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Erin Stevenson, Student Dr. Melanie D. Otis, Major Professor Dr. David Royse, Director of Graduate Studies

# EXAMINING CHRONIC NON-CANCER PAIN AMONG A SAMPLE OF INDIVIDUALS IN OPIOID TREATMENT PROGRAMS

# DISSERTATION

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Social Work at the University of Kentucky

> By Erin Stevenson, M.S.W., C.S.W. Lexington, Kentucky

Director: Dr. Melanie D. Otis, Associate Professor of Social Work Lexington, Kentucky

2012

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# ABSTRACT OF DISSERTATION

# EXAMINING CHRONIC NON-CANCER PAIN AMONG A SAMPLE OF INDIVIDUALS IN OPIOID TREATMENT PROGRAMS

National rates of chronic non-cancer pain (CNCP) are rising alongside increasing reports of prescription opioid abuse and mortality. Associations between the rise in CNCP and in opioid abuse seem logical, yet research on CNCP among individuals with opioid dependence is currently limited due to the complicated nature of comorbid conditions in research and treatment. This study aims to expand the CNCP knowledge base by responding to the question: *Do individuals with CNCP participating in an opiate treatment program have better or worse treatment outcomes than individuals without CNCP*?

This study used a secondary dataset including 483 adults from Kentucky's Opiate Recovery Treatment Outcome Study. Individuals in the sample met DSM-IV-TR criteria for opioid dependence and were in treatment at a licensed opiate treatment program (OTP). Analysis compared cases with and without CNCP on national treatment outcome measures including substance use, recovery support, education, employment, mental health symptoms, and criminal justice system involvement.

Results indicated no differences at follow-up between the CNCP (n=163) and non-CNCP (n=320) individuals on substance abstinence, recovery supports, education level, or criminal justice system involvement. At baseline and follow-up there were more unemployed individuals and individuals receiving disability benefits in the CNCP group than the non-CNCP group. Reported anxiety and depression symptoms increased at follow-up, while use of prescription medicine for mental health symptoms declined for both groups (non-significant differences). The only predictors for CNCP cases in this sample were tobacco use and presence of a chronic medical condition.

Recommendations include expansion of smoking cessation programs in substance abuse treatment settings. Future research might examine integrated treatment and medical home health models to better address biopsychosocial components of clients with comorbid conditions like opioid dependence and CNCP.

KEYWORDS: chronic non-cancer pain (CNCP), opioid dependence, opiate treatment programs (OTPs), chronic medical conditions, tobacco

Erin Stevenson

Signature

March 26, 2012

Date

# EXAMINING CHRONIC NON-CANCER PAIN AMONG A SAMPLE OF INDIVIDUALS IN OPIOID TREATMENT PROGRAMS

Ву

Erin Stevenson

Dr. Melanie Otis

Director of Dissertation

Dr. David Royse

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March 26, 2012

Date

# DEDICATION

This dissertation is dedicated to my spouse of 15 wonderful years, Diana, whose support, love, and encouragement are beyond words and to my daughter Natalie who I hope can also learn the joy of a job well done.

I also dedicate this dissertation to my dear family and friends whose love and encouragement bolsters me on a daily basis. May I return the favor one day soon!

Finally, this dissertation is in memory of Joan Van Blarcom who taught me about truth and love amidst the joy and pain in life.

# ACKNOWLEDGEMENTS

I am extremely grateful to Dr. Melanie Otis for chairing my dissertation committee and for patiently steering me along the path towards completion of this dissertation. Thank you also to my committee members Dr. TK Logan, Dr. Seana Golder, and Dr. James Clark for your wise words of guidance and direction. Thank you also to Dr. David Royse, Director of the Doctoral Program in the College of Social Work; Robert Walker, L.C.S.W., Dr. Sharon Walsh, and Dr. Carl Leukefeld of the Center on Drug & Alcohol Research; Louis Kurtz and Jeff Jamar of the Kentucky Department for Behavioral Health, Developmental and Intellectual Disabilities; and to the directors, staff, and clients of opiate treatment programs across Kentucky.

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#### **CHAPTER 1. INTRODUCTION**

Individuals experiencing physical non-cancer related pain that persists or recurs for three months or longer are considered to have chronic-non-cancer pain or CNCP (International Association for the Study of Pain Society [IASP], 2011). CNCP prevalence rates are on the rise worldwide (Haanpaa et al., 2009) with 1 in 10 adults newly diagnosed each year (IASP, 2011). Recent estimates from the Institute of Medicine indicate CNCP affects over 116 million adults annually (2011). These numbers are expected to continue rising in the United States due to a variety of issues including high rates of obesity, diabetes, arthritis, and an increasingly aging population (Institute of Medicine [IOM], 2011). Though the natural aging process itself is not associated with pain, the odds of developing painful health conditions does increase with age (Tunks, Crook, & Weir, 2008) and United States census estimates show almost 60% of the population will be age 50 or older by the year 2025 (U.S. Census Bureau, 2010).

Opioid analgesics are frequently prescribed for acute and chronic pain relief, despite their high abuse liability potential (Katz, 2010). A review of 24 studies found less than 1% of legitimate opioid analgesic users without prior substance abuse history ever abused or developed opioid dependence to prescribed pain medication (Fishbain, Cole, Lewis, Rosomoff, & Rosomoff, 2008), however. Nevertheless, two-thirds of a nationally representative sample of clients in substance abuse treatment reported their initial use of opioids, which led to their current opioid dependence, was through a legitimate opioid analgesic prescription for pain (Cicero, Lynskey, Todorov, Inciardi, & Surratt, 2008). In fact, between 1992 and 2009 the rate of substance abuse treatment admissions reporting opioid abuse quadrupled while rates of reported use for other drug categories stayed the same or dropped slightly (SAMHSA, 2010). The rise in prevalence of CNCP parallels this rapid rise in prescription painkiller abuse and opioid dependence (Cicero, Inciardi, & Munoz, 2005; SAMHSA, 2003b; SAMHSA, 2010) and highlights

an area of research needed in regards to CNCP among individuals who are already addicted to opioids and are in substance abuse treatment.

The literature currently provides limited information regarding the overlap between CNCP and opioid dependence (Manchikanti et al., 2006; Strain, 2002). Studies among opioid dependent individuals in methadone maintenance treatment found 37% to 66% of clients reported CNCP (Barry et al., 2009; Rosenblum et al., 2003). Other studies found 24% of residential drug treatment patients (Rosenblum et al., 2003) and 29% of individuals in outpatient substance abuse treatment (Sheu et al., 2008) reported CNCP. Self-medication of pain was a primary reason clients gave for abuse of prescription medications (Khantzian, 1998; Sheu et al., 2008). Guidance on how best to provide effective treatment for individuals in opioid dependence treatment programs (OTPs) with comorbid CNCP is a gap in the current literature. Yet, it is an important area to address as these conditions continue to expand their influence and may have a negative association to recovery. Research protocols including samples with a variety of comorbidities like CNCP are currently limited, thus a good first step is to examine CNCP in relation to opioid dependence treatment outcomes.

#### **Purpose of this Dissertation**

The concurrent rise in CNCP and opioid abuse rates triggered a dissertation that explores CNCP amongst a secondary client-level dataset from Kentucky's opiate treatment programs (OTPs). The study examines treatment outcomes for a sample of 483 individuals who were clients in licensed OTPs in Kentucky between March 2007 and December 2010. Admission to the OTP required that all individuals meet clinical criteria for opioid dependence (DSM-IV-TR definition). All clients in state OTPs are offered the opportunity to participate in the Kentucky Opiate Replacement Treatment Outcome Study (KORTOS) from which the secondary dataset is derived. KORTOS examines long-term outcomes and treatment effects among clients in

maintenance methadone or buprenorphine treatment at OTPs, thus the range of exposure to treatment varies within the dataset. It is important to note there are strict regulations guiding treatment protocols across all federally licensed OTPs. These guidelines require annual medical check-ups, random observed drug screens, random take-home medication checks to ensure clients are not diverting take-home medication doses, and substance abuse counseling (Center for Substance Abuse Treatment [CSAT], 2005). OTP clients across the state of Kentucky have very similar cross-site treatment experiences due to the strict Federal and state oversight of the treatment program protocols.

Within the dataset analyzed for this paper, 37% of clients reported the presence of CNCP (i.e., chronic physical pain persisting or recurring for three months or longer and not related to cancer [IASP,2011]). Research provides some evidence of a correlation between CNCP and opioid dependence (Hojsted, Nielsen, Guldstrand, Frich, & Sjogren, 2010; Manchikanti, Fellows, Damron, Pampati, & McManus, 2005), but to my knowledge there have been no studies to date that address the impact of the comorbidity of CNCP and opioid dependence on outcomes for individuals receiving maintenance treatment with methadone or buprenorphine medication at a licensed OTP. Thus, the purpose of this exploratory study is to examine treatment outcomes specifically based on the presence or absence of CNCP. Outcomes will focus on national measures that compare OTP client self-reported status from baseline to follow-up regarding the following areas of interest:

- 1. Abstinence from alcohol use;
- 2. Abstinence from illicit drug use;
- 3. New or maintained employment;
- 4. Decreased mental health symptoms;
- 5. Decreased criminal justice system involvement; and

6. Recovery support use.

#### **Study Aims**

The study's primary goal is to expand the research regarding CNCP by examining outcomes among opioid dependence treatment clients. The dataset used for this study was compiled by staff at the University of Kentucky who followed a research protocol that started the process of locating and contacting clients for a follow-up telephone interview two months prior to the client's follow-up eligibility date calculated as baseline date plus 180 days. The window for follow-up remained open two months after the eligibility date in order to allow sufficient time to locate the client and complete the 30-minute follow-up phone interview. Individuals had been in treatment for an average of 15 months at follow-up.

Specifically, this study aims to examine characteristics of the sample by comparing individuals with and without CNCP on key variables including: sex, age, race/ethnicity, geographical location for treatment (Appalachian, non-Appalachian), length of time in treatment, dose level, education level, employment status, substance use history, and mental health symptoms.

In addition, the study aims to explore the relationship between CNCP and treatment outcomes. The outcome most relevant to OTPs is abstinence from or reduction in illegal drug use and alcohol use (CSAT, 2005). In addition, the study will examine changes by individual pain group status from baseline to follow-up while controlling for age, gender, race/ethnicity, geographical location of treatment, and presence of chronic medical conditions. Key follow-up variables will include employment status, mental health symptoms, abstinence from drug use, abstinence from alcohol use, and connection with recovery supports (i.e., narcotics anonymous (NA), methadone anonymous (MA), family and friends who are supportive of recovery). Each of these outcomes can help provide a measure of the individual's ability to participate in and

contribute to family and/or work communities in a stable way while also participating in opioid maintenance treatment.

# **Conceptual Framework of the Study**

The literature indicates biological, psychologial, and social conditions can influence the likelihood of an individual developing CNCP and/or opioid dependence. Though research is minimal and in no way definitive, it is clear that biopsychosocial factors play a part in the process of developing these conditions (Strain, 2002; IOM, 2011). Thus, this study relies on the biopsychosocial framework as a guide for its research questions and data analyses. The biopsychosocial framework is not a stand-alone testable theory, but is rather a combination of concepts that provides a useful heuristic for the examination of the complications inherent in both opioid dependence and chronic pain. The use of a wider structure such as offered by the biopsychosocial framework is essential to help us understand these disorders and attempt to capture and weave together the physical, mental, and emotional aspects of the disorders involved (Gatchel & Kishino, 2011; Gatchel, Peng, Peters, Fuchs & Turk, 2007). The following paragraphs will expand on the inter-relatedness of the biopsychosocial framework in relation to CNCP and opioid dependence.

#### **Biopsychosocial framework and CNCP.**

The concept of pain with which most people are keenly aware is the individual psychological and emotional reaction to a negative physical sensation. In the early 1900's, scientists began examining the wide range of individual differences found among persons with medically similar painful conditions, but who expressed very different ranges of pain ratings and reactions. This discovery triggered scientific exploration of potential pain centers in the body theorized as interacting with neural structures in the brain in order to guide how a person's mind translates and reacts to pain (Bonica & Loeser, 2001).

In 1965, Melzack and Wall published their seminal work on the gate control theory of pain, which identified the transmission of pain signals across the dorsal horn area at the top of the spinal cord and into the central nervous system. Specialized nerve cells with temporal and spatial patterning were acknowledged and the basis of the theory was that the brain had the ability to gate or control impulses from the nervous system regarding pain. The implication of this theory was particularly significant for pain control research and new treatment methods quickly expanded based on the theory. One method developed to mediate pain was called transcutaneous electrical nerve stimulation (TENS) which was a mechanism used to block transmission of pain messages across the dorsal horn in the brain and thus reduce the individuals' perception of painful stimuli (Patel, 2010).

Over the next few decades, the biological aspects of pain were linked to the psychological and social aspects including such phenomena as loss of work and strained family relationships due to CNCP (Gatchel et al., 2007). In fact, diagnosing conjoint depression with CNCP is very difficult because of the shared symptomology between diagnoses including sleep disturbances, fatigue, and attention/memory issues (Sharp & Keefe, 2006). Thus, since the spectrum of consequences of CNCP encompass not only the biological elements of a person, but also social and psychological elements, the biopsychosocial framework has become the most applicable framework for understanding and researching CNCP (Gatchel et al., 2007).

#### Biopsychosocial framework and opioid dependence.

The primary variable of interest in this study is CNCP, yet everyone in the sample has in common opioid dependence. Consequently, it is also important to understand opioid dependence within the context of the biopsychosocial framework. The American Society of Addiction Medicine defines substance abuse and dependence as "a chronic recurring brain disease" characterized by compulsive alcohol or drug use despite evidence of harmful effects

(12 April 2011, www.asam.org; National Institute on Drug Abuse, 2010). In the not so distant past, chemical dependence was viewed as moral weakness (Brown, 2006; O'Brien & McClellan, 1996), an attempt to self-medicate untreated mental health issues (Mueser, Drake, Turner, & McGovern, 2006), or simply a failure by individuals to control their behavior (O'Brien & McClellan, 1996; Straussner & Attia, 2002). In 1914, the Harrison Act set in motion the criminalization of drug use and dependence in the United States by penalizing physicians for maintaining opiate dependent clients, often morphine dependent as this was before synthetic opioids were widely available, to prevent them from going into withdrawal. Many women at the turn of the century were prescribed opiates like paregoric or opium derivatives for nervous conditions and the 1914 law began a forced shift in thinking about whether or not this reliance on drugs was acceptable in society (Campbell, 2010). Ironically, at the turn of the century, it was morally and socially unacceptable for women to drink, yet they were encouraged to take alcohol and opiate-based medications for all manner of aches, pains, and complaints (Brown, 2006). For men, drinking together was a social event and a strong part of work and business culture. In fact, the initial Alcoholics Anonymous (AA) meetings in 1935 were for men only which points towards the beginning of a shift in cultural values surrounding alcohol use (Brown, 2006). During this period, psychoanalysts described substance abuse in terms of an individual failing to control impulses or to act responsibly (Straussner & Attia, 2002). Drug and alcohol use problems were viewed as a personal or family problem and as a moral flaw leading to degenerate and dangerous behavior. This was a particularly strong criticism made by the upper classes towards individuals with lower socioeconomic resources and the rising number of immigrants at the turn of the century (Campbell, 2010). The criminalization of drug or alcohol dependence even led to forced sterilization of some women (Straussner & Attia, 2002).

Further attempts to control drug and alcohol use was the establishment of treatment and research facilities. In 1935, the Federal prison in Lexington, Kentucky established the Narcotic Treatment Farm. The Lexington research facility was a human laboratory developed to examine heroin and morphine dependence and to develop appropriate treatment for addiction. The center had joint oversight both by the United States Public Health Service and the Federal Department for Corrections. In 1938, a similar facility was established in Fort Worth, Texas. For many decades, these were the only alcohol and drug dependence treatment and research facilities that worked with human subjects (Campbell, 2010).

Early biological studies of addictive behavior were also conducted on alcohol and morphine addicted monkeys and found that once an animal habituated to use of a drug, the body's natural desire is to maintain homeostasis, including maintaining levels of drugs in the system (Campbell, 2010). Around 1960, Morton Jellinek publicized a disease model for abuse and dependence on drugs and/or alcohol, which helped to ease stigma attached to substance abuse and brought a renewed focus on understanding the biology behind drug and alcohol dependence and effective treatment (Brown, 2006). Today, most behavioral health professionals accept that abuse and dependence on drugs and/or alcohol is a chronic relapsing brain disease caused by damaged reward-based circuits in the brain (Koob, 2006; 2011) and influenced by psychological and social factors (Gatchel & Kishino, 2011). In fact, changes in brain activity can be traced to even minor levels of opioid use (Younger et al., 2011). Brain scans and post-mortem examinations of opioid dependent brains shows negative correlation between years of drug use and volume of the prefrontal cortex, an area of the brain, which is heavily involved in decision-making (Garcia-Sevilla et al., 1997; Liu, Matochik, Cadet, & London, 1998). The central nervous system (CNS) plays a key role in an individuals' decision-making abilities and

the damaged CNS found among long-term drug users is outwardly reflected in their poor social decisions and ongoing drug use, despite negative consequences (Lyvers, 2000).

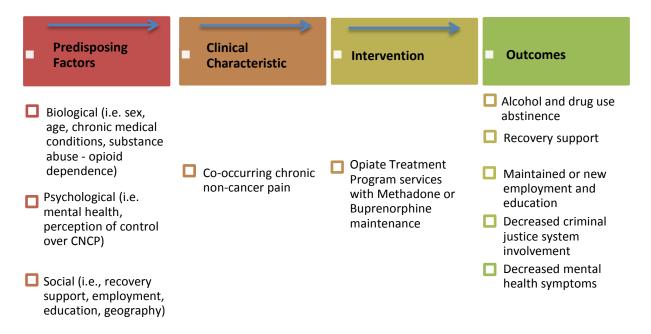
The currently accepted standard for substance abuse research and treatment is a biopsychosocial framework that includes the biological, psychological, and social life circumstances that increase an individual's vulnerability to substance abuse and play a role in recovery and/or relapse behaviors (Gatchel & Kishino, 2011; Koob, 2011). Neuroscientific and medical research contributes information on the biological perspective of chemical dependence, while psychology provides insight into the mind's perception of the body's need for drugs to cope with daily living. Sociological and behavioral research contributes information on the social influences of environment and social network (i.e., family, friends, intimate partners, work cohorts) in initiating and perpetuating chemical dependence. These factors weave together to form a biopsychosocial framework for understanding abuse and dependence on drugs and alcohol.

#### Biopsychosocial framework within this study.

For this study, opioid dependence treatment outcomes will be examined among OTP clients, comparing individuals with and without CNCP (i.e., chronic pain persisting or recurring for 3 months or longer as reported during the baseline interview). *Figure 1* displays the conceptual framework for this exploratory study using the biopsychosocial framework. Predisposing factors include characteristics like age, sex, chronic medical conditions, mental health and substance use history. The clinical characteristic examined in this study is CNCP. The intervention for this sample is treatment with either methadone or buprenorphine medication provided within a Federally regulated OTP. The fact that the treatment is provided in an OTP is important to note because of the strict guidelines and protocol for dosing, counseling, and monitoring that occur at these programs under Federal and state oversight (CSAT, 2005).

Outcomes are the "successes" that clients hope to achieve as they progress through treatment including reduced drug and alcohol use, employment, improved recovery support connections, and decreased mental health symptoms.

# Figure 1. Conceptual framework



# Predisposing factors.

Both CNCP and opioid dependence have biological, psychological, and social components (Bruns & Disorbio, 2005) that interact with each other in a variety of ways for each person. An individual's biologically determined factors of sex, age, and physical health may be linked to an increased likelihood of CNCP, drug or alcohol abuse, depression, or anxiety. For example, research indicates females in the general population are twice as likely as males to develop chronic pain and females have higher rates of depression than men (Tsang et al., 2008). In addition, the likelihood of developing physical health problems and painful conditions increase in prevalence as a person ages (Tunks et al., 2008). Race (a biological factor) is

correlated with lack of employment (a social factor) which is in turn linked to poor mental health (a psychological factor) (Crum, 2009).

Mental health conditions like depression or anxiety are correlated with an increased risk of developing opioid dependence and/or CNCP. Depression and anxiety are also correlated with having a history of sexual, physical, or emotional abuse, which in turn increases an indiviudal's risk of developing drug or alcohol dependence and/or CNCP (Sansone, Whitecar & Wiederman, 2009). Substance abuse has been linked to a history of psychological problems, physical/sexual abuse (Engstrom, El-Bassel, Go, & Gilbert, 2008), and pain perception (Gatchel & Kishino, 2011). Specifically, opioid dependence is correlated with depression (Becker, Sullivan, Tetrault, Desai, & Fiellin, 2008) and tobacco use is related to significantly poorer opioid treatment outcomes (Ziedonis et al., 2009). Even a person's perception of their ability to control their pain is related to the interference or impairment CNCP has in a person's life (Gatchel & Kishino, 2011; McCracken & Vowles, 2008).

An individual with CNCP who lives in a rural or geographically isolated area will likely have limited resources for pain management support (Hamilton et al., 2008) or treatment of drug dependence (Havens et al., 2007). Social factors such as socioeconomic levels of income and support are hamperd by limited access to resources and economic development opportunities in many rural areas (Hamilton et al., 2008). Limited peer support is correlated with negative treatment outcomes and includes the difficulty small town or rural individuals may have in establishing new connections separate from their old drug using or trafficking friends (Skinner, Haggerty, Fleming, Catalano, & Gainey, 2011). Additionally, community-level economic issues make employment more difficult to maintain and improve in rural or geographically isolated areas like Appalachia compared to more urban or metropolitan areas (Hamilton et al., 2008). For example, the United States declared a recession between 2007 and

2009. December 2011 Bureau of Labor Statistics data show rural areas in the state still below national averages in available jobs with about 3.7% fewer jobs available in rural areas. To be effective, treatment must take into account all of these different and intertwining biopsychosocial combinations present in each individual. Notably, in the dataset for this study, less than 1% of the cases are non-white, thus the issue of race cannot be fully examined here.

### Co-occurring CNCP.

This study focuses on the intersection between opioid dependence and chronic noncancer pain (CNCP) as it relates to treatment outcomes. Though it is physiological phenomenon, in this study chronic non-cancer pain (CNCP) is self-reported and is not captured through clinical tests. Individuals met clinical criteria for opiate dependence and reported CNCP at baseline in order to be considered as having co-occurring CNCP and opioid dependence in this study.

#### Intervention.

The intervention in this conceptual model is the treatment provided to the client through the OTP. Federally licensed OTPs must follow the regulatory requirements of the Substance Abuse and Mental Health Administrative Services, Center for Substance Abuse Treatment, and the Office of Drug Control Policy. In addition they must follow state regulations (Kentucky Narcotic Treatment Agency Regulations 908 KAR 1:340) or accrediting body protocols (i.e., Joint Commission for Accreditation of Healthcare Organizations, Commission on Accreditation of Rehabilitation Facilities). Kentucky regulations are among the most stringent in the country and go above and beyond Federal guidelines. Admittance for treatment requires proof that the person has been addicted to opioids for at least one year. All new clients receive a full physical and are medically monitored as they are inducted to find the appropriate medication dose for their body's metabolism of methadone or buprenorphine. Daily in-person medication dosing is required at all OTPS, along with weekly random observed urine drug

screens, and weekly counseling sessions for the first 180 days of treatment. If the client has been compliant with the treatment plan, including negative drug screens, the client may earn the right to have one take-home dose per week. Weekly drug screens and counseling continue through the sixth month of treatment and may continue longer or be reinstated depending on client compliance with regulations and drug screens (908 KAR 1:340).

