the loss of the individual risk/benefit assessment indicated.

RQ2 was: What common themes related to the treatment of chronic pain and opioid restricting policies are present among the study participants? Two themes were used to address this question. The first RQ2 theme was: shame and stigma. A common theme in participants' treatment of chronic pain and opioid-restricting policies was shame and stigma. Participants felt shamed by doctors and pharmacists who presumed they were drug-seeking addicts, particularly when resistance to prescribing opioids or filling opioid prescriptions was associated with privacy violations, public humiliation, and implicit accusations of dishonesty and illicit behavior. Pervasive public discourse that conflated legitimate use of prescription opioids for pain management with addiction to and overdoses from street drugs further contributed to participants' shame and stigmatization. Participants described themselves as particularly frustrated and hurt when that discourse influenced their loved ones to withdraw emotional and practical support.

The second RQ2 theme was: reduced quality of life. Reduced quality of life took a variety of forms for participants. Most participants experienced increased functional impairments as a result of their inability, after the reclassification, to obtain the care they needed to manage their pain effectively. Increased functional impairments were associated with strain on relationships and decreased productivity. For most participants, intolerable pain resulting from the unavailability of needed treatment had triggered suicidal thoughts. Chapter 5 includes discussion, interpretation, and implications of these findings.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this phenomenological study was to understand how the U.S. DEA's 2014 reclassification of HCPs affected patients with chronic pain. A significant problem with current federal opioid policy in the United States is that federal policy makers have inadvertently instituted measures that harm patients with chronic pain (Kroenke et al., 2019). Researchers in the United States, Poland, and Canada believe that opioid-restricting regulations impede appropriate access to pain management medications for patients and should be reformed using evidence-based methods (Cleary & Maurer, 2018; Covvey et al., 2015; Dzierżanowski & Ciałkowska-Rysz, 2017; Vogel, 2017). Gathering this evidence requires scrutiny of the impact of regulations on patients requiring long-term treatment with opioids. This study was conducted to address the current lack of research available on the experiences of patients with chronic pain in accessing appropriate pain treatments. Data collection in this qualitative, phenomenological study was through one-to-one, semistructured interviews with a purposive sample of 12 adult participants.

The audio-recorded data from the telephone interviews was transcribed verbatim and analyzed using Giorgi's (2009) five-step, descriptive phenomenological procedure to identify common themes in participants' lived experiences. Five themes were identified during data analysis to address the five research questions. The themes were as follows: (a) chronic pain was manageable before the DEA reclassification, (b) new restrictions associated with the reclassification made appropriate care more difficult to access, (c) heightened provider vigilance about opioid abuse after the reclassification made appropriate care more difficult to access, (d) shame and stigma, and (e) reduced quality of life.

The purpose of this chapter is to present discussion and interpretation of the study findings. The following section of this chapter is an interpretation of the findings, in which the findings are compared to the relevant, previous literature. Next, this chapter includes a description of the study limitations, followed by recommendations for further research. This chapter continues with a section addressing the implications of the findings, including recommendations for practice. A concluding statement ends this chapter and the dissertation.

Interpretation of the Findings

This interpretation of the findings is organized under the five themes identified during data analysis and first presented in Chapter 4. The purpose of this section is to indicate how the findings in this study confirm, disconfirm, or extend the relevant, previous literature described in Chapter 2. Under the subheading for each finding, a brief summary of the finding is also included.

Theme 1: Chronic Pain Was Manageable Before the DEA Reclassification

The finding indicated that participants considered their chronic pain to be manageable using prescribed HCPs before the 2014 reclassification by the DEA. This finding confirmed previous literature indicating that pain management efficacy for many patients was higher before the reclassification and that it declined afterwards. In a study by Chambers et al. (2016), 61% of respondents with fibromyalgia indicated that their pain management was more effective before the reclassification, and that the reclassification significantly and immediately disrupted their established pain management therapies. Golembiewski (2015) and Mack (2018) found that many providers who were able to prescribe HCPs for effective pain management before the reclassification were compelled to switch to less-effective, Schedule III treatments such as Tylenol with codeine as a result of the reclassification.

The findings in the present study potentially extended those of previous researchers in indicating that all 12 participants experienced a significant decline in the efficacy of their pain management treatments immediately after the reclassification. Although qualitative findings such as those in this study are not generalizable, this finding suggests that it may be fruitful to conduct additional quantitative research to determine whether higher percentages of patients with conditions causing chronic pain other than fibromyalgia or cancer experienced significant disruptions in their therapies after reclassification. Most patients in this study suffered from chronic pain-causing conditions that made the existence and intensity of their pain difficult or impossible to verify objectively. It is possible that patients of this kind suffered more disruptions to their established pain management regimens after the reclassification than patients with an objectively measurable condition such as cancer.

Theme 2: New Restrictions Associated With the Reclassification Made Appropriate Care More Difficult to Access

This finding indicated that regardless of the level of success with which participants were able to manage their pain before the 2014 DEA reclassification of

HCPs, pain management became significantly more challenging after the reclassification. One new set of challenges consisted of the new administrative requirements that were imposed as safeguards to prevent abuse of HCPs. Participants cited requirements such as quarterly urinalysis for drug screening, random pill counts, monthly specialist visits, and caps on the number of different opioids that could be prescribed and on MMEs as decreasing the accessibility of appropriate care.

