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Evaluation of an Opioid Risk-Assessment Screening Tool

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Abstract

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

According to the Centers for Disease Control and Prevention, prescribers should evaluate risk factors related to opioid use prior to initiation of opioid medication. The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. An opioid risk-assessment screening tool (ORAST) has the potential to identify patients at high risk for opioid misuse and/or abuse. The purpose of this Doctor of Nursing Practice project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Rosswurm and Larrabee's model for evidence-based practice served as the framework that helped guide project development. Evidence in the literature review supported The Opioid Risk Tool (ORT) as the most appropriate tool for the clinic. An 11-member project team voted unanimously for the ORT and to develop a policy to guide the use of the tool in the clinic. The ORT and its policy were evaluated by the team using the AGREE II Instrument. The team agreed that the ORT and its policy should be implemented into their practice setting (64% *strongly agreed* and 36% *moderately agreed*). A summative evaluation supported the Doctor of Nursing Practice student leadership of the project. Use of an ORAST has the potential to create positive social change by reducing the number of prescribed opioid by assisting providers in determining a patient's plan of care based on the patient's level of risk for prescription opioid misuse and/or abuse. Patient outcomes may be improved through reduction in opioid misuse and/or abuse.

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Dedication

I would like to dedicate my doctoral research to my best friend and husband. Together we will always be superheroes. I am now ready to write our next chapter together.

Acknowledgments

I would like to express my deepest appreciation and indebtedness particularly to Dr. Cheryl McGinnis. Thank you for your endless support, mentorship, understanding, and kindness throughout my doctoral studies.

I would also like to declare my undying thankfulness to Mr. Anthony Guerra. Through this process you have been my rock and the cornerstone of my very being. No matter how great the task at hand, your belief in me to make astounding accomplishments despite all odds is unwavering.

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Section 1: Overview of the Evidence-Based Project

Introduction

The United States is presently facing an opioid epidemic due to the cultural shift related to opioid prescribing that started approximately two decades ago which encompassed over 259 million opioids being prescribed in 2012 (Sengal, Manchikanti, & Smith, 2012). This equates to one bottle for every adult in America. According to the U.S Department of Health and Human Services (2017), on average 650,000 opioid prescriptions are written daily. The Center for Disease Control and Prevention (CDC, 2017), has reported that opioid-related deaths have quadrupled since 1999.

One of the main ways to reduce opioid misuse, abuse, addiction, dependence and related deaths is to ensure proper opioid prescribing. According to the CDC (2017), proper opioid prescribing means that providers follow three categories of evidence-based recommendations. Providers must give careful consideration (a) about when to initiate or continue opioid management for chronic pain, (b) to opioid selection, dosage, duration, follow-up and discontinuation; and (c) assessing patients' risk and addressing the potential harm of opioids. Currently, at an inner city ambulatory care clinic (the clinic under study) providers do not consistently assess patients for potential risk of opioid misuse and/or abuse prior to initiating opioids in patients with complaints of pain. One way to consistently assess patients for potential opioid misuse and/or abuse is to screen them with an opioid risk-assessment screening tool.

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to

initiating opioid medication. This clinic sees about 3,000 patients annually, 30% of which are seen for noncancer-related pain complaints (S. Cole, personal communication, March 10, 2017). A large number of these patients have a history of aberrant behaviors, of physical and/or sexual abuse, of psychological illness, and/or family history of substance abuse (S. Cole, personal communication, April 21, 2017). According to Passik (2008), these factors have the potential to increase a patient's risk of opioid misuse and/or abuse. In the United States over 5,000 individuals abuse opioids for the first time each day, while more than 100 die from opioid-related overdoses daily (Barrus, Averil, Sudweck, Averil, and Mota, 2016). The number of opioid prescriptions written varies from state to state, but according to the CDC (2014), Connecticut prescribed 73 opioid prescription pain killers per 100 people in 2012, while surrounding states ranged from 52-71 pain-killer prescriptions per 100 people, excluding Rhode Island which prescribed 90 pain-killer prescriptions per 100 people.

Current evidence-based guidelines for prescribing opioids recommend than an opioid risk-assessment screening tool (ORAST) be used prior to the initiation of prescribing opioids for patients with complaints of pain in order to assess for risk of opioid misuse and/or abuse. According to the CDC (2017), improving prescribing practices for opioids includes strategies to (a) reduce exposure to opioids, (b) prevent abuse, (c) prevent misuse, and (d) stop addiction and dependence. This includes implementing the use of opioids as a last resource after other treatment modalities have failed. According to Cheattle (2017), guidelines recommend that providers prescribing opioids first assess patients using an ORAST. Additionally, the CDC (2016) reported that

evidence-based guidelines include evaluating risk factors related to opioid use prior to the initiation of opioid medication management. An ORAST has the potential to identify those patients at high risk for opioid misuse and/or abuse. According to Passik, Kirsh, and Casper (2008), opioid risk-assessment screening tools can help providers identify high-risk patients for misuse and/or abuse, and then monitor and adjust their opioid treatment accordingly. They would allow providers to avoid initiating opioid medication management to patients who have high-risk stratification. A provider may not want to prescribe to a patient with a high-risk stratification as that patient has an increased probability of misusing and/or abusing opioid medications. Doing so can yield adverse outcomes up to, and including death. Additionally, an ORAST can help providers select the frequency and intensity of adherence monitoring during opioid medication management.

Addressing this practice problem is both meaningful and relevant to this inner-city ambulatory care clinic. The DNP project introduced clinic providers to a comprehensive ORAST for use in identifying patients at risk for opioid misuse and/or abuse prior to initiating opioid medications. Identifying at-risk patients will allow providers to make a comprehensive assessment as to whether initiating opioids is appropriate for their patient, including the potential risks and benefits of opioid use for the patient with complaint of pain.

The purpose of this Doctor of Nursing Practice project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Opioid-related aberrant behaviors include nonadherence to

medical dosing, nonadherence to the treatment plan, attempts to refill opioid medications early, misplacing opioid medications, and illegally obtaining and distributing opioid medications. Introducing an ORAST in this inner-city ambulatory clinic in the northeast of the United States will help to reduce opioid exposure, misuse, abuse, dependence, addiction, subsequent deaths by identifying patients at risk for opioid misuse and/or abuse. When providers screen patients at risk for misuse and/or abuse, fewer opioid prescriptions may be written, and patient adherence monitoring can be implemented as a strategy to decrease the number of patients misusing and abusing prescription opioids.

