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DEVELOPMENT AND EVALUATION OF AN OPIOID MONITORING CLINIC

by

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A doctoral document submitted in partial fulfillment
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May 2014

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THE GRADUATE COLLEGE

We recommend the doctoral project prepared under our supervision by

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Development and Evaluation of an Opioid Monitoring Clinic

is approved in partial fulfillment of the requirements for the degree of

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EXECUTIVE SUMMARY

Development and Evaluation Of An Opioid Monitoring Clinic

By

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An APRN-led Opioid Monitoring Clinic was developed and implemented in the primary care setting of Las Vegas' Department of Veterans Affairs in July 2013 to assist primary care providers (PCP) in the management of high risk patients on chronic opioid therapy for chronic noncancer pain. The clinic assisted in monitoring patients for abuse and misuse of opioids and referred patients for treatment when abuse and misuse were discovered. A study to evaluate the OMC was undertaken from November 22, 2013 through February 23, 2014 to assess the effectiveness of the OMC in meeting its objectives. A total of 61 patients and 26 PCPs participated in the study. The OMC was able to identify 26 patients who were abusing and misusing their prescription opioids that resulted in the discontinuation of their opioid therapy and referral for treatment. The study also found improved compliance among PCPs in following recommendations from the VA/DoD clinical practice guideline in the management of chronic pain using opioid therapy. All PCPs who referred patients to the OMC reported overall satisfaction in having the OMC co-manage their patients on chronic opioid therapy.

ACKNOWLEDGEMENTS

I would like to thank Dr. Jennifer Kawi, my advisor and chair, for her guidance and support. I would like to thank her for reaching out a hand when I was down in my knees, and for her perseverance in getting my confidence back and helping me find the right direction. Without Dr. Kawi, I don't think I would be at this stage of writing my DNP project. I would also like to thank my committee members, Dr. Lori Candela and Dr. John Filler as well as Dr. Larry Ashley, my previous committee member, for their support and feedback. I would like to thank the DNP faculty from both UNLV and UNR for their dedication in teaching. I would like to give thanks to Elizabeth Gardner for her unwavering support to me and all the students who have sought assistance from her. She definitely took off some of the stress of being in the DNP program. I also would like to thank Dr. Chad Cross for his support and guidance in statistics involved with this project.

I would like to thank Sister Marion Reed for her kindness. She was the person who opened the door to get me into the nursing program at Dominican College dating back in 1995. Lastly, I again would like to thank Dr. Lori Candela for being an educator role model. The valuable lessons I learned from her classes and her style as well as strategies in teaching were so powerful and effective that they have made a lasting impression on me that I will forever try emulating them as a mentor for others and as an educator for students and patients.

DEDICATION

To all my patients, mentors, students,

and future patients, mentors, and students,

I am and will be forever grateful

for the opportunity to learn and share knowledge.

Thank you.

TABLE OF CONTENTS

EXECUTIVE SUMMARY……iii

ACKNOWLEDGEMENTS……iv

DEDICATION……v

LIST OF TABLES……viii

LIST OF FIGURES……ix

CHAPTER 1 INTRODUCTION…… 1
Problem Statement…..……3
Purpose Statement.....……4
Project Objectives……..……5

CHAPTER 2 REVIEW OF THE LITERATURE……6

CHAPTER 3 THEORETICAL UNDERPINNING OF THE PROJECT……...15

CHAPTER 4 PROJECT PLAN……...…19
Needs Assessment……..…19
Population Identification…….…..…22
Identification of the Project Sponsor and Key Stakeholders..……..…23
Organizational Assessment…..……..24
Team Selection and Formation…..……27
Define the Scope of the Project……..……...28
Setting…….……...30
Population of Interest…….31
Measures and Instruments...……...31
Timeline…….……35
Project Objectives and Activities..……..35
Resources and Supports…….…….....44
Risks and Threats……...45
Marketing Plan……..……46
Financial Plan…….……46
Institutional Review Board Approval…….……...46

CHAPTER 5 SUMMARY OF IMPLEMENTATION AND RESULTS……48
Initiation of the Project……..48
Threats and Barriers to the Project……..…50
Monitoring of the Project……...52
Data Collection……..…53
Data Analysis……..…54
Giving Meaning to the Data…….……..……75

Dissemination and Utilization of the Results……..…82

APPENDIX A VA OPIOID MONITORING CLINIC (OMC) POLICY……..86

APPENDIX B CHIEF OF PRIMARY CARE LETTER OF SUPPORT……..92

APPENDIX C OPIOID MONITORING CLINIC PROTOCOL……...93

APPENDIX D OPIOID MONITORING CLINIC NOTE…….94

APPENDIX E PROVIDER SATISFACTION SURVEY…….97

APPENDIX F BRIEF PAIN INVENTORY-SHORT FORM…….101

APPENDIX G BRIEF PAIN INVENTORY PERMISSION TO USE……103

APPENDIX H PAIN SCREENING TOOL…….104

APPENDIX I PAIN SCREENING TOOL PERMISSION TO USE.……105

APPENDIX J UNLV INSTITUTIONAL REVIEW BOARD APPROVAL……..……..106

APPENDIX K OPIOID MONITORING PROJECT TIMELINE……...……107

APPENDIX L PATIENT INFORMED CONSENT……108

APPENDIX M OPIOID MONITORING PROJECT BUDGET……..110

REFERENCES ……...…111

VITA..……..118

LIST OF TABLES

Table 1	Summary of Study Participants and Nonparticipants (n=114)……..	56
Table 2	Summary of Study Participants and Nonparticipants that had Positive UDS……..	57
Table 3	Patients found to be "Doctor Shopping"……	57
Table 4	Morphine Equivalent Dose (MED) Comparison Between Participants and Nonparticipants……...	58
Table 5	Retention Outcomes of Patients in OMC Study (n=114)…..……..	60
Table 6	Relationship between Screening Tool/BPI and Patient Retention Outcomes……...…	62
Table 7	Comparison of Opioid Abuse and Misuse Among OMC Participants and Nonparticipants……..	64
Table 8	Comparison of Pre and Post BPI scores among all patients seen in OMC……..	66
Table 9	Top 6 Opioids Cost to VA Las Vegas for 2 Quarters Compared to Fiscal Year 2012 Quarterly Cost……...	67
Table 10	Results of Provider Satisfaction Survey from all PCP Respondents (n=30)……...……	72
Table 11	Results of Provider Satisfaction Survey: PCPs who participated in the OMC study and has Referred Patients in the OMC (n=11)……	75

LIST OF FIGURES

Figure 1	Opioid-related overdose deaths from 1990-2008	7
Figure 2	Percentage of PCPs interested in the Opioid Monitoring Clinic	19
Figure 3	PCPs' knowledge of the VA/DoD opioid use clinical practice guideline	20
Figure 4	Percentage of PCPs who follow the VA/DoD clinical practice guideline	20
Figure 5	Percentage of PCPs who regularly monitor their patients using urine drug screens	21
Figure 6	VA Las Vegas data on the number of patients on opioid therapy	22
Figure 7	Quarterly data of urine drug screens ordered by clinicians in VA Las Vegas	69

CHAPTER 1

INTRODUCTION

According to the International Narcotics Control Board (2013), the United States continue to face an opioid prescription drug abuse problem that threatens its public health system. The use of opioids in the management of chronic, noncancer pain, has become too common in the United States that the nation has become the number one prescriber of opioids in the world with about 200 million prescriptions of opioids written in 2009 (Volkow, McLellan, Cotto, Karithanom, & Weiss, 2011). The United States with only 5% of the world population is estimated to consume about 56% of the world's supply of opioid medications (International Narcotics Control Board, 2013). For example, a more striking statistic is that the United States consumes 99% of the world's supply of hydrocodone and 83% of world's supply of oxycodone (Manchikanti et al., 2012). These statistics are despite the fact that long term use of opioids in the management of chronic pain is becoming more controversial especially with the lack of solid evidence of its effectiveness in the management of chronic noncancer pain and due to its associated long term adverse effects like addiction, abuse, and misuse of opioids (Krebs, Ramsey, Miloshoff, & Bair, 2011; Manchikanti et al., 2012).

Birnbaum et al. (2011) reported that about 5-10% of total healthcare spending dealing with chronic pain was spent on care related to opioid abuse and misuse. In 2007, the United States healthcare system spent $55.7 billion on care of patients who abused opioids. The prevalence of opioid abuse/misuse in the United States has been estimated at around 4-26% (Von Korff, Kolodny, Deyo, & Chou, 2011). Among veterans, the prevalence of abuse and misuse of opioids has been reported at around 18-32% (Ives et

al., 2006; Krebs et al., 2011; Reid et al., 2002). Even though the Department of Veterans Affairs has large purchasing power in negotiating down drug prices, in 2013 the Southern Nevada Healthcare System (VA-Las Vegas) dispensed nearly 700 million pills containing opioids amounting to nearly $90 million in opioid related pharmaceutical cost. This accounts for nearly 12,000 pills for each veteran enrolled in the VA Las Vegas.

The focus of this project was the development and the implementation of an Opioid Monitoring Clinic (OMC) as a clinical referral service within the Primary Care service of the VA-Las Vegas which already had an approved policy for the development and implementation of this OMC (See Appendix A). The project also involved a study to evaluate the effectiveness of the OMC in meeting its goals and objectives.

The growing problem with chronic use of opioid therapy in the management of chronic pain includes addiction, diversion of opioids, and drug overdose (Manchikanti et al., 2012). Compliance with the recommendations from evidenced-based clinical practice guidelines has been asserted as sound mitigation strategy to assist healthcare providers in their decision making process in preventing abuse and misuse of opioids that can potentially reduce opioid-related complications (Trescot et al., 2006). To assist with compliance with using the clinical practice guideline for chronic opioid therapy, the OMC provided regular monitoring of patients to help identify abuse and misuse of prescription opioids. The strategies involved in the operation of the OMC may also benefit the general public by reducing and/or stopping the diversion of opioid prescriptions written and dispensed for patient use from reaching other people who may not be familiar with its use which can lead to harm from opioid-related complications such as accidental overdose.

The VA has a specific clinical practice guideline recommended to healthcare professionals for the use of opioids in chronic pain. The collaborative clinical practice guideline from the Department of Veterans Affairs and Department of Defense (VA/DoD), *VA/Dod Clinical Practice Guideline For Management Of Opioid Therapy For Chronic Pain*, was originally developed in 2003 and later revised in 2010. This guideline recommends trial of opioids to patients with moderate to severe pain who have failed to adequately respond to non-opioid and non-drug therapy in the management of chronic noncancer pain. Additionally, this clinical practice guideline recommends routine urine drug screening (UDS) for patients on chronic opioid therapy to screen for presence of illegal drugs, minimal or avoidance of short acting opioids for breakthrough pain (instead, conversion from short to long acting opioids to reduce potential for abuse or misuse of opioids and to help maintain stable analgesic affect), and avoidance of opioid use on patients with active opioid misuse or abuse (Department of Veterans Affairs and Department of Defense, 2010).

Problem Statement

Reports of opioid abuse and misuse among patients are common in both commonplace readings such as local newspapers as well as in professional, peer-reviewed journals. Reports of addiction to prescription opioids, opioid diversion to support an addiction to other illicit substances, and opioid-related complications such as opioid-related deaths are unfortunately fairly common nowadays. Additionally, reports of prescribers abuse in illegally or illegitimately writing opioid prescription to people who may or may not be their patients are serious problems that contribute to an epidemic level of prescription opioid abuse (Federation of State Medical Boards, 2013; SAMHSA,

2011). Further, studies have shown that many prescribers of opioids are not following current guidelines in the long term use of opioids for the management of chronic noncancer pain (Starrels et al., 2011). A survey of all PCPs in the VA-Las Vegas showed that more than one third (38%) of all PCPs were not familiar with the guideline; and for those who were familiar with the guideline, more than a quarter (28%) were not following the guideline. Further, the survey showed that all (100%) PCPs who responded indicated that they and/or their patients were likely to benefit from an opioid monitoring clinic to assist them in the management of patients on chronic opioid therapy for chronic noncancer pain.

Purpose Statement

The purpose of this project was to develop an OMC in VA-Las Vegas for intensive monitoring of opioid use to help identify veterans who abuse and/or misuse their opioids. Once patients were evaluated and admitted in the OMC, veterans' opioid use was strictly managed by the OMC. The OMC handled the renewal, dose adjustment, opioid substitution, and opioid discontinuation, if needed. Additionally, veterans admitted in the OMC underwent intensive monitoring for abuse and misuse of opioids and other illicit substances. Patients' chronic opioid therapy was aligned with the current VA/DoD clinical practice guideline for the management of chronic pain using opioid therapy. The OMC assisted PCPs, through several educational presentations, in identifying veterans at high risk for opioid abuse and/or misuse based on published data of characteristics of these patients. Published reports showed that patients with history of substance abuse including alcohol, cocaine, heroin, and marijuana were considered high risk individuals (Ives et al., 2006; Manchikanti et al., 2012; Starrels et al., 2011;

Wiedemer, Harden, Arndt, & Gallagher, 2007). Furthermore, patients who consistently tested negative for prescribed opioids were also identified as high risk individuals for misuse or diversion of opioids (Becker, Meghani, Barth, Wiedemer, & Gallagher, 2009; Meghani, Wiedemer, Becker, Gracely, & Gallagher, 2009; Wiedemer et al., 2007; Worley, 2014; Worley & Hall, 2012).

Project Objectives

The following were the project objectives: (1) Develop an Opioid Monitoring Clinic as a referral service within the VA Primary Care Service Line, (2) Implement risk reduction strategies in the OMC for patients admitted to the OMC, and (3) Evaluate OMC effectiveness as far as ability to identify misuse/abuse of opioids through implemented risk reduction strategies, pharmacy cost reduction for opioid use, increased provider satisfaction, and improved PCP compliance with VA/DoD clinical practice guideline.

CHAPTER 2

REVIEW OF LITERATURE

In 1997, the average sales and distribution of opioids in the United States was 96mg morphine equivalents per person. Morphine equivalent is a calculated approximate morphine dose of the opioid prescribed to the person per day. For example, a Hydrocodone 10/325mg is equivalent to 10mg of oral morphine (McAuley, 2013, April 18).

In 2000, when the Joint Commission on the Accreditation of Healthcare Organizations (The Joint Commission) started recommending that pain level be the 5th vital sign, the average sales and distribution of opioids jumped to 710mg morphine equivalents per person. The Joint Commission recommendation increased awareness in the right to pain relief which may have inadvertently resulted in the significant increase in the use of opioids in the management of pain (Manchikanti et al., 2012; Phillips, 2000).

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), there are approximately 12 million people in the United States who abuse and misuse prescription opioids by using them for nonmedical reasons or by obtaining opioid painkillers without a legitimate prescription and using them for nonmedical reasons. Annually, the prevalence rate of Americans who abuse and misuse opioids is around 2 million people (SAMHSA, 2011). Despite the growing problem with opioid use in the United States, there is still a current prevailing thought among patients and healthcare providers that the use of opioids in chronic non-cancer pain is highly effective and carry little adverse effect to patients (Manchikanti et al., 2012). Even when opioids are used according to accepted prescribing guidelines, many adverse effects have

occurred including death due to overdose and other inappropriate use of opioids. Inappropriate use of opioids includes opioids obtained through drug diversion (giving or selling opioids to others). In 2010, 75% of all people who died from prescription drugs died from opioid overdose. Nearly 17,000 people died of opioid overdose in 2010 that the number of opioid-related deaths continues to outpace the number of people dying from a motor-vehicle for persons 34-54 of age (Jones, Mack, & Paulozzi, 2013). The number of unintentional opioid-related overdose death has more than tripled since 1990 (Figure 1).

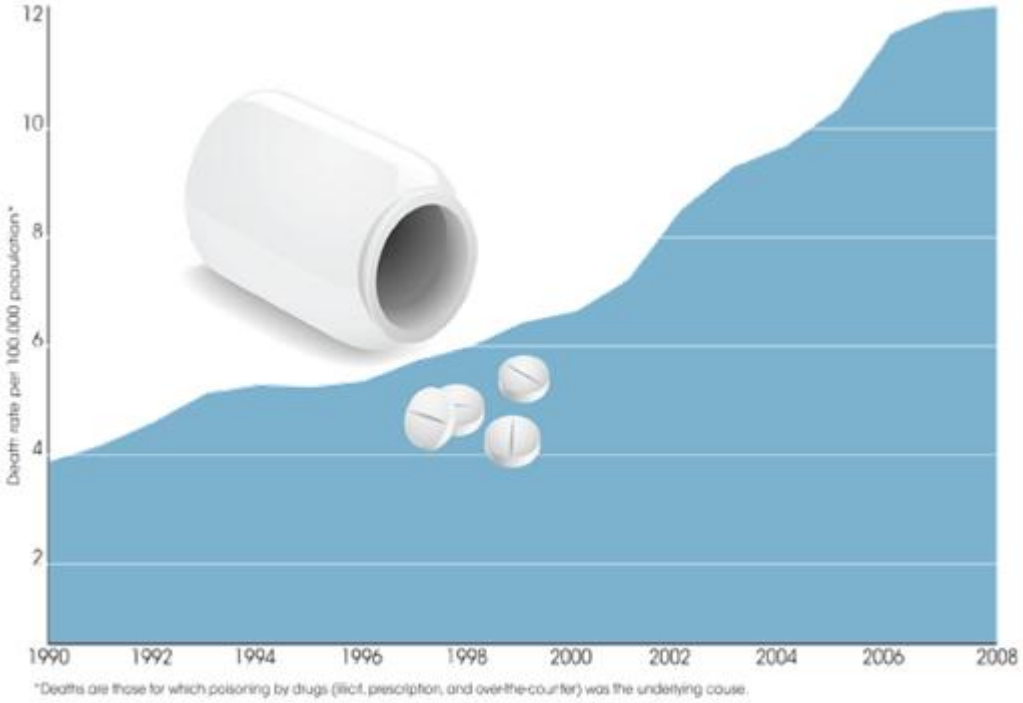


Figure 1. Opioid-related overdose deaths from 1990-2008. (CDC, 2011, November 1). Retrieved from http://www.cdc.gov/homeandrecreationalsafety/rxbrief/

According to the SAMHSA, more than 12 million people reported using opioids for purposes other than management of pain (SAMHSA, 2011). The Centers for Disease

Control and Prevention has declared that abuse of prescription opioids in the United States has reached epidemic proportions; and that the number of nonmedical users of prescription opioids has equaled or exceeded the number of users of marijuana (CDC, 2013, July 2; Heit & Gourlay, 2010). Ives et al. (2006) reported in their prospective study that about a third of patients with chronic pain on chronic opioids misuse their opioids. Another report estimated that 1 in 3000 patients who have been exposed to opioids will develop drug aberrant behaviors that place them at high risk for abuse and misuse of opioids (Cepeda, Fife, Chow, Mastrogiovanni, & Henderson, 2012). Further, those with history of substance abuse were at much higher risk of abuse or misuse of opioids than those with no history of substance abuse (Fishbain, Cole, Lewis, Rosomoff, & Rosomoff, 2008).

Injudicious prescription of opioids among healthcare providers is often cited as a contributor to the growing problem of opioid abuse and misuse in the United States (Federation of State Medical Boards, 2013). Healthcare provider knowledge in the proper and judicious use of opioids in the management of chronic pain is crucial in reducing the complications of chronic opioid therapy (Federation of State Medical Boards, 2013; Manchikanti et al., 2012). One way to assist healthcare providers in their decision making in the management of patients with chronic pain is through the use of clinical practice guidelines. A clinical practice guideline is defined as, "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances"(Field & Lohr, 1990). Clinical practice guidelines are formulated based on best practices that focus on patient safety and effectiveness of clinical decisions. However, Krebs et al. (2011) reported that there is a

lack of compliance with the VA/DoD guideline for opioid use among providers who write opioid prescriptions to veterans with chronic pain. Poor compliance with evidence-based clinical practice guidelines such as guidelines from the VA/DoD and the joint guidelines from the American Pain Society and the American Academy of Pain Physicians may have an impact in the high rate of accidental death from opioid overdose among veterans (Bohnert, Ilgen, Galea, McCarthy, & Blow, 2011). Further, poor compliance with evidenced-based clinical practice guidelines my exacerbate the problem with opioid abuse and misuse among patients at high risks for opioid abuse and misuse. Reid et al. (2002) reported that 31% of veterans on chronic opioid therapy for chronic noncancer pain in their study were found to be abusing and/or misusing opioids. The percentage of veterans abusing and misusing their opioids in the Reid et al. (2002) study was similar to findings by Von Korff et al. (2011) which reported an opioid abuse and misuse rate of nearly 30% among patients on chronic opioid therapy for chronic noncancer pain. A more recent study by Baser et al. (2013) found that the five year prevalence rate of opioid abuse and misuse among veterans on chronic opioid therapy for chronic noncancer pain was 3.26%, and that the prevalence of opioid abuse among veterans is nearly 7-fold as compared to the general population. This is noteworthy because many patients are often continued on opioid therapy for many years and thereby increasing their risk of abuse and misuse of their prescription opioid as they accumulate years on chronic opioid therapy. In fact studies have shown that it becomes very difficult for patients to come off opioid therapy once they start on it. A study by Martin et al. (2011) reported that once a patient is on opioid therapy for at least 90 consecutive days, the chance of them being on continued opioid therapy in their lifetime remained high;

50% of patients in their study remained on opioid therapy years after the start of opioid therapy.

