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Effect of Therapeutic Alliance of Clients on Methadone Maintenance Treatment Outcomes

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Walden University
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MCC, University of Phoenix, 2006

BS, Elizabeth City State University, 2003

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Opioid abuse costs affect the majority of the adult population in our society directly or indirectly. The current prevailing medical treatment for opioid addiction is methadone maintenance treatment (MMT). MMT reduces infectious disease spread, illicit drug use, criminal activity, and overdose potential. MMT is only as effective as the length of time a client remains active and compliant with the program. In previous studies, therapeutic alliance (TA) has been shown to positively influence the effectiveness of substance abuse treatment. However, a gap exists in research in regards to the impact of TA on the effectiveness of MMT outcomes. The theoretical framework of this study is based on therapeutic alliance, which guided an examination on whether therapeutic alliance (as measured by the Session Rating Scale) influenced MMT retention and compliance (drug screens and session attendance). Archival data from 264 clients receiving MMT for opioid dependence were reviewed from a nonprofit community-based agency in Arizona. Logistic regression results revealed that TA did not significantly affect retention or compliance. However, issues were noted such as how the SRS was administered, a lack of understanding by clients regarding scoring the SRS, and unique social desirability demands when clients are in MMT. The finding that TA alone did not significantly affect retention and compliance does not decrease the need to find effective means to improve MMT outcomes. Rather, the findings suggest a critical need to identify and utilize measures more appropriate for clients receiving MMT. In doing so, positive social change may be achieved by assisting clinical staff in developing a strong therapeutic alliance with MMT clients as they focus on problem solving as a joint venture when challenges in the recovery process arise.

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Dedication

I dedicate this to the most amazing husband on earth, Tomas Fresquez who stood by me through-out this process, even with the cross country and cross state moves to find practicum, internship and supervision. I love you for being funny, supportive, tolerant and for the most part patient, but also for allowing me to be me and pursue my dream through to reality. To my father, George Osborne recently deceased, whose constant staying on top of me was annoying, but also kept the push on for me to not give up. To my daughter, Taya and grandsons, whose lives were ended way before their time. So many times, when I would be feeling like crying, I would remember her humor and infectious laughter and find the strength to continue on. And most importantly to my Lord God who gave me all that I have and am.

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Chapter 1: Introduction to the Study

Background

With numerous cutbacks in Medicaid funding, and rising health care costs, it is beneficial to examine potential cost factors in various areas of treatment and determine means to reduce those costs. In this study, I focused on treatment for opioid dependence. The negative stigma surrounding methadone maintenance treatment may often bring this form of treatment into scrutiny. Opioid abuse costs are a burden on the United States (Ghate, Harooutiunian, Winslow, & McAdam-Marx, 2010). Opioid abuse related costs have increased in several areas; medical associated costs, criminal activity costs and emotional costs to families of the substance abuser (White et al., 2005; SAMHSA, 2013; Birnbaum, Reynolds, Jetley, Zhang, & Vallow, 2004). White et al, (2005) pointed out that in the 2-year period from 1999 to 2001 admissions for treatment of prescription opioids increased by 15,000 and from the prior reported two-year period of 1999 to 2001, and emergency room visits related to illegal or nonmedical use of prescription drugs increased by 75,000 incidents. SAMHSA (2013) reported that the number of individuals in 2012 with heroin dependence or abuse (467,000) was close to double that of 10 years earlier (214,000). The Centers for Disease Control and Prevention (CDC), (2002) reported that over one third of AIDS cases have been directly and indirectly related to injection drug use. Birnbaum et al. (2004) determined that prescription opioid abuse costs in 2001 were $9.2 billion. The National Institute of Drug Abuse (2013) reported that in 2011, approximately 4.2 million Americans age 12 years or older had used heroin at least once in their lives and approximately 23% of those individuals who use heroin become dependent on it. Paulozzi (2006) reported that from 1997 to 2002 the number of heroin, cocaine, and

opioid analgesic deaths increased 28.7 % to 10,727, with a reported increase of 96.6% in opioid analgesics. Opioid abuse includes not only heroin, but abuse of prescription pain medications such as Codeine, Morphine, Diluadid, Oxycontin/Oxycodone and others. The Centers for Disease Control (CDC; 2012) has identified prescription drug use (opioid based pain medications and benzodiazepines) as the fastest growing drug problem in the United States; pain pills are included in the class of opioids that are abused. The CDC also identified that there are approximately 9 million individuals who are prescribed and have long-term medical use of opioids and approximately 5 million individuals who report illegal use of opioid analgesics in the past month. The financial and emotional costs of opioid addiction are a burden on society.

Methadone is a synthetic narcotic analgesic used for treatment of people addicted to opioids. Methadone is also used for other medical purposes such as treatment of pain but for the purpose of this research the focus is purely on the treatment of opioid addiction. The purpose of methadone is to keep the individual from experiencing withdrawal symptoms and control the cravings for illicit use, and when the dose is sufficiently high enough, it produces blocking of the effects of illicit opioid drugs. The purpose of methadone maintenance therapy (MMT) in opioid addiction is to reduce withdraw symptoms from opioids, prevent infectious disease spread, prevent illicit drug use, prevent criminal activity associated with drug use, and decrease overdose potential and interpersonal difficulties (Ward, Hall, & Mattick, 1999; Reisinger et al., 2009; Krambeer, Von McKnelly, Gabrielli, & Penick, 2001). Since the 1960s, MMT has been shown an effective treatment for improving quality of life for opioid-dependent individuals and society. MMT has contributed to reduced death rates related to

overdoses, reduced criminal behavior related to drug seeking or use, and reduced spread of diseases related to intravenous needle. Methadone can be effective to assist in stabilizing an individual so that attention can be given to other areas such as medical and mental health and in the long-term maintenance until an individual is ready for detoxification (Krambeer et al., 2001). Safe, proper use of methadone does continue opioid dependency but offers freedom from compulsive and disruptive behavior associated with heroin addiction. However, there is a gap in the literature with regard to factors that are most cost effective and are significantly related to retention and compliance for those involved in MMT. In this exploratory study, I intended to offer an understanding of the effects of TA on MMT compliance and retention to improve the effectiveness through improving TA, with the goal of keeping the cost factors of improvement low.

Studies Addressing the Problem

Kayman, Goldstein, Deren, and Rosenblum (2006) identified that length of time engaged in substance abuse treatment is associated with improved quality of life outcomes, and those individuals that do not complete treatment are at high risk. Kayman et al. (2006) described success with MMT as requiring the individual to stabilize in areas such as a returning to a normalized brain functioning level, ability to control triggers, urges and stabilization in their environment (e.g., employment, housing, social and family relationships). Magura, Nwakeze, and Demsky (1998) conducted a study with 3,248 patients and found the length of treatment was in direct proportion to decreased daily opioid use and decreased criminal behavior. Ball, Lange, Myers, and Friedman (1988) identified that of clients that left treatment programs prematurely that 82% relapsed to intravenous (IV) use

shortly after discharge. Drug treatment studies have shown that retention is a major factor in treatment outcomes and treatment dropout has been an issue (Gossop, Stewart, Browne, & Marsden, 2002; Reisinger et al. 2009; Simpson & Sells, 1982). Clausen, Waal, Thoresen, and Gossop (2009) found that older users were at higher risks for mortality due to over-dose (OD) when MMT ceased. Hubbard, Craddock, and Anderson (2003) and Gossop, Trakada, Steward, and Witton (2005) found in their 5-year follow-up studies of outcomes for those with drug abuse treatment completion that there were substantial reductions in criminal activity. Hubbard et al. also found higher reported rates of full-time employment by those with treatment lengths over 6 months. Ball et al. (1988) conducted a study on six methadone programs and found that a reduction from 100% to 29% in IV drug use in clients active in the methadone program 4 years after initial admission. Research suggests that treatment compliance the first 12 months of MMT is critical to client outcomes (Simpson, Joe & Brown, 1997; Simpson, D., Joe, G. & Rowan-Szal, G., 1997). Simpson (1981) found that time in treatment is a strong indicator of treatment outcomes.

Several variables have been researched in relation to MMT treatment retention. Sociodemographic predictors for retention include age at admission, keeping good relationship with family, source of income, employment, education, marital status, living in rural area, and involvement in the criminal justice system (Magura et al., 1998; Yang et al., 2013; Zhang et al., 2013). In a retrospective longitudinal study with 2,728 clients enrolled across 56 MMT clinics in Guangdong, China, through 2010, Yang et al. (2013) found that statistically significant predictors of retention included the following: age at admission being older than 30 years old, keeping good relationship with family, source of income, the daily

cost of drug use preadmission, living in rural area, sharing needles, and history of being arrested. Magura et al. (1998) conducted a study among 2,454 patients admitted to the 15 clinics throughout New York City found that criminal arrests during MMT significantly affected retention outcomes. Huissoud, Rousson, and Dubois-Arber's (2012) results agreed with other studies and found age under 30 as a significant factor predicting MMT treatment dropout. Another finding of the study is related to race identification: African American clients were not as likely to remain in MMT in comparison with Caucasian or Hispanic clients (Magura et al., 1998). The influence of being African American and experiencing significant dropout rates was further supported by Mancino et al. (2010) and Saxon, Wells, Fleming, Jackson, Calsyn (1996).

The effect of dosing levels with regard to MMT program retention has been studied extensively, and findings have agreed that higher doses encourages retention and lower illicit drug use (Joe, Simpson, & Sells, 1994; Yan-ping et al., 2009; Mohamad, Abu Bakar, Musa, Talib, & Ismail, 2010; Salamina et al., 2010) There has been so much attention and research given in the area of effective dosing and prediction of treatment retention that it is unreasonable to give an adequate representation or summary. The overall consensus is that higher dosing is a significant factor in MMT treatment retention; however, there does not appear to be a consensus on what the higher dose limits are.

Psychosocial treatment is another variable that has been researched in relation to effectiveness in MMT programs. Salamina et al. (2010) found that regardless of the type of psychotherapy conducted, clients receiving psychotherapy were almost twice as likely to be retained in MMT (315 days with psychotherapy vs. 167 days without psychotherapy).

Magura, Rosenblum, Fong, Villano, and Richman (2002) found that in a study of two clinics with cocaine-using methadone patients who were assigned to enhanced methadone treatment, primarily cognitive-behavioral therapy (CBT) in comparison with similar patients in two other clinics who received standard methadone treatment without CBT, the treatment condition of CBT did not significantly affect outcome. Magura et al. (2002) reported that those clients receiving CBT relayed higher reports of TA and obtained more supportive services than those receiving standard treatment.

Insufficient research has been conducted on TA related to retention and outcomes. Palmer, Murphy, Piselli, and Ball (2009) found that poor staff connection (therapeutic alliance) issues are one of the factors identified as contributing to dropout from substance abuse treatment. Joe, Flynn, Broome, and Simpson (2007) stated that a clients' progress is measured by the clients' pattern of drug use and treatment engagement, as well as their alliance with his or her counselor. Kelly, O'Grady, Brown, and Michell (2010) found that clients' that reported they were satisfied with their clinical staff and the program were more likely to be retained in MMT at 12 months. Joe et al. (2001) and Meir, Barrowclough, and Donmall (2005) found that the counseling rapport reported by clients was a predictor of treatment outcomes and in part for treatment retention. The study found higher rates of reported rapport when the client believed they were being supported as opposed to peer confrontational or punitive means of treatment.

Problem Statement

Despite the successful use of longer-term methadone maintenance treatment, problems remain. Sees et al. (2000) and Paulozzi (2006) noted an increase in deaths related

to oxycodone and methadone in urban areas between 1997 and 2002. Modesto-Lowe, Brooks, and Petry (2010) relate higher risk factors in MMT with the fact that clients using MMT are young, exhibit antisocial traits and thus are more prone to misusing methadone or to use multiple substances. The results of their study suggested that by nature that clients of MMT are at risk for low treatment compliance such as lower adherence to attendance to scheduled sessions, illicit drug use, and leaving treatment early, which often leads back to opioid relapse and return to other undesirable behaviors such as crime.

Defining the minimal amount of service needed to ensure higher rates of successful outcomes is important because as Kraft, Rothbard, Hadley, McLellan, and Asch (1997) pointed out, literature states a combination of services such as employment, housing, and medical care services are necessary for drug-addicted clients to obtain recovery but, unfortunately owing to the costs of these services, they are limited in most methadone treatment. The costs of additional services such as day treatment offer no significant difference in outcomes in comparison to individuals that receive services of significantly less costs such as enhanced MMT services (Avants et al., 1999). Determining the necessary cost effective factors that lead to retention and positive outcomes needs to be considered especially with today's economic budget constraints.

Condelli and Dunteman (1993) conducted a study that found of 526 clients admitted into 17 methadone programs in the course of a 2-year period, retention was highest in programs that kept clients apprised of their dose, were accessible, and offered quality case management services. Kelly et al. (2010) found that clients who reported program satisfaction remained with the program for a minimum of 12 months. The definition of

quality services and what it is composed of is a question that is often undefined, but it may be reasonable in reviewing the research to include TA as one measurement of quality service.

The quality of the relationship between the client and the counselor affects retention and compliance in drug treatment and may be a component of quality service. If a client is reporting satisfaction with their program, he or she may also have some form of a positive TA with his or her clinical staff. Meir, Donmall, McElduff, Barrowclough, and Heller (2006) found that clients who reported a weak TA with their counselor dropped out of drug treatment significantly earlier than those clients who reported a stronger therapeutic alliance.

There appears to a problem with how *TA* is defined. There is no one operational definition of *TA*, and the variation in how the clinical staff defines it and how the clients identified it may differ. Krause et al. (2011) identified that clients may have an emotional bond expectation (that the therapist should be gentle, accepting, nonaggressive, nonjudgmental, warm, and empathic) for their definition of *TA*, whereas clinical staff may not value an emotional bond as part of TA. Other factors that Krause et al. stated that the client acknowledged as part of TA is that they felt acceptance by their therapist, that the client trusted the therapist and vice versa, and that the client felt understood. Krause et al. concluded "that the alliance is an emergent quality of working together productively within an asymmetric relationship" (p. 279). Common descriptions of TA appear to include the ability of the therapist and client to work together on common tasks and goals and the affective nature of the relationship (Bordin, 1979; Horvath & Symonds, 1991; Saunders, Howard, & Orlinsky, 1989).

With most states cutting funding for mental health and substance abuse, program funding must distributed among those with the greatest potential of recovery and the highest effect on community improvement (e.g., reduction in crime, reduced dependence on governmental funding). Finding the link between improving the effectiveness of MMT and reducing costs to society will assist in continuation of this treatment modality.

Improving TA may improve the likelihood that clients stay compliant with methadone treatment requirement by being retained longer in treatment. Developing alliance does not increase program costs as significantly as developing social supports because developing therapeutic alliance can be taught through in-service trainings or other means. Therapeutic alliance may improve retention and compliance in a cost-effective and efficient manner, as opposed to buying new group materials, training different therapeutic approaches, or developing social support programs. Duncan and Miller (2008) pointed out that the therapist's ability to build TA with the client accounts for 6% to 9% of the change in clients as opposed to the model or technique used (1%) but therapist effectiveness may range from twenty to seventy percent.

I intended to examine whether client-reported level of TA was associated with improved outcomes, as defined by retention and compliance (attendance to scheduled group/individual sessions and drug screenings). I hypothesized that high levels of reported TA by clients would result in longer length of stay (retention) and higher levels of compliance (less positive drug screenings and higher rates of attendance to scheduled sessions).

Nature of the Study

I attempted to determine whether higher levels of reported TA predicted MMT retention and compliance. Initially, the differences between participants receiving methadone maintenance treatment for opioid dependence reporting positive TA and participants reporting negative TA were analyzed against MMT retention. Further examination included reviewing the differences between participants receiving methadone maintenance treatment for opioid dependence reporting positive therapeutic alliance (Session Rating Scale score > 36) and participants reporting negative therapeutic alliance (Session Rating Score < 36) against compliance measured by number of positive drug screenings and attendance to scheduled individual/group sessions. Therefore, I also attempted to determine whether higher levels of reported TA can predict MMT program compliance as measured by less positive drug screenings and higher attendance to scheduled sessions.

