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OPIOID AND NALOXONE PRESCRIBING PRACTICES IN MISSISSIPPI

By

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Alissa Damiens

Natalie Keyes

Gary Adam McPherson

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A Clinical Research Project
Submitted in Partial Fulfillment of the Requirements for the
Degree of Master of Science in Nursing, College of Nursing
and Speech Language Pathology
Mississippi University for Women

COLUMBUS, MISSISSIPPI

August 2017

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Graduate Committee Approval

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partial fulfillment of the requirements for the Degree of

Master of Science in Nursing

Approved:

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DEDICATION

The researchers wish to recognize their loved ones for their patience, reassurance, and sentiment throughout the graduate program and research process. The completion of this research project signifies the completion of the Master of Science in Nursing degree and the beginning of a new career. We cannot fully express how grateful we are for the support provided by our friends and families. We thank you profusely for the many sacrifices made while we pursued our dreams. Ultimately, without God's love, our success would have been unobtainable. We are eternally indebted to His grace and will strive to utilize the knowledge and skills we have acquired to instill God's grace in our patients.

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Abstract

The purpose of this study was to determine whether primary care providers (PCPs) in Mississippi are following the selected Centers for Disease Control and Prevention (CDC) guidelines published in March 2016 for prescribing opioids for chronic, non-cancer pain. The study also sought to determine if the selected providers prescribed naloxone for opioid overdose reversal. Drug overdoses have increased exponentially in the last 3 decades in the United States (Doyon, Aks, & Schaeffer, 2014)—leading to opioid overdose becoming the most frequent cause of accidental death. Opioid overdose death rates are so high the CDC declared it a problem of "epidemic" status in 2012 (Canada, DiRocco, & Day, 2014).

Mississippi ranks as one of the highest prescribing states for opioid analgesics.

For the purpose of this research, focus was placed on specific aspects of the CDC guidelines as follows: (a) consider nonpharmacological treatment or treat with nonopioids

first, (b) avoid prescribing opioids and benzodiazepines concurrently, and (c) check a urine drug screen prior to opioid initiation and yearly thereafter (CDC, 2016). The CDC now recommends prescribing naloxone, an opioid antagonist, to patients at risk for opioid overdose. Naloxone has demonstrated effectiveness in reducing opioid overdose mortality.

A nonexperimental, quantitative, descriptive, retrospective review of charts was performed in 6 primary care clinics in Mississippi staffed by physicians and family nurse practitioners. A convenience sampling of 600 charts for retrospective chart review was conducted. Inclusion criteria were age 18 years or older, medically treated long-term with opioids (≥ 2 prescriptions written > 21 days apart) for chronic non-cancer pain, and prescribed by a PCP.

The findings suggested that PCPs in Mississippi are not consistently following CDC guidelines for opioid prescribing. It should also be noted that, of the 600 charts reviewed, none of the patients were prescribed naloxone for reversal of a potential opioid overdose. Research demonstrated a need for increased awareness and education among PCPs regarding CDC guidelines for prescribing opioids.

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CHAPTER I

Dimensions of the Problem

Drug overdoses have increased exponentially in the last three decades in the United States (Doyon, Aks, & Schaeffer, 2014). More alarmingly, the leading cause of accidental death in the United States (U.S.) is overdose, specifically opioid overdose. Because opioid overdose death rates are so high, the Centers for Disease Control (CDC) declared this drug a problem of "epidemic" status in 2012 (Canada, DiRocco, & Day, 2014). In 2013, over 43,000 deaths were reportedly due to drug overdose in the U.S. Fifty-six percent were opioid-related deaths; of these, 37% were related to analgesic opioid prescription drugs (Wheeler, Jones, Gilbert, & Davidson, 2015). Prescription opioids account for the greatest negative effects associated with prescription misuse.

Mississippi ranks as one of the highest prescribing states for opioid analgesics where most pain medications prescribed are written by primary care providers and dentists. As of July 2016, hydrocodone is the most prescribed controlled substance in Mississippi, followed by alprazolam and oxycodone. These alarming statistics spotlight a major area of concern in our state for primary care providers (Mississippi State Department of Health, 2012)

Opioids can produce effects of pleasure where patients may intentionally abuse to seek self-gratification. This addiction is a serious problem that affects the health and social welfare of our society. Risk factors for overdose include receipt of more than 50 mg morphine equivalents, concurrent benzodiazepine use, or substance use disorder as reported by the American Medical Association, the Medical Board of California, and the Centers for Disease Control (CDC) (Behar, Rowe, Santos, Murphy, & Coffin,

2016). Due to growing concern over opioid misuse and overdose, recent guidelines have been published by the CDC to assist providers in safely prescribing these drugs. For the purpose of this research, focus was placed on specific aspects of these guidelines as follows:

- 1. Consider nonpharmacologic treatment or treat with nonopioids first.
- 2. Avoid prescribing opioids and benzodiazepines concurrently.
- 3. Check a urine drug screen prior to opioid initiation and yearly thereafter (CDC, 2016).

Recently, recommendations have been made to prescribe naloxone, an opioid antagonist, to patients at risk for opioid overdose. Reductions in opioid overdose mortality have been associated with the increased distribution of naloxone. As of August 2016, all states in the U.S. allow physicians and practitioners to prescribe naloxone to laypersons. Despite having the ability to prescribe naloxone, limited data exist suggesting that primary care providers are seeking recommendations to prescribe naloxone (Behar et al., 2016). Naloxone is a life-saving treatment that has increasingly been prescribed by some providers as an opioid reversal agent. Prescription naloxone has reversed more than 10,000 overdose cases between 1996 and 2010 according to the CDC (2016). However, rural communities have underutilization to many addiction treatment facilities which commonly offer naloxone. A study by Behar et al. (2016) found that when naloxone is prescribed by primary care providers the distribution is higher than with community distribution alone. Behar et al.'s (2016) statistical findings regarding naloxone were alarming and are as follows: 87% of patients reported they were prescribed opioids for pain, 53% reported taking opioids in a manner other

than as prescribed, 37% reported seeking medical treatment for overdose, 53% reported witnessing an overdose, and 27% reported being administered naloxone. Furthermore, 90% of patients had never received naloxone, 60% had never heard of it before the intervention, and 82% filled the prescription. These findings demonstrate that naloxone is drastically underutilized as a lifesaving reversal agent. (Behar et al., 2016)

Factors such as patient safety and addiction rates are primary concerns of prescribers. These concerns are justifiable as the misuse of prescription opioids is a major problem in the U.S. Incorporating screening and opioid education may be the first step by primary care providers in the prevention of opioid drug abuse. Providers may need to initiate a screening tool that highlights risk of misuse, especially for those prescribed opioids for chronic pain. Additionally, opioid education should be a key element of chronic non-cancer pain treatment modalities. The opioid overdose epidemic, whether intentional or accidental, continues to rise.

For the purpose of this research, focus was placed on the following: (a) adherence in Mississippi to select CDC guidelines for opioids; (b) prescribing frequency of naloxone by primary care providers; and (c) opioid education among chronic, non-cancer pain patients. Focus on these key areas may highlight areas with needed improvement in regard to Mississippi's opioid prescribing practices.

Purpose of the Research Project

The purpose of this study was to determine whether primary care providers in Mississippi are following the selected CDC guidelines, as outlined through questions posed by the current researchers for prescribing opioids and whether those providers prescribed naloxone for opioid overdose reversal. The selected questions follow the

treatment progression recommended by the CDC in regard to chronic, non-cancer pain treatment which is outlined as follows: nonpharmacologic therapy, nonopioid therapy, and obtaining a urine drug screen prior to initiating opioid therapy and then annually. It is also recommended to avoid concurrent benzodiazepine and opioid prescriptions.

Furthermore, the current researchers determined whether naloxone was being prescribed and whether education regarding opioid risks and opioid reversal was provided.

Significance of the Research Project

Overdose deaths due to opioids were recognized as an epidemic in 2012 (Doyon et al., 2012). Drug overdose-related deaths have surpassed deaths related to motor vehicle crashes. Now, deaths due to opioid overdose have exceeded the combined total deaths due to heroin and cocaine overdose (Center for Mississippi Health Policy, 2013). Healthcare providers lacked a general consensus on treatment of chronic, non-cancer pain prior to the release of the CDC's latest guidelines. This research project was designed to determine if prescribers in a defined region are adhering to the guidelines set forth by the CDC.

Future researchers can utilize results from this research to assess the urgency for further dissemination of education among practitioners regarding opioid prescribing practices in Mississippi. The results of this research identified the need for all healthcare providers, including nurse practitioners, to follow the selected CDC guidelines and provide patient education regarding opioid use. The lack of patient education regarding the side effects of opioids leads to misuse—oftentimes resulting in lethal overdose. In addition to patient education, provider education regarding appropriate chronic, non-cancer pain management aides healthcare providers in

increasing compliance and safety. This research also identified whether or not providers are prescribing naloxone for opioid overdose. Prescribing naloxone could be a significant component to caring for patients suffering from opioid addiction.

Research regarding prescription naloxone is significant because naloxone has been shown to decrease deaths related to opioid overdose.

The information obtained through this research demonstrates implications to all healthcare providers, including nurse practitioners. Primary care providers need to be prepared to provide proper treatment to these patients by being aware of the CDC prescribing guidelines so that patients are not inappropriately prescribed opioids. Also, nurse practitioners need to be aware of naloxone for opioid overdose so they can make an informed decision about prescribing or not prescribing naloxone.

Another component of prescribing opioids which holds significance predominantly to nurse practitioners in the primary care setting is education about opioid use. Nurse practitioners need to realize the impact they have on their patients when prescribing opioids. Each clinic visit is an opportunity for practitioners to educate patients about opioid use and misuse. Patients need to understand that improper use can be lethal. When nurse practitioners enforce the selected CDC prescribing guidelines, consider naloxone for opioid overdose and provide patient education. Enforcement of these guidelines could decrease the likelihood of negative outcomes due to opioid overdose.