These findings confirmed those in the previous literature indicating that new administrative requirements associated with the reclassification caused measurable disruptions in patients' ability to obtain effective treatment. In a meta-analysis of 122 studies assessing the prevalence of pain, more than one-third of patients with cancer and cancer survivors stated difficulty filling prescriptions for opioids, a percentage that significantly increased after 2016 (Page & Blanchard, 2019). In the 2017 oncology practice census performed by the American Society of Clinical Oncologists, 40% of practices reported that their patients were actively encountering impediments to filling opioid prescriptions related to pill caps, dosing limits, and the need for insurance authorization of prescriptions (Page & Blanchard, 2019). It is significant to note that these are patients with active cancer diagnoses and those with chronic pain conditions attributable to previous cancer diagnoses. Chambers et al. (2016) found that patients with fibromyalgia experienced increased financial burdens related to the need for an office visit each month to obtain new prescriptions, and poorly managed pain related to medication substitutions or the inability to access prescribed HCPs.

Participants in this study expressed perceptions confirming the findings of previous researchers that current public policies impose undue burdens on sufferers of chronic pain without effectively addressing opioid abuse. Policies imposed at the state and federal levels (including the DEA reclassification of HCPs) to combat opioid abuse have little evidence to support their effectiveness (Coleman, 2015; Seago et al., 2016). Current public health policies are focused on MMEs, prescribed days of therapy, and pill targets, as participants in the present study confirmed. Mundkur et al. (2017) concluded that there are no legitimate data demonstrating that arbitrary limits on MMEs or days of therapy reduce addiction rates or are otherwise beneficial to patients. Instead, as participants in the present study confirmed, public policy uninformed by evidence-based guidelines has imposed unnecessary burdens on patients with a legitimate need for pain management involving HCPs (see Chambers et al., 2016; Page & Blanchard, 2019).

Theme 3: Heightened Provider Vigilance About Opioid Abuse After the Reclassification Made Appropriate Care More Difficult to Access

Participants indicated that after the reclassification of HCPs in 2014, they observed increased resistance among doctors to prescribing opioids, as well as increased resistance to filling those prescriptions among pharmacists. This study was intended in part to examine the extent to which patients continued to receive pain management from their regular primary care providers or required referrals to pain management specialists. All participants in this study were required to obtain their opioid prescriptions from pain management specialists continually or at some time since the reclassification. Participants reported that the reason for their referral to pain management clinics and specialists was the refusal of other providers to prescribe opioids. Many of the participants also reported the belief that policies created through the misapplication or misinterpretation of the 2016 CDC guidelines on the treatment of pain further restricted their access to care.

These findings confirmed those of previous researchers who have found that a significant factor in assessing the effects of the HCP reclassification is how it affected provider prescribing habits. The primary finding by researchers across the board was that the reclassification of HCPs resulted in a dramatic decrease in HCP prescriptions (Bernhardt et al., 2017; Chumpitazi et al., 2017; Coleman, 2015; Gibson et al., 2020; Hatfield et al., 2016; Northrup et al., 2019; Seago et al., 2016; Raji et al., 2018). Jones et al. (2016) found that prescriptions for HCPs dispensed by pharmacies fell 22% in the 12 months following reclassification. Because these providers were unable to write prescriptions for HCPs, other, often less effective, medications were used, resulting in inadequately managed pain (Golembiewski, 2015; Mack, 2018). Dineen and DuBois (2016) reported that physician fear of medical board discipline, increased malpractice liability, legal sanctions, and even criminal convictions related to opioid prescribing have severely impacted the physicians' abilities to fulfill their obligations to treat pain. The reclassification of HCPs has forced these practitioners to either change how they manage their patients' pain or to refer their patients to a pain management specialist.

The present study has extended the findings in the previous literature by employing a phenomenological design to characterize patients' lived experiences of the alteration in provider prescribing habits after the reclassification. Participants reported that they and some of their providers were bewildered by the suddenness and arbitrariness of new federal and state restrictions. Most notably, participants in this study reported that their experiences included instances of privacy violation, public humiliation, and shame associated with heightened vigilance about opioid abuse among providers. Participants reported experiences such as being interrogated about their prescription use in front of other patients in pharmacies and being treated with suspicion by doctors. One participant stated that a pharmacist burned his HCP prescription in front of him and other patients. All participants reported that they felt doctors and pharmacists treated them “like a drug addict” or “like a criminal” after the reclassification. These findings have extended the previous literature by indicating that the consequences of the reclassification to chronic pain patients transcend medical considerations related to treatment efficacy. The consequences also included experiences of shame and stigmatization; a finding further explored in Theme 4.

Theme 4: Shame and Stigma

Experiences of shame and stigma were a common theme related to the treatment of chronic pain and opioid-restricting policies among the study participants. This finding confirmed and extended those in the previous literature. There have been increasing anecdotal accounts that restrictions cause harm to patients (Mundkur et al., 2017). One vector found to be harmful to patients with chronic pain is the stigmatizing language frequently used in opioid research papers and subsequently in opioid policies (Broyles et al., 2014). These terms cause patients with chronic pain to feel stigmatized while also deterring people with opioid use disorder from seeking treatment (Mundkur et al., 2017).

