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**DEVELOPMENT OF A PAIN MANAGEMENT POLICY
IN AN INDIGENT PRIMARY CARE CLINIC IN
GALVESTON, TX**

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**Development of a Pain Management Policy in an Indigent
Primary Care Clinic in Galveston, TX**

Capstone

by

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Dedication

I dedicate this paper to my loving parents, Beulah and Wayne Maltz, who instilled in me a deep sense of generosity and caring for others and without whom none of my successes would be possible. Thank you for always encouraging and supporting me. I love you!

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Abstract

Millions of Americans suffer from nonmalignant chronic pain (NMCP), often with life altering consequences, such as loss of job function and expensive medical bills. Opioid prescription therapy has gained acceptance among medical professionals for the treatment of this pain and a substantial increase in the number of opiates prescribed has occurred over the last two decades⁶. Along with this increase in opioid prescribing have come increases in the number of unintentional overdoses and/or deaths secondary to opioids⁷. Physicians may feel reluctant to prescribe opioids on a continued basis due to the increased number of deaths due to unintentional opioid overdose as well as out of fear of causing a patient to become addicted to the medication (termed “opiophobia” in the literature^{3,8,9}). Former or active drug use by patients and psychiatric co-morbidities further compound this complex topic.

At St. Vincent’s clinic, a student and nurse practitioner-run indigent primary care clinic in Galveston, Texas, practitioners have historically avoided prescribing opioids for pain management. It was at their request that a MPH student investigate the possible efficacy of a doctor-patient opioid contract in similar clinical settings and create a pain management protocol based on its effectiveness. Thus, this Capstone aims to 1) review the current literature on the effectiveness of opioid pain contracts in primary care clinics for patients on long-term opioid therapy for non-malignant chronic pain; 2) to review pain management guidelines at indigent clinics in the Houston-Galveston area, and 3) to create a pain management guideline for St. Vincent’s clinic. To do this, a PubMed search was conducted using terms related to opioid use in indigent primary care clinics. Studies that a) used an opioid contract as or in conjunction with an educational intervention for non-malignant chronic pain; b) that took place in primary care or pain management clinics in conjunction with primary care physicians; c) that analyzed characteristics of opioid contracts; and d) were commentaries and expert opinion on the use of pain contracts for non-malignant chronic pain for patients with and without a psychiatric history or a history of substance abuse were identified. Studies that did not use pain contracts and or discuss the use of opioid contracts for managing non-malignant chronic pain were excluded. Of the 103 papers screened, 13 were selected according to inclusion/exclusion criteria, including 8 observational studies using a doctor-patient opioid contract and 5 expert literature reviews from major peer-reviewed journals. Three of the 8 observational studies did not use an opioid contract for an intervention, but rather analyzed characteristics of the contracts.

Their recommendations were analyzed. Additionally, 30 indigent primary care clinics in the Houston-Galveston area were screened for their pain management practices. Seven informal interviews with the medical directors of these clinics were conducted (including one pain medicine specialist and one psychiatrist specialized in addiction medicine). Recommendations from both the literature review and interviews with practicing primary care practitioners were synthesized and a pain contract was created. The contract and recommendations were then presented to St. Vincent’s clinic directors for review and/or use.

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LIST OF COMMONLY USED ABBREVIATIONS

AAPM – American Association of Pain Medicine

APS – American Pain Society

CDC – Center for Disease Control

COT – Chronic opioid therapy

NMCP – Non-malignant chronic pain

RCT – Randomized controlled trial

SVC – St. Vincent's Clinic

UDS – Urine drug screen

UTHSC-SA – The University of Texas Health Science Center at San Antonio

UTMB – The University of Texas Medical Branch

VA – Veteran's Affairs

CHAPTER 1: BACKGROUND

An estimated 50 to 75 million Americans live with chronic pain and an estimated 25 million suffer from acute pain every year¹. Their pain is caused by disease, disorder, accident or surgery resulting in serious economic consequences due to lost wages, medical expenses, lost productivity, compensation payments and legal charges (estimated at \$70 billion per year)². Millions of Americans use opioid analgesics to control their pain, however, it is unclear if they are using the medications appropriately and if their pain is adequately controlled³. Many pain researchers theorize that uncontrolled pain may, in turn, lead to increased drug-seeking behavior^{3,4}. This type of behavior is considered aberrant and describes a patient who will go to any means to obtain an addictive drug, such as frequent phone calls to a doctor's office, demanding language and doctor 'shopping' until pain medications are prescribed.