Conceptual Framework

The theory proposed by Nola J. Pender, PhD, RN, FAAN, is entitled the Health Promotion Model (HPM). The HPM was the theoretical foundation for this body of

work. This model reflects a holistic view of nursing in which providers see patients as people who are responsible for their health and wellness. One significant goal of this research was to expound the relevance of the HPM for opioid prescribing practices in Mississippi.

To better understand the HPM and the application of the model to practice,

Pender defined many major concepts and definitions. These concepts and definitions
have expanded over the years; therefore, they are even more relevant to the promotion
of healthy lifestyles. The HPM consists of the following major concepts: individual
characteristics and experiences, behavior-specific cognitions and affect, and behavioral
outcome (Alligood, 2014). Providers use each of these concepts to predict how a
patient might respond during certain behavioral situations. The following discussion of
a research article review provides further explanation of the concepts and definitions of
Pender's theory applied in practice.

In the research, Nola Pender highlighted patient behavioral responses when counseled on the importance of physical activity. According to Eden, Orleans, Mulrow, Pender, and Teutsch (2002), the findings revealed that most patients struggle to maintain exercise goals. Eden et al. (2002) related the struggles to factors, such as differences in activity levels at the baseline and decreased provider intervention. Utilizing Pender's model in this study allowed the researchers to analyze the motive for physical inactivity.

Eden et al. (2002) first examined the individual characteristics and experiences of the population under study. These characteristics and experiences included sedentary lifestyles and minimal healthy habits. The behavior specific cognitions and affect

during the first part of the study revealed many barriers to action due to low self-efficacy (Eden et al., 2002). There were no specific interpersonal or situational influences listed. Due to the increased level of barriers to action (i.e., overweight, out of shape, and sedentary), the patients' perceived benefits of action did not result in health-promoting behaviors. However, after input and counsel from providers, the patients' behavior specific cognitions and affect changed. The outcome was health-promoting behaviors (Eden et al., 2002). The application of the HPM in this research mirrors how the current researchers applied the HPM to chronic pain patients.

As previously mentioned, the purpose this research was to explore opioid-prescribing practices in Mississippi and the use of naloxone for opioid overdose reversal. The HPM was used in this study to explore practitioners' tendencies to encourage health-promoting lifestyles to chronic pain patients. The HPM also was used as a guideline to assess positive or negative behavioral outcomes of opioid prescription to chronic pain patients.

The guidelines for opioid-prescribing set forth by the CDC can also be incorporated into the HPM. These recommendations served as a beneficial guide to this research project relating to chronic opioid use. Nola Pender's HPM predicts patients' tendencies on how everyone will participate in the behaviors that improve health. Pender's model has contributed to health promotion and has provided practitioners the framework to motivate patients to attain a state of well-being. The CDC guidelines also assist practitioners and other medical professionals with the appropriate measures necessary for monitoring the safety of individuals with chronic opioid use. Data

pertinent to this research can be hypothesized with the use of such guidelines; therefore, information can be examined for the continuum of research on this topic.

Research Questions

Health promotion is important in motivating patients with chronic pain to attain a healthier lifestyle by avoiding misuse of opioids. The purpose of this study was to explore whether primary care providers were following guidelines for prescribing opioids, prescribing naloxone as an opioid reversal agent, and providing sufficient education to patients prescribed opioids. The following research questions addressed each topic:

- 1. Are primary care providers in Mississippi compliant with the following selection of the CDC's latest guidelines for prescribing opioids for chronic pain?
- a. Nonpharmacologic therapy or nonopioid pharmacologic therapy first.
- b. Avoid concurrent prescribing of opioids and benzodiazepines.
- c. Check urine drug screen prior to opioid initiation and then annually.
 - 2. Are primary care providers in Mississippi prescribing naloxone for opioid overdose reversal?
 - 3. Do primary care providers provide education to patients regarding opioid overdose?

Definitions of Terms

For the purpose of this study, the following terms were defined with both theoretical and operational definitions. The theoretical definitions are concrete and broad. The operational definitions are abstract and define the utilization of terminology as it pertains to this research project.

Primary care providers (PCP)

Theoretical: The healthcare provider (i.e., the nurse practitioner, physician's assistant, or physician) to whom a patient first goes to address a problem with his or her health (Venes, 2013).

Operational: A healthcare provider who sees people that have common medical problems. This person may be physician, physician assistant, or a nurse practitioner.

Centers for Disease Control and Prevention (CDC) guidelines

Theoretical: A set of current and relevant guidelines published by a division of the U.S. Public Health Service headquartered in Atlanta, Georgia, that investigates and controls various diseases, especially those that have epidemic potential. The agency is also responsible for national programs to improve laboratory conditions and encourage health and safety (Venes, 2013).

Operational: A set of guidelines published by the CDC which offers recommendations for prescribing practices regarding the management of chronic, non-cancer pain. Specifically, the CDC recommends that prescribers follow the treatment

progression as follows: nonpharmacologic therapy, nonopioid therapy, and obtain drug screen initially and then annually before prescribing opioids.

Opioids

Theoretical: Any synthetic narcotic not derived from opium (Venes, 2013).

Operational: A synthetic drug designed to mimic the effects of opium or opiates; a narcotic prescribed by primary care providers to patients in this study.

Chronic pain

Theoretical: Long-lasting discomfort, with episodic exacerbations. Pain that lasts more than 3 months. Pain that lasts more than a month longer than the usual or expected course of illness or injury (Venes, 2013).

Operational: Pain lasting longer than 12 weeks or longer than normal tissue healing.

Non-pharmacologic therapy

Theoretical: Any therapy prescribed or recommended to improve health or wellness—not related to the use of drugs (Laurence, 2010).

Operational: Any therapy used to treat pain, excluding pharmaceutical drugs; including, but not limited to, cognitive behavioral therapy, physical therapy, exercise therapy, weight loss, biopsychosocial therapy, multimodal pain therapy, and interventional therapy.

Nonopioid pharmacologic therapy

Theoretical: The use of any medicinal treatment to reduce pain, with the exception of drugs falling within the chemical classification of opioids.

Operational: A drug therapy used to treat pain, excluding the opioid class of drugs; including, but not limited to, acetaminophen, nonsteroidal anti-inflammatory drugs, anticonvulsants, and antidepressants.

Concurrent prescribing (opioids and benzodiazepines)

Theoretical: Happening at the same time; simultaneous writing, or administering, of medications such as opioids and benzodiazepines.

Operational: Writing or administering opioids with benzodiazepines which is contraindicated by the latest CDC guidelines.

Benzodiazepines

Theoretical: Any group of chemically similar psychotropic drugs with potent hypnotic and sedative action; used predominantly as antianxiety and sleep-inducing drugs (Venes, 2013).

Operational: A class of drugs that can be harmful if taken in excessive amounts.

Urine drug screen

Theoretical: A test used to detect illegal and some prescription drugs in the urine including opioids and benzodiazepines.

Operational: Testing performed prior to prescribing of opioids to establish current social and medical habits and repeated periodically throughout care to confirm proper administration and avoid concurrent use with other drugs prescribed or illegal.

Naloxone

Theoretical: A drug that is antagonistic to the actions of narcotics and opiates, such as morphine, methadone, and opium. It is helpful in reversing the respiratory depression caused by an overdose of narcotics (Venes, 2013).

Operational: A drug prescribed by primary care providers in an outpatient setting to reverse the effects of opioid overdose.

Overdose

Theoretical: An excessive and potentially toxic amount of a medication given in error or taken intentionally (Venes, 2013).

Operational: An excessive or toxic amount of opioid ingestion requiring administration of the reversal agent—naloxone.

Education

Theoretical: Health information and instruction to help patients learn about specific or general medical topics, such as preventive services, the adoption of healthy lifestyles, the correct use of medications, or the care of diseases or injuries at home (Venes, 2013).

Operational: Information given to a patient regarding proper usage of opioids and the risks associated with opioids, such as central nervous system depression that could lead to respiratory depression or arrest. Education should also include risk of dependence as well as avoidance of alcohol and other sedatives.

Patient(s)

Theoretical: One who is sick with, or being treated for, an illness or injury (Venes, 2013).

Operational: One who is 18 years of age or older and is currently being treated for chronic pain with the use of opioid pain medication.

Assumptions

Assumptions in this study included the following:

- Adherence to CDC guidelines by primary care providers in regard to opioidprescribing practices will reduce the risk of opioid related overdose and opioid misuse.
- Naloxone prescription may prevent a fatal overdose secondary to opioid overdose but may increase risky behavior in patients presenting with chronic pain.
- 3. Patients presenting to the clinic with complaints of acute pain were being screened for chronic pain.
- 4. Primary care providers in Mississippi are following the latest CDC guidelines when prescribing opioids.

The current researchers assumed that the data required to perform this research would be available upon the review of the charts and data would be organized and comprehensible. It was assumed that data would be collected in a legal and ethical manner. Finally, it was assumed that the data collected would be correctly interpreted by the researchers.

CHAPTER II

Literature Review

The purpose of this study was to determine whether primary care providers were following CDC guidelines for prescribing opioids and whether these providers were prescribing naloxone for opioid overdose reversal. Drug overdoses have increased over the last three decades in the U.S., and Mississippi ranks as one of the highest states for prescribing opioids. The most frequent opioids prescribed, according to the Mississippi State Department of Health in 2012, are hydrocodone and oxycodone. Prescription opioid abuse leads to unintended overdoses and ultimately can result in death. These overdoses are related to patients' behavioral experiences regarding opioid use.

To expand knowledge of opioid overdoses and providers' prescribing habits, this research group reviewed numerous research articles. This chapter will present the conceptual framework and related literature through various research articles. The framework for this study and the literature review were used as evidence promoting the need for stricter compliance of CDC-prescribing guidelines and improved education for patients regarding opioid overdose. The literature review also highlighted the importance of prescription naloxone for opioid overdoses.

Conceptual Framework

In determining a conceptual framework for this research, the student researchers reviewed several studies which utilized Pender's HPM as the theoretical basis. One study which employed Pender's HPM was conducted by Conway, McClune, and Nosel (2007). The study focused on a significant problem in the U.S. regarding children's safety and the agriculture industry. Agriculture surpasses all others by measure of

dangerous workplaces, with an accidental work-related death rate six times greater than all other industries combined (Conway et al., 2007). In 1999, the National Agricultural Statistics Service (NASS) reported there were over 2 million farms nationwide. On these farms, 1.5 million children lived and/or worked. Reportedly, over 100,000 injuries occur annually in children while on farms. Of these, 100 children die each year.