The consequential economic cost for chronic pain is substantial. The annual cost is estimated to be between $560-635 billion; and about $99 billion of the total economic cost for chronic pain is spent by the Federal and State governments (Gaskin & Richard, 2012). In 2007, $55.7 billion was spent on care of patients who abused opioids (Birnbaum et al., 2011). Leider, Dhaliwal, Davis, Kulakodlu, and Buikema (2011) reported that patients with chronic pain who abuse and misuse opioids spent 35% more time in the hospital with 14% higher healthcare costs than those who do not abuse and misuse opioids. Patients who misuse opioids had an average excess medical cost of $20,546 per year as compared to those who do not misuse opioids (Birnbaum et al., 2011). The economic burden among veterans is even higher. A recent report by Baser et al. (2013) reported that the annual economic cost of veterans who abused their opioid prescriptions was nearly $29,000.

The incidence of opioid abuse and misuse is high resulting in exorbitant healthcare costs. Opioid abuse and misuse are also major patient safety issues with ramifications that can extend to the welfare of the public. In 2010, 12 million reported misusing their opioid prescriptions by using their pain medications for nonmedical reasons (SAMHSA, 2011). For example, people who misuse their opioid prescriptions may mix their prescription opioids with alcohol and/or other illicit substances such as cocaine, heroin or marijuana to support their addiction. Another example of opioid misuse is the diversion of prescription opioids by sharing their opioids with friends and/or families or by selling their opioids to other people (Manchikanti et al., 2012). In

2008, nearly 15,000 people died from opioid overdose and according to the CDC, this number was higher than the number of people who died from cocaine and heroin combined (CDC, 2011, November 1). Patients who misuse opioids can be challenging to PCPs as these patients present with aberrant behaviors that tend to stress the resources of clinicians and organizations. Worley (2014) reported that patients who go from provider to provider to obtain opioid prescriptions tend to exhibit behaviors that can be psychologically draining to clinicians.

The high prevalence of death from opioid abuse and misuse, the reported epidemic of people who use their opioids for nonmedical reasons, and the high economic cost for people who abuse and misuse their opioids are serious concerns not just for the VA but for the entire nation as well. Based on these evidence-based problems, a need for innovative solutions is much needed. The OMC is an innovative approach to help solve this serious problem. To my knowledge, based on published literature, the OMC is the first opioid monitoring clinic for high-risk patients on chronic opioid therapy in the VA and in the United States that was developed, implemented and operated by an advanced practice registered nurse (APRN).

Opioid renewal clinics have been implemented in the VA in the past but none were directly operated by an APRN. In 2002, a clinic called Opioid Renewal Clinic (ORC) was implemented in the Philadelphia VA to assist PCPs in the management of patients with chronic pain and on chronic opioid therapy (Wiedemer et al., 2007). The ORC was a collaborative co-management between PCPs and pharmacy service. The pharmacy service assisted in ordering and documenting the monitoring of patients referred to the ORC and the PCPs were still responsible in renewing the opioid

prescriptions of patients enrolled in the ORC. The two year pilot study accepted a total of 335 patients. The authors reported that 51% of patients accepted in ORC initially had documented aberrant behaviors and 45% of these patients resolved their aberrant behaviors through intensive opioid monitoring using random urine drug testing. Furthermore, the authors suspected that the 38% of patients who eventually discharged themselves out of the ORC likely had an ongoing addiction or were diverting opioids. The authors suspected that by discharging themselves out of the ORC, they may be protecting their addiction and/or opioid diversion from being caught in the ORC. Thirteen percent (13%) of patients who were accepted in the ORC were found to have an addiction problem with opioid use and eventually were referred to addiction treatment; and 4% were weaned off opioids due to consistently negative urine drug screens. The ORC demonstrated significant pharmacy cost savings, increased use of urine drug screening by PCPs, decreased emergency room visits, and increased PCP satisfaction.

A VA in Ohio created the Controlled Substance Oversight Board (CSOB) to assess compliance of opioid management practice per current VA/DoD clinical practice guideline and created an opioids refill clinic for renewing opiods for veterans. Patients who were identified as abusers and misusers of opioids were convicted for drug trafficking; and those who did not participate in the recommendation of CSOB were flagged by the CSOB to alert staff of their noncompliance with recommended treatment (Climer, n.d.). A VA in New York was able to reduce opioid cost by effectively switching veterans on more expensive long acting opioids such as Oxycontin and Fentanyl to less expensive long acting opioids such a long acting morphine. A secondary purpose of this initiative was to reduce the potential for inappropriate use of expensive

long acting opioids. The initiative was able to reduce the number of prescriptions of expensive long acting and potentially inappropriate opioids from 165 to 69 prescriptions in less than 6 months (from November 2007 through March 2008). Projected annual savings to the facility from the initiative was reported at $276,998. Although not specifically measured, there was a general consensus that the initiative improved overall patient safety due to healthcare providers' increased knowledge on the safe use of opioids and increased awareness of patient safety issues related to the use of methadone, another long acting opioid (Kharlamb, n.d.).

In Northern California VA, a working group developed a program to minimize opioid diversion and to align opioid use within their VA according to their Pain Management Guideline. The results of their work have not been published but the goals of the initiative were fourfold: (1) Better manage chronic pain based on World Health Organization's Pain Ladder, (2) Decrease number of short-acting opioids prescribed, (3) Create continuity in pain management amongst VA clinicians, and (4) Minimize diversion (Lockhart, 2008).

The American College of Preventative Medicine and the American College of Physicians are among several professional organizations that have released formal position statements regarding the growing problems with prescription opioid abuse and the need for patient monitoring to help identify abuse and misuse of opioids (American College of Preventative Medicine, 2011; Kirschner, Ginsburg, & Sulmasy, 2013). The American Association of Nurse Practitioners website has a link in their clinical resource menu where interested practitioners would be redirected to the National Institute of Drug Abuse website for clinical information about prescription opioid abuse and mitigation

strategies including regular monitoring through urine drug screens, use of prescription drug monitoring databases, and pill counts (American Association of Nurse Practitioners, n.d.; National Institute of Drug Abuse, n.d.).

Based on this literature review, there is a dire need for an intervention that could address the worsening problem of opioid abuse and misuse in the United States and the Department of Veterans Affairs. A common theme among currently available clinical practice guidelines such as from the VA/DoD, American Pain Society, and American Academy of Pain Medicine recommend regular monitoring of patients on chronic opioid therapy to help identify abuse as early as possible and refer these patients for treatment. Patients with certain risk factors for abuse and misuse of opioids are at greater risk for opioid related complications and thus would need more intensive monitoring. The OMC was developed and implemented to address this specific need to intensively monitor high risk patients on chronic opioid therapy.

CHAPTER 3

THEORETICAL UNDERPINNING OF THE PROJECT

Kurt Lewin's Change Theory was selected as the conceptual framework for this project. The theoretical framework provided the structure and guidance needed to analyze the process of change to implement the OMC. The theoretical framework identified the forces that drive the change forward and addressed the barriers that resist the change. The project involved the implementation of OMC in VA-Las Vegas as a resource clinic where PCPs could refer patients who were at high risk for opioid abuse and/or misuse. The operational framework embedded within Lewin's Change Theory is the Force Field Analysis Model. This model was used to assess individual and group behavior that can progress or impede change and evaluate organizational readiness for change (Baldonado et al., 2011). Two dynamic and opposing forces that impact change are: driving forces – those that initiate and encourage the change to occur and restraining forces – those that prevent the change from occurring (Baulcomb, 2003). For change to transpire successfully, the driving forces must outweigh the restraining forces.

Lewin's Change Theory identifies three phases to the change process: unfreezing, changing, and refreezing (Maxwell, 2009). Unfreezing requires communication of the need for change. Changing involves implementation of new behaviors and practices. Refreezing occurs when the change has been integrated into practice (Borkowski, 2009). Achievement and sustainment of this practice change renders Lewin's Change Theory the ideal framework for guidance in this OMC.

A change in the long-held belief that chronic opioid therapy as a safe and effective treatment for chronic pain was the greatest positive factor for the development

of the OMC. Current literature and educational offerings like continued medical educations are being bombarded with data that exposes the current problem of chronic opioid therapy. Additionally, professional organizations such as the American College of Preventative Physicians, American College of Physicians, American Pain Society, American Academy of Pain Medicine, and the Federation of State Medical Boards have all released formal position statements regarding the growing problem of prescription opioid abuse and the need to monitor patients to help identify abuse and misuse of prescription opioids (American College of Preventative Medicine, 2011; Chou et al., 2009; Federation of State Medical Boards, 2013; Kirschner et al., 2013). In 2011, the Institute of Medicine (IOM) released its report titled, "*Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*" (IOM, 2011). In its report, the IOM noted a very serious growing problem in the United States of opioid abuse and misuse. Current shortage in PCPs combined with increasing number of patients entering the VA system for medical care is causing access problem to patients and staff dissatisfaction among PCPs who have to manage increased number of patients and more complicated patients. Among the complicated and challenging patients seen in primary care are patients on chronic opioid therapy with history of substance abuse who must be monitored carefully for judicious use of opioids. These patients are often seen more frequently than patients not on opioid therapy because of regulatory mandates in opioid therapy. This problem was clearly demonstrated during the needs assessment survey done for this OMC project whereby 100% of PCPs who participated in the survey voiced their support for the development of the OMC to assist them in the management of patients on opioid therapy. The growing problem with opioid abuse and misuse was a

call for concern that many clinicians including leadership were aware. Using Lewin's Change Theory, the first phase was initiated by communicating with stakeholders, mainly the chief of primary care and PCPs, of a need to develop a specialized referral service that can assist PCPs in managing their patients with risk factors for abuse and misuse of opioids.

The driving forces for change exceeded whatever restraining forces that may be encountered in the development of OMC. The support from stakeholders, such as those from PCPs, and the leadership (Chief of Primary Care) were major driving forces to support the implementation of change through the development of OMC (See Appendix B for the copy of letter of support from Chief of Primary Care). Among the restraining forces that would be expected in the successful implementation of OMC are those that were likely to occur from patients who were referred by their PCPs into the OMC. Patients who currently abuse or misuse their opioids but have not been identified yet by their PCPs were subjected to intensive opioid monitoring that exposed their aberrant behaviors and likely resulted in patient dissatisfaction. In these patients, once they were determined to meet the definition of major aberrant behavior (positive UDS for non-prescribed opioids and/or positive UDS for stimulants like cocaine and methamphetamines), they were referred to the ADTP of the VA-Las Vegas to help them with their problem.

In the movement phase, during the development of the OMC, multiple formative evaluations of the operation of the clinic were strategically designed to ensure that problems and positive experiences in the early implementation of the OMC were noted and corrected if needed. A series of staff and provider educations were implemented and

included in the OMC development plan to ensure continued communication between PCPs and the OMC. Educational offerings provided during the development of the OMC also served another purpose besides garnering feedback and support from stakeholders. The educational offerings also provided the essential information to the PCPs of the problem of opioid abuse and misuse among patients. The offerings helped enhance exposure of PCPs to the problem and helped aligned them to the recommendations from the VA/DoD clinical practice guideline.

In the refreezing phase, summative evaluation of the OMC was conducted to report findings to leadership as well as PCPs for continued operation of the OMC. The positive findings from evaluating the OMC were very encouraging and support the effectiveness of the OMC in identifying misusers and abusers of opioids. The evaluation also showed improved PCP compliance with the recommendations from the VA/DoD clinical practice guideline. The long-term effect of the OMC in increasing provider satisfaction, and in increasing overall patient satisfaction will be evaluated after a year of OMC operation.

CHAPTER 4

PROJECT PLAN

Needs Assessment

A needs assessment was done on January 24, 2013. An online survey using SurveyMonkey was sent to all PCPs in the VA-Las Vegas. At the time the survey was sent, there were forty PCPs in the VA-Las Vegas facility. The response rate for the survey was 80% (32/40). All PCPs who responded to the survey indicated the need for an OMC to assist them in the management of patients on chronic opioid therapy (Figure 2). Of those who responded, 62% reported that they have knowledge of the VA/DoD clinical practice guideline on opioid therapy but less than 60% indicated they follow the clinical practice guideline (Figure 3; Figure 4). Additionally, 80% of the PCPs who responded in the survey indicated that they routinely monitor their patients on chronic opioid therapy (Figure 5).

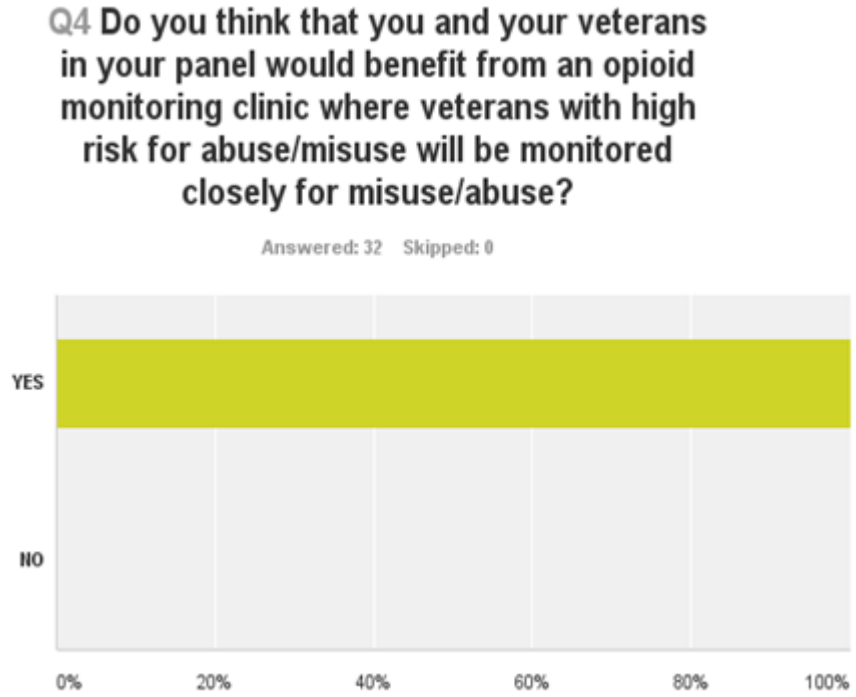


Figure 2. Percentage of PCPs interested in the Opioid Monitoring Clinic.

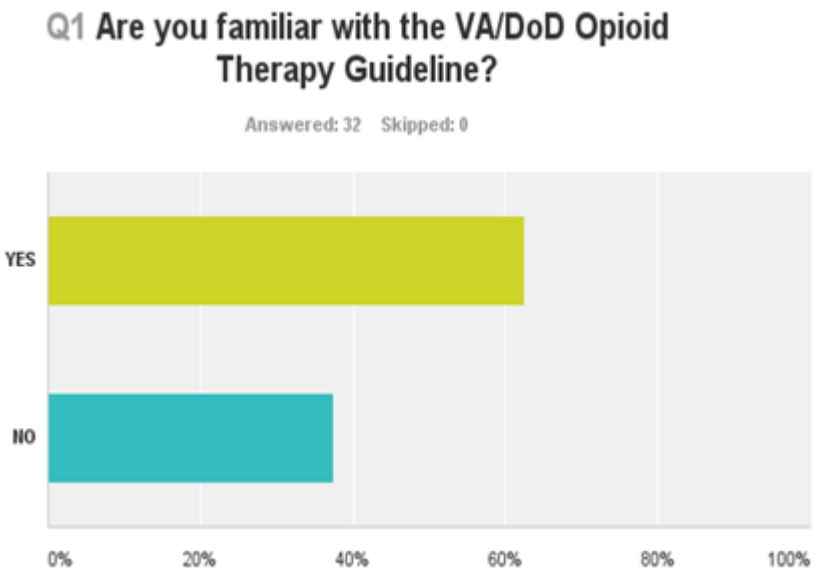


Figure 3. PCPs' knowledge of the VA/DoD opioid use clinical practice guideline.

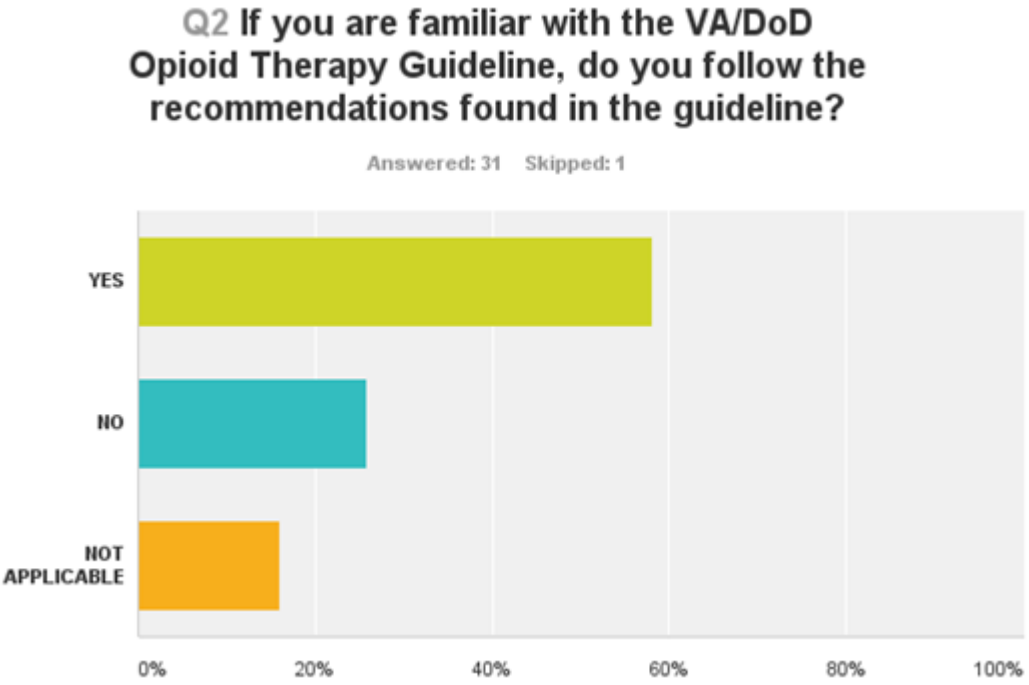


Figure 4. Percentage of PCPs who follow the VA/DoD clinical practice guideline

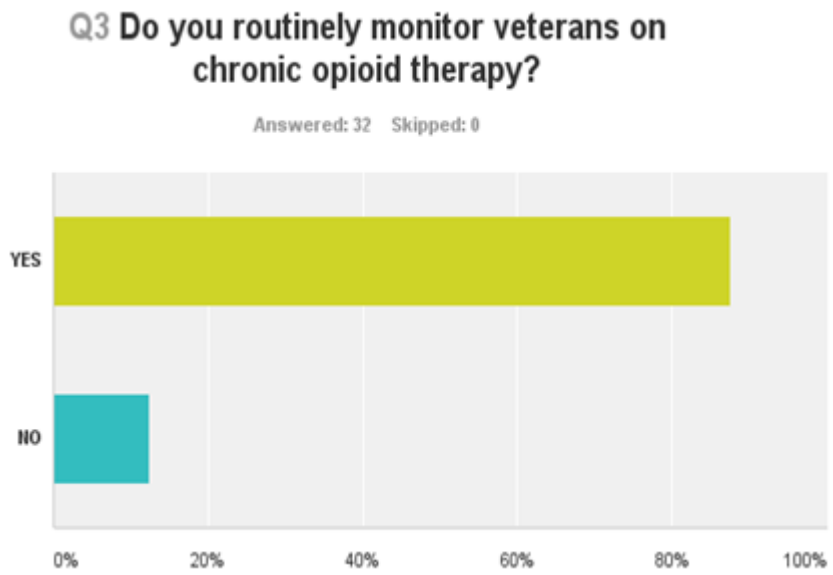


Figure 5. Percentage of PCPs who regularly monitor their patients using urine drug screens.