The majority of OTP clients in Kentucky take methadone, as opposed to buprenorphine (Stevenson, Cole, Walker, Logan, & Mateyoke-Scrivner, 2011). Methadone is a synthetic opioid agonist that binds with and occupies all the opioid receptor sites in the brain hindering other substances from activating those receptors (CSAT, 2005). This means use of methadone reduces or eliminates cravings and withdrawal symptoms, and at the same time does not create euphoria when dosed properly. Methadone can be prescribed at higher doses (60-120mg average), but is only taken daily because it has a half-life in the body of up to 48 hours. Buprenorphine is a partial agonist that also binds with opioid receptors, but has a ceiling of 32 mg at which it hits maximum effectiveness (TIP 43, CSAT, 2005). The 32mg dose of buprenorphine is comparable to about 120 mg of methadone (CSAT, 2005). Since methadone is a full agonist medication, there is no ceiling effect. This allows for higher doses, but also a greater potential for diversion, misuse, and abuse. Therapeutic threshold for methadone dose is at or above 80 mg daily (Pollack & D'Aunno, 2008), while recent studies relate methadone doses around 100 mg per day to better treatment outcomes and fewer relapse episodes (Fareed et al., 2009). Buprenorphine is a more expensive treatment than methadone, but it is generally covered by insurance and Medicaid, while methadone is not currently covered except for use in pain control (Jones et al., 2009).

### Outcomes.

Generally, CNCP treatment focuses on reduction of pain and the impact pain has in the individual's ability to participate in daily life (i.e., work, home, family). The sample of individuals with CNCP for this study is from an opioid dependence treatment setting. Therefore, problems associated with CNCP are not addressed directly. The primary goal of treatment provided by an OTP is to help clients achieve abstinence or reduction in illegal drug use and alcohol use (CSAT, 2005). Other positive outcomes include acquisition of or maintenance of employment, reduction of mental health symptoms like depression or anxiety, reduction in criminal justice system involvement, and connections with recovery support (i.e., Narcotics Anonymous (NA), Methadone Anonymous (MA), family and friends who are supportive of the person's recovery efforts). Each of these outcomes is a measure of client stability and helps to demonstrate an improvement in the individual's positive engagement with family, work, and community. These areas may become the focus of individual substance abuse treatment counseling sessions or may result in referrals to other service providers outside of the OTP. The literature does not currently address whether or not these outcomes are influenced by the presence of CNCP.

### **Description of this Exploratory Study**

The current study is exploratory in nature. Based on an extensive search of the literature, to my knowledge, no research with a sample of OTP clients has explored the impact of CNCP on client-level opioid dependence treatment outcomes. This study proposes an examination of the effect of CNCP among OTP maintenance clients. The study has one primary research question:

Do individuals with CNCP participating in an opiate treatment program (OTP) have better or worse treatment outcomes than those without CNCP (i.e., drug or alcohol use, employment, mental health symptoms, criminal justice involvement, and connection with recovery support networks?

Current research literature does not appear to answer this question and yet such information would be vital in treatment planning, case management, and family/client education. According to Federal regulation, all licensed OTPs must provide clients with regular counseling, an initial and annual medical screening and referrals, and regular testing for illicit drug use (i.e., urine, saliva screens) in addition to opioid dependence treatment medication (i.e., methadone or buprenorphine) (CSAT, 2005; CSAT, 2004). If the OTP identifies the client as having comorbid physical health problems like hepatitis, diabetes, or CNCP, the client is referred to medical treatment outside the OTP. Similarly, mental health problems that cannot be addressed during the client's required counseling sessions during treatment are referred to mental health care providers outside of the OTP. Extant research on substance abuse treatment indicates outcomes are commonly worse for individuals with comorbid mental health problems, particularly depression and/or anxiety (Laudet, Magura, Vogel, & Knight, 2000; Skinner et al., 2011). This referral system perpetuates a uni-dimensional approach to treatment, despite evidence suggesting recovery occurs best within integrated treatment provision (Clark, Power, Le Fauve, & Lopez, 2008).

This study theorizes that individuals in the sample with CNCP will exhibit poorer treatment outcomes at follow-up compared to the individuals without CNCP. Best practices for treating comorbid physical and mental health conditions are to provide integrated treatment services. Since the focus of opioid dependence treatment programs is not on mental health or pain management, it may be that clients in OTPs struggling with CNCP as well as depression or anxiety do not receive the holistic assistance needed to help the individual. This study attempts to provide insights into treatment outcomes for individuals who have CNCP while in opioid dependence treatment programs in order to begin to fill the information gap regarding this condition.

#### **CHAPTER 2. LITERATURE REVIEW**

#### Scope of the Problem

The Institute of Medicine (2011) states CNCP affects 116 million U.S. adults annually. The numbers are rising globally with one in ten adults newly diagnosed with CNCP each year (IASP, 2011). Federal and State government expenditures for medical needs of those with chronic pain were estimated at \$99 billion in 2008 (IOM, 2011). In conjunction with the rising number of adults with CNCP, the numbers of legitimate opioid prescriptions for CNCP have increased in the past decade, with prescriptions obtained through general practitioners and specialized pain management clinics (Stannard, 2011). Per capita, Kentucky had the fourth highest number of filled prescriptions (17.1) in 2009 compared to the lowest number (6.4) in Alaska (www.statehealthfacts.org). Though these figures include both opioid and non-opioid prescriptions, the high volume of prescription medications per capita in Kentucky means there is an increased potential for accidental overdose and misuse of medications. Despite the fact that many individuals have legitimate opioid prescriptions for treatment of CNCP (Zacny et al., 2003), there have been coinciding increases across the U.S. in emergency room visits for overdose. These overdose numbers are correlated with the increased number of filled prescriptions and increased non-medical use of prescription opioids (SAMHSA, 2003b).

Alongside the increase in legitimate opioid prescriptions in the U.S., there has also been a significant increase in misuse of prescription painkillers with the largest percentage reported among the 18-24 year old population (SAMHSA, 2003a). A 2009 general population U.S. survey found that 5 million adults reported non-medical prescription opioid use in the past year and opioid dependence related treatment admissions were at their highest in ten years (SAMHSA, 2010). Comparing state by state, Kentucky has one of the highest percentages of individuals

seeking treatment for opioid abuse at 24% of admissions in 2009 compared to only 7% of admissions nationwide (SAMHSA, 2011a).

Despite the increases in CNCP and prescription opioid abuse and the distinct correlations between these disorders, data and journal articles available on individuals in opioid dependence treatment with CNCP is currently limited. A trend in the past has been to exclude individuals with an opioid dependence history from medical studies and similarly to exclude patients with chronic pain from opioid treatment samples in an effort to exclude the confounding effects of the comorbid conditions (Angelino, Clark, & Treisman, 2005). This literature review will summarize current research that defines, describes, and provides insights into CNCP.

## **Defining CNCP**

Most people understand pain to be a noxious stimulus experienced by the body that is by nature unpleasant and uncomfortable. Pain can be classified using distinctions based on the temporality or length of time the pain has been endured, primarily divided between pain that is acute (i.e., short-term) and pain that is chronic (Johannes, Le, Zhou, Johnston, & Dworkin, 2010; Portenoy, Payne, & Passik, 2005). Acute pain occurs suddenly in response to an injury such as a twisted ankle, burned finger, or broken arm. In most cases, the source of acute pain is known and treatment is available to help heal the injury. Acute pain is short lived and intensity of the pain decreases as healing occurs (Field & Swarm, 2008). On the other hand, chronic pain is persistent or recurring pain that lasts beyond the expected healing period for an injury. Most medical and research studies define 3 months as the marker at which point pain moves into the category considered chronic (Jamison, Butler, Budman, Edwards, & Wasan, 2010). Cancerrelated pain is often considered medically different from non-cancer pain in that the cause of the pain is understood and a course of treatment is typically available. Pain that is not acute, or

is not rooted in a diagnosed cancer is termed chronic non-cancer pain or CNCP. This pain is much more complex than either acute or cancer-based pain because of its enduring quality and its long-term interference with daily functioning and overall physical and emotional health (Field & Swarm, 2008; Portenoy et al., 2005).

#### **CNCP** prevalence.

Prevalence rates for CNCP range from 19% to 66% depending on the survey methods and sample, though all of these studies used the same definition of CNCP which is pain persisting or recurring for 3 months or longer, not related to cancer (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2008; Portenoy, Ugarte, Fuller, & Haas, 2004; Tsang et al., 2008). A large European study found 6-month CNCP prevalence rates of 19% among adults in the general population who responded to a random digit-dialed phone survey (Breivik et al., 2008). Tsang and colleagues (2008) combined data from 18 adult population surveys and found past 12month CNCP prevalence rates of 41.1% in developing countries and 37.3% in developed countries. A 2003 telephone survey with adults in the U.S. found one-third of individuals had experienced chronic pain in the past year (Portenoy et al., 2004). Despite extensive searches, no literature was found that could provide state-by-state prevalence or estimates of CNCP. The Centers for Disease Control (CDC) report annually on state-level risks for chronic diseases like diabetes, pulmonary disorders, and musculoskeletal conditions that may lead to disability and CNCP (2008). Reviewing Kentucky's risk factors for chronic diseases compared to the general U.S., state data reflect higher rates of being overweight or obese (69.1% KY vs. 63.0% U.S.), cigarette smoking (28.2% vs. 19.8%), and lack of preventive health care or health coverage (19% vs. 17%) among Kentucky adults (CDC, 2008). Though CNCP is not directly identified in the CDC reports, it is understood that poor health and disability are correlated with the development of CNCP (Katz, 2010).

Causes of pain are diverse and may include multiple injuries and damage to tissue or nerves. Among a general population survey of adults in the U.S. with CNCP in the past 3 months, 25% reported low back pain while 13% reported neck pain with similar prevalence rates among racial groups and by sex (Lawrence et al., 2008). Other examples of CNCP sources include diabetes, HIV/AIDs, shingles, migraine, trauma from an accident or surgery, and endometriosis. Locations of CNCP in the body are also diverse and may shift around the body in the case of nerve damage, or may hover in one area like low back, knees, chronic headache, or neck pain. In a recent analysis of the general U.S. population, over 26% of adults reported arthritis and respondents with a BMI of 30 or greater were 1.9 times more likely to report arthritis compared to adults with a lower BMI (Wilson, Zakkak & Lanier, 2009). Using standardized prevalence rates adjusted for age another study examined specific chronic pain conditions in the past 12 months as reported by survey respondents (N=42,249) across both developing (n=10) and developed (n=7) countries. Respondents reported CNCP conditions of back pain (20.0%), arthritis or joint pain (16.5%), headache (14.4%), and other unspecified chronic pain (6.9%) (Tsang et al., 2008). A European sample of adults with CNCP in the general population reported that 66% of respondents rated their pain as moderately severe (5-7 on a scale from 0=no pain to 10=worst possible), while another 34% reported very severe pain (8-10 on scale) (Breivik et al., 2008). In the same sample, 59% of respondents reported they had struggled with CNCP for a range of 2 and 15 years, and 40% stated their pain was inadequately managed by their physician (Breivik et al., 2008).

# **Biology of CNCP.**

As stated previously, the origin of an individual incidence of CNCP may be a single accident or injury or condition, or it may have multiple origins, or the origin may be unknown (Field & Swarm, 2008). Despite the wide variance in origin, CNCP is usually identified as having

one of the following primary modes of pain transmission within the body: nociceptive, central, or neuropathic. *Nociceptive pain* refers to tissue damage and is usually responsive to opioids and over-the-counter medications like aspirin or acetaminophen for pain control (Field & Swarm, 2008). *Central pain* includes pain due to a damaged central nervous system (brain and spinal cord) such as a brain injury incurred by many returning war veterans. *Neuropathic pain* refers to damage in either peripheral or central nerves such as occurs with multiple sclerosis, diabetes, and fibromyalgia. This type of pain is very difficult to treat and the opioid class of drugs rarely provides long-term analgesia (Dworkin et al., 2007). Compared to central or nociceptive pain, neuropathic pain correlates with a significantly lower quality of life and with a higher degree of impairment in day-to-day activities (Doth, Hansson, Jensen & Taylor, 2010).

Over the past decade, CNCP has been labeled an illness in itself due to the complicated mass of symptoms it encompasses within the biological, psychological, and social realms of an individual's life (Gatchel & Kishino, 2011; Turk, Wilson, & Cahana, 2011). The process by which our bodies recognize and respond to pain begins with the biological impact when the body sustains an injury, wound, or illness that causes tissue discomfort or inflammation. The process of the body as it responds to the injurious stimuli is called *nociception* (Patel, 2010). Nociception triggers the sending of a signal about the stimuli to the affected nerve tissues through neurotransmitter messengers, which then travel through the central nervous system to the brain (Gazzaniga, 1989). The injury is typically not labeled *pain* until the information is processed by the brain upon receipt of the message from the nerve tissues, though pain can begin to occur without nociception or obvious tissue damage in patients with CNCP due to permanent damage to the nervous system (Patel, 2010). CNCP is very complex in nature because of the heavy involvement of the brain and nervous system in its detection, moderation, and the resulting response signals the brain sends back to the body.

## Endogenous opioids.

A discussion of the biochemistry of CNCP naturally leads to one of the body's key internal mechanisms for moderating pain: the endogenous opioid system. Endogenous opioids include enkephalins, endorphins, and dynorphins, which all work by readily binding to opioid receptors and helping naturally modulate pain in the body (Patel, 2010). Nociceptive or inflammatory pain triggers release of endogenous opioids that help to inhibit and control pain at the mu receptor as an agonist (Harvey & Dickenson, 2010). This innate pain relieving system consists of neurons and opioid neurotransmitters that bind with three types of receptor cells – the mu, kappa, and delta receptors (Holden, Jeong, & Forrest, 2005) and opioid-based drugs bind with these same three receptor sites to provide analgesia. Chemokines, a type of protein cell, moderates pain, tissue inflammation, and analgesia by regulating the migration of endogenous opioid cells into the inflamed area of tissue after injury or strong stimuli occurs. The chemokines cells connect to the mu, kappa, and delta receptor sites to provide analgesia. The use of synthetic opioids for analgesia (i.e., oxycontin, hydrocodone) is important for acute pain relief. All opioids register a "reward" signal in the brain, which in effect encourages the person to continue taking the pain relieving medications. The same occurrence happens when opioids are taken for their euphoric effects. Repeated opioid use strengthens the connections to receptors, which has led researchers to theorize an association with opioid dependence where this reward mechanism is continually triggered by opioid use (Fields, 2007; Koob & LeMoal, 2008). The question of whether or not the nervous system has a mechanism to differentiate between opioids for pain relief versus opioid use to stave off withdrawal due to opioid dependence is not clear. There is some evidence of a psychological as well as a physiological component to how the body responds to drugs.

The body's natural endogenous opioid system is one key in understanding opioid dependence problems. Opioids connect with the mu, gamma, and delta receptors in the brain by mimicking its naturally occurring chemicals and fitting into existing neurotransmitter sites (Hyman & Malenka, 2001). When an individual ingests an opioid drug like oxycontin, the synthetic opioid fills the slots in opioid receptors, encourages the body's dopamine production, and contributes to a feeling of euphoria and pleasure (Savage & Horvath, 2009). Compared to the body's naturally occurring endogenous opioids, synthetic versions can fill up to 10 times more receptors, which explains why these chemicals are useful for pain management, but also very highly addictive (Savage & Horvath, 2009).

### **Defining Opioid Dependence**

The current definition of prescription opioid abuse is a chronic brain disease characterized by intentional use of a prescription opioid for purposes outside of a medical condition (Compton and Volkow, 2006). Opioid dependence may manifest in a variety of ways, but the common strand with all substance-related disorders defined by the Diagnostic and Statistical Manual of Mental Disorders is: *When an individual persists in use of alcohol or other drugs despite problems related to use of the substance, substance dependence may be diagnosed. Compulsive and repetitive use may result in tolerance to the effect of the drug and withdrawal symptoms when use is reduced or stopped* (DSM IV-TR; American Psychiatric Association, 2000).

In addition to the clinical criteria, other behavioral flags associated with opioid dependence are often present. For example, when compared to individuals who do not abuse drugs, research indicates drug dependent individuals are more likely to spend time in jail, lose custody of children due to neglect or abuse charges, be charged with a DUI (driving under the influence of drugs and/or alcohol), or have other ongoing involvement with the criminal justice

system (Gossop, Marsden, Stewart, & Rolfe, 2000). The drug dependent individual is also more likely to be unemployed or have more difficulty maintaining paid employment than the nondependent individual (Henkel, 2011). When a person is informed that continued opioid abuse may lead to jail time, loss of child custody rights, or loss of a job and this information does not deter the individual from continuing to abuse opioids, opioid dependence is likely present.

## Prevalence of opioid dependence.

In 2009, the National Survey on Drug Use and Health, which annually surveys a representative sample of the general U.S. population, reported 5 million adult respondents had abused prescription opioids in the past year (SAMHSA, 2010). Figure 2 displays the rate of prescription opiate abuse across Kentucky (SAMHSA, 2010). The highest rates are reported in northern and central Kentucky with 6.17 % to 6.85% of individuals having reported abuse of prescription pain relievers in the past year.

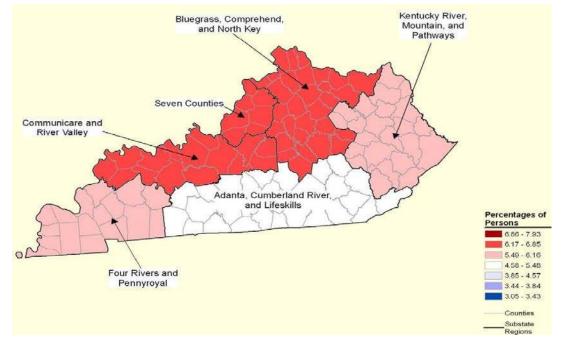


Figure 2. Percentages of persons in general population reporting past year nonmedical pain reliever use across Kentucky

Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health 2006-2008.

Opiates are natural chemical derivatives of the poppy plant and opioids are the synthetic version of these natural compounds; the term *opioid* refers to both the natural and synthetic varieties of opium (Albertson, 2007). Prescription opioids include methadone, codeine, hydrocodone, hydromorphone, meperidine, morphine, opium, oxycodone, pentazocine, propoxyphene, tramadol, and any other drug with morphine-like effects (SAMHSA, 2011b). According to National Treatment Episode Dataset (TEDS), abuse of prescription pain relievers which are primarily the opioid class of drugs was reported by 2.5% of substance abuse treatment admissions in 1999 (SAMHSA, 2011a). Ten years later in 2009, this number increased to 11.5% of admissions (SAMHSA, 2011a). In Kentucky, the percentage of opioid users in treatment jumped from 3.7% in 1999 to 32% in 2009. Compared to other alcohol and drug use rates, opioid use has increased dramatically. Table 1 displays the percentage of substance abuse treatment admissions between 1999 and 2009 by drug types and compares the United States to Kentucky on major drug classes.

## Table 1

Comparison between the United States and Kentucky on Percentage of Individuals Reporting Use of Specific Drugs or Alcohol When Seeking Substance Abuse Treatment between 1999 and 2009

			Percent in Treatment Reporting Use of:									
Year	United States:	Kentucky:	Opioids		Alcohol		Marijuana		Cocaine		Benzodiazepine	
	Total population (% in treatment)	Total population (% in treatment)	U.S.	КҮ	U.S.	KY	U.S.	КY	U.S.	KY	U.S.	KY
2009	307,006,550 (63.9)	4,314,113 (49.8)	11.5	32.0	60.7	54.6	38.1	40.1	24.3	21.6	3.9	15.1
2008	304,374,846 (65.6)	4,287,931 (51.7)	9.9	27.9	60.9	58.6	37.2	42.2	27.8	27.3	3.3	13.3
2007	301,579,895 (63.2)	4,256,278 (56.6)	8.5	22.0	61.2	60.2	36.5	43.0	30.7	31.3	2.9	11.4
2006	298,593,212 (63.8)	4,219,374 (58.5)	7.4	18.2	60.8	62.4	36.4	43.5	31.8	32.2	2.6	11.2
2005	295,753,151 (63.9)	4,182,293 (54.3)	6.5	15.2	61.0	64.3	36.9	44.6	31.6	31.0	2.3	9.5
2004	293,045,739 (61.7)	4,147,970 (49.0)	5.9	10.7	62.2	49.3	36.3	34.8	31.1	17.7	2.2	7.7
2003	290,326,418 (64.1)	4,118,627 (74.4)	5.1	9.0	63.6	54.4	35.8	34.4	30.8	19.5	2.0	6.9
2002	287,803,914 (65.5)	4,091,330 (64.1)	4.5	6.8	65.1	52.1	35.6	32.7	30.2	17.3	1.9	6.1
2001	285,081,556 (62.0)	4,069,191 (62.3)	3.8	5.9	66.4	51.5	35.4	31.8	30.2	14.4	1.8	6.2
2000	282,171,957 (62.0)	4,048,903 (45.6)	2.9	4.6	68.1	49.4	34.7	28.6	31.2	14.0	1.6	4.9
1999	277,840,888 (61.7)	4,018,053 (40.1)	2.5	3.7	70.2	49.2	34.7	27.4	32.5	14.3	1.5	4.4

\* excludes heroin since Kentucky's primary problem is prescription opiate abuse. Table created using U.S. Census data (census.gov) and TEDS admission public data concatenated 1999-2009 files retrieved from <u>http://dx.doi.org/10.3886/ICPSR25221.v4</u>.

Among a nationally representative sample of 1408 methadone treatment clients, 66% reported their initial use of opioids, which led to their current opioid dependence, was through a legitimate opioid analgesic prescription for pain (Cicero et al., 2008). Table 2 displays the number of prescriptions in 2009 filled by retail pharmacies, including new prescriptions and refills of both brand name and generic drugs (Retrieved from http://www.statehealthfacts.org). These data include prescriptions for opioid medications, but are not exclusively opioids. Southern states like Kentucky are at the top of the list. West Virginia had the highest number of prescriptions filled per capita at 18.92 compared to Alaska with only 6.43. Whether or not the high prescriptions per capita are due to unusual prescribing practices or an increased burden of disease in the southern states is not clear.

Table 2Average per Capita Number of Prescriptions Filled at Retail Pharmacies in 2009

Top Five	Prescriptions	Bottom Five	Prescriptions		
States	per capita	States	per capita		
West Virginia	18.92	D.C.	8.65		
Tennessee	17.33	8.45			
Alabama	17.13	New Mexico	7.69		
Kentucky	17.10	Colorado	7.58		
Arkansas	16.70	Alaska	6.43		

(Table created using data retrieved from www.statehealthfacts.org)

Concern with prescribing practices led researchers to examine particular opiate use trends related to the newer medication, buprenorphine (SAMHSA, 2011b). In 2000, the Drug Addiction Treatment Act (DATA) allowed private physicians to dispense buprenorphine-based opioids approved for treatment in their offices instead of being required to dispense through the oversight of a licensed opioid treatment program (OTP). Trends in prescription opioid abuse rose along with the new prescribing regulations for buprenorphine-based medications (SAMHSA, 2011b). Though physicians must complete special training, obtain a federal waiver to prescribe and dispense buprenorphine, and maintain caps on the maximum number of patients for which they prescribe medications, buprenorphine remains a Schedule III controlled substance. The increased abuse of opioids and increased availability of prescription opioids seem linked with one another (Compton & Volkow, 2006; Gilson, Ryan, Joranson, & Dahl, 2004).

