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Implementation of a Pain Medicine Contract Protocol:

An Evidence Based Clinical Practice Change Project

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Abstract

Drug misuse with controlled substances is on the rise. To be proactive in prevention, practitioners need to access pertinent drug information, educate their patients, and establish contracts with patients to outline their responsibilities. The purpose of this evidence-based practice (EBP) pilot project was to develop and implement a pain medicine protocol that included a contract that met health literacy recommendations. The Model for Diffusion of Innovations Theory (Rogers, 1995) guided the project. A review of the literature revealed a need for the development of a practitioner protocol that would (1) explore patients’ use of controlled substances, (2) educate patients about the risks and benefits of controlled substances, and (3) establish pain medicine contracts with patients before controlled substances are prescribed to treat non-malignant pain. The author developed and implemented a pain medicine contract protocol at an outpatient neurology clinic in an academic health center. Written surveys were used to identify practitioners’ current practices when prescribing controlled substances, practitioner responses to the implementation of the protocol, and patient responses to the implementation of the contract. Responses of the practitioners who completed the pre-implementation survey indicated they incorporated several components of the protocol but also indicated that they did not use a drug reporting system or establish a contract with patients. Patients indicated that the protocol was helpful and that the contract was easy to read and understand. Following implementation of the protocol, eight healthcare members registered to use the Ohio Automated Rx Reporting System (OARRS). Recommendations based on this study include the use of a protocol that establishes a method to explore the documented use of controlled substances and establishes of a contract when a controlled substance is prescribed.
The Pain Medicine Contract Protocol is suitable for use in a neurology outpatient clinic to assure the highest level of evidence-based care.

Key Words - Non-malignant pain, contract, evidence-based practice
Introduction

Misuse of controlled substances is on the rise across the nation. Incontrovertible evidence supports the fact that an epidemic of prescription drug misuse exists and remains a problematic public health issue (Chapman et al., 2010; Trescot et al., 2008). In response, it is essential that healthcare practitioners be proactive in the prevention of this problem. It is the right of every patient to receive evidence-based care and to maintain the potential to reduce or minimize the risk for misuse of controlled substances.

An extensive review of the research literature revealed that prevention of the misuse of controlled substances needs to incorporate several steps to be effective. First, practitioners need to determine whether patients have been prescribed controlled substances from other practitioners before they prescribe controlled substances to treat non-malignant pain (Trescot et al., 2008). Second, it is essential that practitioners provide patients with education to enable them to understand the drug risks and benefits of controlled substances (Trescot et al., 2008). In addition, contracts need to be established that provide patients with clear descriptions of patients’ responsibilities related to the use of the controlled substance (Roskos et al., 2007; Safeer & Keenan, 2005; Trescot et al., 2008; Wallace et al., 2007). In its simplest terms, a contract is defined as a mutual agreement that outlines or defines the responsibilities of one or both parties (Oxford English Dictionary, 2003). A comprehensive protocol that incorporates these essential elements does not currently exist, yet one is needed to guide practitioners in best practices for prescribing pain medicine for the treatment of non-malignant pain. In response to this deficit, the author developed a protocol that incorporated all of the essential steps in the process of prescribing controlled substances for the treatment of non-malignant pain in order to provide increased quality of care.
**Purpose**

The purpose of this evidence-based practice (EBP) project was to conduct a small test of change (Levin et al., 2010) of an evidence-based comprehensive pain medicine contract protocol. The following question guided this project: Compared to usual method of implementing a controlled substance (narcotic) contract, does the implementation of a comprehensive pain medicine contract protocol (1) increase the usage of the Ohio Automated Rx Reporting System (OARRS), (2) increase documentation of patient education, and (3) increase usage of contracts by practitioners who prescribe controlled substances to treat non-malignant pain in an outpatient neurology clinic? Conducting this small test of change provided evaluation data upon which to base recommendations for further implementation.

**Theoretical Framework**

The theoretical model selected to guide this project was Rogers’ Diffusion of Innovations Theory (Rogers, 1995). This model was selected since it best outlined the process that was needed for the implementation of an innovation within a social system. This framework outlined the steps needed to change clinical practice in a group or in a large organization. For the purpose of this project, the innovation was a pain medicine contract protocol, and the members of the social system were the physicians, nurses, and patients. One aspect of Levin et al.’s (2010) Evidence-Based Practice Improvement model guided the implementation and confirmation phases of the project. That aspect was a ‘small test of change’.

Rogers’ Diffusion of Innovations Theory consists of five stages: knowledge, persuasion, decision, implementation, and confirmation (Rogers, 1995). The knowledge stage for the implementation of a pain medicine contract protocol includes relevant evidence about the health
care intervention. Knowledge was obtained from an extensive literature search focusing on contracts and health literacy principles as well as discussions with expert practitioners in the management of pain. Information about state legislation governing drug monitoring systems across the nation was obtained from the Ohio Board of Pharmacy. The persuasion stage includes a critical review of the characteristics of the innovation, organization, environment, individual influences, and decisions about whether to adopt the innovation. Academic detailing and educational outreach was a strategy used in the persuasion stage. This strategy included meeting with practitioners in practice settings to provide information designed to increase awareness of the potential benefits of a pain medicine contract protocol. This stage provided opportunities to share information with practitioners about drug misuse statistics, health literacy, and the state’s drug monitoring program.

In the decision stage, a decision is made to either adopt the innovation or not to adopt the innovation. The decision about whether to adopt or reject the innovation was largely the responsibility of the stakeholders who found the protocol beneficial in clinical practice. Considerations that were assessed during the decision-making process included the level of research evidence and health care resources, the culture of the organization and target population, preferences of patients, circumstances in various clinical settings, and clinical expertise from the stakeholders and team members.

