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Biopsychosocial Multidisciplinary Treatment Impact on Risk of Opioid Misuse

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by

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COLLEGE OF NURSING

"Biopsychosocial Multidisciplinary Treatment Impact on Risk of Opioid Misuse"

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Abstract

From 1999 to 2014, over 165,000 persons in the United States died from an overdose related to prescription opioids (Centers for Disease Control and Prevention [CDC], 2016). In response, the CDC released guidelines that propose nonpharmacologic and nonopioid pharmacologic therapy as preferred methods for chronic pain control (Dowell et al., 2016). The purpose of this project was to examine the biopsychosocial multidisciplinary treatment impact on risk of opioid medication misuse among adult chronic opioid-dependent noncancer pain clinic patients with and without a psychiatric disorder. Engel's (1977) biopsychosocial model was used to evaluate whether multidisciplinary treatment impacted the risk of opioid misuse for noncancer chronic pain patients at San Diego Pain Institute pain management clinic. A quantitative retrospective four-group design study was completed to determine whether biopsychosocial multidisciplinary treatment impacts the risk of opioid medication misuse. A medical chart review was used to identify those patients with and without a psychiatric disorder who are participating in a biopsychosocial treatment program comprising (a) a pain management program, (b) a physical therapy program, and (c) cognitive behavioral therapy (CBT) and those who are not participating in a treatment program with those three services. The Pain Medication Questionnaire (PMQ) was used to compare the risk of opioid medication misuse between the four groups (Adams et al., 2004). The results showed a biopsychosocial multidisciplinary treatment approach comprising pain management, physical therapy, and CBT reduced the risk of opioid medication misuse among chronic pain patients with a psychiatric disorder and may provide patients and providers an alternative method for opioid misuse prevention.

Keywords: opioids, opioid misuse, biopsychosocial, chronic pain, pain management, multidisciplinary, pain reduction, patient education, noncancer pain, Pain Medication Questionnaire

Dedication

I am grateful to the individuals who have allowed me to care for their acute and chronic ailments over the years. All of you have taught me more than you can imagine, and this project would not have been possible without you. I would also like to thank my parents for their continued support and words of encouragement. Evidently, my environmental upbringing influenced my adaptability and drive to accomplish academic goals. Finally, I would like to thank my wife, Claire Palacio, and our children, Alandro and Makayla Palacio. Words cannot describe the sacrifices made for this achievement. I am forever in your debt and look forward to the next chapter together in our lives.

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List of Acronyms

ANOVA: One-way analysis of variance

CBT: Cognitive behavioral therapy

CDC: Centers for Disease Control and Prevention

HADS: Hospital Anxiety and Depression Scale

IRB: Institutional Review Board

PMQ: Pain Medication Questionnaire

MME: Morphine milligram equivalents

MS: Multiple sclerosis

SPSS: Statistical Package for the Social Sciences

VA: Veterans Affairs

Chapter 1. Introduction and Background

In 1980, a letter published in the *New England Journal of Medicine* reported that only 4 out of 11,882 hospitalized people prescribed opioids became addicted (Porter & Jick, 1980). Six years later, Portenoy and Foley (1986) evaluated 38 patients to determine the indications, course, safety, and efficacy of opioid analgesics for nonmalignant pain and concluded that opioid maintenance therapy was a safe and effective alternative for intractable nonmalignant pain. In 1996, the American Pain Society introduced pain as the "5th vital sign," and this concept was also adopted by the Veterans Health Administration (Levy et al., 2018). That same year, the American Academy of Pain Medicine and the American Pain Society determined that opioids should be included as a treatment option for chronic noncancer pain. Subsequently, the Food and Drug Administration approved the manufacturing of OxyContin, a long-acting opioid, by Purdue Pharmaceuticals (Hirsch, 2017). In 2001, the Joint Commission on Accreditation of Healthcare Organizations standardized the use of the pain scale, which resulted in a combination of published medical studies and pharmaceutical influence contributing to opioid prescribing as an accepted method in reducing the numerical value of pain (Hirsch, 2017). As opioid prescribing increased, the risks associated with chronic prescription opioid use became increasingly evident among adults in the United States. From 1999 to 2014 in the United States, over 165,000 persons died from an overdose related to prescription opioids (CDC, 2016). Furthermore, extant research lends little support to the effectiveness of long-term opioid therapy to treat chronic pain (Buchman et al., 2016). In 2007, an affiliate of Purdue Pharma and three Purdue Pharma executives pled guilty to criminal charges related to misleading the public regarding the addictive properties of OxyContin. The case was subsequently settled with a $634.5 million fine (Zee, 2009).

The estimated cost of addressing the impact of substance abuse in the United States is more than $600 billion annually (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019b). According to the 2018 National Survey on Drug Use and Health, an estimated 2 million people aged 12 or older had an opioid use disorder (SAMHSA, 2019a). Despite the lack of evidence supporting continuous opioid use for chronic pain, opioid therapy is the most prescribed treatment for chronic pain (Speed et al., 2018). Unfortunately, prescription opioid use can lead to opioid use disorder, which is common among individuals with chronic pain. Using an electronic health record database, Hser et al. (2017) examined chronic pain in 5,307 adult patients with opioid use disorder. The study compared the presence of comorbidities, such as substance use disorder, mental health disorders, and disease conditions. Importantly, 64.4% of opioid use disorder patients had chronic pain, and 61.8% of those had chronic pain before opioid use disorder. Moreover, opioid use disorder is associated with increased morbidity and mortality (Hser et al., 2018).

In 2015, the Medical Board of California initiated the Death Certificate Project, in which investigators review the Department of Justice's prescription drug database to identify opioid prescribers. These results are then cross-referenced to patients who died from an opioid overdose (Dembosky, 2019). Once the opioid prescriber has been identified, an investigation is launched to review their practices. The project has been criticized because it includes any prescriber who provided opioids three years before the patient's death; does not account for suicide by overdose; and reviews records as far back as 2013, which is three years before the CDC opioid guidelines were issued.

In 2016, the CDC released guidelines for opioid prescribing that proposed nonpharmacologic and nonopioid pharmacologic therapy as preferred methods for treating

chronic pain, with the goal of altering clinicians' prescribing habits (Dowell et al., 2016). The opioid guidelines were developed using the Grading of Recommendations Assessment, Development, and Evaluation method, which is a framework for presenting summaries of evidence, appraising controlled studies, and applying a systematic approach for clinical practice recommendations. The guidelines are intended for those 18 years or older with chronic pain (defined as pain lasting more than 3 months) outside of palliative and end-of-life care. Nonopioid options, such as physical therapy, clinical pain psychology, acupuncture, and nonsteroidal anti-inflammatories, are recommended as a first line of therapy. After opioid therapy has been initiated, the recommendation is to reassess the benefits and risks of opioid therapy when increasing the dosage to 50 or more morphine milligram equivalents (MME) per day and to avoid increasing the dose to 90 or more MME/day. While the CDC recommends nonopioid medications as a first-line therapy, it acknowledges that many people suffer from side effects associated with those medications. The CDC also acknowledges that pain is subjective and dependent on individual needs, which can lead to doses greater than 90 MME/day (Dowell et al., 2016). Conservative therapies, such as clinical pain psychology, physical therapy, and acupuncture, are recommended; however, some insurance plans may not provide coverage for this therapy, and the out-of-pocket costs can be high. The CDC (2016) also recognizes that limitations in complex activities; lost work productivity; reduced quality of life; stigmas; and biological, psychological, and social factors are associated with chronic pain. Multidisciplinary therapies that address biological, psychological, and social factors associated with chronic pain have been shown to reduce pain and improve functionality more effectively when compared to single-focus therapies (Miller-Matero et al., 2016).