The participants were sorted and randomly selected from a database of clients that had a history of receiving outpatient MMT from one of the four MMT clinics operated by the agency used for this study, which was located in Arizona. The agency is a not-for-profit agency, and clients were evaluated from 2010 to 2014. The hypothesized independent variable was defined as reporting of positive or negative therapeutic alliance (Session Rating Scale scores +/- 36), and the dependent variables were defined as treatment retention at or > 1 year, and treatment compliance described as number of positive drug screens while in treatment and attendance to scheduled appointments for individual/group sessions.

The study was a quantitative cross-sectional design, and I used a logistic regression analysis. The predictors of retention as measured by > or equal to 12 months of retention and

compliance as measured by positive drug screenings and attendance to all scheduled sessions (individual/groups) were evaluated compared to reports of TA from the clients' perspective using logistic regression analysis. Demographic variables collected were also evaluated in the same manner to control for their effect on the relationship between alliance, retention, and treatment compliance.

I used the following research questions and hypotheses to guide this study:

Research Question 1:

Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict retention (as measured by length of stay in treatment) among patients receiving methadone maintenance treatment?

H_{a1}: Report of positive therapeutic alliance as measured by a raw score of 36 or above on the SRS will predict treatment retention measured as 12 or more months in MMT.

H_{01}: Report of positive therapeutic alliance as measured by a raw score of 36 or above on the SRS will not predict treatment retention measured as 12 or more months in MMT.

Research Question 2**:**

Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict compliance (as measured by attendance to scheduled appointments) among patients receiving methadone maintenance treatment?

H_{a2}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will predict treatment compliance as measured by client's attendance record

showing three or less non-excused missed appointments over the preceding 12 months of MMT treatment.

H_{02}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will not predict treatment compliance as measured by client's attendance record showing three or less nonexcused missed appointments over the preceding 12 months of MMT treatment.

Research Question 3:

Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict compliance (as measured by results of drug testing analysis) among patients receiving methadone maintenance treatment?

H_{a3}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will predict treatment compliance as measured by client's drug test results showing fewer than three positive illicit drug results over the preceding 12 months of MMT treatment.

H_{03}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will not predict treatment compliance as measured by client's drug test results showing fewer than three positive illicit drug results over the preceding 12 months of MMT treatment.

Purpose Statement

The purpose of this quantitative research study was to develop an understanding of the effects of TA on MMT. The intent of this study was to evaluate whether report of positive TA can predict MMT retention and compliance. The purpose of this research was to offer

another perspective to improve the effectiveness of retention in Methadone Maintenance Treatment (MMT) by focusing on improving therapeutic alliance, with the goal of keeping the cost factors of improvement low. This researcher proposed that clients that have a healthy TA with their clinical staff will show evidence of stronger retention rates. This understanding will allow treatment providers to design treatment that will better engage clients and address issues of attrition by increasing retention and compliance rates for those within this level of care.

The independent variable of this study was the client's reported therapeutic alliance with their assigned clinical staff as measured by the Session Rating Scale (SRS). The first dependent variable was treatment retention as measured by categorizing continuous retention as > or equal to one year. The second dependent variable was compliance and divided into two components. The first component of compliance was measured over the last year of MMT, by categorizing client's attendance to scheduled sessions of individual and group as attendance compliant or non-compliant with compliant being measured as < 3 non-excused missed sessions. The other component of treatment compliance was measured by categorizing clients as treatment compliant and non-compliant based on recorded drug test, with positive compliance being measured as equal to or < 3 positive drug screenings.

The potential covariates: The following variables have been identified as potential predictors by past research that were discussed in the previous section of "Studies Addressing the Problem" and was collected through demographic information: Age, race, gender, marital status, employment status, and current methadone dosing level or dosing

level at discharge. These variables were added into the regression model to see if they also play a role in retention and compliance.

Theoretical Framework

The theoretical framework of this study is based on therapeutic alliance and that having a positive therapeutic alliance will increase retention and compliance with MMT. Retention and compliance with MMT for opioid addiction reduces withdraw symptoms from opioids, and contributes to prevention of infectious disease spread, prevents illicit drug use and criminal activity associated with drug use, decreases overdose potential and interpersonal difficulties (Ward et al., 1999; Reisinger et al., 2009; Krambeer et al., 2001).

Therapeutic alliance (Duncan, Sparks, & Miller, 2006) is commonly also referred to as working alliance (Bordin,1979; Fitzpatrick & Irannejad, 2008; Marmarosh & Kivlighan, 2012), client and counselor rapport or relationship (Knox, Hess, Hill, Burkard, & Crook-Lyon, 2012), and helping alliance or relationship (Topor & Denhov, 2012; Ruglass, Miele, Hien, Campbell, Hu, Caldeira, and ... Nunes, 2012). Therapeutic alliance describes the relationship between the client and the counselor. Bernal, Bonilla, Alvarez and Greaux (1993) simply described psychotherapy alliance as the relationship between the client and the therapist. Bordin (1979) defined alliance as an agreement between client and therapist on treatment goals, agreement on how to achieve the goals and the personal bond between the therapist and client.

Positive client evaluations of the quality of social services, program accessibility and informed dosing levels were found to be predictors of retention in a study of 351 opioid users in MMT (Condelli & Dunteman, 1993). Kelly et al. (2010) found that clients who reported

satisfaction with their counselors and programs were more likely to be retained in treatment for at least 12 months. Reisinger et al. (2009) found that on top of program noncompliance another factor that was highly related to discharge was conflict with their counselor. Trujols, Garijo, Siñol, del Pozo, Portella and Pérez de los Cobos (2012) found that client participation in treatment decisions and less negative effects of social functioning were more likely to be satisfied with MMT. Zhang, Gerstein and Friedmann (2009) reported that independent of treatment duration, counseling intensity, patient adherence to treatment protocols, pre-treatment drug use patterns, and other characteristics of patients and treatment programs, a favorable evaluation of treatment at discharge had a significant influence on positive treatment outcomes. Joe et al. (2007) conducted a study of 497 MMT clients and categorized them over 3 month intervals into improvers, decliners and continuing users. They found that in the continuing user category clients reported lower TA and less time in treatment. The majority of factors related to treatment program would seem to be somewhat influenced by the counselor and thus a factor of the therapeutic alliance between the client and counselor. Counselors work directly with the client and their treatment planning, usually are part of the team deciding outcomes of policy infractions and implementation of social interventions for the client. Clinical staff have influence on several internal factors that contribute to the clients' perception of the MMT program. Therapeutic alliance is a key factor in engagement and retention in drug treatment (Meier, Barrowclough, & Donmall, 2005).

Deck and Carlson (2005) identified that numerous amounts of research have provided evidence that duration of substance abuse treatment, especially with MMT, results in higher rates of improved outcomes. This study has a goal of increasing retention rates within a cost-

effective model. Therefore, this study aimed to evaluate the theory that TA is an important contributing factor that would significantly improve retention rates (Palmer et al., 2009; Kelly et al., 2010; Joe et al. , 2001; Meir et al., 2005). The aim was an evaluation of the effect of TA for predicting increased retention and compliance in MMT. The discussion of the influence of TA on treatment retention and compliance is discussed in more detail through presentation of past research in Chapter 2.

Definition of Key Terms

Clinical staff: For the purpose of this study the clinical staff members include the therapy staff member and the case manager.

Compliance: Compliance is defined as attendance to scheduled individual and group sessions in MMT.

Group session: Group sessions are group substance use or mental health psychoeducational or process group sessions that the client has been required to attend by the clinical staff members and facilitated by clinical staff members. For the purpose of this study it does not include AA/NA, Smart Recovery or other peer ran social support groups not facilitated by a clinical staff member.

Individual session: An individual session is any session schedule with the client between the client and clinical staff member for the purpose of counseling or treatment progression discussion. This does not include appointments for administration of methadone or prescriber evaluations.

Methadone: Methadone is a synthetic narcotic analgesic used for treatment of people dependent on opioids (Center for Substance Abuse Treatment. Medication-Assisted

Treatment for Opioid Addiction in Opioid Treatment Programs. Rockville (MD): SAMHSA, 2005). Methadone is also used for other medical purposes such as treatment of pain (Rosenblum, Marsch, Joseph & Portenoy, 2008, p.405; Toombs & Kral, 2005). but for the purpose of this research the focus is purely on the treatment of opioid addiction. The purpose of methadone is to keep the individual from experiencing withdrawal symptoms, control the cravings for illicit use and when dose is sufficiently high enough it produces blocking of the effects of illicit opioid drugs (Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs).

Methadone Maintenance Treatment (MMT): A program in which opioid addicted individuals receive daily doses of methadone as a medical intervention, under the guidance of a prescriber with monitoring. Methadone maintenance is a long-term therapeutic intervention for dependence to heroin and other opiates **(**Centers for Disease Control and Prevention, 2002; National Institutes of Health, 1997).

Pharmacological interventions: For the purpose of this research the only pharmacological intervention included is an agonist (methadone).

Psychosocial interventions: For the purpose of this research these were interpreted as any non-pharmacological intervention carried out in a therapeutic structure by a clinical staff member with an individual client or within the confounds of a group of clients.

Retention: Retention is defined as length of stay in MMT.

Substance Use Disorder: The newest version of the Diagnostic and Statistical Manual (DSM): DSM-5 was released in May 2013. In this version of the DSM Substance Use Disorder is a singular diagnosis which combines substance abuse and substance dependence.

In order to be diagnosed with Substance Use Disorder the patient must meet at least 2 of the 11 criteria for the diagnosis. The criteria are very similar to those outlined in DSM-IV for abuse and dependence combined. A patient meeting 2-3 if the criteria indicates mild substance use disorder, meeting 4-5 criteria indicates moderate, and 6-7 indicates severe (American Psychiatric Association (APA), 2013, 541).

Diagnostic Criteria in relation to Opioids

- Continuing to use opioids despite negative personal consequences
- Repeatedly unable to carry out major obligations at work, school, or home due to opioid use
- Recurrent use of opioids in physically hazardous situations
- Continued use despite persistent or recurring social or interpersonal problems caused or made worse by opioid use
- Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount
- Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal
- Using greater amounts or using over a longer time period than intended
- Persistent desire or unsuccessful efforts to cut down or control opioid use
- Spending a lot of time obtaining, using, or recovering from using opioids
- Stopping or reducing important social, occupational, or recreational activities due to opioid use
- Consistent use of opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using opioids

- Craving or a strong desire to use opioids (APA, 2013, p. 541)

Therapeutic Alliance: There are variations in the report of the definition of therapeutic alliance, for the purpose of this study it will be defined as the ability of the therapist and client to work together on common tasks and goals and the affective nature of the relationship and identified by self-report of the participant, measured as a raw score of 36 or above on the Session Rating Scale.

Assumptions

1. The study is based on the prior evidence that suggests that methadone treatment is the most effective treatment for opioid addiction and it is consistent across age, cultural and gender dimensions.

2. The clients are able to form some type of therapeutic alliance with clinical treatment providers through direct contact. Furthermore, that clinical staff makes adjustments as necessary for cultural and other factors.

3. The SRS is a reliable and valid assessment instrument that will measure therapeutic alliance among participants from the perspective of the client.

4. That retention in methadone treatment increases positive outcomes.

5. Participants were honest when scoring the SRS.

6. Participants accurately reported their drug use history, demographics and other self-reported information.

7. Reports of the results of drug screenings are accurate.

8. The reports of number of sessions the client has attended are accurate.

Scope and Delimitations

This study was based on research stating that report of therapeutic alliance increases retention and compliance in social programs or interventions, and this study intended to apply that same concept to evaluate if it also has the same effect in regards to MMT specifically. But there may be numerous reasons for program retention and compliance. In order to control for those potential variables that have already been researched, they have been included in the demographic information and were included in the analysis.

Sociodemographic predictors for retention age at admission, keeping good relationship with family, source of income, employment, race, education, marital status, living in rural area and involvement in the criminal justice system (Maura, Nwakeze & Demsky, 1998; Yang, Lin, Li, Long, Li, Luo, 2013; Zhang et al., 2013). This study will only look at sociodemographic predictors available in the charts of the sample participants; age, gender, employment status, race, marital status and peak dosing level.

The population included for the purpose of this study is opioid dependent male/female clients, age 18+ years old, who have been receiving MMT for at least 1 year in a non-profit agency in Arizona. Influences on external validity are presented in the limitations section as are potential generalizability issues related to the population.

Limitations

1. A significant limitation of this study relates to the selection bias due to the small sample size in comparison to the national population of MMT clients. In the United States alone it is estimated that 151,882 clients are in outpatient methadone treatment for opioid addiction (The National Substance Abuse Treatment System, 2003).

2. The study only examined individuals that were enrolled in outpatient MMT program treatment modality; therefore, those in a higher treatment level or in a different environment (e.g. PCP office) might exhibit different retention rates.

3. There is also a possible geographic influence as the study's target population is limited to one state Arizona, so it is difficult to generalize to other areas of the nation. Results from this study cannot be generalized to the population as a whole.

4. The study's participants could possibly provide false answers on the self- reported demographic information; thereby, the data would be inaccurate.

5. The study is limited to participants participating in MMT solely for the treatment of opioid addiction and not pain management.

6. The study's internal and external validity could be affected by the individual's previous treatment history, the existence a co-occurring disorder, age and gender of the client, family history of SA, history of physical, psychological, or sexual abuse, or type of substance being used.

7. Another significant limitation is within the measurement bias related to the self-reporting nature of the study from the clients' perspective, clinical staff's perspective and the influence of the client and clinical staff desiring to present themselves in a favorable manner. One other limitation is the intervention (exposure) bias related to the inability to ensure that every survey question with each client was scored precisely in the same manner (This will be discussed in more detail in Chapter 3 under the Session Rating Scale section).

Significance of Study

This study contributes to the limited existing research on the effect of TA from the clients' perspective. The significance of TA within a target population of individuals in outpatient MMT and the retention of these clients was fully examined, with the goal of providing guidance to clinicians on developing treatment that will address improving alliance to reduce attrition rates in MMT. The researcher anticipates that the findings of this study will stimulate new treatment methodologies that would reduce attrition rates within MMT.

Social Change Implications

The goal of this research was to offer MMT a focus on TA which may be currently understated in MMT in order to influence increased retention and compliance rates, thus reducing the negative impacts and costs factors. Training and implementing a focus on TA to increase successful MMT program treatment is an inexpensive, easily initiate and relatively quicker method than reevaluating internal methodologies such as instructional materials. This could allow the costs and risk factors to be reduced which is currently a concern in mental health and substance abuse treatment.

Summary of Chapters

Research has linked that the length of MMT over 12 months is associated with lower risks of relapse, criminal justice involvement, disease risks and improved quality of life outcomes (Kayman et al., 2006). It takes time to stabilize areas such as returning to a normalized brain functioning level, ability to control triggers and urges and stabilization in environment (e.g. employment, housing, social and family relationships and etc.), and success with MMT is more likely if there is stabilization in these areas. Therapeutic Alliance

has been shown to have an impact on the progress a client makes in treatment (Joe et al., 2007) and likelihood of clients being retained in MMT at 12 months (Kelly et al., 2010).

Chapter 1 provides a brief overview of the study's purpose in examination of the effect of TA. Chapter 2 reviews the literature delineating the effects on successful methadone treatment. Chapter 3 details the research methodology used in the study. Chapter 4 reviews the description of the sample, reviews the hypotheses, discusses the data collection process and presents the results. Chapter 5 discusses the implications of the results, the limitations of the study, summarizes and offers suggestions for future studies.

Chapter 2: Literature Review

My purpose in this study was to evaluate whether therapeutic alliance is a predictor of methadone treatment outcomes, defined as retention and compliance. The purpose of the literature review is to review research supporting TA as a contributor for successful treatment outcomes. Because there was limited research related to TA and methadone in combination, I focused on two distinct subjects: TA and methadone maintenance treatment. The primary factors related to successful treatment outcomes in MMT is retention and compliance in treatment. I examined in the variable of therapeutic alliance as a contributor of successful outcome defined by retention and compliance.