Conway et al. (2007) conducted this pilot study to examine farm safety education for families and children provided by healthcare professionals. The researchers used Pender's model to depict how primary care providers (PCPs) promote healthy behaviors in their practice regarding farm safety education. Furthermore, the study was threefold in purpose: (a) quantify the number of farm accidents through PCPs healthcare records, (b) determine barriers to safety equipment or protocol, and (c) determine the rate at which PCPs provide education regarding farm safety. The conceptual framework for the study was based on Pender's HPM. The researchers discussed one of Pender's major assumptions that individuals are constantly transforming their surroundings, while at the same time their surroundings are constantly transforming the individual. Conway et al. (2007) stated that, "The individual variable of perceived benefits of action, personal barriers of action, perceived self-efficacy, activity-related effects, situational influences, and interpersonal influences can be modified to increase health-promoting behaviors" (p. 45).

The method utilized was a survey that focused on farm safety issues confronted by PCPs. Included in the survey were demographics, documented farm injuries, and PCPs' knowledge of farm safety educational materials. A panel of experts reviewed the content for validity. A convenience sample of 110 PCPs was used from 5 separate

northwestern Pennsylvania counties. The surveys were sent out via mail to be returned anonymously with prepaid return envelopes; follow-up reminders were sent at 2 weeks to increase response rates. There was a low return of 22 surveys.

The returned surveys included PCPs as the participants. These PCPs were medical, osteopathic, and chiropractic physicians; physician's assistants; and nurse practitioners. Injuries reported included lacerations, animal injuries, muscle strains, machinery/equipment injury, and one fatality. One child was mauled by an animal and required surgery. Forty-five percent of PCP's reported that their initial assessments included questioning new patients if children lived or worked on a farm. Eighteen percent (18%) of PCPs reported performing specific education on farm injury prevention. Only 5% had related handouts available for distribution; however, 73% voiced interest in attaining farm injury prevention materials.

The results of Conway et al.'s (2007) study found that additional education is recommended to promote safer farm environments for children. A limitation of the study would be generalization. A continuation of the pilot study would be required for validation using a larger population. Potentially, a continuation study could provide data to ensure health-promoting resources to decrease farm-related injuries and death.

Agazio and Buckley (2010) conducted a study to explore women's health promotion behaviors in the U.S. military. In this study, the researchers used a descriptive correlational design. Their conceptual framework was based on Pender's HPM, specifically two categories of factors: personal factors and behavior-specific cognitions. The purpose of the study was to differentiate between causative factors for health-promoting behaviors. Personal factors were defined as demographic

characteristics, perceived health status, and definition of health (Agazio & Buckley, 2010) while behavior-specific cognitions were defined as perceived self-efficacy and interpersonal influences (Agazio & Buckley, 2010).

The research questions focused on these personal factors and behavior-specific cognitions and their correlation to demographics, interpretations of health, self-worth, and resources. Another research objective was to decipher the differences among healthy behaviors in differing groups of military women. Agazio and Buckley (2010) believed that with more women involved in the military, there was a growing burden of balancing work and family responsibilities. Agazio and Buckley predicted that this, in turn, affected health-promoting behaviors. The population sample was comprised of 491 military women and included active duty, reservists, childbearing, and nonchildbearing individuals. The participants were recruited from 2 military hospitals and enrolled voluntarily via phone or email. Up to 150 participants were included in each group. If a participant volunteered, a study packet was sent with a stamped envelope to the participant. Included in the packet was a study instrument with instructions to complete and return in the stamped envelope. The study instrument included 2 of Pender's resources, the Perceived Health Status (Pender, Walker, Frank-Stromborg, & Sechrist, 1990) and the Health-Promoting Lifestyle Profile II (HPLP-II) (Pender et al., 1990); other instruments were included in the packet (Agazio & Buckley, 2010).

The instruments attained quantitative measurement of each of Pender's HPM variables and utilized several Likert-rating scales. Descriptive statistics were used and determined statistical significance of the data. Pearson correlation coefficients were also used to interpret the research findings. The research concluded that 59% of

participants were on active duty and 51.2% had children. The average age of participants was 37.2 years. Surprisingly, the most significant finding was the comparison between active duty women with children (ADWWC) and all other categories. ADWWC scored significantly higher for all health-promoting behaviors which was not the anticipated outcome based on previous research by Agazio and Buckley (2010). The researchers explained the findings, assuming ADWWC high scores were due to time management skills, improved organization, and increased awareness and commitment to personal wellness. The researchers suggested these attributes may have been acquired during motherhood due to role modeling and conscious efforts towards building healthy behaviors in children. Other findings were that all groups scored the highest in spiritual growth. Accordingly, all groups scored the lowest on ability to manage stress.

Agazio and Buckley (2010) concluded that, though the study validated Pender's model of behavior-specific cognitions (perceived self-efficacy and interpersonal resources), none of the personal characteristics (age, marital status, ethnicity, health conception scale, and personal health status) were determined to be significant indicators of health promotion amongst the groups. Limitations to the study could have consisted of higher proportion of Caucasians, sample age median of 37 years, recruitment site for participants, and possible lack of causative factors not identified in the study. The variance could have been explained in more detail had the researchers identified situational influences, barriers to health, and benefits of health promotion from Pender's most recent HPM. Another possible limitation was that there are factors unique to military women that have not yet been determined.

The implication of this body of research by Agazio and Buckley (2010) was that self-efficacy is highly predictive of successful health-promoting behaviors. Therefore, future healthcare interventions might include assisting in personal success recall strategies, assisting with achievable goal-setting, and sharing of successful strategies used by other women. The study also implicated that self-efficacy did not suffice on its own; instead, tangible support proved to be necessary to implement goal-reaching strategies. Interventions for this factor could be achieved at the organizational level by improving policies relating to extended hours for childcare, flexible work hours, family-friendly work environments, worksite health promotion programs, on-site health facilities, and respecting non-work hours. Pender's HPM guided the entire body of research. Each individual aspect of the study was based on Pender's model (Agazio & Buckley, 2010).

In conclusion, Pender's HPM was a solid model from which the student researchers based their work. Its holistic approach was applied to the current research and allowed the student researchers to carefully examine PCPs' health promotion strategies regarding opioid prescribing.

Review of Related Research

Review of research studies validated the necessity of the research topic of the student researchers. These research studies highlighted the importance of primary care providers' compliance to opioid prescription guidelines as well as the need for improved patient education regarding the consequences of opioid overdose. These studies also revealed providers' views on naloxone prescription for opioid overdose reversal.

Decision to prescribe opioids. Harle et al. (2015) explored the decision-making processes of primary care providers for managing patients' chronic pain with opioids. Many providers struggle to provide effective pain management while avoiding opioid misuse and abuse. According to the Institute of Medicine, chronic pain is a major burden on 100 million Americans annually. A lack of pain specialist physicians results in the need for primary care providers to manage chronic pain. Primary care providers also report frustration and hindrance in prescribing opioids due to lack of time and minimal training in chronic pain management. In this study, Harle et al. sought to determine if certain providers failed to use recommended guidelines due to lack of time and insufficient knowledge.

Harle et al. (2015) used qualitative interviews to conduct this study. The locations were 9 medical facilities in rural and urban settings in the Gainesville and Jacksonville areas of north central Florida. The providers, differing in age and experience, volunteered for the study and submitted written informed consent. Throughout the interviews, the providers discussed clinical information pertinent to them when prescribing opioids for chronic pain. After the interviews, the researchers identified 5 themes: (a) importance of objective and consistent information, (b) identifying *red flags*, (c) significance of physical function and goals, (d) trust, and (e) time constraints.

Each theme enlightened the researchers on the providers' decisions to prescribe or not to prescribe opioids. The first theme highlighted the issue of inconsistency with subjective versus objective information. Identifying *red flags* was an important theme because these revealed patients' tendencies to seek opioid treatment due to addiction.

The third theme established goals for seeking pain management, and the fourth theme addressed a provider's "sense" of a patient's need for pain management. The fifth theme developed due to providers' lack of time during clinic visits based on patients' comorbidities as well as chronic pain. After the study, Harle et al. (2015) acknowledged the need for future research to develop and disseminate decision support tools for prescribing opioids.

Harle et al. (2015) had strengths and weaknesses. Two strengths were identified: (a) dissimilarity in age and experience of the providers and (b) differentiation in practice specialty, location, and practice ownership. One weakness was the lack of transferability of decision-making approaches across different cultures and larger international boundaries. Unfortunately, the study also had limitations due to the small sample size consisting of providers only from only one state. As a result, the findings of Harle et al. (2015) did not reflect feelings and thoughts from provider groups in other states. The limitations in the current study may mimic this study's limitations due to sample size and population.

Harle et al. (2015) related to the current research by addressing the issues concerning opioid prescribing. While Harle et al. did not address any of the current researchers' research questions specifically, there was still enough information to strengthen the researchers' first question. This study explained that some providers have difficulty abiding by such guidelines due to certain barriers. The findings in this study strengthened the current researchers' foundation for the first research question by identifying providers' decision-making processes for prescribing opioids. While the current researchers may not directly respond to the challenge for future research, the

study will strengthen the need for future researchers to disseminate decision support tools and to provide education about managing chronic pain.

Opioid crisis and resolution. Wolfe, Bouffard, and Lowe (2016) discussed the problem of opioid overdoses. The Centers for Disease Control and Prevention stated that too many physicians are prescribing opioids to patients who are in serious pain without trying other methods first. Wolfe et al. (2016) wanted to discuss the problem of opioid overdoses and provide information on how to reduce the number of deaths from opioid overdoses.