The implementation stage outlines the strategic activities that are used to facilitate the integration of the protocol into clinical practice. This stage occurred when the innovation was adopted into clinical practice. The confirmation stage creates an iterative loop that leads back to the knowledge stage and includes evaluation activities to support either adoption or rejection of the innovation and new information for implementation (Dobbins, Ciliska, & DiCenso, 2002;
This confirmation stage represents the final stage in evaluating whether the implementation of the innovation into practice was successful. The implementation and confirmation stages were complemented by the concept of the “small test of change” proposed in the Evidence-Based Practice Improvement Model (Levin et al., 2010). This model promotes the initial testing of a practice innovation through a “small test of change” prior to implementation throughout a larger unit or organization. The small test of change provides an opportunity to make revisions in the initial testing of an innovation to enhance future implementation.

**Literature Synthesis**

An extensive search of the literature was conducted to acquire research and non-research articles that were published between 1990 and 2010. The search of the literature was conducted using the following search terms: *narcotic agreement, medicine contract, patient-physician contracts, opioid contract, drug contract*, and *health literacy*. The databases search included CINAHL, Medline, Cochrane, PubMed, and National Clearinghouse Guidelines. The articles retrieved from the initial searches were reviewed for relevancy and whether they met the inclusion criteria—e.g., the articles were required to include adult samples and focus on outpatient-based clinical settings. The search provided articles that included clinical practice guidelines, systematic reviews, non-experimental research, and expert opinions. These articles were critically appraised for quality and then further rated for level of evidence according to the Johns Hopkins Nursing Evidence-Based Practice Evidence rating scale (Newhouse et al., 2007).

The John Hopkins Nursing Evidence-Based Practice Evidence rating scale incorporates a quality (flaws) rating of the research method (low through high). The quality rating of “high” reflects the use of rigorous research approaches with reliable and valid measures. A good quality rating indicates that there are relatively defined methods as compared with those articles that are
of low quality that have major flaws. The rating of quality can also be used to evaluate the quality of expert reviews based on level of creditability.

The John Hopkins Nursing Evidence-Based Practice Evidence rating scale incorporates an evaluation of evidence (I through V) based on the type of research design employed. The level of evidence rating defines “level I” articles as those that use an experimental design/randomized controlled trial (RCT) or meta-analysis. “Level II” articles include quasi-experimental studies, and “level III” articles include non-experimental studies, qualitative studies, or meta-synthesis. Opinions of nationally recognized experts based on research evidence or expert consensus panels (systematic review, clinical practice guideline) are rated as level IV. Level V includes articles that feature the opinions of individual experts based on non-research evidence (case studies, literature reviews, quality improvement and financial data, clinical expertise, or personal experience).

The articles used for this project included a wide range of designs. The quality of evidence rating of all articles used for this project was “high.” The level of evidence of the articles used for this project included levels I, III, IV, and V.

One clinical practice guideline relevant to this project provided practitioners with direction when prescribing controlled substances to treat non-malignant pain (Trescot et al., 2008). The guideline was developed by the American Society of Interventional Pain Physicians for the purposes of (1) providing guidance for practitioners who prescribe opioids, (2) improving treatment outcomes, and (3) reducing prescription drug abuse among patients. This guideline reflects primarily level IV evidence and consists of several components, including opioid use in chronic pain, pharmacological considerations, terminology of abuse and addiction, clinical effectiveness, adherence monitoring, principles of opioid use, documentation, and medical
records. Two specific components of this guideline relevant to this project include “Controlling Diversion and Abuse” and “Informed Consent and Controlled Substance Agreement.” Both of these components are addressed in the relevant section of the literature review. Even though this guideline is comprehensive in content, it fails to incorporate a concise protocol to guide practitioners when establishing a contract.

The “Controlling Diversion and Abuse” section of the previously mentioned guideline provides evidence for the need to “explore” the use of controlled substances prescribed to patients through prescription drug monitoring programs (PDMP). Drug diversion and misuse of controlled substances in our nation is a widespread problem today and has created a need for the PDMP. The worldwide use of the Internet has amplified the rates of drug misuse, resulting in closer monitoring by the U.S. Drug Enforcement Agency (DEA) and other agencies to prevent controlled substance diversion (Trescot et al., 2008). Prescription drug monitoring programs were created to help physicians monitor Schedule II substances as early as the mid-1900s (Trescot et al., 2008). Today, these drug monitoring programs are available, in the majority of states, to help practitioners monitor all controlled substances prescribed to patients. The protocol was implemented in Ohio which is one of the states with a statewide drug monitoring program. The program does exist in the state of the testing of the protocol.

Patient education is vital to effective use of controlled substances, and practitioners should educate their patients about the risks and benefits of controlled substances (as well as drug dependence and tolerance) in order to prevent drug diversion and identify drug misuse (Trescot et al., 2008). Documentation of the education is essential. The essential elements of “education” can be incorporated by establishing a contract with attention to addressing health literacy issues. The following section reviews the literature related to these concepts.
The “Informed Consent and Controlled Substance Agreement” component of the guideline stresses the need to incorporate the use of a contract to improve treatment outcomes and prevent drug misuse among patients prescribed opioid pain medications. The idea of a protocol contract for use with patients who experience chronic non-malignant pain dates back to 1994 (Kirkpatrick et al., 1998). Contracts have been used in behavioral therapy and to support decisions about treatment appropriateness (Bosch-Capblanch et al., 2009). Several trials demonstrated a positive effect (level I) when forming contracts in certain situations when combined with other interventions. Yet, these trials demonstrated that forming contracts may be ineffective or even harmful in other situations (Bosch-Capblanch et al., 2009). Future research on the development of more consistent and effective use of contracts as well as larger high-quality trials have been recommended (Bosch-Capblanch et al., 2009; Chapman et al., 2010).

“Health literacy” has been defined as the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions (Institute of Medicine, 2003). Research has suggested that patients with limited health literacy skills and chronic illnesses possess greater knowledge deficits concerning illness management than those with higher health literacy skills (Institute of Medicine, 2003). In addition, patients are able to develop a clearer understanding of medical information when practitioners speak slowly to them, when simple words are used in place of medical jargon, and when a restricted amount of information is presented (Institute of Medicine, 2003; Safeer & Keenan, 2005).