Findings identified through the phenomenological design used in this study have extended those in the previous literature. Most significantly, the findings have indicated that experiences of shame and stigma are the predominant theme in the reported lived experiences of this sample of patients with chronic pain. Participants described public discourse that conflated the use of prescribed opioids for management of chronic pain with addiction to street drugs as causing family members to withdraw emotional and practical support, resulting in feelings of isolation and shame. Provider vigilance about opioid abuse was often experienced as an implicit accusation of dishonesty. In the experiences of all participants, the attribution of dishonesty and drug-seeking behavior was occasionally made explicit, sometimes publicly. When pharmacists loudly disputed the legitimacy of opioid prescriptions in front of other patients, or when providers in emergency rooms reacted to any mention of pain with unfounded accusations of drug-seeking, participants felt shamed, unjustly accused, and humiliated.

Several participants in this study indicated that the humiliation they experienced when obtaining pain management treatment from doctors was so intense that they were occasionally tempted to seek pain relief from black-market opioid products. They experienced this temptation even though they described themselves as abhorring criminality and aware that use of street drugs involved a high risk of fatal overdose. This finding was consistent with that of Mundkur et al. (2017), who documented that patients who become desperate to obtain some level of pain relief, and who are unable to access prescribed opioids due to restrictions, may turn to illicit substances. These findings suggested that emotional distress arising from arbitrarily restrictive public policies may endanger sufferers of chronic pain, such as by causing them to avoid needed emergency room care or to seek black-market substitutes for legal but humiliating treatment. It was also notable that the theme of shame and stigma was more common in participants' responses than the theme of reduced quality of life, which included increased pain and associated functional impairment.

Theme 5: Reduced Quality of Life

Findings indicated that experiences of reduced quality of life were a common theme related to the treatment of chronic pain and opioid-restricting policies among the study participants. This finding confirmed those of previous researchers who indicated that the reclassification resulted in undertreatment of pain for many patients who previously relied on therapies involved opioids. LeBaron et al. (2019) found that pain was considerably undertreated in 60-90% of patients with cancer. Both patients with cancer and those with other chronic pain conditions have significant difficulty accessing appropriate opioid pain medications (LeBaron et al., 2019; Page & Blanchard, 2019; Chambers et al., 2016). Additionally, the restrictions surrounding regulations for accessing opioid medications directly affected most of the study participants as evidenced by noted descriptions of social and/or geographic isolation. The findings in the present study extended those of previous researchers by indicating the intensity of the distress participants felt when their pain was no longer adequately managed. A majority of participants reported that intolerable pain levels and the resulting functional impairments had caused them to consider suicide, with one participant having already attempted to kill himself for this reason. As with the theme related to shame and stigma, this finding suggested that intangible consequences of opioid-restricting public policies can result in tangible danger to patients with chronic pain.

The themes indicating participants' experiences of reduced quality of life and shame and stigma after the DEA reclassification were significant in relation to the theoretical framework of narrative-based bioethics. Bioethics, a branch of ethics focused on moral questions related to medicine and medical treatment, can be discussed either in terms of principlism or narrative. Principlism in ethics involves the deduction of ethical guidelines from a set of principles that are accepted as axiomatic and invariable. While principlism can be useful in ensuring that overarching considerations such as the autonomy of persons are respected, the guidelines deduced from the foundational principles are not amenable to modification according to the needs and special circumstances of individuals. Narrative-based bioethics may be used to supplement principlism by centering the stories of individuals to ensure that ethical decisions are sensitive to legitimate, individual needs.

In the present study, the DEA reclassification may be conceptualized as based on the ethical principle of protecting persons and preserving life, in this case by restricting the availability of addictive opioids to prevent accidental overdoses and other negative consequences of opioid abuse. The policymakers behind this principled alteration of DEA classification rules did not sufficiently take into account the needs and circumstances of a large number of individuals, however, as the major findings in this study have suggested. Narrative-based bioethics, in which the stories of individuals are reported as a means of ensuring that ethical decisions are sufficiently adapted to the needs of persons they effect, is recommended as a necessary supplement to the principlism behind the DEA reclassification. When principled decisions harm vulnerable persons as the DEA reclassification has done, the stories of the persons who are negatively impacted should be adduced as evidence of the need for policies that allow the legitimate, medical needs of all individuals to be met without undue restrictions.

Limitations of the Study

This study had three significant limitations, two of which were methodological and one of which was associated with the study design. The methodological associations were entailed by the qualitative approach used in this study. First, qualitative findings are not generalizable, meaning that the findings in this study cannot confidently by attributed to target population as a whole (Yin, 2016). This limitation is a consequence the grounding of all qualitative data in specific perspectives and contexts, and with the advantage in qualitative research of being able to investigate a phenomenon in its natural setting, without separating it from its social, organizational, and personal contexts (Merriam & Tisdell, 2016).

The second methodological limitation is that qualitative findings are not objective, but instead are potentially influenced by the biases and preconceptions of the participants and the researcher (Merriam & Tisdell, 2016). This limitation potentially threatened the credibility, dependability, and confirmability of the findings (Denzin & Lincoln, 2008). To mitigate the potential for participants' individual biases to influence the findings, common themes across the experiences of all or most participants were identified as the findings. To mitigate the potential for researcher bias to influence the findings, the bracketing procedure described by Giorgi (2009) was implemented as the first step of data analysis.