A substantial increase in the prescribing of analgesics has occurred over the last three years⁴. The number of adults taking a narcotic analgesic remained fairly stable at 3.2% in 1988-1994 and 4.2% 1999-2002⁵. From 2002 to 2005, there were 190 million prescriptions for opioids in the United States, resulting in 9.4 billion doses⁶. Marijuana was displaced by opioids as the new illicit drug of choice in 2005⁶. Sales of hydrocodone increased by 244 % from 1997 to 2006, oxycodone increased to 732% and methadone usage increased 1,177%². Coupled with increased retail sales in therapeutic opioid usage, the type of opioid medication being prescribed has also changed². In 1997, the most commonly used opioid was codeine, followed by hydrocodone and oxycodone. However, in 2006, the most commonly used opioid was oxycodone, followed by hydrocodone and morphine². This data suggests an increase in the

potency of the opioids prescribed over the last ten years, possibly a consequence of increased pharmacy access to more potent opioids during this time frame. Another worrisome statistic is the rise in deaths associated with inadvertent narcotic or hallucinogenic drug overdoses in people aged 15-64; more than 10,800 (56 percent of all poisoning deaths) were recorded in 2005 by the CDC National Center for Health Statistics (NCHS), an 83% increase from 5,921 deaths (50 percent of all poisoning deaths) from the same cause in 1999⁷.

Despite the dramatic increase in opioid prescribing practices of doctors, many primary care doctors may feel uncomfortable prescribing drugs with such high abuse and addiction potential. This fear has been termed “opiophobia” in pain management literature³. There are also increased federal and state regulations for opioid prescribing which, in turn, may help to fuel clinicians’ fear of prescribing opioids^{8,9}. For example, a recent evaluation of three national policies on pain management by Gilson, et al, found an estimated 3.5-fold increase in the number of statutes, an estimated 4-fold increase in the number of regulations and an estimated 4-fold increase in the number of guidelines or policy statements pertaining to the control of opioid prescribing from 1995 to 2006⁸. These regulations, in certain cases, make it difficult for physicians to prescribe opioids due to increased governmental oversight, possibly impeding adequate availability and medical use of opioid pain medications⁹. This is where interventions, such as a doctor-patient pain contract and/or pre-screening of patients for abuse potential prior to prescribing opioids, may play a role; they may clarify a patient’s treatment plan and help physicians feel more comfortable in prescribing these addictive medications. Current pain management literature yields few original research articles on the use of these contracts and prescreening methods in the primary care/indigent population.

St. Vincent's Clinic (SVC) is situated in one of the poorest areas of Galveston with a patient population consisting of low-income, medically uninsured patients. Approximately 2000 patients, of whom about 40% currently abuse or have a history of substance abuse, are seen in the clinic every year. Clinicians at St. Vincent's have historically avoided prescribing opioids for pain management. The purpose of this project is to investigate the possibility of using opioids in the clinic in conjunction with a doctor-patient opioid contract.

CHAPTER 2: METHODS

2.1 Study Design

Information concerning opioid contracts came from 1) scientific studies with original data using such contracts, 2) expert commentary/literature reviews and position papers on the use of opioid contracts and, 3) interviews with medical practitioners experienced in dealing with indigent healthcare, pain management or addiction. A thorough PubMed and Medline literature search was completed using the search terms “opioid use”, “pain contract”, “non-malignant chronic pain”, “pain management”, “indigent” and “primary care”. 103 articles were screened for appropriateness. Studies meeting the following inclusion criteria were used: a) studies using an opioid contract as or in conjunction with an educational intervention for non-malignant chronic pain; b) studies that took place in primary care or pain management clinics in conjunction with primary care physicians; c) studies analyzing characteristics of opioid contracts; and d) commentaries and expert opinion on the use of pain contracts for NMCP for patients with and without a psychiatric history or a history of substance abuse. In addition, informal interviews with healthcare practitioners at local indigent clinics as well as a pain management physician and an addiction psychiatry specialist were conducted regarding their opinions on the use of opioid contracts. Clinicians were questioned on whether or not they prescribed opioids for non-malignant chronic pain (NMCP) in their clinic and if so, whether or not they used a pain contract with these patients (see Figure 1). Clinicians that used opioids for pain management for NMCP were asked for feedback on the effectiveness of these contracts. Clinicians who did not use opioids in their clinics were instead questioned as to how chronic

pain is managed among their patient population. Information from literature reviews, recent guidelines and personal interviews were synthesized to propose a policy on how such guidelines can be implemented at SVC.

2.2 Study selection

Articles were chosen based on the following inclusion criteria: a) studies using an opioid contract as or in conjunction with an educational intervention for non-malignant chronic pain; b) that took place in primary care or pain management clinics in conjunction with primary care physicians; c) studies analyzing characteristics of opioid contracts; and d) commentaries and expert opinion on the use of pain contracts for NMCP for patients with and without a psychiatric history or a history of substance abuse. Studies not directly relevant to pain contracts or not discussing the use of opioid contracts for managing NMCP were excluded. Twelve articles were identified and are displayed in Tables 1, 2 and 3 according to study type.

2.3 Main Outcome Measures

The primary outcome measure for interventional studies was the percentage of patients adhering to the terms of the opioid agreement they signed in the studies. Other important outcome measures included subject characteristics, intervention type, improvements in subjects' pain, pain-related disability and/or depression scores, number of patients weaned from chronic opioid therapy (COT) and the number of patients whose contracts were

terminated. Characteristics of opioid contracts themselves and opinions of clinicians on the use of the contracts for NMCP were assessed for the analyses in Tables 2 and 3, respectively.