Problem Statement

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. Individuals with complaints of chronic pain and co-occurring substance use disorders, and/or mental illness are at a higher risk for opioid misuse and abuse (Sehgal, Manchikanti, & Smith, 2012). This clinic serves a patient population that is known to have a history of aberrant behaviors, physical and/or sexual abuse, psychological illness, and/or a family history of substance abuse (S. Cole, personal communication, April 21, 2017). These factors have the potential to increase a patient's risk for opioid misuse and/or abuse (Passik, Kirsh, & Casper, 2008). The gap in practice was that, despite guidelines that recommend evaluating risk factors related to opioids prior to the initiation of opioid medication, providers continued to prescribe them without consistently assessing the patients. As a result, high-risk patients being seen in the clinic for complaints of pain are being prescribed opioids without an appropriate opioid risk-

assessment. These high-risk patients are not being adequately screened for potential aberrant behaviors before receiving a prescription for an opioid. Strategies to mitigate against opioid misuse and/or abuse include using (a) opioid risk-assessment screening tools to identify patients with substance abuse disorders, (b) data from the Prescription Monitoring Drug Program, (c) urine drug screening, and (d) provider-patient adherence contracts (Volkow & McLellan, 2016). The major source of diverted opioids is provider prescriptions, and opioid analgesics are the most widely diverted and improperly used medication in the United States (Volkow & McLellan, 2016).

In April of 2017, among the 10 resident-based primary care teams at the clinic, 92 patients were documented as being actively managed on opioids for chronic pain complaints (S. Cole, personal communication, April 21, 2017). Of those 92 patients, approximately 70% had a diagnoses or a history of mental illness and/or substance abuse disorders (S. Cole, personal communication, April 21, 2017). A critical component of preventing opioid misuse and/or abuse is being able to identify patients who are at risk for these aberrant behaviors.

This doctoral nursing project holds significance for nursing practice as it addresses the importance of using an ORAST to identify patients at risk for opioid misuse and/or abuse in the outpatient ambulatory clinic. Although this particular clinic does not use nurse practitioners in their outpatient ambulatory care clinic, they may do so in the future. Within the state, nurse practitioners provide direct patient care within a variety of clinical settings and specialties. Nurse practitioners are commonly used to address the growing demand for primary care providers either by working independently or in

collaboration with a physician. According to the Department of Public Health (2017), in Connecticut nurse practitioners are able to either independently or in collaboration with a physician practice within the full extent of their scope including prescribing, dispensing, and administering medications.

This doctoral project is expected to guide nurse practitioners on the use of an opioid risk-assessment screening tools in outpatient ambulatory clinics. Nurse practitioners who adapt the current evidence guidelines and use an ORAST prior to initiating opioids can identify patients at high risk for misuse and/or abuse. By completing a comprehensive risk assessment on patients with complaints of pain, nurse practitioners can tailor each patient's plan of care based on individualized risk stratification in order to manage pain complaints with taking the least amount of risk. For patients identified as being at high risk for opioid misuse and/or abuse, the result may be deferring from initiating opioids and starting a trial of alternative therapies, initiating opioids with intensified adherence monitoring, and/or referring to a specialist in pain management. Using an ORAST can help providers to include nurse practitioners reduce prescription opioid related abuse, misuse, exposure, dependence, addiction, and overdose.

Purpose

The purpose of this Doctor of Nursing Practice project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Currently, providers in the inner-city, ambulatory care clinic, in the northeastern United States continue to prescribe opioids without first completing a comprehensive opioid risk-assessment on patients with complaints of pain. The practice-

focused question was as follows: “Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?”

Nature of the Doctoral Project

Peer-reviewed, research articles published within the past 10 years were reviewed as apart of a comprehensive, systematic approach to the literature review on opioid risk-assessment. Although older than 10 years, some articles were included because they evaluated the selected opioid risk-assessment screening tools in terms of sensitivity and specificity. The following databases were used: PubMed, Ovid, Medline, and the CDC. Additionally, the Boolean search of key words was applied when reviewing the sources of evidence. The following keywords were used: *addiction assessment tool* and *compliance*, *predicting aberrant behavior* and *opioids*, *opioid prescribing*. I used Boolean operators, AND and OR, to optimize the results.

The strategy utilized to obtain the evidence needed to complete this doctoral project included completing an integrated literature review and critically appraising the strength of evidence to recommend an ORAST to clinic providers. The recommended ORAST was presented to the team. A policy was developed with the team based on the needs of the clinic. The ORAST and the policy to guide providers in using it was then presented to, and evaluated by, the team using the AGREE II Instrument. Team members were then asked to provide a summative evaluation of the DNP student learning leadership within the project.

Significance

The stakeholders that have been identified for the purpose of this DNP quality improvement project are the medical director and one resident from each primary care team. The medical director's role within the clinic in addition to patient care is overseeing the clinic's day-to-day operations to include facilitating policy changes based on evidence-based practice guidelines. Additionally, he serves as an attending for the residents, which includes supervising, teaching, and training them. This inner-clinic ambulatory care clinic divides its primary care patients amongst 10 resident-based primary care teams. Each team has between three and four residents assigned to it at any given time. The resident from each team was chosen to participate by the medical director. Stakeholder criteria for selection included availability to attend all meetings, provide feedback on the selected ORAST and the developed policy guiding its use, and a willingness to serve as a positive social change agent within the clinic. I served as the pain management expert on the team.

It is expected that this doctoral project will contribute to nursing practice in four ways: (a) If nurse practitioners use it, it could improve patient safety and prevent deaths; (b) It could change the primary care providers' management of patients with complaints of pain; (c) It could change prescribing practices within the clinic; (d) It could create positive social change by identifying patients at risk for opioid misuse and/or abuse prior to initiating opioid treatment, reduce the amounts of opioids that are prescribed, decrease opioid misuse, abuse, dependence, addiction, and opioid-related deaths, and the associated economic burden.

Recommendations included the selection of an ORAST applicable to the clinic's patient population and the development of a policy to guide providers' use of the opioid risk-assessment screening tool. Stakeholders completed the AGREE II Instrument and provided summative evaluation of the project. Revisions were made based on stakeholder evaluations. Implementation of the tool and policy will occur after graduation. The project has the potential to change the primary care provider's management of patients with complaints of pain. The patient's plan of care can include the risk-benefit analysis of initiating opioid medications, and determinants of adherence monitoring if the provider chooses to move forward with initiating opioid medication therapies.

Utilization of an ORAST has the potential to change prescribing practices within the clinic and create positive social change by reducing the amount of opioids that are prescribed, and tailor adherence monitoring specifically to each patient's risk stratification through a policy to guide providers in the use of the tool. This DNP project is translating the evidence into practice through application of an opioid risk-assessment screening tool. Limiting the amount of opioids that are prescribed and identifying patients at risk for opioid misuse and/or abuse prior to initiating opioid management may decrease opioid misuse, abuse, dependence, addiction, opioid related deaths and the associated societal economic burden.