## Monitoring of prescription drugs.

The use of prescription pain medication has been monitored in a variety of ways since 1970 when the Controlled Substances Act gave the duty of monitoring controlled substances to the Drug Enforcement Agency (DEA). The DEA set up a schedule of drugs based on the abuse and diversion liability or danger associated with each drug (DEA, 2011). Most opioids are Schedule II, meaning their abuse and opioid dependence liability are very high, but there is medical value to allowing physicians to prescribe opioids. Schedule I drugs such as heroin have been deemed to have no medical benefit and thus cannot be prescribed. Schedule II-IV drugs are rated based on addictive liability and potential for abuse; the higher the number, the less dangerous the drug has been deemed by the DEA. All physicians who prescribe and/or dispense controlled substances must register with the DEA (2011). Pharmacists and physicians have shared responsibility for the legal implications of prescribing controlled substances, such as opioids. In 2005, the National All Schedules Prescription Electronic Reporting Act (NASPER) was signed into law and provided funding to states for development of prescription drug monitoring databases that could cross-reference with other states (Public Law No: 109-60. H.R. 1132). Kentucky was one of the first to develop a statewide All Schedule Prescription Electronic Reporting program (KASPER) which provides regular data to the DEA on prescribing practices in the state.

The DEA also monitored OTPs until 2001 when this role was shifted to SAMHSA. OTPs have always been highly regulated at both the Federal and state levels because the medicine primarily dispensed by OTPs is methadone (schedule II). The other regular dispensers of

methadone are physicians who treat chronic pain. The regulation and oversight of physicians who prescribe pain medications and of Pain Management Clinics is conducted state-by-state with the help of Medical Licensure Boards and state Medical Associations.

This means that physicians, pharmacists, and substance abuse treatment professionals have three different monitoring agencies providing guidelines, protocols, and monitoring tools regarding controlled substance use. In 2006, hearings were held to examine the reports that prescription drug abuse was rising at an alarming rate. Fingers were pointed at OTPS, pain management clinics, and the prescribing physicians as being at fault, while conclusions reported in the Federal Register (2006) indicated all of the above were part of the problem. The significant increase in percentage of emergency room visits for prescription opioid overdose over the past decade (SAMHSA, 2010) along with a 48% increase in prescriptions written for opioids between 2000 and 2009 has drawn further legislative attention (White House, 2011). Concerns are bolstered by continuing increases in the number of opioid addicted individuals as well as significant increases in new opioid abusers (i.e., new initiates). State and Federal bills are being proposed suggesting increases in control over pain management clinics and prescriptions for pain medication.

The Researched Abuse, Diversion, and Addiction-related Surveillance (RADARS) system used by physicians and emergency facilities for documenting the abuse of prescription drugs tracked the increasing trend of opioid abuse, with oxycontin and hydrocodone as the most often reported substances by survey respondents (Cicero et al., 2005). Data from RADARS also point to the widespread nature of prescription drug abuse, including opioids by tracking zip codes where abuse cases are reported. In 2004, RADARS data indicated 60% of zip codes across the U.S. had at least one case of prescription drug abuse (Cicero et al., 2005).

## **Biology of Opioid Dependence**

Over the past decade, data supporting the biological origin of abuse and dependence on drugs and/or alcohol has helped shift focus away from moral and societal explanations for drug and alcohol abuse (National Institute on Drug Abuse [NIDA], 2005). The currently accepted definition of abuse and dependence on drugs and/or alcohol is a chronic relapsing brain disease (ASAM, 2011; NIDA, 2005, 2010). The data tying abuse and dependence on drugs and/or alcohol to brain and nervous system malfunctions has been framed within the context of the disease model and has helped to link substance abuse with research agendas that include other chronic illnesses like diabetes, arthritis, asthma and chronic non-cancer pain (Campbell, 2010). Research using animal models has helped scientists understand a wide range of phenomena including opioid dependence patterns in humans. For example, lab animals allowed to self-administer opioids will readily do so, but when mu opioid receptors in the brain are chemically blocked, as with methadone or buprenorphine, self-administration of the opioids stops (Gardner, 2011; Koob, 2011). These lab animal cases of drug self-administration behaviors help illustrate the strength of the drug dependence process, while also showing how the body's drug cravings can be tamed with medication.

Chronic opioid abuse damages the nervous system's drug reward mechanism and redirects the CNS and brain from focusing on obtaining the euphoric effects of opioids to focusing on avoiding the dysphoric post-use state (Gardner, 2011). This process strengthens an anti-reward CNS pathway, which heightens sensitivity to past drug use, and makes the individual prone to relapse triggered through biopsychosocial means (i.e. people, places, and things that remind the individual of drugs or drug use) (Gardner, 2011; Koob, 2011). The transition from taking drugs for the euphoric effect to taking drugs to meet a compulsive biological need to prevent the extreme discomfort of opioid withdrawal is due to neural changes in the brain

caused by drug abuse. CNS damage from substance abuse helps explain why opioid abuse may persist despite obvious threats to one's livelihood, health, familial, and societal connections (Everitt & Robbins, 2005; Volkow & Li, 2004). In fact, opioid dependent individuals are more likely to have used multiple substances in the past year compared to individuals whose primary drug of abuse was not an opioid, and therefore opioid addicted individuals have a higher risk of increased neural damage over time (Gossop, Marsden, Stewart, & Kidd, 2003).

Further evidence of how opioid dependence impairs the brain's ability to function with memory and motor changes is seen not just in behavior patterns, but has also been isolated on magnetic resonance imaging or MRI scans (Volkow & Li, 2004). In fact, MRI brain studies have identified a connection between the changes to the endogenous opioid system and regular use of drugs including marijuana, alcohol, opioids, and nicotine (Maldanado, Valverde, & Berrendero, 2006; Trigo, Martin-Garcia, Berrendero, Robledo & Maldanado, 2010). The brain chemistry behind opioid dependence is complicated and the tangled neurochemical changes from opioid abuse present incredible barriers to maintaining long-term abstinence from opioid abuse (Gardner, 2011; Lyvers, 2000). Passetti, Clark, Mehta, Joyce & King (2008) studied these brain changes by exploring decision-making skills among 37 opioid dependent individuals who were clients in a community-based treatment program. At baseline, and then 3 months into treatment, participants performed decision-making tests (Iowa Gambling Task and Cambridge Gamble). Poor decision-making abilities were correlated with lower abstinence rates at the 3month follow-up time period. The researchers indicated that neural connections, particularly in the anterior cingulate gyrus, which are necessary for accurate decision-making, are damaged by opioid abuse. Thus, use of pre-treatment screening could help specifically target individuals who need more help with decision-making and coping skills in order to maintain abstinence from opioids (Passetti et al., 2008).

While these studies raise a number of concerns, the good news is that brain pathways can recover with prolonged abstinence from drug use (Volkow & Li, 2004). Literature indicates genetics, environment, and the neurological changes that occur with substance abuse may all impact an individual's ability to sustain drug and alcohol abstinence over time (Erickson & White, 2009). These data also suggest a link between neural dysregulation existing prior to opioid dependence that may have influenced a person's attraction to abusing specific drug classes. In particular, the effect of opiate abuse on neural pathways in conjunction with the development of CNCP is not yet clear. Targeting these potential problems will be a key future research area to prevent opioid dependence problems and augment faulty neurochemistry (Erickson & White, 2009).

### **Comorbidity of CNCP with Opioid Dependence**

The drug treatment field has a special interest in understanding CNCP, as the rising prevalence rates for prescription painkiller abuse repeatedly make the headlines (Chou, Ballantyne, Fanciullo, Fine, & Miaskowski, 2009; SAMHSA, 2010). Developing a clear understanding of substance abuse and dependence behaviors is also important in settings like pain management clinics, which do not typically treat opioid dependence (CSAT, 2005). In 2001, the American Pain Society, American Society of Addiction Medicine, and American Academy of Pain Medicine worked together to define key terms related to opioid dependence and pain treatment and help move the research field forward in regards to CNCP and opioid dependence. These professional organizations suggest *pseudoaddiction* may better describe patients with undertreated chronic pain who exhibit what appear to be addictive behaviors like aggressively seeking higher doses, obtaining prescriptions from two or more doctors at the same time, and running out of medicine significantly ahead of schedule (American Pain Society, 2001; Passik, Kirsh, & Webster, 2011). In contrast, individuals with a true opioid dependence exhibit

observable patterns of behavior including craving, compulsive and uncontrolled substance use, and a desire to use a medication for more than pain relief. When pain is effectively managed, these pseudoaddiction behaviors disappear (American Pain Society, 2001; IASP, 2011).

Though research on chronic pain has expanded over the past decade, there is still limited information about individuals with both a history of opioid dependence and CNCP. Many pain clinics exclude clients who have a history of opioid dependence from their clinical populations, and individuals with a history of opioid dependence are generally omitted from research studies on CNCP due to the complicating nature of substance abuse (Angelino et al., 2005). Comorbid CNCP and drug/alcohol dependence have been identified in 37% to 61% of methadone treatment samples (Jamison, Kauffman, & Katz, 2000; Rosenblum et al., 2003) compared to 29-66% found in general substance abuse treatment samples (Barry et al., 2009; Sheu et al., 2008). Among chronic pain management samples, it is estimated that 18-41% of clients have substance abuse problems (Manchikanti et al., 2005), though development of opioid dependence when using opioids medically for analgesia occurs in less than 1% of individuals who do not have a prior history of drug or alcohol abuse or dependence (Fishbain et al., 2008). The literature indicates CNCP is also prevalent among clients from psychological treatment samples and studies have linked mood disorders, unemployment, increasing age, and severity of pain to poorer treatment outcome (Tunks et al., 2008).

### Risk factors related to development of CNCP.

Research separately indicates potential risk factors for developing CNCP and opioid dependence, but currently no research presents risk factors for their comorbid presentation. Sex, race, ethnicity, age, and physical or mental health conditions are predisposing factors to the development of CNCP, as well as to development of opioid dependence. The following section describes the currently available empirical data on risk factors for developing CNCP.

*Sex.* Women are twice as likely as men to develop CNCP during their lifetime (Tsang, et al., 2008). The literature indicates similar increased risk for women in regards to opioid dependence (Green, Serrano, Licari, Budman, & Butler, 2009), which is particularly important to note since opioid medication is commonly used to treat pain. Overall, women start using prescription drugs illicitly at lower doses than men do, but women escalate to abuse and dependence faster and are at greater risk of relapse after substance abuse treatment (Becker & Hu, 2008). Furthermore, a higher percentage of women than men report depression in their lifetime (Tsang, et al., 2008) and mental health disorders have been correlated with prescription opioid abuse for women (Tetrault et al., 2008) and with the development of CNCP for both sexes (Becker et al., 2008). It appears that being male or female has a role in the development of CNCP, though the literature does not indicate whether this is due to biological, cultural, or psychological aspects of one sex or the other.

*Race/ethnicity.* The sample for this study overwhelmingly report being white, nonhispanic (95%); therefore, little can be examined in regards to race/ethnicity and CNCP among the study sample. Other research has indicated race or ethnicity in conjunction with low socioeconomic status has been found to increase the odds of an individual developing CNCP (Johannes et al., 2010; Rashiq & Dick, 2009). In one U.S. study, white subjects reported longer pain duration, but lower pain severity ratings compared to other racial groups (Portenoy et al., 2004), but in a Canadian sample, whites were less likely than other racial groups to have CNCP (Rashiq & Dick, 2009). On the other hand, non-white race and lower socioeconomic status have been correlated to lower rates of employment (Crum, 2009). Future studies should include a sample which incorporates a wider range of race and ethnicities in order to further examine race/ethnicity in relation to CNCP.

*Age.* It is common knowledge that the odds of developing painful conditions increase as a person ages. Increasing age is correlated with increased physical health problems, but also with decreased substance abuse (Rashiq & Dick, 2009). Thus, individuals with CNCP who are in substance abuse treatment may have better outcomes as they age, though whether or not untreated CNCP will negatively impact outcomes needs further exploration.

### Physical and mental health.

Pain is an internal warning system native to our bodies and one of the most primitive systems we have. Part of coping with CNCP is learning to ignore the pain-alert system wiring since it is no longer useful in regards to long-term pain (Eccleston, 2010). Research primarily focused on pain management clinic samples identifies substance abuse history and mental health problems as the key predictors of future opioid dependence problems for individuals with CNCP (Edlund, Steffick, Hudson, Harris, & Sullivan, 2007). A study of 6,000 women in the general population found significantly more daily tobacco smokers reported CNCP than non-smokers (Mitchell et al., 2011) indicating a link between legal drug use in the form of tobacco with presence of CNCP. Sensitivity and pain-related anxiety also help to perpetuate CNCP (Gonzalez, Zvolensky, Hogan, McLeish, & Weibust, 2011). Having a history of sexual, physical, or emotional abuse increases a person's likelihood of developing CNCP and particularly fibromyalgia which occurs most frequently among women (Sansone et al., 2009). Finally, a person's perception of their ability to control or moderate their pain can have a significant impact on development and recurrence of CNCP (Dersh, Gatchel, Mayer, Polatin, & Temple, 2006; Gatchel & Kishino, 2011).

Coping and perception of pain are extremely tricky when part of the body is in high-alert mode due to painful stimuli. The person's perception of the ability to cope with and control the pain has an impact on how well the person can manage CNCP (Turner, Holtzman, & Mancl,

2007). Particularly, individuals who are catastrophic thinkers may perceive themselves as having less control over their pain and have more difficulty coping on a day-to-day basis (Chapman & Turner, 2001). Similarly, highly anxious individuals have an increased attention to pain, increased negative affect from pain, and are harder to distract from pain (Verhoeven et al., 2010). In addition to the level of control a person feels over their pain and their reactions to painful stimuli, other emotional factors influence CNCP (Turner et al., 2007). Through fast magnetic resonance imaging (fMRI) studies of the brain, scientists identified the role of the prefrontal cortex in processing emotions surrounding pain (Gatchel & Kishino, 2011). In addition, fMRI's identify the anterior cingulate gyrus as part of the limbic system which helps moderate mood and pain perception in regards to CNCP (Luu & Posner, 2003).

This understanding of the chemistry of pain and emotion can help guide development of treatment to target the specific body/mind areas impacted by pain and help explain why many other psychological processes interact with CNCP. Emotional reactions to long-term, unremitting pain and its implications for daily living are subjective and can vary greatly from person to person. Most reactions are negative and include depression, anger, and hopelessness (Disorbio, Bruns, & Barolat, 2006) with an estimated 40-50% of individuals with CNCP reporting depression due to their painful conditions (Dersh et al., 2006). Anxiety and fear of more pain can lead to substance use problems and avoidance of physical or social activities, though this reaction negatively affects the overall functionality of an individual with CNCP and may in fact increase pain levels over time by decreasing mobility and support (Gatchel, 2005; Gatchel et al., 2007; Gatchel & Kishino, 2011). *Figure 3* depicts the inter-connectedness of CNCP, stress, substance use, and psychological problems. This diagram illustrates how CNCP triggers depression, anxiety, sleep problems, and daily coping difficulties such as substance abuse, which then leads to an increase in pain and a continuance of the cycle.

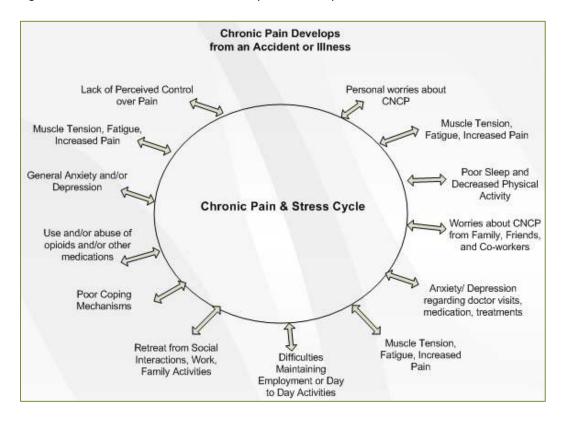


Figure 3. Illustration of inter-relationship of chronic pain and stress

*Socio-cultural.* The development of CNCP is influenced by heritable and environmental components, though research shows that neither are completely deterministic (Agrawal & Lynskey, 2008). CNCP prevalence rates in developing and developed countries vary only slightly with lower rates reported in the developing nations. This could be due to lack of available healthcare or that different cultures are more likely to care for family members at home and thus do not publicly report their painful conditions (LeResche, 2001). Social exclusion by the person with CNCP may occur due to the person's social circle moving away from the individual because CNCP is such a large part of the individual's life (Tollefson, Piggot & Fitzgerald, 2008). Women have higher pain prevalence rates compared to men, thus socially ingrained messages may make it less acceptable for men to report pain or coping difficulties than for women (LeResche, 2001; Tsang et al., 2008). In addition, family, friends, and coworkers may make

moral judgments about the individuals' reaction to their painful condition including doubt about the validity of pain, particularly if there is no specific diagnosis or visible cause (Giddings, & Roy, 2008). Others might question the level of assistance requested to help the individual cope, or about the emotional state of the patient, assigning blame for the chronicity of the condition to something the individual has or has not done to help themselves (Tollefson et al., 2008).

CNCP affects a person's ability to perform regular household chores, attend to work duties, enjoy leisure activities, and concentrate on day-to-day events. Estimated social costs of chronic pain in lost workdays, health care, disability and other expenses are approximately \$210 billion per year for the United States (National Research Council, 2001). Ongoing pain that individuals experience with CNCP can affect a person's mood leading to depression, anxiety, lethargy, increased substance abuse risk, and a general inability to cope with daily living activities (Turk et al., 2011). This is illustrated in a study of 4,839 individuals reporting past 6month CNCP where 61% had difficulty maintaining employment, 19% had lost their job, and 13% had switched jobs due to chronic pain (Breivik et al., 2008). Individuals who continue to use drugs and alcohol 12-months after treatment have significantly lower rates of employment and household income compared to individuals who maintain abstinence post-treatment (Walker, Cole, Logan, Mateyoke-Scrivner, & Stevenson, 2011).

High economic costs of CNCP affect the individual, her/his family, and society (Field & Swarm, 2008), and this is likely increased two-fold for those clients who also have comorbid CNCP. As previously noted, relationships and social connections may be limited by CNCP as many individuals recede from social circles when pain makes daily activities difficult (Disorbio et al., 2006). Yet, many of the same social issues occur within the lives of someone struggling with opioid dependence where social context can affect perpetuation of drug and alcohol abuse. On one hand, families and social networks that are drug- free and supportive of recovery act as a

protective factor from drug and alcohol use (Davidson et al., 2010). On the other hand, a social atmosphere in which drug use is accepted as part of the environment is a risk factor for substance abuse and relapse (Davidson et al., 2010; McCrady, 2006). For example, social bonding around drinking at bars and baseball games is common. In a family or neighborhood struggling with poverty, abuse, or other stressors, substance abuse is more likely to flourish (Moos, 2006). In fact, reaching a point where someone with a substance use problem is ready to change is heavily influenced by surrounding cultural acceptance or ignorance of drug and alcohol problems (Carlson, 2006) and by the support or resistance of family and friends (McRady, 2006). Low socioeconomic status and a family history of substance abuse increase the risk of an individual developing alcohol or drug dependence (Crum, 2009) while unemployment decreases socioeconomic resources and increases risk for relapse from substance abuse recovery (Henkel, 2011).

Cultural roles, family, and social responsibilities, for women in particular, make participating in behavioral health treatment difficult, and many residential treatment facilities do not have childcare or other resources while a woman participates in treatment (Straussner & Attia, 2002). Learning to cope with CNCP through individual and small group therapy along with peer support has been shown to aid functionality (Wetherall et al., 2011). Similarly, participation in peer-based recovery groups like Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) positively impacts recovery and maintenance of abstinence from drug and alcohol use, particularly for women (Grella, Scott, Foss, & Dennis, 2008; Timko, Finney, & Moos, 2005). Online support groups for CNCP are fairly new, but have been growing in number and offer a confidential place to share CNCP issues and talk with peers who struggle with similar health problems (i.e., www.dailystrength.org; www.cpsginc.org ).

### **CNCP** Treatment

Myths and stereotypes surround CNCP and the medications used to treat pain symptoms. Some patients do not report pain or report when pain medication is not working because they harbor a stoic *no pain, no gain* mentality. Others feel that being a good patient means not complaining or that if they discuss the pain, surgery will be required or treatment will become more complicated (IOM, 2011). Even if an individual does seek help for their pain symptoms, many rural areas have shortages of physicians and professionals versed in pain management techniques. This may affect military personnel returning from war with painful conditions who cannot afford treatment outside of the Veteran's Administration (VA) healthcare system (VA), but do not have access to VA or other services in their rural hometown to which they are returning after active duty (Tanielian & Jaycox, 2008). Unresolved and persistent acute pain becomes chronic pain and this is a growing issue for the returning veterans for whom becoming opioid dependent may be a growing issue as needs outpace resources for combat veterans (Clark, Bair, Buckenmaier, Gironda, & Walker, 2007).

The goal of CNCP treatment is to reduce the severity of the pain and to increase functioning for individuals with CNCP. It is accepted practice to differentiate between palliative care for cancer or end-of-life issues compared to rehabilitative pain management. Currently the literature provides only minimal support for long-term use of opioid medications in treating CNCP (Chou et al., 2009; Katz, 2010). This is also an issue in regards to continuity in criteria used for prescribing pain medications. Some physicians fear prescribing controlled substances because of the DEA's regulation of the drugs. The DEA (2011) affirms that there is no one guideline that would fit all patients and that prescribing should be on a case-by-case basis. Thus, the DEA monitors prescribing of controlled substances with this in mind and does not specifically target or single out pain management physicians for audit any more than they do

OTPs or buprenorphine prescribing physicians. Pharmacological treatment is considered best practice for palliative care while non-pharmacological treatment like behavioral therapy, vocational rehabilitation, and physical therapy are best for treating long-term chronic pain (Robinson, Leo, Wallach, McGough, & Schatman, 2010). The goal is not to "cure" or eliminate the pain entirely as that is not possible for most CNCP. As illness and CNCP persist over time for an individual, the stress of dealing with pain and the ongoing cycle of pain and stress may create ingrained patterns of coping behaviors. These patterns of coping behavior can help and hinder reactions to CNCP. For example, the standard expectation for medical treatment of patients with acute pain mindfulness training to help disrupt the underlying cognitive workings that help maintain the biopsychosocial substance dependence and provide coping skills to prevent relapse (Bowen, Witkiewitz, Dillworth, & Marlatt, 2007; Garland, Boettiger, & Howard, 2011).