Problem Statement

In 2017, the U.S. Department of Health and Human Services (2019) declared an opioid crisis and identified an increase in the rate of opioid prescriptions as a contributing factor (Volkow & Blanco, 2021). With the declaration of an opioid crisis, introduction of the CDC opioid prescribing guidelines, and the creation of the Death Certificate Project, methods to prevent opioid misuse must be identified. Current research has emphasized the dangers associated with prescription opioids and the benefits of multidisciplinary treatment (Craner et al., 2016; Huhn et al., 2019; Kamper et al., 2015; Purcell et al., 2019). However, few studies have been conducted exploring how biopsychosocial treatment affects opioid use (Dowell et al., 2016). The purpose of this project was to examine the association between biopsychosocial multidisciplinary treatment and the risk of opioid medication misuse among adult chronic opioid-dependent noncancer pain clinic patients.

PICOT Question

For (P) chronic pain patients with and without a psychiatric disorder, as defined by the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, (I) does biopsychosocial multidisciplinary treatment positively impact the risk of opioid medication misuse, (C) compared to no biopsychosocial multidisciplinary treatment, (O) as observed by a lower score on the Pain Medication Questionnaire?

Objectives and Aims

The objective of this study was to determine the effectiveness of biopsychosocial multidisciplinary treatment as an alternative method for pain management in order to prevent opioid misuse. This study aimed to evaluate the risk of opioid medication misuse among noncancer chronic pain patients actively in biopsychosocial multidisciplinary treatment,

compared to those who are not, at the San Diego Pain Institute outpatient pain management clinic.

Chapter 2. Literature Review

To explore the concept of biopsychosocial multidisciplinary treatment and opioid misuse, the researcher conducted an electronic database literature search using Worldcat.org, PubMed, ScienceDirect, Cochrane Library, BioMed Central, and Google Scholar and the terms "biopsychosocial model chronic pain" and "biopsychosocial model opioids." Inclusion criteria consisted of English-language, peer-reviewed, full-text articles published within the past five years. Pediatric and opinionated articles were excluded. Article screening resulted in the selection of five studies that correlated the biopsychosocial model, pain reduction, and opioid use.

Integration of the Biopsychosocial Model Among Veterans

Purcell et al. (2019) explored the idea of whether biopsychosocial model integration can improve the care experience among Department of Veterans Affairs (VA) chronic pain patients. They designed a qualitative study to evaluate 41 patients treated by an integrated pain team (i.e., medical provider, psychologist, and pharmacist) in the primary care setting. The integrated pain team prescribed opioid medication; educated the patients about chronic pain; and provided behavioral interventions, psychotherapy, and self-management strategies for pain reduction. They conducted telephonic semistructured interviews with those who had completed at least three visits with the integrated pain team at the San Francisco VA. Exclusion criteria included untreated mental illness and active suicidal or homicidal thoughts. Interview times ranged from 30 to 60 minutes, with a response rate of 49%. Questions focused on the overall experience, impact of pain care, quality of life, and pros and cons of working with the integrated pain team.

Results of the study were categorized into three themes: (a) interdisciplinary treatment model, (b) treatment planning and communication, and (c) treatment results and impact. Patient experiences with the interdisciplinary treatment model were described as both effective and beneficial by some patients but awkward and confusing by others. Treatment planning and communication produced conflicting results because some patients viewed their individuality as being appreciated, whereas others viewed opioid reduction as being the primary goal of the integrated pain team's treatment plan, regardless of pain levels. Regarding treatment results and impact, nearly all patients underwent opioid reduction or elimination. This opioid reduction led to improved pain control, quality of life, and functionality for some patients; however, those issues worsened for others. Rigor, validity, and credibility of the study were achieved through intercoder agreement of central themes; analyst triangulation of interviews; robust sample size; and the use of rich, thick descriptions. Limitations included selection bias and potential inability to generalize findings to nonveteran or veteran patients at other VA facilities.

Associations of Multiple Sclerosis Pain

Day et al. (2016) conducted a quantitative cross-sectional survey among adults ages 21 to 81 years with multiple sclerosis (MS) to (a) identify associations between pain, MS symptoms, depression, and psychosocial and functional variables and (b) determine whether MS duration, subtype, and demographics function as risks and protective factors among pain, MS symptoms, depression, and psychosocial and functional variables. A sample of 424 (92% White and 80% female) participants were recruited by mailed letter invitation from the Greater Northwest Washington chapter of the National Multiple Sclerosis Society. Interested individuals were provided a mailed or online link to the survey. Surveys with missing data were followed up by phone, and all participants received a $25 gift card upon completion. The survey consisted of a

demographic questionnaire and self-reported measures to assess pain severity, pain interference, depression, fatigue, and insomnia. Statistical data analysis to explore the variables' associations was completed with Mplus version 7.2.

The results supported two primary themes: (a) the functional variables of pain interference, sleep quality, and fatigue were not correlated after controlling for MS symptoms, depression, and pain severity, and (b) underlying symptoms, such as pain, fatigue, depression, and sleep impairment, should be evaluated and managed in those with MS. A secondary result found that those with depression, low socioeconomic status, or lack of social support may be at risk for poor outcomes in pain and MS. These findings suggest that pain and MS symptoms could improve with coping skills and social support interventions. Limitations included the study's narrow demographic profile, which prevents generalization; reliance on self-report measures, which may limit accuracy; and the short time frame. Longitudinal studies may provide more accurate information because depression, sleep disturbance, and fatigue may manifest physical symptoms that are undetectable in short-term studies.

Meta-analysis of Multidisciplinary Treatment

Kamper et al. (2015) completed a systematic review and random effects meta-analysis of 41 randomized controlled trials to assess the effectiveness of multidisciplinary rehabilitation in pain reduction, disability, and work absence in adult patients with chronic (lasting more than 3 months) low back pain. Multidisciplinary rehabilitation comprised biopsychosocial concepts and was defined as physical, psychological, social, and work interventions. Inclusion criteria were any language, full-text, and peer-reviewed journals.

Seventy-five percent of reported patients had chronic low back pain, and 25% of reported patients had low back pain. Specific causative factors of low back pain, such as metastasis or

infection, were excluded from the study. Multidisciplinary rehabilitation was compared to the control interventions of usual care, physical treatment, surgery, and waiting list. Pain, disability, and work absenteeism were identified as long-term (12-month or longer assessments) primary outcomes. Psychological functioning, quality of life, adverse events, and health service utilization were identified as short-term (less than 12-month assessments) secondary outcomes.

The researchers searched the Cochrane Back Review Group Trials Register, CENTRAL, MEDLINE, Embase, PsycINFO, and CINAHL databases for articles published between 1998 and February 2014. They then assessed the quality of the collected evidence with the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach and the bias risk with the 12-point Cochrane Risk of Bias Tool. To conduct the statistical analysis, they used the RevMan 5.1 software. The findings of the statistical analysis revealed that multidisciplinary rehabilitation interventions were significantly more effective in pain reduction and disability compared to usual care and physical treatment and that, secondarily, they seemed to be more effective for work outcomes compared to physical treatment. Kamper et al. (2015) concluded that multidisciplinary rehabilitation using biopsychosocial concepts can reduce pain. Limitations of the study included inconsistent measurements of work absenteeism, diverse definition of physical treatments, and inability to generalize findings because most studies occurred in Europe.

Perspectives of Chronic Pain Patients

To understand the perspectives of chronic pain patients, Craner et al. (2016) conducted a mixed methods study to investigate what patients perceive as important for pain management. The study consisted of a 120-hour group-based outpatient pain rehabilitation program comprising cognitive behavioral and biopsychosocial concepts of chronic pain treatment. The study's pain rehabilitation program incorporated multiple modalities, such as CBT, physical

therapy, biofeedback, family education, occupational therapy, pharmaceutical education, and relaxation training. Patients completed the West Haven-Yale Multidimensional Pain Inventory before and after the program. Four hundred ninety-eight out of 679 chronic pain patients ages 18 years and older completed the study. At admission, 14.7% of patients were considering additional surgery for pain alleviation, and 22.9% were unsure. The researchers obtained patient demographics through reviewing medical records and collected computerized assessment measures upon admission and discharge. They then completed the statistical analysis using the IBM SPSS Statistics version 22.0 software.