The concept of health literacy supports the need for the patient to be able to read and understand a contract. Contracts used in clinical practices across the United States have exceeded the recommended sixth-grade reading level and contained sophisticated medical language;
multisyllable, nonmedical terms; and vocabulary not used in typical everyday conversation. These contracts have required patients to possess proficient health literacy skills (Roskos et al., 2007; Safeer & Keenan, 2005; Wallace et al., 2007), that is often an unrealistic expectation among some populations. All patients should have a clear understanding of their responsibilities when they sign a contract to maintain a trusting relationship with their practitioner and to adhere to instructions for using the controlled substance (Hayes, 2000; Institute of Medicine, 2003; Roskos et al., 2007; Safeer & Keenan, 2005; Trescot et al., 2008).

In light of current knowledge about practitioner-patient communication, practitioners developing pain medicine contracts (particularly involving opioids) need to be cognizant of their patients’ actual health literacy skills. This awareness is vital since most adults are able to read proficiently at an eighth grade level, and 20 percent of the population is able to read at or below a fifth-grade level (Roskos et al., 2007; Safeer & Keenan, 2005; Wallace et al., 2007).

Wallace et al. (2007) developed a low literacy opioid pain medicine contract (OPC) that met the guidelines for health literacy. This OPC was tested, evaluated, found reliable, and validated based on the evidence. The criteria used to develop and validate the OPC included content identification, attention to low literacy guidelines, and evaluation based on a Suitability Assessment of Materials (SAM) model. The contract was written at the seventh grade reading grade level as determined by the Flesch Reading Ease (FRE) scale. The six page contract is composed of four parts: Part 1: directions about how and when to take the prescribed pain medicine; Part 2: a set of procedures that patients agree to follow related to their prescribed pain medicine; Part 3: a list of consequences for not abiding by the terms of the contract; Part 4: signatures of all parties included in the terms of the contract. Eighteen patients participated in a pilot study to test the contract. The contract was determined to be comprehensive, valid,
readable, formatted to low literacy guidelines, and suitable for use in clinical practice. The contract provides clear and easily accessible information to help patients fully understand their responsibilities to the practitioner.

The review of the literature revealed knowledge deficits and research gaps related to pain medicine contract protocols. Although the need for practitioners to participate in prescription drug monitoring programs is evident, the actual number of those who have decided to participate or use this program is not known. If not used, the first step toward prevention of the misuse of prescribed medication for non-malignant pain is not being met.

Two clear types of deficits within the literature knowledge base were found to be relevant to contracts and to this pilot project. The first deficit is a knowledge deficit and becomes apparent when there is a mismatch between the language used to construct a pain medicine contract and the actual health literacy skills of adult patients who enter into these contracts. Practitioners intentionally or unintentionally may deny patients the care they deserve when language used to construct pain medicine contracts is difficult to understand, inaccessible, or confusing (Institute of Medicine, 2003; Safeer & Keenan, 2005; Trescot et al., 2008). Practitioners should be especially sensitive to this problem because most patients are unwilling to admit when they have limited health literacy skills. As a result, a greater understanding is needed about how practitioners can become more aware of this deficit.

An additional deficit exists in the academic and professional literature knowledge base related to the number and quality of studies that have been conducted to determine the most effective methods of using pain medicine contracts. Specifically, a review of the literature revealed that there is a lack of large, high-quality randomized controlled trials targeting the effectiveness of patient contracts within established health systems. Clearly, more robust
research methods and strategies are needed in order to fully investigate the use of contracts in larger health systems, especially since the use of such contracts has proved to have multiple advantages in the treatment of non-malignant pain.

In response to these deficits, a change in practice was considered necessary. The synthesis of the existing guideline and literature produced five recommendations for the development and implementation of a pain medicine contract protocol. These recommendations are explicated below.

Recommendation I: Practitioners should employ the use of a written agreement between physicians and patients outlining patients’ responsibilities in the use of opioids for the management of non-malignant pain (Chapman et al., 2010; Trescot et al., 2008). Practitioners are given a chance to explore patients’ past usage of controlled substances when contracts are established. This could possibly be effective in reducing the misuse and diversion of these medications because patients will mutually agree to get their medications from one practitioner.

Recommendation II: Practitioners should discuss with their patients the risks and benefits of using controlled substances (Chapman et al., 2010; Trescot et al., 2008). Another opportunity that exists for practitioners to possibly reduce the misuse and diversion of these medications is to educate their patients about the medicine they are being prescribed, including physical dependence and tolerance. Patients should have a clear understanding of potential interactions among their prescribed medications and other medications, herbs, and supplements.

Recommendation III: Practitioners should present the “contract” as a mutual agreement that outlines the responsibilities of one or both parties and explain the contracting process (Bosch-Capblanch et al., 2009). Patients’ understanding of the contract process and their responsibilities can be increased by knowing what to expect in a contract.
Recommendation IV: Patients’ educational materials should be written at a sixth grade reading level or lower, preferably including pictures and illustrations (Safeer & Keenan, 2005). Patients’ comprehension and compliance is optimized when the health information is clearly understood.

Recommendation V: Opioid contracts developed in accordance with low-literacy recommendations should be evaluated within the patient population in which they will be delivered (Roskos et al., 2007). Patients’ understanding of the contract process and understanding of their responsibilities can improve when health information is presented at low reading levels. This understanding can better equip patients to make appropriate health decisions, such as signing a pain medicine contract. A summary of the recommendations and related examples are provided on Table I.