The main objective of Wolfe et al. (2016) was focusing on the administering of naloxone (Narcan) to stop the effects of the opioid. The CDC labeled the epidemic of opioid overdoses in 2012, but the problem has only gotten worse. One reason for the growing epidemic is the availability of heroin in the U.S. Another reason is the growing number of prescriptions being given to patients for pain. Many of the overdose victims did not take the medication as prescribed or obtained the medication from someone else to try and eliminate their pain. Wolfe et al. (2016) listed four subcategories of prescription medicine: pain relievers, tranquilizers, stimulants (including Ritalin), and sedatives. About two thirds of the misused prescriptions were gotten from a friend or relative or were stolen. Wolfe et al. (2016) stated that in 2010 there were "enough prescriptions written annually for painkillers to medicate every adult American around the clock for a month" (p. 326). Some people even believe that the painkiller is safe because a physician prescribed it.

The population with the highest overdoses is non-Hispanic white males while overdoses among women are increasing. West Virginia has the highest overdose rate,

and North Dakota has the lowest. To reduce these numbers, the CDC recommends that the naloxone be administered when an overdose is expected. Many argue that prescribing naloxone to reduce the effects of the opioid will only encourage the continued use of the opioid. If a person stays off the opioid for 3 or more days, then the tolerance that has been built up will be reduced. A smaller amount of the opioid can cause an even greater risk because the tolerance level has been reduced.

Wolfe et al. (2016) recommended that naloxone be administered to reduce the effects of an overdose by policemen, emergency responders, and hospital staff. Wolfe et al. (2016) stated that anyone who administers the drug should be properly trained. A Good Samaritan law was passed that allowed someone to call in a suspected overdose victim without being charged with a crime involving drugs. The legislation from 2015 requires that anyone who might administer naloxone (e.g., physicians, physician assistants, advanced practice registered nurses, and dentists) must take a one-hour continuing medical education on safe opioid prescribing methods.

Specific guidelines were set forth by the CDC for prescribing opioids. These guidelines recommend that a doctor should not start with opioid medication, and alternative treatment should be tried first. The CDC also recommends setting a goal for how long the opioid should be prescribed. An immediate release opioid should be used instead of an extended release form. The lowest possible dose should be given. The physician should evaluate the benefits and the harm of the opioid medication. The physician should also avoid the opioid prescription if there are risk factors of an overdose. A urine test should be taken before prescribing the opioid to determine if the

patient is on any other drug. Finally, the physician should check the prescription drug monitoring system regularly.

Wolfe et al. (2016) was not based on studies that were conducted in a controlled environment with set members. Wolfe et al. (2016) presented their beliefs on the use of naloxone and discussed the necessity of using the drug for overdose victims to reduce the number of deaths. Wolfe et al. (2016) presented the information clearly and effectively and explained the steps to be taken in the event of a drug overdose and the dosage of naloxone which could be used. Wolfe et al. (2016) believed that physicians prescribed opioids too often before trying other methods like exercise, relaxation techniques, and others.

These authors were a knowledgeable group of experts who had PhDs or medical degrees, and they worked as mental health experts. Wolfe et al. (2016) realized the mental associations that could cause an overdose—stress, anger, depression, etc. To reduce the number of overdose deaths, Wolfe et al. (2016) encouraged physicians to be careful about prescribing opioid medications and encouraged the physicians to try other methods of pain relief before prescribing opioids. Of course, Wolfe et al. (2016) did not just advocate the use of naloxone, they also recommended treatment programs to reduce illegal drug use or misuse involving prescription medicine.

Better approach to opioid prescribing. Canada, DiRocco, and Day (2014) conducted a study to evaluate opioid-prescribing practices, providers' attitudes toward competent management of chronic non-cancer pain (CNCP) patients and knowledge regarding prescribing opioids. Misuse of prescription opioids is a major problem in the U.S., and opioid overdose death rates are so high that the CDC declared it a problem of

"epidemic" status in 2012. Canada et al. (2014) developed and implemented a new electronic medical record-based protocol to improve opioid prescribing practices. This protocol included an educational intervention for providers, standardization of documentation, and standardization of management of CNCP. The researchers tested their protocol and found providers who adhered had higher satisfaction rates with management of CNCP patients.

The apparent hypothesis for Canada et al. (2014) was that "a clinical protocol for opioid prescribing could improve the care that physicians and staff were providing to CNCP patients, as well as improve the satisfaction that clinicians felt in providing this care" (Canada et al., 2014, p. 2). An additional stated goal was "to determine whether this initiative would result in adherence to the protocol and improve provider and staff knowledge and satisfaction with management of patients prescribed opioids for CNCP" (Canada et al., 2014, p. 2).

Canada et al. (2014) performed this study within their own clinics (3 internal medicine practices) at the University of Pennsylvania, Division of General Internal Medicine. Providers included attending physicians and nurse practitioners. Staff members included were registered nurses, licensed practical nurses, medical assistants, and patient service representatives. The study took place over one year. During this time, the first 3 months consisted of educating the providers and staff, while the remaining 9 months was the actual period of evaluation. Pre- and post-surveys were conducted but were anonymous. A protocol was developed based on expert opinion and best-practice guidelines. The goal was quality improvement. The protocol initiated standardization of documentation and management and required urine drug screenings

(UDS) and Controlled Medication Agreements (CMA). A "smart set" was created to streamline and standardize the documentation in the electronic medical record (EMR). The protocol, "smart set," and surveys were developed via monthly meetings of expert anesthetists, pain management specialists, and psychiatrists who reviewed the latest evidence-based practices and recommendations.

The method for the study by Canada et al. (2014) was comprised of 4 components: the development of the protocol, instruction for using the protocol, data collection, and a monetary incentive for providers who followed the protocol. Included in the study were patients with > 2 opioid prescriptions over 6 months; acute pain conditions were excluded. The variables of interest were the different provider roles: attending physicians, resident physicians, and nurse practitioners. Patient demographics were also a variable.

The study by Canada et al. (2014) was measured by examining the compliance levels, pre- and post-provider satisfaction, and pre- and post-knowledge. This was done using paired t tests. Stata 11.2 was used to analyze the data. Compliance to the protocol was measured by comparing the study year to the previous year in regard to "number of UDS's ordered, number of chronic pain diagnoses on EMR problem lists, and the number of office visits with CNCP patients" (Canada et al., 2014, p. 4). Statistically significant findings were noted in all 3 practices with UDS orders increased by 145%. Practice 1 had the greatest improvement at 430% (p<.05). Chronic pain diagnoses saw increases of 424% overall. Again, Practice 1 saw the greatest improvement at 918% (p<.05). Statistically significant improvements of attitudes were seen in multiple categories of the surveys. The knowledge portion of the survey

for providers only saw a 15% increase (p < .05). However, knowledge for staff did increase significantly.

Canada et al. (2014) discussed the implications of the study and stated, "By increasing adherence to best practice standards, we believe this protocol will lead to improved management of patients with CNCP by providing objective urine data to guide a treatment plan, patient education with the CMA, and a documented evaluation and care plan" (p. 7).

Limitations of the study included educational background of practitioners, years of experience of practitioners, analysis of patient data on safety, abnormal lab results, and patient outcomes related to interventions. Canada et al. (2014) believed a more comprehensive study was warranted to determine better outcomes for patients and improve patient safety.

Initial development of patient-reported instruments. Jenkinson and Ravert (2013) conducted a quantitative and qualitative research citing that opioid abuse is a global issue affecting both industrialized and developing countries. This study found that 13.7% of patients admitted to misuse or abuse of opioid prescriptions by primary care providers at some point in their lifetime. Nurse practitioners (NPs) have become sole providers to underserved communities and give more health advice compared to physicians who write prescriptions without proper screening. Under current legislation laws in the U.S., NPs are prohibited from prescribing opioids which could help lessen the gap to increased opioid prescription writing.

Jenkinson and Ravert (2013) hypothesized one goal of office-based treatment of opiate dependence was to evaluate how providers stay compliant with the CDC's latest

guidelines for opioid prescribing. Understanding current guidelines, providers are now attempting to replace those who have an opioid addiction with methadone; however, the increasing problem continues to rise due to underutilized programs for proper guidance and treatment option, especially in rural areas.

According to Jenkinson and Ravert (2013), the CDC estimated billions were spent on costs associated with prescription opiate addiction (POA) in 2005 with an estimated rise since 2010. This escalation places opioid addiction second to marijuana use. Naloxone, an opioid antagonist, received Food and Drug Administration (FDA) approval to help curtail addiction in case of overdose. The efficacy has proven a successful outcome for those who were compliant. Extensive empirical evidence demonstrates that naloxone is safe and effective for treatment of opioid addiction in the primary care setting. Prescription opiate users usually have better outcomes with overuse because they come from a more stable environment and the addiction may not be as severe.

Weaknesses in this research, according to Jenkinson and Ravert (2013), indicated lack of experience or training by physicians was the most significant barrier. The next weakness was limited access to sufficient education or screenings prior to opioid initiation. Primary care physicians (PCP) face overcoming barriers that affect those who need treatment the most; however, nurse practitioners have legal authority to identify how they can control their chronic and harmful addiction.

Jenkinson and Ravert identified that office-based treatments were being unmet due to lack of screening for opioid addiction which causes potential problems to becoming addicted rather than being evaluated for treatment to help the addiction. According to Jenkinson and Ravert (2013), goals were not met with current system to monitoring monthly prescriptions for pain management or other symptoms.

Statistically, NPs deal with POA in primary care settings and have been providing excellent care with positive outcomes for patients who have a chronic problem.

Jenkinson and Ravert (2013) indicated that NPs have received the highest patient satisfaction scores because they usually provide more health advice when compared to physicians to individuals who need the prescriptions but may be limited due to the awareness of the rising problem.

Regional variance. Paulozzi, Mack, and Hockenberry (2012) presented findings to the CDC's Morbidity and Mortality Weekly Report in July 4, 2014, which showed variation in prescription rates of opioids and benzodiazepines among states in the U.S. The study was conducted due to the prevalent, imminent threat of opioid misuse and overdose. As reported by the CDC in 2011, there were 16,917 deaths resultant of opioid overdose. Opioid-prescribing can present as a double-edged sword in that opioids are highly effective in treating pain, though highly addictive with potentially life-threatening side effects. Paulozzi et al. found that opioid pain relievers were more frequently prescribed among southeastern states. The study referenced other studies in which the former researchers could find no discernible explanation to the variance among states in opioid prescription. No theoretical framework was identified in the study. The study posed no hypothesis or research questions, though the purpose was clearly to determine variance among opioid prescribing practices among the states in America. The study also included benzodiazepine prescription rates; however, the current researchers focused solely on prescribing rates of opioids.