The limitation associated with the study design was a consequence of the delimitation of data collection to participant self-reporting. This limitation is common in phenomenological studies, in which data about participants' perceptions and lived experiences is unlikely to be accessible through sources other than self-reporting (Merriam & Tisdell, 2016). This limitation potentially threatened the credibility and dependability of the findings (Denzin & Lincoln, 2008). Identifying themes across the experiences of all participants mitigated the threat that any inaccuracies in participants' responses would influence the findings significantly. Comparisons in this chapter between the findings and the previous literature have further strengthened the credibility and dependability of the findings by indicating that they are consistent with those of previous researchers, as recommended by Shenton (2004).

Recommendations

The first recommendation for future research is that a quantitative study be conducted to confirm or disconfirm the generalizability and objectivity of the findings in this study. Quantitative research using a validated questionnaire instrument and an appropriately large, random sample of the target population would be appropriate for this purpose. The benefit of conducting such research is that it could potentially strengthen the utility of the findings in this study as a basis for policy recommendations. Such research would address the methodological limitations in this study.

The second recommendation for future research is that this study be replicated using different samples. The findings in this study are believed to be trustworthy, but given the methodological limitations of all qualitative research, the transferability of the findings must be assessed on a case-by-case basis (Denzin & Lincoln, 2008). Replication of this study using different samples can assist in confirming the transferability of the findings to other settings and in refining the findings prior to their validation through quantitative research.

The fourth recommendation is that narrative-based bioethics be employed as a framework for gathering, understanding, and presenting the stories of individuals whom the DEA reclassification has harmed. Principled ethics can allow for fairness through universality, but only when all the individuals affected by ethical decision-making are similarly situated. The DEA reclassification has imposed restrictions on chronic pain treatment that cause shame and stigma to sufferers and reduce their quality of life. These individuals have legitimate, medical needs confirmed by their doctors, and they should not be treated as though they are likely to be drug addicts. In other words, sufferers of chronic pain are differently situated than opioid abusers, and restrictions devised to prevent opioid abuse should not be applied to them. Narrative-based bioethics indicates that telling such individuals' stories is the first step toward justifying and implementing the policy changes these patients need and deserve.

Implications

The findings in this study have underscored the urgency of implementing evidence-based opioid restrictions rather than arbitrary ones, and on more effectively targeting addiction remediation policies toward abusers of opioids rather than patients with chronic pain who have legitimate pain management needs. The findings in this study and in the previous literature have indicated that patients who need HCPs for pain management experience reduced quality of life, shame, and stigma as a result of arbitrary opioid-restricting policies, heightened provider vigilance, and indiscriminate public condemnation of opioid use (Chambers et al., 2016; Coleman, 2015; Dineen & DuBois, 2016; LeBaron et al., 2019; Mundkur et al., 2017; Page & Blanchard, 2019; Seago et al., 2016). Findings in this study have added that the intangible consequences of opioid-restricting policies and discourse such as shame, emotional distress, and functional impairment resulting from increased pain create real dangers for patients with chronic pain. Dangers include suicide risk and increased motivation to engage in the high-risk behavior of purchasing narcotics through the black market. Increased functional impairment and severe pain may also cause patients with chronic pain to experience significantly decreased productivity and strain on relationships. The potential for positive social change associated with these findings is that they may contribute significantly to the evidence indicating the need for a revision of public policy to ensure that the needs of patients with chronic pain for pain management are met without unnecessary, negative consequences.

Three practical recommendations have emerged from a comparison of the findings in this study to the previous literature. First, it is recommended that federal policymakers restore discretion in pain management to doctors, and that federal and state oversight be limited to monitoring data such as number of opioid prescriptions issued for indicators that this discretion is being abused. Findings in this study and in those of numerous previous researchers have indicated that opioid-restricting public policies deprive doctors of the ability to treat patients for pain in the manner their familiarity with the patients' needs and medical expertise indicate is most appropriate (Bernhardt et al., 2017; Chumpitazi et al., 2017; Coleman, 2015; Gibson et al., 2020; Hatfield et al., 2016; Northrup et al., 2019; Seago et al., 2016; Raji et al., 2018). Restoring discretion to doctors would free them to provide appropriate care.

The second recommendation for practice is that policymakers at the state and federal levels refine public messaging about opioid abuse to target the abuse of illicit street drugs that account for the overwhelming majority of negative societal effects of opioid abuse (Haynes et al., 2016; Kertesz et al., 2017; McCall et al., 2017; Mundkur et al., 2017). A refinement of public messaging to distinguish legitimate use of prescription medications to manage pain from the illicit abuse of substances obtained through the black market can contribute to reduced shame and stigmatization among patients with chronic pain, as findings in this study and in Broyles et al. (2014) and Mundkur et al. (2017) have indicated. Such refinements can take forms as simple as not using images of prescription pill bottles to illustrate cautionary information about opioid abuse and overdoses.

The third recommendation for practice is that doctors, pharmacists, and other providers treat patients with legitimate pain management needs in the same manner that they treat other patients. Some of the provider discrimination against sufferers of chronic pain who need opioids for effective pain management may be attributable to excessive and arbitrary state and federal interference in doctors' prescribing practices, as Dineen and DuBois (2016) found. However, participants in the present study reported discriminatory behaviors on the part of providers that were entirely discretionary, such as one pharmacist's theatrical burning of a participant's prescription, pharmacists' frequent haranguing of participants in front of other patients, and doctors' unfounded accusations of drug-seeking behavior. As findings in this study have indicated, discretionary provider behaviors of this kind may cause patients with chronic pain to suffer significant emotional distress. These forms of provider discrimination may also contribute to tangible, negative outcomes for patients, such as elevated suicide risk and increased motivation to purchase narcotics on the black market.