Pain Medicine Contract Protocol

A pain medicine contract protocol (see Figure 1) was developed by the author specifically for use in a neurology outpatient clinic setting. The change intervention included implementing a pain medicine contract protocol at one neurology outpatient clinic as a small test of change. This protocol includes a step-by-step process and was designed to be implemented during an outpatient clinic appointment by practitioners when prescribing or considering prescribing a controlled substance to treat non-malignant pain experienced by neurological patients. The steps are “explore,” “educate,” “contract,” and “prescribe.”
The step-by-step protocol features a checklist format so that practitioners can check off each step as it is completed. This checklist also includes a section at the end to document whether any education was delivered to the patient and whether a contract was signed.

The first step of the protocol is to explore patients’ current and prior status pertaining to controlled substances. The purpose of this step is to determine whether the patient currently has been prescribed a controlled substance and whether a contract related to that prescription is in place. One approach to obtaining patients’ prescription histories reports by using the Ohio Automated Rx Reporting System (OARRS).

OARRS is an electronic prescription drug monitoring program governed by the state’s pharmacy board to assist practitioners with treatment and to identify patients with drug-seeking behaviors. Healthcare professionals who wish to use this service are required to register for one of two programs available through OARRS: prescriber or delegate. The prescriber program is designed for use by physicians, nurse practitioners, and physician assistants with prescriptive authority. The delegate program is designed for use by for persons employed or supervised by a prescriber, which include medical residents who have earned a training certificate, registered nurses, and licensed practical nurses.

Practitioners need to further explore by asking patients if they received prescriptions for controlled substances and if contracts existed with other practitioners. Based on patients’ responses practitioners decided either to establish or not to establish a pain medicine contract with patients based on the information obtained from OARRS and direct conversations with patients.

The second step of the protocol is to educate patients about the use and misuse of controlled substances. If practitioners decide to establish contracts with patients, drugs risks and
benefits need to be reviewed and discussed. Printed drug information is needs to be given to patients.

Confirmation of the patients’ understanding of drug risks and benefits is determined by patients repeating key components of the education. Documentation of the educational process then becomes part of the patients’ health record as part of the contract.

The third step of the protocol requires that patients mutually agree to establish contracts with practitioners after being educated about the drug risks and benefits. Practitioners provide patients with a pain medicine contract and allowed time for patients to read the contract, ask questions, and repeat key components of the contract. The OPC developed by Wallace et al. (2007) was used as the contract for this protocol. This OPC was selected because it incorporated the National Guidelines on health literacy and had been determined to be easy to read and understand by patients. Before employing this particular OPC as part of the protocol, the author obtained permission from its creator—i.e., Wallace. (The OPC can be obtained from the author upon request.)

Practitioners introduce the benefits of pain medicine contracts to patients and subsequently provide a written contract for the patients to review. Once a mutual agreement has been established between practitioners and patients, contracts are signed. Practitioners document established dates of contracts, diagnoses, and the types of pain treated in each patient’s electronic health records. Patients receive copies of the contracts, and the original contracts are kept with their medical records.

The final step of the protocol is the decision whether to prescribe the controlled substance. The decision is made by the practitioner based on the information obtained from the prior steps. Either decision is documented in the health record.
Method

Setting

The setting for the implementation of this small test of change project was an outpatient neurology clinic in an academic health center. In this setting, approximately 10 patients are routinely prescribed controlled substances for non-malignant pain every month. The clinic setting featured characteristics that made it appropriate for the initial testing of the protocol implementation. Patients diagnosed with neurological disorders who present with complaints of non-malignant pain is the primary population of this setting. The clinic operates every week day Monday through Friday. The author serves as a practitioner in the clinic and is familiar with the staff and daily operations.

No special accommodations were required to implement the pain medicine contract protocol. During the implementation of the protocol practitioners provided professional services to patients with neurological disorders as a regular part of their clinical practice and research.

There were two aspects of the evidence-based protocol that the clinic was not implementing. First, the best evidence to make decisions about whether to prescribe pain medicine for non-malignant pain was not used by many practitioners. Rather, practitioners relied on patients’ verbal reports to determine whether controlled substances had been prescribed and whether a contract existed with another practitioner. The author recognized that practitioners lacked information about which controlled substances already had been prescribed for their patients.

Secondly, a contract between practitioners and patients was not considered standard practice at this setting even though recommended in the evidence reviewed (Bosch-Capblanch et al., 2009; Roskos et al., 2007; Trescot et al., 2008). The Controlled Substance Narcotic
Agreement (CSNA) that had been used prior to implementing the protocol in this particular outpatient clinic did not meet the guidelines for health literacy, and the language in some sections of the CSNA were not relevant to patients’ responsibilities (Institute of Medicine, 2003; Safeer & Keenan, 2005). Several clinical cases provided evidence that patients did not fully understand the responsibilities associated with their signed contract. For example, in more than one instance, patients had been receiving controlled substances from more than one practitioner. In another example, practitioners commented on how quickly patients often read and signed the CSNA without asking any questions about the content of the contract or the controlled substance being prescribed.

The practitioners within the clinic indicated that they were eager to participate in the prevention of drug misuse and wanted their patients to understand their responsibilities when they were prescribed controlled substances. This setting provided a venue for this pilot project to accurately identify the patient population that would benefit from the protocol inclusive of the desire and readiness for change. The medical director of the clinic supported the implementation of the protocol.

**Population of interest.**

The population of interest includes patients who have been prescribed a controlled substance as part of their treatment for non-malignant pain. The population of interest also includes practitioners who prescribe pain medicine for patients who suffer from non-malignant pain. It is only through changing the practice of practitioners that the population of interest can be effectively targeted. Specifically, the population for this study includes practitioners at an outpatient neurology clinic in an academic health center who prescribe controlled substances to treat non-malignant pain. This population was selected because these practitioners evaluate and
treat patients who suffer with non-malignant pain, and they prescribe controlled substances on a routine basis. At the time the pain medicine contract protocol was implemented and this small test of change project was conducted, 25 practitioners were included in the population. This population is similar to the population studied by Roskos et al. (2007). It is also similar to the populations in the randomized controlled trials conducted by Bosch-Capblanch et al. (2009).