Organization of the Chapter

I will present a scholarly conversation on methadone treatment in general and TA research and links why research into the effect of TA on methadone treatment retention is warranted. This chapter begins with a description of the literature search and the results related to how and why methadone treatment is one of the preferred forms of treatment of opioid dependence, the definition of *opioid dependence*, and research prevalence of opioid addiction. Discussion will include why opioid dependence is a significant problem, alternative methadone treatment options, and goals of opioid dependence treatment. Completing the discussion with the reason retention in methadone treatment is important, history and research on TA in treatment, and how development of improving TA can be a cost effective way to increase methadone maintenance treatment retention. The review revealed the economic costs of opioid dependence and the costs to society. The literature reviews on TA offered information related to success rates using therapeutic alliance for

various disorders and treatment applications. The chapter ends with an overall summary of the information presented. The literature review chapter expands on the introduction and background information presented in Chapter 1.

Literature Search Strategy

The literature on the research gathered for this review was obtained from September 2008, to June 2014, from various journals at various libraries, and a variety of electronic databases both through Walden University's library as well as other university libraries and online resources. The variety of electronic databases that were searched to gather relevant resources included ProQuest, Academic Search Premier, ERIC, Funk and Wagnalls, Mental Measurements Yearbook, PsycArticles, PsycBOOKS, PsycINFO, SocINDEX with Full Text, PsycEXTRA, Psychology: A SAGE Full-Text Collection, Wiley Online Library and Academic Search Complete/Premier, Google Scholar and Sciencedirect. Requirements and regulations regarding opioid treatment programs were acquired through access of Title 42 of the Code of Federal Regulations (CFR), Part 8. Online sites accessed for research included: Texas Christian University, University of Phoenix Library, and Arizona State University Library, US Department of Health and Human Services, National Institute of Drug Abuse (NIDA), Centers for Disease Control, Psychotherapy.net, White Rose Research online and SAMHSA. I acquired numerous hard copies of journals either through subscription or through professionals who work in the field and allowed me to use their resources.

I used the following words or phrases in the search for articles: *methadone, history of methadone treatment, drop out from opioid treatment, retention, opioid treatment, substance abuse, substitution therapy, opioids, opioid guidelines, indicators of successful treatment for*

methadone treatment, goal of methadone treatment, opioid abuse, opioid misuse, nonmedical use of psychotherapeutic drugs, nonmedical use of opioids, history of methadone treatment, counseling rapport, working alliance and *therapeutic alliance.* In addition, books, statistical reports, and factsheets, and I reviewed websites sponsored by national research agencies such as NIDA and SAMHSA to support the review.

As I conducted the literature review the utilization of methadone as a treatment of opioid dependence was made clearer as well as defining successful methadone treatment. An understanding of opioid dependence and its effects on society assisted with an understanding of the need for successful treatment means and ways to recognize successful treatment. The effect of TA within treatment modalities revealed how it contributes to the concept of successful treatment regardless of the modality implemented.

The first section of this review addresses the history of methadone as a treatment for opioid dependence, physical and psychological effects of opioid dependence, the economic effects on society and a comparison of treatment for opioid dependence.

A Historical Perspective of Methadone Treatment for Opioid Dependence

During the 19th century opioids or medications with synthesized opium, were one of the most prescribed medications (Leavitt, 2000). The consequence of this was an epidemic of persons who became dependent on opioids. This epidemic affected people across socio-economical lines and therefore with that factor and the mass of people who developed the dependence, the problem came into public view. These opioid dependent individuals were not just the undesirable, these were the middle and upper middle class that were mothers, fathers, professionals therefore including white collar workers (Leavitt, 2000).

The theoritical framework of this study is Methadone Matintence Therapy (MMT) and that retention in MMT for opioid addictiton reduces withdrawal symptoms from opioids, and contributes to prevention of infectious disease spread, prevents illicit drug use and criminal activity associated with drug use, and decreases overdose potential and interpersonal difficulties (Ward et al., 1999; Reisinger et al., 2009; Krambeer et al., 2001). Methadone became a treatment for opioid dependence in 1964 as a response to post World War II opioid dependence in New York City (Joseph, Stancliff, & Langrod, 2000). In the 1963 Dr. Vincent Dole and Dr. Marie Nyswander conducted an experiment with chronic heroin dependent persons utilizing pharmaceutical opiates to treat heroin dependence (National Alliance of Methadone Advocates (NAMA), 2003; Leavitt, 2000). When Dr. Dole and Dr. Nyswander did not get the results they desired and decided to use a synthetic opioid called methadone. Methadone did not produce the sedated effects prior attempts at treating with pharmaceutical opiates had, and yet the patients were no longer focused on drug seeking and returned to activities they had participated in prior to their dependence (NAMA, 2003). This was when methadone treatment was developed for opioid addiction.

Methadone treatment became a topic of discussion and went under great scrutiny when it was suggested that methadone was as addicting (Winick, 2001). The difference was that methadone was much less expensive and patients could continue to function in normal activities day to day. Still the medical community and the public struggled with the idea of exchanging one dependence for another. In 1998 Mayor Giuliani of New York City lobbied against methadone maintenance treatment clinics (Winick, 2001; Leavitt, 2000) and in 1999 Senator John McCain introduced a bill to limit length of treatment with methadone (Leavitt,

2000). The standard of clinics that exist today is harm reduction through maintenance treatment. The current regulation of opioid treatment programs is laid out in Title 42 of the Code of Federal Regulations (CFR), Part 8 and states all opioid treatment facilities must have current valid certification through SAMHSA (section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)). This regulation doesn't stop lobbying against methadone maintenance treatment or those in office from submitting bills to attempt to change the regulation, but it does offer protection for Opioid Treatment Programs to provide methadone maintenance within the regulations until something in the regulation changes.

What Is Opioid Dependence or Abuse?

Opioids are included in a class of drugs that encompass both natural and synthetic drugs. There are four classes of opioids: Phenanthrenes (morphine, codeine, hydromorphone, levorphanol, oxycodone, hydrocodone, oxymorphine, buprenorphine, nalbuphrine, and butorphanol), Benzomorphines (pentazocine), Phenylpiperidines (fentanyl, alfentanil, sufentanil, and meperidine) and Diphenylheptanes (propoxyphene and methadone) (Trescot, Datta, Lee, & Hansen (2008). The source for all natural opioids is the poppy papaver somniferum; there are synthetic opioids made in a lab and semi-synthetic opioids which are a mixture of the natural opioids synthesized (e.g. heroin, oxycodone and hydrocodone) (U.S. Department of Justice Drug Enforcement Administration, 2011).

Opioid dependence is a chronic, relapsing substance abuse disorder that is often life-threatening and has high rates of mortality (Scherbaum & Specka, 2008). Life-threatening describes the potential of over dose (OD), the potential of HIV/AIDS and potential dangers

of the life style in general (Scherbaum & Specka). The American Psychiatric Association (2013) describes the DSM-V criteria for substance use disorder as:

Substance Use Disorder: A singular diagnosis which combines Substance Abuse and Substance Dependence. In order to be diagnosed with Substance Use Disorder the patient must meet at least 2 of the 11 criteria for the diagnosis. The criteria are very similar to those outlined in DSM-IV for abuse and dependence combined. A patient meeting 2-3 if the criteria indicates mild substance use disorder, meeting 4-5 criteria indicates moderate, and 6-7 indicates severe (APA, 2013, 541).

Diagnostic Criteria in Relation to Opioids

- Continuing to use opioids despite negative personal consequences.
- Repeatedly unable to carry out major obligations at work, school, or home due to opioid use
- Recurrent use of opioids in physically hazardous situations.
- Continued use despite persistent or recurring social or interpersonal problems caused or made worse by opioid use.
- Tolerance as defined by either a need for markedly increased amounts to achieve intoxication or desired effect or markedly diminished effect with continued use of the same amount.
- Withdrawal manifesting as either characteristic syndrome or the substance is used to avoid withdrawal.
- Using greater amounts or using over a longer time period than intended.

- Persistent desire or unsuccessful efforts to cut down or control opioid use.
- Spending a lot of time obtaining, using, or recovering from using opioids.
- Stopping or reducing important social, occupational, or recreational activities due to opioid use.
- Consistent use of opioids despite acknowledgment of persistent or recurrent physical or psychological difficulties from using opioids.
- Craving or a strong desire to use opioids (APA, 2013, p.541).

Prevalence of Opioid Abuse in the United States

According to United Nations Office on Drugs and Crime (UNODC) (2011), 40% of global opioid users are located in North America. The United States uses 80% of the world's supply of opioids (Manchikanti, 2007; Institute of Addiction Medicine (IAM), 2014). One of the major contributors to this statistic is the abuse of prescription drugs which in the United States rates second only to marijuana use (UNODC, 2011; SAMHSA, 2010). From 1992 to 2003 there was a 140% increase of opioid prescription painkillers (IAM, 2014), even though narcotic analgesics are pain relievers that can become habit forming. Manchikanti, Helm II, Fellows, Janata, Pampati, Grider and Boswell (2012) stated that narcotic analgesics prescriptions exceeded 238 million in 2011. According to the 2010 National Survey on Drug Use and Health (SAMHSA, 2011) there were 5.1 million abusers of pain relievers (opiates) which does not include those abusing opioids for other than pain (illicit drug use). SAMHSA further stated in that same report that one in six or 17.3% of those users of non-therapeutic opioids had obtained opioids from a prescription written by a licensed physician. Perhaps this

suggest that due to the use of opioids for pain treatment, the opioid dependence epidemic has grown to more than just those that participates in illicit opioid drug use.

Effects of Opioid Abuse on Society

Ruetsch (2010) reported the costs of opioid abuse at around half a trillion dollars factoring in social, medical and criminal related costs. Rinaldo, S. and Rinaldo, D. (2013) stated that according to the 2011 report by the CDC illicit use of opioid pain relievers costs U.S. health insurers approximately $72.5 billion dollars each year in healthcare costs, and that the opioid overdose fatalities are comparable to those for motor vehicle incidents for individuals under age 65. Disley, Mulcahy, Pardal, Rubin and Ruggeri (2013) conducted a research study to look at evaluating the costs of opioid dependence in Europe, including: health impacts (mortality, morbidity), effects on employment, impacts on children and families, and crime and victimization. That study found that opioids were present in 80-90% of the drug related deaths in Europe. The most common cause was overdose, followed by trauma (e.g. accidents), suicide and disease-specific mortality (for example, HIV/AIDS and liver disease). Sullivan, Metzger, Fudala and Fiellin (2005) stated that 10% of all new HIV infections in 2003 were related to sharing of needles with injection drug users.

There are numerous potential work-related costs such as shutdowns or having to pay to bring in temporary staff to cover shortages by those not coming in to work due to their opioid abuse. Ruetsch (2010) stated that in the United States the National Survey on Drug Use and Health (NSDUH) survey, individuals miss more than 2.2 days of work when abusing opioids than those who do not abuse opioids (.83 days per month). Birnbaum, White, Schiller, Waldman, Cleveland and Roland (2011) reported that $25.6 billion (46%) of costs

are related to workplace losses in the United States. In 1996, Mark, Woody, Juday and Kleber (2000) reported the overall loss of specifically heroin dependence was $21.9 billion, of which the largest portion (52.6%) was related to the workplace indirect costs.

Impact on families of opiate abusers is difficult to measure, it is often an emotional cost and thus studies reporting these costs as a monetary value were not located. But some of the monetary costs for families would also include loss of monies due to loss of wages, court costs, lawyer fees, providing monies to incarcerated individuals, treatment costs and other costs.

Mark, Woody, Juday and Kleber (2000) stated that they found the cost of heroin dependence related to criminal justice was $522 million. Birnbaum, White, Schiller, Waldman, Cleveland and Roland (2011) identified criminal justice costs related to opioid prescription abuse in 2007 was $5.1 billion dollars. Criminal justice costs include policing, legal, incarceration and cost to crime victims.

The costs of opiate abuse effects more than just the United States. The overall social costs for Canada was reported by Wall, Rehm, Fischer, Brands, Gliksman, Stewart…Blake (2000) to be about 5.086 million Canadian dollars related to crime victimization (44.6%) and law enforcement (42.4%), followed by productivity losses (7.0%) and the utilization of health care (6.1%). The overall costs of opioid dependence are complicated and often not fully able to be expressed in an easily applied monetary value.

Medication Assisted Treatment Approaches for Opioid Abuse/Dependence and Effectiveness

Clonidine, Levomethadyl acetate, Naltrexone, Buprenorphine, and methadone are common medications used for treatment of opioid addiction. Clonidine is used to treat withdrawal symptoms such as anxiety, agitation, muscle aches, sweating, runny nose, and cramping but not as a long-term treatment to avoid relapse (Gold, Pottash, Sweeney, & Kleber, 1980). Farrell, Wodak and Gowing (2012) stated that methadone and buprenorphine are options for opioid treatment in 73 countries and offer the strongest evidence of effectiveness than other treatments for severe heroin dependence.

Anesthesia-assisted rapid opiate detoxification (AAROD)

AAROD was developed during the 1980s and the goal was to reduce the discomfort of withdrawal. Detox under anesthesia involves placing the individual under anesthesia and injecting large doses of opiate-blocking drugs. There is controversy regarding this type of detox due to several deaths associated with the procedures, particularly when it is done outside a hospital. The Center for Disease Control and Prevention (CDC, 2013) conducted an investigation into a clinic in New York City where it was reported that three individuals experienced adverse effects that led to the death of one those. Of the 75 patients at that New York City clinic who underwent AAROD over a nine-month period in 2012 it was reported that two of the individuals died, and five others were hospitalized. Findings on AAROD suggest it has a potential for high risk of severe adverse effects and it does not appear to reduce subjective opioid withdrawal symptoms more than traditional opioid detoxification modalities (CDC, 2013).

Levomethadyl acetate

Levomethadyl acetate hydrochloride (LAAM) was approved in 1993 by the US Food and Drug Administration for the treatment of opioid dependence (Jones, Strain, Bigelow, Walsh, Stitzer, Eissenberg, & Johnson, 1998). LAAM works similar to methadone as it is a μ-opioid agonist and produces opioid blockade, and due to the longer half-life dosing frequency is only three times a week. Jones, Strain, Bigelow, Walsh, Stitzer, Eissenberg and Johnson conducted a study with 180 individuals on three different levels of LAAM (low, medium and high) doses for the purpose of induction. They concluded that higher does can be safely achieved in 17 days but had risks of patient dropout. They further identified that opioid agonist adverse effects are also higher than the low and medium doses in which safe, stable induction can be achieved within seven days. An oral solution of levomethadyl acetate HCl (ORLAAM) developed by Roxane Laboratories Inc. was approved in 1993 for treatment of opioid dependence treatment for individuals that failed to show evidence of acceptable response or intolerability to other forms of medicated opioid treatment. In 2003, Roxane Laboratories, Inc. notified the Food and Drug Administration (FDA) that ORLAAM was being discontinued. The FDA (2011) investigated and determined that ORLAAM oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness. Preda (2013) reported that there have been several cases of cardiac arrhythmia and death related to LAAM resulting in it being removed from the market in Europe and the FDA gave it a black box warning in the US.

Naltrexone

Naltrexone is an opioid antagonist; thus, it blocks the euphoric effects of opioids (ADIS International Limited, 2012). In a review of 15 studies of 1076 clients there was variation in the reporting of effectiveness of naltrexone in treating opioid dependence; the variable that influenced the effectiveness appeared to be retention in treatment and in with high retention there did appear to be significant evidence of reduced positive opioid positive drug screenings (Johansson, Berglund, and Lindgren, 2006). Minozzi, Amato, Vecchi, Davoli, Kirchmayer and Verster (2011) conducted a review of 13 studies with 1158 participants that compared those treated with naltrexone versus placebo or no pharmacological treatments. This study showed no statistically significant differences, therefore the authors determined there was no evidence to support naltrexone as a maintenance therapy.

Buprenorphine

The FDA approved buprenorphine products for use in opioid addiction treatment at the end of 2002. Buprenorphine is a m μ-opioid partial agonist that suppresses withdrawal and cravings, but it also works as a partial antagonist which means it has a "ceiling effect" (Ling and Smith, 2002). Ceiling effect means that individuals prescribed buprenorphine achieve a dose level where higher doses cause no additional effects, leading to less potential of overdose (Preda, 2013). Buprenorphine is an opioid, and therefore individuals may still experience typical opioid agonist effects such as euphoria and respiratory depression but at its “ceiling effect” those effects are no longer experienced. Farrell, Wodak and Gowing (2012) report that retention with buprenorphine in

treatment is lower than with Methadone treatment; for every nine individuals receiving methadone treatment, one more than treated with Buprenorphine will be retained.