In addition to the needs assessment survey, data from a VA Las Vegas facility was obtained to quantify the number of patients on chronic opioid therapy. In March 2013, there were 5,881 patients on opioid therapy (Figure 6). Of these, there were 738 patients on at least 120mg of morphine equivalent dose (MED) per day and 333 patients were on at least 200mg MED per day. At least 13% of patients on opioid therapy in VA Las Vegas were on high dose of opioids (>100mg MED/day). Previous published studies reported that the incidence rate of patients on chronic opioid therapy for chronic noncancer pain who abuse their prescription opioid is about 30% (Reid et al., 2002; Von Korff et al., 2011). The five year prevalence rate of opioid abuse among veterans is at least 3% (Baser et al., 2013). Based on these baseline data, there may be around 1,800 veterans who are likely abusing and misusing their opioids. The need to prevent abuse and misuse of opioids is clearly indicated in VA Las Vegas. In effect, the OMC is specifically designed to identify abuse and misuse of opioids through evidence-based

mitigation strategies that would help identify patients who abuse and misuse their prescription opioids.

Location	Patients (n)Daily Morphine >120mg	Patients (n) Daily Morphine >200mg	All Patients with Opioid Rx (n)	%Patients with Morphine >120mg	% Patients with Morphine >200mg
Las Vegas	738	333	5,881	13%	6%

Figure 6. VA Las Vegas data on the number of patients on opioid therapy.

Population Identification

The VA Las Vegas is a catchment area for the 240,000 veterans living in Southern Nevada. Approximately 60,000 veterans are enrolled in the VA Las Vegas. About 10% of veterans eligible to be seen in the VA Las Vegas are women. The OMC receives referrals from all Primary Care Clinics of the VA-Las Vegas including referrals from specialists of the VA Las Vegas Integrated Pain Clinic. The Primary Care Clinics see veterans with ages ranging from 18 years old and over.

Patients admitted to the OMC are veterans with chronic pain and on chronic opioid therapy. Additionally, they have certain risk factors that put them at high risk for abuse or misuse of opioids. These factors include documented aberrant behaviors such as multiple early refill requests, history of lost medications, negative drug screens, positive drug screens for substance not prescribed, and noncompliance with plan of care. History of substance abuse including alcohol, cocaine, heroin, and marijuana are also known risk factors for opioid abuse and misuse of opioids (Krebs et al., 2011; Meghani et al., 2009).

OMC patients were eligible for inclusion in an OMC Study aimed at evaluating OMC effectiveness if the patients gave their informed consent. Eligibility for study participants seen and evaluated in the OMC included age 18-65 with provider-diagnosed chronic noncancer pain and on chronic opioid therapy. Study participants also needed to have a history of substance abuse (i.e. heroin, cocaine, alcohol), and/or provider-identified and documented aberrant behaviors (i.e. report of medication loss, request for early refills) (See Appendix C for OMC protocol and eligibility requirements).

For provider participants on this study, the eligibility criteria included physicians, physician assistants, and advanced practice nurse practitioners working for the VA Las Vegas Primary Care on a full time and part time basis with ages ranging from 25-80. Forty-two PCPs were eligible to participate in the study when the online survey was sent to all PCPs in VA Las Vegas on February 18, 2014.

Identification of the Project Sponsor and Key Stakeholders

The development and implementation of the OMC as a referral service within the Primary Care service in the VA Las Vegas has strong support from the PCPs and leadership. The growing problem of opioid abuse among patients is a constant concern for clinicians as well as administrative leadership. The problem not only affects patients but it also has far reaching effects to clinicians who prescribe opioids, the pharmacy service that dispenses the opioids, and the organization that is burdened with the high economic cost of opioid abuse and misuse. The general public is likewise affected. Patients who divert their opioids by selling them or by sharing them with friends and families are at risk for opioid-related complications including death by using these diverted opioids for nonmedical reasons (CDC, 2011, November 1). The strong support

from key leadership, mainly the of Chief of Primary Care, was further strengthened by the findings from the needs assessment survey which revealed an overwhelming interest by PCPs in VA Las Vegas for a clinic that would assist them in the management of high risk patients on chronic opioid therapy. Furthermore, the growing concern of an epidemic problem of prescription opioid abuse in many cities including Las Vegas and nationwide is also a main motivation for the development and continued support in the development and the implementation of the OMC.

Organizational Assessment

The major components of the VA health system structure are Primary Care Service, the Mental Health Service, Medicine Service, and Nursing Service. The OMC is administratively accountable to the Primary Care Service with close collaboration with the Mental Health Service and Medicine Service. There are currently six Primary Care Clinics in the VA-Las Vegas system (four in Las Vegas, one in Pahrump, and one in Laughlin, Nevada). The OMC is administratively assigned to the Primary Care Service under the supervision of the Chief of Primary Care. The Primary Care Service was responsible for clinic profile development, OMC clinic staffing, and OMC logistical support including allocation of clinic rooms, and patient examination equipments. Each Primary Care Clinic has their own mental health clinic staffed by mental health clinicians including psychiatrists, psychologists, mental health nurse practitioners, substance abuse counselors, and mental health nurses.

The Mental Health Service – alcohol and drug treatment program (ADTP) of the VA-Las Vegas is administratively run by the Mental Health Care Line. The ADTP is utilized for patients found to be abusing and/or misusing their opioid medications. The

Medicine Service is where the Integrated Pain Clinic belongs. The VA-Las Vegas has an Integrated Pain Clinic located in the main hospital of the VA-Las Vegas. The Integrated Pain Clinic is administratively run by the Medicine Service. The clinic is staffed by physicians and physician assistants who specialize in pain management. The following services are offered in the integrated pain clinic: (a) chronic pain management, (b) acupuncture, (c) chiropractic services, (d) anesthesia injections, (e) physiatry and rehabilitation medicine, and (f) osteopathic manipulation therapy. Patients with MED of >200mg per day of opioid therapy were referred to the Integrated Pain Clinic per OMC clinic protocol for further pain evaluation and management. In addition to referring patients on very high MED, the OMC also referred patients to the Integrated Pain Clinic when there was a discovery of abuse and misuse of prescription opioids. Patients who were found to be abusing their prescription opioids were referred to the ADTP and sometimes to the Integrated Pain Clinic for management of their pain symptoms through non-opioid therapy using one or more of the services that the Integrated Pain Clinic provides. Patients referred to the Integrated Pain Clinic due to abuse and misuse of opioids were eventually discharged from the OMC but may be referred back in the future by the Integrated Pain Clinic clinicians or by their PCPs according to the OMC eligibility criteria. Lastly, OMC referred patients to the Integrated Pain Clinic when there was no history of using non-pharmaceutical modality in the management of pain symptoms in veterans referred and seen in the OMC.

The OMC is supported by the other clinical services including the Pharmacy Service, Laboratory Service, Nursing Service, and Health Administration Service (HAS). The pharmacy service is located in the same building as the OMC and stocks most of the

prescribed medications in Primary Care including controlled substances, antihypertensive, hypoglycemic, cholesterol lowering drugs, antibiotics, and others. Although some patients can choose outside pharmacy to dispense their medications, all controlled substances including opioids are only dispensed in the VA-Las Vegas. The Pharmacy Service provided the baseline and subsequent evaluation reports of opioid use in the VA Las Vegas including number of total opioid use with breakdown to specific type of opioids and its associated pharmacy cost. The Laboratory Service provided the testing of urine drug screens for patients admitted in the OMC. Confirmatory tests using gas chromatography and mass spectrometry (GC/MS) are done by the laboratory service. The nursing service provided the nursing staff for the OMC. The HAS provided the Medical Support Assistant (MSA) staff that assisted in scheduling patients and performed other front desk administrative duties.

The OMC is an APRN-led clinic. The APRN is responsible in the development, implementation and sustenance of the OMC in collaboration with other specialty clinics within the VA-Las Vegas, and in consultation with the Chief of Primary Care. The OMC is headed by an APRN and assisted by a team of a Registered Nurse (RN), Licensed Practical Nurse (LPN), and MSA. This teamlet came from the Primary Care team in the Southwest Primary Care Clinic (SW PCC) and worked full time (Monday through Friday) from 0800-1700. The teamlet operates in the same rooms where the team works full time on other times not related to the OMC. The rooms are dedicated to the teamlet so the use of the rooms is exclusive for primary care visits or for OMC visits. The APRN has two patient rooms to see patients and alternated rooms with an RN/LPN for intake of patient information.

Team Selection and Formation

The OMC was conceptualized by an APRN who worked ten years in the primary care management of veterans including homeless veterans. This APRN is also the VA Las Vegas Primary Care Champion in Pain Management. A Primary Care Champion in Pain Management is a clinician who has been identified by organization leadership to be a clinician with competence and skills to be a resource in Primary Care pain management for other clinicians in the facilities. Each facility in the VA has at least one Primary Care Champion; the VA Las Vegas has one Primary Care Champion. All Primary Care Pain Champions were sent by the VA for advanced training in evidenced-based pain chronic pain management. The Pain Champion collaborates closely with the Integrated Pain Clinics in the VA and are members of the local and network Pain Management committees in the VA. The APRN was the team leader for the development and implementation of the OMC.

Once commitment by the Chief of Primary Care was secured to support the development and implementation of the OMC by the APRN, team selection was identified as the next phase. OMC staff were diverted from the current Southwest Primary Care Clinic teamlet led by the APRN.

The OMC development team was also supported by the Information Technology Department in the development of clinical templates that needed to be integrated in the electronic medical record of the VA Las Vegas. A clinical application coordinator (CAC) provided the expertise in the integration of the electronic templates including the electronic consults and progress notes that were associated in the operation of the OMC. The CAC assisted in the development of a test clinic in the test account of the VA CPRS

for OMC staff to practice, modify and improve. OMC staff practiced with consult management and documentation in the OMC clinic using the test clinic. Consult management practice involved using a practice patient to refer a patient to the OMC to ensure receipt of the electronic consult in the practice environment of CPRS. Once the electronic consult was ordered, the OMC staff practiced with the consult by leaving comments in the electronic consult to ensure receipt of additional comments by all OMC and the referring provider. A trial of patient scheduling was also done during the practice session. Lastly, test OMC clinical notes were attached to the consult to ensure that all personnel associated with the consult were being alerted of any activities associated with the electronic consult. Among the activities tested during the testing phase of the electronic consult included consult receipt, consult discontinuation when an OMC was not an appropriate consult for the OMC, consult transfer when a consult was incorrectly sent to the OMC but was intended for other specialty consult, patient scheduling, attachment of notes, and OMC staff comment addition. Once members of the OMC staff were satisfied with the OMC electronic consult management including documentation, the test account was activated into the live account for live implementation of the OMC in VA Las Vegas. Immediately after the OMC consult service was placed into the live account, PCPs interested in referring patients to the OMC were able to refer patients to the OMC using the electronic consult option in CPRS.

Define the Scope of the Project

The operation of the OMC is dedicated to the management of patients on chronic opioid therapy. First, it is expected that the OMC has the potential to improve overall patient satisfaction in the long term since patients admitted in the OMC had their opioids

renewed timely and had their opioid therapy aligned with the VA/DoD clinical practice guideline. Timely renewal of opioids can result in a decrease in unscheduled clinic visits and/or off-hour visits to local emergency departments (Wiedemer et al., 2007). Further, the potential for opioid-related complications can be reduced as opioid therapy is geared toward current guideline recommendations in the management of chronic pain using chronic opioid therapy. By reducing the pill burden associated with using short acting opioids (these opioids tend to be taken at least four times daily in order to achieve a continuous analgesic effect), the change to long acting opioids based on the VA/DoD clinical practice guideline has the potential to significantly reduce the number of pills dispensed to patients each month. For example, hydrocodone/acetaminophen is usually written to be taken one to two tablets every four to six hours during the day resulting to at least 180 tablets of this prescription opioid being dispensed to a patient every single month. In contrast, morphine sulfate sustained acting tablets can be given to a patient with the same MED as the hydrocodone but with fewer pills per month. The morphine sustained acting pills can be taken twice daily and would reduce the number of pills per month being dispensed to a patient with high risk factors for opioid abuse and misuse from 180 pills to 60 pills per month.

Second, the scope of change within the VA Las Vegas can be a "win-win" scenario to everyone involved. The OMC can decrease the workload from the Integrated Pain Clinic since some patients who would otherwise be referred to their service were referred to the OMC. The VA Las Vegas facility would benefit from expected pharmacy cost savings and reduced utilization of outside services (i.e., ED visits), and expected improvement in patient access to PCPs since patients admitted to the OMC would allow

openings for other patients seeking appointments with their PCPs. Lastly, the VA Las Vegas also would benefit from the expected increased PCP and patient satisfaction.

Third, the public would benefit from the OMC as potentially dangerous prescription opioids being diverted into the community via sale or sharing can be reduced or stopped through the OMC's process of identifying patients who abuse and misuse opioids.

In summary, the creation and implementation of the OMC can effectively assist PCPs in the management of high risk patients on chronic opioid therapy for chronic noncancer pain. PCPs would be able to refer eligible patients to the OMC based on specific eligibility criteria. In return, the OMC has the potential to improve the quality of patient care by aligning the use of opioids in the management of chronic noncancer pain with VA/DoD current evidence-based guideline. The implementation of the OMC also has the potential to be an effective strategy to reduce the cost of healthcare delivery to patients by reducing the number of unnecessary opioids pills dispensed by the VA-Las Vegas, and by potentially preventing opioid-related complications by discontinuing opioid therapy on patients who are found to be abusing and misusing their prescription opioids. Lastly, the OMC has the potential to improve PCP satisfaction by off-loading some of their time in the management of complicated high risk patients on chronic opioid therapy.

Setting

The OMC was piloted in the SW PCC of Southern Nevada Healthcare System Las Vegas under the Primary Care Line and staffed by a teamlet that belonged to the Primary Care Line. Arrangements were made with the Chief of Primary Care, laboratory

service, pharmacy service, ADTP staff, nursing service, and HAS in the development and implementation of the OMC. The Chief of Primary Care has approved the development of the OMC and supported the implementation of OMC within the Primary Care line to assist PCPs in the management of high risk patients on chronic opioid therapy for chronic noncancer pain.

Population of Interest

Veterans who were enrolled in the VA Las Vegas, assigned to a primary care provider, and had risk factors for abuse and misuse of opioids were the target population for the OMC development and the study to evaluate the OMC. These veterans were on chronic opioid therapy for chronic noncancer pain. Veterans with history of substance abuse such as history of cocaine, heroin, alcohol abuse, and marijuana use can be referred to the OMC by their primary care providers. Veterans with documented aberrant behaviors such as frequent requests for early refills due to loss of opioid medications and/or due to running out early were also eligible to be referred to the OMC. Veterans who consistently test negative for their prescribed opioids despite regularly refilling their opioids with documentation that they were indeed taking their opioids were also eligible to be referred to the OMC for regular monitoring.

Measures and Instruments

The OMC used the following tools to manage patients evaluated and admitted in the clinic. At admission, a basic demographic data were documented in the initial clinical note template which is an electronic documentation system that healthcare providers working for the VA utilize to document each patient visit. The initial OMC clinical note template included gender, age, main source of pain, history of substance abuse (i.e.

opioid, alcohol, cocaine, heroin, marijuana, and/or other history of substance abuse such as methamphetamines, barbiturates and benzodiazepines (See Appendix D for the OMC clinic note).

Patients were screened for suicidal or homicidal thoughts. At each visit, patients were asked if they had suicidal or homicidal thoughts in the last 30 days. Further, patients were also asked if they had a history of suicidal attempt in the past. Based on patient responses to these questions, patients were categorized into four categories of risk threats: (1) no risk (2) low risk (3) moderate risk and (4) high risk. Anyone who was found to be suicidal or homicidal or who were placed on moderate risk or high risk categories were excluded from OMC and instead referred to appropriate specialty care for further evaluation. The No risk category included those patients who did not have any suicidal thoughts in the last 30 days and no suicidal attempts in their history. The low risk category included those patients who had no suicidal thoughts or homicidal thoughts in the last 30 days but had distant history of suicidal attempts in the past. The mode of suicidal attempt in the past was documented in the OMC clinical note. The OMC staff also had the discretion to screen patients further when indicated using various screening tools integrated in the VA CPRS such as the PHQ-2 and PHQ-9 as depression measures. The OMC staff also had the discretion not to admit patients into the OMC and refer patients to the Mental Health Care service when the OMC staff based on their professional opinion and evaluation that patients would not be a candidate for the OMC due to unstable or untreated mental health conditions. Next, vital signs were obtained which included blood pressure, heart rate, respiratory rate, height, weight, temperature,

and current pain intensity (0-10 with zero as having no pain and 10 as having the worst pain they could imagine).

The OMC utilized intensive monitoring for opioid abuse/misuse through urine drug screens, pill counts, and controlled substance drug utilization review. The controlled substance drug utilization review was done by reviewing the Nevada Prescription Monitoring Program (PDMP) database which is a database of patients in Nevada who received schedule II-IV controlled substances. For veterans with addresses in or near Arizona, the Arizona Controlled Substance Prescription Monitoring Program (CSPMP) was also accessed. For addresses in or near Utah, a PDMP report was requested via a fax request to Utah's PDMP office as Utah only allows access to their PDMP database to clinicians licensed in their state. The PDMP databases are operated by each respective state to allow healthcare providers who were given access to the database to inquire about controlled substance use of a patient based on certain identifying information such as name and date of birth. Information that can be found in these databases includes the name, dosage, and amount of opioid pills dispensed, the healthcare provider who wrote the prescription, the pharmacy that dispensed the opioid prescription and the date the opioid prescription was dispensed to the patient. Accessing the state prescription monitoring program database in addition to accessing the VA medical record can be helpful in identifying aberrant behaviors such as "doctor shopping" among patients who misuse their opioid prescriptions.

Urine drug screens were done at the conclusion of the initial visit with the OMC, and repeated at the discretion of the OMC staff. Patients were asked to complete the Brief Pain Inventory (BPI) short form and the results were documented in CPRS. A pain

Screening Tool by Alturi and Sudarshan (2004) was also completed and documented in CPRS at the initial visit.

Lastly, an online provider satisfaction survey was developed through SurveyMonkey and sent to all PCPs in the VA Las Vegas on February 18, 2014 to assess the satisfaction of PCPs who referred patients to the OMC (See Appendix E for a copy of the Provider Satisfaction Survey). Additionally, the provider satisfaction survey included questions related to PCP compliance with the VA/DoD clinical practice guideline.

Brief Pain Inventory. The short form of the BPI was used at admission and in every subsequent clinic visit to assess for trend in pain intensity and functional status (See Appendix F). The BPI is a self administered pain assessment that has been widely used in documenting pain intensity and how pain interferes with function among patients with chronic noncancer pain. The BPI measures sensory pain intensity and the functional intensity or the degree that pain interferes with different areas of life (Cleeland & Ryan, 1994). The validity of BPI is well reported in the literature (Keller et al., 2004; Mendoza, Mayne, Rublee, & Cleeland, 2006). Permission to use the BPI instrument was obtained from the developer (See Appendix G).

Pain Screening Tool. Additionally, each patient evaluated in the OMC for admission in the clinic had the pain Screening Tool developed by Atluri and Sudarshan (2004) completed by the OMC clinician to assess their risk for inappropriate use of opioids (See Appendix H). In their validity study, patients who scored more than 3 points on the 6 item questionnaire (1 point each for each item) were noted to have a 17 fold increased risk of opioid abuse/misuse than those who scored less than 3 points. When used in combination with other risk reduction strategies, the likelihood of

identifying patients who abuse or misuse opioids can be dramatically improved. Permission to use the Screening Tool was obtained from the instrument developer for use in this project and study (See Appendix I).

Timeline

As part of a continuous quality improvement (CQI) initiative for the VA-Las Vegas, the OMC was developed and implemented. The OMC started screening patients in July 2013. An OMC Study aimed to evaluate the clinic commenced immediately after approval from the University of Nevada Las Vegas (UNLV) Institutional Review Board (IRB) on November 22, 2013 through an expedited review approval process (See Appendix J for the copy of the UNLV IRB approval). Patients who were previously seen in the OMC and eligible to be participants for the OMC study were asked to participate in the study through voluntary informed consenting process. New referrals to the OMC after the IRB approval were asked to participate in the OMC study if they met the eligibility criteria for the OMC study. Data for the OMC study were collected from July 1, 2013 through February 23, 2014 for those patients who elected to participate in the OMC study.

In addition, the provider satisfaction and OMC evaluation online survey was sent via secure email to all PCPs on February 18, 2014 and data from these surveys were collected for analysis on February 28, 2014. Findings from the three and six months OMC evaluation were reported to leadership for continued operation and/or possible expansion of program (See Appendix K for the project timeline).