**Approaches to Evaluating Outcomes**

Several different approaches were used to evaluate the outcomes of implementing the pain medicine contract protocol. The need for the different approaches was based on the two populations of interest, patients and practitioners, as well as the time periods of evaluation (prior to implementation and following implementation).

Outcomes related to the practitioners were obtained from several approaches. A pre-implementation survey was developed by the author to determine the current practices of the practitioners when prescribing controlled control. Practitioners were asked to rate the importance of knowing whether another practitioner had prescribed a controlled substance for their patients and whether a contract had already been established by another practitioner. The next 15 questions were developed based on the categories of the step-by-step protocol (explore, educate, contract). Practitioners rated the degree to which they completed important aspects of each step with their patients when considering the prescription of a pain medication for non-malignant pain. The following is one example of a question: *How important is it to know if another practitioner prescribes controlled substances for your patient?* Response options for these items included “very important,” “neutral,” and “not important.”

This survey was administered prior to implementing the protocol. The purpose of this survey was to determine which evidence-based protocol initiatives were being implemented prior
to initiating the protocol. Another approach to evaluating the protocol was to have those practitioners who implemented the protocol rate the utility of various components of the protocol on an evaluation survey. The protocol questions were worded so that they would serve as a reminder for practitioners to access OARRS and to provide patient education about the risks and benefits of drug prescribed. Practitioners were also contacted individually by the author to discuss their perspective of the protocol implementation process. The number of practitioners who registered for the OARRS was tracked since this was an essential component of the protocol implementation.

A patient evaluation survey was developed by the author to gain clarity and increase understanding of the protocol process from patients’ perspectives. Patients were asked to rate the process of education about the controlled substance as well as their ability to understand the contract and the content of the contract.

**Implementation Process**

Following approval by the Institutional Review Board (IRB), the pain medicine contract protocol was implemented during a four-week period. The activities of implementation are presented in Table 2. The author engaged in strategic activities consistent with multifaceted interventions that facilitated the test of change in practice for practitioners using the protocol in a clinic setting. During this stage, the author met and discussed the protocol implementation with the neurology department chairperson, clinic manager, and medical resident coordinator. Practitioners and nurses were approached one-to-one and encouraged to register with OARRS. The author asked the practitioners and nurses on a weekly basis about their current status of registration with OARRS during the four weeks of implementation to serve as a reminder to register for the program. Email reminders with drug misuse statistics and the project slogan “No
ifs, ands or buts. Be sure with OAARS” were sent every two weeks to practitioners and nurses to encourage feedback on the project.

(Discuss Table 2 here)

During the four-week implementation phase, the author monitored the daily clinic schedules and identified patients who were returning to the clinic to be evaluated by the practitioner. The prescription history of these patients was reviewed by the author to determine if a refill prescription of the controlled substance would be needed.

Eight patients were identified based on the above criteria. The protocol was not implemented for five of these eight patients for a variety of reasons, including cancelled appointments and patients who presented with an acute condition. The author assisted two practitioners in implementing the protocol with three patients.

**Outcomes**

**Pre-implementation practitioner use of essential elements.**

A pre-implementation survey was used to measure the practitioners’ current practices for prescribing a controlled substance to treat non-malignant pain. Eleven practitioners completed the pre-implementation survey. All practitioners (100%) indicated that they believe it is very important to know whether another practitioner has prescribed controlled substances for their patients. Of those practitioners, 10 (91%) indicated that they believe it is important to know whether their patients have entered a drug contract with another practitioner, and one (9%) indicated neutral beliefs about the importance of knowing whether a prior drug contract with another practitioner had been established.

The results of the remaining 15 questions of the pre-implementation survey are reported using the categories of the step-by-step process: “explore”, “educate”, and “contract”.
Regarding questions reflecting the degree to which practitioners explored their patients’ drug histories (“explore”), 10 (91%) practitioners indicated that they asked their patients whether they had received prescriptions for controlled substances from another practitioner, and one (9%) indicated that he/she had not. However, only four (36%) practitioners indicated that they asked their patients whether a contract existed with another practitioner. The current rate of registration with OARRS among practitioners was low, with only two (18%) of the 11 practitioners indicating that they were currently registered. Eight (73%) of the practitioners responded that they did access OARRS, which indicates that six of these respondents obtained their patients’ history records from OARRS using information through an approved registered practitioner.

Responses to questions related to practitioners’ attempts to educate their patients (“educate”) about the pain medicine contract protocol indicated that the majority of practitioners did in fact provide education. Ten (91%) practitioners indicated that they reviewed and discussed drug risks and benefits with their patients, and nine (82%) of these practitioners indicated that they documented the education. Six (55%) of the practitioners indicated that they provided their patients with printed drug information from an electronic resource.

Responses related to the category “contract” revealed that nine (82%) practitioners prescribed controlled substances for their patients to treat non-malignant pain. Three (27%) practitioners explained contracts to their patients, and only two (18%) practitioners attempted to establish a contract.

**Practitioner Evaluation of Implementation.**

One practitioner implemented the step-by-step process of the protocol with two patients. The practitioner and these two patients mutually agreed about their responsibilities, and the contracts were signed. The other practitioner who used the step-by-step process with a patient
was faced with an unexpected situation of the patient who reported they periodically smoked marijuana cigarettes which is among the excluded substances. Thus, a contract was not established between the other practitioner and patient. The practitioner was not aware of this patient’s situation prior to the use of the protocol. It was noted that neither practitioner routinely documented the contract date regarding a controlled substance prescription or resigned the contract with their patients on a yearly basis.