Methadone maintenance treatment (MMT)

Development of MMT occurred in the U.S. around 1964 when it was used as a medical response to the heroin epidemic in New York City related to vets returning from World War II (NAMA, 2003). Dr. Vincent Dole and Dr. Marie Nyswander conducted an experiment with chronic heroin dependent persons utilizing pharmaceutical opiates to treat heroin dependence (NAMA, 2003). They did not get the results they desired and decided to use a synthetic opioid called methadone. What they found is instead of the sedated effects prior attempts at treating with pharmaceutical opiates had, the patients were no longer focused on drug seeking and desired to return to activities they participated in prior to their dependence (NAMA, 2003); methadone treatment was developed. Farrell, Wodak and Gowing (2012) stated that methadone is an option for opioid dependence treatment in 73 countries and offers the strongest evidence of effectiveness compared to other treatments for severe heroin dependence.

Methadone hydrochloride is a synthetic opioid agonist at the m-opioid receptor that persists for up to 48 hours after oral administration. Methadone maintenance treatment (MMT) is one of the most widely known pharmacotherapy treatments for illicit opioid dependence (Krambeer, McKnelly, Gabrielli, & Penick, 2001). At therapeutic dosages, methadone appears to suppress opioid cravings and the preferred therapeutic treatment is at doses of 50 mg. or higher (Farré, Mas, Torrens, Moreno, & Camí, 2002). The goal of MMT is to help opioid drug users return to productive lives and with methadone actual monetary

costs are less than buprenorphine (Farrell, Wodak, & Gowing, 2012). ADIS International Limited (2012) state that MMT has been associated with a reduction in criminal behavior and HIV risk behaviors. One serious potential risk with methadone is misuse and overdose and the risks are highest in the first month of treatment (ADIS, 2012).

Opioid Dependence Treatment Goals

The Federation of State Medical Boards (2013, p.3) stated that "the primary goals of addiction treatment are to reduce or stop opioid use, to improve the patient's overall health and social functioning, and to help the patient avoid some of the more serious consequences of opioid addiction." The approaches in methadone treatment to achieve these goals range from harm reduction, to long-term maintenance, to abstinence from all illicit drugs.

Goals of MMT are to address the issues stated previously: reduce high rates and costs of medical issues (e.g. HIV disease spread and overdoses), reduce criminal related costs, reduce dependence on government funded programs caused by unemployment rates, and improve overall social functioning. There is some heterogeneity in the research related to which treatment is the most cost-effective to treat opioid dependence but the majority state that methadone is cost-effective (Barnett & Hui 2000; National Institutes of Health, 1997).

Importance of and Factors of Retention in Methadone Treatment

Research has shown that the first year of MMT is critical mile marker in successful outcomes, and discharge prior to this is often related to clinic policy (Reisinger et al., 2009). Research studies have found that high rates of relapse to opioid use when methadone treatment is discontinued such as due to programs that focus on detoxification and dose reduction towards abstinence (Magura and Rosenblum, 2001; Gossop, Marsden, Stewart, &

Treacy, 2001). Return to illicit opioid use also means a return to opioid use behavior, criminal activity, high risk disease spread behavior (e.g. sharing needles), decreased pro-social and family activities, reduced stable employment leading to more dependence on government funded programs, and higher mortality rates. A study of 307 opioid dependent individuals found that participants were 3 times more likely to die when not participating in MMT (Caplehorn, Stella, Dalton, Cluff, & Petrenas, 1994).

Rates of retention are significantly lower in programs that discharge clients related to rule violations and financial inability to pay (Deck & Carlson, 2005; Strike, Gnama, Urbanoskia, Fischer, Marsh, & Millson, 2005). Mitchell, Morioka, Schacht Reisinger, Peterson, Kelly, Agar, and et al. (2011) reported that clients' perspective of recovery was based more on positive progress forward toward their goals that may include some steps backwards (e.g. relapses) during the process.

If we look at comparing length of treatment, Farre, Mas, Torrens, Moreno, and Cami (2002) reported retention rates from 20% at 17 weeks to 85% at 40 weeks. Strike, Gnama, Urbanoskia, Fischer, Marsh and Millson (2005) found in a study conducted in Italy, that client's retention rates were as high as 40% at one year of MMT and 50% of patients remained in treatment for 730 days or more. They further found that methadone dosage, age and clinic policy were the most important factors determining retention, while number of treatment episodes decreased likelihood of retention. Fortuin Corsi, Kwiatkowski and Booth (2002) stated that at interviews conducted with clients participating in MMT at 5-9 months, the best predictor of positive outcomes appeared to be still being in treatment and length of treatment.

Much of the research on retention in MMT has provided evidence of the effect of dosing levels on methadone treatment retention (Amato, Davoli, Perucci, et al., 2005; Gossop, Marsden, Stewart, et al., 2001; D'Ippoliti, Davoli, Perucci, et al., 1998; Farré, Mas, Torrens, Moreno, & Camí, 2002). There has been no agreement on the level of effective methadone dosing.

The Theory: Therapeutic Alliance

The field of substance abuse has been slower than other fields in embracing research on the effect of therapeutic alliance on treatment outcomes (Ritter, Bowden, Murray, Ross, Greeley, &Pead, 2002). Perhaps in part it is due to the history of treatment such as therapeutic communities in which practices existed that focused on tearing a client down and then rebuilding them. There was no research found that explained why substance abuse has been delayed in evaluating therapeutic effect on treatment outcomes. Other fields such as mental health, medical practitioners and nurses are researching the relationship of TA and treatment outcomes with various diseases and disorders, symptoms reduction, environments and difficult client cases.

Examination of the therapeutic relationship and its influence has been examined as far back as Freud in 1912. Freud was “aware of deep and intense feelings emerging in the therapeutic relationship” and that these feeling may influence the therapist-client relationship (Pereira, 2010, p. 2). The actual term “therapeutic alliance” was introduced in 1956 by Elizabeth Zetzel as she described the condition of the relationship between the clinician and the client that was a needed component of transference in order for effective analysis to occur (Catty, 2004). Carl Rogers (1957) discussed his view of how “constructive personality

change" could occur, identifying that the therapist needs to hold an unconditional positive regard for the client and provid empathic understanding while communicating this to the client.

Orlinsky, Grawe and Parks (1994) identified that the relationship between the therapist and the client mediated the quality of client participation in treatment and that participation was the most important determinant of outcome. Duncan et al. (2006) stated that research has shown that most of the variance of outcomes in therapy is accounted for by extratherapeutic factors, which are characteristics that facilitate growth from the client and their environment and the TA. Duncan et al. further pointed out that research by Lambert (1992) suggested that 40% of the variance in therapy outcomes was attributable to the client-extratherapeutic factors and he identified that 30% was attributable to the therapeutic relationship. Thirty percent may contribute a large impact to the outcomes of therapy.

Martin, Garske and Davis (2000) conducted a meta-analytic review of 58 published and 21 unpublished studies and found that TA was related to outcomes moderately but consistently regardless of other influences. Knuuttila, Kuusisto, Saarnio and Nummi (2012) found that client alliance ratings in the early stages of the therapeutic relationship were significant predictors of treatment satisfaction at follow-up.

Factors influencing perception of therapeutic alliance

Alliance is the relationship, defined by Merriam Webster Dictionary as:

1: a bond or connection between families, states, parties, or individuals e.g. a closer *alliance* between government and industry

2: an association to further the common interests of the members; specifically: a confederation of nations by treaty

3: union by relationship in qualities

Results by Marmarosh and Kivlighan (2012) suggested that as the therapist and client exhibit more evidence of a positive perception of alliance at the early stages of treatment that there are less reports of negative symptoms. Ritter, Bowden, Murray, Ross, Greeley, and Pead (2002) stated that certain characteristics of the client may influence the outlook on the TA. They noted that with the clients they studied, those with anxiety or lower cognitive functioning viewed the counselor as exhibiting less therapeutic tendencies and that affected the response to treatment as well as the outcomes of treatment. Bordin (1979) acknowledged the influence of personality of the clinical staff member and of the client influences each in meeting the needs of the other. Meier, Donmall, Barrowclough, McElduff, and Heller (2005) noted that clients who reported higher motivation levels, positive coping strategies, strong social support and a secure attachment style reported a higher likelihood of developing good alliances. Deering, Horn and Frampton (2012) conducted a survey of 93 clients receiving opioid substitution treatment (OST), and found that characteristics such as being employed improved reports of treatment satisfaction, while use of benzodiazepine and longer treatment duration (with females) resulted in lower treatment satisfaction. They also found that overall findings indicated a general satisfaction with OST and that in their study many of the participants spoke highly of their clinical staff. Due to this Deering, Horn and Frampton offered key strategies to improve the quality of OST treatment that included many things controllable by staff that would be defined as part of the TA.

The influence of therapeutic alliance on treatment

Joe, Simpson and Broome (1999) found that a strong correlation existed between the subjective components that consisted of ratings of therapeutic involvement (therapeutic alliance) between counselor and client and drug treatment compliance outcomes, including illicit drug use and session attendance. Horvath and Symonds (1991) conducted a meta-analysis of 24 studies, and found there was a reliable, consistent relationship between the working alliance (WA) and therapy outcomes. This relationship existed regardless of the therapeutic approach, length of treatment and number of participants in the study. They also noted the WA was the most predictive factor related to treatment outcome. Arnow, Steidtmann, Blasey, Manber, Constantino, Klein, and... Kocsis (2013) found that regardless of whether cognitive behavioral therapy approach or brief supportive psychotherapy approach was utilized TA was a predictor of outcome. Cournoyer, Brochu, Landry and Bergeron (2007) found that in a study of 248 clients in a drug rehabilitation program there was an increased rate of drop out from treatment when the clients' perception of the counselor was that they lacked understanding, were less involved and when counselors did not believe in the clients' perseverance to treatment. Cooley and Lajoy (1980) found in a study in a mental health clinic that client perceptions of their therapist as understanding and accepting were correlated most highly with self-reported improvement. Barber, Connolly, Crits-Christoph, Gladis and Siqueland's (2009) findings agreed with numerous other studies that early TA predicted the outcome of psychotherapy. Early working alliance between client and therapist consistently predicts retention in substance abuse treatment (Meier et al., 2005;

Knuuttila, Kuusisto, Saarnio, & Nummi, 2012; Crits-Christoph, Johnson, Connolly Gibbons, & Gallop, 2013).

Effect of therapeutic alliance on treatment retention

The length of stay in treatment is one of the most consistent predictors of reduced drug use, fewer arrests, decreased unemployment, and a reduction in health risk behaviors among adults in substance abuse treatment (Simpson, Joe, Broome, Hiller, Knight & Rowan-Szal, 1997; Simpson, Brown & Joe, 1997; Joe et al., 2009). Safran and Muran (2000) suggest that research has provided the evidence that early development of therapeutic alliance affects the treatment outcome and therefore it is the key to resolve issues related to alliance in order to improve outcome.

Brocato and Wagner (2008) found in a study of 141 male offenders that were mandated to long term residential drug treatment that motivation to change was related to retention in treatment, and motivation to change was related to positive reports of TA and response to treatment, although they did not find a direct length to reports of positive TA reports and length of treatment. They did identify that mandated clients may be more focused on leaving treatment if there are no legal consequences than remaining in treatment. This factor could influence the length the stay.

De Weert-Van Oene, G., Schippers, G., De Jong, C. and Schrijvers, G. (2001) reported in their study of 93 clients enrolled in an inpatient treatment that the clients' perception of the TA was one of the important factors in treatment retention predictors. Knuuttila, Kuusisto, Saarnio and Nummi (2012) stated that next to amount of time abstinent, the early report of positive TA by the clinician predicted treatment retention. Kasarabada,

Hser, Boles and Huang (2002) stated that clients that reported more favorable opinions of their counselor showed evidence of longer treatment retention in outpatient treatment. Meier, Donmall, McElduff, Barrowclough and Heller (2006) conducted a study with 187 clients in residential drug treatment in the UK and found that stronger reports of TA resulted in longer retention in treatment.

Ruglass, Miele, Hien, Campbell, Hu, Caldeira and ... Nunes (2012) conducted a study with 223 females with a diagnosis of with posttraumatic stress disorder (PTSD) and substance use disorders examining the effect of TA on treatment outcomes. They had two groups they examined; the first was a cognitive behavioral treatment called Seeking Safety and the other was a Women's Health education group. TA reports were significantly more positive in the Seeking Safety group, although it did appear in both groups more positive reports of alliance resulted in a decrease of PTSD symptomology and better attendance.

Teaching clinical staff therapeutic alliance skills

An important assumption of this study in regards to its social contribution is that therapeutic alliance can be taught. For the purpose of this research the underlying benefit of evaluating the effect of TA is in order to improve the quality of the alliance and thus impact potential quality of treatment with retention in services. If the effect of TA is substantiated, then later research may look at the qualities and characteristics of the therapeutic relationship that can be changed and taught to clinical team members.

Sharpley, Tabary-Collins, Bates, Lee and Fairne (2000) found while being good listeners is important, a balance of listening and responding effectively may be looked on much more favorably by clients. Learning when to respond and how to respond is a skill that

can be taught and learned by clinical staff. Contrary to what some schools have taught, this study found that counselors with greater amounts of verbosity received higher ratings of rapport than counselors who exhibited less verbosity. Sharpley, Jeffrey and McMah (2006) further found that facial expressions that clinical staff use with the client conveys nonverbal communication and can have a significant effect on reports of the clients' perception of rapport. It would be assumed that clinical staff could become aware of their facial expressions and be able to manage them, perhaps through practice in a mirror or other means.

Knox, Hess, Hill, Burkard and Crook-Lyon (2012) found that how a clinician responds to a client can assist the client in experiencing corrective relational experiences (CREs). It is within the therapeutic relationship that the client can experience an awakening in the area of experiencing the value of a healthy relationship, and then can begin to apply that to their other relationships. Levensen (2003) discusses how the difficult clients with maladaptive relationship skills can see how the therapist responds to them differently than others have and can begin to apply that knowledge in knowing they too can interact differently in their current relationships. This takes the skill of the therapist to respond appropriately, be helpful, supportive, and patient, and to avoid negative response to the client that could damage the therapeutic relationship they are trying to build. Once again it would appear that traits such as being helpful, supportive, patient and knowing how to avoid responding negatively could be taught to clinical staff. Safran and Muran (2000) wrote "Negotiating the Therapeutic Alliance" for guidance for the clinician is not only in recognizing negative processes and therapeutic impasses, but in learning how to manage them within the confines of the therapeutic relationship. Saffran and Muran emphasize the

importance of training of clinicians to deal with the negative processes and therapeutic impasses they encounter. Falkenström, Granström and Holmqvist (2013) repeat the sentiments of Safran and Muran, by producing results that show the importance of therapists paying attention to ruptures and work on repairing the therapy alliance.

Summary

This chapter presented the literature associated with methadone maintenance treatment and TA. The review revealed that the prevalence of opioid abuse and the issues related to it (crime, health care and other social factor costs) are significant in the United States. It also provided evidence that methadone maintenance treatment for opioid is a successful and necessary treatment approach. This chapter further provided evidence that retention in methadone maintenance treatment is imperative to successful outcomes and therapeutic alliance may be an important factor in creating retention in methadone maintenance treatment. The mutuality of the relationship in therapy reveals that there are at least two individual perspectives on the therapeutic relationship. The chapter closed with acknowledging that at least some of the components of characteristics (learning when and how to respond, nonverbal and etc.), that affect therapeutic alliance can be taught to clinicians, and that it is the clinical staff's responsibility to repair damage to therapeutic alliance.

In Chapter 3, the research design of the study is discussed. The discussion includes a description of the population and instruments that were used to explore the relationship between therapeutic alliance from both clients' and the clinical staff's perspective and the effect on methadone maintenance treatment retention.

Chapter 3: Research Method

I sought to evaluate the effect of therapeutic alliance specifically on MMT retention and compliance. By focusing on MMT, my goal was to offer another perspective to improve the effectiveness of retention and compliance in MMT by focusing on improving TA with existing staff, as opposed to spending additional money on hiring more staff, buying group materials, or other items. This researcher proposed that clients who have a healthy TA with their clinical staff will show evidence of stronger retention rates and compliance.