The study collected data on prescribing in 2012 from IMS Health's National Prescription Audit (NPA). The NPA provides estimates in each state by pooling opioids dispensed from retail pharmacies which accounts for approximately 80% of prescriptions in the U.S. The CDC then calculated prescribing rates per 100 persons for the U.S., each region, and each state. Paulozzi et al. (2012) found that prescribing rates were highest in Alabama, Tennessee, West Virginia, Kentucky, Oklahoma, and Mississippi, respectively. Paulozzi et al. found that prescribing rates were lowest in Hawaii, California, New York, Minnesota, New Jersey, and Alaska, respectively. The rates demonstrated a three- to fivefold variance from the highest to lowest states.

Paulozzi et al.'s (2012) study has strength and validity in demonstrating a difference among states in opioid prescription rates, though leaving a need for interpretation of the rationale for such difference. The researchers suggested that the gradient could not be explained by an underlying health disparity among the states—rather that it may be due to a lack of consensus among healthcare providers. Though several studies have found no correlation between regional health status and the rates of opioid prescription, it cannot be dismissed as a plausible explanation. Many of the regions with the highest rates of opioid prescription are known to have a greater prevalence of physical ailments linked to pain—most notably obesity.

Perhaps, the most definitive research to prove, disprove, or at least suggest a correlation between regional comorbidities and opioid prescription would be regional chart audits. Audits could aid in examination of the patient's presentation and comorbidities as well as the provider's adherence to guidelines in opioid prescription. Thus, this presents pertinence to the current research in which chart reviews were used

to examine patient presentation and adherence to guidelines. According to data obtained in the current research, Mississippi has the 6th highest rate of opioid prescription.

Overdose education and naloxone prescription. Binswanger et al. (2015) conducted a study to investigate the use of naloxone distribution in the primary care setting. Binswanger et al. also delved into the beliefs and attitudes of those primary care providers about overdose and overdose education. The background of the study consisted of information regarding the unintentional overdose of opioid medications. The numbers of overdose have continually risen since the 1990s, but naloxone is an effective antagonist to these harmful side effects. Primary care providers represent a large number of providers able to educate patients regarding overdose and naloxone education. Binswanger et al. used the Theory of Planned Behavior and the Health Belief Model as theoretical frameworks for the study.

The study was conducted from August 2013 and October 2014 with 56 participants taking part in 10 focus groups. Of the focus group participants, each group had at least one prescriber, such as a nurse practitioner, physician, or physician assistant. The goal of the study was to determine information in the following content areas: knowledge, barriers, benefits, and facilitators. The setting of the study took place in 3 large Colorado health systems that included family medicine, infectious disease/HIV practice, and primary care internal medicine. The results of focus groups were digitally recorded, and the results were used to analyze themes using both inductive and deductive analysis.

Binswanger et al. (2015) chose to divide information into 4 content areas that included knowledge, barriers, benefits, and facilitators. The first content of *knowledge* found that most primary care providers did not have proper information of outpatient naloxone-prescribing, and many had not used the drug since their training days. The study also found that many of the providers were not aware if their patients had overdosed in the past. Binswanger et al. also stated that they were not knowledgeable enough about naloxone to feel comfortable about prescribing it to their patients. The results of the study identified several high-risk patient groups including those prescribed high-dose opioids or benzodiazepines, history of or predisposition of substance abuse disorders, or those with mental health disorders noted as the top 3 areas. The focus groups also identified barriers to the outpatient use of naloxone that included time consumption, difficulty in initiating conversations about overdose, lack of confidentiality with bystander training, patient cost and training, and the pharmacy availability of naloxone to the patient and pharmacy.

The benefit that was identified through this study by Binswanger et al. (2015) was the decrease of death with naloxone use. Binswanger et al. also identified areas that would need to be set up prior to implementing the use of naloxone, such as protocol for prescribing and plans for what to do after the administration of naloxone in the outpatient setting. Future research included in the study suggested that research needs to be implemented for patient satisfaction with the idea of naloxone administration. Future research also should determine if naloxone promotes risk compensation. Binswanger et al. (2015) also discussed the need to research the true effectiveness of naloxone in the outpatient setting.

CHAPTER III

Methodology

The purpose of this study was to determine if primary care providers in Mississippi were compliant with the CDC's latest guidelines for opioid prescribing. Opioid overdose deaths have increased exponentially in recent years, and opioid prescribing practices have become a growing area of concern (Doyon et al., 2014). Mississippi has very high opioid prescribing rates, when compared to the national average (MSDH, 2016). Therefore, the student researchers examined opioidprescribing practices in Mississippi to determine the most recent guideline adherence rates. This body of research first focused specifically on 3 key elements of the current CDC guidelines: (a) prescribing nonopioid treatments first, (b) avoiding concurrent prescribing of opioids and benzodiazepines, and (c) checking urine drug screens prior to opioid initiation and then annually. The secondary focus of the research was determining whether PCPs in Mississippi were prescribing naloxone for opioid overdose reversal, as recent research has shown naloxone to be highly effective as a life-saving treatment for opioid overdose (Wheeler et al., 2015). Finally, the researchers examined whether PCPs in Mississippi provided sufficient patient education related to opioids. The student researchers assumed that, through patient education, adherence to CDC guidelines, and naloxone prescribing, patients would have reduced risk of opioid overdose and misuse.

Design of the Study

A nonexperimental, quantitative, descriptive, retrospective review of charts in 6 primary care clinics in the southeastern United States was conducted to evaluate

adherence to the CDC guidelines of opioid-prescribing by primary care providers. A convenience sampling of 600 charts for retrospective chart review was conducted. All chart reviews were conducted within each clinic; no charts were removed from the clinics for the purpose of this study. This design type was beneficial due to the accessibility of charts for review, limited time to obtain data, and the ability to preserve anonymity of the individual patient.

Setting for the Research Project

The setting for the research project was primary care clinics in the southeastern region of the U.S. More specifically, the student researchers collected data from 6 clinics in Mississippi staffed by physicians and nurse practitioners. The clinics were in the following regions: east central, west central, and northeast Mississippi.

Population and Sample

The population considered for this study included men and women above the age of 18 years, of all ethnicities and socioeconomic statuses, and formally diagnosed with chronic pain. Inclusion criteria were as follows: (a) age 18 years or older, (b) medically treated chronically with opioids (defined as 2 or more opioid prescriptions written > 21 days apart) for CNCP, and (c) prescribed by a PCP (physician or nurse practitioner). Oncology patients, except non-melanoma skin cancer and prostate cancer patients, were excluded from the study. A random convenience sampling of 600 medical records was selected for the purposes of chart review in this study. The chart selection included the ICD-10 diagnosis codes G89.2 chronic pain (not elsewhere classified), G89.21 chronic pain due to trauma, G89.22 chronic post-thoracotomy pain, G89.28 other chronic post-procedural pain, G89.29 other chronic pain, G89.4 chronic

pain syndrome, R52 pain unspecified, M25.5 pain in joint, M25.50 pain in unspecified joint, M25.51 pain in shoulder, M25.52 pain in elbow, M25.53 pain in wrist, M25.54 pain in joints of hand, M25.55 pain in hip, M25.56 pain in knee, M25.57 pain in ankle and joints of foot, M54.2 cervicalgia, M54.9 dorsalgia, M54.5 low back pain, M54.6 pain in thoracic spine, M79.60 pain in limb, M79.62 pain in upper arm, M79.63 pain in forearm, M79.64 pain in hand and fingers, M79.65 pain in thigh, M79.66 pain in lower leg, or M79.67 pain in foot and toes. For this research, 6 primary care clinics were chosen; 100 charts were reviewed from each of the clinics. The clinics are in rural areas as well as some more urban settings of Mississippi. Site A is an internal medicine clinic with a single MD provider treating adults only for acute and chronic illnesses. Site B is a family medical clinic which employs 3 providers (1 MD and 2 NPs). This clinic treats patients from 4 months and older. Site C is a federally-funded facility with 2 MDs, 3 FNPs, 1 PNP, and 1 DMD. This site treats patients from birth throughout the lifespan. Site D is a family medical clinic with 1 MD and 3 NPs. This facility treats patients from age 2 months and older, acute and chronic illnesses, and women's health. Site E is a combination family practice and urgent care clinic with 1 MD who treats acute and chronic illnesses from age 6 months and older. Site F is a regional health system employing 14 MDs, 7 DOs, and 2 NPs. This site treats adults for acute and chronic illnesses.

Clerical staff from each primary clinic pulled charts that were specific to the criteria for this study. From those, 100 charts were chosen for review per researcher. Each chart was reviewed using a data collection worksheet to determine prescribing practices with regard to opioids. These charts were reviewed in a legal and ethical

manner, with no interaction with patients. The charts were reviewed using the latest CDC guidelines for opioid-prescribing in Mississippi.

Methods of Data Collection

Prior to conducting the study, consent was obtained from the Institutional Review Board (IRB) at the Mississippi University for Women (see Appendix A). After consent from the IRB was obtained, each research team member contacted his or her respective clinic manager and obtained consent to perform a chart review to obtain data (see Appendix B). Each member reviewed the charts pulled by office staff in a random convenience sample of 100 charts. The Opioid and Naloxone Prescribing Practices Data Collection Worksheet was utilized by each member to collect the data (see Appendix C). Once the data collection was completed, each researcher compiled their respective data into a single word processing spreadsheet. These data were stored on a password-protected USB drive. There was no patient interaction for data collection.