Conclusion

The purpose of this phenomenological study was to understand how the U.S. DEA's 2014 reclassification of HCPs affected patients with chronic pain. The study aim was to address the current lack of research available on the experiences of patients with chronic pain in accessing appropriate pain treatments. The findings in this study and in the previous literature have indicated that patients who need opioids for pain management experience reduced quality of life, shame, and stigma as a result of arbitrary opioid-restricting policies, heightened provider vigilance, and indiscriminate public condemnation of opioid use. Findings in this study have extended the previous literature by indicating that intangible consequences of opioid-restricting policies and discourse such as shame, emotional distress, and functional impairment resulting from increased pain may create real dangers for patients with chronic pain. Dangers include suicide risk and increased motivation to engage in the high-risk behavior of purchasing narcotics through the black market.

The potential for positive social change associated with these findings is that they may contribute significantly to the evidence indicating the need for a revision of public policy to ensure that the needs of patients with chronic pain for pain management are met without unnecessary, negative consequences. Changes to public policy are recommended to restore discretion in pain management to treating physicians who are familiar with patients' needs and histories, and whose medical expertise enables them to engage in evidence-based decision-making rather than arbitrarily restrictive practices. Changes to public messaging were recommended to reduce stigma and shame in patients with chronic pain by intentionally distinguishing between legitimate use of prescribed medications and abuse of opioids purchased through the black market. Changes to provider behavior were recommended to reduce discriminatory treatment of patients with chronic pain. Overall, findings underscored that evidence-based opioid-restricting policies are urgently needed. Patients with chronic pain may be punished for their legitimate medical needs through discrimination, stigmatization, and inadequate care to an extent that may cause them to engage in high-risk behaviors. These findings demonstrate the importance of treating patients with chronic pain in the same manner as any other patient with a legitimate medical need. Current opioid restrictions, which are based on arbitrary benchmarks, unsupported by strong scientific evidence, and imposed without consideration of many of the persons they affect, are unethical when applied to individuals who are not opioid abusers. Considering the voice of patients such as those who sufferer with chronic pain is a first step toward increasing the fairness of restrictions by better understanding the unnecessary harm they do to non-abusers.

References

Abutalibov, R., & Guliyev, S. (2013, June 17). *Qualitative research and the process of constructing qualitative data*. http://www.ssrn.com/abstract=2233863

Bailey, L. F. (2014). The origin and success of qualitative research. *International Journal of Market Research, 56*(2), 167-183. https://doi.org/10.2501/IJMR-2014-013

Bailey, R. W., & Vowles, K. E. (2015). Chronic noncancer pain and opioids: Risks, benefits, and the public health debate. *Professional Psychology: Research and Practice, 46*(5), 340-347. http://doi.org/10.1037/pro0000022

Baškarada, S. (2014). Qualitative case study guidelines. *The Qualitative Report, 19*(24), 1-18. http://nsuworks.nova.edu/tqr/

Bernhardt, M. B., Taylor, R. S., Patel, N., Fox, K. A., & Glover, C. (2017). Evaluation of opioid prescribing after rescheduling of hydrocodone-containing products. *American Journal of Health-System Pharmacists, 74*(24), 2046-2053. https://doi.org/10.2146/ajhp160548

Beskow, L. M., Check, D. K., Namey, E. M., Dame, L. A., Lin, L., Cooper, A., Weinfurt, K. P., & Wolf, L. E. (2012). Institutional Review Boards' use and understanding of certificates of confidentiality. *PLOS ONE, 7*(1), 1-10. https://doi.org/10.1371/journal.pone.0044050

Broyles, L. M., Binswanger, I. A., Jenkins, J. A., Finnell, D. S., Faseru, B., Cavaiola, A., Pugatch, M., & Gordon, A. J. (2014). Confronting inadvertent stigma and pejorative language in addiction scholarship a recognition and response. *Substance Abuse, 35*, 217-221. https://doi.org/10.1080/08897077.2014.930372

Burkholder, G. J., Cox, K. A., & Crawford, L. M. (2016). *The scholar-practitioner's guide to research design* [Vitalsource Bookshelf version]. https://bookshelf.vitalsource.com/books/9781624580314

Carvalho, A. S., Pereira, M., Jacomo, A., Magalhaes, S., Aroujo, J., Hernandez-Marrero, P., & Schatman, M. E. (2018). Ethical decision making in pain management: A conceptual framework. *Journal of Pain Research, 11*, 967-976. http://dx.doi.org/10.2147/JPR.S162926

Centers for Disease Control and Prevention. (2019, April 24). *CDC advises against misapplication of the Guidelines for Prescribing Opioids for Chronic Pain*. https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

Centers for Disease Control and Prevention. (2020, May 5). *Commonly used terms*. https://www.cdc.gov/drugoverdose/opioids/terms.html