Upon program completion, 88.7% of the patients had discontinued opioid use, 6.1% of the patients who had considered additional surgery were no longer considering it, 16% of the patients who were unsure whether they would have additional surgery no longer considered surgery an option, and pain severity and pain interference had each decreased by 1.3 points. Relaxation strategies were the most endorsed (84.7%) by patients, with 82.7% referencing diaphragmatic breathing techniques. Activity modification was endorsed by 47.4% of patients, 24.3% of patients endorsed positive self-talk, and 16.2% of patients endorsed distraction techniques. The results of the study indicated that relaxation strategies were the most useful tool for pain reduction. Opioid medication use also declined, despite not being the study's primary goal.

Associations of Chronic Pelvic Pain

Miller-Matero et al. (2016) examined the associations of pain, psychological symptoms, and functional impairment among chronic pelvic pain patients. They conducted a retrospective chart review to evaluate 107 female patients between the ages of 18 and 67 who were evaluated by a physician at a multidisciplinary chronic pelvic pain clinic. The researchers then used a

convenience sample to review the records of those who had completed a routine psychiatric evaluation and the Hospital Anxiety and Depression Scale (HADS), which is a 14-item self-report questionnaire designed to evaluate the symptoms of depression and anxiety. The routine psychiatric evaluation consisted of a semistructured interview regarding history of pelvic pain, psychosocial factors (e.g., history of psychiatric symptoms and emotional and sexual abuse), existing functional impairments, and completing the visual analog pain scale questionnaire. They conducted the statistical analysis with SPSS version 20.

The study results indicated that 53.8% of patients had had a history of a depressive episode; 25.7% endorsed experiencing current probable depression; 38.6% endorsed experiencing current probable anxiety; and 44.9% had experienced some form of abuse, with the majority (72.7%) being sexually abused. Chronic pelvic pain was present in 8.9% for less than 6 months, 7.8% for 6 to 12 months, 34.4% for 1 to 5 years, 15.6% for 5 to 10 years, and 33.3% longer than 10 years. Functional impairment of household activities was present in 66.4% of patients, followed by sleep deficits in 53.3%. A comparison of those with and without impairment in household activities, $t(106) = -2.06$, $p = .04$, and sleep, $t(106) = -2.61$, $p = .01$, indicated a significant correlation with higher levels of anxiety. A comparison of those with and without impairment in household activities, $t(106) = -3.72$, $p = <.001$, and sleep, $t(106) = -2.40$, $p = .02$, indicated a significant correlation with higher levels of depression. Pain severity was not significantly associated with anxiety, $r(106) = .13$, $p = .24$, or depression, $r(106) = .08$, $p = .44$. A comparison of pain severity scores between those with and without a history of emotional and sexual abuse found no statistical difference, $t(106) = -.26$, $p = .80$. The findings suggested that impairments are associated with depression and anxiety, not pain severity. Based on the results, Miller-Matero et al. (2016) determined that a multifaceted approach incorporating both medical

and psychological therapies may be beneficial in the evaluation and treatment of chronic pelvic pain. Limitations included the study's narrow demographic profile of chronic pelvic pain patients; reliance on self-report measures, which may limit accuracy; and limited research indicating the effectiveness of psychological treatments for chronic pelvic pain patients.

Discussion

The literature review provided relevant data regarding the associated factors of pain; however, the studies are not without their limitations. Miller-Matero et al. (2016) evaluated females only; therefore, the results cannot be generalized to both sexes. It should also be noted that Kamper et al.'s (2015) study identified chronic pain as pain lasting more than 3 months, whereas the other studies lacked a definition, and that the study did include articles in which at least 75% of the participants had chronic low back pain and 25% did not; those 25% may have skewed the results. The limitations of the Craner et al. (2016) study included lack of diversity (95% Caucasian); high education level of participants (mean of 14.9 years); and peer influences, all of which could affect generalization. Miller-Matero et al. (2016) relied on self-reports, rather than objective data, which could have potentially affected the results.

While it is promising that all studies reported pain reduction, the reduction of opioid use that was noted in Purcell et al.'s (2019) study should be further explored because some patients reported increased pain. Perhaps reports of increased pain represented the patient's mistrust of the integrated pain team. Some patients viewed opioid reduction as the treatment's primary goal regardless of pain levels. Therefore, the study emphasized the importance of discussing that the goal of the biopsychosocial model is to improve pain management, not opioid reduction. Day et al.'s (2016) highlighting of increased risk for poor outcomes in pain among those with low socioeconomic status and lack of social support leads to the question of whether those with good

socioeconomical standing would benefit from a biopsychosocial model. If true, limited resources may present a challenge in biopsychosocial model implementation among those with low socioeconomic status because it can be costly and time consuming (Cheatle, 2016). Craner et al.'s (2016) qualitative coding methods were not directly specified, which could have affected the reliability and validity of their study.

The qualitative study by Purcell et al. (2019) noted that all patients underwent an opioid reduction or elimination while undergoing multidisciplinary treatment. Day et al.'s (2016) quantitative cross-sectional survey method used a self-assessment tool to evaluate the associations of pain, functionality, and psychological variants, the results of which suggested pain symptoms could improve with coping skills and social support interventions. These findings correlate with the findings of Kamper et al.'s (2015) systematic review, where it was also concluded that multidisciplinary rehabilitation using biopsychosocial concepts can reduce pain. Despite not being the primary goal, pain reduction was also noted in the study by Craner et al. (2016). These findings are consistent with the study by Day et al. (2016), who also found that a biopsychosocial program led to pain reduction. The study by Miller-Matero et al. (2016) found that psychological symptoms, not pain, were associated with functional impairment in patients with chronic pelvic pain, and they concluded that incorporating both medical and psychological therapies may be beneficial in its treatment.

Historically, opioid prescribing has been an accepted method for pain reduction. The results of these studies present an understanding that the concept of pain encompasses biological, psychological, and social factors and is not just a numerical value. It is apparent to prescribers that the reliance on pain scales to determine severity of pain can result in unnecessary opioid prescribing to reduce the experience of pain (Speed et al., 2018). The risk for misuse of

prescribed opioids is much higher in patients with chronic pain (Hser et al., 2017). Currently, therapeutic approaches are needed that balance treating chronic pain and minimizing risks for opioid misuse. The CDC (2016) recommends opioid misuse monitoring strategies, such as the use of risk assessment instruments, opioid management plans, patient education, prescription drug monitoring program data, pill counts, and urine drug testing. However, the CDC (2016) recognizes that research is unavailable that demonstrates the effectiveness of those strategies. The researchers of the reviewed articles concluded that implementation of a biopsychosocial multidisciplinary team approach for pain management resulted in pain reduction. Once appropriate pain relief had been established, opioid misuse behaviors tended to decrease (Kaye et al., 2017). The researcher anticipated that those who are actively being treated with a biopsychosocial multidisciplinary team approach will have a decreased risk of opioid misuse.