CHAPTER 3: RESULTS

3.1 Literature Review

Of the 103 articles screened, 91 were excluded because they did not meet inclusion criteria. 74 of the 91 studies were not relevant to the topic and 17 did not discuss the use of opioid contracts for managing NMCP. Of the 13 articles remaining, 8 contained original data and 5 were commentaries and policy statements. Of the studies containing original data, three were prospective intervention trials, three were retrospective cohort studies and two were cross-sectional studies. No randomized controlled trials comparing opioid contracts to pain management without an opioid contract were found.

An evaluation of a program in which chronic pain patients (most of whom were considered 'high risk' for opioid dependence) were managed by their PCP and a nurse practitioner specially trained in pain management, found success in keeping patients on their pain contracts²⁵. Additionally, PCP's expressed high levels of satisfaction with the program and significant pharmacy savings were demonstrated²⁵. A five-year retrospective cohort study of opioid contract use in primary care clinics by Harihan, Lamb and Neuner¹⁰ found that over 60% of NMCP patients had no violations of their contracts (measured by random urine drug screens (UDS)) during the study period. Seventy percent of these study participants were in indigent care programs. Among study participants, younger, male patients with sickle cell anemia receiving combination opioid therapy were most frequently tested for illicit drug use by UDS. Only 38% of the drug screens were positive for illicit drugs. Among the patients whose contracts were canceled, 50% were terminated for positive UDS while 25% were canceled for prescription drug abuse. Twenty percent of patients discontinued opioid use voluntarily, indicating some

accountability of patients on opioid contracts for NMCP. Based on these findings, the authors concluded that “medication contract systems have great potential as a systems-based approach to management of pain in...academic primary care practices that serve diverse patient populations”.

Other studies into pain contracts for NMCP have yielded similar results. In 1995, Burchman and Pagel evaluated the efficacy of an opioid contract among 81 NMCP patients at an outpatient VA pain management clinic over one year¹⁶. Seventy-nine percent of the study participants reported improvements in chronic pain and pain-related disability as measured by validated self-report measures. Only 4% of study participants developed tolerance to opioids while 3% were found to have abused prescription medications during the study period. This last group of patients (those found to abuse prescribed medications) were admitted to inpatient rehab facilities for treatment.

In similar fashion, a 2005 pre-test/post-test study by Chelminski, et al²¹, found significant improvements in self-reported pain, depression and disability (secondary to pain) scales after a multidisciplinary pain management program, including a pain contract, was instituted ($p < 0.001$ for all three measures). These findings are important in that 44% of the study’s participants had a history of substance abuse and 51% carried a diagnosis of depression at some time in the past.

These findings were duplicated in a randomized cluster trial of 408 NMCP VA patients by Dobscha, Corsin & Perrin, et al¹⁸. The authors of this study found decreased self-reported pain intensity, pain-related disability and depression scores ($P = 0.01, 0.040, 0.003$, respectively) in a group of patients treated by general internists specially trained for pain management over 12

months. The internists and patients were blinded and randomized to a control group or an intervention group that consisted of physician attendance at two 90 minute clinician education sessions. These sessions provided training in chronic pain patient assessment and education, symptom monitoring and recommendations and facilitation of specialty care. Care managers worked alongside intervention doctors to create personalized pain management protocols for intervention patients. Patients in the control group (considered “treatment as usual”) had access to a pain management clinic, physical and occupational therapies and mental health services. No statistically significant improvements in self-reported pain intensity and pain-related disability were found among control patients.

A difficult aspect of using current versions of opioid contracts for management of NMCP lies in the language used and the great degree of variation among contracts. A cross-sectional analysis of opioid contracts from 39 large academic centers by Fishman, et al¹⁵, in 1999, found 125 unique statements grouped into 43 statement groups used by the collection of analyzed contracts. Each of the 39 contracts reviewed contained 22.5% (plus or minus 10.9%) of the entire list of statements and only 32.6% (plus or minus 11.2%) of the 43 statement categories. This analysis touches on the great variation that exists among opioid contracts. Additionally, a cross-sectional analysis of 162 opioid contracts used in clinical practice by randomly selected members of the American Pain Society (APS)¹⁹ revealed that a high level of literacy (mean literacy level was above the 14th grade reading level) is needed to understand the wording and vocabulary used in common pain contracts. This confounds matters even more as only an estimated 12% of Americans are considered to be proficiently health “literate”²⁰. This same executive summary performed by the National Center for Education Statistics reports that

lower average health literacy levels among those living under the poverty line in comparison to those living at or above the poverty line²⁰. In terms of use of opioid contracts, Touchet, Yates and Coon¹⁷ found that physicians-in-training (residents) use them more frequently than their faculty, theorizing that residents have less experience with the use of these potent medications. This same study found that 54% of physicians that routinely implement pain contracts with their patients stated that the contracts improve their sense of mastery and comfort with prescribing opioids for NMCP¹⁷.