The purpose of this chapter to provide a clear overview of the study's design, as well as the reasoning for this design selection. This researcher explained the proposed sample characteristics and size, discussed the data collection process and analysis, and explored the ethical considerations surrounding this study.

The independent variable was therapeutic alliance and this researcher collected the data for therapeutic alliance from clients by accessing a database of the four clinics ran by the agency used for this study. The agency that provided the data for this study collects the information from every SRS at each session. On the SRS, positive TA is measured as scores of 36 or greater. There is no cut off score that would imply a negative alliance, but all scores under 36 are reviewed with the client as the score implies there may be some issue within one or all of the four scales of the SRS. In the Measures section of this chapter I discuss the reasoning for using this instrument, process of collecting the data with this instrument, validity and reliability, and other instrument details.

I intended to examine whether participant-reported level of TA (the independent variable) was associated with improved outcomes as defined by the retention (length of stay)

and compliance (attendance to scheduled group/individual sessions and drug screenings). I hypothesized that high levels of reported TA by participants would result in retention (of at least 1 year) and higher levels of compliance (fewer positive drug screenings and higher rates of attendance to scheduled sessions). The dependent variables (DVs) were treatment retention, as measured by categorizing retention as 1 or more years and compliance divided into two components. The first component of compliance was measured by categorizing each participant's attendance to scheduled sessions of individual and group as attendance compliant or noncompliant, with compliance being measured as 3 or less nonexcused missed sessions per year. The other component of treatment compliance was measured by categorizing participants as treatment compliant and noncompliant based on recorded drug test, with positive compliance being measured as less than 3 positive drug screenings within a year. The nonparametric measure was logistic regression. This researcher performed he statistical analysis using SPSS (V.21).

Research Design and Approach

In this quantitative cross-sectional study, I used a logistic regression analysis in testing the proposed hypotheses. Archival data was used for the analyses in the present study. The data was accessed using a database through an agency in the state of Arizona. The agency used for this study collects various information including client demographic information, drug screenings, session attendance and the results of a TA measure (SRS) from each patient session. This research design is consistent with Hopkins (2000) who claimed that, in quantitative research, the aim is to explore the relationship between the independent

and dependent variables. Measures of the predictor variable of participant perceptions of therapeutic alliance, and the criterion variables of client compliance and retention, were gathered from the clinic records of randomly selected clients who had participated in methadone maintenance treatment at the agency used for this study and who were living in Arizona at the time of their MMT.

The present study was conducted using a quantitative method of inquiry wherein numerical data was collected to explain or predict a phenomenon of interest, it was then converted into categorical responses. Logistic regression is a regression model where the dependent variable (DV) is categorical. All data analyzed for this study was sorted and organized as categorical data. For the purpose of this study, the goal was to gain a clearer understanding of the role of TA on retention and compliance in MMT. Dichotomous indices were computed as follows: Therapeutic alliance was coded as positive (Y) if scores on the SRS were greater or equal to 36 and negative TA was coded (N) for total SRS scores of less than 36. Retention was coded as successful if the client was retained for one year or more (Y); otherwise it was coded as unsuccessfully retained (N). Successful compliance (Y) for drug screening results was coded for those clients whose drug screening reports were negative for any drug other than methadone less than 3 times in a twelve-month period. A case was coded as noncompliant (N) for those clients who show positive drug screenings 3 or more times in a twelve-month period for any drug other than methadone. A case was coded as successfully compliant (Y) for attendance for those clients who had 3 or less unexcused missed attendance sessions in a twelve-month period. A case was coded as noncompliant (N)

for those clients who had more than 3 unexcused missed attendance sessions in a twelve-month period.

From the time of approval by the IRB to the retrieval of the data held in the database by the agency it was four months. A specific report of all the data needed for this study was programmed by the developers to protect access to other information in client charts not needed for the purpose of this study. Once the data was received it took 4 more months to sort through all the data to organize it and an additional two months to complete the analysis of the raw data.

The first step was to review the data looking for missing items, outliers, and review whether the sample meets the assumptions of normalcy required by the proposed analysis. All relevant variables were computed and categorized based on the criteria described previously. A descriptive analysis was then computed calculating frequencies, percentages, means, medians, modes and SD for all relevant variables (e.g. demographic variables, predictor variables, and criterion variables). The initial analysis was completed using a jackknife approach with logistic regression. In testing TA (as measured by the SRS), the first step in the analysis was to remove case one from the complete data set. A logistic regression analysis using SRS scores for the report of TA as the independent variable was completed using the other 263 cases. Then the removed case was tested against the model built by the logistic regression analysis. Then, the second case was removed, and the same process as described above was completed. This strategy of remove one case, build the model, test the one case was completed a total of 264 times (for all 264 cases in the dataset). The series of analyses provided information on the relative strength of the SRS in predicting retention.

Furthermore, the remove one-build the model-test the case classifications provided valuable information about the effectiveness of a jackknifed logistic regression model for those in MMT in Arizona.

In testing compliance (measured by drug screening results), a logistic regression analysis using SRS scores for the report of TA as the dependent variable was completed using the other 263 cases. Then the removed case was tested against the model built by the logistic regression analysis. In addition, the test classified the case as treatment compliant or non-compliant (based on drug screening results). Then, the second case was removed, and the same process as described above was completed. This strategy of remove one case, build the model, test the one case was completed a total of 264 times (for all 264 cases in the dataset). To evaluate session attendance for compliance, the same steps were again repeated for the 264 cases as done for drug screening results, only this time the test classified the case as treatment compliant or non-compliant (based on attendance for sessions).

To be included in the study the client participant had to be over the age of 18 and be a current or discharged client consistently receiving administration of methadone through the approved non-profit methadone maintenance treatment clinic (at the agency used for this study) in the state of Arizona. Demographic information related to age, race, gender, and marital status were collected on each participant through review of the database information from client charts. Details of how this study addressed confidentiality and anonymity are provided in the procedures section of this chapter.

Population

The target population for this study was adults over the age of 18 who were receiving or had received MMT for opioid dependence, in one of the four methadone maintenance treatment outpatient programs run by the agency used for this study in the state of Arizona. In addition to aforementioned criteria, there needed to be availability to sufficient data required for this study; demographics, SRS scores, drug testing results and attendance records. For the purpose of this study, the clinic was a state funded treatment program. Due to HIPPA regulations it is very difficult to track the numbers of clients involved in private pay methadone maintenance treatment that could occur through primary care physicians (who have the appropriate credentials) or other private inpatient and outpatient facilities as there is no central data base that offers that information. The agency that runs the MMT programs used for this study serves private pay clients, insurance and AHCCCS (which is Arizona's program for Medicaid) and all types of payment clients were included in the study.

The original population consisted of 926 participants who had or currently were receiving methadone maintenance treatment services from one of four methadone clinics in Arizona, operated by the agency used for this study. After sorting through all the data for the 926 participants, 264 participant's data included all the components needed for this study.

Demographics that were gathered from archival data on the participants for the purpose of future studies. The demographics collected included clinic, age, gender, race, employment status, and marital status. The effect of these demographic variables has been researched previously in regards to MMT retention and compliance (Clausen et al., 2009;

Yang, Lin, Li, Long, Li, Luo, 2013; Zhang et al., 2013; Huissoud et al., 2012) but they were not analyzed in this study.

Sampling

There were three different reports of client's information that was utilized for this study from clients at four different methadone maintenance clinics. The three reports were the participant list, SSRS/ORS scores and drug screening results. After sorting through the data of the original 926 participants, 264 participants were selected into the sample because those cases included all the information needed for this study. The remaining participants were eliminated from the study for missing critical data (no ORS/SRS scores, insufficient or no reports of drug screenings, or because of different classification used by some of the clinics reports made it impossible to match critical pieces of data with the appropriate participant).

To be included in the sample, participants had to be currently enrolled or discharged from participating in MMT for opioid addiction at a licensed and publicly funded facility at the agency used for this study, in the state of Arizona and participated in the MMT program for a period of at least one year. To be eligible for this level of care, individuals must have had an opioid use affect their lives in some manner. For the purpose of this study, the clients that were currently enrolled but had not been receiving services for at least 2 years were excluded from the study.

The proposed sample size for this study was established by using Cohen's table (Cohen, 1992; p. 158) to estimate the number of participants needed. For one predictor of therapeutic alliance a sample size of at least 76 participants per group of clients would be

required to ensure adequate power to detect medium treatment effects with an alpha set at .05 and a power of 80. This study had 264 participants, thus meeting the criteria for power.

Overview of the agency used for this study their MMT Program

The agency used for this study is a non-profit community-based provider of behavioral health and substance use services located throughout the greater Phoenix area and rural Maricopa, Gila, Pinal, Mohave, Coconino, and Yavapai Counties in Arizona. They currently have more than 115 sites and over nine hundred employees. The agency used for this study was established in 1969 as a federally funded program and became incorporated in 1974 as a 501(c) 3 non-profit.

The agency used in this study believes that recovery is possible and that pharmacological management is a vital tool in the recovery effort. Methadone and Suboxone services, unlike other substance abuse treatment, they are not based on a program of abstinence. Methadone Maintenance treatment is a long-term process that is individually paced and may require lifelong participation in the program. The agency's methadone maintenance program used in this study, offers counseling (individual, family, and group), case management, psychiatric evaluations/medication monitoring along with methadone and suboxone (Opioid Assisted Treatment). The aforementioned service and any additional services are put into the client's treatment plan.

The program performs random urine screenings for drugs. Missed screenings are considered to be a positive indication of substance use, and refusal for drug screenings along with positive drug screenings are monitored and reviewed with the client in staffing's. A possible result of too many positive drug screenings or non-compliance to other conditions of

the treatment plan could result in discharge from the program. The agency used for this study does not immediately discharge for non-compliance; through staffing with the client, updated goals, reinforcement of current goals, dosing level decisions are reviewed and addressed to offer the client the best opportunity at success. Non-compliance is taken seriously and on some occasions, continued non-compliance can result in administrative detox and discharge from the MMT program.

Procedures

This study was presented to the Institutional Review Board (IRB) of Walden University for review because the proposed methodology involves information of individuals engaging in MMT. This researcher also contacted the Chief of Clinical Services for the agency used for this study and arranged a meeting to discuss the research process. During the meeting, this researcher provided an overview of the research process. The procedures were explained, and that it did not appear that were any potential issues that would impact their clients directly. Also discussed were any potential issues that could impact their clients for example if somehow the data were compromised during transmission, or hard copy data got into the hands of anyone outside of the study. All security precautions this researcher would be taking were discussed. After all the questions and concerns were discussed, the Chief of Clinical Services signed a Data Use Agreement (See Appendix A). In order to keep each individual's data confidential, numbers were utilized in place of names on all research material. Confidentiality is a key factor in research. Since the study was conducted using archival research method, drawn from clients' record review, a prior consent was not required. After IRB approval the archival data was obtained from three different databases

through the agency used for this study from the four methadone clinics they operated. A specific report of all the data needed for this study was programmed by the developers to protect access to other information in client charts not needed for the purpose of this study. Data was sorted and imported into an excel spreadsheet. The data was then imported into SPSS (V.21) for analysis.

A rational for the utilization of existing agency data was offered by Dobrof, Dolinko, Lichtiger, Uribarri and Epstein, (2002), whereas they suggested: it is less intrusive on clients and staff, issues are avoided that come up with low response rates and time consumptions noted with questionnaires and data is more agency relevant. Archival data also exhibits strong external validity. All the data from cases in a database of information for each of the treatment sites kept by the agency used for this study were reviewed. The data from Session Rating Scales (See Appendix B) completed by the clients over the last 12 months of their MMT program was collected from the database maintained by the agency used for this study. I also received each subject's demographic information, drug screening results and treatment sessions attendance records that are held in an electronic database. After all the data was gathered, each client was assigned a number that was recorded on the data sheet from the review of participants' data. Their names were not recorded to protect their anonymity. The data collected was entered into and analyzed by this researcher using SPSS 21. Any client with omitted information from the SRS, drug screening results, session attendance or missing admission/discharge data was omitted from the study. The evaluation for omitted information was conducted on each randomly selected participant from the database of the agency used

for this study until there was no missing data for any of the cases in the sample. All information for continuing subject information was stored in a locked file cabinet in my home and the remainder data were destroyed. At the time of data collection and analysis the researcher did not work for the agency involved in this study, but the researcher had previously worked for the agency. The researcher did not work in methadone treatment and thus did not have interaction with participants involved in this study to the best of the researcher's knowledge.

Measure: Session Rating Scale

The original Session Rating Scale (SRS) was created by Lynn Johnson in the early 1990s to help track his own progress with clients. Elements of each measure were combined and converted into a 10-item, Likert-scaled instrument. The original SRS consisted of 10 items, but there were complaints about the time needed to complete the SRS. The SRS V.3 was developed to address this issue and consisted of 4 items that combined identified measures of therapeutic alliance that clinical staff could review for each session. The Session Rating Scale Version 3.0 (SRS V.3) was developed by Lynn D. Johnson, Scott D. Miller and Barry L. Duncan in 2000 as an ultra-brief alliance measure of "working" alliance designed to be utilized for every session. Permission to use the SRS was granted for this research by Scott Miller, one of the developers of the SRS (See Appendix C and Appendix D). The SRS is a four-item visual analogue instrument that addresses the following areas of the therapeutic alliance: (a) Client rating of the relationship between the clinical staff member and the client; (b) Client rating of whether their clinical staff member is utilizing the session to work on the goals and topics the client wants to work on; (c) Client rating of whether the clinical staff

member's approach or method is a good fit for them; (d) Client rating of the overall session the day seen. Participants are asked to rate each of the 4 items presented on a scale of 0 to 10. All four scales are then added together for an overall score. Based on a total possible score of 40, any score lower than 36 overall, or less than 9 on any scale, could be a source of concern in regards to therapeutic alliance and is discussed with the client by the clinical staff member. Scores under 36 are suggestive of having an issue with the therapeutic alliance.

The first scale is the "Relationship" scale and is measured with 1 = I did not feel heard, understood, and respected; and 10 = I felt heard, understood, and respected. The second scale is the "Goals and Topic" scale and is measured with 1 = We did *not* work on or talk about what I wanted to work on and talk about; and 10 = We worked on and talked about what I wanted to work on and talk about. The third scale is the "Approach or Method" scale and is measured with 1 = the therapist's approach is not a good fit for me; and 10 = the therapist's approach is a good fit for me. The fourth and final scale is the "Overall" scale and is measured with 1 being = There was something missing in the session today; and 10 = Overall, today's session was right for me. The lower the score, the less TA indicated; an overall score of 36 is the threshold of measuring good TA. The agency used for this study collects these data for every client and for every individual and group session and maintains the scores in the client's electronic chart.

Scoring is to be done in front of the client using a centimeter ruler. Each of the four visual analogue scales is 10cm, so the score for each of the four visual analogue scales is the measurement length on the ruler (e.g. 3.3 cm = score of 3.3) with 10 being the highest score for each scale. You simply write the score in the right margin (based on the mark on the

ruler), and then add the four scores for the overall score. The overall score is rounded up or down to a whole number. The total possible score is 40. One limitation is that although a ruler is used to score the SRS and all staff are trained to use the SRS and score it, there is no way to know for fact that each clinical staff member did use a ruler or if they eyeballed the score, as the researcher was not there at the time of administration. Therefore, there is no way to verify that the scoring is consistent from one clinical staff member to the next. The concern in consistency comes to light in noting that the SRS does not have a numbered scale, thus a mark close to the middle between two numbers could be the lower number for one staff member and raised for another staff member (e.g., close to 3.5 could look more like 3.4 to one clinician and 3.6 to another). This could affect the validity and reliability of the instrument.

The Revised Helping Alliance Questionnaire (HAQ-II) (Luborsky, Barber, Siqueland, Johnson, Najavits, Frank, & Daley, 1996) was used to evaluate the psychometric properties of the SRS in a study by Duncan, Miller, Sparks, Claud, Reynolds, Brown and Johnson (2003). The coefficient alpha for all administrations ($N = 420$) was .88. "The coefficient alpha for the SRS compared favorably with that reported for the HAQ II (.90)" (Duncan, Miller, Sparks, Claud, Reynolds, Brown & Johnson, 2003, p. #). The fact that the 4-item measure correlated such a high reliability with the 19 items from the HAQ-II is reported by Duncan, Miller, Sparks, Claud, Reynolds, Brown, and Johnson to suggest evidence that the four items of the SRS consisted of a good global measure of TA.