Summary

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. The gap in practice was that, despite guidelines that

recommend evaluating risk factors related to opioids prior to the initiation of opioid medication, providers continued to prescribe them without consistently assessing the patients. The practice-focused question was as follows: “Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?”

The purpose of this DNP project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. This doctoral nursing project holds significance for the field of nursing practice as it has the potential to guide nurse practitioners on the use of an ORAST so patients at risk for opioid misuse and/or abuse are identified and alternative treatment methods offered.

Section 2: Background and Context

Introduction

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. In April of 2017, 92 patients were prescribed opioids within the clinic (S. Cole, personal communication, April 21, 2017), none of which had been screened for risk of opioid misuse and/or abuse using an ORAST prior to initiating opioid management by the provider. Evidence-based guidelines for prescribing opioids stipulate that providers must assess patients for risk of aberrant behavior prior to initiating opioid medications. Of all patients prescribed opioid medications, 50% of patients do not take it as prescribed; this in turn, inflates health costs (Walghmare, Lelito, Detscher, & Salcedo, 2017). Predicting the risk of aberrant opioid drug-related behaviors may help providers in developing a treatment plan that includes deterring prescribing opioids for a patient at high risk for abuse and/or misuse and the amount of rigidity needed to monitor for treatment adherence if opioids are initiated (Chou, Fanciullo, Fine, Miaskowski, Passik, & Russel, 2009). In 2007 it was estimated that 12.5 million Americans used opioid pain relievers for nonmedical purposes, and approximately 1.7 million of them met the diagnostic criteria for abuse or dependence (Birnbaum, White, Schiller, Waldman, Cleveland, & Roland, 2011). In 2007 it was found that opioid prescription abuse in the United States accounted for $25.6 billion in workplace costs, $25.0 billion in healthcare costs, and $5.1 billion in criminal justice costs (Birnbaum et al., 2011). Developing risk

evaluation and mitigation strategies in support of initiating opioid medication can reduce the societal and economic burden associated with misuse and/or abuse.

The practice-focused question was as follows: "Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?" The purpose of this DNP project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic.

In the next section, I discuss the theoretical framework used to inform this doctoral project, the relevance of this doctoral project to nursing practice, the local background and context, and the role of the DNP student.

Concepts, Models, and Theories

Translation of evidence into current practice is essential in order to improve patient outcomes, patient safety, and the quality of the healthcare provided. A conceptual model or framework guides the implementation of evidence-based practice (White, Dudley-Brown, & Terhaar, 2012). The model used to guide and inform this DNP project is Rosswurm and Larrabee's model for evidence-based. The six steps of this model include assessing the need for change in practice by comparing internal data with external data, linking the problem with interventions and outcomes, synthesizing the best evidence, designing a change in practice, implementing and evaluating the change in practice (including processes and outcomes), and integrating and maintaining the change in practice using diffusion strategies (White, Dudley-Brown, & Terhaar, 2012). According to Pipe (2007), Rosswurm and Larrabee's model for evidence-based practice

is versatile for translating evidence-based practice into practice in order to optimize the level and quality of patient care.

Rosswurm and Larrabee's Model for Evidence-Based Practice

Rosswurm and Larabee's conceptual framework guides nurses through a systematic process to translate research into practice (Pipe, Wellik, Buchda, Hansen, & Martyn, 2005). The first of the six steps is to assess the need for change in practice. This includes speaking with and building relationships with key stakeholder, collecting data about the current practice setting and then comparing the internal data with external data in order to identify a practice problem.

The second step is to link the problem, intervention, and outcomes. According to Wellil, Buchda, Hansen, and Martyn (2005), through utilization of classification systems and language potential interventions and activities are identified. Thereafter outcome indicators can be selected. The third step of the Rosswurn and Larrabee's model for evidence-based practice is to synthesize the best evidence. This is done through a comprehensive review of the literature, evaluating and critiquing the evidence, synthesizing the best evidence, and moving forward to assessing the feasibility, benefits, and the risks of the evidence that was synthesized (Wellil, Buchda, Hansen, & Martyn 2005).

The fourth step is to design a practice change. According to Wellil, Buchda, Hansen, and Martyn (2005), this step includes defining the proposed change, identifying any needed resources to support the change, plan the implementation of the practice change, and finally defining outcomes. Implementing and evaluating the change in

practice is the fifth step of Rosswurm and Larrabee's model for evidence-based practice. According to Wellil, Buchda, Hansen, and Martyn (2005), this step includes using a pilot study demonstration, evaluating the process and outcomes, and finally to decide to adapt, adopt, or reject the practice change. The final and sixth step of Rosswurm and Larrabee's model for evidence-based practice change is to integrate and maintain the practice change. According to Wellil, Buchda, Hansen, and Martyn (2005), this includes communicating the recommended change to stakeholders, present staff in-service education on the practice change, integrate the practice change into the standards of practice, and finally to monitor process and outcomes.

Definitions of Key Terms

For the purpose of this DNP project the following key terms have been defined in order to clarify any terms that may have multiple meanings in related to opioids.

Adherence monitoring: methods in clinical practice utilized to identify problematic drug use from onset through continuation of opioid management (Matteliano, Marie, & Olive, 2014).

Noncancer pain: pain that can be acute or chronic in nature but is not related to an underlying cancerous pathology.

Opioid abuse: is the non-medical use of an opioid medication repeatedly, or sporadically for the psychoactive affects that they produce (Hahn, 2011).

Opioid misuse: is using the prescription opioid for other than which it was prescribed (Hahn, 2011).

Opioid related aberrant behaviors: include non-adherence to medical dosing, non-adherence to the treatment plan, attempts to refill opioid medications early, misplacing opioid medications, and obtaining and distributing opioid medications.

Opioid risk-assessment screening tool: measure factors involved in a patient's overall level of risk of misusing and/or abusing opioids.

Providers: refers to anyone rendering medical care to include physicians, physician assistants, and nurse practitioners.

The key difference between opioid misuse and opioid abuse is with opioid misuse the opioid medication is not being taken for an intentional euphoric affect. Examples of opioid misuse include taking more of less of the prescribed opioid at different intervals other than the way it was prescribed, using the opioid medication for other conditions that the condition it was prescribed for.

Relevance to Nursing Practice

According to Hahn (2011), the use of prescription opioid medications has the potential to lead to patient's misusing and/or abusing these medications as well as becoming addicted or dependent on them and possibly diverting them to others. According to Hahn (2011), the healthcare costs for an opioid abuser is eight times higher than a non-opioid abuser while the retail sales of opioid medications have skyrocketed. Between 1997 and 2006 the sales of hydrocodone has increased by 244%, oxycodone by 732%, and methadone by 1177% (Hahn, 2011). The total United States societal costs for prescription opioid abuse were estimated to be $55.7 billion in 2007.