A practitioner evaluation survey was used to judge the protocol’s step-by-step process. Both practitioners indicated that the protocol was easy to understand and provided clear instructions. Its usefulness served as a reminder for the practitioners to access OARRS and educate their patients. Comments from the two practitioners who implemented the protocol included recommendations for improving the protocol. One practitioner suggested that we “refine the section on illegal drugs whether to include marijuana among the excluded substances.” Practitioners indicated that there was a need to add information about the process of notifying patients’ primary care providers about the establishment of a contract. The statement was as follows: “I am unsure as to how to easily notify the primary care physician or other medical doctors regarding the contract.” The final comment addressed the time of implementation “seems fine as is but is a little time consuming”.

OAARRS Registration. A total of 22 staff members were eligible to register with OARRS. Prior to implementing the protocol, only three (12%) staff members (including the author) were registered. Following the fourth week of implementation, eight staff members, over one-third of those eligible, had submitted their application to register for OARRS. This increase was distributed among the various levels of providers at the clinic. Two of the nine certified neurologists were registered with the prescriber program prior to the implementation, and two
more registered after the implementation. One of four nurse practitioners/physician assistants was registered with the prescriber program prior to the implementation, and one additional nurse practitioner registered after the implementation. None of the clinic nurses was registered prior the implementation, yet all three (100%) were registered with the delegate program after the implementation. None of the 12 medical residents was registered prior to the implementation, but two registered with the delegate program after the implementation. One neurologist had started the registration process, but when the process required the neurologist’s driver’s license number he chose not to complete the due to privacy, the registration application was not completed.

**Patient Evaluation of the Contract Process**

An evaluation survey was used to gain perspective about the contracting process from patients regarding education and the pain medicine contract. The three patients who participated in the step-by-step process with their practitioners completed the survey. This survey was completed after the patients had mutually decided with the practitioners whether to enter the contract. All the patients responded that the drug information, including the education about the risks and benefits, was clear and easy to understand. All the patients who reviewed the contract indicated that the content was easy to read and understand. They indicated that they understood their responsibility to the practitioner regarding the controlled substance and the consequences of not abiding by the terms of the contract.

**Recommendations**

The evaluation of the protocol by the author and practitioners served to identify several recommendations for the future implementation of the protocol. The recommendations are related to the implementation of the protocol, documentation and select situations with establishing a drug contract.
The process of implementation was effective, but a greater amount of time was needed for implementation than was anticipated. The initial plan was to present the project to a larger group during a staff meeting. This was not possible due to the timing of the implementation. As an alternative the project was presented individually to each practitioner while in the clinic setting. The group meeting would have provided time for practitioners to ask questions and discuss the practice change, as well as made it more cost effective.

Another recommendation related to implementation was related to OARRS registration. Alerting practitioners that the opening page for OARRS requests the recording of the driver’s license number is another recommendation. Sharing this information was a concern to several of the practitioners due to reasons of personal security and resulted in one practitioner refusing to register for this reason. Communication with OARRS staff member clarified that the driver license number is required for approval but an alternative method for submission can be negotiated.

A review of the educational materials regarding the prescribed medicine provided to the patients from electronic resources indicated that these materials were written at a high reading level. It is recommended that drug information materials be submitted to a reading-level review before distributing them to patients. The reading level of the contract was at a seventh-grade level, which is also recommended for patient education material.

In addition to recommendations regarding the implementation of the protocol, several additional recommendations can be made related to the documentation process. As the clinic moves from paper health records to electronic health records, the opportunity exists for creating a template of this protocol. Electronic health records will make it possible to include dates when contracts were initiated and when they were terminated. These innovations have been discussed
with stakeholders within healthcare settings, and the technological capabilities appear to be possible in the near future. This electronic health records system can be used to alert pharmacists when controlled substances have been prescribed by other practitioners. When screening patients, it was noted that contracts had been in place for three to four years. It is recommended that a yearly review of the contract be conducted as a reminder to the patient and practitioner of the continued mutual agreement.

Documentation of the establishment of a contract is recommended in the OAARS. Currently no information exists in OAARS related to established contracts. It is recommended that the effective dates of an established contact and the name of practitioner who established the contract be included on OAARS.

A select situation during the process of establishing a contract presented when a patient disclosed that they have used an illegal substance, marijuana. In this small test of change project, the patient declined to sign the contract because of admission to marijuana use. This situation helped to identify an ethical concern related to this protocol specifically to the contract. Some states have legalized the use of medical marijuana. This is not a problem in those states that has legalized medical marijuana. It is recommended that practitioners use ethical principals when addressing these select situations.

The overall recommendation is that the protocol be adopted as policy for clinical practice in the neurology outpatient clinic with the incorporation of the above revisions. The small test of change indicated that the implementation of the protocol in a neurology outpatient clinic was feasible and cost effective. The minimal additional time in the initial implementation can be reduced with repetitive use of the protocol. It is further recommended that it be implemented as a policy. As a policy it would assure that all practitioners are registered and access OARRS prior
to prescribing a controlled substance. The use of a contract that meets health literacy guidelines along with the appropriate patient education is not an option based on the evidence a policy would be one step assuring implementation.

Discussion

The protocol is presented in a step-by-step process to prevent drug misuse for non-malignant pain. Evidence indicates that prevention needs to incorporate several steps to be effective. First, the practitioner needs to determine whether patients have received or are currently receiving controlled substances from other practitioners before prescribing a controlled substance to treat non-malignant pain (Trescot et al., 2008). Initially, only 3 (12%) of the 25 practitioners who participated in this pilot project had accessed the state’s drug monitoring program. Following implementation of the protocol during this pilot project, more than one-third of those eligible had registered for OARRS access. Finding creative ways to encourage those not registered to do so should continue.

Evidence indicated that patients need to receive education and understand the drug risks and benefits of controlled substances (Trescot et al., 2008). Both practitioners who implemented the protocol documented the fact that they provided education. Without the implementation of the protocol, documentation of patient education is not easily retrievable making it difficult to determine whether patient education was provided and understood.