The SRS concurrent validity was computed using Pearson product-moment correlations between the SRS total score and HAQ II total score. The data from a sample of

420 paired administrations for the 70 participants produced a correlation between the two measures of .48, which suggest evidence of concurrent validity for the SRS (Duncan, Miller, Sparks, Claud, Reynolds, Brown & Johnson, 2003). Correlations between each of the 4 individual SRS items and the HAQ II score were within a range of .39 to .44. These correlations provided evidence of the degree to which the SRS items are assessing the same construct as the HAQ-II.

The relationship to outcome of treatment was also evaluated to ensure it could predict outcome indications similar to other established alliance measures, in order to validate its construct validity. Outcome indicators in relation to this study were also important as retention and compliance in methadone treatment are the outcome indicators for this study. A random sample of 100 clients was utilized to compare to the outcome from the Outcome Rating Scale (Duncan & Miller, 2000). The results revealed a correlation of .29 between the second or third session of the SRS scores and the final session ORS scores. Duncan, Miller, Reynolds, Sparks, Claud, Brown, and Johnson (2004) stated that studies have found the SRS to be a valid measure of the therapeutic relationship in regards to retention in and outcome of treatment.

Data Analysis

This study involved collecting information on the report of therapeutic alliance as measured from the client's perception and the relationship to methadone maintenance treatment retention and compliance. Calculations were made for both descriptive and inferential statistics using SPSS 21. The study employed four types of analysis. In order to provide descriptions of the sample, descriptive statistics were used to gain information on

gender, age, race, marital status, employment status, and dosing levels. The means and standard deviations of the SRS and measures of client compliance scores were gathered. Also, mode, median, and range was used to measure for any overall patterns in the sample. All variables were assessed for normalcy. In addition to histograms and boxplots, measures of skewness and kurtosis were used to evaluate whether the sample collected meets normalcy assumptions.

To assess the relationship and test the hypotheses between SRS scores and compliance scores and retention measure, appropriate correlation coefficients and regression analyses was computed. After all the scores were analyzed logistic regression was applied to the variables of Hypothesis 1, 2 and 3. This was utilized because the data was reviewed as categorical for both the dependent and independent variables. This researcher was looking at whether there was a positive TA reported (yes or no), the client was retained > or equal to 12 months, and the client was treatment compliant in area of drug screenings and attendance to scheduled sessions (individual and group). Lastly, to identify the existence of any specific patterns or relationships between the aforementioned demographic variables and survey or test scores, additional group tests such as chi-square, t-tests, and/or analysis of variance were used to examine for any significant differences among the scores and demographics.

Research Questions and Hypotheses

The research questions that drove the analysis were stated in Chapter 1 as:

Research Question 1: Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict retention (as measured by length of stay in treatment) among patients receiving methadone maintenance treatment?

H_{a1}: Report of positive therapeutic alliance as measured by a raw score of 36 or above on the SRS will predict treatment retention measured as 12 or more months in MMT.

H_{01}: Report of positive therapeutic alliance as measured by a raw score of 36 or above on the SRS will not predict treatment retention measured as 12 or more months in MMT.

Research Question 2: Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict compliance (as measured by attendance to scheduled appointments) among patients receiving methadone maintenance treatment?

H_{a2}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will predict treatment compliance as measured by client's attendance record showing three or less non-excused missed appointments over the preceding 12 months of MMT treatment.

H_{02}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will not predict treatment compliance as measured by client's attendance record showing three or less nonexcused missed appointments over the preceding 12 months of MMT treatment.

Research Question 3: Does positive therapeutic alliance as measured by the Session Rating Scale (SRS) predict compliance (as measured by results of drug testing analysis) among patients receiving methadone maintenance treatment?

H_{a3}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will predict treatment compliance as measured by client's drug test results

showing fewer than three positive illicit drug results over the preceding 12 months of MMT treatment.

H_{03}: Report of positive therapeutic alliance as measured as a raw score of 36 or above on the SRS will not predict treatment compliance as measured by client's drug test results showing fewer than three positive illicit drug results over the preceding 12 months of MMT treatment.

Threats to Validity

With any research, there is some potential threats to validity. This section will discuss possible threats to this research project specifically. The degree a study establishes a cause-and-effect relationship between the treatment and the observed outcome is internal validity (Slack & Draugalis, 2001; p 2173). It is possible that there could be potential for an internal effect that could not be controlled for in this study called an interaction of temporal and group composition effects. Although archival data was used for this study, many of the participants had been involved in MMT for 1 year or more and there could have been changes in their behavior that are related to pre-existing differences among the participants (e.g. pre-existing differences such as age, marital status, geographical location of treatment, employment and etc.) that could obscure the effects of therapeutic alliance. Demographic characteristics also can impact the study, there were differences among the sample participants that could have influenced the building of TA such as gender, age, marital status, co-occurring diagnosis and etc. In this study it is possible that one or more of these demographic characteristics may not have equally been accounted for. One other threat noted to internal validity is potential of selective sample attrition. In MMT some of the participants

discharged due to voluntary reasons and some discharged involuntarily such as in situations of noncompliance.

Another threat to validity of a study is related to external validity issues one such possibility is the reactive or interaction effect of testing. One concern with external validity is how representative the sample is to the population as a whole. Once potential concern in this area is that the sample was comprised of opioid addicts only in Arizona. While there may be many generalizations in regards to opioid addicts in general, this study did not look at demographic influences in regards to geographic location that may influence the forming of therapeutic alliance. Another potential issue Interaction effect of testing, this occurs when there is pretesting. In the case of this study the SRS is presented to clients every session, which could have a possible effect of pretesting such as overtime the clients may become so familiar with the questions that they don't answer them how they really feel but according to a learned response (e.g. selecting all one score every session). Another possible threat to external validity is interaction effects of selection biases and the experimental treatment. While there was no direct experimental treatment with this study, there were a number of cases that were eliminated from the study due to not having all the necessary information to be included in the study. There is no way to account for the potential effects that those members of the population's data may have had on the outcomes of this study.

One final concern in psychological study is construct validity which is the extent that an

instrument measures what it purports, to be measuring. Duncan, Miller, Sparks, Claud, Reynolds, Brown & Johnson, (2003) identified that the SRS was developed as an "ultra-brief" alliance scale to be utilized by mental health staff session to session. It may be notable that the measures used to compare and determine psychometric properties of the SRS had been "designed for research and theoretical purposes" and thus may not have taken into account the difference utilizing the SRS session to session.

Summary

This chapter covered the processes and methods that this researcher undertook to examine the differences between the report of client and the clinical staff member's perception of therapeutic alliance, and whether the perception of TA by either the client or clinical staff member may have a significant effect on treatment compliance results and/or retention outcomes.

This quantitative study examined individuals who have been receiving MMT from various MMT outpatient clinics ran by the agency used for this study in Arizona. The data associated with TA was gathered by using data from the SRS, treatment compliance was determined by reports on drug screening results and reported attendance to scheduled individual and group sessions held in electronic records by the agency used for this study.

In Chapter Four, the results of study are presented to determine if differences exist between the report of client's and the clinical staff's perceptions of therapeutic alliance, and whether the perception of therapeutic alliance by either the client or clinical staff member is related to treatment compliance and/or retention outcomes.

Chapter 4: Results

Introduction

I investigated the relationship between TA and the variables of retention and compliance in methadone maintenance treatment. Significant amounts of research relate to the role and influence of TA in mental health psychotherapy with adult clients, which is a critical component influencing outcomes and retention within counseling in the mental health field. There is comparatively little known about the relationship between alliance and therapy outcome with regard to the influence of retention and compliance with methadone maintenance treatment.

I used research questions to examine the effect of TA (measured using the Session Rating Scale) on MMT retention and compliance (drug screens and session attendance). I analyzed archival data from 264 clients at four methadone clinics using logistic regression. With the first research question, I examined whether positive TA, as measured by a raw score of 36 or above on the SRS to evaluate whether positive reporting of TA can predict retention among patients receiving MMT. Retention was measured as the client remaining in MMT for 12 or more months. Using the second research question, I examined whether positive reporting of TA predicted compliance of attendance to scheduled appointments with clients receiving treatment at MMT. In my second hypothesis, I stated that a report of positive TA would predict compliance measured by client's attendance record showing three or less non-excused missed appointments during the preceding 12 months of MMT. I used the third and final question of this study to examine whether positive reporting of TA predicted compliance with maintaining clean negative drug testing analysis among patients receiving

MMT. In my third hypothesis, I stated that report of positive TA would predict treatment compliance as measured by client's negative drug test results showing fewer than three positive illicit drug results during the preceding 12 months of MMT.

In this chapter, I present the variables, both nominal and scaled, along with descriptive and inferential statistics pertinent to the hypotheses of study, as outlined in Chapter 3. The independent variable for analyses was report of TA, measured by SRS scores. In the first section of this chapter, I describe the data collection process, based on the research methods reviewed in Chapter 3. In the second section, I present the data analyses and in the final section, I present the summary and conclusions.

Data Collection

All the data from cases in a database of information for each of the MMT treatment sites kept by the agency used for this study were reviewed. The data from Session Rating Scales (See Appendix B) completed by the clients over the last 12 months of their MMT program was collected from the database maintained by the agency used for this study. This researcher also received each subject's demographic information, drug screening results and treatment sessions attendance records that are held in an electronic database by the agency used for this study. Any client data with omitted information from the SRS, drug screening results, session attendance or missing admission/discharge data was omitted from the study. The evaluation for omitted information was conducted on each randomly selected participant from the database of the agency used for this study until there was no missing data for any of the cases in the sample. The agency is a not for profit agency, and clients were evaluated

from the timeframe of 2010-2014. From the time of approval by the IRB to the retrieval of the data held in the database by the agency it was four months. This time lapse was so that a specific report of all the data needed for this study was programmed by the developers to protect access to other information in client charts not needed for the purpose of this study. Once the data was received it took 4 more months to sort through all the data to organize it and an additional two months to complete the analysis of the raw data.

The independent variable for this study was therapeutic alliance which was measured utilizing SRS scores. In this study, it was noted that based on overall SRS scores ($M = 37.3$, $SD = 3.12$) more than 78% of the sample reported a positive therapeutic alliance ($N = 207$) regardless of all other factors, while less than 22% ($N = 57$) reported not having a therapeutic alliance.

The predictor variables were compliance with negative drug testing, compliance with attendance to sessions and retention in treatment. The information for these variables was obtained through archival records maintained in three databases maintained by the agency used for this study. The three databases were comprised of the SRS/ORS scores, client demographics, drug screening reports and attendance records. The data was obtained on excel spreadsheets from the databases. The first step involved matching up the data from the three reports (client demographic taken from Health Management System (HMS) and ensuring that all necessary variables were present (length of service, attendance, and drug screening results). Participants who had less than two ORS/SRS scores were eliminated because there could not be an accurate start of service, completion of service and average score obtained. Also, eliminated from the sample were clients that had less than four reported

drug screenings in order to be able to look at the results over a course of 1 year. After this sorting 264 clients were remaining that were able to be matched with all the criteria. The next step involved adding all the SRS scores which were individually given. The number of SRS reported scores reviewed in the original raw data for all clients with all data for this study were $N = 4{,}601$. The SRS scores for each client ranged from 3 per client to up to 111 per client. Each set of scores for the 264 participants was placed on an Excel spreadsheet with the client's start of service and end of service to determine number of months a client was retained in treatment. The total of all SRS scores for each participant (range 3 recorded scores to 111 recorded scores) was totaled and the overall mean score was calculated for each participant, and the mean was used to determine overall report of TA during length of treatment. Therapeutic alliance was coded as positive alliance with SRS score of 36 or above. The overall sample report on SRS scores (M=37.30, SD=3.12) suggested that there was a report of TA regardless of any of the other variables (length of treatment, attendance and drug screen results), as well as any demographic variables or clinic.

The third step involved sorting and coding the drug screening results for each client. The total number of positive drug screenings was totaled for each client and noted on the spreadsheet. The range of total number of positive drug screenings ranged from 0 to 18. Compliance was coded as compliant if there were less than 3 positives in a one-year period. Out of 264 total participants, 137 participants almost 52% were reported as compliant with drug screenings compliance criteria (M=3.7, SD 4.09).

The fourth step involved sorting and coding the attendance for individual and group appointments. Attendance was only able to be followed if it was placed in the HMS system. The total of missed appointments was tallied and noted on the spreadsheet. The range of reported missed appointments was from 0 missed to 68 missed appointments. Compliance was coded as compliant if there 3 or less missed sessions in a one-year period. Out of 264 participants only 67 participants or about 25% were reported as compliant. The overall missed appointments rate was much higher than 3 in one year (M=12.99, SD=11.21).

The next step was totaling and coding treatment retention. The length of service months was determined by totaling the number of months between the admission dates to the discharge date for discharged clients. The length of service months for current clients was based on the number of months between the admission date and the date of the report. Retention criteria was based on length of service of 12 months or more. Out of 264 participants 217 participants (82%) were retained and 47 participants (18%) were not retained for 1 year or more. The overall length of treatment for this sample was just over 19 months (M = 19.30, SD = 8.171).

The final step before analysis was conducted was to take the data and convert it to categorical data to become dichotomous variables**,** in preparation for the logistic regression analysis. At this point TA was coded either yes = 2 (overall scores of 36 and greater) or no = 1 (<36). Retention was coded as retained for 1 year or more as yes = 2 and retained for <1 year as no = 1. Compliance for drug screening was coded as compliance –drug screening < 3 positive drug screenings yes = 2 and non-compliant with drug screenings >2 no = 1. And

finally, compliance – session attendance was coded as 3 or less missed sessions yes = 2 and non-compliant to session attendance as no = 1.6

Sample Description

After verifying all data, the following Descriptive Analysis describes the demographics of the 264 remaining participants that comprised the sample for this study. The sample was composed of 54.5 % (N = 144) males and 45.5 % (N = 120) females, age of 21 to 77 (M = 39.47, SD = 12.34). Almost 68% of the participants were Caucasian (N = 179), the remaining distribution of ethnicity included 23% Hispanic (N = 60), 6 % Black (N = 16), 3% American Indian (N = 7), and less than 1% each Asian or Pacific (N = 1) or other or not provided (N = 1). About 48% (N = 126) of the participants were single, 22.3% (N = 59) were married, 4.5% (N = 12) were separated, 13.3% (N = 35) were divorced, 2.7% (N = 7) were widowed and 9.5% (N = 25) did not report their marital status. The largest percentage of the participants came from an urban clinic that for confidentiality purposes will be known as clinic A, 37.5 % (N = 99) which was to be expected as it was located in a major city, the remainder of the distribution was 16.7% (N = 44) from clinic B, 15.9% (N = 42) from clinic C and 29.9% (N = 79) from clinic D. Client treatment status was coded and was fairly equally divided with current clients making up 52% (N = 136) and discharged clients making up 48% (N = 128) of the sample. In regards to a co-occurring mental health diagnosis 89.4% (N = 236) had no other mental health diagnosis while those remaining 10.6% (N = 28) were reported with an Axis I non-substance related mental health diagnosis.

Table 1

Frequency and Percentage Breakdown of Demographic Variables (N= 264)

Variable	*N*	*%*	**Descriptives** *M*	*SD*
Clinic				
A	99	37.5%		
B	44	16.7%		
C	42	15.9%		
D	79	29.9%		
Gender				
Male	144	54.5%		
Female	120	45.5%		
			1.45	.5
Age Group				
18-30 years old	7	5.7%		
31-55 years old	42	34.4%		
56-70 years old	65	53.3%		
71 and over	8	6.6%		
			39.47	12.3
Employment Status				
Volunteer	1	.4%		
Unpaid rehab	1	.4 %		
Homemaker	3	1.1 %		
Student	8	3.0%		
Retired	4	1.5%		
Disabled	32	12.1%		
Fulltime Employed	50	18.9%		
Part-time Employed	34	12.9%		
Unemployed	128	48.5%		
Unknown or did not report	1	.4%		
Race				
other	2	.8%		
African American	16	6.1%		
Caucasian	179	67.8%		
Hispanic	60	22.7%		
Native American	7	2.7%		
Marital Status				
Single	126	47.7%		
Married	59	22.3%		
Separated	12	4.5%		
Divorced	35	13.3%		
Widowed	7	2.7%		
Did not report status	25	9.5%		
			2.29	1.653

(Table Continues)

Occurrence of an Axis I mental health diagnosis	28	10.6%		
	236	89.4%		
Axis I mental health diagnosis				.327
No other mental health diagnosis			1.12	
	136	51.5%		
Treatment status	128	48.5%		
Currently enrolled				.501
Discharged			1.52	

The proposed sample size for this study was established by using Cohen's table (Cohen, 1992, p. 158) to estimate the number of participants needed. For one predictor of therapeutic alliance a sample size of at least 76 participants per group of clients would be required to ensure adequate power to detect medium treatment effects with an alpha set at .05 and a power of 80. This study had 264 participants, thus meeting the criteria for power.