Project Objectives and Activities

Objective 1. Developing an OMC within the Primary Care Service allowed PCPs to refer patients who meet the eligibility criteria. Once the OMC was developed, implemented, and activated, the OMC took over the management of chronic opioid therapy including opioid renewal, opioid dose adjustment, opioid substitution (from short acting to long acting using an established online opioid morphine equivalence calculator [GlobalRPH] developed by McAuley (2013, April 18), monitoring for misuse/abuse of opioids, and regular clinic visits for pain management based on the 2010 VA/DoD clinical practice guideline. The guideline recommends the use of long acting opioids instead of short acting opioids in the management of chronic pain using chronic opioid therapy and the use of regular and random screening using urine drug screens and the PDMP (Department of Veterans Affairs and Department of Defense, 2010). The following tasks were completed to develop the OMC within the VA Las Vegas:

(1) Members of the OMC staff were diverted from the current Southwest Primary Care Clinic teamlet lead by the APRN. The teamlet consisted of the lead APRN, RN, LPN, and a MSA. The teamlet assumed the OMC operation on daily clinic basis (Monday through Friday from 0800-1400).

(2) An electronic clinic referral template was developed to allow PCPs to refer patients to the OMC electronically using the VA's CPRS. The electronic referral template allowed communication between the OMC and PCPs electronically every time a clinic note associated with the referral was documented and electronically signed in the CPRS. The OMC also developed PCP in-service informational sessions regarding the OMC and the VA/DoD Clinical Practice Guideline for the management of chronic pain using opioids and were presented to the PCPs in their monthly staff meeting in June

2013. Three additional clinician in-services were developed by the OMC staff and were presented to VA Las Vegas APRNs in their Quarterly Meeting in October 2013, VA Las Vegas Primary Care Nursing staff in their monthly meeting in November 2013, and to the Southwest Primary Care Clinic's Primary Care Providers in their monthly meeting in December 2013. All presentations were done using PowerPoint.

Another PowerPoint presentation to all clinicians in the VA Las Vegas was presented on March 18, 2014 during the monthly Grand Rounds to update clinicians in the encouraging the trend of decreased use of opioids in the facility, the use of long acting opioids, the increased use of urine drug screens to monitor patients on opioids, and the increased use of the Prescription Drug Monitoring Program state database to monitor potential "doctor shopping" (obtaining opioids from multiple healthcare providers). These presentations also allowed for interaction between the OMC staff and PCPs with questions addressed.

(3)The laboratory protocol was developed and finalized to allow for urine drug screening and for positive results to be automatically sent for confirmation for certain substances like amphetamines due to high false positive results of this substance in the urine drug screen.

(4)An application for access to the Nevada's Prescription Monitoring Program and Arizona's Controlled Substances Prescription Monitoring Program were filed and completed allowing OMC staff access to these databases.

(5) The lead APRN developed a training program for the staff of the OMC prior to OMC activation. The purpose of the training was to orient staff with the goals of the OMC and the protocols of the OMC including the tasks for each respective discipline.

(6) An OMC clinic profile was developed in collaboration with the Chief of Primary Care which was activated prior to the OMC implementation. The clinic profile facilitated scheduling of patients to the OMC on specific OMC clinic days and time periods to allow for adequate time for blocking primary care clinic visits of the teamlet that would be allocated to the OMC schedule.

Objective 2. The activation and implementation of the OMC took place once the OMC was developed and prepared for activation. The OMC accepted patients to be admitted to the OMC if they were found to be eligible to be admitted to OMC. The eligibility criteria included all of the following: (a) Pain of more than three months in duration, morphine equivalent dose of 100mg per day, and documented evidence of aberrant behaviors including early requests for opioid refills, report of loss of opioid medications, multiple emergency room visits for pain while on opioid therapy, non-compliance with drug monitoring such as urine drug screen (orders for drug screen not being done by patient), negative urine drug screen for prescribed opioids, or (b) history of substance abuse including heroin, cocaine, alcohol and marijuana, or (c) morphine equivalent dose of 0-100mg per day but exhibiting aberrant behaviors.

Any eligible veteran with high risk for opioid abuse or misuse can be referred by their PCPs to the OMC. A notification within the electronic consultation was done to identify referred patients admitted to the OMC. For patients who were accepted to the OMC, the MSA or the nursing staff scheduled an initial clinic appointment in one of the time slots specific for OMC clinic scheduling. The OMC staff provided call back confirmation of the appointment 1-3 days prior to the appointment date to decrease the

risk of no-shows and rescheduled an appointment if the appointment time was no longer feasible to the patient.

At the initial OMC clinic appointment, patients were given information about the OMC and the reason they were referred to the OMC. Eligible patients for the OMC study were then given an explanation of the study and were asked to sign the Informed Consent for voluntary participation in the study (See Appendix L for a copy of the Informed Consent). A copy of the signed informed consent was given to each patient for their review and record keeping. The original signed informed consent was kept and secured in the clinic for record keeping and for accounting on the number of participants in the study. Eligible patients who elected not to participate in the study were given an explanation that declining to participate would have no difference in the care they receive from the OMC compared to patients who elected to participate in the study.

Patients were then asked to complete the BPI short form and sign an Opioid Pain Agreement, if not already completed previously. The Opioid Pain Agreement served two purposes. First, the content in the agreement provided patient education information regarding the potential hazards of opioid use. Second, the content provides specific expectations from the patient if opioid therapy is to be initiated. For example, the agreement contained instruction for the patient that there should only be one healthcare provider prescribing opioids to the patient and that a patient should inform other healthcare providers who may potentially prescribe them opioids that they were currently getting opioids from the VA-Las Vegas. Further, patients were informed in the agreement that failure to comply with recommendations for chronic opioids therapy could result in appropriate discontinuation of opioid use in the management of their

chronic pain. Lastly, the agreement also contained statements that patients on opioid therapy agree to submit to random drug screens, abide with random pill counts, and comply with other risk reduction strategies recommended by the opioid prescribing healthcare provider. The Opioid Pain Agreement was signed electronically and became integrated in the patient's medical record once signed by both the patient and the opioid prescribing healthcare provider. A copy of the signed agreement was given to the patient for reference.

Vital signs were obtained which included blood pressure, heart rate, respiratory rate, height, weight, temperature, and current pain intensity (0-10 with zero as having no pain and 10 as having the worst pain they could imagine). After the intake with nursing staff (this can be done by the LPN or RN), patients were then seen individually by the APRN for review of history, suicidal/homicidal risk assessment, physical exam, and management of their pain as it related to opioid therapy. A pain Screening Tool by Alturi and Sudarshan (2004) was completed by the APRN clinician at admission and documented in the electronic record. All documentations were done in the CPRS.

Every initial OMC clinical note included the following information that were documented electronically via CPRS: (a) reason for referral to OMC, (b) history of substance abuse, (c) relevant diagnosis for opioid therapy, (d) pain history, (e)suicidal/homicidal risk assessment, (f) BPI, (g)adverse drug reaction or side effects, (h)aberrant behaviors, (i) current opioid therapy including last dose taken (j) morphine equivalent dose of current opioid therapy (k) last urine drug screen date and results (l) PDMP report and findings (m) vital signs, (n) physical exam findings, (o) Screening Tool, and (p) plan of care including opioid therapy continuation, dose adjustment, opioid

substitution (from short acting to long acting), or opioid discontinuation; opioid misuse/abuse monitoring, referral to other pain modality clinics or ADTP; and return visit.

After each clinic visit, patients were evaluated for the need to submit a random urine drug screen according to the OMC protocol. If a urine drug screen was recently done (less than 30 days) prior to the OMC visit, the OMC staff had the discretion if a repeat testing was necessary. If no recent urine drug screen on record can be found in the CPRS, patients seen initially in the OMC were asked to submit a urine specimen to the laboratory for screening. They were given a laboratory number and were instructed to submit a urine sample to the laboratory located in the same building as the OMC. The OMC staff verified submission of urine sample by patients through the CPRS which showed active status for the ordered laboratory test. Once the laboratory results were back, the results were documented in the CPRS OMC clinic note with annotation of change in the plan of care as needed. Patients noted to have a positive urine drug screen for illicit substance such as cocaine, heroin, methamphetamines, barbiturates, and marijuana (without documentation of receipt of Nevada legal marijuana program) were informed of the unexpected findings in their urine drug screen and were recommended for referral to the ADTP of the VA-Las Vegas.

A PDMP database inquiry to the state database on controlled substance use was done on each patient on the initial visit and was repeated as needed when there was suspicion for obtaining multiple opioid prescriptions from other healthcare providers. After each clinical visit, patients who were recommended to continue on opioid therapy had their new prescription of opioid ordered electronically. These patients were also

given an appointment for follow up at the recommended time frame which could be monthly but was decided by OMC staff depending on the patient's case. Follow up appointments ranged from every week to every three months. Patients with recommended face to face follow up of more than a month had their PDMP record pulled every time patients requested timely refill of their opioids. Patients noted to have positive PDMP findings of 'doctor shopping" were informed of the unexpected findings and were recommended for referral to the ADTP or the MHC of the VA-Las Vegas. A notification was also sent to the Behavioral Abuse Committee of the VA Las Vegas for consideration in adding an electronic flag in CPRS that would alert any clinicians who open the patient's record to not provide any opioids due to documented history of "doctor shopping". The Behavioral Abuse Committee meets on a monthly basis and receives notifications from clinicians regarding behavioral issues related to their patients that warrant notification of all clinicians to ensure communication among all clinicians regarding serious patient behaviors.

After each OMC clinic note was signed by the OMC clinician, the referring PCP was automatically notified of the action of the OMC on their referred patients. Additionally, PCPs were notified if the patient was discharged from the OMC which was documented in CPRS OMC clinic note. PCPs were notified by telephone, face-to-face communication or through the additional signer feature in CPRS that required the recipient of the alert to electronically co-sign the note of the OMC discharge. Further, OMC recommendations for future treatment were offered to the PCP. Patients meeting the OMC discharge criteria were as follows: (a) use of stimulants such as cocaine, heroin or methamphetamines on urine drug screen, (b) documented diversion of opioids through

patient admission of opioid diversion, (c) negative urine drug screen on at least two occasions for prescribed opioids with confirmation test ordered by OMC staff, and (d) failure to comply with the treatment plan which may result in opioid treatment being discontinued appropriately and thus resulting to discharge from the OMC; A patient receiving chronic opioid therapy was required to comply with the treatment plan, including diagnostic tests, specialty consultations, and other treatments ordered by the VA PCP or OMC staff. Other discharge criteria included: (e) self-referral around local non-VA primary care clinics or to other VAs in search of multiple providers to prescribe opioids as documented by the Nevada/Arizona/Utah controlled substance monitoring program database or CPRS record, (f) abusing, threatening or intimidating VA staff members; and (g) overt drug seeking behaviors such as multiple requests for early refills of opioid medications due to loss or self dose escalation or multiple visits to community emergency rooms or local clinics to obtain opioid prescriptions. Patients who were discharged from the OMC due to abuse/misuse of medications can be reconsidered for readmission to the OMC after they have completed at least 6 months of ADTP therapy.

Objective 3. At three months and six months of OMC operation, clinic evaluations were done to assess the function of the OMC as it related to the specific goals and clinic objectives. A follow up provider satisfaction evaluation was done through SurveyMonkey at approximately six months of clinic operation. The online survey was sent to all PCPs in VA Las Vegas on February 18, 2014. All PCPs in the VA-Las Vegas belong to a primary care mail group. The survey was sent to the mail group via secured VA email. A follow up email from the Chief of Primary Care was sent to all PCPs encouraging participation in the survey a day after the original email that asked PCPs to

participate in the online survey. Another email was sent to all PCPs in VA Las Vegas a week after to encourage those who have not yet participated in the survey. When this survey was sent, there were forty two (42) PCPs employed by the VA Las Vegas and all forty two were eligible to participate in the study. Thirty PCPs responded to the survey so the response rate for the provider satisfaction survey was 71%. In the initial needs assessment survey, 80% of the PCPs responded to the survey.

In addition to the online survey, a three month and six month chart review were also done for all patients in the OMC to obtain information and compare data from the initial OMC admission to the latest OMC clinic note. The OMC is a CQI project in the VA Las Vegas that was initiated and implemented due to the growing concern among PCPs of opioid abuse and misuse among veterans on chronic opioid therapy. Evaluation of the OMC as part of the CQI allowed for documentation of clinic effectiveness in improving the quality of care provided to the veterans. Data obtained for this CQI included scores from the pain Screening Tool, BPI short form, and any other provider notes that were essential to evaluating the OMC including challenges and barriers to the change process. The number of admitted patients to the OMC and the number of discharges from OMC were also tallied including the number of participants in the OMC study. Data of baseline number of opioid pills dispensed and its associated pharmacy cost from about the same time period of the previous year were compared to the 3 month period of the OMC operation to see if there was any difference between the two periods. Data gathered were compared to evaluate for any differences between data set points as appropriate.

Resources and Supports

The following resources and supports within the VA-Las Vegas were utilized in the operation of the OMC: (1) ADTP, (2) Integrated Pain, (3) Chief of Primary Care, (4) Pharmacy Service, (5) Laboratory Service, (6) Nursing Service, and (7) Health Administration Service.

Risks and Threats

Veterans opting to be discharged from the OMC and return to their PCP for management of opioids can be a potential threat to the success of the OMC. In this situation, the PCP who initially referred the patient to OMC was alerted via the VA CPRS to advise the PCP of patient discharge from the OMC. Additionally, the PCP was directly contacted via telephone or face to face interaction (if the PCP is in the same clinic as the OMC) to discuss the discharge along with OMC recommendation for future care of the discharged veterans.

Another possible threat to the success of the OMC would be PCPs not referring their patients who are at high risk for opioid abuse/misuse. This was mitigated by the delivery of multiple planned provider in-service informational sessions regarding the OMC prior to initiation of the OMC and during the OMC implementation. Further, the OMC staff sent regular notification messages via email to all PCPs of the availability of the OMC and how the OMC can assist them in the management of patients on chronic pain.

Lastly, PCP's continued noncompliance with current guidelines in the management of chronic pain with chronic opioid therapy could present a threat to the effectiveness and success of the OMC. This was mitigated with leadership support and

planned provider in-service sessions that addressed the importance of the OMC and discussed recommendations from the current VA/DoD clinical practice guideline.

Marketing Plan

The OMC had strong support from leadership and was validated by the initial needs assessment which showed that all PCPs who responded in the survey were interested in the OMC to assist them in monitoring opioid use of patients on chronic opioid therapy. The OMC staff provided an in-service to all PCPs through the scheduled monthly PCP staff meeting. Advertisement of the OMC was done through email to all healthcare providers in the VA-Las Vegas which included PCPs and other healthcare providers. In addition to the email notification to PCPs, a flier was also developed and posted in the Southwest Primary Care Clinic where the OMC was located.

Financial Plan

The OMC was implemented using current staffing. A teamlet consisting of an APRN, a registered nurse, a licensed practice nurse and a medical clerk made up the staff of the OMC (0.1 full time equivalent [FTE] Primary Care NP, 0.1 FTE Primary Care RN, 0.1 FTE Primary Care LPN, 0.1 FTE Medical Clerk) (See Appendix M for budget).

Institutional Review Board Approval

The Evaluation of an Opioid Monitoring Clinic study received IRB approval on November 20, 2013. The study was approved through an expedited review process. As soon as the study to evaluate the OMC received the IRB approval, the OMC immediately started enrolling patients into the study. As of February 23, 2014, a total of sixty-one patients were recruited and participated in the study. Additionally, as of February 28, 2014, a total of thirty PCPs have completed the online provider satisfaction survey sent to

all VA Las Vegas PCPs on February 18, 2014. Twenty-six PCPs elected to participate in the study and four elected not participate in the study. The online survey response rate was 71%.

CHAPTER 5

SUMMARY OF IMPLEMENTATION AND RESULTS

Initiation of the Project

The effectiveness of the OMC clinic was measured and evaluated through the use of screening tools such as the BPI, Pain Screening Tool, PDMP, urine drug screens, and opioid pharmaceutical costs. Based on the number of patients who were identified to be abusing and misusing their opioid prescriptions, the OMC has shown effectiveness in identifying veterans who were abusing and/or misusing their prescription opioids. These patients were promptly referred for treatment in the ADTP or MHC.

The OMC was able to align chronic opioid use in accordance with the VA/DoD clinical practice guideline for chronic opioid therapy as evidenced by self-report by PCPs in the provider satisfaction survey of increased use of the Opioid Pain Agreement, increased PCP compliance in the use of urine drug screens to monitor patients on chronic opioid therapy, increased use of PDMP to monitor patients who may be "doctor shopping", and increased PCP report of compliance with the VA/DoD clinical practice guideline for chronic opioid therapy. Additionally, patients who had no history of being referred to other pain modalities such as physical therapy, physiatry, acupuncture, chiropractor, interventional anesthesia injection, and/or osteopathic manipulation therapy were recommended for referral to these clinics as an adjunct to pharmaceutical pain management.

The opioid schedule of patients at admission were evaluated and if the current opioid therapy was a combination of short acting and long acting opioids, an opioid substitution from short acting opioids to a long acting opioid was recommended based on

morphine equivalent calculation to reduce the number of pills and to reduce the use of short acting opioids. If the patient was on short acting opioids only, the same opioid substitution recommendation of changing from short acting to long acting opioids was done. These strategies were consistent with the Va/DoD clinical practice guideline (Department of Veterans Affairs and Department of Defense, 2010). The purpose of using long acting opioids as opposed to short acting opioids was two-fold. First, the substitution of long acting opioids can reduce the number of pills dispensed per month on patients with high risk for abuse and misuse of opioids. High quantity of opioid pills dispensed per month can be a factor in the decision to misuse or divert prescription opioid medications (Gomes, Mamdani, Dhalla, Paterson, & Juurlink, 2011; Katz, El-Gabalawy, Keyes, Martins, & Sareen, 2013). Second, long acting opioids can provide a more stable pain management at longer duration than short acting opioids thereby potentially eliminating the need to take extra doses when pain is at high intensity as seen in patients taking short acting opioids.

At six months, the change process in implementing the OMC was evaluated as it related to the project objectives. This evaluation consisted of the following: (1) Provider satisfaction evaluation survey through SurveyMonkey which were sent to all PCPs in the VA-Las Vegas for completion, and (2) A chart review completed for all patients admitted in the OMC to obtain data and compare from the initial OMC admission note to the last OMC clinic note. Data obtained included scores from the pain screening tool and BPI short form, as well as other relevant information including challenges and barriers to the change process, number of admitted patients to the OMC and the number of discharges from OMC which were tallied, and baseline number of opioid pills dispensed with its

associated pharmacy cost from about the same time period the year before compared to the three month period of the OMC operation to see if there was any difference between the two periods. For example, opioids dispensed by pharmacy between the months of July to September 2013 (4th fiscal quarter) were compared to the same months in the prior year (2012) and to the previous fiscal quarter (3rd fiscal quarter 2013) to evaluate any change. All findings were reported to the VA-Las Vegas leadership on February 18, 2014.

Threats and Barriers to the Project

Despite strong leadership support of the development and implementation of the OMC in the VA Las Vegas, there were unexpected delays that were encountered during the implementation phase of the OMC. Bureaucratic delays in the actual implementation of the consultation process into the electronic medical record resulted in extensive delay in the full implementation of the clinic into the computerized electronic medical record. The integration of the OMC consultation process into the electronic record was necessary because it eased the notification and communication between the referring PCP and the OMC staff. The integration also eased the accounting of all patients referred to the OMC as each consult was associated with workload credit specific to the OMC that can be easily be pulled from the CPRS for accounting purpose. The approval process for the integration of the clinic into the electronic medical record had to come from many layers of committee approvals. To compensate for the extensive delay in the approval process of integrating the consult service of the OMC into the electronic medical record, a temporary solution was implemented to start the clinic and see patients into the clinic while the clinic electronic consult templates and associated clinical notes awaited formal

approval from several committees in the VA Las Vegas. This was done through advertising the clinic to clinic chiefs and PCPs of the existence of the OMC despite current inexistence of a formal electronic consult to refer their patients to the OMC. Referring providers were able to temporarily refer patients into the OMC by having the APRN clinician in the OMC as an additional signer to their note that included a reason as to why the referring clinician would like to refer their patient to the OMC. This work-around allowed the OMC to admit and evaluate patients into the clinic for monitoring based on protocol. As soon as the electronic consult received final approval on February 12, 2014 from several layers of committees, the electronic consult was finally implemented into the live system of the electronic medical record. The live consult was activated in CPRS on February 13, 2014. The referring primary care providers were also automatically notified of any activities in the electronic consultation such as new visits in the OMC. This served as an effective line of communication between the OMC staff and the referring primary care provider.