3.2 Expert reviews and position statements

Of 5 non-data articles, 4 were expert reviews and one was a set of professional guidelines from the American Academy of Pain Medicine (AAPM) and American Pain Society (APS). The 4 expert reviews were written by pain management researchers. The recently published set of guidelines¹¹ outlined strategies for chronic opioid therapy for NMCP in the primary care setting after careful review of pain medicine literature by a panel of pain management experts and clinicians. This guideline shed light on the existing medical evidence on the use of pain contracts and thus became very important in writing this review. The four remaining articles, literature reviews based on expert opinion, provided further insight into the issues surrounding the use of opioids for chronic non-malignant pain.

One such literature review discussed the controversy associated with treating chronic pain in patients with a history of narcotic abuse. As mentioned in the background literature review, many clinicians shy away from treating pain in patients with histories of opioid abuse as they fear inducing a relapse in their patients' addiction. After reviewing pain management and

addiction literature, Weaver and Schnoll found that patients with a history of narcotic abuse can successfully have their pain treated with opioids¹². They recommend using a pain contract with these patients as well as frequent monitoring for signs of relapse with UDS, clinic visits and pill counts. In the event of relapse, patients should be referred for treatment. In addition, the authors recommend the encouragement of healthy behaviors among this patient population. Thorough repetitive investigations into the characteristics, location and quality of the patient's pain are also recommended to assess the need for opioid therapy^{4,11}.

A contradictory review by Arnold, Han & Seltzer argued that despite widespread acceptance of opioid contracts for patients on chronic opioids, little true objective evidence for their efficacy exists in current medical literature¹⁴. The authors stated that opioid contracts serve mainly as informed consent documents for legal risk minimization, suggesting that opioid contracts may foster under treatment of chronic pain, stigma for patients on the contracts and a paternalistic doctor-patient relationship.

Other methods of management of COT for NMCP were discussed in two articles^{4, 11}. One such technique involves screening patients for their likelihood to abuse or divert opioids prior to starting them on COT. Two validated pre-screening tools are the Screener and Opioid Assessment for Patients with Pain (SOAPP) survey^{4, 11} and the Opioid Risk Tool (ORT)⁴. Both are widely used self-report questionnaires thought to have moderate to high accuracy for the detection of abuse potential based on the person being screened^{4, 11}.

3.3 Survey of indigent primary care clinics in Houston-Galveston area

Of the 30 indigent primary care clinics surveyed by phone, email and in person, 12 responses were obtained. Seven of these clinics did not offer any form of pain management, preferring to refer their patients to a pain management specialist. Three of the clinics offered pain management but did not use opioid contracts. The remaining two clinics offered pain management and used opioid contracts for patients with NMCP on chronic opioids. The medical directors of these two clinics reported positive opinions of doctor-patient opioid contracts. They found them to be effective tools for establishing guidelines and boundaries for patients on chronic opioids. In addition, a University of Texas Medical Branch (UTMB) pain management specialist and a University of Texas Health Science Center at San Antonio (UTHSC-SA) psychiatrist specializing in addiction medicine were consulted on their opinions about the use of opioid contracts for patients on chronic opioids for NMCP. Both specialists encouraged the use of opioid contracts by clinicians for patients on chronic opioids. The pain management specialist provided a copy of the pain contract and a dismissal letter (to be used when a patient violates the contract and must be dismissed from the pain clinic) used in her office for review. Each patient seen by a pain management specialist is asked to sign a pain contract prior to starting treatment with opioids. After signing the contract, patients are expected to bring all medications in at each visit and are subjected to random urine drug screens and occasional pill counts.

Table 1 – Intervention studies using opioid contracts

Article/ Author(s)	Journal	Study type	N	Outcome Measures	Results	Limitations
<p>“Collaborative care for chronic pain in primary care”</p> <p>Dobscha, Corsin, Perrin et al.¹⁸</p>	JAMA, 2009	Randomized cluster trial	<ul style="list-style-type: none"> - Clustered & randomized by PCP at a VA medical center - 214 subjects in treatment as usual group, 187 subjects in intervention group 	<ul style="list-style-type: none"> - Self-reported pain intensity, disability, depression scales, all over 1 yr 	<ul style="list-style-type: none"> - Dec pain intensity, pain-related disability and depression scores. (P= 0.01, 0.040, 0.003, respectively) in intervention group 	<ul style="list-style-type: none"> - Not easily Generalized due to Large number of VA patients - Modest results when compared to other studies (thought to be due to older, less motivated Ss)
<p>“The Opioid Renewal Clinic: a primary care managed approach to opioid treatment in chronic pain patients at risk for substance abuse”</p> <p>Weidemar, Harden, Arndt, Gallagher et al.²⁵</p>	Pain Medicine, 2007	<p>Naturalistic prospective outcome study (2 yr prgm evaltn)</p> <ul style="list-style-type: none"> - Intervention: Regular assessments & monitoring of pain pts by PCP & specially trained nurse practitioner 	<ul style="list-style-type: none"> - 335 pain contract patients w/ NMCP at large urban VA clinic - Considered “at-risk” – 49% w/ history of substance abuse, 51% w/ current misuse 	<ul style="list-style-type: none"> - Providers’ use of contracts - Patient adherence to contracts - Provider satisfaction - Pharmacy costs 	<ul style="list-style-type: none"> - 100% pt’s w/ h/o sub abuse but no current misuse were adherent. - In those w/ documented aberrant behaviors, 38% self-discharged from program, 13% referred for addiction treatment, 4% weaned off for consistently negative urine for opioids 	<p>Results, cont:</p> <ul style="list-style-type: none"> - PCP’s use of opioid contracts & random UDS increased by four-fold. - PCPs expressed high levels of satisfaction w/ program, significant pharmacy savings were shown <p>Limitations: No control</p>
<p>“Long term opioid contract use for chronic pain management in primary care practice”</p> <p>Hariharan, Lamb & Neuner¹⁰</p>	Journal of General Internal Medicine, 2007	5 year retrospective cohort study at large academic general internal medicine	<ul style="list-style-type: none"> - 330 NMCP patients on pain contracts in large practice - 70% unfunded 	<ul style="list-style-type: none"> - # of subjects violating or cancelling pain contract 	<ul style="list-style-type: none"> - 60% of subjects stayed on pain contracts without violations - UDS obtained on 42%, 38% were positive 	<ul style="list-style-type: none"> - Small sample - Lack of systematic drug testing - Multiple medical co-morbidities