Varieties of pharmacotherapies are available for treating substance dependence. For nicotine dependence, bupropion has proven to help increase quit rates among smokers compared to a placebo (O'Malley & Kosten, 2006). For alcohol dependence, clinically monitored benzodiazepine use has helped individuals manage withdrawal symptoms and a monthly naltrexone injection was approved in 2010 (CSAT, 2009). Similarly, disulfiram, naltrexone, and acamprosate have proven effective for alcohol withdrawal and detoxification (O'Malley & Kosten, 2006). There are also several opioid replacement treatment medications approved by the U.S. Food and Drug Administration (FDA) that bind with the body's opioid receptors, stop withdrawal symptoms, and reduce the likelihood an individual will relapse (CSAT, 2005). The primary medications used for opioid dependence treatment are methadone and buprenorphine.

In order to be admitted into a formal opioid treatment program (OTP) with a maintenance therapy medication like methadone, individuals must meet the DSM IV-TR criteria for opioid dependence and have failed past treatment attempts in standard abstinence-based

treatment (CSAT, 2005; Federal Register, 2006). OTPs are heavily regulated by both federal and state drug control policy agencies because the primary opioid dependence treatment medications are controlled substances (Federal Register, 2006). Specifically in Kentucky, 908 KAR 1:340 defines the OTP regulations that govern operation and dispensing of the replacement therapy drugs. The Controlled Substances Schedule created by the Drug Enforcement Agency (DEA; Federal regulation 21 CFR Sections 1308.11-1308.15) defines whether substances have an approved medical use and rates the drug according to its abuse and dependence potential on this Schedule. Drugs with the highest danger for abuse are assigned a Level I while the drugs with the lowest danger are assigned a Level V (DEA, 2011). For example, buprenorphine (brand names of Subutex and Suboxone) is a Schedule III drug, methadone and morphine are Schedule II, and heroin and MDMA are Schedule I drugs not approved for any medical purpose and with a high risk of abuse (DEA, 2011). Regulations allow methadone (Schedule II) to be administered only in a specially licensed clinic approved by the Substance Abuse and Mental Health Services Administration. Methadone must be taken daily with a clinical staff person witnessing the client swallowing the medication at the clinic for the first 90 days of treatment. After that period, if a client meets compliance with all rules at the clinic and consistently has negative drug screens, approval for take home doses may begin.

Methadone was first approved to treat opioid dependence in the 1960's as a longacting (8-59 hour) highly potent full mu-opioid agonist therapy (CSAT, 2005). In 1993, the FDA approved another long-acting mu-opioid agonist called levo-alpha-acetyl methadol (LAAM) with a similar drug profile to methadone except that it only needed to be administered three times a week instead of daily (CSAT, 2005). No pharmaceutical company currently manufactures LAAM. A partial mu-opioid agonist called buprenorphine was formulated with naloxone to make it less abusable (Suboxone) and FDA approved in 2002 for opioid dependence treatment (Crum, 2009).

Initially, buprenorphine was developed as a prescription painkiller, but researchers found it also worked for opioid dependence. The most research is available on methadone since it has been around the longest time, but data are rapidly being gathered on the newer formulations of opioid dependence pharmacotherapies. Physicians in standard office settings can write a 30day buprenorphine prescription that is filled by a retail pharmacy (Federal Register, 2006). Methadone and buprenorphine can also be prescribed through a pain management clinic, but the purpose of use in these settings is reduction of pain rather than prevention of withdrawal symptoms.

## Background on Opioid Treatment Programs (OTPs) in Kentucky.

Approximately 270,881 individuals in the United States are enrolled annually in an OTP of which 98.5% take methadone (SAMHSA, 2010). Kentucky has 11 OTPs that serve the entire state. Table 3 provides a comparison of the U.S., Kentucky, and surrounding states on the number of certified OTPs, types of medication provided, and their primary payment mechanisms. The majority of clients are taking methadone medication. Medicaid coverage for methadone is limited in most states to only pain management treatment, not for opioid dependence treatment, though most states have OTPs, which offer a sliding scale fee or treatment at no charge. The issue is where OTPs are located since most public non-profit agencies are in large urban areas of the state, not in a rural county. Table 3 also shows the wide range of service availability versus OTP capacity. Tennessee had fewer OTPs than Kentucky, yet fewer clients are servedis that the source of pain is identified, cured, and the patient achieves a full recovery. For CNCP, this goal must be modified since elimination of CNCP is not generally an option. Rather than focusing on curing the patient, the model for CNCP must be a biopsychosocial one with a goal of helping the patient to determine the best methods for

reducing pain levels, coping with the pain, and improving functionality and quality of life. Partners, friends, and other caregivers can be taught to help provide at-home support for individuals with CNCP and communication between all those involved in the care of the patient is critical to increasing the patient's quality of life and functioning (Tollefson et al, 2008). Research on best practices for CNCP has expanded over the past decade and includes treatments with behavioral therapy, pharmacological therapy, physical, and occupational therapy (Sanders, Harden & Vicente, 2005; Wetherall et al., 2011).

### **Opioid Dependence Treatment: An Overview**

Overall, research literature indicates that medication-assisted treatment for opioid dependence is an effective and cost-efficient method of treatment (Belenko, Patapis, & French, 2005; Connock et al., 2007; Harwood et al., 2002), especially when compared to the costs of opioid abuse left untreated. Birnbaum et al., (2006) provided a detailed cost analysis related to opioid abuse which estimated costs of \$9.5 billion in 2005 or \$10.6 in 2010 dollars (conversion from Officer & Williamson, 2011). When this estimate is broken down, workplace costs including employment, productivity, and wages accounted for 53% of the total; healthcare costs including local, state, and private care accounted for 30%; and criminal justice costs for individuals who abuse opioids, an average year of healthcare (including emergency room visits) can cost up to \$17,600 compared to only \$2,030 for a non-opioid abuser (White et al., 2005; conversion from Officer & Williamson, 2011).

OTPs are required to include behavioral counseling as part of the medication-assisted treatment protocol; however, buprenorphine prescribed for treatment through a physician's office does not always have this requirement (Veilleux, Colvin, Anderson, York, & Heinz, 2010). The inclusion of behavioral therapies with medication-assisted treatment like methadone

increases the number of individuals who are able to maintain abstinence at follow-up points (Veilleux et al., 2010). With any substance dependence problem, comorbid mental health issues complicate treatment and decrease the long-term positive outcomes for many patients (Cacciola, Alterman, Rutherford, McKay, & Mulvaney, 2001). Recent research has shown brief cognitive-behavioral treatment models can be as effective as longer, more intensive models by teaching clients healthy skills for coping with daily stressors (Carroll & Rounsaville, 2006; Laudet, 2008a; Wetherall et al., 2011). Other behavioral therapies with data to support their efficacy include brief motivational therapy, cognitive behavioral therapy, contingency management, and social and family network therapy (Carroll & Rounsaville, 2006).

	U.S.	KY	TN	ОН	WV	IN	IL	MO
Number of OTPs	1233	11	8	17	9	16	60	12
Percent public non-profit	45.6%	18.2%	0%	82.4%	0%	33.3%	55.0%	54.5%
Average daily client census*	321,130	1710	4856	6861	4939	7571	14708	3546
Methadone client census	277,104	1487	4844	4334	4690	7279	12035	3485
Buprenorphine client census	5647	129	12	137	249	56	102	61
Percent taking payment type:								
Self-pay/cash	97.5%	90.9%	100.0%	94.1%	100.0%	100.0%	96.7%	91.7%
Private health insurance	50.9%	27.3%	12.5%	81.3%	77.8%	56.3%	51.7%	33.3%
Medicaid	64.5%	27.3%	0	76.5%	0%	6.7%	61.0%	45.5%
Sliding fee scale	48.4%	18.2%	0	76.5%	33.3%	31.3%	50.0%	50.0%
Treatment at no charge	32.8%	9.1%	0	76.5%	11.1%	12.5%	46.7%	50.0%
Federal military insurance	21.6%	27.3%	0	33.3%	25.0%	12.5%	25.9%	41.7%

Table 3Comparison of U.S., Kentucky, and Surrounding States on OTP Features Using 2009 N-SSATS Data

Table created using public use data files from 2009 SAMHSA National Survey of Substance Abuse Treatment Services (N-SSATS) retrieved from <u>http://oas.samhsa.gov/SAMHDA.htm</u> \*Daily census varies so it represents a snapshot in time and thus methadone plus buprenorphine client census does not necessarily equal the total census.

Locations for OTPs across the state are displayed in *Figure 4*. Public non-profit agencies are marked with a star (n=2). Sites are color-coded to denote which ones offer buprenorphine versus methadone. Less than 2% of OTPs nationwide currently have clients taking buprenorphine for maintenance treatment (CSAT, 2005).

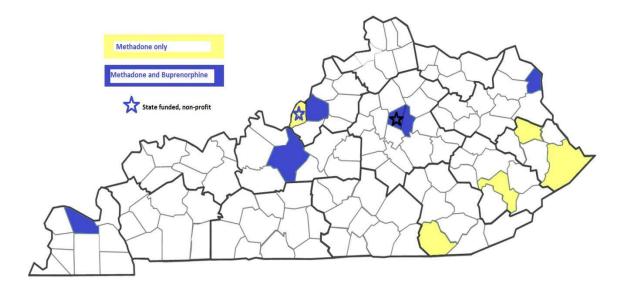


Figure 4. Map of OTP locations across Kentucky by type of opiate replacement medication

In Kentucky, six of the eleven OTPs provide both methadone and buprenorphine medication. The other five OTPs only provide methadone for treatment of opioid dependence. The oldest clinic in the state is centrally located in Lexington, which is where the original Narcotic Treatment Farm was located thus establishing Lexington as one of the primary sites for provision of opioid dependence treatment in the state. Lexington has one of the only two public non-profit treatment sites available in the state; the other location is about an hour north in another major metropolitan area of the state, Louisville. Both public sites in Kentucky are centrally located in metropolitan areas. Only about 3% of OTPs across the nation are in nonmetropolitan areas (SAMHSA, 2009), so it is unique that the majority of Kentucky's OTPs (n=6) are in rural towns, though they are all private for-profit clinics. Federal and state regulations guide how, when, and where new OTPs can operate (CSAT, 2005). In Kentucky, these guidelines include a required public notice of intent to provide treatment services, approval by the state narcotic treatment authority, accreditation by an authorized entity (i.e., Commission on Accreditation of Rehabilitation Facilities, Joint Commission on Healthcare Organizations). Medications must be secured in a safe to prevent theft and security around the OTP premises must be assured. Many of the regulations were developed specifically because the facilities provide methadone a Schedule II drug with high liability for abuse, overdose, and diversion. Clients must purchase special locked containers in which to secure their medications once they are allowed to have take-home doses.

According to the Federal buprenorphine education website

(http://www.buprenorphine.gov) there are 12,973 physicians and 1839 practices in the United States that can prescribe buprenorphine for opioid dependence treatment. Table 4 displays a count of physicians and behavioral health practices in Kentucky and surrounding states that have obtained the necessary training for a Federal DATA 2000 waiver allowing them to prescribe buprenorphine for opioid dependence treatment outside of an OTP. To my knowledge, there is no public census of clients prescribed buprenorphine for opioid dependence treatment through non-OTP sites.

### Table 4

*Count of Authorized Buprenorphine Prescribers and Practices Offering Buprenorphine for Opioid Dependence Treatment in Kentucky and Surrounding States* 

State	Physicians that can prescribe buprenorphine (n)	Practices offering buprenorphine⁺(n)				
United States	12,973	1,839				
Kentucky	201	23				
Tennessee	272	24				
Ohio	383	48				
West Virginia	96	17				
Indiana	181	54				
Illinois	306	64				
Missouri	119	13				

[Data retrieved from <a href="http://www.buprenorphine.gov">http://www.buprenorphine.gov</a>]

+ includes OTPs and public/private physician practices

### **Summary of Literature Review**

Both CNCP and opioid dependence are biologically complex (Banta-Green, Merrill, Doyle, Boudreau, & Calsyn, 2009; Zacny et al., 2003) and encompass social and psychological aspects of an individual (Gatchel and Kishino, 2011). Rates of CNCP are increasing with 1 in 10 individuals newly diagnosed annually (IASP, 2011). Pain treatment includes opioid medications when appropriate, though increasing opioid abuse nationwide raises concerns for prescribing practices. Current research is limited regarding CNCP among individuals with opioid dependence (Angelino et al., 2005; Clark, Stoller, & Brooner, 2008). Historically, research studies on CNCP have excluded individuals with opioid dependence, while most substance abuse research has not addressed CNCP, and the majority of research does not provide specific information on the comorbid effects of CNCP and opioid dependence (Angelino et al., 2005; Portenoy et al., 2005). Developing a clear understanding of the relationship between CNCP and opioid dependence is important to clinicians and essential to individuals seeking treatment. To begin to address the issue, this study proposes an examination of the effect of CNCP in relation to treatment outcomes among clients in opioid treatment programs.

#### **CHAPTER 3. METHODOLOGY**

### **Research Question and Design**

The goal of this study is to build the knowledge base around CNCP by examining outcomes for a statewide sample of 483 individuals who met DSM IV-TR criteria for opioid dependence with methadone or buprenorphine at a federally licensed opioid treatment program (OTP) in Kentucky between March 2007 and December 2010. The primary research question the study attempts to answer is this: How does the presence of CNCP among clients in a community-based OTP affect treatment outcomes? Are outcomes at follow-up significantly different for clients with CNCP compared to clients without CNCP regarding abstinence from drug use, employment, mental health symptoms, criminal justice system involvement, and connection with recovery support networks?

The study will examine characteristics of the sample at treatment baseline by comparing individuals with and without CNCP (dependent dichotomous variable) using frequencies, crosstabs, t-tests, and bivariate correlations between key variables including: sex, age, race/ethnicity, geographical location for treatment (Appalachian, non-Appalachian), education level, employment status, criminal justice system involvement, methadone or buprenorphine dose level, time in treatment, substance use history, and mental health symptoms.

In addition, the study aims to explore the relationship between CNCP and treatment outcomes. The outcome most relevant to OTPs is abstinence from or reduction in illegal drug use and alcohol use (CSAT, 2005). In addition, the study will examine changes by individual pain group status from baseline to follow-up. Key follow-up variables will include abstinence from drug use, abstinence from alcohol use, employment status, criminal justice system involvement, mental health symptoms, and connection with recovery supports (i.e., narcotics anonymous (NA), methadone anonymous (MA), family and friends who are supportive of recovery).

## **Description of Data Source for Analyses**

A secondary dataset from the Kentucky Opiate Replacement Treatment Outcome Study (KORTOS) was used for analyses. Baseline data were collected in face-to-face interviews at the OTP and follow-up data were collected during phone interviews conducted by independent evaluators. The sample of 483 cases includes 163 individuals (33.7% of sample) who reported experiencing chronic pain at baseline (i.e. pain persisting or recurring for 3 months or longer over the past year). KORTOS is a statewide data collection system that follows clients through maintenance treatment for opioid dependence. Treatment typically includes methadone or buprenorphine medication, substance abuse counseling, and annual medical check-ins with a physician on an outpatient basis. In 2007, Kentucky's Division of Behavioral Health, Developmental, and Intellectual Disabilities initiated data collection for KORTOS in collaboration with the Center on Drug & Alcohol Research at the University of Kentucky (UK CDAR). The Division of Behavioral Health requires data collection of all state-licensed Kentucky OTPs that span the state from east to west. For these analyses, ten of the eleven OTPs are represented since one clinic had just opened and was not yet providing data for KORTOS at the time of data collection for this sample.

Baseline data for KORTOS were collected in face-to-face interviews by OTP staff during the initial clinical assessment phase of treatment, reading questions from a structured interview online, and entering client responses into the web-based data collection program. Baseline questions focus on circumstances prior to entry into treatment, unless otherwise specified (i.e., current events, date of birth). Baseline data are obtained as part of the treatment process covered under the OTP's standard consent for treatment. At the end of the baseline interview, clinicians describe the follow-up telephone interview and ask if the client is willing to volunteer for the second part of the outcome study. Clients who volunteer must provide locator

information including phone numbers of two relatives or friends who could help UK CDAR locate the client for the interview in about 6-months post-baseline. Data along with informed consent releases for follow-up are electronically transmitted to UK CDAR and stored as encrypted files on secure servers.

Over the past several years, approximately 30% of the 1,000 clients who were admitted to treatment at a Kentucky OTP volunteered to participate in the KORTOS follow-up study. Anecdotally, OTP staff relay the primary reason provided by clients who do not choose to participate in the follow-up study is fear of having personal information and substance use history accessed by researchers. This trend continues, despite assurances provided in the informed consent process regarding the study's Certificate of Confidentiality from the Federal government that prohibits access to identifying information in relation to survey response, which includes probation or parole officers or subpoenas.

Follow-up data were collected by UK CDAR staff through telephone interviews for the sample of clients who were still active at an OTP and who gave informed consent at baseline to participate in the follow-up interview. These interviews are independent of the treatment agency with the goal of tracking the ongoing progress of clients receiving medication-assisted maintenance treatment in the state. The follow-up interviews include questions matching much of the baseline interview and focus on current substance use, employment, education, mental health status, criminal justice system involvement, and use of recovery supports. Individuals report the current medication type and dose in milligrams per day of methadone or buprenorphine during the follow-up interview.

# **Measures and Instrumentation**

The statewide sample of secondary data used for these analyses includes 483 baseline and follow-up records collected between March 2007 and December 2010 from individuals in

maintenance opioid dependence treatment at ten of the eleven state-licensed OTPs in Kentucky. Secondary data for this study was provided to the researcher with permission of the Kentucky Division for Behavioral Health, Developmental, and Intellectual Disabilities and the state Narcotic Treatment Authority. The data collection instruments for KORTOS are based on the Addiction Severity Index, 5th edition (ASI; McLellan et al., 1992). Multiple studies over the past 20 years have evaluated and support the ASI's test-retest reliability, concurrent, predictive, and discriminate validity for identifying abuse and dependence levels across genders, racial groups, and treatment setting samples including inpatient (i.e., hospitals), prisoners, outpatient, residential, (Alterman, Bovasso, Cacciola, & McDermott, 2001; Alterman et al., 2001; McLellan et al., 1985). Comparable results were also found with methadone treatment clients (Bovasso, Alterman, Cacciola, & Cook, 2001). In 1985, McLellan and colleagues conducted a cross-site evaluation of the ASI and reported concurrent reliability concordance scores at an average of .89 between interviewers. Test-retest reliability was measured over a 3-day interval with no significant differences in interviewer ratings even with varied interviewers conducting the tests.

Discriminant validity tests on the ASI questions have found expected between group differences and report moderate internal consistency for subscales of between .65-.89 (Cronbach's alpha) and weak correlations between subscales (<.05; Leonhard, Mulvey, Gastfriend, & Shwartz, 2000). Thus, the subscale scores are not included in this study. On the other hand, the composite scores for alcohol and drug dependence measures matched to DSM-IV diagnoses had 85% concordance between the two diagnoses (Rikoon, Cacciola, Carise, Alterman, & McLellan, 2006). When comparisons between clinical diagnoses and ASI composite scores were made with a sample of adults in substance abuse treatment in Kentucky, the ASI score identified more alcohol dependence than was identified by the actual client diagnoses, but similar numbers of drug dependence (Walker et al., 2011). Topics derived from the ASI included

in the KORTOS data collection interviews include substance use, employment, caretaking roles, mental health, physical health, and involvement in recovery support groups. Calculation of ASI composite scores for drug or alcohol dependence, but not for the subscales (i.e., employment, mental health) is maintained in the KORTOS study.

Chronic pain measures were derived from the Brief Pain Inventory (BPI; Cleeland, 1991). Reliability of the BPI has been compared to that of studies with cancer patients and arthritis patients (.70 or higher; Keller et al., 2004). The BPI has high discriminate ability for rating pain severity and is sensitive to changes over time (Guyatt's statistics = .46 to 1.14) making it a good measure for research as well as clinical diagnoses (Keller et al., 2004). Williams, Smith, and Fehnel (2006) evaluated the BPI interference scale with osteoarthritis pain patients and found high reliability (Cronbach's alpha = .82) and discriminant validity (t41=-.71, p<.05).

## **Outcome variables.**

Description of the specific measures included for this study are detailed in the following segments along with the type of variables and levels of measurement (nominal, ordinal, or ratio). As described previously, all data were collected as part of a structured interview with clients of OTPs and were self-reported by the client to the interviewer who recorded the client responses. Outcome measures of interest for this study include substance use, employment status, education status, criminal justice system involvement, recovery support, and mental health symptoms.

## Alcohol and drug use abstinence.

Information on substance use was self-reported by clients during structured interviews at baseline and follow-up using questions adapted from the ASI. Abstinence from alcohol and drug use are measured with continuous ratio measures for the number of days of use in the past 30 days to capture recent use patterns. In addition, number of months of use in the past 12-

months was captured at baseline to examine patterns of use over the long term for tobacco, alcohol, and the major drug classes (cocaine, opioids, marijuana, barbiturates, tranquilizers, amphetamines, inhalants). Variables were also recoded into dichotomous yes/no responses for any use in the past 30 days.

The ASI alcohol and drug dependence scale was utilized as well, which allows for calculation of a severity score for individual alcohol and drug use. This calculation includes the addition of responses to the amount of money spent on alcohol in the past 30 days, and the number of days the client experienced alcohol problems and days of drug problems (i.e., craving, withdrawal, want to quit but unable) in the past 30 days. Also, questions asked the client to rate (ordinal measure: 0=not at all to 4=extremely) how troubled or bothered he/she was by drug problems, by alcohol problems, and how important treatment is now to him/her for alcohol problems and for drug problems. A formula developed by McClellan et al. (1992) calculates an alcohol dependence score and a drug dependence score based on the composite of answers to these questions. The recommended ASI composite cutoff scores (CS) at which a clinical diagnosis of dependence is considered likely is set at 0.17 for alcohol and 0.16 for drug use (Rikoon et al., 2006). These composite scores will be used in the analyses for this study.

Specifically, abstinence from alcohol abuse (as opposed to legal use) is measured by the number of days in the past 30 days (interval measure: 0-30) that a client reports being intoxicated from drinking alcohol. Since alcohol use is legal, the primary concern for this sample is with problem drinking as indicated by intoxication. The ASI questions about the number of days a client was intoxicated from alcohol are included in both the baseline and follow-up interviews allowing for calculation of percentage change in alcohol intoxication from baseline to follow-up.

## Employment.

Current employment status was measured at baseline and follow-up using structured interview questions adapted from the ASI. The nominal variable included these response options: full-time (35 or more hours per week, includes service/military), part-time (less than 35 hours per week, includes occasional/seasonal employment), or currently unemployed (includes student, retired, disabled).

### Education.

Current education completion was measured at baseline and follow-up using ASI questions. Individuals select their highest level of education completion from 0=no formal education to 20=graduate level degree.

## Mental health symptoms.

Mental health information focused on depression and anxiety, two factors that the literature identifies as strong correlates with both CNCP and with opioid dependence. Questions from the ASI were used to ask clients at baseline and follow-up: 1.) *Have you had a significant period (that was not related to your drug or alcohol use) in which you experienced serious anxiety in the past 30 days?* (dichotomous measure: Yes/No). 2.) *Have you had a significant period (that was not related to your drug or alcohol use) in which you experienced serious anxiety in the past 30 days?* (dichotomous measure: Yes/No). 2.) *Have you had a significant period (that was not related to your drug or alcohol use) in which you experienced serious depression in the past 30 days?* (dichotomous measure: Yes/No). 3). *Have you been prescribed medication for any psychological/emotional problem within the past 30 days?* (dichotomous measure: Yes/No).