Methods of Data Analysis

The collected data were compiled into a word processing document. These data were then analyzed to determine if primary care providers were adhering to the CDC's guidelines for administration of opioid pain medications and if they were prescribing Narcan for patients who were prescribed opioid pain medications for patients 18 years of age or older with chronic, non-cancer pain. After data collection, the data were subjected to analyses using descriptive statistics including, but not limited to, frequency, distributions, and percentages.

CHAPTER IV

Presentation of Findings

Drug overdoses have increased in the last 3 decades in the U.S. (Doyon et al., 2014). The purpose of this study was to determine if primary care providers in Mississippi are compliant with the CDC's latest guidelines for opioid prescribing. The student researchers examined opioid-prescribing practices in Mississippi to determine the rates of adherence to the guidelines. The primary focus of this research was 3 key elements of the current CDC guidelines: (a) prescribing nonopioid treatments first, (b) avoiding concurrent prescribing of opioids and benzodiazepines, and (c) checking urine drug screenings prior to opioid initiation and then annually. The secondary focus of the research was determining whether PCPs in Mississippi were prescribing naloxone for opioid overdose reversal as recent research has shown naloxone to be highly effective as a life-saving treatment for opioid overdose (Wheeler et al., 2015). Finally, the researchers examined whether PCPs in Mississippi provided patient education related to opioids and overdose. Nonexperimental, quantitative, descriptive, retrospective review of charts in 6 primary care clinics in the southeastern United States was conducted to evaluate adherence to the CDC guidelines of opioid-prescribing by primary care providers.

A convenience sampling of 600 charts was conducted by performing a retrospective chart review. The Opioid and Naloxone Prescribing Practices Data Collection Worksheet was utilized by each member to collect the data. This chapter describes the study's sample. This chapter also answers the research questions by

applying the findings from the study and discusses the profile of study participants.

Statistical results are summarized in figures.

Profile of Study Participants

Data for the research study were collected by method of convenience sampling. A retrospective chart review was performed on 100 charts from 6 clinics in the southeastern United States. Each researcher drew their sample from a different clinical site. The sample included patients 18 years or older with an active diagnosis of chronic, non-cancer pain. Cancer patients, with the exception of non-melanoma skin cancer and prostate cancer, were excluded from the sample. Acute pain was also excluded from the sample. The sample was used to examine provider adherence to the most recent CDC Guidelines for Opioid Prescribing.

If treatment was initiated before the guidelines were released, the following categories were marked as *not applicable*: Nonpharmacologic therapy initiated prior to opioids, nonopioid therapy initiated prior to opioids, and urine drug screen performed prior to initiation of opioids. If there was clear documentation of these criteria being met, however, it was included in the findings. The selected charts represent patients that were 18 years and older with an active diagnosis of chronic, non-cancer pain. The selection was made after the CDC guidelines were published in March of 2016; therefore, the sample population only included patients treated from March 2016 through May 2017. At each clinical site, a random convenience sampling of 100 medical records was selected for the purposes of chart review in this study. Five of 6 clinical sites utilized EMRs, while one clinic still utilized paper charting. The EMRs were selected by searching for the ICD-10 criteria. The paper charts were chosen by

random selection of charts until 100 pain patients were identified. The chart selection included the following ICD-10 pain diagnoses: G89.2 chronic pain not elsewhere classified, G89.21 chronic pain due to trauma, G89.22 chronic post-thoracotomy pain, G89.28 other chronic post-procedural pain, G89.4 chronic pain syndrome, R52 pain unspecified, M54.5 low back pain, M54.6 pain in thoracic spine, or G89.29 other chronic pain. Demographic information extracted included age and gender. Other information documented from the charts included provider type and ICD-10 pain diagnoses.

Age. The research sample consisted of individuals ranging in age from 25 years to 94 years old.

Gender. The sample population was comprised of more females than males. The gender distribution was 45% male (n = 267) and 55% female (n = 332). Figure 1 represents the gender distribution among the sample population.

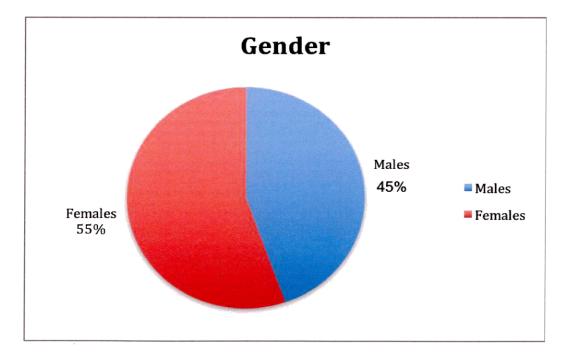


Figure 1. Percentage of gender distribution in the sample population.

Provider type. The researchers determined the type of prescribing provider while collecting their data. Of the sample population, 65% of providers were Doctors of Medicine (n = 388), 29% were Nurse Practitioners (n = 177), and 6% were Doctors of Osteopathic Medicine (n = 34). Figure 2 represents the distribution of provider types amongst the sample population.

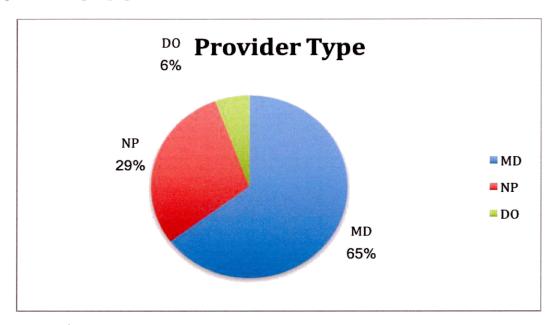


Figure 2. Percentages of opioid-prescribing providers.

Statistical Results

A random convenience sampling of 600 medical records were reviewed to complete this retrospective chart review. Inclusion criteria were as follows: (a) age 18 years or older, (b) medically treated long-term with opioids (defined as 2 or more opioid prescriptions written > 21 days apart) for chronic non-cancer pain, and (c) prescribed by a PCP (physician or nurse practitioner). The Opioid and Naloxone Prescribing Practices Data Collection Worksheet was utilized by each member to collect the data.

The researchers entered all statistical information from the data collection worksheets into a Microsoft Excel spreadsheet and formulated to determine n = number for each category. The researchers investigated the following research questions:

- 1. Are primary care providers in Mississippi compliant with the following selection of the CDC's latest guidelines for prescribing opioids for chronic pain in Mississippi?
 - a. Nonpharmacologic therapy or nonopioid pharmacologic therapy first.
 - b. Avoid concurrent prescribing of opioids and benzodiazepines.
 - c. Check urine drug screen prior to opioid initiation and then annually.
- 2. Are primary care providers in Mississippi prescribing naloxone for opioid overdose reversal?
- 3. Do primary care providers provide education to patients regarding opioid overdose?

Research question 1. Are primary care providers in Mississippi compliant with the following selection of the CDC's latest guidelines for prescribing opioids for chronic pain in Mississippi?

a. Nonpharmacologic therapy or nonopioid pharmacologic therapy first. The researchers determined if primary care providers used nonpharmacologic therapy or nonopioid pharmacologic therapy before prescribing opioids. After performing a random convenience sampling of 600 medical records, the researchers found the following: Of the 600 charts reviewed, 9% of the patients were prescribed nonpharmacologic therapy first (n = 54), 12% of the patients were not prescribed nonpharmacologic therapy first (n = 70), and 79% of the selected charts were classified

as *not available* (n = 475), as initiation of therapy was prior to initiation of the CDC guidelines. Of the 600 charts reviewed, 26% of the patients used nonopioid therapy first (n = 156), 14% of the patients did not use nonopioid therapy first (n = 84), and in 60% of the selected charts this information was *not available* (n = 360).

- b. Avoid concurrent prescribing of opioids and benzodiazepines. The researchers determined if primary care providers avoided concurrent prescribing of opioids and benzodiazepines. After performing a random convenience sampling of 600 medical records, the researchers found the following: Of the 600 charts reviewed, 20% of the patients were prescribed opioids and benzodiazepines concurrently (n = 120) and 80% of the patients were not prescribed opioids and benzodiazepines concurrently (n = 479).
- c. Check urine drug screen prior to opioid initiation and then annually. The researchers determined if primary care providers checked a urine drug screen prior to opioid initiation and annually. After performing a random convenience sampling of 600 medical records, the researchers found the following: Of the 600 charts reviewed, 20% of the patients had urine drug screens (n = 120) and 80% of the patients did not have urine drug screens (n = 479).

See Figures 3-6.

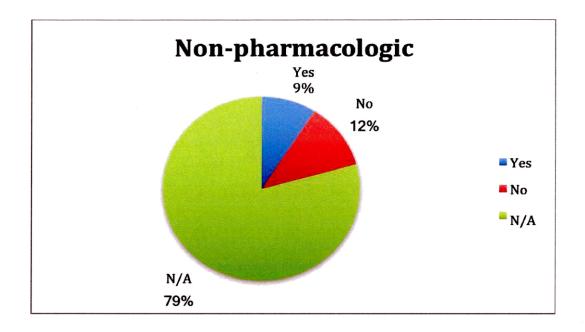


Figure 3. Percentage of patients prescribed nonpharmacologic therapy first.

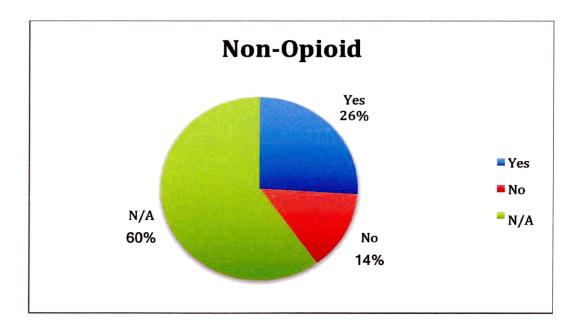


Figure 4. Percentage of patients prescribed nonopioid therapy first.

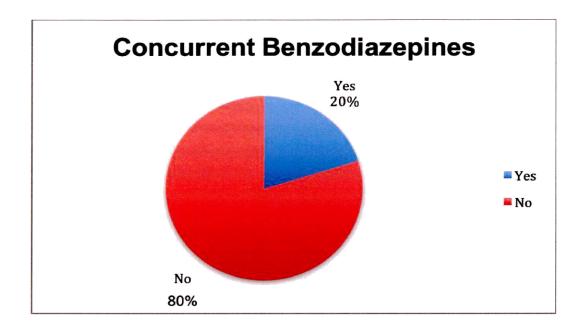


Figure 5. Percentages of patients concurrently prescribed opioids and benzodiazepines.