According to the CDC (2016), improving prescribing practices for opioids includes strategies to reduce exposure to opioids, prevent abuse, prevent misuse, and stop addiction and dependence. Current evidence-based guidelines include evaluating risk factors related to opioid use prior to initiation of opioid medication management. An ORAST has the potential to identify those patients at high risk for opioid misuse and/or abuse (CDC, 2016). In 2007, it was estimated that 5.2 million people aged 12 or older abused prescription opioids in the previous month. According to Chou, Fanciullo, Fine, Miaskowski, Passik, and Russel (2009), predicting the risk of aberrant opioid drug-related behaviors may help providers develop an opioid treatment plan to include to deter prescribing opioids for a patient at high risk for misuse and/or abuse and the amount of rigidity needed to monitor for treatment adherence if opioids are initiated.

The development of theories and translation of research into nursing practice allows evidence-based practices to be implemented in order to improve patient outcomes. According to White, Dudley-Brown, and Tehaar (2016), translating evidence into routine clinical practice is pivotal to ensure quality care however, despite data that has been generated from rigorous research studies takes more than 17 years for research findings to be implemented into daily practice. By that factor alone the scientific underpinnings of health care practices will remain outdated while current research remains available and waiting to be implemented. Doctoral prepared nurses must be leaders in the discipline of nursing and overall healthcare. The responsibilities of a DNP prepared nurse includes being able to appraise research, identify evidence-based practice, assess gaps in health

care, and implement these findings into practice in order to improve patient care. This DNP project addresses each of the eight DNP Essentials (AACN, 2006).

- Scientific Underpinnings for Practice
- Organization and Systems Leadership for Quality Improvement and Systems Thinking
- Clinical Scholarship and Analytical Methods for Evidence-Based Practice
- Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care
- Health Care Policy for Advocacy in Health Care
- Interprofessional Collaboration for Improving Patient and Population Health Outcomes
- Clinical Prevention and Population Health for Improving the Nation's Health
- Advanced Nursing Practice

According to the American Association of Colleges of Nursing (2006), Advanced Practice Nurses assess, manage, and evaluate patients at the most independent level of clinical nursing practice by utilizing highly refined assessment skills while being able to make improvements in their particular patient populations in the systems within which they practice. The development of a policy to guide the use of an ORAST can be implemented by nurse practitioners in outpatient ambulatory clinics to improve the quality and safety of care provided to patients within the clinic with complaints of pain.

Local Background and Context

The practice-focused question was as follows: "Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?" Prescription opioid medications are highly diverted and improperly used in the United States (Volkow & McLellan, 2016). In 2014, 245 million prescription opioids were dispensed in America (Volkow & McLellan, 2016). This is feeding the national opioid epidemic that we are facing resulting in opioid overdose deaths, dependence, addiction, and the skyrocketing societal burden. According to the CDC (2016), improving prescribing practices for opioids includes strategies to reduce exposure to opioids, prevent abuse, prevent misuse, and stop addiction and dependence. Current evidence-based guidelines for prescribing opioids recommend that an opioid risk-assessment be completed prior to the initiation of prescribing opioids for patients with pain in order to assess for risk of opioid misuse and abuse.

According to Jones, Moore, Levy, Daffaron, Browder, Allen, and Passik (2012), risk assessment stratification has become an important component in prescribing opioids to patients with complaints of pain. From November 2016-April 2017, the clinic's providers have prescribed 457 active opioid prescriptions (S. Cole, personal communication, May 8, 2017). Active refers to medications that are still being actively dispensed to the patient currently and have not been discontinued. According to Hahn (2011), the use of prescription opioid medications has the potential to lead to opioid misuse, abuse, addiction, and diversion. Without providers assessing for the risk of

misuse and abuse of opioids for these patients the risk of opioids versus the potential benefits cannot be assessed.

The information collected through using the ORAST will allow each primary care provider to individualize each patient's plan of care to include whether the benefits outweigh the potential risks of initiating opioid medications, as well as determine the intensity of adherence monitoring if the provider chooses to move forward with initiating opioid medication therapies. Opioid medication adherence monitoring includes follow-up visits and assessment, urine toxicology screening, pill counts, and checking the Prescription Monitoring Program's database. According to Walghmare, Lelito, Detscher, and Salcedo (2017), out of all patients prescribed opioid medications 50% of them do not take their opioid medications as prescribed, this in turn, inflates health costs. The cost of prescription opioid misuse and abuse represents a substantial economic burden for the United States. According to Birnbaum, White, Schiller, Waldman, Cleveland, and Roland (2011), the United States societal costs of prescription drug misuse and abuse totaled $55.7 billon in 2007. In 2007, 12.5 million Americans utilized pain relievers for non-medical purposes (Birnbaum et al., 2011).

Role of the DNP Student

I have dedicated my career as a nurse practitioner to serve patients with both acute and chronic pain complaints. My passion and motivation for this doctoral project is to improve the quality of life of the community and society. According to the American Association of Colleges of Nursing (2006), the DNP graduate prepared for an Advanced Practice Nursing role make improvements in the care of their particular patient

population through utilization of a holistic perspective and use of diverse evidence-based interventions. According to McCarbera, Nicolson, Todd, Palmer, and Penles, (2008), untreated pain negatively impacts psychological, physical, and economical components of every day life. For example, back pain alone accounted for $85-$100 billion in healthcare expenditures in 2004 and 2005 (Jones et al., 2012). Pain, when not effectively treated and/or relieved has a detrimental affect on all aspects of quality of life (Katz, 2002). Through utilization of a holistic, nursing approach that encompasses a variety of non-opioid pain management modalities I am able to manage patients with complaints of pain, improve their quality of life, and utilize opioids as a last line of treatment only after calculating the benefits versus the risks.

My professional role in this doctoral project as a Family Nurse Practitioner who specializes in pain management was to serve as the team leader, to review the evidence, and present the evidence to the identified group of stakeholders in order to determine the best ORAST for the ambulatory clinic's population to recommend a practice change. There are no other pain management specialists within the clinic. The ultimate goal of this project is to setup the framework to have 100% of the ambulatory clinic's primary care providers utilize the selected ORAST prior to initiating opioid treatment. This will allow for risk for aberrant behavior to be identified and treatment plans to be individualized in order to improve patient safety and quality of care provided to reduce opioid misuse, abuse, dependence, addiction, exposure, and overdose. Additionally, I served as a pain management expert to the ambulatory care clinic. A potential bias I may possess may include that I am practice as a pain management specialist within the same

geographical location at the ambulatory care clinic. My passion for this specialty of pain management may also pose as a potential bias. Steps to address these potential biases included my being aware of them and seeking feedback from stakeholders.