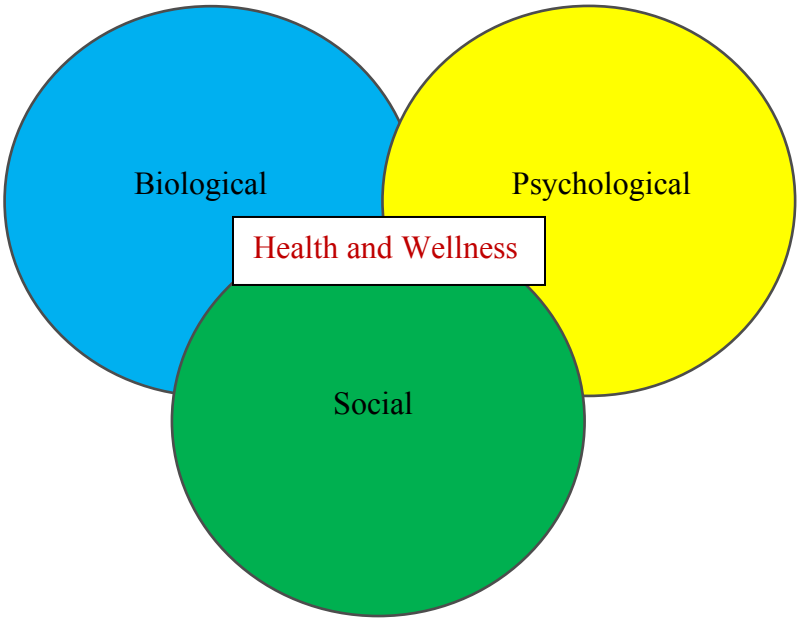
Chapter 3. Theoretical Model and Methodology

Theoretical Model

Engel's (1977) biopsychosocial model provides a systematic interdisciplinary approach to health and wellness. The model considers biological, psychological, and social factors as equivalent and interrelated components in health and wellness (Figure 1). Modification of any component can directly or indirectly influence the other components. Published research using this model continues to grow because it is frequently used in rehabilitation, disability, and chronic pain research and is one of the most recognizable and best-established models (Wade & Halligan, 2017).

Figure 1

Biopsychosocial Model



The biological component of the model accounts for physiological causes, clinical data, pathological issues, and disabilities. The contributions of the biological component in chronic pain are evident in the study by Huhn et al. (2019), who used the Brief Pain Inventory, Pain Catastrophizing Scale, and Subjective Opioid Withdrawal Scale to survey 101 men and 80 women to assess the relationship between pain and opioid misuse. The results indicated that women reported higher levels of current, average, and worst pain compared to men. A clinician's role is to recognize these biological factors and devise a treatment plan to manage chronic pain and improve functionality. The addition of rehabilitative services, such as physical therapy, to address physiological causes for chronic pain has been shown to reduce opioid use (Sun et al., 2018).

The psychological component of the model accounts for human experiences, behavior, personality, and underlying mental health conditions as influential factors. This relationship is

evident in those with anxiety and chronic pain. Rogers et al. (2020) completed a cross-sectional analysis of 396 adults with chronic pain and found that pain-related anxiety significantly mediated the relationship between pain severity, opioid misuse outcomes, and psychosocial disability. CBT is a form of personalized psychological therapy that provides learning strategies to explore one's thought processes and how they connect concepts. CBT can assist in revealing negative thinking and provide tools to address challenges in an effective way, evaluate family and social dynamics, and provide patient and family education (Majeed & Sudak, 2017). CBT has also been shown to reduce opioid medication misuse (Wilson et al., 2015).

The social component of the model accounts for community, environment, religion, culture, peers, family, and economic background. The concept of pain is known to be influenced by cultural and social factors. Some religions view pain as a necessity to bringing one closer to God. Seen in this light, as a positive process, pain would be accepted by sufferers as a challenge to deepen their religious faith (D'emeh et al., 2016).

The concept of pain is a subjective experience unique to each person. Relying on the use of opioid medications for chronic pain management has led to an opioid crisis. Liberal opioid prescribing practices have also led to health provider license suspensions. The biopsychosocial model recognizes that physical, psychological, and social factors are related, and it promotes an integrated approach to treatment. The incorporation of clinical pain management, physical therapy, and CBT to address those factors in chronic pain patients should reduce the risk of opioid medication misuse.

Project and Study Design

The researcher used a quantitative retrospective four-group study design and conducted a medical chart review to identify patients with and without a psychiatric disorder diagnosis who

were participating in a biopsychosocial treatment program comprising (a) a pain management program, (b) a physical therapy program, and (c) CBT and those who were not participating in a program with those three services. The Pain Medication Questionnaire (PMQ; Appendix A) was provided to the four groups, who were allotted 14 days in which to complete and return it via the provided prepaid postage envelope. Participants were contacted on day 15 via text or telephone if responses had not yet been received. The study design was compatible with what this study was seeking—data collection at a single point in time with a four-group comparison.

Setting and Resources

The study was conducted at the San Diego Pain Institute outpatient pain management clinic. For two years, the researcher collaborated with the management group at San Diego Pain Institute in San Diego, California, regarding the association between biopsychosocial multidisciplinary treatment and its impact on risk of opioid medication misuse. Support was obtained from San Diego Pain Institute after the researcher presented evidence indicating biopsychosocial multidisciplinary treatment may impact the risk of opioid misuse among chronic pain patients (Kamper et al., 2015). The managers and ancillary staff agreed to no direct involvement with the study except for one clinical staff member employed by San Diego Pain Institute who assisted in data collection. Office equipment, printing materials, Amazon gift cards, and REDCap software were used.

Study Population

Participants were recruited into the study by the clinical staff member at San Diego Pain Institute outpatient pain management clinic. The clinical staff member performed a retrospective chart review of 435 medical charts, dated from July 19, 2020, through November 2, 2020. Power analysis was conducted with G*Power 3.1 to calculate a one-way analysis of variance (ANOVA)

sample size. A total sample size of 180 was calculated using input parameters of medium effect size of 0.25 (Cohen's *f*), error probability of 0.05, power of 0.80, and number of groups of 4. A convenience sample of 435 participants were identified in the chart review to ensure the target sample size of 180 was obtained. The total sample size was evenly distributed among four groups of 45 each. The sampling frame consisted of patients from San Diego Pain Institute outpatient pain management clinic who were and were not actively being treated with pain management, physical therapy, and CBT.

Inclusion Criteria

Following are the inclusion criteria:

- Diagnosed with chronic pain (pain > 6 months)
- Age ≥ 18 years
- No active pregnancy
- English speaking
- No history of substance abuse
- Not actively using medical cannabis and/or illegal substances
- Treated with continuous opioid therapy > 6 months
- Morphine equivalence > 50 MME/day
- No presence of terminal illness
- Not a surgical candidate
- Actively being treated by pain management
- Physical therapy and CBT for 3 consecutive months
- Actively being treated by pain management only
- Actively being treated by pain management and physical therapy only

- Actively being treated by pain management and CBT only

Exclusion Criteria

Following are the exclusion criteria:

- Pain present for < 6 months
- Actively incarcerated
- History of substance abuse
- Actively using medical cannabis and/or illegal substances
- Has not tried and failed conservative therapy
- Surgical candidate
- Treated with continuous opioid therapy < 6 months
- Morphine equivalence < 50 MME/day

Sources of Data

The PMQ was used to measure risk of opioid medication misuse (Adams et al., 2004). This self-assessment instrument was designed to assess for the risk of medication misuse among chronic pain patients through a 26-item questionnaire that measures dysfunctional attitudes and aberrant behaviors associated with the use of pain medication (Adams et al., 2004). Items include 1. I have clear preferences about the type of pain medication I need; 2. My pain medication makes it hard for me to think clearly sometimes; and 3. At times, I think I may be too dependent on my pain medication. The PMQ is a 5-point Likert scale with each point representing a verbal anchor to reflect a person's conformity with a behavior (Adams et al., 2004). Reponses range from 0 (never) to 4 (always). Pearson's *r* is .85, and Cronbach's alpha is .73 (Adams et al., 2004). Higher scores (70 to 104) are associated with reduced functionality, substance abuse history, and increased levels of psychosocial distress. Lower scores (0 to 34) are associated with

a lower risk group and lower potential for opioid misuse (Adams et al., 2004). Higher scores reflect greater presence of behaviors associated with potential risk for opioid misuse.