Even though the early results for the OMC were encouraging, some PCPs voiced concern that even with the help of the OMC, the number of walk-in patients in the PCP practice did not improve. This concern may not have any relationship with the OMC since patient walk-ins may be for reasons other than for pain management or opioid needs. One PCP who referred at least one patient to the OMC disagreed that he/she received fewer complaints regarding pain medications. It was very likely that patients referred to the OMC who had their opioids reduced/discontinued would be very unhappy with the change in their opioid therapy and may have voiced their dissatisfaction with the

change in their opioid therapy to their PCP who referred them to the OMC. These could become barriers to continued PCP referral to the OMC.

It is also possible that PCPs who receive many patient complaints may give in to patient requests to resume opioid therapy despite evidence of abuse and misuse of opioids. PCPs may become overwhelmed with patient complaints and may opt to a "path of least resistance" and succumb to patients request for opioids despite evidence of lack of medical necessity for opioid therapy.

Monitoring of the Project

Besides effectiveness in identifying active illicit substance use, doctor shopping, and other aberrant behaviors that can lead to opioid-related complications such as accidental overdose and death, the OMC has also shown effectiveness in helping PCPs become more aligned with the VA/DoD clinical practice guideline in the management of patients with chronic pain and on chronic opioid therapy. The satisfaction among PCPs who have referred patients to the OMC has been very positive. An overwhelming number of PCPs who participated in the survey reported following the recommendations by the VA/DoD clinical practice guideline in the regular use of urine drug screens and the PDMP to monitor patients on chronic opioid therapy. Further, most PCPs reported completing an Opioid Pain Agreement with their patients.

To maintain and sustain change, long term evaluations are necessary. A twelve month evaluation will be done identical to the initial three months evaluation for this project. Lastly, a patient satisfaction survey will be given to all patients admitted in the OMC after one year of operation to assess their satisfaction with the OMC. If the goals and objectives are met, continued operation and possible expansion of the OMC would be

likely supported by the VA Las Vegas leadership. Further, the VA-Las Vegas pharmacy cost for opioids will be compared with baseline (FY 2013 compared to FY 2014) to continually monitor the effect of increasing use of urine drug screen, and PDMP. The number of opioid pills dispensed will be compared between FY 2013 and FY 2014. Also, the number of short acting opioids and long acting opioids will be compared between FY 2013 and FY 2014.

Data Collection

All patients who were seen and evaluated in the OMC since the start of the clinic implementation had an electronic health record of their visit in the OMC. Patients were asked to complete the BPI questionnaires. In addition to the BPI questionnaires, patients were interviewed regarding their pain history and their history of pain treatments. Patients were also asked any history of substance abuse if none were documented in the CPRS or in the PCP referral documentation. A suicide and homicidal risk assessment was done on each patient and documented in the OMC clinic note. The MED was calculated based on the current opioid therapy of the patient. Patients were asked about the last opioid dose taken to correlate their responses with the amount of opioids patients receive per month and their refill habits. A pain Screening Tool assessment was done on each patient. All patients also had a PDMP inquiry. In addition to the PDMP, a urine drug screen history was also searched in the electronic health record to document previous urine drug screen results. All patients also were asked to submit a urine drug screen as per OMC clinic protocol. All results were documented in the OMC clinic note in the CPRS.

When the study to evaluate the OMC was approved by the UNLV IRB on November 20, 2013, the OMC immediately started enrolling patients to the study. Eligible patients who were currently being seen in the OMC were asked to participate in the study. New referrals from the PCPs who were eligible to participate in the study were also asked to participate. All documentations were done in the VA CPRS.

Data Analysis

Pertinent patient data related to the OMC evaluation study were stored in secured Microsoft Access for database record keeping. The database included patient ID, age, gender, major source of pain, concurrent use of other controlled substances, presence of a pain agreement prior to admission, presence of urine drug screen prior to admission, MED prior to admission, MED at last visit, PDMP report, BPI scores, Pain Screening Tool score, and retention outcome of patients seen and evaluated in the OMC. The CPRS was reviewed for history of urine drug screen on record and its associated results, history of aberrant behaviors including documented report of multiple requests for early refills due to loss of opioid medications or requests for escalating dose for opioid prescriptions. Additionally, a preliminary review of PDMP was also done to screen patients prior to the initial visit. Once patients were seen and evaluated in the OMC, some patients who were found to be abusing and misusing their opioid prescriptions were informed of the findings with subsequent recommendations from the OMC. This included a referral to the ADTP and discontinuation of opioid therapy when there was evidence of multiple receipts of opioid prescriptions from both the VA and outside pharmacies as reported by the PDMP, or by tapering (when there is evidence that the patient was taking their opioids based on laboratory opioid confirmation but misusing).

Patient outcomes in the OMC included those patients who were retained by the OMC for continued monitoring and management of their opioid therapy; and patients who were discontinued on opioid therapy due to discovery of abuse and misuse of opioids either at the time of the initial visit and/or during the monitoring of the patient in the OMC. Data from the Microsoft access were then imported to SPSS for data analysis. The SPSS version used for this study was version 21. Statistical data analyses results were verified by a biostatistician.

Table 1 shows the summary of all patients seen in the OMC whether they participated in the OMC evaluation study or not. A total of one hundred fourteen (114) veterans were seen and evaluated in the OMC from July 1, 2013 through February 18, 2014. Sixty-one (61) patients volunteered to participate in the study and signed the informed consent. The average age of both participants in the study and the nonparticipants was fifty-three (53) years old. There were four (4) female and fifty-seven (57) male participants; and three (3) female and fifty (50) male nonparticipants.

The most common source of pain among nonparticipants and participants in the OMC study was back pain. Forty-two nonparticipants (79%) reported back pain as the major source of pain. For the study participants, thirty-eight (62%) reported back pain as the major source of pain. Twenty-two (42%) nonparticipants and twenty-five participants (41%) were on concurrent use of opioids and benzodiazepines. Thirty-six (68%) nonparticipants and fifty-four participants (89%) had a signed a pain agreement prior to being seen in the OMC. Forty-two (79%) nonparticipants and forty-nine participants (80%) had a urine drug screen prior to being seen in the OMC. Sixteen (30%) nonparticipants and twenty-three (38%) participants were found to have unexpected urine

drug screens at their initial OMC visit or at subsequent OMC visits. Unexpected findings in urine drug screen included positive findings for illicit substances in the urine including methamphetamines, barbiturates, cocaine, heroin, and/or benzodiazepines when none were expected, and negative opioid level in the urine drug screen even with confirmation testing. Presence of other opioids in the urine such as methadone when methadone was not being prescribed was considered an opioid abuse.

Table 1.

Summary of Study Participants and Nonparticipants (n=114)

	Average Age	Gender	Major source of Pain	Concurrent use of a controlled substance	Prior Pain Agreement	Prior Urine Drug Screens	POS UDS
Participants n=61	53	M:57 F:4	Back 37(62%)	25 (41%)	54(89%)	49(80%)	23(38%)
Nonparticipants n=53	53	M:50 F:3	Back 42 (79%)	22(42%)	36(68%)	42(79%)	16(30%)

POS UDS=positive urine drug screens at initial OMC visit or later

Table 2 shows the breakdown of patients who tested positive in their urine drug screens at their initial OMC visit. One patient participant (2%) had a combination of illicit substance in their urine and negative opioid level despite being on active opioid therapy. Nine participants (15%) had consistent negative opioid level in their urine even with confirmation testing. Twelve participants (20%) were found to have illicit substance in their urine. Among the nonparticipants, eleven patients (21%) were found to have a combination of illicit substance and negative opioid level in their urine. Two

nonparticipants (4%) had consistently negative opioid level in the urine and ten (19%) were found to have an illicit substance in their urine.

Table 2

Summary of Study Participants and Nonparticipants that had Positive UDS

Type of Abuse	Participants n=23	Nonparticipants n=16
Combination of SA/Neg	1(2%)	11(21%)
Negative Opioid	9(15%)	2(4%)
Substance Abuse	12(20%)	10(19%)

SA/Neg= combination of substance abuse and negative opioid level

Table 3 shows the number of patients seen in the OMC who were found to have been "doctor shopping". Twelve (20%) patient participants and sixteen (30%) nonparticipants were found to be "doctor shopping".

Table 3

Patients found to be "Doctor Shopping"

Participants n=61	Nonparticipants n=53
12(20%)	16(30%)

Table 4 shows the change in MED per day before admission to the OMC and after admission to the OMC. Prior to evaluation and admission to the OMC, the average

morphine equivalent dose (MED) per day among the participants was 96mg per day. After admission to the OMC, the average MED went down to 46mg per day, a 52% reduction in MED. For OMC nonparticipants, the before admission average MED was 80mg per day and the after admission average MED was 45mg per day, 44% reduction in MED. The large drop in the MED between before admission and after admission was mainly from the discontinuation of opioids due to discovery of abuse and misuse of their opioids among patient participants in the OMC study. Using the exact single-tailed Wilcoxon Signed- Rank Test, the before and after MED difference was found to be highly significant with a $p<.001$. Further analysis was done with MED category by comparing to see if there was any difference between the patients who participated in the OMC study and those who did not. The Mann-Whitney test was used to compare the change in MED among OMC participants and nonparticipants. There was no difference between the two groups ($p=.830$). The OMC was able to reduce the MED per day among all patients seen in the OMC regardless of study participation.

Table 4

Morphine Equivalent Dose (MED) Comparison Between Participants and Nonparticipants

	MED per day prior to admission	MED per day after admission	Change in MED	p-value
Participants	96mg	46mg	-48%	p<.001
Nonparticipants	80mg	45mg	-54%	P<.001

Table 5 shows the retention outcomes of OMC participants. Thirty-nine (64%) individuals remained as patients in the OMC and continued to be monitored by the OMC. Twenty-two (36%) participants had their opioids discontinued due to discovery of active illicit substance use, "doctor shopping", opioid abuse, noncompliance with the treatment plan and/or self-decision to discontinue opioid therapy. Of those who had their opioids discontinued, twelve (20%) were referred to the ADTP according to the protocol due to either the discovery of illicit substance use or the discovery of "doctor shopping"; nine (15%) were referred to the Integrated Pain Clinic for non-opioid pain management, and one patient (2%) decided to discontinue their opioids on their own and self-discharged from the OMC. Among nonparticipants, eleven patients (21%) were continued to be seen and monitored in the OMC. Seventeen patients (32%) were referred to the Integrated Pain Clinic, eighteen patients (34%) were referred to ADTP, and seven (13%) transferred to another PCP and did not return for follow up with the OMC. All patients discharged from OMC including those who decided to discontinue their opioid therapy on their own had their CPRS record reviewed by the OMC staff to document if any of them ended up returning on opioid therapy by their referring provider or another PCP if they transferred to another PCP. At the time final data collection was done on February 23, 2014, none of the patients who were discharged from the OMC were known to resume their opioid therapy with their PCP (or new PCP if they transferred) or with the pain clinic. The planned one year follow up evaluation of the OMC would provide better outcome data of what ends up happening to these patients after they were recommended for discontinuation of opioid therapy.

Table 5

Retention Outcomes of Patients in the OMC Study (n=114)

Outcomes	Participants (n=61)		Nonparticipants (n=53)	
	#	%	#	%
Retained in OMC	39	64%	11	21%
Discharged to ADTP	12	20%	18	34%
Discharged to Pain Clinic	9	15%	17	32%
Transferred to new PCP	0		7	13%
Self-discontinuation of opioid	1	2%	0	

To evaluate whether there is any relationship between patient retention outcomes among all patients seen in the OMC and the Pain Screening Tool as well as the BPI, a Chi-Squares test was done (Table 6). Since majority of the Pain Screening Tool scores were less than three, the Likelihood Ratio Chi-Square Test was used to determine the relationship between the two variables.

Table 6 shows the relationship between the Pain Screening Tool, BPI and OMC patient retention outcomes. The relationship between the Pain Screening Tool scores and patient retention outcomes (continuation in the OMC or discharged from OMC) were found to be significantly correlated (p=.006). In order to examine this further, Screening Tool scores 0-2 were recoded in SPSS as one category of score and scores 3 and higher were recoded as another category. There were two reasons for this recoding. First, the sample size for scores equal or higher than 3 was small. The second reason for the

recoding of data was due to previous work by Atluri and Sudarshan (2004) that found scores 3 and higher were of clinical significance to determine risk of abuse and misuse of opioids. The authors in their development and validation study for the Pain Screening Tool found that those who scored 3 and higher were at high risk for abuse and misuse of opioids. With the recoding, the Pain Screening Tool scores were found to be highly correlated to patient retention outcomes ($p=.003$) using the Likelihood Ratio Test (LR). The Pain Screening Tool score was also found to be highly correlated to patients who were discharged from the OMC due to abuse and misuse of opioids (LR $p<.001$). This means that the Pain Screening Tool scores of patients seen in the OMC correlated well with what happened to patients seen in the OMC. In other words, patients who scored less than 3 in the Pain Screening Tool were likely to be retained by the OMC for monitoring due to compliance with opioid therapy and absence of adverse findings such as abuse and misuse of opioids. Similarly, patients who scored at least 3 on the Pain Screening Tool were likely to be discharged from the OMC due to discovery of abuse and misuse of opioids.

Using LR, there was no significant relationship between admission BPI pain intensity score and patient retention outcomes ($p=.162$) for all patients seen in the OMC. There was also no significant relationship found between BPI functional intensity and patient retention outcomes ($p=.084$) for all patients seen in the OMC. Additionally, there was no significant relationship found between all OMC patients who were abusing their opioids, "doctor shopping", and/or actively using illicit substance based on urine drug screen and the admission BPI pain intensity score (LR $p=.275$). The BPI functional intensity score was also not found to be significantly correlated to all OMC patients who

were found to be abusing their opioids, "doctor shopping", and/or actively using illicit substance (LR p=.149). Participation in the OMC study was also analyzed to see if participation in the study was related to patient abuse and misuse of opioids. The relationship between OMC participation and patient abuse and misuse of opioids was found to be unrelated (LR p=.374).

These results indicated that data analyses of BPI scores of patients seen in the OMC and patient outcome (patient retention and discharge from OMC) were found to be unrelated. Patients who scored low for either the pain or functional intensity of the BPI was not associated with being retained in the OMC. Similarly, patients who scored high for either the pain or functional intensity of the BPI was not associated with being discharged from the OMC due to abuse and misuse of opioids. Less than half (49%) of patients seen in the OMC had an assessment for BPI scoring. This likely affected data analyses.

Table 6

Relationship between Pain Screening Tool/BPI and Patient Retention Outcomes

	P-value
Patient Outcomes and Pain Screening Tool Score	0.003
Discharged from OMC and Pain Screening Tool score	<0.001
Patient Outcomes and BPI pain intensity score	0.162
Patient Outcomes and BPI functional intensity score	0.084
Discharge from OMC and BPI pain intensity score	0.275
Discharge from OMC and BPI functional intensity score	0.149

Table 7 shows the number of patients who were identified by the OMC to be abusing or misusing their opioids which resulted in the discontinuation of their chronic opioid therapy. A total of twenty-six (43%) of participants and twenty-seven (51%) nonparticipants were discontinued from opioid therapy. Thirteen participants (21%) and eight (15%) nonparticipants were found to be actively using an illicit substance such as cocaine, heroin and/or marijuana. Nine participants (15%) and twelve nonparticipants (23%) were found to be "doctor shopping". Three participants (5%) and six nonparticipants (11%) were found to be abusing an opioid other by having an opioid in their urine that is different from the one they were prescribed or by having hospital admissions related to opioid overdose. Patients who were admitted to the hospital for opioid overdose were automatically followed by the mental health clinic as per VA policy upon discharge from the hospital. One patient from the nonparticipant group was admitted in the hospital for opioid overdose. One participant (2%) was found to be "doctor shopping" and using an illicit substance. One nonparticipant (2%) had consistently negative opioids which resulted in the discontinuation of opioid therapy by the OMC. All patients who were found to be actively using an illicit substance and/or "doctor shopping" had their opioids discontinued either immediately, as appropriate, or by tapering. These patients were also discharged from the OMC and were referred to the ADTP, pain psychology, and/or the Integrated Pain Clinic for evaluation and proper treatment.

Table 7

Comparison of Opioid Abuse and Misuse Among OMC Participants and Nonparticipants

	Reasons for Opioid Discontinuation	#	%
Participants N=26	Illicit Substance Abuse	13	21%
	"Doctor Shopping"	9	15%
	Opioid Abuse	3	5%
	Combination SA/DD	1	2%
Nonparticipants N=27	Illicit Substance Abuse	8	15%
	"Doctor Shopping"	12	23%
	Opioid Abuse	6	11%
	Negative Opioids	1	2%
	Combination SA/DD	1	2%

Combination SA/DD=Substance abuse and "Doctor Shopping"

The BPI data collected on patients admitted in the OMC and enrolled in the OMC study were also analyzed (Table 8). The scoring for both the pain intensity and functional assessment of the BPI is based on the 0-10 scoring system. For the pain intensity portion of the BPI, 0 means no pain and 10 means worse pain they can imagine. For the functional assessment portion of the BPI, 0 means that their pain does not interfere with the function-related questions in the BPI and 10 means that pain completely interferes with the function-related questions in the BPI.

There were 56 patients seen in the OMC who had a BPI scoring in the CPRS record. There were 22 patients who had subsequent BPI scoring after the initial visit.

The reason for the difference in the number of BPI assessments between the initial visit and the follow up visits was because many of patients seen in the OMC for the initial visit were recommended for immediate discontinuation of opioids such as those who were found to be "doctor shopping" and/or those who were found to have positive urine drug screens for illicit substance at the time of referral to the OMC. Most of these patients were discharged from the OMC in a single OMC visit and did not return for OMC follow up. Many of the patients who did not want to participate in the OMC study and did not want to be seen in the OMC after explanation of the reason for referral and purpose of the OMC did not have a complete documentation of visit as per OMC clinic note due to patient refusal to complete the BPI questionnaires or lack of time during the visit to assess the BPI scores. Additionally, many patients who had missing BPI assessments tend to be patients who were referred to the OMC during the first few weeks of the OMC operation where clinic efficiency was still in infancy. Patients who were referred in the OMC after the OMC electronic consult was approved along with its associated clinic notes had complete documentation in CPRS. Patients who did not have a complete documentation in the OMC had their data reviewed by the OMC through CPRS chart review for data collection. Lastly, patients who were seen in the OMC and had initial BPI assessments were captured for BPI reassessment only after they returned for follow up visits. In the OMC, follow up visits can range from weekly to every three months.

The average admission BPI pain intensity score for all 56 patients seen in the OMC was 6.3. The average BPI pain intensity score dropped to 5.8 after patients were seen in the OMC. For the functional pain assessment, the average admission BPI score

for the functional portion of the BPI was 6.3. In similar fashion as with the pain intensity assessment, the average functional BPI score at latest patient OMC visit decreased to 5.8. Table 7 shows the data analysis of BPI scores at admission and comparing it to the BPI scores with the latest patient visit using the exact 1-tailed Wilcoxon Signed-Rank test because the data was normally distributed and the sample was small. When comparing before and after pain intensity score of the BPI for all patients seen in the OMC, there was no significant difference between the two groups (p=.090). When comparing before and after functional intensity of the BPI for all patients seen in the OMC, there was also no significant difference between the two groups (p=.389).

Table 8

Comparison of Pre and Post BPI scores among all patients seen in OMC

PreBPI-Post BPI pain intensity	p=.090
PreBPI-Post BPI functional intensity	p=.389

The OMC has shown effectiveness in identifying abuse and misuse of opioids through intensive urine drug screening and PDMP inquiry to discover "doctor shopping". The identification of abuse and misuse of opioids among veterans resulted in the discontinuation of their chronic opioid therapy. Additionally, patients who continue to be monitored in the OMC were also recommended to change their opioid therapy from using short acting opioids to using long acting opioids as much as possible. The combination of discontinuation of opioids among patients who were found to be abusing and misusing their opioids coupled with the decrease in pill burden with the change from short acting

to long acting opioids resulted in significant savings for the VA Las Vegas. Table 9 shows the quarterly cost of opioid utilization in the outpatient clinics of VA Las Vegas. In the 4th Quarter Fiscal Year 2013 (July-September), the VA Las Vegas spent $241,166 for pharmaceutical costs of the six most commonly prescribed opioids in VA Las Vegas (in order of frequency- Hydrocodone, Oxycodone, Morphine, Percocet, Tylenol with codeine, and Methadone). For the 1st Quarter Fiscal Year 2014 (October-December), the pharmaceutical cost for the same six most commonly prescribed opioids in VA Las Vegas increased to $310,926. The fiscal year 2012 quarterly cost for the same six opioids was $235, 280. VA Las Vegas data on opioid pharmaceutical cost for the top 6 most commonly prescribed opioids in primary care shows an increasing pharmaceutical cost even before the OMC was initiated in the VA Las Vegas. There are several possible explanations for this. First, it is possible that there were more patients who were on opioid therapy. Second, it is also possible that the cost for these opioids has been increasing and that may account for the increasing opioid pharmaceutical cost.