This DNP project has the potential to assist primary care providers in identifying the potential risk of misuse and/or abuse of opioids prior to initiating opioid management for patients with complaints of pain through utilization of an ORAST. This will allow primary care providers to be able to calculate the risk of misuse and/or abuse of opioids for each patient with complaints of pain in order to customize a plan of care, which may include deferring to prescribe opioids, or choose to prescribe with more intensified adherence monitoring.

Role of the Project Team

The doctoral project team includes the stakeholders that have been identified for the doctoral project. The stakeholders that have been selected for the purpose of the DNP quality improvement project are the medical director and one resident from each of the primary care teams. The medical director's role within the clinic in addition to patient care is overseeing the day-to-day operations to include facilitating policy changes based on evidence-based practice guidelines. Additionally, he serves as an attending for the residents, which includes supervising, teaching, and training them. It is important to include the medical director, as he will oversee that the selected ORAST and policy guiding provider use is being followed after graduation. The medical director supports this doctoral project as he recognizes the need for an ORAST to be selected and

implemented within the clinic, as there are a large number of patients being managed for pain without application of the guidelines.

This inner-city ambulatory clinic divides its primary care patients amongst 10 resident-based teams; each team has between three and four residents. One resident from each team was chosen to participate by the medical director. Stakeholder criteria for this selection included availability to attend all meetings, provide feedback on the ORAST and the developed policy guiding its use, and willingness to serve as a positive social change agent within the clinic. It was important to have one primary care physician from each team so there is cohesive involvement and representation from each team within the clinic as they will be end-users of the selected ORAST in order to make a comprehensive risk assessment of potential misuse and/or abuse prior to initiating opioids. Implementation of the selected ORAST and policy guiding provider use will not be completed until after graduation. At that time the resident doctoral team members will be responsible for educating the other residents in each of their primary care teams. According to White, Dudley-Brown, and Terhaar (2016), a microsystem approach engages clinicians who provide direct care in order to improve the probability of translation of evidence into practice. Ultimately failing to include a representative from each team could later translate into failed acceptance of the selected ORAST and the defined policy.

The strategy utilized to obtain the evidence needed to complete this doctoral project included completing an integrated literature review and critically appraising the strength of evidence to recommend an ORAST to clinic providers. The recommended

ORAST was presented to the team. Together with the team a policy was developed based on the needs of the clinic. The ORAST and policy to guide provider use was then presented to and evaluated by the team using the AGREE II Instrument. Team members were then asked to provide a summative evaluation of the DNP student learning leadership within the project. The medical director will be the end decision maker as to whether the selected ORAST and policy developed will be implemented. Implementation of the ORAST and the policy guiding provider use will not be completed until after graduation.

Summary

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. The sources of evidence and the analysis and synthesis of this doctoral project will now be depicted.

Section 3: Collection and Analysis of Evidence

Introduction

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. Individuals with co-occurring substance use disorders and/or mental illness with complaints of chronic pain are at a higher risk for opioid misuse and abuse (Sehgal, Manchikanti, & Smith, 2012). This clinic serves a patient population that is known to have a history of aberrant behaviors, physical and/or sexual abuse, psychological illness, and/or a family history of substance abuse (S. Cole, personal communication, April 21, 2017). Of the 3,000 patients that the clinic serves approximately 30% of those them are prescribed opioids for chronic, noncancer related pain complaints (S. Cole, personal communication May 19. 2017). The patient demographic for this clinic includes patients who have low health literacy levels, are of low socioeconomic status, are insured by Medicaid and/or Medicare, have a history of psychological illness, have complaints of chronic pain, have history a of substance abuse disorders, and have a familial history of substance abuse (S. Cole, personal communication May 19, 2017). Such patient populations have the potential to be at high risk for opioid misuse and abuse.

Section 3 of this DNP project will depict the practice-focused question, the sources of evidence, as well as analysis and synthesis of the evidence.

Practice – Focused Question

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. The practice-focused question was as follows: "Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?"

The purpose of this Doctor of Nursing Practice project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Currently, providers within the inner-city, ambulatory care clinic, in the northeast of the United States continue to prescribe opioids without first completing a comprehensive opioid risk-assessment on patients with complaints of pain. This is most likely attributed providers lacking knowledge of the evidence-based practice guidelines regarding safe opioid prescribing. According to Chou, Fanciullo, Fine, Miaskowski, Passik, and Russel (2009), predicting the risk of aberrant opioid drug-related behaviors through utilization of an ORAST may help providers develop an opioid treatment plan to include deterring prescribing opioid medications for a patient at high risk for abuse and/or misuse and the amount of rigidity needed to monitor for treatment adherence if opioids are initiated.

Sources of Evidence

The sources of evidence used to address the practice-focused question were the PubMed, Ovid, Medline and the CDC databases. The following keywords were used: *addiction assessment tool* and *compliance*, *predicting aberrant behavior* and *opioids*, and

opioid prescribing. I used Boolean operators AND and OR to optimize the results. The scope of the review included literature sources between 2006 and 2017 as well as primary resources prior to 2010. The strategy utilized to obtain the evidence needed to complete this doctoral project included completing an integrated literature review and critically appraising the strength of evidence to recommend an ORAST to clinic providers. The recommended ORAST was presented to the team. Together with the team a policy was developed based on the needs of the clinic. The ORAST and policy to guide provider use was then presented to and evaluated by the team using the AGREE II Instrument. Team members were then asked to provide a summative evaluation of the DNP student learning leadership within the project.

Systematic Review of the Literature

According to Chou et al. (2009), ORAST can assist in developing an opioid treatment plan that minimizes the risk of long-term opioid dependence and other substance use problems. Additionally, risk stratification can assist in determining the amount of opioid treatment structure in order to monitor the progress of opioid therapy such as opioid agreements and frequency of urine toxicology testing. Opioid risk-assessment screening tools measure potential risk of opioid misuse and abuse through several factors to include history of aberrant behaviors, physical and/or sexual abuse, psychological illnesses, or a family history of substance abuse as the presence of these factors in a patient's life may increase their risk of opioid misuse and abuse (Passik, 2008). According to Passik (2008), prior to prescribing opioids a patient's risk of developing an addiction should be assessed in order for opioid therapy to be effective and

for the provider to be able incorporate this information in an opioid treatment plan. According to Chou et al. (2009), all patients being considered for chronic opioid therapy should be first screened for potential risk of substance misuse and abuse. It is important to consider that every ORAST will not meet the individualized needs of each practice.