Chambers, J., Gleason, R. M., Kirsh, K. L., Twillman, R., Webster, L., Berner, J., Fudin, J., & Passik, S. D. (2016). An online survey of patients' experiences since the rescheduling of hydrocodone: The first 100 days. *Pain Medicine, 17*, 1686-1693. https://doi.org/10.1093/pm/pnv064

Chumpitazi, C. E., Rees, C. A., Camp, E. A., & Bernhardt, M. B. (2017). Decreased opioid prescribing in a pediatric emergency department after the rescheduling of hydrocodone. *Journal of Emergency Medicine, 52*(4), 547-553. http://dx.doi.org/10.1016/j.jemermed.2016.08.026

Cleary, J. F., & Maurer, M. A. (2018). Pain and policy studies group: Two decades of working to address regulatory barriers to improve opioid availability and accessibility around the world. *Journal of Pain and Symptom Management, 55*(2S), 121-136. http://dx.doi.org/10.1016/j.jpainsymman.2017.03.029

Colaizzi, P. (1978). Psychological research as the phenomenologist views it. In R. S. Valle & M. Kings (Eds.) *Existential-phenomenological alternatives for psychology* (pp. 48-71). Oxford University Press.

Coleman, J. J. (2015, April 10). Rescheduling hydrocodone products: Addressing the abuse of America's favorite opioid. *ASAM Magazine*. https://www.asam.org/QualityScience/publications/magazine/read/article/2015/04/10/rescheduling-hydrocodone-combination-products-addressing-the-abuse-of-america-s-favorite-opioid

Covvey, J. R., Pfalzgraf, A. R., & Cohron, P. P. (2015). U.S. pharmacist opinions regarding the rescheduling of hydrocodone combination products: A pilot study. *Pharmacy, 3*, 129-136. https://doi.org/10.3390/pharmacy3030129

Curtiss, C. P. (2016). I'm worried about people in pain: Efforts to address prescription opioid abuse may lead to unintended consequences. *American Journal of Nursing, 116*(1), 11.

Denzin, N. K., & Lincoln, Y. S. (2008). *Collecting and interpreting qualitative materials* (Vol. 3). Sage.

Dineen, K. K., & DuBois, J. M. (2016). Between a rock and a hard place: Can physicians prescribe opioids to treat pain adequately while avoiding legal sanction. *American Journal of Law & Medicine, 42*, 7-52. https://doi.org/10.1177/0098858816644712

Dzieržanowski, T. & Ciałkowska-Rysz, A. (2017). Accessibility of opioid analgesics and barriers to optimal chronic pain treatment in Poland in 2000-2015. *Support Care Cancer, 25*, 775–781. doi: 10.1007/s00520-016-3460-3

Drug Enforcement Administration. (n.d.). *The Controlled Substances Act*. Retrieved from the U.S. Department of Justice's website https://www.dea.gov/controlled-substances-act

Dubiel, H. (2011). What is "narrative bioethics". *Frontiers in Integrative Neuroscience*, 5(10). https://doi.org/10.3389/fnint.2011.00010

Flemming, M.L., Driver, L., Sansgiry, S.S., Abughosh, S., Wanat, M., Pickard, T., Reeve, K., & Todd, K.H. (2016). PSY98: Impact of hydrocodone rescheduling on Texas physicians' future pain management. *Value in Health*, 19, A258.

Foundation Recovery Network. (2020). *History of the opioid epidemic*. Retrieved from https://dualdiagnosis.org/infographics/history-of-the-opioid-epidemic/

Gibson, D.C., Chou, L.-N., Raji, M.A., Baillargeon, J.G., & Kuo, Y.-F. (2020). Opioid prescribing trends in women following mastectomy or breast-conserving surgery before and after the 2014 federal reclassification of hydrocodone. *The Oncologist, 25*, 281-289. http://dx.doi. org/10.1634/theoncologist.2019-0758

Giorgi, A. P., & Giorgi, B. M. (2003). *The descriptive phenomenological psychological method.* In P. M. Camic, J. E. Rhodes, & L. Yardley (Eds.), *Qualitative research in psychology: Expanding perspectives in methodology and design* (p. 243–273). American Psychological Association. https://doi.org/10.1037/10595-013

Giorgi, A. (2009). The descriptive phenomenological method in psychology: A modified

Husserlian approach. Duquesne University Press.

Golembiewski, J. (2015). Rescheduling of hydrocodone combination products: Potential impact and alternatives for postoperative pain management. *Journal of Perianesthesia Nursing, 30*(3), 244-248. http://dx.doi.org/10.1016/j.jopan.2015.01.005

Guba, E. G., & Lincoln, Y. S. (1981). Effective evaluation: Improving the usefulness of evaluation results through responsive and naturalistic approaches. San Francisco, CA: Jossey-Bass.

Haker, H. (2006). Narrative bioethics. In: Rehmann-Sutter, C., Duwell, M., Miethm D. (eds) Bioethics in Cultural Contexts. International Library of Ethics, Law, and the New Medicine, vol 28. Springer, Dordrecht. https://doi.org/10.1007/1-4020-4241-8_24

Hatfield, M.D.., Sangsgiry, S.S., Johnson, M.L., Essien, E.J., Todd, K.H., & Fleming, M.L. (2016). Rescheduling hydrocodone combination products: Assessing the impact on opioid utilization. *Value in Health, 19*, A255.