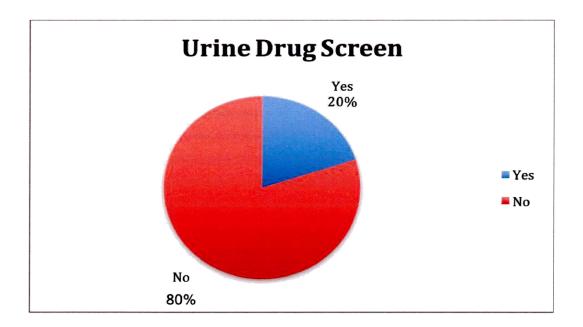


Figure 6. Percentages of patients with urine drug screens prior to opioid initiation and then annually.

Research question 2. Are primary care providers in Mississippi prescribing naloxone for opioid overdose reversal? The researchers determined if primary care providers prescribed naloxone therapy for opioid overdose reversal when prescribing opioids. After performing a random convenience sampling of 600 medical records, the researchers found the following: Of the 600 charts reviewed, 0% of the patients were prescribed naloxone therapy (n = 0) (see Figure 7).

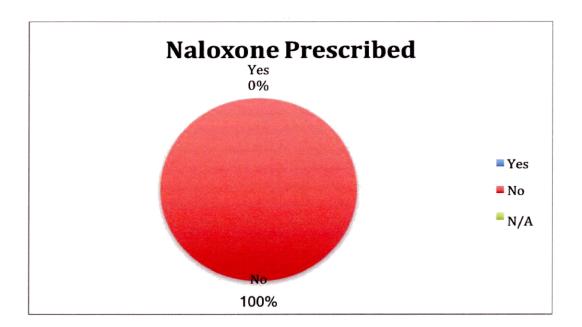


Figure 7. Percentage of patients that received naloxone therapy.

Research question 3. Do primary care providers provide education to patients regarding opioid overdose? The researchers determined if primary care providers gave education regarding opioid overdose before prescribing opioids. After performing a random convenience sampling of 600 medical records, the researchers found the following of the 600 charts reviewed: 48% of those patients did receive education

regarding opioid overdose (n = 286) and 52% did not receive education regarding opioid overdose (n = 314) (see Figure 8).

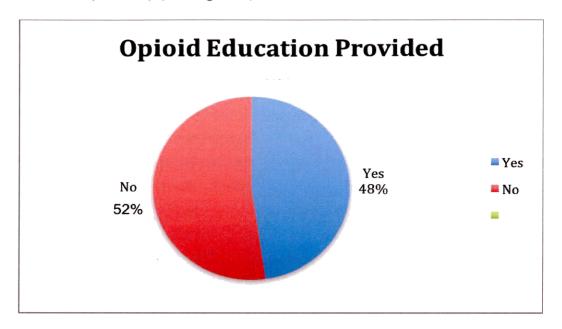


Figure 8. Percentages of patients who were educated about opioid overdose.

Summary of Findings

Chapter IV presented the researchers' findings from the retrospective review of 600 patients from 6 clinics in the southeastern United States. Findings from the demographics and research questions were presented in figures. The results of this analysis revealed noncompliance among primary care providers regarding the prescription of nonpharmacologic and nonopioid therapy first. The results also revealed that most primary care providers did avoid concurrent prescribing of opioids and benzodiazepines, and most of the primary care providers were noncompliant with urine drug screens prior to opioid initiation and annually. Furthermore, primary care providers in the selected clinics did not prescribe naloxone for opioid overdose reversal. Finally, the results revealed that < 50% of the patients received education regarding opioid overdose. These conclusions highlight the opportunity for improvement among

primary care providers, especially nurse practitioners, regarding opioid prescribing practices. Figure 9 represents the overall adherence to CDC guidelines and naloxone prescribing practices per individual guideline.

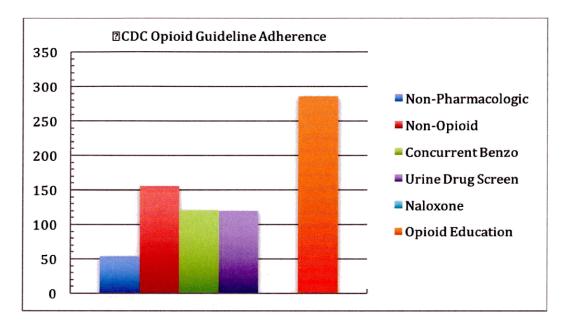


Figure 9. Summary of reviewed charts in compliance with CDC opioid-prescribing guidelines and naloxone prescribing practices.

CHAPTER V

Summary and Conclusions

The study determined whether the selected primary care providers were following CDC guidelines for prescribing opioids and whether providers were prescribing naloxone for opioid overdose reversal. The study also sought to determine if the selected primary care providers were providing education regarding the risks of opioids, as well as education about naloxone, if prescribed. Hydrocodone and oxycodone continue to be the most numerous prescriptions written according to the MSDH in 2016, and they continue to be the leading cause of unintended overdoses and death of many individuals. Many of the overdoses are not only resulting from opioids smuggled into the country, but additionally as a result of indiscriminate opioid prescribing by healthcare providers.

The research project allowed knowledge expansion of opioid overdose and providers' prescribing habits. The research group formulated questions based on the CDC guidelines for treatment of chronic, non-cancer pain which were published in March of 2016. The purpose of the research project was to determine compliance with the selected guidelines. The secondary goal was to determine the need for increased education among providers regarding opioid treatment of chronic, non-cancer pain. Compliance was evaluated by the following research questions:

- 1. Are primary care providers in Mississippi compliant with the following selection of the CDC's latest guidelines for prescribing opioids for chronic pain in Mississippi?
 - a. Nonpharmacologic therapy or nonopioid pharmacologic therapy first.

- b. Avoid concurrent prescribing of opioids and benzodiazepines.
- c. Check urine drug screen prior to opioid initiation and then annually.
- 2. Are primary care providers in Mississippi prescribing naloxone for opioid overdose reversal?
- 3. Do primary care providers provide education to patients regarding opioid overdose?

The research was guided by previous studies related to the opioid epidemic. An overview of the literature review is as follows. According to Venes (2013), chronic pain is the leading cause of disability. Harle et al. (2015) found that a lack of pain specialists has resulted in the need for primary care providers to manage chronic pain although effective management is often challenging. Wolfe et al. (2016), in reference to the CDC, found that too many physicians are prescribing opioids without trying other methods first. Canada et al. (2014) developed and implemented a new EMR-based protocol to improve opioid prescribing practices. Canada et al. determined their EMR-based protocol increased adherence to best practice standards and led to safer and more effective management of chronic, non-cancer pain (Canada et al., 2014). Finally, according to Jenkinson and Ravert, naloxone has been approved by the FDA for use in the primary care setting. These previous studies established a foundation to guide the principles of this study.

A random convenience sampling of 600 medical records were reviewed to complete this retrospective chart review. Inclusion criteria were as follows: (a) age 18 years or older, (b) medically treated long-term with opioids (defined as 2 or more opioid prescriptions written > 21 days apart) for chronic non-cancer pain, and (c) prescribed by

a PCP (physician or nurse practitioner). Data were collected and analyzed in the results section and will be discussed in the following sections: Summary and Discussion of the Findings, Conclusions, Implications, Limitations, and Recommendations.

Summary of the Findings

The sample project consisted of 600 participants. The participants received care at 6 primary care clinics in the southeastern United States between March 2016 and May 2017. The sample consisted of 45% (n = 267) males and 55% (n = 332) females. The age ranges were from 25-94 years. Of the charts reviewed, 0% of the patients were prescribed naloxone therapy (n = 0) for emergent opioid overdose reversal. Of the charts reviewed, 48% of the patients received education regarding opioid overdose (n =286) and 52% did not receive education regarding opioid overdose (n = 314). Of the charts reviewed, 9% of the patients utilized nonpharmacologic therapy first (n = 54), 12% of the patients were not treated by nonpharmacologic therapy first (n = 70), and in 79% of the selected charts, this information was not applicable (n = 475). Of the charts reviewed, 26% of the patients used nonopioid therapy first (n = 156), 14% of the patients did not use nonopioid therapy first (n = 84), and in 60% of the selected charts, this information was not applicable (n = 360). Of the charts reviewed, 20% of the patients were prescribed opioids and benzodiazepines concurrently (n = 121) and 80% of the patients were not prescribed opioids and benzodiazepines concurrently (n = 479). Of the charts reviewed, 20% of the patients had urine drug screens (n = 120), and 80% of the patients did not have urine drug screens (n = 479). Of the sample population (n =600), 65% of providers were Doctors of Medicine (n = 388), 29% were Nurse

Practitioners (n = 177), and 6% were Doctors of Osteopathic Medicine (n = 34) of the sample population.

Discussion of the Findings

Many of the charts reviewed were of patients who were prescribed opioid therapy for chronic, non-cancer pain prior to the March 2016 publication of the CDC guidelines for prescribing opioids for chronic pain, thus data prior to the date of publication were excluded from the study. Since prior data were excluded, it cannot be determined if the patient was treated with nonpharmacologic and/or nonopioid therapy prior to initiation of opioid therapy; in these instances, findings were labeled as not applicable. Approximately 43% of the applicable 178 charts reviewed were prescribed nonpharmacologic therapy prior to opioid therapy (n = 54). Of the 396 applicable charts reviewed, 65% were prescribed nonopioid therapy prior to opioid therapy (n =156). Of the 600 charts reviewed, 20% of patients were prescribed opioids and benzodiazepines concurrently (n = 120). Of the 600 charts reviewed, 20% of patients had a drug screen in compliance with the CDC guidelines, i.e. a drug screen prior to opioid treatment and an annual drug screen thereafter (n = 120). The researchers found that of the 600 charts reviewed, none of the patients received naloxone therapy (n = 0). This is most likely due the cost of prescription naloxone. The cost of a naloxone autoinjector ranges from \$2,250 to \$2,460 out-of-pocket and coverage varies among health insurance companies. However, this may also be attributed to common practice, as well as the fear that prescribing naloxone will lead to more risky use of opioids by patients. The researchers found that 48% of the charts reviewed received education regarding the risks of opioids (n = 288).