The researcher provided each patient with a PMQ, which was collected after 2 weeks. Those who did not complete the PMQ within 2 weeks were reminded via telephone or text by the clinical staff member and provided one additional week. A $5 Amazon gift card was given to those who completed the study in its entirety. Demographic data of sex, age, educational level, and daily MME were collected via chart review. Daily MME was calculated with the formula strength per unit × (number of units/day supply) × MME conversion factor = MME/day (CDC, 2016). Names and addresses were redacted, and the PMQ results were accessible only to the researcher.

Data Analysis

Survey responses and opioid doses were examined with descriptive statistics (median, mean, and standard deviation), histograms, Q-Q plots, and boxplots. The normality, linearity, and equal variance assumptions were met. The differences in responses in the four groups were assessed with a one-way ANOVA. Significance was set at a p-value of ≤ 0.05. Statistical analysis was completed with IBM SPSS Statistics version 27 software.

Quality

Internal Validity—Maturation

Summertime was avoided due to the high probability of vacations. Severe winter weather was avoided due to the possibility of higher-than-normal pain levels. The PMQ was found to be highly reliable (26 items; $\alpha = .88$).

Construct Validity—Experimenter Expectancies

Because the investigator may influence the participants' questionnaire responses, the researcher did not directly interact with the participants during the questionnaire. All participants had the same standardized process to access and complete the PMQ.

Statistical Conclusion Validity—Low Statistical Power

To increase the sample size, a $5 Amazon gift card was provided as an incentive to complete the PMQ. Sample size was calculated using a medium effect size of 0.25 (Cohen's *f*) and a power of 0.80.

Ethics and Human Subjects Protection

Confidentiality

Dates of birth and geographic identifiers, such as address, zip code, city, and county, were not collected. The clinical staff member conducted the retrospective medical chart review.

Competence

The researcher, Michael Palacio, is a board-certified nurse practitioner who has actively practiced in pain management for over 9 years. He provides pain management education for over 4,000 patients annually, trains health care providers in pain management, provides legal expert witness testimony for health-related cases, and is an expert practice consultant for the California Board of Nursing. He has authored evidenced-based institutional policies for University of New Mexico Hospital, New Mexico Pain and Spine, and San Diego Pain Institute.

Institutional Approval

The University of New Mexico Health Sciences Institutional Review Board (IRB) obtained approval for the research protocol before the process was begun. Participants were informed and educated about the research and provided voluntary informed consent before they participated in the study. Participants were free to withdraw at any time and instructed to contact

the IRB with any concerns they may have had about the study. Potential benefits for participants included contribution to health care advancements, compensation, and knowledge gain. Potential harms included severe emotional strain and unintentional disclosure of private data. Reimbursement for two counseling sessions up to $150 and reimbursement of identity theft protection up to $120 were offered to those who experienced adverse effects.

Time Frame

8/3/20: Met with key stakeholders individually to review study and answer any remaining questions

8/5/20: Drafted informed consent letter

8/7/20: Submitted IRB application

10/1/20: Obtained IRB approval

10/2/20: Placed posters in clinic regarding study and began recruitment

10/3/20: Began retrospective chart review

11/2/20: Analyzed chart review results

11/9/20: Provided PMQ access to participants

11/15/20: Began providing $5 Amazon gift cards to participants

11/23/20: Collected PMQ responses, and clinical staff member contacted those who did not complete the questionnaire

3/2/21: Collected remaining PMQ responses

3/2/21: Began analysis of PMQ responses

3/6/21: Completed analysis of all data

3/7/21: Reviewed results and began final write-up

4/17/20: Completed final write-up

Total time: 8.5 months

Operational Budget

Office and printing supplies: $60

Amazon gift cards: $900

Total budget: $960

Results and Discussion

Results and Outcomes

The clinical staff member sent a study recruitment letter to the convenience sample of 435 participants from San Diego Pain Institute. A total of 183 participants responded; however, three participants failed to answer all the items of the PMQ and thus were excluded from the analysis, resulting in a final sample of 180 participants for a total response rate of 41.38%. The total sample (n = 180) had a mean PMQ score of 26.56 (SD = 12.84) and a median score of 26.65. The range was 52 points, with a minimum score of 4 and a maximum score of 56 out of a possible 104.

Data collection time frames for the participants follow:

- No psychiatric disorder with the biopsychosocial multidisciplinary treatment group, 11/1/20 to 11/25/20 and 1/25/21 to 2/3/21
- No psychiatric disorder without biopsychosocial multidisciplinary treatment group, 11/26/20 to 12/10/20 and 2/4/21 to 2/13/21
- Psychiatric disorder with biopsychosocial multidisciplinary treatment group, 12/11/20 to 12/29/20 and 2/14/21 to 2/23/21
- Psychiatric disorder without biopsychosocial multidisciplinary treatment group, 12/30/20 to 1/15/21 and 2/24/21 to 3/2/21

The demographic details of the participants are presented in Table 1. In the no psychiatric disorder diagnosis with biopsychosocial multidisciplinary treatment group, 42.22% were male, 57.77% were female, and their ages ranged from 25 to 65 years and over. For participants in the no psychiatric disorder diagnosis without biopsychosocial multidisciplinary treatment group, 1% were unknown sex, 55.55% were male, 42.22% were female, and their ages ranged from 18 to 65 years and over. For participants in the psychiatric disorder diagnosis with biopsychosocial multidisciplinary treatment group, 2% were unknown sex, 31.11% were male, 64.44% were female, and their ages ranged from 25 to 65 years and over. For participants in the psychiatric disorder diagnosis without biopsychosocial multidisciplinary treatment group, 37.77% were male, 62.22% were female, and their ages ranged from 18 to 65 years and over.

Table 1

Demographics of Study Sample

	No psychiatric disorder dx with biopsychosocial treatment	**No psychiatric disorder dx without biopsychosocial treatment**	**Psychiatric disorder dx with biopsychosocial treatment**	**Psychiatric disorder dx without biopsychosocial treatment**
Sex	n(%)	n(%)	n(%)	n(%)
Unknown	0(0)	1(2.22)	2(4.44)	0(0)
Male	19(42.22)	25(55.55)	14(31.11)	17(37.77)
Female	26(57.77)	19(42.22)	29(64.44)	28(62.22)
Age				
18–24	0(0)	1(2.22)	0(0)	2(4.44)
25–34	1(2.22)	4(8.88)	2(4.44)	3(6.66)

35–44	11(24.44)	8(17.77)	8(17.77)	6(13.33)
45–64	16(35.55)	14(31.11)	19(42.22)	18(40)
65+	17(37.77)	18(40)	16(35.55)	16(35.55)
Educational Level				
No High School	0(0)	0(0)	2(4.44)	2(4.44)
High School or GED	4(8.88)	11(24.44)	11(24.44)	13(28.88)
Some College	15(33.33)	16(35.55)	13(28.88)	8(17.77)
Associate's Degree	7(15.55)	5(11.11)	8(17.77)	6(13.33)
Bachelor's Degree	14(31.11)	10(22.22)	11(24.44)	11(24.44)
Master's Degree	5(11.11)	3(6.66)	0(0)	3(6.66)
Doctorate Degree	0(0)	0(0)	0(0)	2(4.44)

Using IBM SPSS Statistics version 27 software, the data set "group" was labeled as the independent variable and "PMQ score" as the dependent variable to explore the distribution data of the four groups. Descriptive statistics for PMQ score were no psychiatric disorder diagnosis with biopsychosocial multidisciplinary treatment group (M = 14.67, SD = 3.43), no psychiatric disorder diagnosis without biopsychosocial multidisciplinary treatment (M = 15.24, SD = 4.71), psychiatric disorder diagnosis with biopsychosocial multidisciplinary treatment (M = 34.31, SD = 5.13), and psychiatric disorder diagnosis without biopsychosocial multidisciplinary treatment (M = 42.02, SD = 5.38).