Table 1 continued

<p>Implementation of a formal treatment agreement for outpatient management of CNMP w/ opioids”</p> <p>Burchman & Pagel¹⁶</p>	<p>Journal of Pain & Symptom Management, 1995</p>	<p>Retro-spective Chart review</p>	<ul style="list-style-type: none"> - 81 Ss over 3 yrs - VA patients w/ NMCP - Failed conventional treatment 	<ul style="list-style-type: none"> - Improved pain/pain-related disability scores - Tolerance to opioids - Prescription misuse 	<ul style="list-style-type: none"> - 79% had favorable outcome (decreased pain/pain-related disability) - 4% developed tolerance to opioid - 3% abused opioids 	<ul style="list-style-type: none"> - All VA pt’s - No control
<p>“Trilateral Opioid Contract: Bridging the pain clinic & the PCP through the opioid contract”</p> <p>Fishman, Mahajan, Jung & Wilsey¹³</p>	<p>Journal of Pain & Symptom Management, 2002</p>	<p>Retro-spective chart review</p>	<ul style="list-style-type: none"> - 81 NMCP pt’s - 45 (50%) on trilateral pain contracts 	<ul style="list-style-type: none"> - # of subjects and physicians agreeing to sign and abide by pain contract between PCP, pt & pain management specialist - History of opioid abuse, history of substance abuse, Ψ DO, sex, medical co-morbidities 	<ul style="list-style-type: none"> - 69% of Ss signed contract. Of those, 72% were signed by PCP - Of the 50 patients w/ a completed contract, none encountered difficulty in obtaining opioids from their PCP upon transfer of care - Only significant difference between Subjects who refused to sign the contract and those who did not - inc incidence of h/o Ψ illness in the former group (75%) versus 38% in latter group 	<p>Results, cont:</p> <ul style="list-style-type: none"> - This group found to have 2x increased risk of contract non-compliance <p>Limits:</p> <ul style="list-style-type: none"> - No control - Small sample size - Some difficulty w/ establishing trilateral care - 35% of contracts were not returned

Table 2 – Studies analyzing opioid contracts

<p>“The opioid contract in management of chronic pain”</p> <p>Fishman, Bandman, Edwards & Borsook¹⁵</p>	<p>Journal of Pain & Symptom Management 2002</p>	<p>Cross sectional analysis of opioid contracts</p>	<p>- 39 opioid contracts analyzed</p>	<p>- # of similar statements among contracts</p> <p>- Length of contracts</p>	<p>- 125 unique statements, 43 statement groups</p> <p>- Of the 39 contracts reviewed, each contained approx 22.5% +/- 10.9% of the entire list of 125 statements and 32.6% +/- 11.2% of the 43 statement categories</p>	<p>Results cont:</p> <p>- Average length of contracts - less than 3 pages (range: 1 to 10, mean 2.2)</p> <p>Core themes – a) description of treatment parameters & established procedures should problems arise, b) bilateral agreement, c) informed consent</p>
<p>“Literacy demands and formatting characteristics of opioid contracts in chronic nonmalignant pain management”</p> <p>Roskos, Keenum, Newman & Wallace¹⁹</p>	<p>Journal of Pain, 2007</p>	<p>Cross-sectional analysis of opioid contracts</p>	<p>- 162 opioid contracts used by randomly selected members of American Pain Society (APS)</p>	<p>- Readability – assessed w/ SMOG (Simple Measure of Goobledygook formula)</p> <p>- Formatting – assessed w/ Suitability of Materials Assessment & User-Friendliness Tool</p>	<p>- 61.7% of opioid contracts were written at or above the 14th grade reading level</p> <p>- 0% were written at or below recommended reading level of 6th grade</p> <p>- very few contracts scored in superior range on any typographical/layout feature</p>	<p>- Possibility of selection bias (only 40% response rate)</p> <p>- Subjectivity of formatting features according to rater may have caused inter-rater variability</p> <p>- Verbal explanations of contracts not evaluated</p>