The review of the literature identified that contracts need to be established to provide patients with a clear description of responsibilities of the prescriber (Roskos et al., 2007; Safeer & Keenan, 2005; Trescot et al., 2008; Wallace et al., 2007). Practitioners also need to recognize that the contract meets the health literacy guideline (Roskos et al., 2007; Safeer & Keenan, 2005; Wallace et al., 2007). Evidence indicated that patients with limited health literacy skills and
chronic illness have less knowledge about illness management than those with higher health literacy skills (Institute of Medicine, 2003). This protocol incorporated the pain medicine contract developed and validated by Wallace et al. (2007) and met health literacy guidelines. This contract was found to be easy to read and understand by the three patients included in the implementation.

The utility and feasibility of this evidence-based practice project was evaluated based on the small test of change advocated in the Evidence-Based Practice Model (Levin et al., 2010). For example, the use of a pain medicine contract protocol can provide valuable time savings. Consider that practitioners often spend time outside the clinic examination room discussing whether to prescribe a controlled substance for patients to control non-malignant pain. Practitioners question whether patients are telling the truth about the use of current controlled substances to treat their pain. This discussion time spent outside the examination room debating whether to prescribe or not to prescribe could be spent on more productive and patient-centered activities, such as evaluating other patients. Practitioners would not need to rely solely on the honesty of patients if practitioners had access to pertinent information. This protocol features a process that helps practitioners make decisions about whether to prescribe a controlled substance to treat non-malignant pain. The pain medicine contract protocol is clinically feasible at this particular facility because there are computers in every examination room and two to three computers in both conference work rooms, which can facilitate quick access to OARRS. Lastly, this protocol can be incorporated into the usual time allocated for an appointment. One practitioner in this pilot project who used the protocol for a second time reported that it was less time consuming.
The potential benefits of implementing a pain medicine contract protocol to reduce cost are quite substantial when it comes to the overall healthcare expenditure associated with caring for patients who are addicted to opiates. The reduction in cost also extends to individuals in families who pay cash out of pocket to care for members with drug addictions who have either no health insurance or inadequate coverage. Millions of dollars could be saved if drug abuse were nonexistent (Bosch-Capblanch et al., 2009; Chapman et al., 2010; Trescot et al., 2008). Another benefit includes improved patient education and understanding of the contract process and responsibilities. And finally, this pilot project may conceivably lead to a reduction in the abuse and diversion of controlled substances as the benefits of implementing it far outweigh the risks of not doing so.

**Limitations**

One limitation of the project was the lack of time to educate practitioners about the protocol and to assist practitioners in registering with OARRS. Some practitioners were on vacation or assigned to inpatient services, and two practitioners were on medical leave, further limiting the number of participants. Educating practitioners about the project in a group setting would have lessened the burden of having to educate each practitioner individually in the clinic setting.

Another limitation of the project there were only two practitioners who implemented the protocol during the four weeks of the small test of change in clinical practice. Yet these two practitioners are recognized as leaders in the clinic. Targeting these two practitioners will enhance the continuation of the protocol implementation.

One limitation is related to the assumption that patients will follow a signed contract. As mentioned previously, a contract is a mutual agreement that outlines or defines the
responsibilities of one or both parties. Even though trusting relationships are established between practitioners and patients, one party (patient) may relinquish their responsibilities. The recommendation of documentation of contract establishment on OARRS and the health record addresses this assumption. The yearly review of contracts is recommended to remind both parties of their responsibilities.

**Conclusions**

Drug misuse with controlled substances is on the rise. The implementation of the pain medicine contract protocol as a small test of change resulted in recommendations for continued implementation at the neurology outpatient clinic. As a result of the initial implementation, more healthcare members registered to use the Ohio Automated Rx Reporting System. The pain contract initiated as part of the protocol was evaluated by patients as readable and understandable. The step-by-step protocol provided the guidance needed to incorporate evidence into practice and with slight modifications will be suitable for use in a neurology out-patient clinic to assure the highest level of care based on evidence. This protocol has the potential to make a substantial difference in the ways that pain medications are prescribed and, as a result, it also has the potential to reduce and prevent drug misuse.
Reference


Table I

Application of the Recommendations from Evidence Appraisals

<table>
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<tr>
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<tr>
<td><strong>Recommendation I:</strong> Advisable to employ the use of a written agreement between physicians and patients outlining patient responsibilities in the use of opioids in the management of chronic non-malignant pain</td>
<td>“access patient prescription history reports by logging into the Ohio Automated Rx Reporting System “</td>
<td>“only get my pain medicine from Dr. ____________’s office”</td>
<td>Chapman et al., 2010; Trescot et al., 2008; Wallace et al., 2007</td>
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<td><strong>Recommendation II:</strong> Recommend practitioners to discuss with their patients the risks and benefits of controlled substances</td>
<td>“review and discuss drug risks and benefits with patient”</td>
<td>“tell Dr. __________ about ALL of the medicines (over-the-counter, herbs, vitamins, those ordered by other doctors) I am taking”</td>
<td>Chapman et al., 2010; Trescot et al., 2008, Wallace et al., 2007</td>
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<td><strong>Recommendation III:</strong> Present the contract as a mutual agreement and explain the contracting process</td>
<td>“allow time for the patient to read the contract and to ask questions”</td>
<td>“This contract has 4 parts”</td>
<td>Bosch-Capblanch et al., 2009; Wallace et al., 2007</td>
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<td><strong>Recommendation IV:</strong> Patient education material should be written at a sixth grade or lower reading level to include the use of pictures and illustrations</td>
<td>“have patient to repeat key components of the education”</td>
<td>“I will not use illegal drugs (crystal meth, marijuana, cocaine)”</td>
<td>Safeer &amp; Keenan, 2005; Wallace et al., 2007</td>
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<td><strong>Recommendation V:</strong> Opioid contracts developed in accordance with low-literacy guidelines should be evaluated in the patient population in which they will be used</td>
<td>“if the patient mutually agrees to establish a contract with the practitioner and agrees with the content in the contract”</td>
<td>“I understand if I do not do all of the things listed”</td>
<td>Roskos, et.al., 2007; Wallace et al, 2007</td>
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Level of evidence: III, IV, I, III, III, V
The level of evidence rating “level I” experimental design/randomized controlled trial (RCT) or meta-analysis. “Level II” articles include quasi-experimental studies, and “level III” articles include non-experimental studies, qualitative studies, or meta-synthesis. Opinions of nationally recognized experts based on research evidence or expert consensus panels (systematic review, clinical practice guideline) are rated as level IV. Level V includes articles that feature the opinions of individual experts based on non-research evidence (case studies, literature reviews, quality improvement and financial data, clinical expertise, or personal experience).
Figure 1. Pain Medicine Contract Protocol (STEP-BY-STEP process)