A one-way between groups ANOVA was conducted to explore whether there was a significant difference in the scores of the PMQ across the four groups. Equal variance was assumed because the test of homogeneity was not significant ($p = .06$); therefore, a one-way ANOVA was appropriate. A statistically significant difference was indicated at the $p < 0.05$ level among the four groups: F (3, 176) = 381.71, $p < .001$, partial eta squared = .86 (Table 2). No statistical differences were found between educational level ($p = .14$), age ($p = .32$), and sex ($p = .27$).

Table 2

One-Way ANOVA Results Between Groups

	Sum of Squares	df	Mean Square	F	Sig
Between Groups	25,589.39	3	8,529.79	381.71	<.001
Within Groups	3,932.93	176	22.34		
Total	29,522.32	179			

Post-hoc comparisons using the Tukey test indicated that the mean PMQ score for the groups without a psychiatric disorder diagnosis demonstrated a significant difference ($p < .001$) compared to the groups with a psychiatric disorder diagnosis. The mean PMQ score for the psychiatric disorder diagnosis with biopsychosocial treatment group demonstrated a significant difference ($p < .001$) compared to the psychiatric disorder diagnosis without biopsychosocial treatment group (Table 3).

Table 3

Post-Hoc One-Way ANOVA Tests, Tukey HSD

(I)Group	(J)Group	Mean Difference (I-J)	Sig.

No psychiatric disorder diagnosis with biopsychosocial treatment	No psychiatric disorder diagnosis without biopsychosocial treatment	−.578	.93
	Psychiatric disorder diagnosis with biopsychosocial treatment	−19.64	<.001
	Psychiatric disorder diagnosis without biopsychosocial treatment	−27.35	<.001
No psychiatric disorder diagnosis without biopsychosocial treatment	No psychiatric disorder diagnosis with biopsychosocial treatment	.57	.93
	Psychiatric disorder diagnosis with biopsychosocial treatment	−19.06	<.001
	Psychiatric disorder diagnosis without biopsychosocial treatment	−26.77	<.001
Psychiatric disorder diagnosis with biopsychosocial treatment	No psychiatric disorder diagnosis with biopsychosocial treatment	19.64	<.001
	No psychiatric disorder diagnosis without biopsychosocial treatment	19.06	<.001
	Psychiatric disorder diagnosis without biopsychosocial treatment	−7.71	<.001
Psychiatric disorder diagnosis without biopsychosocial treatment	No psychiatric disorder diagnosis with biopsychosocial treatment	27.35	<.001
	No psychiatric disorder diagnosis without biopsychosocial treatment	26.77	<.001
	Psychiatric disorder diagnosis with biopsychosocial treatment	7.71	<.001

Discussion

Between the groups no psychiatric disorder diagnosis with biopsychosocial treatment and no psychiatric disorder diagnosis without biopsychosocial treatment there was no significant statistical difference. One possible explanation for this is that San Diego Pain Institute limits the

opioid prescribing to a dose of 90 MME/day. It is unknown whether patients with higher daily doses of opioids would affect the results because they may fall into a higher risk group related to increased physiological causes, pathological issues, and disabilities.

The significant statistical difference between those in the groups with no psychiatric disorder diagnosis and those in the groups with a psychiatric disorder diagnosis is consistent with the findings of existing studies. A study conducted by Martel et al. (2020) found that opioid misuse was not significantly associated with pain intensity when controlling for psychological factors, which indicated an association between opioid misuse and psychological factors. Rogers et al. (2019) found that anxiety sensitivity was associated with opioid misuse, severity of opioid dependence, and number of opioids used to get high. Barry et al. (2016) found that psychiatric comorbidities correlate with opioid use disorder and chronic pain. The study results reinforced that those with a psychiatric disorder diagnosis are at a higher risk for opioid misuse compared to those without a psychiatric disorder.

A significant statistical difference was found between the groups psychiatric disorder diagnosis with biopsychosocial treatment and psychiatric disorder diagnosis without biopsychosocial treatment. These findings suggest that participation in biopsychosocial treatment is associated with a decreased risk of opioid misuse among adult chronic opioid-dependent noncancer pain clinic patients with a psychiatric disorder. Traditional chronic pain management tends to focus on the biological components with minimal emphasis on the psychological or social components. Acknowledging the biological, psychological, and social components could potentially affect patient outcomes. A study by Baranyi et al. (2017) found an inverse relationship between social support and depression; it is plausible that, if the social component is unacknowledged, it could affect the psychological component, which is a known contributing

factor to opioid use. Incorporation of the biopsychosocial model addresses all components and appears to have provided an alternative to opioids for pain management among those with a psychiatric disorder.

The CDC (2016) recognizes that psychological comorbidities can interfere with pain management and opioid tapering and patients may be prescribed benzodiazepines, leading to an increased risk for overdose. Effective pain management relies on improved functionality, development of coping mechanisms, and a reduced reliance on opioid medications. Research has found that opioid medications are not an effective treatment modality for all patients, can lead to addiction and dependency, and place patients at risk for accidental overdose (CDC, 2016). Addressing the psychological and social components of those with a psychiatric disorder can potentially improve pain management, decrease opioid misuse, and contribute to the national goal of opioid reduction.

Implications for Practice

The purpose of this project was to examine the association between biopsychosocial multidisciplinary treatment and its impact on risk of opioid medication misuse to provide patients and providers with an alternative method for preventing opioid misuse. Prior to this study, the clinical staff and providers at San Diego Pain Institute had limited knowledge of the biopsychosocial model and its applicability to chronic pain patients. The minimal impact found between the groups with no psychiatric disorder would likely not alter current practices; however, the significant statistical difference found between the groups with a psychiatric disorder may improve patient care. Patients with a psychiatric disorder are known to have a higher risk of opioid misuse and overdose and are often prescribed benzodiazepines, which can negatively interact with opioid medications (CDC, 2016). The findings of this study suggest that

adult chronic opioid-dependent noncancer pain clinic patients with a psychiatric disorder may reduce their risk of opioid misuse when participating in multidisciplinary biopsychosocial treatment. Inclusion of biopsychosocial treatment for adult chronic opioid-dependent noncancer pain clinic patients with a psychiatric disorder could potentially reduce the risk of opioid misuse, overdose, and medication interactions and combat the national opioid crisis. A standardized process should be implemented to educate patients with a psychiatric diagnosis and the clinical staff and providers on the benefits of the biopsychosocial model.

Limitations for Health Policy

Currently, San Diego Pain Institute does not have collaborative partnerships with cognitive behavioral therapists, clinical psychologists, or physical therapists. Implementing a collaborative partnership with other clinics would require that changes be made to the policies of the involved clinics. Each clinic would need to take a vested interest in the biopsychosocial treatment model and its potential to decrease opioid misuse. The increased demand for effective communication among clinics to share records and treatment plans could result in higher administrative costs. It is feasible that clinics may consider that the costs outweigh the benefits presented in this study.

The clinical services incorporated within the biopsychosocial treatment model may not be attainable by all patients. Not all insurance plans provide coverage for mental health services, which is a necessary component of the biopsychosocial treatment model. The inclusion of coverage for mental health services on all insurance plans would require changes be made to national and state policies. Stakeholders, such as policy makers, insurance providers, patients, clinicians, therapists, pharmacists, and health care associations, may conclude that the findings of this study do not warrant such changes to current policies.