## Criminal justice system involvement.

Using measures adapted from the ASI, criminal justice system involvement was measured with questions about arrests and parole, probation, or drug court involvement. Clients were asked at baseline and at follow-up: *Are you currently on probation?* (nominal

measure: Yes/No); Are you currently on parole? (nominal measure: Yes/No); Are you currently involved in a drug court program? (nominal measure: Yes/No). At baseline clients were asked: Were you arrested in the past 12-months? (nominal measure: Yes/No). This was changed to: Were you arrested in the past 6-months? (nominal measure: Yes/No) at follow-up to cover the time period between baseline and follow-up.

### Recovery support.

To evaluate recovery support for each client, questions were asked about self-help group attendance. Clients were asked at baseline and follow-up: *How many AA/NA/MA meetings have you attended in the past 30 days*? The data collection program capped the number of meetings that could be entered at 100 since the researchers estimated that clients could potentially attend an average of 3 meetings per day (ratio measure: 0-100). Since AA/NA meetings are abstinence focused and generally non-supportive of medication assisted treatment provided by OTPS, this measure may be a limitation to examining true recovery support for this sample.

### Predictor variable.

# Chronic non-cancer pain (CNCP).

Using the definition of chronic pain established by the International Association for the Study of Pain, the following question was asked of all clients: *We all have pain like headaches and sprains, but sometimes the pain from an injury or illness can last longer, beyond the usual healing time that is expected, and the pain becomes chronic. In the past 12-months, have you had any chronic physical pain? By chronic I mean pain that has lasted more than 3 months, beyond the usual healing time for an injury or illness.* (Nominal measure: Yes/No). Clients who answer "yes" to this question about chronic pain and do not identify cancer as one of their chronic health conditions (previous question) are considered to have chronic non-cancer pain

(CNCP). Cancer pain and its treatment are considered a completely different medical condition than chronic non-cancer pain. This study focuses on non-cancer pain, thus any clients from the sample that reported cancer as a current medical condition were excluded from the CNCP group; no clients met this criteria in this sample.

Individuals reporting CNCP were asked a series of questions adapted from the BPI. *Rate* your level of pain at the present moment (ordinal measure: 0=no pain at all to 10=worst possible pain); *Rate the degree to which bodily pain has interfered with your normal work, including* household duties, in the past 30 days (ordinal measure: 0=not at all to 4=extremely interfered).

To examine control individuals feel over their CNCP, a question was asked: *Rate the level* of control you feel you have over your pain. (ordinal measure: 1=no control at all to 6=a great deal of control). Though this question is not on the BPI, the literature indicates perceived level of control over pain is a strong indicator of how a patient will respond to the chronicity of pain (Turner et al., 2007).

Clients who stated they had chronic pain were also asked about use of prescription drugs for which they did not have a prescription. This helps capture an indication of selfmedication for CNCP. The question read: *Do you take any prescription painkillers for your pain (whether or not you have a prescription from a doctor)?* (nominal measure: Yes/No). If the individual reports any painkiller use, they were asked: *Do you have a personal prescription for all the pain medications you have taken?* (nominal measure: Yes/No).

## Socio-demographic characteristics.

Questions on socio-demographic characteristics asked at baseline were adapted from the standardized Government Performance and Reporting Act of 1993 (GPRA; Public Law 103-62) monitoring tool. This data collection instrument is used with all Center for Substance Abuse Treatment (CSAT) and Substance Abuse and Mental Health Services Administration (SAMHSA)

funded grants (KORTOS is funded through federal block grant dollars which funnel through CSAT and SAMHSA to the state government entities). This study includes the following:

- A. Sex: a nominal measure with responses that include male=1, female=2;
- B. Race/ethnicity: nominal measure with responses that include Non-Hispanic white=1,
  Non-Hispanic black=2, Other= 3 (i.e., American Indian, Alaskan native, Asian or
  Pacific Islander, Hispanic-Mexican, Hispanic- Puerto Rican, Hispanic-Cuban, other
  Hispanic);
- C. Client birthdate (month/day/year), in order to calculate current age at baseline;
- D. Current marital status: nominal measure including responses for married=1, divorced=2, widowed=3, separated=4, never married=5, and cohabiting=6;
- E. Geographical location of OTP: a variable was created to identify if the treatment location was in an Appalachian or non-Appalachian setting based on the zip code of each OTP (www.census.gov);
- F. Physical health: Clients were asked to identify whether or not they had any chronic physical health conditions diagnosed by a physician (nominal measure: Yes/No). If the client responded affirmatively to any chronic health problems, he/she was asked to select from a list of chronic conditions (based on World Health Organization major chronic disease categories): cancer, cardiovascular disease, arthritis, HIV, asthma, hepatitis B or C, severe dental problems (gum disease, bad teeth), and diabetes.

## Opioid dependence treatment medication and dose.

Clients also reported at follow-up which maintenance treatment medicine they were currently taking (i.e., methadone or buprenorphine-based formulations of Suboxone, or Subutex) and the current dose in milligrams per day. Dose fluctuates during the first month of treatment while clients move from an initial dose of about 10mg to their maintenance dose which prevents withdrawal and limits craving symptoms. Dose in this report is the maintenance dose recorded by the clients at follow-up. High, medium, and low dose methadone were calculated to allow for comparison between methadone dosing which may range from 20-150 milligrams per day versus buprenorphine dosing which ranges from 2-32 milligrams per day. Medication dose was grouped using standard equivalency recommendations to match low dose methadone (20-49mg) and low dose buprenorphine (2-6mg), moderate dose methadone (50-80 mg) with moderate dose buprenorphine (7-15mg) and high dose methadone (81-150mg) with high dose buprenorphine (16-32 mg) (Mattick, Kimber, Breen, & Davoli, 2002).

#### Human Subjects Protection

Study protocols, which include human subject protection measures and data safety guidelines, were approved by both the University of Kentucky Institutional Review Board (IRB) and the Kentucky Cabinet for Health and Family Services IRB (see Appendix A). All clients entering one of the eleven state-licensed OTPs in Kentucky were eligible to be included in the baseline interview dataset and consent for these baseline data is covered by the OTP's consent to treatment and HIPAA guidelines. Ten of the eleven OTPs were included in this dataset, since one site had just opened and was not yet providing data for KORTOS at the time of data collection for this sample. On average, about 30% of clients volunteer for the follow-up study; data analyses from the 2010 KORTOS annual report reflect no significant differences between clients who agree to follow-up and those who do not (Stevenson et al., 2011). The secondary dataset used for this study has been de-identified. Matching of baseline to follow-up records is accomplished by using the unique number assigned to each client's record and maintained from baseline to follow-up to match responses in the data files and maintain that no duplication in client cases occurred in the dataset.

## **Data Entry and Data Cleaning**

Data were entered into an online electronic data collection program by OTP staff at baseline. The baseline data program requires all fields be filled before moving forward with the question sequence, which ensures minimal missing data. Follow-up interview data are recorded on a paper form during the phone interview and then data are entered into an electronic database by UK CDAR staff. Initial data cleaning was conducted by the follow-up interviewers in PASW 19 by running frequencies and correcting any errant or invalid appearing responses based on the handwritten notes taken during the interview. Normal distributions were examined and the baseline and follow-up databases were combined by the researcher using PASW 19 for the detailed data cleaning prior to running analyses. Data were screened for outliers and frequencies were examined for missing responses or miscoded items (i.e., response "3" when only options available were 0-2) and corrected when possible. New variables were created by recoding responses into comparison groups of clients with and without CNCP.

#### **CHAPTER 4. RESULTS**

All analyses were conducted using the IBM PASW 19 statistical program. Univariate and bivariate analyses were conducted to examine client characteristics based on the presence or absence of CNCP. Analyses included crosstabs for categorical variables and ANOVAs for interval or ratio variables. Baseline to follow-up changes in the percentage of individuals reporting abstinence from alcohol and drugs, recovery support, employment status, educational achievement, mental health symptoms, and involvement in the criminal justice system was examined. Percent of change is calculated based on *n* values at baseline (n1) and follow-up (n2) using the formula:  $[(n2 - n1)/n1)] \times 100$ . A positive percent change indicates an increasing trend, and a negative percent change indicates a decreasing trend. Change was considered statistically significant if the probability of the finding was less than .05.

For categorical variables (i.e., count of individuals who were employed full-time or alcohol abstinent), a z test for proportions was calculated to determine if the change was statistically significant. In addition, analysis of change from baseline to follow-up for continuous variables (i.e., number of arrests, number of days of illicit drug use) was conducted with paired sample t-tests to determine if the change was statistically significant. Addiction Severity Index (ASI) composite scores were calculated to determine substance use severity at baseline. Severity is determined by using established cutoff scores (0.17 for alcohol and 0.16 for drug use) which are correlated with DSM-IV diagnostic criteria for alcohol and/or drug dependence (Rikoon et al., 2006).

The primary question on which these analyses focus is: *Does the presence of CNCP worsen or improve the outcomes for clients of opiate treatment programs (OTP)?* Outcomes examined to help answer this question include abstinence from illicit drug use, alcohol use and

intoxication, recovery support use, employment status, mental health symptoms, and criminal justice system involvement. The results section is organized as follows:

- Description of the sample and examination of baseline statistics for key outcome variables;
- 2. Examination of dose variance related to CNCP status, gender, and anxiety symptoms;
- Examination of changes from baseline to follow-up on the key variables using crosstabs, ANOVAs, t-test, z-test; and
- 4. Multivariate regression for odds of an individual having CNCP.

# Socio-Demographic Characteristics of Sample

Slightly more individuals in the sample were male than female and over 97% reported being non-Hispanic white. Results from crosstab and ANOVAs comparing demographics for the sample by pain status groups are displayed in Table 5 with statistically significant group differences noted for alpha of .05 or less. Individuals with CNCP were significantly older with an average age of 35 years compared to 32 years on average for the non-CNCP group (p<.001). Both groups reported a body mass index (BMI) in the overweight range, though t-test for means indicates the non-CNCP group BMI at 27.7 is significantly higher than the BMI of 26.1 for the CNCP group (p<.01). A higher percentage of individuals with CNCP were receiving OTP services in Appalachian counties (37.4%) compared to the non-CNCP group (28.4%; p<.05). In addition, a higher percentage of individuals with CNCP were widowed, divorced, or separated (34.3%) compared to those without CNCP (23.9%; p<.01). A significantly higher percentage of individuals with CNCP (61.2%; p<.01). Among those with children, around 24% of individuals in either group were involved with child protective services. Half of individuals with CNCP (50.3%) reported ever having a chronic medical condition compared to only 7.8% of individuals without CNCP (p<.001). Though conditions can be chronic, as in asthma or migraines, they do not always trouble an individual if a medical regimen is followed and managed by the individual. A follow-up question was asked about current trouble with the chronic condition, and among the 107 cases who reported lifetime chronic medical problems, only 33 cases had current trouble. The majority of those cases with current medical problems were among the CNCP group (n=31 vs. n=2). Among those with current medical issues, about 67% of CNCP cases reported arthritis, 32% reported chronic dental issues, between the two groups except for arthritis, which was reported by 67.4% of the CNCP group compared to none of the non-CNCP group.

Table 5
Socio-Demographics of the Sample at Baseline by Pain Status Group (N=483)

	Percentage or Mean		
Characteristics	CNCP (n=163)	Non-CNCP (n=320)	
Male	54.0%	57.2%	
Non-Hispanic White	97.5%	97.8%	
Average age ***	34.8 (sd=9.6)	31.9 (sd=8.8)	
Average Body Mass Index (BMI)** <sup>a</sup>	26.1 (sd=5.5)	27.7 (sd=5.9)	
OTP services received in an Appalachian county*	37.4%	28.4%	
Marital Status** <sup>b</sup>			
Never married	5.1%	13.6%	
Cohabiting/ married	60.6%	62.6%	
Widowed/separated/divorced	34.3%	23.9%	
Have children under the age of 18** Among individuals with children (n=316), percent	73.6%	61.2%	
with any child protective services involvement	24.1%	24.5%	
Lifetime chronic medical problems***	50.3% (n=82)	7.8% (n=25)	
Current chronic medical problems troubling the client at baseline**	37.8% (n=31)	8.0% (n=2)	
Arthritis*	67.4% (n=21)	0	
Asthma	3.2% (n=1)	0	
Diabetes	12.9% (n=4)	50.0% (n=1)	
Heart problems	6.5% (n=2)	50.0% (n=1)	
Hepatitis B or C	12.9% (n=4)	50.0% (n=1)	
Severe dental problems	32.3% (n=10)	0	
Cancer	0	0	
HIV/AIDS	0	0	
Receiving treatment for chronic medical Problems	64.5% (n=20)	50.0% (n=1)	
Taking a prescription medication for physical health problems	54.8% (n=17)	50.0% (n=1)	

\*p<.05, \*\*p<.01, \*\*\*p<.001

a- BMI categories defined as: lower than 20 –underweight; 20-24 optimal weight; 25-29 overweight; 30-39 obese; 40+ morbidly obese.

b -missing marital status data for 103 cases.

# **CNCP** levels and ratings.

Individuals reporting CNCP were asked a series of additional pain-related questions.

Perception of pain control has an impact on ability to maintain daily tasks and has some

implication for pain rating as well (Turner et al., 2007). Among the 163 individuals in the sample with CNCP, the average pain level rating at baseline was 4.4 (sd=2.1) on a scale where 0=no pain and 10=worst possible pain. A score of 4 or higher is considered a clinically significant pain level requiring medical attention and 64.4% of cases with CNCP rated their pain at a clinically significant level. The average rating of control individuals reported feeling over their pain was a 3.4 (sd=1.6) on a scale where 1=no control at all and 6=great deal of control. In addition, over half of clients felt moderate to no control over their pain. When asked to rate the degree of interference their pain has on normal daily activity in the past 30 days, 23.3% reported considerable or extreme interference. The majority (60.7%) reported moderate to slight interference, and about 16.0% reported no interference. No correlation was found between pain level and perceived control over pain, neither were there correlations with gender and pain ratings. Crosstabs were used to examine differences by gender in level of pain control and degree of CNCP interference with daily activities. Figure 5 displays perceived level of control over CNCP which was statistically different by gender as indicated in the crosstab results ( $X^2$ =(5, 163)12.79, p<.05). Females reported higher levels of control over their pain than males reported. There were no gender differences in reported interference of pain with daily activities.

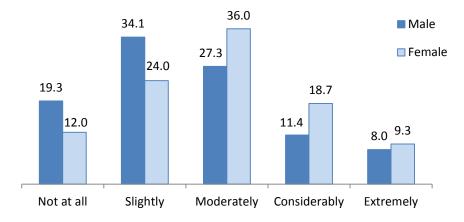


Figure 5. Percentage by Gender of Levels of Control Over CNCP (n=163)

Among individuals who reported taking prescription painkillers for CNCP (n=158), only 13.3% reported having a legitimate prescription for their pain medication. Among the 86.7% who took prescription painkillers without a prescription, there were no statistically significant differences by gender. Individuals were also asked if they were currently taking a prescription for a physical health condition, regardless of pain status. Of the CNCP cases 12.0% were taking a prescription for a medical condition compared to 12.8% of non-CNCP cases.

#### Changes in Outcome Variables from Baseline to Follow-up

Key outcome variables were examined comparing individuals with CNCP to those without CNCP regarding changes from baseline to follow-up. Outcome variables include tobacco, alcohol, and drug use abstinence, recovery support involvement, education completion, employment status, criminal justice system involvement, and mental health status.

#### Abstinence from tobacco, alcohol, and illicit drugs at baseline.

Table 6 displays crosstab results for abstinence from tobacco, alcohol, and illicit drugs reported by individuals at baseline for the past 12 months and the past 30 days by pain status group. There was no significant difference in abstinence from tobacco, alcohol, and illicit drugs at baseline when comparing the two groups either for past 12 months use or more recent past 30 days use. Tobacco abstinence and prescription opioid abstinence remained stable over the past year and during the preceding 30 days before OTP baseline, which reflects a regular use pattern for both drugs among the sample. Alcohol abstinence increased from almost 41.1% of individuals with CNCP reporting past 12 month abstinence to 68.7% reporting abstinence in the past 30 days at baseline. A similar pattern occurred for the non-CNCP group and for both groups in regards to intoxication from alcohol at both points in time.

# Table 6

Tobacco, Alcohol and Illicit Drug Use Abstinence in the Past 12 Months and Past 30 Days at Baseline by Pain Status Group (N=483)

Substance Abstinence at	In the Past 1	.2 Months	In the Past	30 Days
Baseline	CNCP	Non-CNCP	CNCP	Non-CNCP
	(n=163)	(n=320)	(n=163)	(n=320)
Tobacco	12.9%	13.8%	12.9%	14.7%
Alcohol	41.1%	43.1%	68.7%	74.4%
Alcohol intoxication (among				
cases who used any alcohol)	37.5%	36.8%	43.1%	42.7%
Prescription opioids	4.9%	6.2%	11.0%	10.9%
Non-prescribed methadone	46.0%	44.7%	63.8%	59.4%
Non-prescribed buprenorphine	83.4%	81.6%	92.0%	93.4%
Heroin	83.4%	84.7%	90.2%	88.4%
Marijuana	47.9%	47.5%	60.7%	60.3%
Cocaine	61.3%	63.8%	77.9%	82.2%
Hallucinogens	96.9%	95.3%	99.4%	98.8%
Stimulants	82.8%	83.4%	95.7%	93.1%
Barbiturates	91.4%	92.8%	94.5%	96.9%
Tranquilizers	43.6%	51.9%	68.7%	74.7%
Inhalants	95.1%	90.9%	100.0%	99.4%

\*p<.05, \*\*p<.01, \*\*\*p<.001

# Dependence on alcohol and illicit drugs at baseline.

In addition to looking at abstinence from substance use, an Addiction Severity Index composite score was calculated for each case. This composite score uses a specific formula, which incorporates number of days of alcohol or drug use in the past month, rating of difficulty with drug or alcohol use, and rating of need for treatment (not shown in a table). The highest possible ASI composite score is 1.0 with client score values of 0.17 for alcohol and 0.16 for drug use indicating alcohol or drug dependence (Rikoon et al., 2006). Composite scores are thus used to identify individuals whose self-reported substance use met criteria indicating likely drug or alcohol dependence. Almost 98% of the sample met ASI cutoff criteria for drug dependence. At baseline, 97.4% of the CNCP group and 96.4% of the non-CNCP group had a composite score that met criteria for drug dependence (ns). Much smaller percentages of both groups met

alcohol dependence criteria with 14.3% in the CNCP group and 11.5% in the non-CNCP group. None of the group differences was statistically significant.

# Recovery support at baseline.

Table 7 displays results for crosstabs examining differences in pain status group by recovery support and mutual self-help group use at baseline. Only 17.8% of individuals with CNCP and 18.1% of individuals without CNCP reported use of mutual self-help groups like alcoholics or narcotics anonymous before baseline. Of those individuals who did report attending any mutual help group meetings, the mean number of meetings attended was 5 for the CNCP group and 6 for the non-CNCP group. The majority of individuals in both groups reported having had contact in the past 30 days at baseline with friends and/or family who were supportive of their recovery efforts.

#### Table 7

Recovery Support in the 30 Days before Baseline by Pain Status Group (N=483)

Recovery Support in the 30 Days before Baseline	Percentage or Mean	
	CNCP (n=163)	Non-CNCP (n=320)
Attended mutual self-help group meetings ( AA/NA)	17.8%	18.1%
Among those attending any meetings, mean number of meetings attended	5 (sd=7)	6 (sd=8)
Had contact with friends/family supportive of your recovery	87.1%	89.7%

\*p<.05, \*\*p<.01, \*\*\*p<.001

# Education and employment status at baseline.

Table 8 displays crosstab results of education and employment information for

individuals at baseline by pain status group. No significant differences were found by education

level with the majority of individuals reporting a high school degree or GED completed at

baseline. There were also no differences by pain status group in the percentage of individuals

working full-time at baseline, though significantly more cases with CNCP were unemployed and

not looking for work (26.5% vs. 15.9%; p<.05).

# Table 8

Education and Employment Status at Baseline by Pain Status Group (N=483)

Characteristics	CNCP (n=163)	Non-CNCP
		(n=320)
Highest completed education level <sup>a</sup>		
Less than HS diploma or GED	18.2%	18.4%
HS graduate/GED completed	35.8%	36.2%
Postsecondary education	45.9%	45.4%
Employment status		
Full-time (includes military)	51.5%	57.5%
Part-time (<35 hrs, irregular)	14.1%	14.1%
Unemployed, looking for work	8.0%	12.5%
Unemployed, not looking for work*	26.4%	15.9%
Among those unemployed, not looking for		
work: Receiving SSI/ SSDI income (n=94)	48.8%	31.4%
* ~ · OF ** ~ · O1 ** * ~ · O01		

\*p<.05, \*\*p<.01, \*\*\*p<.001

a-missing education level data for 9 cases

# Mental health symptoms at baseline.

Table 9 displays crosstab results comparing mental health symptoms at baseline by pain status group. Similar percentages of cases in both pain status groups reported depression. A significantly higher percentage of individuals with CNCP reported anxiety (21.9%) compared to individuals without CNCP (12.6%; p<.01). In addition, more individuals with CNCP (16.5%) reported taking prescription medications for mental health problems than those without CNCP (9.1%; p<.05).

# Table 9Mental Health Symptoms at Baseline by Pain Status Group (N=483)

Mental Health Symptoms, in the Past 30 Days	CNCP	Non-CNCP
Not Related to Drug or Alcohol Use	(n=163)	(n=320)
Depression symptoms	10.7%	6.7%
Anxiety symptoms**	21.9%	12.6%
Prescription medication for mental health	16.5%	9.1%
symptoms*		

\*p<.05, \*\*p<.01, \*\*\*p<.001

# Criminal justice system involvement at baseline.

There were no differences by criminal justice system involvement between individuals

with and without CNCP at baseline (See Table 10). Less than 10% of individuals with CNCP

reported an arrest in the 12 months before baseline compared to 12.6% of those cases without

CNCP. Very few individuals in either group were involved with probation, parole, or drug courts.

# Table 10 Criminal Justice System Involvement at Baseline by Pain Status Group (N=483)

Characteristics	CNCP	Non-CNCP
	(n=163)	(n=320)
Arrested in past 12 months	9.3%	12.6%
Currently on Probation	8.6%	10.3%
Currently on Parole	2.5%	0.6%
Currently Enrolled in Drug Court	0.6%	0.3%

\*p<.05, \*\*p<.01, \*\*\*p<.001

# Medication Dose and Time in Treatment at Follow-up

During the first few months of OTP services, individuals are titrated onto a dose of either buprenorphine or methadone. The Center for Substance Abuse Treatment (CSAT) provides dosing recommendations based on the type of medication provided to the client (2005). Methadone is a full opiate agonist, while buprenorphine is a partial-agonist. Methadone has a long half-life in the body and has an average dose of around 80-120 milligrams. Buprenorphine's chemical make-up has a ceiling of effectiveness at 32 milligrams. The initial methadone dose is no more than 30 milligrams with dose titrated up by 10 milligram increments until the physician determines the client's symptoms of withdrawal and craving are managed adequately (CSAT, 2005). For both medications, the prescribing physician determines the client dose through monitoring client vital signs, withdrawal, and craving reports of the client. CSAT notes there are wide variations in client dose response affected by weight, metabolism, co-occurring conditions, and genetics.