Practitioners use this protocol when prescribing or considering to prescribe a controlled substance.

Before prescribing a controlled substance, the practitioner will:

EXPLORE

______ Access patient prescription history report by logging into the Ohio Automated Rx Reporting System (OARRS) to obtain the names of prescribers for controlled substances, names of pharmacies that dispense the drugs, names of the drug that is dispensed, including quantity.

______ Ask patient if they receive prescriptions for controlled substances from another practitioner to obtain drug name, dose, and frequency of use.

______ Ask patient if a contract exists with another practitioner to honor any preexisting contract between the patient and other practitioner.

If the practitioner decides to establish a contract with the patient, the practitioner will:

EDUCATE

______ Review and discuss drug risks and benefits with patient

______ Provide patient with printed drug information from Micromedex CareNotes

______ Provide the patient with Pain Medicine Contract (OPC) to read.

______ Allow time for the patient to read the contract and to ask questions.

______ Have patient repeat key components of the education.

If the patient mutually agrees to establish a contract with the practitioner and agrees with the content in the contract, the CONTRACT is signed by the patient and practitioner.

Practitioner will:

______ Document the established date of the contract, diagnosis, and type of pain being treated.

______ Send notification that a contract was established to the primary care physician, and other practitioners involved in the care of patient.

______ Give a copy of the initial contract to the patient. Retain the original with medical record

Note: Review contract every year with the patient to make the necessary changes in the pharmacy location, and names of physicians. Practitioner and the patient will date and sign the review.

PRESCRIBE controlled substance.

(Initial all steps performed and return to the DNP student mailbox)
Pain Medicine Contract (For Chart)

Pain Medicine Contract between ______________________________ (practitioner) and patient
established on ______________ (date) with end date ______________________________

Diagnosis:__________________________      Type of Pain ______________________

____________(date) Drug risks and benefits reviewed and discussed with patient.
____________(date) Patient was given printed drug information from CareNotes.

Notification of Pain Medicine Contract sent to:        ____________________________________

____________________________________
____________________________________

Contract reviewed and resigned (yearly)

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<thead>
<tr>
<th>Patient</th>
<th>Practitioner</th>
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(To be filed in patient medical record with original contract)
Table 2.

*Implementation process of protocol*

<table>
<thead>
<tr>
<th>Week 1: Engagement of Healthcare Team.</th>
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<tbody>
<tr>
<td>Inform Staff of Project</td>
<td>• Met with the clinic manager to discuss dissemination of project (initial dissemination with project slogan “no ifs, ands or buts Be sure with OAARS” on conference room board, creation of a poster for posting in conference room)</td>
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<td>• Individual meeting with registered nurses and practitioners in the clinic setting to explain the project</td>
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<tr>
<td>Facilitate OARRS Registration</td>
<td>• Met with the resident coordinator to discuss notarize signatures on OARRS applications</td>
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<td>• Individually assisted each practitioner and registered nurse in the registration process for the OARRS.</td>
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<tr>
<td>Administration of Pre-Implementation Survey</td>
<td>• Each practitioner individually approached to complete the survey while at clinic. Completed and returned to project director.</td>
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<th>Week 2: Initial Implementation of the Protocol</th>
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<tr>
<td>Implement Protocol</td>
<td>• Screen patients for potential implementation.</td>
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<tr>
<td></td>
<td>• First patient agreed to participate but declined to sign the contract.</td>
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<tr>
<td></td>
<td>• Continued to screen for potential participants.</td>
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<tr>
<td>Protocol Evaluation</td>
<td>• Patient asked to complete evaluation questionnaire of protocol process and contract.</td>
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<tr>
<td></td>
<td>• Practitioner asked to completed evaluation questionnaire of protocol process and contract.</td>
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</tbody>
</table>
### Continued Project Dissemination
- Poster announcing the evidence based project
- Project slogan was posted on the board in the conference room.

### Week 3: Continued Implementation

#### Implement Protocol
- Second patient agreed to participate and signed the contract.
- Continued to screen for potential participants.

#### Protocol Evaluation
- Patient asked to complete evaluation questionnaire of protocol process and contract.
- Practitioner asked to complete evaluation questionnaire of protocol process and contract.

#### OARRS Registration Evaluation
- Follow-up with practitioners regarding their registration status.
- Contacted Ohio State Board of Pharmacy to obtain additional information on medical resident’s registration. Recognized that medical residents need to register for delegate program necessitating registration of certified neurologists first so that residents can obtain approval as delegate.

### Week 4: Continued Implementation and Follow-up

#### Implement Protocol
- Third patient agreed to participate and signed the contract.
- Continued to screen for potential participants.

#### Continued Dissemination
- A reminder with drug abuse statistics and project slogan “no ifs, ands or buts Be sure with OARRS” was sent by group email to the practitioners and nurses.
| Protocol Evaluation | • Patient asked to complete evaluation questionnaire of protocol process and contract.  
• Practitioner not asked to complete Pre-Implementation Survey was completed with prior implementation. Practitioner asked to complete evaluation questionnaire of protocol process and contract. |