In comparing representation of the sample of the current study to the population as a whole there were some similarities and differences found. The National Survey of Substance Abuse Treatment Services (N-SSATS) (2012) identified that there were 537,676 clients in 2012 that made up 43.1% of the population receiving MMT, that also had a diagnosed co-occurring disorder. This study found only 10.6% of the sample to have a diagnosed co-occurring disorder. Rosenblum et al. (2007) conducted a multi-state survey to determine the prevalence of prescription opioid abuse. The study included 5663 opioid dependent clients from 72 methadone maintenance treatment programs across the U.S. The Rosenblum et al. study identified that a mean age of 35, while the current study the mean age was 39.47. Further the Rosenblum study found 36.6% of their sample included women, while the current study included 45.5% women. In regards to race, Rosenblum reported 73.1% of

the sample was white, 13.0% black and 11.7% Hispanic. Similarly, the current study included 67.8 % of the sample was white, but only found 6.1% to identify as black and there was a larger representation of Hispanic 22.7%. The difference in the Hispanic representation maybe related to the proximity of Arizona to the border of Mexico. Both studies evidenced the majority of the sample from counties with over 1 million population 59.3 % in the Rosenblum study and 37.5% in the current study. In regards to employment there was a difference in the representation of those employed, 46.7% employed in the Rosenblum study while in the current study only 31.8% of sample was employed.

Results

Three separate logistic regressions were conducted to test each of the three hypotheses. Logistic regression was deemed appropriate for this analysis because the independent variable was dichotomous (yes/no), as were the dependent variables. The independent variable was therapeutic alliance. The dependent variables were also dichotomous: retention, compliance –drug screening, and compliance – session attendance.

Results for Hypothesis 1

The first logistic regression was performed to ascertain whether TA predicted retention for 1 year or more in methadone maintenance treatment. The model was not statistically significant χ^2 (1) = .508, p = .476, suggesting that TA is not a significant predictor of the likelihood of retention (see Table 2). The model explained less than 1% of the variance in retention (Nagelkerke R^2 = .003). The null hypothesis was retained.

Results for Hypothesis 2

The second logistic regression was performed to ascertain whether therapeutic alliance predicted compliance in drug screening. The model was not statistically significant χ^2 (1) = .223, p = .636, suggesting that TA is not a significant predictor of the likelihood of retention (see Table 2). The model explained less than 1% of the variance in drug screening compliance (Nagelkerke R^2 = .001. The null hypothesis was retained.

Results for Hypothesis 3

The third logistic regression was performed to ascertain whether therapeutic alliance predicted compliance in session attendance. The model was not statistically significant m^2 (1) = .026, p = .872, suggesting that TA is not a significant predictor of the likelihood of retention (see Table 2). The model explained less than 1% of the variance in compliance in session attendance (Nagelkerke R^2 < .001. The null hypothesis was retained.

Table 2

Summary of Logistic Regression Using Therapeutic Alliance to Predict Retention and Compliance (n = 264)

	Retention			Compliance: Drug screening			Compliance: Session attendance		
	B	*SE B*	e^B	*B*	*SE B*	e^B	*B*	*SE B*	e^B
Alliance	0.17	0.374	1.31	0.141	0.299	1.152	0.055	0.346	1.057
χ^2		0.508	476		0.223	p = .636		0.873	p = .872
df		1			1			1	

*p < .05.

Summary

This chapter reported the results of three hypotheses addressing factors that examined effect on clients completing methadone maintenance treatment. Data for 264 participants was analyzed for the purpose of this study. For Hypothesis 1, the model was not effective in reporting those cases that would be retained in methadone maintenance treatment. Hypothesis 2 purported that clients reporting a strong TA would be compliant with scheduled sessions. The model was not effective in reporting those cases that would meet the attendance criteria. The third hypothesis, regarding whether positive reporting of TA would correctly predict the successful compliance to the drug screening criteria was also not supported.

The interpretation of findings, discussion regarding the significance of the study and the limitations of the study, social change implications, recommendations for further study and a summary are discussed in Chapter 5.

Chapter 5: Summary, Conclusion, and Recommendations

Introduction

The use of opioids continues to increase and approximately 8 million people worldwide abuse opioids (Van der Burgh, 1999). Opioid abuse costs include medical associated costs, criminal activity costs, and emotional costs to families of the substance abuser and are a significant burden on society (Ghate et al., 2010; White et al., 2005; SAMHSA, 2013; Birnbaum et al., 2004). MMT is an effective treatment for opioid addiction with regard to improving both the life of the opioid-addicted individual and society (Teoh Bing Fei, Yee, Hussain Bin Habil, & Danaee, 2016). As explained in Chapter 1, opioid abuse affects society with burdens related to health costs of HIV infections, criminal behavior, and deaths from overdose. Studies have identified that retention in MMT is a major factor in reduction of risks and successful outcomes (Kayman et al., 2006; Magura et al., 1998).

Studies have shown that treatment dropout has been an issue with MMT (Gossop et al., 2002; Reisinger et al., 2009; Simpson & Sells, 1982). Therefore, maintaining retention in MMT is an important factor for society and the opioid-addicted individual. A poor therapeutic connection (therapeutic alliance) has been found to affect success of treatment, especially with regard to retention and compliance (Palmer et al., 2009; Joe et al., 2007; Kelly et al., 2010; Meir et al., 2006; Duncan & Miller, 2008). My underlying approach in this study was that finding the link between improving the effectiveness of MMT while not adding to the costs of the treatment could assist in continuing this treatment modality that has been shown to be effective. Developing TA would not necessarily increase program costs as significantly as developing social supports such as vocational training, more intensive

treatment, costs of criminal justice structure, or other options. Building therapeutic rapport can be taught through in-service trainings or other means. Therefore, it appeared that improving TA may be one of the least expensive ways to improve retention and compliance in MMT, which prompted the current study.

Prior research suggests that a better report of therapeutic alliance would suggest better treatment outcomes (Zhang et al., 2009; Joe et al., 2007; Meier et al., 2005). As I detailed in Chapter 2, several studies have identified that the relationship between the client and the clinical staff on working on mutual goals (therapeutic alliance) affects treatment outcomes and participation in treatment (Orlinsky et al., 1994; Duncan et al., 2006; Martin et al., 2000).

The reports of the overall sample from the SRS scores suggested that regardless of any of the variables, of the 264 participants, 78% of participants ($N = 207$) reported a positive TA regardless of length of treatment, attendance, and drug screen results; therefore, in the current study, TA was reported regardless of treatment outcomes. The sample for this study included individuals who had been discharged owing to noncompliance issues, and according to prior research, it would have suggested that those clients should have reported lower levels of TA, but this was not the case. Various theories explain the difference from the actual outcome and what was expected. I will discuss this in further detail in the Limitations section. Due to the finding of high levels of positive TA regardless of the variable, further research should attempt to narrow the reasoning for the SRS scoring suggesting TA.

I examined the possibility that a positively reported therapeutic alliance could predict retention and compliance in methadone maintenance treatment. The positive social change implications meant for this study were to allow therapists to integrate strategies into

treatment that would promote building therapeutic alliance, thus improving the retention and compliance with MMT.

The purpose of this chapter is to discuss the results of the study reported in Chapter 4, including how these findings relate to other researchers' results, implications of these findings for practice and social change, strengths and limitations, and recommendations for future research. The organization of this chapter is: (a) interpretation of the findings, (b) limitations of the study, (c) implications for social change, (d) recommendations for future research, and (e) conclusions noting how the findings fit with existing literature.

Interpretation of the Findings

Research Question 1

The first regression analysis assessed whether the report of positive therapeutic alliance could help predict retention of 12 months or more in Methadone Maintenance Treatment (MMT). The research found that therapeutic alliance did not significantly associated with retention. The results of this sample showed the average length of treatment was about 19 months and the overall sample reported a positive therapeutic alliance regardless of any of the other variables. The information that there was a report of therapeutic alliance regardless of any other influence in this study offered some speculation and more questions for future research that will be discussed in the discussion and future research section.

While this study did not support a relationship between therapeutic alliance (TA) and retention the role of therapeutic alliance in the outcome of drug treatment, has been very well researched and found to be an important factor (Safran & Muran, 2000). Studies by Simpson

(1982, 1997) found that the quality of therapeutic relationship significantly influences length of stay. Meier, Donmall, McElduff, Barrowclough & Heller (2006) identified that therapeutic alliance ratings were among the strongest predictor of dropout in drug abuse treatment. Nathan & Gorman (2015, p. 744) identified that therapeutic "alliance early in treatment is associated with a longer length of stay in treatment". Davila Torres (2010) identified that the staff-patient relationship (therapeutic alliance) was an important factor that promotes the retention in the MMT. The findings of this study did not support therapeutic alliance as a predictor for methadone maintenance treatment outcomes related to retention, and compliance.

It may be difficult to speculate why there was no significant association found between therapeutic alliance and retention in this study. However, it is important to note that the report of negative or positive therapeutic alliance result also does not clearly guarantee that treatment will be not be successfully completed therefore, further research should continue to work to determine the variables that most effectively relate to successful MMT outcomes. Results of this study suggested that therapeutic alliance was reported as positive regardless to whether retention was maintained or not and could have been impacted by numerous influences that were unable to be controlled for in this study. Suggestions for future research to evaluate those influences will be discussed more in the section on limitations and suggestions for future research.

Research Questions 2 and 3

The second and third regression analysis assessed whether the report of positive therapeutic alliance could help predict compliance in Methadone Maintenance Treatment

(MMT). Research question 2 specifically addressed compliance in regards to attendance for scheduled sessions and question 3 compliance in regards to adherence with illicit drug use policies. In this study the report of positive therapeutic alliance did not assist with predicting compliance with attendance or adherence with illicit drug use policy.

Again, while this study did not support a relationship between therapeutic alliance (TA) and compliance to attendance with scheduled counseling and case management sessions the role of therapeutic alliance in attendance has been researched and supported in other studies. Better attendance was associated with better outcomes in substance abuse treatment (Hubbard, Craddock, Flynn, Anderson, & Etheridge, 1997; Simpson, 1981; Zhang, Friedmann, & Gerstein, 2003). Therapeutic alliance has been identified as a predictor for attendance (Fiorentine, Nakashima, & Anglin, 1999; Simpson, Joe & Brown, 1997). Joe et al. (1999) determined that a strong correlation existed between the ratings of therapeutic alliance and drug treatment compliance outcomes, including illicit drug use and session attendance. A meta-analysis of 24 studies, found there was a reliable and consistent relationship between the working alliance with the counselor and the client and therapy outcomes (Horvath & Symonds, 1991). Meier, Donmall, McElduff, Barrowclough & Heller (2006) identified that the report of early alliance appeared to be a consistent predictor of engagement.

Based on this study it appears there may be other variables that would influence whether someone makes it to their schedule sessions regularly. If clients are not committed to the need for further therapy and their belief is they just need the methadone, this could explain the lack of attendance to counseling and case management sessions. The methadone takes care of the withdraw symptoms, which is what clients may want, there could be a

disconnect on the need for therapy. If someone is experiencing pain, they are more likely to justify taking time out of their life to go see the doctor in order to get rid of the pain. It is may be harder for individuals to justify going to see the doctor for well visits. This finding will be discussed in more detail in the discussion and suggestions for future research section.

The final component of compliance selected for this study was compliance in avoiding illicit drug use which is the main goal of MMT. The final logistic regression was performed to evaluate the effect of reported therapeutic alliance on the likelihood that participants would be compliant to drug use policy. This study identified that once again the model was not effective in predicting compliance with regard to drug screenings.

Part of the benefit of MMT is the contribution of prevention of infectious disease spread through IV drug use (Ward et al., 1999; Reisinger et al., 2009; Krambeer et al., 2001). But in a study conducted of cohort study of 764 HIV-1-infected patients it was found that forty-four percent of active drug users failed to utilize highly active antiretroviral therapy (HAART) (Lucas, Cheever, Chaisson, Moore, 2001). This finding may suggest that compliance with avoidance of illicit drug use is an important factor in receiving treatment for infectious diseases. There was limited research related directly to whether therapeutic alliance contributes directly to reduction in illicit drug use, the majority of the research focused on treatment outcomes overall.

Although the results of this study did not yield a significant finding that therapeutic alliance had a strong influence on successful MMT outcomes, there may have been other influences such as anyone or combination of demographic characteristics. The real implications of this study should indicate that there is need for further research.

Limitations

The current study's intention was to add to the body of knowledge on therapeutic alliance and improving methadone maintenance treatment retention and compliance by examining archival data. There were many limitations associated with this study. Shultz, Hoffman & Reiter-Palmon (2005) identified that researchers experience several methodological and statistical issues when using archival data. Further Shultz, Hoffman & Reiter-Palmon identified some of the downfalls of utilizing archival data and there were a couple that also could have been an influence with the current study such as; completeness of documentation, inability to detect errors in the data. The data used in this study was archival in type and thus the method with which the data was collected originally was a significant concern for consistency and accuracy. Further, the archival data collection sample from the agency used for this study was not collected under controlled circumstances.

A potential limitation of this study and utilizing the Session Rating Scale relates to the law of diminishing returns. The law of diminishing returns originally was utilized by economists to explain that at a particular point, additional input produces less output (Mold, Hamm & McCarthy, 2010) and it was identified that the law may also offer insight into situations related to clinical medicine. The theory may relate to the current study in which the more you experience something, the less effective it becomes. The client's in this study were administered the SRS at every session, initially the client's may have put effort into the scoring, but over time being exposed to the SRS numerous times the client's may have been influenced decreased motivation in scoring the SRS. A study was conducted in order to examine the short-term effects on treatment alliance and patient satisfaction from using the

PCOMS scales (ORS and SRS) in out-patient mental health treatment, compared to treatment without using feedback scales (Rise, Eriksen, Grimstad & Steinsbekk (2012), which after six weeks showed no statistical difference on alliance and satisfaction.

The way the SRS/ORS was presented may have varied from one clinical staff member to another. There exist inabilities to ensure that every survey question with each client was scored precisely in the same manner. Also there was an assumption that clinical staff made adjustments as necessary for cultural and other related factors, such as a need for an interpreter.

In reviewing the data, although not factored into analysis it was noted that there was a difference between clinics. As discussed in the study there were a total of 4 different MMT clinics that data was collected from. One clinic was in a major city with a census of over 1.5 million (37.5%) in 2014 (U.S. Census Bureau, 2014), the other three were located in towns with populations ranging from 39,000 to 70,000, and those three locations were located in rural areas. Comparing this in relation to other studies such as Rosenblum et al. (2007), where the study evidenced the majority of the sample from counties with over 1 million population 59.3 %. There could be a difference in the reporting of TA between rural and urban MMT clinics and in outcomes of treatment. One last major difference between the clinic's is that the one located in the major city was also the oldest clinic having opened in 1994. The other three clinics were acquired in 2012. Perhaps due to the length of time that the oldest clinic has existed has offered the staff there an opportunity to build more experience on developing TA. It also could be that just the length of time the clients had worked with the staff had influenced the strength of TA over time. There may also be other

influences related to being located in an urban area as opposed to a rural area in regards to availability to get to the clinic, due to limited public transportation options. It may be beneficial to study the variables of rural vs. urban influence on TA, compliance and retention. One other issue with the data may have been the fact that it was categorized from the original data. If the data had been left in its original form, there may have been more precise results that could have affected the outcomes.