Haynes, A., Kleinschmidt, K., Forrester, M.B., & Young, A. (2016). Trends in analgesic exposures reported to Texas Poison Centers following increased regulation of hydrocodone. *Clinical Toxicology, 54*(5), 434-440. http://dx.doi.org/10.3109/15563650.2016.1148720

Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigour in qualitative case-study research. *Nurse Researcher, 20*(4), 12-17. doi:10.7748/nr2013.03.20.4.12.e326

Ingham-Broomfield, R. (2015). A nurses' guide to qualitative research [online]. *Australian Journal of Advanced Nursing*, *32*(3), 34-40. Retrieved from http://www.ajan.com.au/

International Association for the Study of Pain. (2018). *Declaration of Montreal*. Retrieved from https://www.iasp-pain.org/DeclarationofMontreal

Irvine, A., Drew, P., & Sainsbury, R. (2012). "Am I not answering your questions properly?" Clarification, adequacy and responsiveness in semi-structured telephone and face-to-face interviews. *Qualitative Research, 13*(1), 87-106. doi:10.1177/1468794112439086

Jones, C.M., Lurie, P.G., & Throckmorton, D.C. (2016). Effect of US Drug Enforcement Administration's rescheduling of hydrocodone combination analgesic products on opioid analgesic prescribing. *JAMA Internal Medicine, 176*(3):399–402. doi:10.1001/jamainternmed.2015.779*9*

Kertesz SG, Gordon AJ. (2017, February 24). Strict limits on opioid prescribing risk the 'inhumane treatment' of pain. *Stat News.* Retrieved from https://www.statnews.com/2017/02/24/opioids-prescribing-limitspain-patients/

Kroenke, K., Alford, D.P., Argoff, C., Canlas, B., Covington, E., Frank, J.W., Haake, K.J., Hanling, S., Hooten, W.M., Kertesz, S.G., Kravitz, R.L., Krebs, E.E., Stanos, S.P., & Sullivan, M. (2019). Challenges with implementing the Centers for Disease Control and Prevention opioid guideline: A consensus panel report. *Pain Medicine, 20*(4), 724–735. doi: 10.1093/pm/pny307

LeBaron, V.T., Camacho, F., Balkrishnan, R., Yao, N., & Gilson, A.M. (2019). Opioid epidemic or pain crisis? Using the Virginia All Payer Claims Database to describe opioid medication prescribing patterns and potential harms for patients with cancer. *Journal of Oncology Practice, 15*(12), 653. https://doi.org/10.1200/JOP.19.00149

Liaw, V., Kuo, Y.-F., Raji, M.A., & Baillargeon, J. (2020). Opioid prescribing among adults with disabilities in the United States after the 2014 federal hydrocodone rescheduling regulation. *Public Health Reports, 135*(1), 114-123. doi:10.1177/0033354919892638

Lincoln, Y. G., & Guba, E. G. (1985). *Naturalistic inquiry*. Newbury Park, CA: Sage Publications, Inc.

Mack, R. (2018). Food and Drug Administration upscheduling of hydrocodone and the effects on nurse practitioner pain management practices. *Journal of the American Association of Nurse Practitioners, 30*, 312–319. doi:10.1097/JXX.0000000000000063

McCall, C., Baldwin, G.T., & Compton, W.M. (2017). Recent increases in cocaine-related overdose deaths and the role of opioids. *American Journal of Public Health, 107*, 430-432. doi:10.2105/AJPH.2016.303627

McCusker, K., & Gunaydin, S. (2015). Research using qualitative, quantitative or mixed methods and choice based on the research. *Perfusion, 30,* 537–542. doi:10.1177/0267659114559116

Merriam, S. B. (2009). Qualitative research: A guide to design and implementation. San Francisco, CA: Jossey-Bass.

Merriam, S. B., & Tisdell, E. J. (2016). *Qualitative Research: A Guide to Design and Implementation*. John Wiley & Sons.

Morse, J. M. (2015). Critical analysis of strategies for determining rigor in qualitative inquiry. *Qualitative Health Research, 25*, 1212-1222. doi:10.1177/1049732315588501

Mundkur, M.L., Gordon, A.J., & Kertesz, S.G. (2017). Will strict limits on opioid prescription duration prevent addiction? Advocating for evidence-based policymaking. *Substance Abuse, 38*(3), 237-238. https://doi.org/10.1080/08897077.2017.134519

Munhall, P.L. (1994). *Revisioning Phenomenology: Nursing and Health Science Research*. New York: National League of Nursing Press.

Northrup, T.F., Carroll, K., Suchting, R., Villarreal, T.R., Zare, M., & Stots, A. L. (2019). The impact of increased hydrocodone regulation on opioid prescribing in an urban safety-net health care system. *Journal of the American Board of Family Medicine, 32*(3), 362-374. doi: 10.3122/jabfm.2019.03.180356

Oehler, C., Day, R.L., Robinson, D.B., & Brown, L.H. (2016). Has the rescheduling of hydrocodone changed ED prescribing practices? *American Journal of Emergency Medicine, 34*, 2388-2391. http://dx.doi.org/10.1016/j.ajem.2016.09.002 0735-6757/

Page, R. & Blanchard, E. (2019). Opioids and cancer pain: Patient’s needs and access challenges. *Journal of Oncology Practice, 15*(5), 229. https://doi.org/10.1200/JOP.19.00081