Table 9

Top 6 Opioids Cost to VA Las Vegas for 2 Quarters Compared to Fiscal Year 2012 Quarterly Cost

Opioid	Qtrly FY 2012 Cost $	4th Qtr FY 2013 Cost $	1st Qtr FY 2014 Cost $
Hydrocodone	$68,991	$69,293	$146,484
Oxycodone	$132,637	$137,176	$128,702
Morphine	$24,327	$23,529	$4,376
Oxycodone/APAP	$4124	$4,809	$4,376
APAP/Codeine	$2429	$2,640	$2,794
Methadone	$2772	$3,719	$3860
Total	$235,280	$241,166	$310,924

The increase in the number of urine drug screens being ordered in the VA Las Vegas is very encouraging. The number of urine drug screens that are ordered in the VA Las Vegas continued to increase quarterly (Figure 7). Prior to implementation of the OMC, 1606 urine drug screens were ordered in VA Las Vegas for the period of three months (April 1, 2013 through June 30, 2013). This number has been steadily increasing since the implementation of the OMC. From July 1, 2013 through September 30, 2013, there were 1849 urine drug screens ordered in VA Las Vegas or an increase of 13% from the previous quarter. From October 1, 2013 through December 31, 2013, the number increased further to 2293 urine drug screens ordered for the 1st quarter fiscal year 2014 or an increase of 19%. Since the start of the OMC in July 2013 though the end of December 2013, the number of urine drug screens ordered in the VA Las Vegas increased by 30%. The cost for each urine drug screen in VA Las Vegas is $9.00. The associated cost of doing urine drugs for the 114 patients seen in the OMC was $1026. The associated cost with the increase in the overall urine drug screens ordered in the VA was $6183 (2293 urine drug screens ordered in 1st quarter fiscal year 2014 minus 1606 urine drug screens ordered in 3rd quarter fiscal year 2013 equal 687 more urine drug screens x $9.00). The number of urine drug screens ordered in the VA Las Vegas was expected to go up as more PCPs follow the VA/DoD clinical practice guideline to monitor their patients on chronic opioid therapy. However, the increased cost associated with ordering more urine drug screens is dwarfed by the potential cost saving from preventing even one patient from a complication of opioid abuse such as an opioid overdose as each opioid abuse is estimated to cost a minimum of nearly $29,000 for each patient (Baser et al., 2013). Additionally, the associated cost of the increase in urine drug screens likely was offset by

the associated opioid pharmacy cost from the discontinuation of opioids due to discovery of abuse and misuse of opioids.

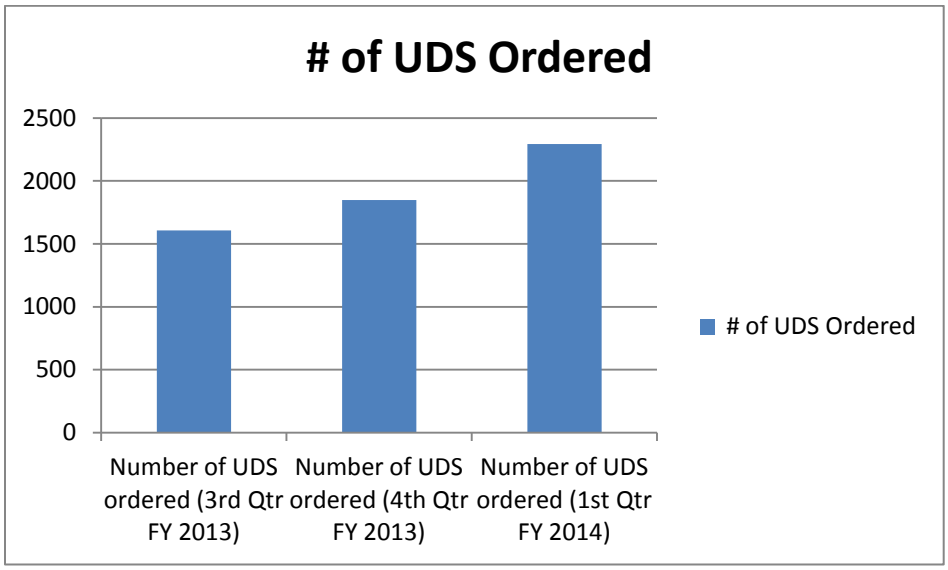


Figure 7. Quarterly data of urine drug screens ordered by clinicians in VA Las Vegas. 3rd Qtr FY 2013=April 1, 2013 to June 30, 2013; 4th Qtr FY 2013 =July 1, 2013 to September 30, 2013; 1st Qtr FY 2014=October 1, 2013 to December 31, 2013; UDS=urine drug screen.

The increasing trend in the use of urine drug screens among PCPs is a very encouraging result. To explain this trend, a provider satisfaction survey was sent to all PCPs in VA Las Vegas on February 18, 2014. Table 10 shows the results of the provider satisfaction survey. Thirty of the forty-two eligible PCPs (71%) completed the survey. Twenty-six PCPs participated in the study. Four PCPs elected not to participate in the study but all four responded to the questions in the survey.

A total of twelve PCPs (40%) out of the thirty PCPs who responded in the survey reported that they have referred at least one patient to the OMC and eighteen (60%) reported that they have not yet referred a patient to the OMC. Twenty-seven (90%) PCPs reported that they follow the VA/DoD clinical practice guideline for chronic opioid

therapy. Three PCPs (10%) responded with a neutral response to the Likert-type question. Among PCPs who responded that they have referred at least one patient to the OMC, all twelve (100%) reported that they follow the VA/DoD clinical practice guideline.

When it comes to the use of opioid pain agreement, twenty-four PCPs (80%) responded that they use the Opioid Pain Agreement more often than the previous 12 months. Five of the PCPs (17%) responded neutral to this question and one PCP (3%) disagreed that he/she uses the Opioid Pain Agreement more often than the previous 12 months. Among PCPs who responded that they have referred at least one patient to the OMC, eleven (91%) reported that they use the Opioid Pain Agreement more often than the previous 12 months.

When it comes to the use of urine drug screens, twenty-seven (93%) of the PCPs responded that they routinely order a urine drug screen for their patient on opioid therapy. Two PCPs (7%) responded neutral to this question and one PCP did not respond to this question. Among PCPs who responded that they have referred at least one patient to the OMC, all twelve (100%) reported that they follow the routinely order a urine drug screen for their patient on opioid therapy.

Sixteen PCPs (54%) responded that they routinely access the PDMP to check for "doctor shopping". Seven PCPs (23%) responded neutral to this question and seven PCPs (23%) disagreed that they routinely access the PDMP. Two PCPs left a comment in this question that both were unable to access the PDMP because they have not signed up yet for access to the PDMP. Among PCPs who responded that they have referred at least one patient to the OMC, eight (67%) reported that they routinely access the PDMP.

The use of PDMP to screen patients on opioid therapy is an important strategy to identify patients who are “doctor shopping”.

The percentage of PCPs reporting that they follow the VA/DoD clinical practice guideline in this subsequent survey is an improvement from the baseline survey when only 58% of PCPs who participated in the survey reported that they follow the VA/DoD clinical practice guideline. The number of PCPs reporting that they are using the Opioid Pain agreement more to manage their patients on opioid therapy is an encouraging result from this survey as it further provides support that PCPs are following the recommendations from the VA/DoD clinical practice guidelines. Furthermore, more than half of the PCPs who responded to the survey reported using the PDMP to screen their patients on opioid therapy. This is also an encouraging result since 25% of patients seen and evaluated in the OMC were found to be “doctor shopping”. By accessing the PDMP to screen their patients on opioid therapy, PCPs can help identify and stop abuse and misuse of opioids as early as possible with subsequent referral for treatment as indicated.

Table 10

Results of Provider Satisfaction Survey from all PCP Respondents (n =30)

I would like to participate in the study to evaluate the Opioid Monitoring Clinic	
Yes	26 (87%)
No	4 (13%)
Have you referred patients to OMC?	
Yes	12 (40%)
No	18 (60%)
I follow the recommendations in the VA/DoD Clinical Practice Guideline for Chronic Opioid Therapy.	
Strongly Agree/Agree	27 (90%)
Neutral	3 (10%)
Disagree	
I use the Opioid Pain Agreement more often than the previous 12 months?	
Strongly Agree/Agree	24 (80%)
Neutral	5 (17%)
Disagree	1 (3%)
I routinely order urine drug screens when indicated.	
Strongly Agree/Agree	27 (93%)
Neutral	2 (7%)
Disagree	
I routinely access a Prescription Drug Monitoring Program (PDMP) to check for double dipping or "Doctor Shopping".	
Strongly Agree/Agree	16 (54%)
Neutral	7 (23%)
Disagree	7 (23%)

Table 11 shows the results of PCPs who elected to participate in the OMC study and have referred at least one patient to the OMC (n = 11). Ten (91%) PCPs who responded think that the OMC has a positive impact on the Primary Care practice. One PCP (9%) responded neutral to this question.

Six PCPs (55%) who have referred at least one patient to the OMC responded that they have received fewer complaints regarding pain medications since they started referring patients to the OMC. Four PCPs (36%) responded neutral to this question and one PCP (9%) responded that they disagreed about having fewer complaints since they started referring patients to the OMC.

Seven PCPs (64%) who referred patients to the OMC responded that they had fewer patient walk-ins for pain management issues since they started referring patients to the OMC. Five PCPs (36%) responded neutral to this question. One PCP left a comment in this question that "we still gets lots of walkins for pain mgt issues."

Ten PCPs (91%) who referred at least one patient to the OMC responded that they were able to spend more time with the patient's other medical problems when their patients on opioid therapy were followed by the OMC. One PCP (9%) responded neutral to this question.

All eleven PCPs (100%) who referred at least one patient to the OMC reported overall satisfaction with the OMC in helping them manage their patients on chronic opioid therapy. The baseline needs assessment survey that was done in January 2013 indicated the need for the OMC clinic as all PCPs who responded in that survey indicated interest in the OMC. In this follow up survey, it appears that PCPs who have referred a patient to the OMC are benefiting from service that the OMC has provided to their patients.

Lastly, nine (82%) PCPs who referred patients to the OMC did not find anything in the referral process that needed improvement. Two PCPs (18%) left a comment to this question that the OMC was, "simple, easy and accessible" and that the referral process

was “so far, it is great”. Another PCP left a comment, “I want patients who are suicidal but still need pain control with narcotics to be addressed.”

PCPs who have referred patient in the OMC were reporting satisfaction with the both referral process associated with the OMC as well as with the purpose of the OMC to assist them in the management of high-risk patients on chronic opioid therapy. It was expected that PCPs may be contacted by patients who were seen in the OMC and had their opioid therapy switched to a longer acting opioids or had their opioid therapy discontinue due to discovery of abuse and misuse of opioids. In an attempt to resume opioid therapy, patients may walk-in and/or complain more to their PCPs due to their perception of dissatisfaction of care they received from OMC. These behaviors were expected but with high buy-in among PCPs for the OMC coupled with their concerns for chronic opioid therapy for high risk patients, PCPs stood fast against reinitiating opioid therapy on patients discontinued on opioid therapy due to discovery of opioid abuse and misuse. At the time data was collected on February 23, 2014, patients who were discontinued on opioid therapy by the OMC were still not on opioid therapy. Long-term follow up data would be helpful to examine if opioid therapy are re-initiated at a later point.

Table 11

Results of Provider Satisfaction Survey: PCPs who participated in the OMC study and has referred Patients in the OMC (n =11).

The service has a positive impact on the Primary Care service.	
Strongly Agree/Agree	10 (91%)
Neutral	1 (9%)
Disagree	
I receive fewer complaints regarding pain medications.	
Strongly Agree/Agree	6 (55%)
Neutral	4 (36%)
Disagree	1 (9%)
There are fewer walk-ins for pain management issues.	
Strongly Agree/Agree	7 (64%)
Neutral	4 (36%)
Disagree	
I can spend more time with patient's other medical problems when they are being followed by this service.	
Strongly Agree/Agree	10 (91%)
Neutral	1 (9%)
Disagree	
Overall, are you satisfied with the Opioid Monitoring Clinic in helping you manage chronic pain patients?	
Strongly Agree/Agree	11 (100%)
Neutral	
Disagree	
Do you find anything in the OMC referral process that needs improvement?	
Yes	2 (18%)
No	9 (82%)

Giving Meaning to the Data

The implementation of the OMC in the VA Las Vegas has shown great promise in identifying abuse and misuse of prescription opioids among patients at high risk for abuse and misuse opioids as reported in published literature (Ives et al., 2006; Manchikanti et

al., 2012; Starrels et al., 2011; Wiedemer et al., 2007; Worley, 2014). The positive results from the evaluation of the OMC can help ensure the continued support from VA Las Vegas leadership.

Patients referred in the OMC had risk factors that put them at high risk for abuse and misuse of opioids. The OMC was able to identify abuse and misuse in sixty-seven (59%) of all patients referred and evaluated in the OMC. The finding is similar to the study by Wiedemer et al. (2007) that reported 55% opioid abuse rate among patients referred to the ORC. Additionally, the findings from the OMC evaluation also supported Wiedemer et al.'s, 2007 findings of increased use of urine drug screens among PCPs and increased PCP satisfaction. OMC patients who were found to be abusing and misusing their opioid prescriptions were promptly referred to specialty care for further management. When patients who abuse and misuse their prescription opioids are discontinued on opioid therapy, the risk of them having opioid-related complications such as opioid overdose and even death become much less (Trescot et al., 2006). Lastly, opioids that were potentially being diverted by patients through "doctor shopping" and possibly by patients with consistent negative opioid level in their urine were discontinued from opioid therapy by the OMC. These opioids have the potential to reach someone who may not be familiar with the use of an opioid and result in opioid-related complications including death.

The OMC was able reduce the morphine equivalent dose per day for patients seen and evaluated in the OMC regardless of their participation in the OMC study. The average MED per day for all patients seen in the OMC dropped by 43mg. A rough estimate of what this average drop in MED can be represented by multiplying this drop

by the number of patients seen in the OMC. The calculated number can be applied to the average opioid concentration that might have been stopped as the result of the discovery by the OMC of substance abuse and "doctor shopping". In this case, multiplying 43mg by the 114 patients seen in the OMC would yield around 4,900mg MED of opioids that were stopped as the result of the OMC's strategy to identify patients who may be abusing and misusing their prescription opioids. The calculated 4,900mg MED of opioids is equivalent to about 980 hydrocodone 5/325mg pills. This means that for each month after the OMC identified a patient who was abusing their opioid prescription and discontinued their opioid therapy, the VA Las Vegas gets to dispense 980 less pills of hydrocodone 5/325 per month. In a year, nearly 11,800 hydrocodone 5/325mg pills can be prevented from being dispensed for inappropriate use by the VA Las Vegas due to the direct action by the OMC. Besides the decrease in the number of opioid pills, the healthcare cost savings associated with each veteran who was discontinued on opioid therapy is much higher. According to Baser et al. (2013), each veteran on opioid therapy who abuse their prescription opioids cost the VA approximately $29,000. There were forty-five patients who were discontinued on opioid therapy because of the mitigation strategies involved with the OMC. By multiplying 45 (number of patients discontinued on opioid therapy) with $29,000, the potential savings of more than $1.3 million for early identification of abuse and misuse of opioids may be estimated. The savings come from preventing opioid-related complications to occur by stopping the use of inappropriate opioids in the first place as recommended by Federation of State Medical Boards (2013). This number was just from the OMC. Since there is evidence of higher compliance among PCPs in following the VA/DoD clinical practice guideline in the management of

patients on chronic opioid therapy, it is probably safe to say that PCPs who follow the guideline are also discovering abuse and misuse of opioids among their patients who were not referred to the OMC. When the cost savings from the number of patients who were stopped on opioid therapy by their PCPs and by the OMC are added up, the potential cost saving to the VA Las Vegas is likely to be much higher than the estimated cost savings from OMC alone. The potential cost saving to the VA Las Vegas due to discovery of abuse and misuse of opioids can be approximated based on the 3% five-year prevalence rate of opioid abuse and $29,000 annual healthcare cost of veterans who abused their opioid prescriptions that Baser et al. (2013) published. There were nearly 5,900 veterans on opioid therapy when the OMC was initiated. Based on the 3% 5-year prevalence rate that Baser et al. (2013) reported and the 5,900 veterans on opioid therapy, approximately 177 new cases of abuse and misuse of opioids might be identified by regular opioid monitoring every 5 years (5,900 x 3%). The 5-year potential savings to the VA Las Vegas based on this number is about $5.1 million every 5 years (177 x $29,000).

The effectiveness of the OMC in improving the pain scores of patients seen in the OMC is still unclear and too early to be determined. The planned evaluation at 12 months of the OMC operation may provide a better insight as to the effectiveness of the OMC in improving BPI pain scores of patients seen in the OMC. Even though the difference between the BPI scores at admission and BPI scores at the latest OMC appointment was not significant, the clinical trend of lower pain intensity and functional intensity scores from the BPI are encouraging. Further, early results from the OMC evaluation showed that the Pain Screening Tool was highly related to patient retention

outcomes of patients seen in the OMC. The evaluation also found that BPI scores were not related to patient retention outcomes of patients seen in the OMC. One viable explanation in the difference in the relationship between the two instruments used in the OMC is that the Pain Screening Tool is based on clinician objective input while the BPI is based on patient subjective input. A clinician with expertise in detecting opioid abuse and misuse by thoroughly reviewing medical record and using specific patient questions (i.e. "as the last time you took your opioid medications", "describe to me your usual intake of prescription opioid including timing and how many tablets you take with each dose") to correlate chart review (refill pattern and results of screening) with patient responses to these questions would expectedly result to high correlation between the Pain Screening Tool scores and patient retention outcomes. In contrast, BPI scores are based on patient input to questions included in the BPI instrument. Patients who abuse and misuse their medications or unhappy with the change in their opioid therapy may be exaggerating their pain intensity and functional intensity to avoid changes in the current opioid therapy. For example, patients found to be abusing and misusing their opioids and were on slow tapering dose of opioids to avoid withdrawal symptoms tend to have higher BPI pain intensity and functional intensity scores at follow up visits. These patients tend to also report better pain relief with the use of short acting opioids. Future evaluation of BPI scores in patients seen in the OMC should probably exclude those patients who were found to be abusing and misusing their opioids and only include those who were complying with the recommendations by the OMC and continue to be monitored by the OMC. By including only the patients who continued to be monitored by the OMC, BPI scores at admission and at one year after admission should likely provide a better insight

as to how effective the OMC in improving pain outcomes for patients over time. Improved pain scores in the BPI has been shown to correlate well with improved overall pain management quality of patients with pain (Cleeland & Ryan, 1994).

Many patients seen in the OMC did not have complete OMC documentation according to the OMC clinic note. Half (49%) did not have any BPI scoring done which may have affected the data analyses related to BPI scores and its association with patient retention outcomes. Many patients who did not have BPI scoring done were patients seen very early in the OMC operation where scheduling conflicts and specific steps involved with each OMC visit were still unfamiliar to the OMC staff. Since the full implementation of the OMC in February 2014, all patients referred to the OMC and seen in the OMC had full completion of the OMC clinic note.

The pharmaceutical cost for opioid use in VA Las Vegas has been going up even before the initiation of the OMC. There are several reasons for the increasing trend in the opioid pharmaceutical cost for the VA Las Vegas. First, the cost of these opioids may have gone up to account for the higher cost for opioids from one quarter to the next. Second, the number of veterans enrolling in the VA Las Vegas continues to increase, and many of these newly enrolled veterans are young veterans with chronic pain. According to a recent study, 50% young veterans coming from the Iraqi and Afghanistan wars have chronic pain symptoms (Hoge & Castro, 2012). Many of these veterans enrolling in the VA healthcare system also suffer from Post Traumatic Stress Disorder (PTSD). Research has shown that nearly 86% of veterans with PTSD also suffer chronic pain (Vasterling et al., 2010). The continued increase in the number of newly enrolled veterans coming in the VA Las Vegas healthcare system coupled with high percentage of these veterans with

chronic pain might be the reason for the continued rising cost of opioids in the VA Las Vegas despite increased awareness among PCPs to monitor their patients on opioid therapy for opioid abuse and misuse.