Limitations and Strengths of the Study

The use of convenience sampling in a private practice pain clinic is vulnerable to selection bias and may not generalize to other clinics without a similar patient population. San Diego Pain Institute does not accept Medicaid insurance and limits opioid prescribing to a dose of 90 MME/day. Patients with Medicaid insurance and those who require higher doses of opioid medication may have an increased complicated medical history that contributes to a higher risk for opioid misuse. The PMQ relies on patient self-reporting, and an assumption is made that truthful responses were provided. The study results would be altered if questions were not understood or untruthful responses were given. While the study did account for patients with a psychiatric disorder, it did not account for specific psychiatric disorders and how they could affect the results. Moreover, the study does not account for other factors that may contribute to opioid misuse, such as physical abuse, sexual abuse, or a history of high risk-taking behaviors. Data collection time frames were affected by the COVID-19 pandemic. Data were to be obtained over four points within a 3-month period. However, closure of the clinic to physical appointments limited the clinical staff member's ability to review medical records, which resulted in an inadequate sample size and extension of the data collection to eight points over a 5-month period.

Strengths of the study include the absence of a significant difference between the variables sex, age, and educational level, which indicates that the PMQ scores were unrelated to the demographics. Additionally, the use of G*Power 3.1 to calculate the sample size should have provided a sufficiently sized cohort. An adequately sized cohort should have produced clinically relevant data.

Suggestions for Further Research

While the present findings provide evidence that biopsychosocial treatment impacts the risk of opioid misuse among adult chronic opioid-dependent noncancer pain clinic patients with a psychiatric disorder, future studies are recommended to evaluate the direct correlation between social support systems and opioid misuse. Identifying how and what types of social support deficiencies contribute to the risk of opioid misuse could assist providers in recognizing high-risk patients, which could lead to interventions that may alter behaviors. Research should also be considered for patients' and providers' perceptions of the biopsychosocial model. The lack of collaborative partnerships with pain management clinics, cognitive behavioral therapists, clinical psychologists, and physical therapists indicates a disconnect between the services. Understanding patients' and providers' current knowledge and perceptions of the biopsychosocial model could identify barriers to implementing collaborative partnerships. While this study did provide clinically relevant data, they were limited in scope. A larger sample size with broader demographics, increased daily opioid MME, and a variety of insurance plans would make the study results more generalizable to other pain clinics. The researcher hopes that the results of this study will contribute to opioid misuse prevention and stimulate future research to improve chronic pain management clinical decisions.

Concluding Remarks

Differences in perception and the subjective nature of pain pose treatment challenges for health care providers. As U.S. deaths related to opioid prescriptions increased, stricter guidelines for opioid prescribing were adopted nationwide. These changes have led to both patients and providers searching for alternative pain control methods. Traditional pain management has relied on observable ailments and medication administration, rather than the biological, social, and

psychological aspects of pain. A literature review was conducted to gain an understanding of how the biopsychosocial model correlates with risk of opioid misuse. Engel's (1977) biopsychosocial model evaluates the individual's biological, psychological, and social components for health improvement. This model shifts our treatment options from a generalized to an individualized plan. To identify an association between biopsychosocial multidisciplinary treatment and its impact on risk of opioid medication misuse among adult chronic opioid-dependent noncancer pain clinic patients, a quantitative retrospective four-group study design was conducted. The results found that biopsychosocial multidisciplinary treatment reduced the risk of opioid medication misuse among chronic pain patients with a psychiatric disorder at San Diego Pain Institute. The researcher hopes that the results will encourage collaborative partnerships between health services, stimulate interest in biopsychosocial multidisciplinary treatment research, and provide an alternative method for opioid misuse prevention.

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Appendix A

PMQ PAIN MEDICATION QUESTIONNAIRE© **NAME:** _____

In order to develop the best treatment plan for you, we want to understand your thoughts, needs and experiences related to pain medication. Please read each statement below and indicate how much it applies to you by marking your response with an "X" anywhere on the line below it.

1) I believe I am receiving enough medication to relieve my pain.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

2) My doctor spends enough time talking to me about my pain medication during appointments.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

3) I believe I would feel better with a higher dosage of my pain medication.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

4) In the past, I have had some difficulty getting the medication I need from my doctor(s).

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

5) I wouldn't mind quitting my current pain medication and trying a new one, if my doctor recommends it.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

6) I have clear preferences about the type of pain medication I need.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

7) Family members seem to think that I may be too dependent on my pain medication.

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

8) It is important to me to try ways of managing my pain in addition to the medication *(such as relaxation, biofeedback, physical therapy, TENS unit, etc.)*

Disagree *Somewhat Disagree* *Neutral* *Somewhat Agree* *Agree*

(Please continue on the next page)

9) At times, I take pain medication when I feel anxious and sad, or when I need help sleeping.

Never Occasionally Sometimes Often Always

10) At times, I drink alcohol to help control my pain.

Never Occasionally Sometimes Often Always

11) My pain medication makes it hard for me to think clearly sometimes.

Never Occasionally Sometimes Often Always

12) I find it necessary to go to the emergency room to get treatment for my pain.

Never Occasionally Sometimes Often Always

13) My pain medication makes me nauseated and constipated sometimes.

Never Occasionally Sometimes Often Always

14) At times, I need to borrow pain medication from friends or family to get relief.

Never Occasionally Sometimes Often Always

15) I get pain medication from more than one doctor in order to have enough medication for my pain.

Never Occasionally Sometimes Often Always

16) At times, I think I may be too dependent on my pain medication.

Never Occasionally Sometimes Often Always

17) To help me out, family members have obtained pain medications for me from their own doctors.

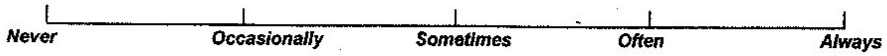
Never Occasionally Sometimes Often Always

18) At times, I need to take pain medication more often than it is prescribed in order to relieve my pain.

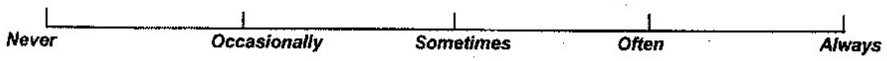
Never Occasionally Sometimes Often Always

(Please continue on the next page)

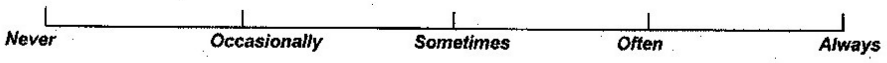
19) I save any unused pain medication I have in case I need it later.



20) I find it helpful to call my doctor or clinic to talk about how my pain medication is working.

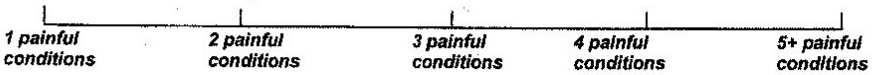


21) At times, I run out of pain medication early and have to call my doctor for refills.

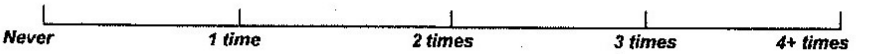


22) I find it useful to take additional medications *(such as sedatives)* to help my pain medication work better.

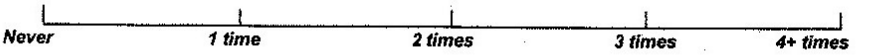
23) How many painful conditions *(injured body parts or illnesses)* do you have?



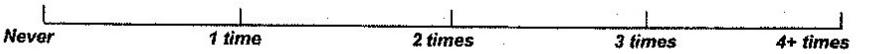
24) How many times in the past year have you asked your doctor to increase your prescribed dosage of pain medication in order to get relief?



25) How many times in the past year have you run out of pain medication early and had to request an early refill?



26) How many times in the past year have you accidentally misplaced your prescription for pain medication and had to ask for another?