Individuals self-reported the type of medication and stabilized dose in milligrams during the follow-up interview. Though all individuals reported their type of medication, 1 CNCP and 3 non-CNCP cases declined to provide their dose, and 3 CNCP and 13 non-CNCP cases did not know their dose. Comparisons using crosstabs and ANOVAs for pain status group by medication type and dose in milligrams are displayed in Table 11. The majority of cases in the sample were taking methadone, though a significantly higher percentage of individuals taking buprenorphine were in the non-CNCP group. Among individuals taking methadone, the mean dose in milligrams was higher for the CNCP group (82.2 mg) compared to the non-CNCP group (75.2 mg). This contrasts with individuals taking buprenorphine where those with CNCP had a lower average dose (9.7 mg) compared to individuals without CNCP (14.0 mg). When dose levels for methadone and buprenorphine were matched for high, moderate, and low dose amounts, there were no statistically significant differences in dose level by pain status group.

Table 11	
<i>Opiate Dependence Medication Type and Dose by Pain Status Group (N=483)</i>	

Medication for Opiate Dependence	Percentag CNCP (n=163)	ge or Mean Non-CNCP (n=320)
Methadone	95.1%	89.1%
Among individuals taking methadone: Average dose (mg) (n=422) <sup>a</sup> **	82.2 (sd=31.0)	75.2 (sd=23.7)
Buprenorphine *	4.9%	10.9%
Among individuals taking buprenorphine: Average dose (mg) (n=43) <sup>b</sup>	9.7 (sd=5.7)	14.0 (sd=10.4)
Matched Methadone/ Buprenorphine groups		
High dose	35.9%	46.5%
Moderate dose	51.3%	40.9%
Low dose	12.8%	12.6%

\*p<.05, \*\*p<.01, \*\*\*p<.001

a -Four cases declined to provide their methadone dose; 14 cases did not know their methadone dose.

b- Two cases did not know their buprenorphine dose.

Average length of time in treatment at the OTP for both pain status groups was about the same with 17 months (sd=12.4) for individuals with CNCP and 15 months (sd=12.3) for those without CNCP. Despite the variation in length of treatment, there was no significant correlation between months in treatment and CNCP, gender, dose level, or presence of chronic medical conditions.

As there were no significant buprenorphine dose differences among individuals with CNCP and very few cases in the buprenorphine medication group, no further analyses were conducted with buprenorphine-dosed cases. On the other hand, individuals taking methadone medication did show variation. Thus, further analyses were conducted to examine dose variation by key characteristics using a one-way analysis of covariance (ANCOVA). CNCP, sex, and anxiety were the variables of interest examined in relation to variation in methadone dose in milligrams. The assumption of homogeneity of variance and homogeneity of slope were met. Table 12 displays the mean dose for the predictor variables based on presence or absence of CNCP for males and for cases with anxiety symptoms. The average dose for males with CNCP was 89 mg which is significantly higher than males without CNCP (76 mg; p<.01). Individuals with anxiety symptoms in addition to CNCP had a significantly higher mean dose (83 mg) compared to individuals who had anxiety symptoms but did not report CNCP (73 mg; p<.01).

Table 12

*Influence of CNCP Status on Average Methadone Dose in Relation to Sex and Anxiety Symptoms* (*n*=394)

Variables	Mean (standard error)	95% Lower, Upper Confidence Interval
Males**		
CNCP	88.65 mg (3.39)	69.81, 81.81
No CNCP	75.81 mg (3.05)	81.99, 95.31
Anxiety symptoms**		
CNCP	82.86 mg (4.58)	73.85, 91.87
No CNCP	73.03mg (4.88)	63.44, 82.62
*p<.05, **p<.01, ***p<.00	1; Covariates evaluated at	values: age=32.95, BMI=26

Displayed in Table 13 are the main and interaction results for the ANCOVA with Bonferroni adjustment to reduce potential Type 1 error in relation to the number of comparisons in the model. Main effects for presence of CNCP (F (1, 393)=3.89, p<.05) and being male (F (1,393)=8.90, p<.01) had a statistically significant influence on methadone dose variation for this sample. The interaction term for being male and having CNCP was found to significantly influence methadone dose variation as well (F(1,393)=3.84, p<.05) .

Source	Sum of Squares	df	Mean Square	F
Corrected Model**	16512.54	7	2358.93	3.32
Intercept***	46823.41	1	46823.41	65.80
BMI (covariate)	784.51	1	784.51	1.10
Age (covariate)	1435.21	1	1435.21	2.02
CNCP*	2764.40	1	2764.40	3.89
Anxiety in past 30 days	1.67	1	1.67	.01
Male**	6330.71	1	6330.72	8.90
CNCP X Anxiety	324.66	1	324.66	.46
CNCP X Male*	2731.42	1	2731.42	3.84

Table 13ANCOVA of Current Methadone Dose Variance Related to Gender, Anxiety, and CNCP (n=394)

\*p<.05, \*\*p<.01, \*\*\*p<.001;

<sup>a</sup> Adjusted R Squared = .04

#### **Analyses of Outcome Variables**

The goal of OTP services is to assist individuals in obtaining recovery from drug and alcohol abuse and opioid dependence, as well as to improve positive participation in family, work, and recovery support. The following tables provide outcome information by pain status group for education, employment, criminal justice system involvement, mental health, and recovery support as self-reported at follow-up by individuals in the sample. Changes from baseline to follow-up are calculated when possible using a percent change formula [(n2-n1)/n1x100] where n1 represents baseline data and n2 represents follow-up data.

# Tobacco, alcohol, and drug use abstinence at follow-up.

In Table 14, crosstab results are displayed reflecting abstinence reported by the sample in the past 30 days at follow-up by each substance type. There were no significant differences in abstinence from alcohol, tobacco, or illicit drug use by pain group status. No one in either group reported use of hallucinogens. Overall, the majority of clients abstained from illicit drug use at follow-up. None of the cases reported use of hallucinogens at follow-up. No one in the CNCP group and only one or two cases in the non-CNCP group reported use of non-prescribed buprenorphine or inhalants. Among individuals reporting any alcohol use, 64% of cases were

abstinent from intoxication in the CNCP group compared to about 69% of the non-CNCP cases.

#### Table 14

Tobacco, Alcohol, and Drug Abstinence 30 Days before Follow-up by Pain Status Group (N=483)

Substances	CNCP (n=163)	Non-CNCP (n=320)
Tobacco	17.2%	14.7%
Alcohol	84.7%	83.8%
Alcohol to intoxication (among	64.0%	69.2%
cases reporting any alcohol use)	04.076	09.276
Marijuana	90.8%	90.9%
Prescription opioids	91.4%	92.8%
Non-prescribed methadone	96.9%	96.2%
Non-prescribed buprenorphine	100.0%	99.7%
Heroin	97.5%	99.4%
Cocaine	96.9%	98.1%
Hallucinogens	100.0%	100.0%
Stimulants	100.0%	98.1%
Barbiturates	98.8%	100.0%
Tranquilizers	96.9%	96.9%
Inhalants	100.0%	99.7%

\*p<.05, \*\*p<.01, \*\*\*p<.001

#### Changes in substance abstinence from baseline to follow-up.

Table 15 displays the percent change in abstinence from baseline to follow-up by pain status group for major drug classes, including prescription opioids. No significant changes occurred in tobacco use, though there was a slight increase in tobacco abstinence for the CNCP group from baseline (12.9%) to follow-up (17.2%). Past 30 day alcohol abstinence increased significantly for both groups. The CNCP group went from 68.7% reporting abstinence at baseline to 84.7% at follow-up, representing a 23.2% increase in alcohol abstinence (p<.001). Though this is a statistically significant increase in abstinence from illicit drug use and specifically for prescription opioid use, it is important to note that individuals had to meet opioid dependence criteria for admittance to the OTP. In addition, all clients are required to participate in weekly observed drug screens to monitor illicit drug use. Alcohol use, particularly intoxication, is discouraged but not prohibited; similarly, tobacco use is not monitored or discouraged by most

OTPs. Both groups show a significant increasing trend in opioid and illicit drug use abstinence

from baseline to follow-up.

# Table 15

Percent Change in Past 30 Day Substance Abstinence from Baseline to Follow-up Comparing CNCP and Non-CNCP Groups (N=483)

	Abstinent at Baseline <sup>a</sup>		Abstinen	nt at Follow-up <sup>a</sup>	Percent	
	n	Valid %	n	Valid %	Change <sup>b</sup>	
Tobacco						
CNCP (n=163)	21	12.9%	28	17.2%	+33.3%	
Non-CNCP (n=320)	47	14.7%	47	14.7%	0.0%	
Alcohol						
CNCP (n=163)	112	68.7%	138	84.7%	+23.2%***	
Non-CNCP (n=320)	238	74.4%	268	83.8%	+12.6%**	
Alcohol to intoxication						
CNCP (n=163)	134	82.2%	154	94.5%	+14.9%***	
Non-CNCP (n=320)	272	85.0%	303	94.7%	+11.4%***	
Prescription opioids						
CNCP (n=163)	18	11.0%	149	91.4%	+727.8%***	
Non-CNCP (n=320)	35	10.9%	297	92.8%	+748.6%***	
Any illicit drug use						
CNCP (n=163)	8	4.9%	132	81.0%	+1550.0%***	
Non-CNCP (n=320)	5	4.7%	270	84.4%	+1700.0%***	

\*p < .05, \*\*p < .01, \*\*\*p < .001.

a- Between group significant differences established using chi-square test.

b- Within group significant differences established using z test for proportions

### Changes in recovery support at follow-up.

Recovery support measured through self-reported attendance at mutual-help group

meetings like alcoholics or narcotics anonymous (AA or NA) is displayed in Table 16. The

percent of individuals by pain group status reporting use of mutual help groups increased

significantly for both pain status groups. The number of meetings attended in the past 30 days

increased for both groups from 1 meeting at baseline to 2 meetings at follow-up.

Table 16Changes in Past 30 Day Recovery Support at Follow-up by Pain Status Group (N=483)

Percent or Mean			
Baseline	Follow-up		
17.8%	35.6%		
18.1%	33.8%		
(n=87)	(n=165)		
5 (sd=7)	7 (sd=7)		
6 (sd=8)	5 (sd=5)		
	Baseline 17.8% 18.1% (n=87) 5 (sd=7)		

\*p<.05, \*\*p<.01, \*\*\*p<.001

## Changes in education and employment at follow-up.

Education and employment status at follow-up is displayed by pain status group in Table 17. No education differences appeared by pain status group with both groups increasing their education levels by follow-up (18.9% CNCP and 23.2% non-CNCP). A significantly higher percentage of individuals with CNCP reported unemployment and not looking for work (30.1%) compared to the non-CNCP group (17.2%). Within that group of individuals (n=104), significantly more unemployed individuals with CNCP (61.2%) reported receiving disability income compared to non-CNCP persons (25.5%). Allow it seems likely, the data do not include variables to allow examination of whether or not a relationship exists between CNCP source and disability qualifications. Gender differences by CNCP status and employment status were examined with crosstabs. No differences were found for females, but males with CNCP were less likely than males without CNCP to be employed at follow-up [ $X^2$ =(1, 271)7.557, p<.005].

Education and employment at follow-up	Percentage or Mean			
	CNCP (n=163)	Non-CNCP		
		(n=320)		
Highest completed education level <sup>-a</sup>				
Less than HS diploma or GED	16.6%	14.1%		
HS graduate/GED completed	33.1%	35.0%		
Postsecondary education	50.3%	50.9%		
Increased education from baseline to follow-up (n=474) <sup>a</sup>	18.9%	23.2%		
Employment status				
Full-time (includes military)	50.9%	57.5%		
Part-time (<35 hrs, irregular)	12.3%	14.4%		
Unemployed, looking for work	6.7%	10.9%		
Unemployed, <u>not</u> looking for work**	30.1%	17.2%		
Among those unemployed, <u>not</u> looking for				
work (n=104):				
Receiving SSI/ SSDI income ***	61.2%	25.5%		
*n< 05 **n< 01 ***n< 001				

# Table 17 Education and Employment at Follow-up by Pain Status Group (N=483)

\*p<.05, \*\*p<.01, \*\*\*p<.001

a-missing education level data for baseline 9 cases

Table 18 examines the relationship between CNCP-status and changes in employment

status from baseline to follow-up. None of the changes for either group were statistically

significant as determined with a z-test for proportions.

		Baseline <sup>a</sup> *		Follow-Up <sup>a</sup> **		Percent
		n	Valid %	n	Valid %	change <sup>b</sup>
Employed full- time	CNCP (n=163) Non-CNCP	84	51.5%	83	50.9%	-1.19
time	(n=320)	184	57.5%	184	57.5%	
Employed part time	CNCP (n=163) Non-CNCP	23	14.1%	20	12.3%	-13.04
	(n=320)	45	14.1%	46	14.4%	+2.22
Unemployed, <u>not</u> looking for work	CNCP (n=163) Non-CNCP	43	26.4%	49	30.1%	+13.95
	(n=320)	51	15.9%	55	17.2%	+7.84
Unemployed, looking for work	CNCP (n=163) Non-CNCP	13	8.0%	11	6.7%	-15.38
	(n=320)	40	12.5%	35	10.9%	-12.50
Receiving SSI/SSDI income <sup>c</sup>	CNCP (n=49) Non-CNCP	21	48.8%	30	61.2%	+42.86
	(n=55)	16	31.4%	14	25.5%	-12.50

# Table 18Percent Change from Baseline to Follow-up in Employment by Pain Status Group (N=483)

\*At baseline, CNCP and Non-CNCP groups significantly differed from one another at p<.05.

\*\*At follow-up, CNCP and Non-CNCP groups significantly differed from one another at p<.01.

a- Between group significant differences established using chi-square test.

b-Within group significant differences established using z test for proportions

c- Among only those unemployed, not looking for work

# Changes in mental health symptoms at follow-up.

Percent change in mental health symptoms self-reported at baseline and follow-up are displayed in Table 19. Reported depression symptoms increased for both groups, though neither group increased significantly according to z-tests for proportional differences. Anxiety symptoms were reported by 12.6% of the non-CNCP group at baseline compared to 21.2% at follow-up for a significant 83.8% increase (p<.001). Prescription medication taken for mental health symptoms decreased for the CNCP group from 16.5% taking medication at baseline to 7.4% at follow-up representing a significant -53.9% decrease (p<.05). Though not statistically significant when comparing both groups, the percentage of cases in each group reporting

depression and anxiety symptoms increased at follow-up. On the other hand, reported use of

medication for mental health problems declined for both groups.

# Table 19

*Percent Change in Past 30 Day Mental Health Symptoms from Baseline to Follow-up by Pain Status Group (N=483)* 

		Baseline <sup>a</sup>		Follow	/-up <sup>a</sup>	Percent
		n	Valid %	n	Valid %	Change <sup>b</sup>
Depression	CNCP (n=163)	17	10.7%	23	14.1%	+35.3%
symptoms	Non- CNCP (n=320)	20	6.7%	32	10.0%	+60.0%
Anxiety	CNCP (n=163)	35	21.9%	46	28.2%	+31.4%
symptoms <sup>c</sup>	Non- CNCP (n=320)	37	12.6%	68	21.2%	+83.8%***
Prescription	CNCP (n=163)	26	16.5%	12	7.4%	-53.9%*
medication for mental health symptoms <sup>d</sup>	Non- CNCP (n=320)	27	9.1%	18	5.6%	-33.3%

\*p<.05, \*\*p<.01, \*\*\*p<.001

a- Between group differences established using chi-square test.

b- Within group differences established using z test for proportions.

c- Anxiety symptoms significantly different between the CNCP and Non-CNCP groups at baseline (p<.01).

d- Percent cases taking prescription medication for mental health symptoms were significantly different between the CNCP and Non-CNCP groups at baseline (p<.05).

# Changes in criminal justice system involvement at follow-up.

Table 20 displays the between group differences and percent of change from baseline to

follow-up in arrests, probation, parole, and drug court involvement. The low number of cases in

most categories means the percent change statistic should be interpreted with caution. For

example, drug court participation increased from 1 case at baseline to 2 cases at follow-up; a

100% increase though only one case was added to the already small count. Among the non-

CNCP group, 12.6% of individuals had been arrested before baseline and 6.9% were arrested

before follow-up representing a 40.5% decrease in arrests (p<.05). There were no other

significant within group differences or between group differences.

		Baseline <sup>a</sup>		Follow-up <sup>a</sup>		
		n	Valid %	n	Valid %	Percent Change <sup>b</sup>
	CNCP (n=163)	13	9.3%	12	7.4%	-7.7%
Arrested	Non- CNCP (n=320)	37	12.6%	22	6.9%	-40.5%*
	CNCP (n=163)	14	8.6%	12	7.4%	-14.3%
On Probation	Non- CNCP (n=320)	33	10.3%	32	10.0%	-3.0%
	CNCP (n=163)	4	2.5%	2	1.2%	-50.0%
On Parole	Non- CNCP (n=320)	2	0.6%	3	0.9%	+50.0%
Enrolled in Drug	CNCP (n=163)	1	0.6%	0	0.0%	-100.0%
Court	Non- CNCP (n=320)	1	0.3%	2	0.6%	+100.0%

*Percent Change in Criminal Justice System Involvement from Baseline to Follow-up by Pain Status Group (N=483)* 

\*p<.05, \*\*p<.01, \*\*\*p<.001

Table 20

a- Between group significant differences established using chi-square test.

b- Within group significant differences established using z test for proportions.

## **Multivariate Regression**

Based on results from the previous analyses, a multivariate logistic regression was conducted to examine which socio-demographic and baseline health characteristics best predicted CNCP among this sample. Predictor variables from baseline included presence of a chronic medical condition (Yes/No), being unemployed (Yes/No), days of tobacco use (0-30), days of alcohol use (0-30), and use of illicit drugs other than opioids (Yes/No). The regression model included age, sex (Male, not Male), OTP region (Appalachian, not Appalachian), and BMI as control variables. The logistic regression analysis results are displayed in Table 21. Upon entry of the control variables, the model classified 78.1% of the cases correctly. The -2LL dropped from 595.41 to 502.69 with a significant chi-square [ $X^2$ = (7, 476) 114.91, p<.001] with a non-significant Hosmer and Lemeshow test. In the next block, the predictor variables were entered and the model prediction level did not change, though the -2LL dropped again to 496.26 and the chi-square significance remained at with a significant chi-square [ $X^2$ = (10, 473) 121.35, p<.001]. Significant predictors of CNCP included chronic medical conditions (p<.001) and tobacco smoking (p<.05). Presence of chronic medical conditions were related to an 11 times increase in the odds of having CNCP, while each additional day of smoking in the 30 days before baseline increased the odds of CNCP by one time.

Table 21

Logistic Regression Predicting Odds of CNCP by Socio-demographic and Health Characteristics at OTP Baseline (N=483)

Predictors Variables			95% C.I.		
	Wald	Exp(B)	Lower	Upper	
Age	1.42	1.02	0.99	1.04	
Male	1.67	0.73	0.46	1.17	
Appalachian OTP	1.50	1.35	0.84	2.19	
BMI	2.92	1.04	0.99	1.08	
Days between baseline and follow-up	2.37	1.00	1.00	1.00	
Unemployed	0.15	0.91	0.54	1.51	
Chronic medical condition	78.01***	11.27	6.58	19.29	
Days of tobacco use in the past 30 days	4.08*	1.02	1.00	1.04	
Days of alcohol use in the past 30 days	1.36	1.03	0.98	1.07	
Use of any illicit drugs other than opioids	0.36	1.18	0.68	2.05	

\*p<.05, \*\*p<.01, \*\*\*p<.001; reference category listed as variable name. Nagelkirke R<sup>2</sup> =.31

#### **Summary of Results**

This study examined the influence of comorbid CNCP on opioid dependence treatment outcomes. Almost two-thirds of individuals in the sample with CNCP reported clinically significant levels of pain and over half of cases reported feeling moderate to no control over their pain symptoms. Six in ten of the cases with CNCP reported their pain moderately interfered with daily living activities. Men reported significantly lower ratings of control over their pain than did women. Though equal amounts of cases (12%) in the two pain status groups reported taking a prescription for physical health needs, the majority of CNCP group cases (97%) reported use of prescription painkillers for their pain. Among those 158 cases, only 13% reported having a legitimate prescription for the medication they took. The overall picture of the 163 individuals in the sample with CNCP is one of significant pain levels, lack of control over the pain symptoms, and an attempt to self-medicate with non-prescribed opioid medications.

In regards to treatment outcomes, there were no differences at follow-up between the CNCP and non-CNCP groups on substance abstinence, recovery supports, education level, or criminal justice system involvement. At baseline and follow-up there were more unemployed individuals and individuals receiving disability benefits in the CNCP group than the non-CNCP group. Reported anxiety and depression symptoms increased at follow-up and while use of prescription medicine for mental health symptoms declined for both groups (non-significant differences). The only predictors for CNCP cases in this sample were tobacco use and presence of a chronic medical condition.

#### **CHAPTER 5. DISCUSSION**

Individuals with CNCP were compared to individuals without CNCP on treatment outcomes using a biopsychosocial framework. Prior literature indicated likely group differences with more women than men reporting CNCP (Tsang et al., 2008), however, this did not hold true for the study sample. In addition, individuals with CNCP in socially isolated non-metropolitan treatment settings were expected to have worse outcomes compared to those in a metropolitan treatment setting due to the limited resources and social networks often found in more rural areas (Hamilton et al., 2008). Though significantly more individuals in the CNCP group were from Appalachian OTPs, location was not correlated with any of the outcomes. Prior literature also indicated higher methadone doses were likely among cases with CNCP (Peles, et al., 2005). In this study's sample, methadone-dosed cases with CNCP did have significantly higher doses compared to the non-CNCP cases, as well as wider variation in dose levels. In addition, being male was related to greater variance in methadone dose. The threshold for a therapeutic methadone dose is at least 80 mg daily (Pollack & D'Aunno, 2008) and average dose for CNCP cases in this sample was at or slightly above this threshold. A larger sample might allow for examination of more detailed dose differences by gender, age, multi-drug use, and medication type (methadone vs. buprenorphine) in future studies. Key differences in national outcome measure results are discussed in the following sections.

#### **Alcohol and Drug Abstinence**

There were no statistically significant differences in substance use between the pain status groups. At baseline, the majority of clients reported use of tobacco and prescription opioids and over half of each pain status group reported use of alcohol to intoxication. Both groups showed a decline in alcohol and drug use in the 30 days before starting OTP services compared to use in the 12 months before entering treatment. This decline may indicate an

attempt to cut down on drug or alcohol use as individuals prepared to enter treatment. It could also be a reflection of occasional use (i.e., one holiday drink) being captured in the past 12 months measure and more current use captured in the past 30 days measure.

As would be expected due to opioid dependence as a requirement for OTP admission, about 97% of both groups met Addiction Severity Index (ASI) composite score criteria for drug dependence at baseline. Both groups showed significant increases in abstinence from illicit drug use, particularly abstinence from opioids. Rates of abstinence from illicit drugs at follow-up were around 80% with no statistically significant differences between pain status groups. Specifically, prescription opioid abstinence was around 90% for both groups, thus presence of CNCP did not appear to have an effect on an individual achieving abstinence from opioid use. It may also be that the desire to stay in treatment and receive the daily dose of methadone to stave off craving and withdrawal symptoms was powerful enough to help the client maintain abstinence so they could stay in treatment.