Another possible limitation is related to the nature of the clients being served. An assumption had to be that the participants were able to form some type of TA with clinical staff through direct contact. One concern related to TA development was that the population of substance abusers often exhibit characteristics related to Personality Disorders, which in itself suggests potential issues with development of TA such as malingering or the need to present oneself in a positive light. Those with personality disorders are may exhibit significant issues in the formation of a therapeutic alliance (Wright & Davis, 1994; Bender, 2005). Another aspect of substance abuse is there is often a co-occurring diagnosis, SAMHSA (2015) reported that in 2014 there were approximately 7.9 million adults with co-occurring disorders. The current study did not analyze the effect of the mental health disorder on the report of TA. Future studies may want to analyze the effect of Anti-Social characteristics and mental health symptoms on the report of therapeutic alliance.

Another significant limitation is within the measurement bias related to the self-reporting nature of the study from the clients' perspective, clinical staff's perspective and the influence of the client and clinical staff desiring to present themselves in a favorable manner. As stated in Chapter 4, the sample utilized for this study included individuals that had been

discharged due to noncompliance issues, and according to prior research it would have suggested that those clients should have reported lower levels of TA, but this was not the case. It may be that clients report TA because they have a desire to be perceived in a positive light (social desirability). A study was conducted examining socially desirable responding (SDR), (the tendency for people to present a favorable image of themselves) on questionnaires (van de Mortel, 2008). The study by van de Mortel identified out of fourteen thousand two hundred and seventy-five studies using Questionnaire□based research, 43% found that social desirability response influenced their results (van de Mortel, 2008, p 42). The clients know that the therapist will see the results of the SRS and their desire to be perceived in a favorable image may influence their scores on the SRS. Other options that may influence clients scoring of the SRS could be fear being treated differently if they give negative responses. Duncan et al. (2003) identified, "Clients tend to score all alliance measures highly", but did not give possible reasoning. It is also possible that the SRS is presented in a manner that leads the client to believe it is a "grading scale" for the clinician, and thus they may not want to negatively impact the clinician's job. Another thought is that the clients are not invested into the meaning and use of the SRS and thus scoring what they think the clinical staff desires to hear. It also may be that the SRS is not an appropriate assessment of TA in this set of conditions. It may be that the receiving of the methadone treatment itself is the factor acknowledged by the client as the needed treatment and the receiving of that treatment is all that the client needed to report therapeutic alliance. Finally, since methadone treatment is the one factor keeping them from abusing opioids, the client may have a fear that if they report negatively that there could be a repercussion or retaliation

that could affect their continued services. There was no research identified that addressed the above mentioned possible influences on reporting of TA, therefore it may be beneficial to conduct further research addressing such issues.

The National Substance Abuse Treatment System (2003) estimated that 151,882 clients are in outpatient methadone treatment for opioid addiction this study only collected data on individuals that were enrolled in an outpatient MMT program in Arizona, it did not include those receiving treatment in a higher treatment level of care such as inpatient or in a different environment (e.g. a PCP office) which may have yielded different results. Another limitation related to the selection bias, it is the geographic influence as the data was collected from clinics only in Arizona so cannot be generalized to the population as a whole.

Discussion and Recommendations for Future Research

Although the results of this study did not yield a significant finding that therapeutic alliance had a strong influence on successful MMT outcomes, it may have been influenced by one of the previously mentioned limitations. Regardless of outcomes of the treatment and other factors, the majority of participants endorsed positive TA. It may be beneficial to clarify the definition of what TA is and what it is not to clients and clinicians. Bedi, Davis and Williams (2005) point out that often the clients and clinical staff do not see that qualities and the strength of TA the same. This study viewed the TA as occurring within the one to one therapy or the group counseling sessions, it may be possible that the client viewed it from the perspective of the ability to receive the methadone they see as necessary as the treatment. With this scenario, the clients are receiving the treatment (methadone) that

manages their ailment (withdrawal symptoms) and thus regardless of what occurs within an individual or group session they see the overall picture in a positive light.

It is also possible that the client may also desire to be seen personally in a positive light and have concerns that if they report negativity on the SRS that they will be personally viewed negatively. Words that clinical staff report such as; refusal of treatment, in denial, resistive to treatment, may sound intimidating to a client who knows the clinical staff can take their treatment away from them. Reisinger et al., (2009) examined reasons clients discharge from MMT prematurely and found one reason identified as conflicts with staff. If this is a concern of the client, they may feel the need to report TA positively so they are not viewed as refusing or resistive. Perhaps in regards to methadone treatment specifically, further research may be beneficial in the area of whether clients feel they can be honest about their feelings.

Another factor that stood out across the study regardless of outcomes was retention. The majority of the participants in this study were retained for a minimum of 1 year, regardless of whether they were compliant with treatment or not. Interestingly, there did not appear to be any consistency in consequences when clients were not compliant with scheduled sessions or with drug screenings. It could be the perceived lack of response to noncompliance influenced the report of therapeutic alliance. If there was limited to no addressing of noncompliance the client could have viewed that as the clinical staff supporting them and their behavior, thus the client may have viewed it as a positive therapeutic alliance. Therefore, another suggestion for future research consideration would be conducting this study with controls on response to noncompliance to one group and not to the other group,

which may offer some needed information into evaluating whether the retention improved outcomes or whether possible boundary setting of noncompliance could influence outcomes.

Furthermore, the client may lack understanding of how to score the SRS, or there could be a lack of urgency or importance in regards to how the data from the SRS is used. Perhaps the high scoring of TA with this study has to do with the clinical staff's training and then their presentation of the information. The results of the report of TA could be related to the SRS itself and by repeating the study with another assessment, the outcomes may be different. The psychometric properties of the SRS suggest high internal consistency compared to the HAQ and high test-retest reliability in comparison to the HAQ II (Duncan et al., 2003), but as previously stated in this study the used to establish psychometric properties of the SRS were developed for research as opposed to session to session evaluation. One concern in consistency comes to light in noting that the SRS does not have a numbered scale. It is supposed to be measured with a ruler but there is no way to verify if each clinical staff member did use a ruler or if the measured data was estimated. The effect of estimation could be that a mark close to the middle between two numbers could be the lower number for one staff member and raised higher for another staff member (e.g. a mark between 3 and 4 could look closer to 3 for one staff and closer to 4 for another staff). If clinical staff have concerns regarding the instrument scores being used to grade their performance in any form, they also may be more likely to report the marks as higher than lower. There did not appear to be any research addressing the consistency of clinician to clinician scoring and this may be an area for further research in relation to appropriateness of the SRS with this population.

It was interesting that TA was reported whether or not a client was compliant or not, and whether they were retained or not. The original premise of this study was that if a client reported TA that they would also be compliant in attending sessions and with drug screening. Overall, this study suggested that a large portion of clients were not compliant with drug screenings or attendance to sessions and yet they were still retained in treatment for an average of 1.5 years and overall reported TA. It may be important to go back and define what are the important components of MMT outcomes in order to attain the goals of the treatment.

One final thought for future study suggestions is that the outcomes of this study did not address whether an individual remained abstinent after discharge from methadone treatment. It may be beneficial for future studies to conduct a longitudinal type study on maintained abstinence and the benefits of methadone treatment in relation to abstinence.

Social Change Implications

The American Society of Addiction Medicine (ASAM) reported in its Opioid Addiction 2016 Facts & Figures that drug overdose is the leading cause of accidental death in the US and Opioid addiction and opioid related deaths were the highest for all drugs. ASAM reported opioid use disorder figures at 1.9 million for opioid based pain relievers and 586,000 related to heroin use disorders in 2014 (ASAM, 2016). These figures affect a large portion of the population of the U.S., whether someone they know someone who has opioid dependence or through indirect cost such as rising medical costs or working in the medical field or law enforcement. Research has shown that the length of stay in treatment is one of the most consistent predictors positive treatment outcomes (Simpson, Joe, Broome, Hiller, Knight & Rowan-Szal, 1997; Simpson, Brown & Joe, 1997; Joe et al., 2009). Therefore, this study's

hope was to find a potentially low cost way to improve MMT retention and compliance through improving therapeutic alliance.

Some important implications that emanated from the current study's findings related to research methodology. Results from the current study adds to the knowledge base of quantitative research specifically in relation to therapeutic alliance measurement instruments related to this population. This study was undertaken due to the significant gap of research related to successful retention in MMT and MMT outcomes. Research related to therapeutic alliance identified report of positive therapeutic alliance exhibits evidence of positive treatment outcomes within mental health. The majority of the research on therapeutic alliance identified in Chapter 2 was related to mental health. There was limited research related to therapeutic alliance and substance abuse outcomes, as stated previously in this study the field of substance abuse has been slower than other fields in embracing research on the effect of therapeutic alliance on treatment outcomes (Ritter, Bowden, Murray, Ross, Greeley, & Pead, 2002). In relation to methadone maintenance treatment there was almost no research related directly to therapeutic alliance and MMT outcomes.

Closing Summary

Although the results of this study did not represent a finding that TA was a strong influence on successful MMT outcomes, the study results did offer some interesting avenues for further researcher suggesting the need for more research.

The premise of this study was that the therapeutic alliance occurred during individual sessions and group sessions, as that is the only place where it is measured. Assessing with an instrument usually occurs during group or individual sessions and therefore a positive or

negative report was considered directly related to the clinical staff member in that session. It was also assumed that individual and/or group sessions were an essential part of the methadone treatment process. In talking to various staff members at two of the clinics it was identified by staff that a small percentage of clients actually receive individual therapy and may attend an average of 1 group per week. Perhaps more focus on therapy and less focus on compliance could be another way to improve overall methadone maintenance treatment outcomes.

Many people in the U.S. are impacted in some manner by opioid dependence, so we must do all we can to ensure that those who are receiving methadone maintenance treatment are retained in service and compliant with treatment.

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Appendix A: Data Use Agreement

This Data Use Agreement ("Agreement"), effective as of August 15, 2014 ("Effective Date"), is entered into by and between Teresa Fresquez ("Data Recipient") and The agency used for this study ("Data Provider"). The purpose of this Agreement is to provide the Data Recipient with access to a Limited Data Set ("LDS") for use in research **in accord with laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient's educational program.** In the case of a discrepancy among laws, the agreement shall follow whichever law is more strict.

1. Definitions. Due to the study's affiliation with Laureate, a USA-based company, unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the USA "HIPAA Regulations" and/or "FERPA Regulations" codified in the United States Code of Federal Regulations, as amended from time to time.

2. Preparation of the LDS. Data Provider shall prepare and furnish to Data Recipient a LDS in accord with any applicable laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient's educational program.

3. Data Fields in the LDS. **No direct identifiers such as names may be included in the Limited Data Set (LDS).** In preparing the LDS, Data Provider shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research: Session Rating Scale scores, gender, age, race, gender, marital status, employment status, dosing level, drug reports and attendance to individual and group information.

4. Responsibilities of Data Recipient. Data Recipient agrees to:

    a. Use or disclose the LDS only as permitted by this Agreement or as required by law;

    b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;

    c. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;

    d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and

    e. Not use the information in the LDS to identify or contact the individuals who are data subjects.

5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS **for its Research activities only.**

6. Term and Termination.

   a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.

   b. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.

   c. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.

   d. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.

   e. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

7. Miscellaneous.

   a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.

   b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

   c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

   d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

e. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

Appendix B Session Rating Scale

Session Rating Scale (SRS V.3.0)

Name _____Age (Yrs):____
ID# _____ Sex: M / F
Session # ____ Date: _____

Please rate today's session by placing a mark on the line nearest to the description that best fits your experience.

Relationship

I did not feel heard, understood, and respected. I---------- I felt heard, understood, and respected.

Goals and Topics

We did *not* work on or talk about what I wanted to work on and talk about. I---------- We worked on and talked about what I wanted to work on and talk about.

Approach or Method

The therapist's approach is not a good fit for me. I---------- The therapist's approach is a good fit for me.

Overall

There was something missing in the session today. I---------- Overall, today's session was right for me.

Institute for the Study of Therapeutic Change

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Appendix C Session Rating Scale Agreement

IMPORTANT!

By downloading this file you have indicated your complete agreement and willingness to abide by the terms of the **ORS, SRS, CORS, CSRS, YCORS/SRS, GSRS, GCSRS, LASS and Oral Versions Binding License Agreement**

1. Licensee: By signing below, you are hereby licensed by PCOMS International, Inc (hereafter PCOMS) to use the ORS, SRS, CORS, CSRS, YCORS/SRS,GSRS, GCSRS, LASS and Oral Versions (hereafter the measures) for your individual use only. Any use of these measures by an agency, group practice, clinic, managed behavioral care organization, or government requires separate application for a group license and payment of appropriate fees. Click here to apply for or obtain information regarding a group license.

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6. Use, distribution, and Changes: The measures may only be used and distributed by the licensee in connection with licensee's bona fide health care practice and may not be used or distributed for any other purpose.

7. Responsibility: Before using or relying on the measures, it is the responsibility of the licensee to read and understand the ORS and SRS Administration and Scoring Manual. It is also the responsibility of the licensee to ascertain their suitability for any and all uses made by the licensee. The measures are not diagnostic tools sand should not be used as such. The measures are not substitutes for an independent professional evaluation. Any and all reliance on the measures by the licensee is at the licensee's sole risk and is the licensee's sole responsibility. Licensee indemnifies PCOMS and it's officers, directors, employees, representatives, and authors of the measures against, and hold them harmless from, any and all claims and law suits arising from or relating to any use of or reliance on the measures and related products provided by PCOMS. This obligation to indemnify and hold harmless includes a promise to pay any and all judgments, damages, attorney's fees, costs and expenses arising from any such claim or lawsuit.

8. Disclaimer: Licensee accepts the measures and associated products "as is" without any warranty of any kind. PCOMS disclaims any and all implied warranties, including implied warranties of merchantability, fitness for a particular purpose, and non-infringement. PCOMS does not warrant that the measures are without error or defect. PCOMS shall not be liable for any consequential, indirect, special, incidental or punitive damages. The aggregate liability of PCOMS for any and all causes of action (including those based on contract, warranty, tort, negligence, strict liability, fraud, malpractice, or otherwise) shall not exceed the fee paid by the licensee to PCOMS. This license agreement, and sections 7 and 8 in particular, define a mutually agreed upon allocation of risk. The fee reflects such allocation of risk.

9. Construction: The language used in this agreement is the language chosen by the parties to express their mutual intent, and no rule of strict construction shall be applied against any party.

10. Entire agreement: This agreement is the entire agreement of the parties relating to the measures.

11. Governing Law: This agreement is made and entered into in the State of Florida and shall be governed by the laws of the State of Florida. In the event of any litigation or arbitration between the parties, such litigation or arbitration shall be conducted in Florida and the parties hereby agree and submit to such jurisdiction and venue.

12. Modification: This agreement may not be modified or amended.

13. Transferability: This agreement may not be transferred, bartered, loaned, assigned, leased, or sold by the licensee.

14. Violations: Violations of any provision or stipulation of this agreement will result in immediate revocation of this license. Punitive damages may be assessed.

Appendix D **Key Codes**

Original Marital status coding Key	
Single	1
Married	2
Separated	3
Divorced	4
Widowed	5
unknown or not reported	6

Recoded Marital Status (see page 77)
Married=(married or separated)
Single= (single, divorced or widowed)

	Employment Status coding Key
Unemployed	8
Volunteer	14
Unpaid Rehab activity	17
Homemaker	19
Student	20
Retired	21
Disabled	22
Incarcerated	23
Fulltime employed	24
Part-time employed	25
Work adjustment	26
Transitional employment	27
Unknown, not reported	6

Ethnicity coding Key	
Caucasian	1
Hispanic	2
black	3
American Indian or Alaskan Native	4
Asian or Pacific Islander	5
Other or not provided	6

Key codes continued

Retention
Retention under 1 year=No not retained=coded as 1
Retained for 1 year or more=Yes retained=coded as 2
Therapeutic Alliance Report
Therapeutic Alliance not reported=SRS score under 36=1
Therapeutic Alliance reported=SRS score 36 or above=2
Compliance with drug testing
Not compliant=3 or more positive drug test= 1
Compliant=Less than 3 positive drug test=2
Compliance with attendance to scheduled sessions
Noncompliant=more than 3 missed sessions=1
Compliant=3 or less missed sessions=2