(Stop)

Appendix B

HEALTH SCIENCES
OFFICE OF RESEARCH

Human Research Protections Program

October 5, 2020
Stephen Roper
505-272-2375
Fax: 505-272-8901
svroper@salud.unm.edu

Dear Stephen Roper:

On 10/1/2020, the HRRC reviewed the following submission:

Type of Review: Initial Study
Title of Study: Biopsychosocial Multidisciplinary Treatment Impact on Risk of Opioid Misuse
Investigator: Stephen Roper
Study ID: 20-544
Submission ID: 20-544
IND, IDE, or HDE: None

Submission Summary: Initial Study

Documents Approved:
- Consent Form
- Pain Medication Questionnaire
- Recruitment Flyer
- Research Protocol
- Signed letter from research site

Review Category: EXEMPTION: Categories (2)(i) Tests, surveys, interviews, or observation (non-identifiable)

Determinations/Waivers: Provisions for Consent are adequate.
HIPAA Authorization Addendum Not Applicable.

Submission Approval Date: 10/1/2020
Approval End Date: None
Effective Date: 10/1/2020

The HRRC approved the study from 10/1/2020 to inclusive. If modifications were required to secure approval, the effective date will be later than the approval date. The "Effective Date" 10/1/2020 is the date the HRRC approved your modifications and, in all cases, represents the date study activities may begin.

Because it has been granted exemption, this research is not subject to continuing review.

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Please use the consent documents that were approved by the HRRC. The approved consents are available for your retrieval in the "Documents" tab of the parent study.

If the study meets the definition of an NIH Clinical Trial, the study must be registered in the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database.

This determination applies only to the activities described in this submission and does not apply should you make any changes to these documents. If changes are being considered these must be submitted for review in a study modification to the HRRC for a determination prior to implementation. If there are questions about whether HRRC review is needed, contact the HRPO before implementing changes without approval. A change in the research may disqualify this research from the current review category. You may submit a modification by navigating to the active study and clicking the "Create Modification/CR" button.

If your submission indicates you will translate materials post-approval of English materials, you may not recruit or enroll participants in another language, until all translated materials are reviewed and approved.

In conducting this study, you are required to follow the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library.

Sincerely,

Thomas F. Byrd, MD
HRRC Executive Chair

Abbreviated Investigator Responsibilities
NOTE: For a full unabbreviated version of the **Investigator Manual**, please visit the HRPO website at https://hsc.unm.edu/research/hrpo/.

What will happen after HRRC review?
The HRPO will provide you with a written decision indicating that the HRRC has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

If the HRRC has approved the Human Research: The Human Research may commence once all other organizational approvals have been met. HRRC

Human Research Protections Program

approval is usually good for a limited period of time which is noted in the approval letter.
If the HRRC requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the HRRC. If all requested modifications are made, the HRRC will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the HRRC.
If the HRRC defers the Human Research: The HRRC will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the HRRC's reasons for the deferral are addressed in a modification, the Human Research can be approved
If the HRRC disapproves the Human Research: The HRRC will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the HRRC directly at an HRRC meeting.

What are my obligations after HRRC approval?

1. Do not start Human Research activities until you have the final HRRC approval letter.
2. Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
    a. Delegate responsibility to the research staff in accordance with the staff's training and qualifications.
    b. Assure that all procedures associated with the research are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of New Mexico and policies of The University of New Mexico Health Sciences Center.
    c. Monitor the research study and perform quality management activities to ensure the protection of participants and the quality of the research data.
4. Obtain the legally effective informed consent from human participants or their representatives, using only the currently approved informed consent documents, and provide a copy to the participant, if applicable. a) Ensure that only HRRC-approved investigators obtain informed consent from potential participants.
5. If unavailable to conduct the research personally, as when on sabbatical leave or vacation, arrange for another HRRC-approved investigator on the study to assume direct responsibility or notify the HRRC of alternate arrangements.

6. Maintain accurate and complete research records, including but not limited to, original signed informed consent and authorization documents, and retain these records according to HRRC policy and the applicable regulatory retention terms.
7. Fully inform the HRRC of all locations in which human participants will be recruited for this project and obtain and maintain current HRRC approvals/letters of cooperation when applicable.
8. Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
9. Update the HRRC office with any changes to the list of study personnel.
10. Personally conduct or supervise the Human Research.
    a. Conduct the Human Research in accordance with the relevant current protocol as approved by the HRRC.
    b. When required by the HRRC, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the HRRC.
    c. Do not modify the Human Research without prior HRRC review and approval unless necessary to eliminate apparent immediate hazards to participants.
    d. Protect the rights, safety, and welfare of participants involved in the research.
11. Submit to the HRRC:
    a. Proposed modifications as described in this manual. (See "How do I submit a modification?")
    b. A continuing review application as requested in the approval letter. (See "How do I submit continuing review?"
    c. A continuing review application when the Human Research is closed. (See "How Do I Close Out a Study?")
12. Report any of the information items listed in Appendix A-1 to the HRRC within five business days.
13. Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
14. Do not accept or provide payments to professionals in exchange for referrals of potential participants ("finder's fees.")
15. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")
16. See additional requirements of various federal agencies in Appendix A-2 through A-9 of the Investigator Manual. These represent additional requirements and do no override the baseline requirements of this section.

If the HRRC directs or your study is selected for an onsite post-approval review, cooperate with HRPO Quality Improvement program staff to complete it.

Research Data and Study Records

Researchers and staff should have systems or practices for maintaining the essential Research Records that they create in order to be able reasonably to support research

findings, justify the uses of research funds and resources, and protect any resulting intellectual property.

During the life of a study and beyond its closure, many information security and storage policies pertain to the maintenance and archival of study documents and research data. These policies and procedures include those of the researcher's department, UNM HSC, the State of New Mexico, Federal privacy laws (such as HIPAA, FERPA, FOIA, New Mexico IPRA), Federal regulations (FDA, OHRP, DHHS, etc) as well as the data confidentiality requirements associated with research funding (e.g. National Institutes of Health, Department of Defense (DOD), etc.).

PI responsibilities for document and data security are particularly critical during times of study transition, as when a PI is leaving UNM HSC, is transferring PI responsibilities or is closing a study. Be prepared ahead of time and discuss transition and/or long-term storage plans with your department Chair/ Research Chair. Assure that information regarding these plans are documented in a standard place and are using an established process, so that an incoming PI and department personnel can find, understand and follow it.

Appendix A-1 Reportable New Information

Report information items that fall into one or more of the following categories to the HRRC within 5 business days. Reference SOP: New Information (HRP-024).

1. Information that indicates a new or increased risk, or a new safety issue, for example:
    a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
    b. Protocol violation that harmed participants or others or that indicates participants or others might be at increased risk of harm.
    c. Complaint of a participant that indicates participants or others might be at increased risk of harm or at risk of a new harm.
    d. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.
    e. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
    f. Changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
2. Harm experienced by a participant or other individual, which in the opinion of the investigator are unexpected and related or possibly related to the research procedures.

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   a. A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the HRRC in terms of nature, severity, frequency, and characteristics of the study population.
   b. A harm is "related or possibly related" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.
3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the HRRC, or an allegation of such non-compliance.
4. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
5. Change to the protocol taken without prior HRRC review to eliminate an apparent immediate hazard to a participant.
6. Breach of confidentiality.
7. Complaint of a participant that cannot be resolved by the research team.
8. Premature suspension or termination by the sponsor, investigator, or institution.
9. Incarceration of a participant in a study not approved by the HRRC to involve prisoners.
10. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g., FDA Form 483).
11. Written reports of study monitors.
12. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).
13. Unanticipated Problems Involving Risks to Subjects or Others, including any event or problem that is serious, unexpected, and related to the research, where "related" means the event or problem might reasonably be regarded as caused by, or probably caused by, the research.
14. Disciplinary action against the investigator or research staff by federal, state, and local regulatory agencies.