Fewer individuals (14.3% CNCP; 11.5% non-CNCP) met ASI alcohol dependence criteria, though alcohol use to intoxication was reported by 5 in 10 participants who used any alcohol at follow-up. General population prevalence rates for alcohol use to intoxication range from 17.7% to 37.3% (CDC, 2012), while 36.5% of adult treatment seekers in Kentucky reported alcohol misuse and binge drinking in 2009 (TEDS, 2009). Drinking alcohol to intoxication among individuals with CNCP who drank alcohol was reported at follow-up by over one-third of cases. This may be an indication that individuals do not consider alcohol use to be as dangerous or as harmful as illicit drug use. On the contrary, use of alcohol decreases inhibitions and may lead to higher rates of relapse to other illicit drug use (Butler, 2008; Centers for Disease Control and Prevention, [CDC] 2012). A Tufts Health Care Institute study indicated individuals with CNCP who abuse alcohol in conjunction with prescription opioids are more likely also to abuse other

illicit drugs compared to CNCP cases who do not abuse alcohol (Butler, 2008). This is particularly concerning because alcohol is legal for adults and easily obtainable. Addressing binge drinking with individuals in opioid dependence treatment is important for overall behavioral health and recovery. Education about measurement of alcohol beverage size, effects of alcohol that increase pain symptoms, and coping mechanisms that do not include alcohol use may be an important additional treatment component to expand upon in order to further enhance outcomes and prevent relapse for clients with CNCP.

#### **Tobacco Abstinence**

Another legal drug measured in this study was tobacco use. Tobacco abstinence at follow-up increased slightly, though not significantly, for the CNCP group. Use of tobacco correlates with increased physical health risks including coronary, respiratory, and reproductive system damage (CDC, 2004). The issue of addressing legal, but physically damaging tobacco use within substance dependence treatment is controversial (Baca & Yahne, 2009) and studies show tobacco use remains stable in most outpatient treatment settings (Haas, Sorenson, Hall, Lin, Delucchis, Sporer, et al., 2008). Current research indicates outcomes are enhanced by providing smoking cessation programs alongside alcohol and illicit drug dependence treatment (Baca & Yahne, 2009). OTPs could consider incorporating smoking cessation along with opioid dependence treatment to help address the low rates of tobacco abstinence at follow-up and improve the physical health of clients. This may be particularly challenging in Kentucky since the state has historically derived a large proportion of its income from tobacco-related work and tobacco sales. National rates of smoking among adults are around 18%; while in Kentucky, 25% of adults currently use tobacco (CDC, 2008). Among this sample, 83% of CNCP cases were using tobacco at follow-up, which is more than triple the state average. Federal policymakers who manage OTP protocol should consider smoking cessation assistance as standard practice in

order to support the overall health of OTP clients. The negative health consequences of smoking for the individual as well as for family members should be discussed with clients and smoking cessation tools provided in OTPs as a standard part of protocol. In addition, new research findings point to increased pain levels and decreased healing capacity among daily smokers (Ditre, Gonzalez, Simmons, Faul, Brandon, & Jacobsen, 2011), as well as smoking being correlated to increased opioid use among individuals with CNCP (Hooten, Shi, Gazelka, & Warner, 2011). Use of tobacco, in particular smoked tobacco, needs further examination among individuals with CNCP and opioid dependence.

#### **Recovery Support**

Recovery support, especially from peers, is important for sustaining recovery and preventing relapse into drug and alcohol abuse (Boisvert, Martin, Grosek, & Clarie, 2008; Laudet, 2008a). One method used for providing regular support is attendance at 12-step meetings like Alcoholics Anonymous (AA) or Narcotics Anonymous (NA). Historically, AA/NA groups have not accepted individuals receiving OTP services since the model is abstinence-based and individuals on medication assisted treatment with methadone or buprenorphine are not considered abstinent (Hettema & Sorenson, 2009). Methadone Anonymous (MA) was developed as a 12step model peer-based support group for individuals in methadone treatment; however, these groups are mostly online and not available in many areas. The low attendance at meetings for this sample was similar for both the CNCP and non-CNCP groups with about 1 to 2 meetings reported in the past 30 days at both baseline and follow-up. Though meeting counts were low, the percentage of individuals reporting any attendance in the past 30 days increased significantly from baseline to follow-up for both groups. It may be that the attendance is low because meetings that accept and support the OTP clients are limited. There is one MA meeting listed online in Central Kentucky and one group in Western Kentucky, whereas AA and NA

meetings are too numerous to count and span the whole state with daily meeting opportunities. On the other hand, it may be that clients are getting peer and professional support through daily attendance at the OTP and are using NA or AA meetings as supplementary to the OTP services. Research indicates peer support in addition to a treatment program encourages long-term recovery and improves treatment outcomes (Gossop, Stewart, & Marsden, 2008; Laudet, 2008b). Future studies should consider closer examination of a variety of supports considered helpful and important to recovery for OTP clients with CNCP.

#### **Education and Employment**

Regular employment has a positive influence on recovery from illicit drug use (Walker et al., 2011), while relapse is related to unemployment (Henkel, 2011). Not surprisingly, according to the Bureau of Labor Statistics, education level also correlates with increased employment and financial stability (2010). Educational attainment levels increased from 18.9% of the CNCP cases at follow-up compared to 23.2% of the non-CNCP cases. Though not significant statistically, fewer cases with CNCP pursued education and vocational enhancement by follow-up compared to the non-CNCP cases. By follow-up significantly more individuals in the CNCP group remained unemployed and not looking for work compared to the non-CNCP cases. Logically it would seem enhanced education and employment increased the likelihood the non-CNCP cases were able to maintain or gain employment, while lack of education or technical skills would go with unemployment for the CNCP cases. It might be that the CNCP cases were involved in vocational rehabilitation due to chronic medical problems and CNCP, though these specifics are not available in the dataset. Notably, 61% of the unemployed CNCP cases reported receiving disability income compared to 26% of the non-CNCP group who were unemployed. Though this dataset did not include a variable to examine disability qualifications in relation to the source of an individuals' CNCP, this information should be examined in future studies.

Correlations exist between chronic medical conditions like arthritis or diabetes and reduced work performance, unemployment, and lost wages (Li, Gignac, & Anis, 2006). The low rates of employment among the CNCP group may be related to the high prevalence of chronic medical conditions. In the regression model predicting CNCP, the only variables with significant predictive value were presence of chronic health problems and regular tobacco use. The most noted physical health condition among the CNCP cases who reported current health trouble was arthritis. Though the count of cases reporting arthritis is small compared to the overall sample size, we do know prevalence of arthritis increases as BMI increases (Cheng, Hootman, Murphy, Langmaid, & Helmick, 2010) and odds of having arthritis rises with age (CDC, 2010). In fact, rates of arthritis in the United States are expected to increase over the next decade along with an increasingly aging population (CDC, 2010). Rates of rheumatoid arthritis, which is a painful autoimmune disease affecting joints, heart, liver, and kidneys, are trending upward, particularly for women (Arthritis Foundation, 2010). This means that CNCP will also likely rise since chronic pain is often a part of arthritic conditions.

In addition to existing chronic medical conditions, tobacco use greatly increases the risk of chronic pulmonary and lung disorders (CDC, 2004). The high rates of regular smoking among the OTP clients and specifically the clients with CNCP are of special concern. Thus, expanding education and resources for tobacco cessation and physical health including non-opioid pain management will be important in OTPs and other behavioral health treatment programs. In general, managing painful chronic medical conditions without use of opioid medications should be a priority as there is limited evidence to support long-term opioid use for a chronic illness like arthritis (Whittle, Richards, Husni, & Buchbinder, 2011). Non-addictive anti-inflammatory pain medications, physical therapy, and psychological coping techniques including meditation should be examined as better long-term treatment solutions.

#### Mental Health Symptoms

Prior research indicates an association between opioid dependence and depression (Becker et al., 2008), while both depression and anxiety are associated with higher CNCP risk (Sansone et al., 2009). Thus, it was expected among this study sample that a higher percentage of opioid dependent individuals with CNCP would have depression or anxiety compared to persons without CNCP. As anticipated, initial analysis did identify a correlation between opioid dependence, anxiety, and CNCP. At baseline, the percentage of cases in the CNCP group reporting anxiety, depression, or prescription medication for mental health symptoms was significantly greater than percentages in the non-CNCP group. At follow-up, the percentage of cases reporting depression and anxiety symptoms in both groups increased, and differences were no longer statistically significant between groups. On the other hand, reported use of prescription medication to treat mental health symptoms declined for both groups. This finding is concerning since anxiety is related to non-compliance with treatment protocols and worsening CNCP symptoms (Gonzalez et al., 2011). Moreover, prescription anti-anxiety or antidepression medications have positive effects on CNCP and treatment outcomes (SAMHSA, 2011; TIP 54).

At the follow-up, the majority of clients had been in treatment over a year and should have had time to begin seeing the aftermath of drug and alcohol abuse in their lives (i.e., negative impact on relationships with family and friends, ability to maintain employment, financial and temporal cost of OTP services). In an integrated treatment model, mental health would be addressed as part of the process of treatment. Thus, issues that arise as the client is working to regain control over life without dependence on abuse of drugs and alcohol would be addressed along the course of treatment with the help of a professional. In the OTPs, mental health symptoms may not be regularly addressed in the treatment sessions and this may

contribute to the increased reports of depression and anxiety in this sample. Many OTPs refer clients for mental health counseling at other facilities, since the focus of an OTP is on substance abuse treatment. The follow-up on attendance for referred counseling sessions and improved mental health symptoms may not be as closely monitored in these cases. Comorbid mental health, CNCP, and substance use problems decrease long-term outcomes for patients (Cacciola et al., 2001). Yet, the literature indicates brief therapy and cognitive-behavioral models for coping with anxiety are helpful and can be addressed concurrently with substance abuse treatment programs (Carroll & Rounsaville, 2006; Wetherall et al., 2011).

### **Criminal Justice System Involvement**

Random clinical trials of methadone maintenance treatment show reduced recidivism and increased overall social functioning for participants (Sees, Delucci, Masson, Rosen, Clark, Robillard, et al., 2000). In the past, criminal justice populations have not had access to opioid replacement treatment in the form of methadone or buprenorphine maintenance in an OTP setting. The low numbers of criminally involved clients in this study highlights this issue. There were no significant differences among the less than 12% of cases in either group who reported arrests, parole, probation, or drug court involvement at either baseline or follow-up. Both pain status groups showed decreases in criminal justice system activity by follow-up, though the drop in arrests for the non-CNCP group was cut significantly by half (13% to 7%). The larger issue then is to discover what percentage of people in jail, prison, or detention centers are opioid dependent and have CNCP. The current population of OTP clients excludes these cases and yet prevalence data indicates the high probability of unaddressed CNCP and opioid dependent individuals in corrections (Staton-Tindall, McNees, Walker, & Leukefeld, 2009).

Kentucky is unique in providing a wide range of diversion and substance abuse treatment within the criminal justice system, but opioid dependent individuals who could

benefit from OTP services are not allowed to participate because of current criminal justice system regulations. Trends in the Criminal Justice Kentucky Treatment Outcome Study indicate rising rates of incarcerated individuals with opioid abuse and dependence, particularly to prescription painkillers (Staton-Tindall, et al., 2009). In a recent special issue of *Substance Abuse*, the articles focused on a need for methadone maintenance treatment as a standard of care for opioid dependent individuals, including those who are incarcerated, due to strong evidence supporting its treatment effectiveness (Lee & Rich, 2012). As noted earlier, the rates of CNCP continue to rise, thus the overlap between CNCP and opioid dependence is also likely to increase. This means that the demand for OTP services among the criminal justice population with CNCP will likely increase over the next few years. There needs to be ongoing conversation between healthcare providers, corrections administration, and OTP professionals in order to provide the best possible care and recovery opportunities for people with CNCP and opioid dependence.

## **Study Limitations**

There are three primary limitations to discuss in regards to the research. First, this study is exploratory and therefore inherently arrives with some limitations. Secondly, analyses are conducted with a secondary dataset, which relies mostly on client self-reported information. Client selection bias may be an issue regarding who was willing to participate in the follow-up interviews. Thirdly, the measure for CNCP was limited in its scope and may have under or over identified cases for analysis. The following section details these study limitations.

## **Exploratory study.**

Though there is substantial research regarding CNCP and a separate body of literature regarding opioid dependence and treatment, there is limited research that addresses both conditions simultaneously, thus the analyses for this paper were deemed exploratory. Though

an exploratory study is limited in the generalizability of results or ability to make causal statements, it does allow for initial examination of a sample of opioid addicted individuals who have CNCP and provides a starting point for future research. The size of the sample and the variety of available data points allowed for rich initial exploration of the issues regarding CNCP and opioid dependence.

#### Self-report.

A secondary dataset was used for this study and data were derived from client selfreport, which leads to potential limitations in data validity. Though memories are inherently biased, self-reported past year substance use, employment, and mental health has been found to be generally reliable (Harrison, Martin, Enev, & Harrington, 2007; Shannon, Mathias, Marsh, Dougherty, & Liguori, 2007). It is common accepted practice for behavioral health studies to rely on self-reported client level information for day-to-day activities. In fact self-reported prescription analgesic use has been found to be generally accurate comparing the verbal naming of medications taken compared to identifying medications based on images of the drugs (Smith, Rosenblum, Parrino, Fong, & Colucci, 2010). Though clients may be prone to adjust responses in order to please or appease clinical staff, there was little reason for the clients in this sample to modify responses. At baseline, the client is encouraged to be honest about their responses because the nature of requesting treatment implies the client has serious drug use and other issues which need addressing. There were very few criminal justice system and child protective services referred clients, thus these individual who might be afraid to talk openly of their problems due to fear of negative consequences. In addition, though the baseline interview is at the beginning of treatment services for alcohol and drug dependence, all interviews are conducted after clients have obtained initial sobriety (post-detox).

Selection bias affects the study sample in a number of ways. The sample represents clients who are self-referred to an OTP in Kentucky with the funds to pay out of pocket for most of the services, and transportation to and from treatment on a daily basis. The average monthly cost of treatment is around \$500 and this price, which is not covered by most insurance, excludes individuals who do not have funds to cover OTP services. In addition, the sample excludes the majority of clients who may have been involved with criminal justice or child protection services because those systems do not currently endorse methadone or buprenorphine medication-assisted treatment in Kentucky. Hence, this sample is made up of individuals with limited criminal justice system involvement, funds to pay for treatment, and transportation to attend daily treatment sessions.

This is not a random sample and clients are not randomized into/out of treatment protocols; therefore, external validity and representativeness of clients is a limitation. The sample is drawn from a majority of clients at OTPs in the state, with every client entering treatment during the study period being offered the opportunity to participate in the study. About one-third of the baseline interview clients agreed to participate in a follow-up interview, and of those clients, about 70% were successfully interviewed. Therefore, this secondary dataset encompasses only a small portion of the overall OTP population. When comparing baseline interview data for demographic and substance use between cases who did and did not complete a follow-up interview found no significant differences. The wider population of OTP clients with CNCP is not fully understood at this time, but may include higher numbers of CNCP cases, heroin dependence instead of prescription opioid dependence as in this sample (Jamison et al., 2000; Peles et al., 2005; Rosenblum et al., 2003).

#### Dataset measures.

The majority of the dataset measures were based in the Addiction Severity Index (ASI), which has been extensively validated as a reliable tool for measuring substance use and related problems among a wide range of samples (Rikoon et al., 2006). There may an issue with the question used to identify CNCP cases in the study. Clients who self-reported "yes" to the primary question at baseline about chronic non-cancer pain that has recurred or persisted for 3 months or longer in the past year are considered to have CNCP for this study. It may be that clients with chronic pain do not self-report symptoms at baseline because their drug of choice – opioids – has masked the pain symptoms. If data were available, it might reveal an increase in reports of CNCP and pain symptoms at follow-up, which is not necessarily due to actual increased pain, but to increased awareness of pain now that the client is no longer abusing opioid medications. On the other hand, it may be that individuals are reporting CNCP at baseline in order to support opioid dependent behaviors in hopes of getting a regular source of opioids through the OTP. Future research will benefit from identifying the myriad factors that contribute to variation in CNCP. For example, understanding more about the relationship between age of onset for CNCP and age of first illicit drug use and opioid dependence would help to illuminate the underlying mechanisms of these intertwining conditions (Field & Swarm, 2008). In addition, CNCP can take many forms including recurrent versus unremitting pain, neuropathic, central, or nociceptive pain, and may or may not have a known source (i.e., car accident, arthritis, migraine, and endometriosis). A wider range of variables regarding CNCP will be helpful in future studies and can better elucidate the picture of clients with CNCP and opioid dependence.

## Conclusions

Recent literature suggests there should be significant differences between individuals with CNCP in opioid treatment programs compared to individuals without CNCP (Bruns &

Disorbio, 2005; Gatchel & Kishino, 2011). Individuals with CNCP are four times more likely to have depression, anxiety, and other comorbid conditions compared to individuals without CNCP (Gureje, Simon, & von Korff, 2001). In particular, women and individuals with a history of victimization have higher rates of emotional distress and pain which correlates with poorer substance abuse treatment outcomes (El-Bassel, Gilber, Wu, Go, & Hill, 2005). Studies examining outcomes for individuals with CNCP who report substance use disorders while receiving pain management services are limited, but indicate opioid dependence has a negative effect on pain treatment outcomes (IASP, 2011). Conversely, the results from this study point to similar outcomes both for clients with and without CNCP, including substance abstinence, recovery support, employment, mental health, and criminal justice involvement. Even gender differences dissolved in this sample despite extant literature that correlates being female with higher rates of CNCP, opioid abuse, depression, and anxiety (Becker et al., 2008; Gatchel & Kishino, 2011; Tsang et al., 2008). In fact, childhood sexual abuse and partner violence, which correlate with CNCP, are common among women in other research using methadone treatment samples (Engstrom et al., 2008; Gatchel & Kishino, 2011). The lack of gender and other differences in treatment outcomes may be due to the sample being only a small sub-set of the wider population of OTP clients. The individuals in the follow-up study had to have at a minimum a working landline or cell phone, money to continue paying for OTP services, and a willingness to be in the follow-up research study. This means among the clients excluded from the survey are those who did not stay in treatment at the OTP, or were unmotivated to participate in survey research. Nevertheless, this study presents interesting findings about this subset of individuals with CNCP who are in opioid dependence treatment which merit further examination.

#### Tobacco use and physical health.

In this study, predictors of CNCP included tobacco use and chronic medical conditions. Both predictors remained statistically significant regardless of client age, length of time in treatment, use of alcohol, or use of illicit drugs other than opioids. Half of the CNCP cases reported lifetime chronic medical problems compared to only 8% of the non-CNCP cases, and 8 in 10 individuals with CNCP in this sample smoked regularly at both intake and follow-up. Tobacco smoking correlates with poor physical and mental health, decreased quality of life, and increased pain (Hooten et al., 2011). Recent literature examining use of tobacco as a coping mechanism for individuals with CNCP found smoking correlated with higher pain ratings, greater interference with daily living from pain, and greater fear of pain compared to non-smokers with CNCP (Patterson, Gritzner, Resnick, Dobscha, Turk, & Morasco, 2012). In addition, Caucasian race, lower education levels, and history of alcohol dependence or abuse were associated with smoking among individuals with CNCP (Fishbain, Lewis, Cole, Cutler, Rosomoff, & Rosomoff, 2007). Thus, it may be that the use of tobacco is related to coping with CNCP and chronic medical conditions and may even be a contributor to continued opioid use at follow-up (Hooten et al., 2011).

Tobacco use remains a major hurdle, particularly in Kentucky where smoking cessation programs are not typically provided in substance abuse treatment settings, including opiate treatment programs (Kentucky Cabinet for Health and Family Services, 2008). The fact that smoking is related to chronic pulmonary and respiratory diseases is not often disputed (CDC, 2004). Yet, the misguided belief that alcohol and drug use abstinence is negatively impacted by concurrently providing smoking cessation treatment lingers (Baca & Yahne, 2009). The truth is that smoking may contribute to ongoing substance abuse (Hooten et al., 2011; Hooten, Townsend, Bruce, Shi, & Warner, 2009), continued behavioral and physical health problems, and increased pain levels (Ditre et al., 2011). Sharing the findings from this and other research

studies, while providing resources to help support both staff and clients in addressing tobacco use at treatment facilities, could help further improve treatment outcomes, as well as the client's overall behavioral health.

#### **Biopsychosocial framework for OTPs.**

The framework used for this study was a biopsychosocial model. The expectation was that biological (i.e., gender), psychological (i.e., depression and anxiety), and social (i.e., substance use and recovery support) aspects of individuals with CNCP would be different than the biopsychosocial aspects of individuals without CNCP. Thus, differences in the data between the CNCP and non-CNCP groups were expected regarding opioid dependence treatment outcomes. Instead, the study found very similar treatment outcomes. These findings may be an indication that OTPs are closely following the federally mandated protocol for dosing minimum/maximum, pill counts, random observed weekly urine drug screens, substance abuse counseling, and daily face-to-face medication consumption as the method for treating opioid dependence (IOM, 2005; SAMHSA, 2010).

In the 1970's the Drug Enforcement Agency (DEA) was responsible for oversight of OTPs due to the on-site administration of a controlled substance (i.e., methadone) for management of opioid dependence (IOM, 2005). OTPs were originally envisioned by the founders of methadone treatment, Dole and Nyswander, within the context of mutual clinician and client respect where individuals with opioid dependence could regain their lives through medication-assisted treatment and client-specific support (1980). The Vincent P. Dole Research and Treatment Institute in New York is based on an integrated biopsychosocial model of methadone treatment (Curet, Beeder, Joseph, Alexander, Schamisso, & Rodriguez, 2007). Generally, OTPs operate within a social control model with the goal of reducing public health risks of injection drug use and disease (Harris & McElrath, 2012; IOM, 2005). Maintenance of social control may be the

reason for the separation physically of OTPs from community mental health centers, which are the primary source of all other publicly sponsored substance abuse and mental health treatment in most states (Harris & McElrath, 2012).

In 2007, the Federal opioid treatment standards were updated by the Substance Abuse and Mental Health Services Administration (SAMHSA). The new document included the standard requirements for a thorough client assessment at intake, medication dosage and safety, and teaching clients to follow policies and procedures. New additions included standards recommended integrated care for comorbid physical and mental health conditions (42 CFR 8.12). Yet, the document leaves how integration should occur up to each state and generally recommends referral for treatment outside of the OTP, particularly in the case of pain medicine.

The question of what OTPs should be doing with clients who have comorbid CNCP and opioid dependence remains a pertinent issue. Chronic non-cancer pain (CNCP) and prescription opioid abuse are public health problems that will continue to have an impact on society over the next few decades (Clark & Treisman, 2011; IASP, 2011). An examination of best practice models points toward integrated plans of care for concurrent treatment of comorbid conditions like CNCP, opioid dependence, (Gatchel & Kishino, 2011; Koob, 2011) mental health issues, and victimization history (Bennett & O'Brien, 2007; Gilbert, El-Bassel, Manuel, Wu, Go, Golder, et al., 2006). In order to provide this model of care, the treatment program must begin with a thorough biopsychosocial assessment covering all aspects of a client's history including past treatment, substance use, mental and physical health issues.