Selecting Opioid Risk-Assessment Screening Tool

Selecting an ORAST that is specific to the practice setting and patient demographic is imperative. Factors to consider when selecting an ORAST for a specific practice setting are: how the tool will be administered, the ease of scoring, the amount of time it takes to administer and score, if the tool was validated, and the sensitivity and specificity of the tool. According to Chou et al. (2009), using a validated assessment tool conforms to the standard of care in opioid prescribing, as it is more accurate in the information it provides to the prescribing provider. Patients that have a history of aberrant behaviors, physical and/or sexual abuse, psychological illnesses, or a family history of substance abuse may increase their risk of opioid misuse and/or abuse (Passik, 2008). Choosing an ORAST that assesses for the presence of these factors would also be important in order to make sure that the calculated risk stratification was accurate. Finally, it is important to consider when the ORAST will be utilized. Certain tools are validated for use prior to initiation of prescription opioid medication while others assist in monitoring for adherence after prescription opioid medication has been initiated. For the purpose of this doctoral project I focused on opioid risk-assessment screening tools that can be utilized prior to initiating opioid medications.

Validation, Sensitivity, and Specificity of Opioid Risk Assessment Screening Tools

Choosing an ORAST that has been both validated and has high sensitivity and specificity is essential in order to ensure that information obtained from the ORAST is accurate and can be relied obtain by the prescribing provider. Passik, Kenneth, Kirsch, and Casper (2008), completed a comprehensive literature review in the Pubmed database in 2016 using the search terms *opioid* and *screening* or *assessment* with or without the additional terms *risk* and *opioid-related disorders/prevention* and *control* in order to review and critique various opioid risk-assessment screening tools available to pain clinicians for assessment of opioid misuse and abuse in patients with chronic, noncancer pain. 43 publications were selected to review. According to Passik, Kenneth, Kirsch, and Casper (2008), 19 of the 43 publications were rejected because the specific tool was not adequately described. The study concluded that there are a variety of patient administered and provider administered opioid risk-assessment screening tools, however not all of them have been validated for use in patients with chronic pain. This is important as failing to use a tool that is validated within the specific population that it will be used in may change the reliability of the tool. Using a tool that is not validated within a specific population may not adequately identify a patient that is at risk for opioid misuse and/or abuse. According Passik, Kenneth, Kirsch, and Casper (2008), the tools that maybe viable for assessing opioid abuse risk potential prior to initiating opioids are the Screener and Opioid Assessment for Patients with Pain (SOAPP), The Diagnosis, Intractability, Risk, Efficiency (DIRE), and the Opioid Risk Tool (ORT). Each tool has been validated as an opioid risk-assessment screening tools for patients with complaints of pain.

Additionally, clinicians should recognize the psychometric and other features of each ORAST in order to select the ORAST that best suits their patient population. In other words, the ability of the ORAST to account for history of sexual abuse or psychological illness is important as those factor may increase the potential risk of a person to misuse and/or abuse opioid medications. The strengths of the study completed by Passik et al. (2008), include the study design, as it is a comprehensive meta-analysis literature review. The limitations of the study include that no prospective criteria was used to assess the strength of the study design, and article selection was subjective in nature.

Selecting an ORAST that is validated for the patient population it will be utilized within, as well as selecting an ORAST that is of high sensitivity and specificity is important; an ORAST is more reliable if it has higher probability of obtaining accurate information through screening. Butler. Fernandez, Benoit, Budman, and Jamison (2008), completed a prospective study with the purpose of validating an empirically derived version of the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R) that addresses some limitations of the Screener and Opioid Assessment for Patients with Pain (SOAPP). 85 patients were recruited from an urban-based pain clinic in the Boston area. All participants were in treatment for chronic noncancer related pain and on a long-term opioid treatment. The participants completed a beta version of the SOAPP-R. At follow-up, a researcher conducted a semi-structured interview and collected urine specimens. The study concluded that the SOAPP-R had adequate sensitivity (.81) and specificity (0.68) in predicting risk potential for aberrant behavior, which is in improvement from the SOAPP. Additionally, the study summarized that the SOAPP-R

has the potential to provide clinicians with the ability to be more aware of patients who are at risk for aberrant behaviors and may require more stringent adherence monitoring. The limitations of this study include the sampling was of convenience. Additionally, patients included in the study were already on opioid medications. A strength of the study was that of the participants that volunteered to participate, a randomly selected group was asked to complete the beta version of the SOAPP-R to determine retest-reliability.

Jones, Moore, Levy, Daffron, Browder, Allen, and Passik (2012), completed two studies on opioid risk-assessment screening tools. The first was a comparative study with the purpose of comparing different opioid risk-assessment screening tools and their ability to predict patient discharge from opioid treatment within a pain clinic. A sample of 132 patients who were patients within a pain clinic in Knoxville Tennessee participated. Patients were 18 years of age or older, and had their opioid prescription medications discontinued due to aberrant behavior. Between February 2008 and February 2009 each of the participants completed four different opioid risk-assessment screening tools that included, a clinic interview with a psychologist, the SOAPP-R, the PMQ, and the ORT. The study concluded that the risk rating of a clinical psychologist was the most sensitive predictor of discharge (43%). The SOAPP-R identified 32% of patients discharged, PMQ 22%, and the ORT 10%. The limitations of this study include, only the measure of sensitivity was assessed for which comprises one-half of the clinical picture as specificity was not measured. Additionally, all participants were already discontinued from opioid management due to aberrant behaviors. The strengths of the study included

that it identified the importance of selecting opioid risk assessment-screening tools based on both sensitivity and specificity.

The second study that was completed by Jones, Moore, Levy, Daffron, Browder, Allen, and Passik (2012), was a prospective study that collected data amongst patients who presented to a psychologist located in a pain practice in Knoxville, Tennessee between September 2007 and May 2008. All patients were referred by pain consultants in Tennessee for risk assessment prior to initiation of opioids for chronic pain. Opioid risk-assessment screening tools included a semi- structured clinical interview, the SOAPP-R, the ORT, and the PMQ. The study concluded the sensitivity and specificity of each ORAST had the following sensitivity and specificity in regards to predicting aberrant behavior. The ORT had 17.6% sensitivity and 88.1 % specificity; the PMQ had 35.8% sensitivity and 78.1% specificity; the SOAPP-R had 41.4% sensitivity and 71.0% specificity; Psychologist One had 69.2% sensitivity and 62.2% specificity; and Psychologist Two had 16.7% sensitivity and 83.3% specificity. One strength of the study was the participants were reflective of the population of the region. An additional strength of the study was that six months after the initial opioid risk-assessment screenings were completed, information was gathered about each patient's treatment plan and status to verify accuracy of each opioid risk-assessment screening tools ability to predict risk for aberrant behavior.