Table 2 continued

<p>“Opioid contract use is associated with physician training level and practice specialty”</p> <p>Touchet, Yates & Coon¹⁷</p>	<p>Journal of Opioid Management 2005</p>	<p>Cross-sectional web survey</p>	<ul style="list-style-type: none"> - 196 web surveys completed - 52.6% by faculty, 21.4% by residents; 26% by med students - more than 50% of Subjects were primary care physicians 	<ul style="list-style-type: none"> - # of subjects prescribing opiates - # subjects using contracts - Level of training - Comfort w/ prescribing opiates - Sense of mastery/satisfaction w/ contract 	<ul style="list-style-type: none"> - 54% of contract users stated that contracts improved their sense of mastery & comfort w/ prescribing opioids - Resident status a/w contract use, probably secondary to feeling less competent and having more responsibility 	<ul style="list-style-type: none"> - Low resident survey completion - Self reported surveys
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Table 3 – Expert commentaries/literature reviews on using opioid contracts for management of NMCP

Author(s)	Journal	Study type	N	Outcome Measures	Main Points	Main points, cont.
<p>“Opioid contracts in CNMP: objectives and uncertainties”</p> <p>Arnold, Han & Seltzer¹⁴</p>	American Journal of Medicine, 2006	Literature review	24	N/A	<ul style="list-style-type: none"> - Despite widespread acceptance of contracts, no systematic guidelines for developing or using contracts exist - Used as informed consent & for legal risk minimization 	<ul style="list-style-type: none"> - Contracts may foster under-treatment of pain, stigma and paternalistic doctor-patient relationship
<p>“Abuse liability in opioid treatment for pain treatment in patients w/ an addiction history”</p> <p>Weaver & Schnoll¹⁴</p>	Clinical Journal of Pain, 2002	Literature review	N/A	N/A	<ul style="list-style-type: none"> - Few original articles on abuse liability for pt’s w/ addiction history - Those w/ addiction history can be treated successfully w/ opioids 	<ul style="list-style-type: none"> - Rates of addiction of people w/ addiction histories found to be similar to rates of addiction in general population

<p>“Interface between pain and drug abuse and the evolution of strategies to optimize pain management while minimizing drug abuse“</p> <p>Passik and Kirsch⁴</p>	<p>Experimental & Clinical Psychopharmacology, 2008</p>	<p>Literature review</p>	<p>N/A</p>	<p>N/A</p>	<ul style="list-style-type: none"> - Discussed prescreening patients w/ Screener and Opioid Assessment for Patients with Pain (SOAPP) & The Opioid Risk Tool (ORT) - Both excellent predictors of med abuse/addiction behaviors 	<p>- Concept of "in and out of the box" prescribing - focuses on 5 areas of concern for judging whether prescribing patterns match peer prescribing patterns</p>
<p>“The opioid contract”</p> <p>Fishman & Kreis²⁴</p>	<p>Clinical Journal of Pain, 2002</p>	<p>Literature review</p>	<p>Based on cross-sectional review of 39 opioid contracts (Fishman, Bandman, Edwards, et al)</p>	<p>N/A</p>	<ul style="list-style-type: none"> - Great variability among contracts’ content and usage - Potential complications w/ contracts include stigma, assumption of compliance, "binding" nature of contract-court 	<p>N/A</p>

<p>APS/AAPM guidelines</p> <p>Chou, Fanciullo, Fine et al.¹¹</p>	<p>Journal of Pain 2009</p>	<p>Meta-analysis of current pain medicine literature concerning the use of prescription opioids in the U.S.</p>		<p>N/A</p>	<p>25 Recommendations made including:</p> <ul style="list-style-type: none"> - Full physical exam, history (including history of substance abuse), diagnostics & trial of non-opioid pain relief prior to starting chronic opioid therapy (COT) - Informed consent prior to starting COT - Frequent monitoring of patients on COT w/ random UDS - Consider using a written COT management plan to document patient and clinician responsibilities and expectations, also to assist in patient education 	<ul style="list-style-type: none"> - Insufficient evidence from one small retrospective study (Fishman, Bandman, Edwards, et al, results above) to evaluate effects of opioid contracts on clinical outcomes
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Figure 1

Questions asked assessing clinician use of and opinions on opioid contracts for patients on chronic opioids for non-malignant chronic pain

After explaining the purpose of my questionnaire to willing clinicians, they were asked the following questions:

- 1) Do you find the use of opioid contracts effective in helping to manage your patients on chronic opioids?
- 2) Do you find that opioid contracts better establish guidelines and boundaries for patients on chronic opioids for CNMP than not being on a contract?
- 3) Would you recommend the use of opioid contracts to other healthcare professionals for patients on chronic opioids for CNMP?