A random, convenience sampling of 600 medical records were reviewed. The sample population was comprised of more females than males. The gender distribution was 45% male (n = 267) and 55% female (n = 332). There was no statistical significance between gender and opioid-prescribing practices. Of the sample population, 388 of providers were Doctors of Medicine, 177 were Nurse Practitioners, and 34 were Doctors of Osteopathic Medicine. There was no statistically significant effect on prescribing practices between the 3 provider types evaluated.

Conclusions

The purpose of this study was to determine if primary care providers in Mississippi were treating chronic, non-cancer pain in accordance with the CDC guidelines for prescribing opioids. The study evaluated the charts of patients 18 years of age or older. The study design was a retrospective chart review of 600 charts that were selected based on applicable chronic pain diagnoses in patients treated with opioids. The most recent CDC guidelines were published in March 2016, and all data prior to that date were excluded from the study. Based on the research data, the majority of primary care providers in Mississippi were not consistently following CDC guidelines for opioid prescribing. The data were collected within the first year after the 2016 CDC guidelines were published, so it is plausible that the primary care providers were unaware of the changes in approach to managing chronic, non-cancer pain. However, it should be noted that ignorance is not accepted by governing bodies, such as the Board of Medicine, the Board of Nursing, and the Drug Enforcement Agency (DEA). The researchers concluded that primary care providers in Mississippi

demonstrate a need for heightened awareness and education regarding the CDC's guidelines for opioid-prescribing.

Implications

The incidence of opioid-related overdose and death has continuously risen to unprecedented levels, which led to the investigation of the epidemiology of the aforementioned trend. The problem has gained attention of multiple federal and state agencies, such as the DEA and the CDC. In March of 2016, the CDC released new guidelines by which healthcare providers should approach chronic, non-cancer pain management. The guidelines have been accepted as best practice by both the Board of Medicine and the Board of Nursing. While the new guidelines are not rule, regulation, or law, prudent medical judgment should be carefully considered when prescribing outside the CDC recommended criteria. As the CDC guidelines continue to be disseminated, healthcare providers are still finding themselves in the crosshairs of legal fire for failure to adhere to certain guidelines. Some states are enacting new stricter prescribing laws that align with the CDC guidelines in an effort to curb the opioid crisis. As the CDC guidelines continue to be disseminated, it is advised that healthcare providers should practice in compliance with the CDC guidelines for management of chronic, non-cancer pain.

This research project yielded findings that are incongruent with evidence-based best practice as outlined in the CDC Guidelines for Opioid Prescribing. The implications are that nonadherence continues to place patients at risk. Furthermore, nonadherent healthcare providers are at risk of losing their credentials and licensure. These providers are also at risk for financial penalties and potentially criminal charges.

Nola Pender's HPM should serve as a standard that nurse practitioners use in treating chronic, non-cancer pain. The evidence demonstrates the risks associated with nonadherence to the CDC guidelines. The CDC guidelines are evidence-based and congruent with the HPM. The HPM is designed to promote health through prevention and promotion of health-conscious behaviors. Nola Pender described nursing as "the science and art of helping people change their lifestyle to move toward a state of optimal health" (Alligood, 2014, p. 303). Thus, the goal of the nurse practitioner, as well as other healthcare providers, is to promote optimal health by recognizing the risks of opioids and utilizing best practice in regard to managing chronic, non-cancer pain as outlined by the CDC.

Limitations

Limitations readily identifiable prior to performing data collection were identified as small sample size, geographically limited data collection, and the use of convenience sampling. As recognized in the methodology section of this study, data were obtained by performing a retrospective chart review from 6 primary care clinics in Mississippi. The population ranged from central and east central Mississippi to north Mississippi. Data were collected and analyzed from a sample of 600 charts. The study was designed to examine the opioid and naloxone prescribing practices of primary care providers.

The sample size of 600 charts was relatively small and potentially decreased the reliability of generalizing to the entire populous. The study could be replicated to obtain a larger sample size. The larger sample would most likely represent the actual

trend in prescribing practices. Obtaining information from a larger sample consisting of multiple states across the nation would also be beneficial.

The study was geographically limited and unlikely represented prescribing practices across the nation. A similar study was conducted in which the findings suggested a threefold to fivefold variance among states in the U.S. in rates of opioid-prescribing (Paulozzi et al., 2014). Paulozzi et al. (2014) found that Mississippi had the 6th highest opioid prescription rates; this was the trend among multiple southeastern states.

The final limitation known prior to data collection was the use of convenience sampling. As it pertains to research, convenience sampling is the weakest form of sampling. Convenience sampling is often a beginning point to lead to further research. In this study, data were obtained from a random sample of charts. This method may not represent the entire population of the clinic nor is it likely to provide strong assumptions of other clinics. However, the method of chart review may be stronger than data obtained by volunteers.

During data collection and analysis, the researchers recognized that many of the populations sampled were established chronic, non-cancer patients that began treatment prior to the implementation of the CDC guidelines in March 2016. Therefore, several parameters could not be analyzed and were marked as not applicable. Those nonapplicable parameters were identified as implementation of nonpharmacologic and nonopioid therapy prior to opioid initiation as well as an initial urine drug screen. Furthermore, the study may have yielded skewed results due to the relatively short timeframe between data collection and dissemination of the new guidelines.

Recommendations

The researchers recommend that this study be replicated with a larger population throughout multiple regions in the United States. The researchers also recommend that the study be replicated annually to determine if there was an increase in adherence to the CDC guidelines. The timeframe for a newly established guideline to be implemented into common practice is typically 2 years. This amount of time should pass before replicating the study. Therefore, the spring of 2018 would be an appropriate delay before a new set of data could be obtained to analyze. This particular research design could be replicated exactly to determine if there was increased adherence in the same region. Any future study should also evaluate if an increase in naloxone prescription occurs. The researchers recommend correlating adherence to the guidelines with the incidence of opioid-related overdose and deaths.

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APPENDIX A

APPROVAL OF INSTITUTIONAL REVIEW BOARD



Provost and Vice President for Academic Affairs 1100 College Street MUW-1603 Columbus, MS 39701-5800 (662) 329-7142 Fax (662) 329-7141

www.muw.edu

February 17, 2017

Carey McCarter, Ph. D.
Mississippi University for Women
College of Nursing and Speech Language Pathology
1100 College Street, MUW- 910
Columbus, Mississippi 39701-5800

Dear Dr. McCarter:

I am pleased to inform you that the members of the Institutional Review Board (IRB) have reviewed the following proposed research and have approved it as submitted:

Name of Study:

Opioid and Naloxone Prescribing Practices in

Mississinni

Investigator(s):

Rebecca Brown, Brittany Clayton, Alissa Damiens, Natalie Keyes, Gary Adam McPherson, and Anna

Elizabeth Wiygul

Research Faculty/Advisor:

Carey McCarter

I wish you much success in your research.

Inones Ruhards no

Sincerely,

Thomas C. Richardson, Ph.D.

Provost and Vice President for Academic Affairs

TCR/tc

pc: Tammie McCoy, Institutional Review Board Chairman

APPENDIX B

Letter of Consent

DATE:

SUBJECT: Permission to Participate in a Quality Assurance Research Study

We are graduate students at Mississippi University for Women in the Family Nurse Practitioner program in Columbus, MS. As a program requirement, we are conducting a retrospective chart review to assess primary care provider compliance to opioid prescription guidelines set forth by the Centers for Disease Control and Prevention (CDC). The students that are participating in this research project are Rebecca Brown, Brittany Clayton, Alissa Damiens, Natalie Keyes, Gary Adam McPherson, and Anna Elizabeth Wiygul.

We are requesting your permission to utilize your clinic as one of the settings for our study. By providing us with permission, we will have access to your patients' medical records for a retrospective chart review. We recognize the essential need for confidentiality in regard to patient health information. Each student has completed a HIPAA training workshop through Mississippi University for Women. The students further agree to protect all information obtained, and no identifying information will be recorded. We will be utilizing a student-designed data collection worksheet to collect the required information. A copy of this tool is included with this letter. We will transcribe the data directly from the chart to the data collection form, thus no patient identifiers will be removed from the clinic. No identifying personal, provider, or clinic information will be included. A complimentary copy of the study results will be provided to all participating clinics.

If you have any questions concerning this research study, please call Rebecca Brown (601-826-5200), Brittany Clayton (662-397-1159), Alissa Damiens (662-571-2911), Natalie Keyes (601-966-3416), Gary Adam McPherson (601-938-1599), Anna Elizabeth Wiygul (662-574-4774) or you may contact the chair of our research committee, Carey McCarter, DNP, FNP-BC (662-295-1858). Your participation in this study is strictly voluntary. The amount of time required for us to review charts and collect data will be approximately one month. In addition, you may withdraw your consent and participation in this study at any time by contacting one of us or the chair of our research committee.

Sincerely,

Rebecca Brown, Brittany Clayton, Alissa Damiens, Natalie Keyes, Gary Adam McPherson, and Anna Elizabeth Wiygul

APPENDIX C

Opioid and Naloxone Prescribing Practices Data Collection Worksheet

Age:
Gender
Male
Female
Was non-pharmacologic therapy initiated before nonopioid therapy?
a. No
b. Yes
Was nonopioid pharmacologic therapy initiated before opioid therapy?
a. No
b. Yes
Concurrent prescribing of opioids and benzodiazepines?
a. No
b. Yes
Urine drug screen prior to opioid initiation?
a. No
b. Yes
Was naloxone prescribed with the prescribed opioid?
a. No
b. Yes
Was education provided for overdose prevention and overdose awareness?
a. No
b. Yes
Pain related ICD 10
Provider's Type
a. NP
b. MD
c. D.O.
d PA