Belgrade, Schamber, and Lindgren (2006), completed a retrospective study to test the validity and reliability the DIRE tool. DIRE scores were assigned to 61 cases from a pain center's database. The cases were then abstracted into vignettes that were reviewed

and scored by six physicians. Repeat scoring was then completed for 30 additional vignettes two weeks later. The study concluded that the internal consistency of the DIRE tool was high (Cronbach's alpha = .80); sensitivity was 94% and specificity was 87% with an intra class correlation of 0.94 and an interrater reliability of 0.95. Finally, it was concluded the implementing the DIRE tool would take providers 102 seconds to carry out and score. A limitation of the study was its design as it was retrospective. A strength of the study was the physicians completing the DIRE assessment of the vignettes were all primary care providers.

Barriers to Implementing an Opioid Risk-Assessment Tool

Recently, the use of opioid medications for noncancer related pain have been associated with a heightened stigma as there has been an increase in opioid misuse, abuse, dependence, addiction, and deaths. According to Belgrade, Scamber, and Lindgren (2006), providers that treat patients with chronic, noncancer related pain need to be strategic in determining which patients would be most compliant with the opioid prescribing process as well as what patients would benefit from opioid management. According to Shapiro, Coffa, and McCance-Katz (2013), more than 20% percent of primary care providers described themselves as ill prepared to identify substance abuse within their outpatient populations. According to Passik, Kirsh, and Casper (2008), the use of an ORAST allows individual patients to be screened for risk of opioid misuse and/or abuse so their risk stratification can be incorporated in their treatment plan by their providers. The following barriers to utilizing an ORAST prior to initiating opioid management have been identified.

- Until recently, few tools were validated for assessment of opioid related risks for patients with complaints of pain being considered for opioid management (Passik, Kirsh, & Casper, 2008).
- Many clinicians struggle to find an ORAST that they can incorporate into their practice setting and medical record keeping (Passik, Kirsh, & Casper, 2008).
- There is a lack of training in substance abuse amongst primary care providers (Hahn, 2011).
- Providers are often unsure which ORAST is most appropriate for their patient population and screening needs (Passik, Kirsh, & Casper, 2008).
- Not all opioid risk-assessment screening tools have been validated to be used to assess for misuse and/or abuse potential in patients prior to initiating opioid therapies (Passik, Kirsh, & Casper, 2008).

The providers in an inner-city ambulatory care do not consistently assess for potential risk of opioid misuse and abuse prior to initiating prescription opioids medications to patients with complaints of pain. The providers within the clinic are faced with many barriers in selecting and implementing an ORAST in their practice setting. Many of the providers have little to no training in pain management. Additionally, there is a knowledge deficit amongst providers within the clinic in regards to the opioid risk-assessment screening tools that are available and what the benefits and limitations are of each ORAST. Ultimately, the providers within the clinic are looking for an ORAST that is validated in patients with complaints of pain, has a high degree of sensitivity and

specificity, can be self administered by the patient, it easy to administer and score, identifies co-existing substance abuse and mental illness conditions and would take less than two minutes to administer and score so it does not impede workflow.

In completing a comprehensive literature review, I was able to select an ORAST that would best suit the needs of their clinic. The recommended ORAST was presented to the team. Together with the team a policy was developed based on the needs of the clinic. The ORAST and policy to guide provider use was then presented to and evaluated by the team using the AGREE II Instrument. Team members were then asked to provide a summative evaluation of the DNP student learning leadership within the project.

Opioid Risk-Assessment Screening Tools

Four opioid risk-assessment screening tools were analyzed for the purpose of this doctoral nursing project were The Opioid Risk Tool (ORT), The Screening Instrument for Substance Abuse Potential (SISAP), The Screener and Opioid Assessment for Patients with Pain – Revised (SOAPP-R), and the Diagnosis, Intractability, Risk, Efficacy (DIRE). These opioid risk-assessment screening tools were analyzed because they were the only validated opioid risk-assessment screening tools recommended for use prior to initiating opioid management in an outpatient setting. Opioid risk-assessment screening tools that were validated to be used after opioid management is initiated by were excluded. Evidence-based practice guidelines recommend patients with complaints of pain to be screened for potential opioid misuse and/or abuse prior to initiating prescription opioid medications (Passik, Kirsh, & Casper, 2008). Benefits and limitations of each ORAST were analyzed in terms of sensitivity, sensitivity, reliability application

to the practice setting and population, psychometrics of the tool, and the time to administer and score.

Opioid Risk Tool

The Opioid Risk Tool (ORT) provides excellent discrimination between high risk and low risk of aberrant behaviors in patients prior to them being prescribed opioid medications (Passik, 2008). The ORT consists of five items, which include family history of substance abuse, personal history of substance abuse, age, history of preadolescent sexual abuse, and psychological abuse. Scoring for males is separated from females. A cumulative score of three or lower indicated low risk for future opioid risk, while a score of four to seven indicates moderate risk, and a score of eight or higher indicates high risk. This is a patient administered tool, intended for a primary care setting, and takes less that one minute to administer and score. The ORT has "exhibited a high degree of sensitivity and specificity for determining which individuals are at a high risk for opioid abuse" (Webster & Webster, 2005).

Advantages. The advantages of the ORT are as follows.

- The ORT utilizes brief and simple scoring that is validated in pain populations (Passik et al, 2008).
- The ORT is developed specifically for pain patients (Butler, 2008).
- Providers excellent discrimination from patients at low risk versus high risk (Passik et al., 2008).
- The ORT takes less than one minute to administer and score.
- Identifies co-existing mental health conditions.

- Identifies co-existing substance abuse conditions.
- Scoring is gender specific.

Limitations. The limitations of the ORT are as follows.

- The question regarding family history of substance abuse is dependent on the patient's knowledge of family history of substance abuse (Passik et al., 2008).
- The ORT is a self-reporting tool. Therefore scoring is dependent on the patient's degree of honesty.

The Screening Instrument for Substance Abuse Potential

According to Coambs, Larry, Santhiapillai, Abrahamsohn, and Atance (1996), the Screening Instrument for Substance Abuse Potential (SISAP) is an ORAST to assess patients with a substance abuse history as well as a high risk for opioid abuse and/or dependency. The SISAP has a good specificity, a good sensitivity, high correct classification rate, and a low incidence rate of misses (Coambs et al., 1996). The tool is based on five items, takes less than one minute to administer and score, is administered by means of interviewing the patient, and is intended for a primary care setting. The SISAP questions include:

1. If you drink alcohol, how many drinks do you drink on a typical day?
2. How many drinks do you have in a typical week?
3. Have you used marijuana or hashish in the past year?
4. Have you ever smoked cigarettes?
5. What is your age?