CHAPTER 4: DISCUSSION

Five out of 8 (62.5%) of the interventional articles^{10, 13, 16, 18, 25} (see Table 1) and 2 out of 5 (40%) expert reviews^{4, 12} (see Table 3) analyzed for this review were in favor of using an opioid contract as part of a pain management policy for NMCP. Only 2 of the 5 expert review articles discussed possible negative effects of using an opioid contract^{14, 24} for patients with NMCP on COT. These include patient stigmatization, possible under-treatment of pain and possibly the development of a paternalistic doctor-patient relationship. Three of the analyzed studies were cross-sectional analyses of the characteristics of commonly used opioid contracts^{15, 17, 19} and their users. These analyses illustrated great variation among the contracts as well as among the users of the contracts. One of these studies¹⁹ found very complex, difficult language (above a grade 14 reading level) used in the majority of opioid contracts analyzed.

The set of professional guidelines from the AAPM & APS¹¹ concluded that there was insufficient evidence to evaluate effects of opioid contracts on clinical outcomes. However, the guidelines recommend consideration of “a written COT management plan to document patient and clinician responsibilities and expectations and assist in patient education”. They also recommend completing a full physical exam and history (including substance abuse history), appropriate diagnostics, a trial of non-opioid pain relief and informed consent prior to starting COT. In addition, they recommend frequent monitoring of patients on COT with random UDS. Overall, there were no randomized controlled trials found for review.

The use of the opioid contract as part of a comprehensive pain management policy

appears to be a feasible conclusion from this review. However, the lack of randomized controlled trials (RCTs) in the literature creates some discussion as to whether or not there is sufficient evidence from which recommendations about opioid contracts can be made. Retrospective chart reviews^{10, 13, 16} and prospective intervention studies^{18, 25} are credible forms of evidence, however, they do not achieve the ideals of a RCT. Because the intervention studies included in this review were small, non-randomized studies that did not include control groups, the evidence is limited. It is important to note that effective medical management of chronic pain is considered an art based on experience with the medications and their dosing. It is under this presumption that expert opinion stands as valid evidence in regards to the effectiveness of opioid contracts for CNMP. That being said, making concrete recommendations without the foundation of RCTs remains difficult.

Another topic of discussion that must be addressed is whether or not the opioid contracts themselves contribute to improved clinical outcomes (as seen in the interventional studies – Table 1). Opioid contracts are generally considered one small piece of a comprehensive pain management program. It is therefore very difficult to evaluate the success of opioid contracts on directly decreasing a patient's pain level. Some evidence to their single-handed success was illustrated by Burchman and Pagel¹⁶ in the form of decreased pain intensity and pain-related disability scores after introduction of a formal treatment contract. Other studies used physician training and/or collaboration with specially trained nurse educators along with opioid contracts as their interventions. This makes it more difficult to delineate the success of the opioid contract alone.

Along similar lines, distinction between improving patient outcomes (as measured by self-reported pain intensity, pain-related disability and/or depression scores) as opposed to physician comfort with prescribing opioids must be made. In their cross-sectional study of opioid contracts, Touchet, Yates and Coon, et al¹⁷, found that using pain contracts improved physicians' sense of mastery and comfort with prescribing opioids. Many pain specialists may agree with this finding, however, this conclusion does not necessarily translate to improved patient outcomes and must be considered prior to starting a patient on a pain contract.

One limitation of the studies used in this review comes from the use of veterans as subjects in 2 out of the 5 interventional studies^{16, 18}. This limits the generalizability of the studies to the general population. Subjects of other studies reviewed were also categorized into subpopulations of the general population: 1) those suffering from multiple chronic medical conditions¹⁰, 2) those considered high risk for substance abuse²⁵ and 3) those with psychiatric co-morbidities¹³. The use of these types of study patients may actually improve the generalizability of these three studies in this case, as many of the patients seen at St. Vincent's Clinic also suffer from the aforementioned conditions.

CHAPTER 5: IMPLICATIONS AND CONCLUSIONS

Pain management in the primary care setting is complex. It is most effectively handled with a collaborative approach. Opioid contracts can serve as an inexpensive and relatively easy adjunct to a comprehensive pain management protocol. However, sufficient evidence of their efficacy has not been demonstrated. More research into the effectiveness of these contracts in the form of randomized controlled trials is needed. In lieu of needing further research, I recommend the following pain management policy for St. Vincent's Clinic: 1) every patient being assessed for COT for NMCP should receive a thorough history and physical exam, including a substance use and psychiatric history and appropriate diagnostics for assessment of their chronic pain; 2) Opioid contracts are recommended for every patient on COT in conjunction with a pre-screening tool (SOAPP, ORT or subjective assessment). Caution should be taken with patients considered at high risk of abusing opioids on the screening assessment; 3) Clinicians should thoroughly explain the terms of the agreement prior to obtaining patients' signatures (informed consent); 4) Clinicians should use a low-literacy opioid contract when the patient's literacy level is less than the 14th grade level; 5) Clinicians should do their best to encourage healthy behaviors to patients on COT in order to create a collaborative relationship with patients; 6) Extra precautions should be taken with patients on COT with a history of substance abuse and/or psychiatric disorder; 7) Monthly visits and urine toxicology screens should be used to monitor patients for opioid misuse or diversion. A modified version of the AAPM's Long-term Controlled Substances Therapy for Chronic Pain (see Figure 2) and a copy of the Low-Literacy Pain Medicine Contract (see Figure 3) was provided to St. Vincent's Clinic

directors for review and/or use.