The increased opioid pharmacy cost noted in the OMC is counter to what has been reported in by Wiedemer et al. (2007) and Kharlamb (n.d.) which reported significant pharmacy cost savings from the implementation of an opioid renewal clinic and substitution from short acting opioids to long acting opioids in patients on chronic opioid therapy. It is noteworthy to point out that the OMC was able to stop opioid therapy among patients found to be abusing and misusing their prescription opioids and reduced the MED of patients referred to the OMC. The discontinuation of opioid therapy and reduction in dose of opioids resulted in immediate cost saving to the VA Las Vegas.

The increase in compliance of PCPs in following the recommendations from the evidenced-based VA/DoD clinical practice guideline is a very encouraging finding. According to Trescot et al. (2006), compliance with clinical practice guidelines can help reduce opioid-related complication. The use of urine drug screens in the VA Las Vegas continue to increase as evidenced by increasing number of urine drug screens ordered by clinicians in the VA Las Vegas. The use of the Opioid Pain Agreement and PDMP by PCPs has also shown a dramatic improvement from the baseline needs assessment. Based on these findings, PCPs appear to be more adherent in following the recommendations from the VA/DoD clinical practice guideline.

The ease and effectiveness of the OMC also has led to a strong essential buy-in among PCPs in helping them manage their high risk patients. PCPs who referred patients into the OMC were very satisfied with the OMC and reported high satisfaction

with the OMC referral process. Buy-in from PCPs is essential in the continued success of the OMC as the OMC is dependent on PCPs continually referring high-risk patients to the clinic.

Lastly, the development, implementation, and evaluation of the OMC were based on Lewin's Change Theory. By using Lewin's Change Theory as its theoretical framework, the OMC was able to develop and implement the clinic in a structured and evidenced-based fashion. In the unfreezing phase, the OMC used all available evidence as its driving forces to develop and implement the clinic, including a baseline needs assessment survey done on PCPs and the growing problem of opioid abuse among patients on chronic opioid therapy. To address possible restraining forces that may threaten the development and implementation of the OMC, and to support the changing phase of Lewin's Change Theory, multiple educational sessions were done to inform key stakeholders, including PCPs and organization leadership, of the growing problem of opioid abuse among patients on chronic opioid therapy and the need for an intervention to address this problem. In the refreezing phase, findings from the evaluation of the OMC were reported to leadership and PCPs to illustrate the effectiveness of the OMC in identifying abuse and misuse of opioids, and in improving PCP satisfaction in managing patients at high risk for opioid abuse.

Dissemination and Utilization of the Results

The development of the OMC in VA Las Vegas was initiated by an APRN using Lewin's Change Theory as a theoretical framework to garner support for the implementation of the OMC project. The OMC was implemented in the VA Las Vegas in July 2013. From November 2013 through February 2014, the OMC was evaluated

using an IRB approved protocol to evaluate effectiveness. Findings from these evaluations have shown success in meeting the objectives of the OMC. The evaluation has shown improved compliance among PCPs in VA Las Vegas in following the recommendations from the VA/DoD clinical practice guideline. This data was supported by the survey finding of improved compliance in following the recommendations from the VA/DoD clinical practice guideline and by the increase in the number of urine drug screens ordered in the VA Las Vegas. The evaluation of the OMC also showed the effectiveness of the OMC in identifying patients who abuse and misuse their opioid prescriptions.

The OMC is a clinic specific to the needs of the PCPs in the VA Las Vegas and may not be representative of other primary care clinics in the VA nationwide. However, the findings in the evaluation of the OMC provide support for a specialized clinic that can assist clinicians in the management of complicated and high risk patients. The OMC is a specialized clinic similar to other specialty clinic like endocrine or oncology where patients with certain characteristics or diseases can be referred by their primary care providers to help better manage their patients and to improve outcomes.

The findings from the formative evaluation of the OMC were reported to the VA Las Vegas leadership including the Director of VA Las Vegas, Chief of Staff, Nurse Executive, and Chief of Primary Care. A plan to report the one year summative evaluation of the OMC to leadership of VA Las Vegas for future expansion of the clinic will also be conducted. Currently, the OMC has already secured approval from the Chief of Primary Care for the addition of a pain psychologist in the OMC and the addition of the Shared Medical Appointment (SMA) model as an appointment option for patients. In

this group medical appointment model, patients interested in attending a group medical appointment in the OMC would be scheduled an appointment in a group setting where their needs for timely renewal of opioids as well as monitoring of their opioid therapy would be met in a group setting. This addition of the SMA would allow more patients to be seen and evaluated in the OMC by eliminating the structured 30 per patient appointment slots and allow multiple patients to be seen in a two-hour group medical appointment slots. The implementation of the SMA into the OMC is scheduled to be implemented on April 29, 2014.

The development, implementation, and evaluation of the OMC based on Lewin's Change Theory allowed for structured and evidence-based phases to take place which resulted in the overall achievement of the objectives of the OMC project. The development of the OMC was aligned to the needs of the PCP based on the needs assessment survey. The implementation of the OMC was aligned with the VA/DoD clinical practice guideline to ensure evidenced-based strategies that would identify abuse and misuse of opioids among patients. The evaluation of the OMC was aligned to the objectives of the OMC project and in evaluating the outcomes of the OMC against these project objectives. These strategic phases in the development and implementation of the OMC can be of assistance to others who may be looking for a strategy to help address the opioid abuse problems in the United States. It is therefore important that the strategic phases in the development and implementation of the OMC as well as the evaluation findings of the OMC be shared to others through publication. Among the peer-reviewed publications that might be considered include the Federal Practitioner which is a peer-reviewed journal for healthcare professionals in the VA, DoD and the public health

service, and the Journal of Pain which publishes original articles relating to all aspects of pain management.

APPENDIX A: VA OPIOID MONITORING CLINIC (OMC) POLICY

DEPARTMENT OF VETERANS AFFAIRS
VA Southern Nevada Healthcare System
Las Vegas, Nevada

MEDICAL CENTER MEMORANDUM
11-29-12
November 2012

OPIOID MONITORING CLINIC (OMC)

1. PURPOSE: To establish a clinic protocol for the management of chronic noncancer pain patients who are on chronic opioids (COT) therapy. The protocol will address proper management of patient population in Primary Care.

2. BACKGROUND: The Veterans Health Affairs (VHA) National Pain Management Strategy initiated in November 12, 1998, established pain management as a national priority. The overall objective of the national strategy is to develop a comprehensive, multicultural, integrated, system-wide approach to pain management that reduces pain and suffering and improves quality of life for Veterans experiencing acute and chronic pain associated with a wide-range of injuries and illnesses, including terminal illness. VHA employs a stepped-care model of pain care that provides for management of most pain conditions in Primary Care setting. This is supported by timely access to secondary consultation from pain medicine, behavioral health, physical medicine and rehabilitation, specialty consultation, and care coordination with palliative care, tertiary care, advanced diagnostics and medical management, rehabilitation services for complex cases involving co-morbidities such as mental health disorder and traumatic brain injury (TBI). The development of the opioid monitoring clinic (OMC) is an important step in assisting Primary Care Providers (PCP) in the care of chronic pain patients on COT.

3. POLICY:
    a. It is the right of every patient at the VA Southern Nevada Healthcare System (VA-Las Vegas) to receive appropriate pain management.
    b. It is understood that the majority of patients on COT that are Low Risk Category will be managed in the Primary Care setting by their PCP.
    c. The OMC will assist PCPs in their care of patients on COT who are in the High Risk Category.
    d. PCPs will continue to have the option of sending patients for the Step Two, secondary consultation to the Integrated Pain Clinic, Physical Medicine and Rehabilitation, Polytrauma programs and teams, and Pain Psychology. This pertains especially to the patients that have not been previously evaluated by the Step Two Clinics, with history of aberrant opioid use, and illicit use of non-state sanctioned Schedule I substances.
    e. High Risk Category patients on COT who have been previously evaluated by the Step Two Clinics and do not present with a new diagnosis, can be managed by the OMT.
    f. Appropriate monitoring for Veterans on COT is important in reducing the risk for misuse, diversion, or overose, and involves:
        1. Ensuring PCPs comply with all elements for management of patients on COT in order to achieve pain management objectives along the continuum of care of chronic pai,.
        2. Ensuring adherence to opioid medication agreements and/or prescribed therapies.
        3. Providing for appropriate level and frequency of monitoring for improvement in outcomes of pain management including pain control, physical and psychosocial function, quality of life, and complications.

4. Establishing expectations for attitudes, knowledge, and skills in pain management in primary, secondary and tertiary care.
5. Including patients and families as active participants in pain management.
6. Providing for an interdisciplinary, multi-modal approach to pain management that emphasizes optimal pain control, improved function and quality of life.
7. Promiting standardized education and training to ensure that clinicians achieve standard competencies appropriate to their clinical setting (e.g. Primary Care, behavioral health, pain management) and role.

4. ACTION:
   a. Definitions:
      1. Stepped Care: Stepped care is instituted as a strategy to provide a continuum of effective treatment to a population of patients from acute pain caused by injuries or diseases to longitudinal management of chronic pain diseases and disorders that may be expected to persist for more than 90 days, and in some instances, the patient's lifetime.
         1. Step One, PCP: Requires the development of a competent PCP workforce (including behavioral health) to manage common pain conditions. To accomplish this, primary care requires the availability of system supports, family and patient education programs, collaboration with integrative mental health-primary care teams, and post-deployment programs (i.e., OEF/OIF).
         2. Step One: OMC: Is a structured, protocol-driven clinic designed to help identify and reduce opioids misuse among veterans on COT for chronic noncancer pain. The OMC utilizes evidence-based risk reduction recommendations from the 2010 update of the VA/DoD Clinical Practice Guideline (CPG) for the management of opioid therapy for chronic pain. The main objectives of the OMC are the following:
            1. To provide a structured, monitoring program for veterans at high risk for opiate misuse.
            2. To decrease the incidence of opiate related complications such as opiate related drug overdose or adverse effects.
            3. To improve patient outcomes (i.e., reduce pain, increase functional status, and enhance quality of life).
            4. To provide an option for referral by PCP with concerns about COT.
      2. Step Two, Secondary Consultation. Requires timely access to specialty consultation in pain medicine, physical medicine and rehabilitation, polytrauma programs and teams, and pain psychology; occasional short-term co-management; inpatient pain medicine consultation; and the collaboration of pain medicine and palliative care teams.
      3. Step Three, Tertiary, Interdisciplinary Care. Requires advanced pain medicine diagnostics and pain rehabilitation programs accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF).
      4. Low Risk Chronic Pain Patient on COT. Any type of patient that is on a daily dose of Morphine equivalent between 0 and 100mg per day. The patient is compliant with current COT and does not exhibits aberrant behaviors. These patients also do not have significant medical or psychiatric co-morbidities.

5.High Risk Chronic Pain Patient on COT. Any patient that is on a daily Morphine equivalent dose of over 100mg or any patient with a daily dose of 0-100mg Morphine equivalent and possess significant medical or psychiatric co-morbidities or aberrant opioid use behaviors.

6.Misuse:

1. Urine Drug Screen (UDS) negative for prescribed opioids
2. UDS positive for opioids or other controlled substances not prescribed by the VA
3. Evidence of procurement of opioids from multiple providers (Positive findings from Nevada/Arizona State Prescription Monitoring database) (DUS).
4. Diversion of opioids
5. Prescription Forgery
6. Stimulants on UDS (cocaine, methamphetamines)
7. Nonadherence to Pain Agreement or Treatment Plan
8. Unreasonable requests for opioid refills (multiple early refills, lost of medications).

7.Serious Misuse:

1. Stimulants on UDS
2. Positive DUS
3. Documented diversion of opioids through conviction history of admission from patient.
4. UDS negative on at least two (2) occasions for prescribed opioids with confirmation test.
5. UDS positive on at least two (2) occasions for opioids not prescribed in the VA.

b. PROCEDURES:

1.Criteria for referral to OMC:

1. Pain of more than three (3) months in duration AND
2. Morphine equivalent dose of over 100mg per day AND
3. PCP suspecting misuse of opioid medications OR
4. Documented evidence of aberrant behaviors including multiple early refills, report of loss of medications, multiple ER visits for pain while on COT, non-compliance with drug monitoring such as urine drug screen (orders for drug screen not being done by patient), negative urine drug screen for prescribed opioids OR
5. History of substance abuse including heroin, cocaine, alcohol and marijuana OR
6. Morphine equivalent dose of 0-100mg but exhibits aberrant behaviors.

2. Identification of Misuse:

1. The OMC will utilize evidence-based risk reduction strategies to identify miuse among Veterans with chronic pain on COT. The following risk reduction strategies will be utilized in the OMC in accordance with the VA/DoD guideline of COT:
    1. Frequent and regular urine drug screen monitoring. Each patient will be subjected to UDS for the presence of opiates, amphetamines, cannabinoids, benzodiazepines, methadone, cocaine and barbiturates in

urine. In collaboration with VA laboratory, positive UDS would be verified using gas chromatography/mass spectrophotometry (GS/MS) confirmatory assays. Because UDS opiate assay has greater sensitivity and specificity for morphine and codeine, the presence or absence of other opiates will also be confirmed with GS/MS. All positive results for amphetamines are also confirmed with GS/MS. The following interval will be done for UDS:

i. At the time of referral to OMC
ii. At the initial patient visit with OMC
iii. Monthly for 2 months then
iv. Every 3 months thereafter
v. Urine drug screen monitoring will also be done at random when there is suspicion for misuse or abuse by the staff of OMC.

2. Frequent office visits.
    i. Monthly visits
    ii. The OMC may also ask patients for more frequent office visits when there is suspicion of misuse or abuse of opioids.
3. Restricted early refills.
    i. Patients admitted to OMC is educated that the OMC will not do early refills of opioids including due to lost opiate medications, travel plans or for running out of medications early.
4. Interval visits to monitor response to therapy.

3. Use of Opioid Pain Care Agreement:

1. The Opioid Pain Care Agreement will be reviewed and discussed with the Veteran who is expected to be continued on COT. The signed agreement can serve s documentation of an written informed consent discussion.
    1. Patients who are admitted in OMC and lacks Opioid Pain Care Agreement in the medical record, will be required to sign an Opioid Pain Care Agreement after discussion of its content with the patient.
    2. Patients who refuse to sign the Opioid Pain Care Agreement will be discharged from OMC and an alert to the referring PCP will be done via the Computerized Patient Record System (CPRS).

4.Use of written informed consent for DUS:

1. The written informed consent for DUS will be reviewed and signed by the patient admitted to OMC. The informed consent allows the staff of VA-Las Vegas to access the Nevada/Arizona State Prescription Monitoring database to look for multiple prescription of opioids to the same patient from other healthcare providers.
    1. Patients who refuse to sign the written informed consent form will be discharged from OMC and an alert to the referring PCP will be done via the Computerized Patient Record System (CPRS).

5. Criteria for Discharge from OMC:

1. Patients who meet the definition of serious misuse will be discharged from OMC.

1. The referring PCP for the discharged patient will be notified via CPRS.
2. A note in CPRS will be completed with recommendations from OMC for PCPs to take note.
3. Patients who were taken off Opioid by the OMC due to use of non-state sanctioned schedule I substances, including heroin, cocaine, amphetamines will be referred by OMC staff to the ADTP. The OMC may reconsider readmission to the program if a patient has completed at least 6 months of ADTP program.

2. Failure of the patient to comply with the treatment plan may result in opioid treatment being discontinued. A patient receiving chronic opioid therapy is required to comply with the treatment plan, including diagnostic tests, specialty consultations, and other treatments ordered by the VA PCP or OMC staff.
3. Self-referral around primary care clinics or to other VAs in search of multiple providers to prescribe opioids.
4. Abusing, threatening or intimidating VA staff members. This will be reported to VA police and will result in discharge from OMC.
5. Overt drug seeking behaviors

c. RESPONSIBILITIES:

1. OMC staff. The OMC will consist of Primary Care Teamlet which includes a PCP, Registered Nurse (RN), Licensed Practical Nurse (LPN), and a medical clerk (MSA).

2.PCP:

1. Review of incoming referral from PCP for appropriateness of admission to OMC.
2. Assessment of analgesia, activity and function, adverse events, and aberrant drug related behaviors ("4 A's" model, Passik et al., 2000).
3. Review of Opioid Pain Care Agreement with the patient
4. Ordering of UDS
5. Documentation of random pill counts
6. Consultation with PCPs, and other specialty care as needed (i.e., referral to Alcohol and Drug Treatment Program (ADTP) for patients who abuse opiates or other illicit substances, referral to other pain management modalities such as Physical Therapy, Physiatry, Anesthesia Pain Injection, Osteopathic Manipulation Therapy, Acupuncture, or chiropractic services.)
7. Renewal of opiates
8. Opiate adjustment including change of type and dose
9. Review of Nevada and/or Arizona database for opioid prescriptions outside the VA.

3. RN:

1. Care Management of patients on COT and admitted to OMC
    1. Care management includes case management to ensure patients are compliant with recommended plan of care such as referral to other pain modalities, complying with laboratory orders or other ancillary tests.
2. Coordinating patient appointments with MSA or making follow up appointments

4.LPN:

1. Coordinating patient appointment with MSA or making follow up appointments
2. Intake of patients admitted to OMC
    1. Intake includes completion of basic demographic information and completion of Screening Tool and the Short Form Brief Pain Inventory.
    2. Obtaining vital signs

5.MSA:

1. Making initial appointments and follow up appointments.

APPENDIX B: CHIEF OF PRIMARY CARE LETTER OF SUPPORT

DEPARTMENT OF VETERANS AFFAIRS
VA Southern Nevada Healthcare System
6900 North Pecos Road
North Las Vegas, Nevada 89086
(702) 791-9000

In Reply Refer To:

March 8, 2013

To Whom It May Concern,

Mr. Richard Talusan is a Nurse Practitioner providing primary care to his patients at the Veterans Administration Southern Nevada Healthcare System. He has expressed interest in starting an Opioid Monitoring Clinic (OMC). He has the full support of me and my department in this endeavor. This type of project is something I would only entrust to one of my exceptional providers, which Mr. Talusan certainly is.

Armen Nikogosian, MD
Chief of Primary Care
VASNHS
Ext. 19468

APPENDIX C: OPIOID MONITORING CLINIC PROTOCOL

OPIOID MONITORING CLINIC (OMC) PROTOCOL

Referral from Primary Care Providers (PCP)—Meets Eligibility Criteria
Urine Drug Screen (UDS) ordered by referring PCP
Initial Appointment with OMC
- Signed Opioid Pain Care Agreement
- Signed informed consent for Drug Utilization Screening (DUS)- Nevada (Prescription Monitoring Program) / Arizona (Controlled Substances Prescription Monitoring Program)
- Completion of Screening Tool
- Completion of BPI
- OMC clinic note includes: Suicidal/Homicidal risk screening, History including aberrant behaviors, substance abuse, current opiate therapy, vital signs, current pain level, functional ability, adverse drug reaction/side effects, aberrant behaviors, BPI results, Screening Tool results, physical exam findings, and plan of care
- Repeat UDS
- Check State Prescription Monitoring database

If current Chronic Opioid Therapy (COT) uses a combination of short acting and long acting opioids then calculate daily morphine equivalent of current COT and change to long acting opiates with 30% reduction in dose due to cross tolerance.

If change in COT is done by OMC, then have patient return every 2 weeks for reevaluation of pain.

At 1 month
- Renew opioids
- Repeat UDS
- Pill count
- Screening Tool
- DUS, optional

At 2 months
- Renew Opioids
- Repeat UDS
- Pill Count
- Screening Tool
- DUS, optional

At 3 months
- Renew Opioids
- Repeat UDS
- Pill Count
- Screening Tool
- BPI
- DUS, optional

At 6 months
- Renew Opioids
- Repeat UDS
- Pill Count
- Screening Tool
- DUS, optional
- BPI

At 9 months
- Renew Opioids
- Repeat UDS
- Pill Count
- Screening Tool
- DUS, optional
- BDI

At 12 months
- Renew Opioids
- Repeat UDS
- Pill Count
- Screening Tool
- DUS, optional
- BPI

Eligibility Criteria:

1. Pain of more than three (3) months in duration AND
2. Morphine equivalent dose of over 100mg per day AND
3. Documented evidence of aberrant behaviors including multiple early refills, report of loss of medications, multiple ER visits for pain while on COT, non-compliance with drug monitoring such as urine drug screen (orders for drug screen not being done by patient), negative urine drug screen for prescribed opioids OR
4. History of substance abuse including heroin, cocaine, alcohol and marijuana OR
5. Morphine equivalent dose of 0-100mg but exhibits aberrant behaviors.