A recent survey of OTPs nationwide found wide variation in assessment surrounding alcohol use history and case planning for ongoing alcohol use among clients (Harris, Strauss, Katgibak, Brar, Brown, et al., 2010). If basic substance use issues are approached differently across OTP sites, this begs the question of how much variation occurs within overall treatment

planning, monitoring, and case management for comorbid conditions like tobacco cessation, diabetes, hepatitis, or depression. An OTP which is going to provide integrated treatment services needs resources and connections with other local providers in order to develop a plan of care addressing biological, psychological, and social aspects of each unique client (Mueser, Noorsdy, Drake, & Fox, 2003). What this study finds is a picture of an OTP model that focuses entirely on medication-assisted treatment for opioid dependence. This does not mean in some OTPs there are not clinicians who provide referrals for medical and emotional healthcare or that there are not instances of brief smoking cessation groups or mental health support groups incorporated into the service array. What it does mean is the overall picture of OTPs may not include client-specific treatment that integrates care for all biopsychosocial aspects of an individual into the OTP case plan.

#### **Future Recommendations**

In 2010, the Obama administration suggested the national focus shift away from the 1970's "drug war" concept and towards harm reduction along with integrated physical and mental health care for all individuals (Consolidated Appropriations Act; Kerlikowske, 2010). Over the past ten years, the oversight of OTPs has shifted from the DEA to the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Center for Substance Abuse Treatment (CSAT). This shift has allowed a move away from the DEA's regulatory focus and a move toward quality assurance (Pelletier & Hoffman, 2001). SAMHSA has the opportunity to continue updating standards to ensure integrated care becomes a reality for opioid dependence with all other comorbid conditions. This may need to be a two-way street whereby providers outside of OTPs are educated about opioid dependence and medication assisted treatment in order to best work with OTPs for concurrent care of clients (Clark & Treisman, 2011). Policy updates might include requirements for case plans to denote regular check-ins and shared case

meetings amongst pain management physicians, mental health counselors, physical health providers, and OTPs staff. The use of telehealth and online meeting forums would be helpful for rural and non-metropolitan areas where resources may be limited (Smalley, Yancey, Warren, Naufel, Ryan, & Pugh, 2010). Additionally, SAMHSA might encourage OTPS to more closely align with their strategic national initiatives for providing individualized treatment that addresses comorbid mental and physical health issues for all clients (2011c).

With expanded healthcare options for substance abuse treatment on the legislative agenda in Kentucky, uniformity of available resources for behavioral healthcare needs may soon be a reality. In light of national healthcare reform, the use of a medical health home model may be an effective tool for managing multiple conditions (American Academy of Pediatrics, 2012; Curet et al., 2007). A medical health home provides continuity of care, particularly for individuals who have comorbid conditions like CNCP, opioid dependence and anxiety. By using a medical health home model, the OTP staff would collaborate with an individual's primary care physician, a pain management specialist, and mental health counselor to help coordinate client meetings, services, and resources. This model reduces stress for the client and gives professionals who work on the team the benefit of holistic case management. Chronic medical conditions would be reviewed concurrently with opioid dependence treatment and counseling for mental health symptoms in order to help clients manage comorbid conditions and prevent relapse. Future research might examine the use of a medical health home model that combines physical, mental, and social healthcare for clients with comorbid conditions like opioid dependence and chronic non-cancer pain. In particular, the release of Medicaid funds to cover OTP services will be important to help clients with the cost of treatment, transportation, and other needs of individuals who are likely to have limited income and no health insurance.

It would be ideal to conduct a pilot study within an OTP where a multi-disciplinary arrangement is established with existing public health and CMHC services. The model would be set up to mirror the description of treatment for methadone maintained clients at the Dole Research and Treatment Institute (Curet et al., 2007). At admission to the OTP, a client would receive a thorough psychosocial assessment and a physical exam including blood tests and xrays to capture history of medical problems. The team would then develop a case plan to address not only the opioid dependence, but also physical, mental, and social issues that arose during the assessments. The case plan would be reviewed monthly by the team and adapted as needed in order to manage the client's care, medication, and health. To measure the effect of this different model of care on client treatment outcomes, similar assessment would be conducted at a comparable OTP that was not participating in the pilot project. Clients and staff would be interviewed at both sites to identify changes in perceived treatment effects as well as in opioid dependence and other assessed client problems over the course of the project. One of the key measures would be quality of life for clients who participated in the pilot multidisciplinary treatment OTP compared to the clients in the OTP services as usual site. The following paragraph describes more about the importance of quality of life measures in future research.

#### Quality of life data elements.

Much of social work focuses on helping individuals improve quality of life while respecting individuals and supporting non-discrimination and social justice (NASW, 2008). Reducing harmful behaviors (i.e., drug abuse) while increasing pro-social activities (i.e. participation in work, volunteering, peer support) and improving overall behavioral health (i.e. coping with depression and anxiety, managing medical conditions like diabetes, weight management) make up the core quality of life measures, which are prominent in many

behavioral health assessments (Cummins, Lau, & Stokes, 2004; World Health Organization, 1998). The definition of quality of life used in behavioral health is in regards to the individual's perception of well-being and functioning in day-to-day living activities (Tiffany, et al., 2012). In a recent article by Tiffany and colleagues (2012) a key suggestion is for outcome evaluations in substance abuse treatment to expand beyond abstinence measures and begin incorporating quality of life variables. Substance dependence is defined in terms of a maladaptive pattern of behavior (APA, 1994) and improved quality of life perception may be a key predictor for clients who will be able to sustain substance use abstinence (Laudet, Becker, & White, 2009). Specifically because opioid dependence creates biological changes in the brain and CNS (Compton and Volkow, 2006) and often requires long-term treatment, the focus on quality of life factors seems particularly salient. In fact, health-related quality of life among methadone clients in OTPs is generally very poor (Millson, Challacombe, Villeneuve, Fischer, Strike, et al., 2004; Puigdollers, Domingo-Salvany, Brugal, Torrens, Alvaros, et al., 2004; Winklbaur, Jagsch, Ebner, Thau, & Fischer, 2008) as seen within the sample of clients examined for this paper where over half of those with CNCP reported comorbid physical health issues.

This exploratory study sets the stage for further research examining the quality of life for individuals with CNCP receiving opioid treatment. For example, some scientists have found opioid dependence, including use of opioids long-term for pain relief, increases an individual's sensitivity to pain (hyperalgesia) (Angst & Clark, 2006). If this is the case, we might expect to see an overwhelming number of individuals in opioid dependence treatment reporting painful conditions, which may be heightened in the CNS by the person's past abuse of opioids. One of the most difficult aspects of pain for clinicians and addiction treatment specialists is that measurement of pain is subjective and reports of pain vary greatly from person to person (IASP, 2011). If CNCP rates continue to rise alongside the growing number of individuals who report

abusing prescription opioids, there is much more research needed regarding these co-occurring conditions.

There remains a limited amount of information on OTP clients with CNCP and yet the data tell us that the problem will likely be increasing over time, therefore this is a key area of research in the future (Ospina & Harstall, 2002). Examining in more detail the source and type of pain and age of onset will be essential (Rashiq & Dick, 2009). Specifically, questions about a history of victimization as the source of pain should be examined (El-Bassel, Gilbert, Wu, Go, & Hill, 2005). Noting if the pain is unremitting or recurrent, predictable or break-through, neuropathic or centralized can help in understanding the individual reaction to the CNCP and coping techniques used to deal with it. Quality of life measures should be incorporated to examine how much the pain is interfering with the individual's life and goals along with outcomes as treatment progresses (Laudet et al., 2009; Tiffany et al., 2012). Questions about co-occurring physical and mental health issues, reasons for seeking opioid dependence treatment, and what supports work best for individuals will also be important additions to future research. In addition, the sample of OTP clients would be selected carefully to be as representative of the wider population as possible including stratified gender, race, and age groups.

#### Expansion of OTP sample.

Within the scope of a wider population of CNCP cases and opioid dependence treatment programs, it will be important to include buprenorphine medication clients. Though only a small number of OTPs offer buprenorphine, there are thousands of private physicians who have received DATA 2000 authorization to prescribe within their practices or clinics (www.buprenorphine.gov). In Kentucky, Medicaid covers the cost of buprenorphine if purchased with a prescription from a physician for pain relief, but not for medication-assisted

treatment for opioid dependence as administered in an OTP. Researchers need to examine how the buprenorphine prescribing practices compare to the OTPs in relation to assessing and treating CNCP co-occurring with opioid dependence. Are these physicians carefully monitoring their clients or is there an increasing number of CNCP cases with opioid dependence seeking opioids either for craving or for CNCP treatment through these private providers?

As more and more veterans return from deployment in the United States, there may be an influx of new cases of CNCP related to combat injuries (Tanielian & Jaycox, 2008). Soldiers may be treated with opioids during their initial healing phases and may be maintained on pain medications while trying to get them safely home. Once home, a solider in rural Kentucky may not be able to access pain management services as easily as a soldier who lives near the Veteran's Administration Hospital in Lexington. The prescription drug problem is particularly overwhelming in the Eastern part of our state, yet there are limited numbers of OTPs in nonmetropolitan areas (SAMHSA, 2009). There may be a growing number of soldiers returning to this region who have CNCP, opioid dependence, and who have been exposed to traumatic events. These individuals will need an integrated plan of care for their conditions. Researchers should examine current physician practices in relation to assessment, planning, and integration of treatment care for clients with comorbid CNCP, opioid dependence, and other mental and physical health conditions (Clark & Treisman, 2011). Information is needed on how physicians, clinicians, and other behavioral health providers share information about clients with CNCP and opioid dependence history, and how this sharing cane been done most effectively in order to monitor progress, setbacks, and provide continuity of care.

Within each state, there is a designated person in government called the *State Opioid Treatment Authority* (SOTA) whose primary responsibility is oversight of that state's OTPs. A recent study surveyed SOTAs across the U.S. regarding policy statements for alcohol use for

individuals in OTPs and found wide variation in treatment methods and requirements for clients (Harris et al., 2010). Similar data should be collected regarding tobacco use policies and methods found useful for providing tobacco cessation programs within OTPs. The connection between tobacco use, poor physical health, and chronic medical conditions is strong (CDC, 2004). Moving towards a behavioral health model that addresses all biopsychosocial aspects of the client, instead of only opioid dependence will likely be driven by policy makers, SOTAs, and clinical providers. Surveying the practices of each state through the SOTAs and then engaging them in a dialogue around the results would be a good start towards helping evaluate state OTP practices in relation to national behavioral health practices. The annual American Association for Treatment of Opioid Dependence (AATOD) conference would be an ideal location for sharing the results so that not only the SOTAs can evaluate the research, but also the providers and service consumers as well. Individuals with CNCP and opioid dependence in this exploratory study highlight the need for further examination of integrated biopsychosocial treatment.

# Appendix A: UK IRB Protocol Approval Letter

	IZEN PER ICIZY		
	KENTUCKY*		
Continuation Exp Modifications Ap	bedited Review proved: Revised Research Description; Study Personnel		Office of Research Integi IRB, IACUC, RDRC 315 Kinkead Hall Lexington, KY 40506-0057 859 257-9428 fax 859 257-8995
Approval Ends February 10, 20		IRB Number 11-0148-P6H	www.research.uky.edu/
TO:	Erin Stevenson, MSW, CSW 333 Waller Ave., Ste. 480 Lexington, KY 40504 PI phone #: (859) 257-1521		
FROM:	Chairperson/Vice Chairperson Medical Institutional Review Board (IRB)		
SUBJECT:	Approval of Protocol Number 11-0148-P6H		
DATE:	February 15, 2012		
On February 12	2, 2012, the Medical Institutional Review Board approved your protocol er	ntitled:	
Kenti	ucky Opiate Replacement Treatment Outcomes Study (KORTOS)		
and/or phone so [Note, subjects has been obtain	ective from February 12, 2012 until February 10, 2013 and extends to any cript. If applicable, attached is the IRB approved consent/assent document can only be enrolled using consent/assent forms which have a valid "IRB ied from the IRB.] Prior to the end of this period, you will be sent a Contri ted and returned to the Office of Research Integrity so that the protocol ca	(s) to be used v Approval" stan nuation Reviev	vhen enrolling subjects. 1p unless special waiver / Report Form which
research proceed ensure any chan changes made v immediately to	g the research activities, you are responsible for complying with IRB decis lures should be implemented as approved in the IRB protocol. It is the pri ages planned for the research are submitted for review and approval by the vithout prior IRB approval to eliminate apparent hazards to the subject(s) the IRB. Furthermore, discontinuing a study or completion of a study is c fore the IRB should be promptly notified in writing.	ncipal investig IRB prior to in should be repo	ator's responsibility to nplementation. Protocol rted in writing
Guidance to Re Research Integ Additional info	n describing investigator responsibilities after obtaining IRB approval, dow rsponsibilities, Qualifications, Records and Documentation of Human Subj rity's Guidance and Policy Documents web page [ <u>http://www.research.uky</u> rmation regarding IRB review, federal regulations, and institutional polici search.uky.cdu/ori]. If you have questions, need additional information, on	jects Research" . <u>edu/ori/human</u> es may be foun	from the Office of /guidance.htm#PIresp]. d through ORI's web site

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## Vita

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- BJA Co-occurring Treatment Evaluation Grant, Johnson County

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky *Principal Investigator- February 2011 to present* 

- Kentucky's Opioid Treatment Program Outcome Study (KORTOS)
- SAMHSA Assertive Adolescent and Family Treatment Evaluation Grant , Floyd County
- BJA Grant Second Chance Family Based Prisoner Treatment Evaluation Grant, Floyd County

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky *Co-Principal Investigator – January 2010 to present* 

- Kentucky Substance Abuse Treatment Outcome Project (KTOS)
- Adolescent Substance Abuse Treatment Outcome Study (AKTOS)
- Kentucky Opioid Replacement Treatment Outcome Study (KORTOS)
- Recovery Kentucky KTOS
- DCBS-Initiative KTOS
- KIDS NOW Project
- IMPACT Project
- Independence House Pregnant and Postpartum Women Project Evaluation

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky Principal Investigator – March 2007 to November 2009 (project funding ended)

• Kentucky Youth First Project

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky *Project Director- July 2005 to January 2010* 

- Kentucky Substance Abuse Treatment Outcome Project (KTOS)
- Adolescent Substance Abuse Treatment Outcome Study (AKTOS)

- State Data Infrastructure Project (SDI)
- KY Youth First Project
- Kentucky's Opioid Treatment Program Outcome Study (KORTOS)
- Family Futures Drug Court Project

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky Study Coordinator - March 2003 to July 2005

- Kentucky Substance Abuse Treatment Outcome Project (KTOS)
- State Data Infrastructure Project (SDI)

Center on Drug and Alcohol Research, University of Kentucky, Lexington, Kentucky Research Associate - May 2002 to March 2003

• NIAAA Study on Protective Orders and Intimate Partner Violence

University of Kentucky, College of Social Work, Lexington, Kentucky *Project Coordinator - February 2001 to May 2002* 

• Pilot Project Effects of Intimate Partner Violence on Women's Employment

Lexington Fayette Urban County Government, Lexington, Kentucky Project Coordinator - February to December 2001

• Studies on Workplace Violence and Work life Issues

# Scholastic and Professional Honors

- Kentucky Coach, Network for Improvement of Addiction Treatment (NIATx) Jan 2010 present
- Research Article Reviewer for The Journal of Rural Health 2009 to present
- University Of Kentucky, College of Social Work, Lexington Campus Instructor

SW124 Introduction to Social Work SW222 Undergraduate History of Social Welfare SW430 Policy SW450 Introduction to Social Work Research

- SW750 Research Design
- SW751 Research Implementation

# **Professional Publications**

# **Journal Articles**

Stevenson, E., & Cole, J. (2012). Variance in substance use among a among communitybased substance use treatment sample with chronic non-cancer pain. *Paper in progress. Abstract submitted to SSWR 2013 conference for oral paper presentation.* 

Cole, J. & Stevenson, E. (2012). Victimization, mental health, and substance use among

adolescents in substance abuse treatment. Paper in progress.

- Stevenson, E., Cole, J., Walker, R., & Logan, TK. (2011). Association of persistent non-cancer pain with substance abuse treatment outcomes among a Community Mental Health Center sample. *Paper being revised for resubmission*.
- Cole, J., & Stevenson, E. (2011). Tobacco use and psychiatric comorbidity among adolescents in substance abuse treatment. *Journal of Substance Abuse Treatment*, in press.
- Logan, T., Evans, L., Stevenson, E., & Jordan, C. (2005). Barriers to services for rural and urban rape survivors. *Journal of Interpersonal Violence, 20*(5), 591-616.
- Logan, T., Stevenson, E., Evans, L., & Leukefeld, C. (2004). Rural and urban women's perceptions of barriers to health, mental health, & criminal justice services: Implications for victim's services. *Violence and Victims*, 19(1), 37-62.

## **Professional Reports**

- Cole, J., Scrivner, A., Logan, TK, & Stevenson, E. (2012). Differences in substance use by geographical region. *KY Treatment In Focus, 4*(2), 1-4. Center on Drug & Alcohol Research: Lexington, KY.
- Stevenson, E., Mateyoke-Scrivner, A., Cole, J., Walker, R., & Logan, TK. (2012). Kentucky's Opiate Replacement Treatment Outcome Study – 2011 Annual report. Center on Drug & Alcohol Research, University of Kentucky.
- Scrivner, A., Walker, R., Stevenson, E., Cole, J. & Logan, TK. (2011). Regional differences in substance use. *KY Treatment In Focus*, 3(5), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Scrivner, A., Walker, R., Stevenson, E., Cole, J. & Logan, TK. (2011). Substance abuse risk during pregnancy: An overview of the KIDS NOW Plus Evaluation- Birth Event Characteristics.
  *KY Treatment In Focus, 3*(4), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Scrivner, A., Walker, R., Stevenson, E., Cole, J. & Logan, TK. (2011). Substance abuse risk during pregnancy: An overview of the KIDS NOW Plus Evaluation- Characteristics at the beginning of care. *KY Treatment In Focus*, *3*(3), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Cole, J., Stevenson, E., Mateyoke-Scrivner, A., Logan, T., & Walker, R. (2010). Tobacco use among individuals in substance abuse treatment in Kentucky. *KY Treatment In Focus*, 3(2), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Mateyoke-Scrivner, A., Walker, R., Cole, J., Stevenson, E., Logan, TK, & Shannon, L. (2009).
  *Examining prescription opioid abuse in Kentucky: A look at an emerging trend. KY Treatment In Focus, 2*(3), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Cole, J., Stevenson, E., Scrivner, A., Newell, J., & Walker, R. (2010). Adolescent KTOS Follow-up Report 2010. Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Stevenson, E., Walker, R., Logan, TK., Cole, J., & Mateyoke-Scrivner, A. (2009). Supporting medication assisted treatment outcomes research: An overview of Kentucky's Opioid Replacement Treatment Outcome Study. KY Treatment In Focus, 2(2), 1-4. Center on

Drug & Alcohol Research, University of Kentucky. Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.

- Cole, J., Walker, R., Logan, TK., Stevenson, E., & Mateyoke-Scrivner, A. (2009). Following substance abuse treatment clients over time: Tips from the front lines. KY Treatment In Focus, 2(1), 1-6. Center on Drug & Alcohol Research, University of Kentucky.
- Stevenson, E., Shannon, L., Walker, R., Mateyoke-Scrivner, A., Logan, TK., & Cole, J. (2008). Kentucky women in substance abuse treatment: Rural Appalachia. KY Treatment In Focus, 1(2), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Stevenson, E,. Walker, R., Cole, J., Logan, TK, Mateyoke-Scrivner, A., & Corrigan, J. (August, 2008). Substance use treatment clients with traumatic brain injury. KY Treatment In Focus, 1(1), 1-4. Center on Drug & Alcohol Research, University of Kentucky.
- Walker, R., Mateyoke-Scrivner, A., Cole, J., Logan, TK., Stevenson, E., Leukefeld, C., & Jackson, T. (2008). Fiscal year 2007 follow-up findings from the Kentucky Substance Abuse Treatment Outcome Study. Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Mateyoke-Scrivner, A., Cole, J., Logan, TK., Stevenson, E., Leukefeld, C., & Jackson, T. (2007). *Kentucky substance abuse treatment outcome study: Fiscal Year 2005 follow-up findings and summary report* (CDAR Technical Reports 2007-1, 2). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Mateyoke-Scrivner, A., Cole, J., Logan, TK., Stevenson, E., & Leukefeld, C. (2006). Kentucky substance abuse treatment outcome study: FY2004 follow-up findings and summary report (CDAR Technical Reports 2006-3, 4). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Mateyoke-Scrivner, A., Bradshaw, G., Logan, TK., Stevenson, E., Leukefeld, C., & Goltz, M. (2006). Kentucky substance abuse treatment outcome study: FY2003 follow-up findings and summary report. (CDAR Technical Reports 2006-1, 2). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Logan, TK, Bradshaw, G., Leukefeld, C., Goltz, M., & Stevenson, E. (2005). Kentucky substance abuse treatment outcome study: FY2002 regional summary reports of statewide follow-up findings (CDAR Technical Reports 2005-1.1-14). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Logan, TK, Bradshaw, G., Leukefeld, C., Goltz, M., & Stevenson, E. (2004). Kentucky substance abuse treatment outcome study: FY2002 summary report of statewide follow-up findings (CDAR Technical Report 2004-4). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Logan, TK, Bradshaw, G., Leukefeld, C., Goltz, M., & Stevenson, E. (2004). Kentucky substance abuse treatment outcome study: FY2002 follow-up findings (CDAR Technical Report 2004-3). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.
- Walker, R., Logan, T., Leukefeld, C., & Stevenson, E. (2004). Kentucky traumatic brain injury prevalence study (CDAR Technical Report No. 2004-1). Lexington, KY: University of Kentucky, Center on Drug & Alcohol Research.

## **Recent Research Presentations**

- Stevenson, E., & Cole, J. (2012). Variance in substance use among a among communitybased substance use treatment sample with chronic non-cancer pain. *Abstract submitted to SSWR 2013 conference for oral paper presentation.*
- Cole, J. & Stevenson, E. (2012). Victimization, mental health, and substance use among adolescents in substance abuse treatment. Accepted for oral paper presentation at Council on Social Work Education (CSWE) conference in Washington, D.C., November 9-12, 2012.
- Stevenson, E. (2012). Chronic pain among individuals in treatment for opiate dependence:
  Preliminary findings. Presentation of oral paper at Society for Social Work Research (SSWR) annual conference in Washington, DC, January 14, 2012.
- Cole, J., & Stevenson, E. (2011). Persistent tobacco use among adolescents in substance abuse treatment. Presentation of oral paper at Council on Social Work Education (CSWE) conference in Atlanta, GA, October 27-30, 2011.
- Stevenson, E., & Cole, J. (2011). Overview of addiction and chronic pain: Examining outcomes among substance abuse treatment clients with chronic pain. Kentucky Association of Social Work Education (KASWE) conference in Louisville, KY, April 7, 2011.
- Stevenson, E. (2011). Gender differences in chronic pain among opiate treatment clients. Presentation of oral paper at Society for Social Work Research (SSWR) annual conference in Tampa, FL, January 14, 2011.

# Typed Name of Student on Final Copy

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