Figure 2: Sample Pain Contract from AAPM (permission granted for publishing on 6/8/09)²

Long-term Controlled Substances Therapy for Chronic Pain SAMPLE AGREEMENT

SAMPLE FOR ADAPTATION AND REPRODUCTION ON PHYSICIAN LETTERHEAD PLEASE CONSULT WITH YOUR ATTORNEY

A consent form from the American Academy of Pain Medicine

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers, and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is pro-longed. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from the physician whose signature appears below or, during his or her absence, by the covering physician, unless specific authorization is obtained for an exception. (Multiple sources can lead to untoward drug interactions or poor coordination of treatment.)
2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:
_____ phone: _____.
3. You are expected to inform our office of any new medications or medical conditions, and of any adverse effects you experience from any of the medications that you take.
4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability.
5. You may not share, sell, or otherwise permit others to have access to these medications.
6. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.
7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required.
Presence of unauthorized substances may prompt referral for assessment for addictive disorder.

© 2001 American Academy of Pain Medicine Reviewed July 2004.

Figure 2, continued

8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medication and prescription. They should not be left where others might see or otherwise have access to them.
9. Original containers of medications should be brought in to each office visit.
10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.
11. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.
12. Early refills will generally not be given.
13. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.
14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.
15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.
16. Renewals are contingent on keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.
17. It should be understood that any medical treatment is initially a trial, and that continued prescription is contingent on evidence of benefit.
18. The risks and potential benefits of these therapies are explained elsewhere [and you acknowledge that you have received such explanation].
19. You affirm that you have full right and power to sign and be bound by this agreement, and that you have read, understand, and accept all of its terms.

Physician Signature

Patient Signature

Date

Patient Name (Printed)

Approved by the AAPM Executive Committee on April 2, 2001.

AAPM
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Glenview, IL 60025-1485
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E-mail aapm@amctec.com
Web site <http://www.painmed.org>

Figure 3: Low-literacy Pain Medicine Contract

Pain Medicine Contract

This contract has 4 parts.

Part 1 Tells you how and when to take your pain medicine.

Part 2 Lists things you agree to do.

Part 3 Lists things that could happen if you do NOT do the things listed in Part 2.

Part 4 Sign the form.
You and Dr. _____ must sign the form.

PART 1 **MY PAIN MEDICINE**



Medicine	Breakfast	Lunch	Dinner	Bedtime

Go to the next page



Figure 3, continued

I will

- tell Dr. _____ if I get pain medicine from another doctor or emergency room.



- call Dr. _____'s office at least 24 hours in advance if I need to cancel my appointment.

- keep my pain medicine in a safe place AND away from children.



- get my pain medicine from only _____.

Address:

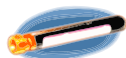
Phone Number:



Pharmacy

- bring all of my unused pain medicine in their pharmacy bottles the next time I come to see Dr. _____. He/she may count the number of pills in my bottle(s).

- allow Dr. _____ to check my urine (pee) or blood to see what drugs I am taking.



Go to the next page



PART 2 THINGS I AGREE TO DO

I will

- only get my pain medicine from Dr. _____'s office.
- take my pain medicine as listed in Part 1.
- tell my other doctor(s) that I am taking pain medicine.
- tell Dr. _____ about ALL of the medicines (over-the-counter, herbs, vitamins, those ordered by other doctors) I am taking.
- tell Dr. _____ about all of my health problems.
- allow Dr. _____ to talk with other doctors about my health problems.
- only ask for refills during an office visit (Monday to Friday from 8:00 am to 5:00 pm).

Figure 3, continued

I will NOT

▪ share, sell or trade my pain medicine with anyone.

▪ use someone else's medicine(s).

▪ use illegal drugs (crystal meth, marijuana, cocaine).



▪ change how I take my medicine(s) without asking Dr. _____.

▪ ask Dr. _____ for extra refills if I use up my supply before my next appointment.

▪ ask Dr. _____ for extra refills if I lose or misplace mine.

Go to the next page

PART 3 I UNDERSTAND

If I do not do all of the things listed in Part 2, Dr. _____:

- will no longer order pain medicine for me.

- may stop giving me medical care.

- may send me to drug abuse treatment.

I know

Dr. _____ and my pharmacy may work with the police to look at any misuse or sale of my pain medicine.



I know if I drive while taking pain medicine, I can be charged with driving under the influence (DUI). If I am charged with DUI while taking pain medicine, Dr. _____ is not to blame.



Go to the next page 

Figure 3, continued

PART 4 **SIGN THE FORM**



Sign your name and write the date.

Sign your name

Date

Print your first name

Print your last name

Street

City

State

Zip Code

Doctor Name

Doctor Signature

Date

Created by:
Lorraine S. Wallace, Ph.D.©

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VITA

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