Criteria for Discharge from OMC:

1. Patients who meet the definition of serious misuse will be discharged from OMC.
   a. Serious Misuse Definition:
      1. Stimulants such as cocaine, heroin or methamphetamines on urine drug screen
      2. Documented diversion of opioids through conviction history admission from patient
      3. Urine drug screen negative on at least two (2) occasions for prescribed opioids with confirmation test ordered by OMC staff.
2. Failure of the patient to comply with the treatment plan may result in opioid treatment being discontinued and thus discharge from the OMC. A patient receiving chronic opioid therapy is required to comply with the treatment plan, including diagnostic tests, specialty consultations, and other treatments ordered by the VA PCP or OMC staff.
3. Self-referral around primary care clinics or to other VAs in search of multiple providers to prescribe opioids as documented by Nevada/Arizona controlled substance monitoring program database or CPRS record..
4. Abusing, threatening or intimidating VA staff members. This will be reported to VA police and will result in discharge from OMC.
5. Overt drug seeking behaviors

Procedure for Discharge from OMC:

1. The referring PCP for the discharged patient will be notified via Computerized Patient Record System (CPRS) with reason for discharge from OMC.
2. The referring PCP will be contacted either face to face or by telephone of their patient's discharge from the OMC. PCP will be given recommendation for future management of patient.
3. A red flag note in CPRS will be completed with recommendations from OMC for PCPs to take note.
4. Patients who were taken off opioid by the OMC due to use of non-state sanctioned schedule I substances, including heroin, cocaine, and amphetamines will be referred by OMC staff to the Alcohol and Drug Treatment Program (ADTP). The OMC may reconsider readmission to the program if a patient has completed at least 6 months of ADTP program.

APPENDIX D: OPIOID MONITORING CLINIC NOTE

OPIOID MONITORING CLINIC NOTE

Reason for being seen in the Opioid Monitoring Clinic:
[ ] Hx of substance abuse
[ ] High Dose Opioids
[ ] Concurrent use with other CS
[ ] Hx of aberrant behaviors
{] Other

History of Substance Abuse:
[ ]None
[ ]Cocaine
[ ]Heroin
[ ]Alcohol
[ ]Marijuana
[ ]Other:

If + Hx of (A)berrant Drug-related behviors:
[ ]Early refills
[ ]Lost of Medications
[ ]Medication Seeking

SOURCE(S) OF HISTORY: Patient

SUICIDE/HOMICIDAL RISK ASSESSMENT
1. Has the veteran had thoughts of suicide in the past 30 days?
[ ]No
[ ]Yes

2. Has the veteran attempted suicide in the past 30 days?
[ ]No
[ ]Yes

3. Has the Veteran ever attempted suicide?
[ ]No
[ ]Yes

4. Has the veteran had homicidal thoughts in the past 30 days?
[]No
[]Yes

5. Risk level:
[ ]no risk
[ ]low risk
[ ]moderate risk
[ ]high risk

Current Analgesic Regimen:
1.
2.

Last Dose:

Current MED dose:

PDMP Result:
Date:
Expected [ ]
Unexpected [ ]
Comment:

UDS Result:
Date:
Expected [ ]
Unexpected [ ]
Comment:

Data from Brief Pain Inventory-Short Form:

(A)dverse Events/Side Effects:

ALLERGIES AS DISPLAYED IN VISTA: |ALLERGIES/ADR| {FLD:VA*PC HXINFO3}

MEDICATIONS (as listed in Vista):
  |OUTPATIENT MEDS LL|
{FLD:VA*WP-INDENT2}

{FLD:VA*PC L-CONST}
  VITALS (most recent, as listed in the electronic record):
           B/P: |BLOOD PRESSURE|
         Pulse: |PULSE|
   Temperature: |TEMPERATURE|
        Weight: |PATIENT WEIGHT|
        Height: |PATIENT HEIGHT|
           BMI: |BMI ALBQ|

Screening Tool Score:

Criteria:	Point	Max Point
Focus on opioids	[ ]	1: Yes 0:No
Opioid overuse	[ ]	1: Yes 0:No
Other drug use	[ ]	1: Yes 0:No
Low-functional status	[ ]	1: Yes 0:No
Exaggeration of pain	[ ]	1: Yes 0:No
Etiology of pain unclear	[ ]	1: Yes 0:No
TotalPoints:		

Examination:

Summary:
Average BPI Analgesia score at admission to OMC:
Average BPI Analgesia score last visit:
Average BPI Analgesia score this visit:

Average BPI functional score at admission to OMC:
Average BPI functional score last visit:
Average BPI functional score this visit:

Screening tool score at admission:

% pain relief from pain medication at admission: %
% paim relief from pain medication at this visit: %

Service Connected Visit:

Diagnosis:
1.
2.
3.

Plan of Care
1. Opiate Therapy ordered
[ ]None at this time
[ ]Continue current COT
[ ]Decrease dose
[ ]Change from SA to LA
[ ]Discontinue COT

2. Monitoring completed/ordered: [ ]UDS [ ]Pill Count

3. Referrals ordered/ongoing

[ ]Pain clinic
[ ]Physiatry
[ ]Physical Therapy
[ ]Acupuncture
[ ]Chiropractor
[ ]OMT
[ ]Anesthesia Injection
[ ]Pain Psychologist
[ ]ADTP
[ ]MHC
[ ]Orthopedics

4. Next follow visit: [ ]month [ ]weeks

Education:

APPENDIX E: PROVIDER SATISFACTION SURVEY

Provider Satisfaction Survey and OMC Evaluation

Consent Page 1

INFORMED CONSENT
Department of School of Nursing

TITLE OF STUDY: Evaluation of an Opioid Monitoring Clinic
INVESTIGATOR(S): Principal Investigator: Kawi, Jennifer
Student Investigator: Talusan, Richard
For questions or concerns about the study, you may contact Jennifer Kawi at 7028955930.

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the UNLV Office of Research Integrity – Human Subjects at 702-895-2794, toll free at 877-895-2794 or via email at IRB@unlv.edu.

Purpose of the Study
You are invited to participate in a research study. The purpose of this study is evaluate the Opioid Monitoring Clinic on: (a) its impact on opioid use, abuse, or misuse; and (b) primary care providers' satisfaction with the clinic and their adherence to using clinical practice guidelines in managing high risk veterans with chronic pain on chronic opioid therapy.

Participants

You are being asked to participated in this study because you fit the eligibility criteria: (a) you are a primary care provider employee at the Las Vegas VA and (b) you are within the age range of 25-80.

Procedures
As a provider participant, you will be asked to complete a provider satisfaction survey.

Benefits of Participation
There may not be direct benefits to you as a participant in this study. However, we hope to learn if the Opioid Monitoring Clinic can facilitate primary care provider satisfaction in the care of patients with chronic pain on chronic opioid therapy as well as adherence to pain management guidelines.

Risks of Participation
There are risks involved in all research studies. As a provider participant, you may feel uncomfortable answering some of the questions in the provider satisfaction survey.

Cost /Compensation
There is no financial cost to you to participate in this study. As a provider participant, the survey will take 10 minutes of your time.

Page 1

Provider Satisfaction Survey and OMC Evaluation

Consent Page 2

Confidentiality
All information gathered in this study will be kept as confidential as possible. No reference will be made in written or oral materials that could link you to this study. All records will be stored in a locked facility at UNLV for 3 years after completion of the study. After the storage time the information gathered will be shredded and destroyed.

Voluntary Participation
Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with UNLV or the Opioid Monitoring Clinic. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Participant Consent*:
I have read the above information and agree to participate in this study and give permission to use my responses on this survey for the research study. I have been able to ask questions about the research study. I am at least 18 years of age.

*Provider participant will not need to sign this consent form.

Provider Satisfaction Survey and OMC Evaluation

1. I would like to participate in the study to evaluate the Opioid Monitoring Clinic.

- ◯ YES
- ◯ NO

2. Have you referred patients to OMC?

◯ Yes ◯ No

3. I follow the recommendations in the VA/DoD Clinical Practice Guideline for chronic opioid therapy.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

4. I use the Opioid Pain Agreement more often.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

5. I routinely order urine drug screens when indicated.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

6. I routinely access a Prescription Drug Monitoring Program (PDMP) to check for double dipping or "Doctor Shopping"

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

7. The service has a positive impact on the Primary Care practice.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

Provider Satisfaction Survey and OMC Evaluation

8. I receive fewer complaints regarding pain medications.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

9. There are fewer walk-ins for pain management issues.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

10. I can spend more time with the patient's other medical problems when they are being followed by this service.

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

11. Overall, are you satisfied with the Opioid Monitoring Clinic in helping you manage chronic pain patients?

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
◯	◯	◯	◯	◯

Other (please specify)

12. Do you find anything in the OMC referral process that needs improvement? Can you please write your suggestions so that we can assess your feedbacks and further improve the OMC referral process.

◯ Yes

◯ No

Other (please specify)

APPENDIX F: BRIEF PAIN INVENTORY-SHORT FORM

1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

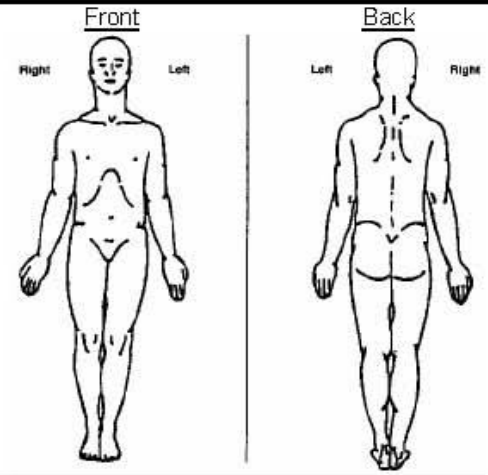
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

Page 1 of 2

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Pain Research Group
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1903

Date: (month) / (day) / (year)

Subject's Initials : _____

Study Subject #:

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

Revision: 07/01/05

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

B. Mood

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

C. Walking ability

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

E. Relations with other people

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

F. Sleep

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

G. Enjoyment of life

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

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Pain Research Group
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APPENDIX G: BRIEF PAIN INVENTORY PERMISSION TO USE

Talusan, Richard L

From: Cleeland,Charles [ccleeland@mdanderson.org]
Sent: Tuesday, February 26, 2013 11:40 AM
To: Talusan, Richard L
Subject: RE: Brief Pain Inventory- Short Form

You have my permission to use the BPI as stated. Good luck.

Charles S. Cleeland, PhD
McCullough Professor of Cancer Research
Chair, Department of Symptom Research
Division of Internal Medicine
U.T. M.D. Anderson Cancer Center, Unit 1450
1400 Pressler
Houston, Texas 77030
713:745-3470
MD Anderson Cancer Center

From: Talusan, Richard L [mailto:Richard.Talusan@va.gov]
Sent: Tuesday, February 26, 2013 1:34 PM
To: Cleeland,Charles
Subject: Brief Pain Inventory- Short Form

Hello Dr. Cleeland. The reason I am sending this email is to ask permission for me to use your Brief Pain Inventory Short Form (BPI) as part of my doctoral project on pain management. I am a doctoral student at University of Nevada Las Vegas and I have a doctoral project proposal of developing an opioid monitoring clinic to help identify abuse and misuse among veterans who are at high risk for abuse and misuse of opiates. I plan to use your Tool along with other pain tools as part of that clinic. I am therefore seeking permission .

I can be best reach through this email address or through my cell phone at 702-556-4679.

Sincerely,

Richard Talusan, FNP-BC, NEA-BC
Primary Care Nurse Practitioner

1

APPENDIX H: PAIN SCREENING TOOL

The Screening Tool

>3 points-High risk of abuse

<3points-Low risk of abuse

CRITERIA	POINTS	
	YES	NO
Focus on opioids	1	0
Opioid overuse	1	0
Other drug use	1	0
Low-functioanal status	1	0
Exaggeration of pain	1	0
Etiology of pain unclear	1	0
Total Score		

APPENDIX I: PAIN SCREENING TOOL PERMISSION TO USE

Talusan, Richard L

From: sairam atluri [saiatluri@gmail.com]
Sent: Tuesday, February 26, 2013 11:57 AM
To: Talusan, Richard L
Subject: Re: Pain Screening Tool

Dear Richard.
Please feel free to use our screening tool. Do not hesitate to get in touch with me if you have any questions.
Also, do you have any experience in designing studies?
thanks
Dr.Atluri

On Tue, Feb 26, 2013 at 2:47 PM, Talusan, Richard L <Richard.Talusan@va.gov> wrote:

Hello Dr. Atluri. Thank you for giving me the permission over the phone to use your pain Screening Tool for my doctoral project.

I just need verification of your permission for me to use the tool. Please reply back with a statement allowing me to use your tool for this project. Thank you again.

I am a doctoral student at University of Nevada Las Vegas and I have a doctoral project proposal of developing an opioid monitoring clinic to help identify abuse and misuse among veterans who are at high risk for abuse and misuse of opiates. I plan to use your Tool along with other pain tools as part of that clinic. I am therefore seeking permission

I can be best reach through this email address or through my cell phone at 702-556-4679.

Sincerely,

Richard Talusan, FNP-BC, NEA-BC

Primary Care Nurse Practitioner

1

APPENDIX J: UNLV INSTITUTIONAL REVIEW BOARD APPROVAL

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

Biomedical IRB – Expedited Review
Approval Notice

NOTICE TO ALL RESEARCHERS:
Please be aware that a protocol violation (e.g., failure to submit a modification for any change) of an IRB approved protocol may result in mandatory remedial education, additional audits, re-consenting subjects, researcher probation, suspension of any research protocol at issue, suspension of additional existing research protocols, invalidation of all research conducted under the research protocol at issue, and further appropriate consequences as determined by the IRB and the Institutional Officer.

DATE: November 20, 2013

TO: **Dr. Jennifer Kawi**, Nursing

FROM: Office of Research Integrity - Human Subjects

RE: Notification of IRB Action
Protocol Title: **Evaluation of an Opioid Monitoring Clinic**
Protocol #: 1307-4514
Expiration Date:November 19, 2014

This memorandum is notification that the project referenced above has been reviewed and approved by the UNLV Biomedical Institutional Review Board (IRB) as indicated in Federal regulatory statutes 45 CFR 46 and UNLV Human Research Policies and Procedures.

The protocol is approved for a period of one year and expires November 19, 2014. If the above-referenced project has not been completed by this date you must request renewal by submitting a Continuing Review Request form 30 days before the expiration date.

PLEASE NOTE:
Upon approval, the research team is responsible for conducting the research as stated in the protocol most recently reviewed and approved by the IRB, which shall include using the most recently submitted Informed Consent/Assent forms and recruitment materials. The official versions of these forms are indicated by footer which contains approval and expiration dates.

Should there be *any* change to the protocol, it will be necessary to submit a **Modification Form** through ORI - Human Subjects. No changes may be made to the existing protocol until modifications have been approved by the IRB. Modified versions of protocol materials must be used upon review and approval. Unanticipated problems, deviations to protocols, and adverse events must be reported to the ORI – HS within 10 days of occurrence.

If you have questions or require any assistance, please contact the Office of Research Integrity - Human Subjects at IRB@unlv.edu or call 895-2794.

Office of Research Integrity - Human Subjects
4505 Maryland Parkway • Box 451047 • Las Vegas, Nevada 89154-1047
(702) 895-2794 • FAX: (702) 895-0805

APPENDIX K: OPIOID MONITORING PROJECT TIMELINE

Due Date	Objective	Task	Status
3/15/2013	DNP Project Approval from DNP Committee		Completed
5/31/2013	Collaborate with ADTP for discharge from OMC		Completed
6/7/2013	Referral Template Completed		completed
6/7/2013	OMC Clinic Schedule Profile Completed		completed
6/15/2013	Urine Drug Screen (UDS) Protocol Completed		completed
6/20/2013	In-service education to PCPs		completed
6/21/2013	OMC Staffing Training		completed
		OMC Forms	
		OMC Clinic Times	
		OMC Protocol	
7/1/2013	Admit patients		completed
11/23/2013	IRB Approval from UNLV		Completed
11/30/2013	Perform 3 months formative clinic evaluation		completed
2/13/2014	Activate Template for referral to OMC		completed
3/17/2014	Stop Primary Care Appt Weds 1st and 3rd week of May		completed
2/12/2014	Activate Template for referral to OMC		completed
2/18/2014	PCP In-service (update of OMC)		completed
2/18/2014	Provider Satisfaction Survey		completed
3/20/2014	Complete DNP Project and develop final paper		completed
4/7/2014	DNP Project defense		
5/2014	Publish DNP Project		

APPENDIX L: PATIENT INFORMED CONSENT

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

INFORMED CONSENT

Department of School of Nursing

TITLE OF STUDY: Evaluation of an Opioid Monitoring Clinic

INVESTIGATOR(S): Principal Investigator: Kawi, Jennifer

Student Investigator: Talusan, Richard

For questions or concerns about the study, you may contact Jennifer Kawi at 7028955930.

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact **the UNLV Office of Research Integrity – Human Subjects at 702-895-2794, toll free at 877-895-2794 or via email at IRB@unlv.edu.**

Purpose of the Study

You are invited to participate in a research study. The purpose of this study is evaluate the Opioid Monitoring Clinic on: (a) its impact on opioid use, abuse, or misuse; and (b) primary care providers' satisfaction with the clinic and their adherence to using clinical practice guidelines in managing high risk veterans with chronic pain on chronic opioid therapy.

Participants

As a patient participant, you are being asked to participate in this study because you fit these criteria: (a) you are a patient in the Opioid Monitoring Clinic with age range 18-65 y/o, (b) with a provider-diagnosed chronic pain, (c) on chronic opioid therapy, (d) with history of substance abuse (i.e., heroin, cocaine, alcohol), and (e) with provider-identified aberrant behaviors (i.e., report of medication loss, request for early refills).

Procedures

If you agree to participate in this study, we will review your medical records. You will not need to be directly involved in this study. For example, we will record a tally of patients (without the use of any information that can identify you) who tested positive for urine drug screen when it should be negative or negative for urine drug screen when it should be positive. This type of research will be helpful in evaluating the effectiveness of the OMC. Other examples of data to be collected include the number of patients with positive findings from the Prescription Drug Monitoring Program and number of patients admitted and discharged from the OMC.

Please note that all the data will be collected from your medical records since you are an OMC patient. The service you receive by OMC will not change – we are asking your permission to review your medical records in a way that we can try to better understand the effectiveness of the services provided by OMC.

Approved by the UNLV IRB. Protocol #1307-4514
Received: 11-15-13Approved: 11-20-13Expiration: 11-19-14

Benefits of Participation
There may not be direct benefits to you as a participant in this study. However, we hope to learn if the Opioid Monitoring Clinic can deter abuse and misuse of opioids.

Risks of Participation
There are risks involved in all research studies. However, as a patient participant, this study will only involve the review of your medical records where recorded data from your medical records will be analyzed. The main risk of participating in this study is loss of confidentiality. However, please understand that as we review your records, we will not record any information that could be used to identify you specifically.

Cost /Compensation
There is no financial cost to you to participate in this study. Your participation will not include any time involvement.

Confidentiality
All information gathered in this study will be kept as private and confidential as possible. No reference will be made in written or oral materials that could link you to this study. All records will be stored in a locked facility at UNLV for 3 years after completion of the study. After the storage time the information gathered will be shredded and destroyed.

Voluntary Participation
Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with UNLV or the Opioid Monitoring Clinic. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Participant Consent:
I have read the above information and agree to participate in this study. I have been able to ask questions about the research study. I am at least 18 years of age. A copy of this form has been given to me.

_____ _____
Signature Date

_____
Name (Please Print)

Approved by the UNLV IRB. Protocol #1307-4514
Received: 11-15-13Approved: 11-20-13Expiration: 11-19-14

APPENDIX M: OPIOID MONITORING PROJECT BUDGET

OPIOID MONITORING CLINIC 3 MONTH BUDGET

Estimated 3 month cost of OMC

	Salary+Benefits	FTE	OMC cost for 3 month period
APRN	$140,000	0.1	$3,500
RN	$71,500	0.1	$1,788
LPN	$34,600	0.1	$865
MSA	$18,750	0.1	$469
			$0

	Cost per testing	Estimated # of patients for 3 months	
Laboratory			
Urine Drug Screening	$9	300	$2,700
Confirmatory Testing	$23	100	$2,300
Office Space	$ -	$ -	$ -
Equipments	$ -	$ -	$ -
Pain related measure (Tools)	$ -	$ -	$ -
Total:	$11,621		

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VITA

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Degrees:

Bachelor of Science in Biology, 1992
Ramapo College

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Pace University

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Doctor of Nursing Practice Scholarly Project Title: Development and Evaluation of an Opioid Monitoring Clinic

Doctor of Nursing Practice Examination Committee:

Chairperson, Jennifer Kawi, PhD
Committee Member, Lori Candela, EdD
Graduate Faculty Representative, John Filler, PhD