Raji, M.A., Kuo, Y.-F., Adhikari, D., Baillargeon, J. & Goodwin, J.S. (2018). Decline in opioid prescribing after federal rescheduling of hydrocodone products. *Pharmacoepidemiol Drug Safety, 27*(5), 513–519. doi:10.1002/pds.4376

Ravitch, S. M., & Carl, N. M. (2015). *Qualitative research: Bridging the conceptual, theoretical, and methodological* [Vitalsource Bookshelf version]. Retrieved from https://bookshelf.vitalsource.com/books/9781483351759

Rubin, H. J., & Rubin, I. S. (2011). *Qualitative interviewing: The art of hearing data* (3rd ed.) [Vitalsource Bookshelf version]. Retrieved from https://bookshelf.vitalsource.com/books/9781452285863

Rudestam, K. E., & Newton, R. R. (2014). *Surviving your dissertation: A comprehensive guide to content and process* (4th ed.) [Vitalsource Bookshelf version].

Scholten, W. & Henningfield, J.E. (2016). Negative outcomes of unbalanced opioid policy supported by clinicians, politicians, and the media. *Journal of Pain & Palliative Care Pharmacotherapy, 30*(1), 4-12. https://doi.org/10.3109/15360288.2015.1136368

Seago, S., Hayek, A., Pruszynski, J., & Greene-Newman, M. (2016). Change in prescription habits after federal rescheduling of hydrocodone combination products. *Baylor University Medical Center Proceedings, 29*(3), 268-270.

Shenton, A. K. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information, 22*, 63-75.

Simon, M., & Goes, J. (2013). *Scope, limitations, and delimitations*. Retrieved from http://dissertationrecipes.com

Snyder, C. (2012). A case study of a case study: Analysis of a robust qualitative research methodology. *The Qualitative Report, 17*(26), 1-21. Retrieved from http://tqr.nova.edu/

Trafimow, D. (2014). Considering quantitative and qualitative issues together. *Qualitative Research in Psychology, 11*, 15–24. doi:10.1080/14780887.2012.743202

Trier-Bieniek, A. (2012). Framing the telephone interview as a participant-centered tool for qualitative research: A methodological discussion. *Qualitative Research, 12*(6), 630-644. doi:10.1177/1468794112439005

U.S. Department of Health and Human Services. (2018). *The Belmont Report*. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Vogel, L. (2017). Proposed opioid prescribing guidelines meet backlash. *Canadian Medical Association Journal, 189*(7), 189. doi: 10.1503/cmaj.1095393

Webster, L. R., Cochella, S., Dasgupta, N., Fakata, K. L., Fine, P. G., Fishman, S. M.Grey, T., Johnson, E.M., Lee, L.K., Passik, S.D., Peppin, J., Porucznik, C.A., Ray, A., Scnoll, S.H., Stien, R.L., & Wakeland, W. (2011). An analysis of the root causes for opioid-related overdose deaths in the United States. *Pain Medicine, 12,* S26–S35. http://dx.doi.org/10.1111/j.1526-4637.2011.01134.x

Yin, R. (2014). *Case study research*. Washington, DC: Sage Publications, Inc.

Yin, R. K. (2016). Qualitative Research from Start to Finish. The Guilford Press.

Appendix A: Demographic Collection Tool

Participant Number:

To be completed by the researcher at the beginning of the personal interview session

Please state your age:

Gender:

Ethnicity:

Marital Status:

Level of Education

Current Employment Status:

Employment status prior to the 2014 reclassification of hydrocodone:

Who do you live with?

What type of Health Insurance do you have?

What part of your body is most affected by pain?

Before the DEA reclassification of hydrocodone in 2014, how long had you used hydrocodone for pain management?

How many years, all together, have you used opioids for pain management?

Appendix B: Interview Tool

Topics to be covered during personal interviews

1. What made you want to participate in this study?
2. Describe your history of opioid use prior to 2014.
3. Tell me about your experience with filling opioid prescriptions through the years.
4. What challenges have you encountered?
5. Studies have shown that immediately following the reclassification of HCPs, patients experienced difficulty getting their regular pain medications from providers, difficulty filling prescription at pharmacies, increased health care costs. Many even resorted to using illicit drugs in an effort to control their pain or avoid withdrawal. Please describe how the 2014 reclassification of HCPs personally affected you and if you still feel as if your life continues to be impacted by opioid limiting legislation.
6. How do you feel about the restrictions placed on patients with chronic pain and the effect of these restrictions on your ability to access care? Do you feel you are unfairly punished for having chronic pain?
7. How have the "requirements" for pain patients such as pain contracts, drug tests, activity restrictions (not allowed to drink alcohol), and the need for monthly MD visits for prescriptions personally affected you? Tell me about how you incorporate the requirements of being a chronic pain patient with your life.

8. How do these restrictions affect your ability to work, interactions with family/friends, finances…
9. In what ways are you satisfied/dissatisfied with the management of your pain? How well does the doctor listen to you? How comfortable are you asking for increases in medications? What frustrates you most about your care?
10. What is your opinion on America’s “opioid crisis”?
11. How do feel that law makers could ensure that you receive the care you need while reducing opioid overdoses?
12. What areas of pain management would you like to see improved? How would you change the public’s negative view of patients with chronic pain?