Based on the scoring of the SISAP, it is recommended that caution be used when prescribing opioids to patients who meet the following criterion.

- Men who drink more than four alcoholic beverages per day or 16 per week.
- Woman who drink more than three alcoholic beverages per day or 12 per week.
- Persons who admit to recreational use of marijuana or hashish in the previous year.
- Persons whom are younger than 40 years of age and smoke.

Advantages. The advantages of the SISAP are as follows.

- The SISAP has been found to have a high sensitivity and specificity in assisting primary care providers in determining if a patient receiving opioids is at risk for opioid misuse and/or abuse (Passik, Kirsh, & Casper, 2008).
- The SISAP was developed specifically for primary care providers to use within their clinical practice (Passik, Kirsh, & Casper, 2008).
- The SISAP differentiates between alcohol and drug risk (Butler, 2008).
- The SISAP takes less than one minute to administer and score.

Limitations. The limitations of the SISAP are as follows.

- The SISAP has not been validated in pain patients (Passik et al., 2008).
- The SISAP does not identify co-existing mental health conditions.

The Screener and Opioid Assessment for Patients with Pain – Revised

According to Butler et al. (2008), the Screener and Opioid Assessment for Patients with Pain – Revised (SOAPP- R) is an ORAST that predicts the possibility of opioid misuse and/or abuse in patients with complaints of chronic pain. The SOAPP-R

consists of 24 items that respondents can answer (0) –Never, (1) – Seldom, (2) – Sometimes, (3) – Often, and (4) Very Often. A provider scores the SOAPP-R by calculating the cumulative scores of questions 2, 7, 10, 11, 12, 13, 15, 17, 18,19, 20, 23, and 24. A cumulative score of seven or higher indicates the patient is high risk for opioid misuse and/or abuse. The SOAPP-R takes approximately five minutes to administer and score, is intended for a primary care setting, and is administered by means of a self-reporting questionnaire. According to Passik et al. (2008), the SOAPP-R is excellent in deciphering the difference between high risk and low risk patients.

1. How often do you have mood swings?
2. How often have you felt a need for higher doses of medication to treat your pain?
3. How often have you felt impatient with your doctors?
4. How often have you felt that things are just too overwhelming that you cannot handle them?
5. How often is there tension in the home?
6. How often have you counted pain pills to see how many are remaining?
7. How often have you been concerned that people will judge you for taking pain medication?
8. How often do you feel bored?
9. How often have you taken more pain medication than you were supposed to?
10. How often have you been worried about being left alone?
11. How often have you felt a craving for medication?

12. How often have others expressed concern over your use of medication?
13. How often have any of your close friends had a problem with alcohol or drugs?
14. How often have others told you that you had a bad temper?
15. How often have you felt consumed by the need to get pain medication?
16. How often have you run out of pain medication early?
17. How often have others kept you from getting what you deserve?
18. How often, in your lifetime have you had legal problems or been arrested?
19. How often have you attended an AA or NA meeting?
20. How often have you been in an argument that was so out of control that someone got hurt?
21. How often have you been sexually abused?
22. How often have others suggested that you have a drug or alcohol problem?
23. How often have you had to borrow pain medications from your family or friends?
24. How often have you been treated for an alcohol or drug problem?

Advantages. The advantages of the SOAPP-R are as follows.

- The SOAPP-R is easily understood by patients (Butler et al., 2008).
- The SOAPP-R was developed specifically for patients with complaints of pain.
- The SOAPP-R is less susceptible for patient deception in comparison to the original SOAPP.

- Best psychometrics of any measure designed to predict aberrant behavior before opioid therapy is begun (Passik et al., 2008).

Limitations. The limitations of the SOAPP-R are as follows.

- The SOAPP-R is less sensitive and less specific to the original SOAPP (Butler et al., 2008).
- Briefer tools than the SOAPP-R may be preferred by providers (Passik et al., 2008).
- The SOAPP-R has 24 items and takes five minutes to administer and score.
- The SOAPP-R is a self-reporting tool. Therefore scoring is dependent on the patient's degree of honesty.

The Diagnosis, Intractability, Risk, Efficacy

The Diagnosis, Intractability, Risk, Efficacy (DIRE) is an ORAST for patients that are potential candidates for long-term opioid management. This tool intended for primary care settings and is comprised of seven items, which are collected by means of a patient interview. It takes less than two minutes to administer and score. According to Passik et al. (2008), the DIRE has been validated by six experts studying patient case vignettes. Additionally, the DIRE has been found to have high internal consistency, sensitivity, efficacy, and specificity (Belgrade, Schamber, Lindgren, 2006). The factors that are included in the DIRE scoring include: diagnosis, intractability, psychological, chemical health, reliability, social support, and efficacy score. A score of seven through thirteen is interpreted, as the patient may not be a suitable candidate for long-term

analgesics. A score of 14 through 21 suggests that the patient may be a candidate for long-term analgesics.

Advantages. The advantages of the DIRE are as follows.

- The DIRE has been specifically designed for primary care use (Passik et al., 2008).
- A patient's DIRE score correlates well with patient compliance and efficacy of long-term opioid treatment (Belgrade, Schamber, Lindgren, 2006).
- The DIRE has been found to be a rapid assessment tool that is both valid and reliable in selecting patients for long-term opioid analgesic management (Belgrade, Schamber, Lindgren, 2006).
- The DIRE takes less than two minutes to administer and score.

Limitations. The limitations of the DIRE are as follows.

- Prospective validation is needed (Passik et al., 2008).

Recommended Guidelines for the Treatment of Chronic Pain

According to the CDC (2016) recommended guidelines for the treatment of chronic pain include:

- Use non-opioid therapies to the extend possible.
- Assess risk and address harms of opioid use and when to initiate opioid medications.
- Identify and address co-existing mental health conditions.
- Focus on functional goals and improving, engaging patients actively in their pain management.

- Use disease-specific treatments when available.
- Use first-line medication options preferably.
- Consider interventional therapies in patients who fail standard non-invasive therapies.
- Use multimodal approaches, including interdisciplinary rehabilitation for patients who have failed standard treatments, have severe functional deficits, or psychological risk factors.

The purpose of the recommended guidelines to treat chronic pain is to limit prescription opioid misuse, abuse, addiction, dependence, and exposure (CDC, 2017). Using alternative treatment modalities for pain and reserving opioid medications for when other treatment options fail is the best approach to pain management (CDC, 2017). Prior to initiating opioid medications an opioid risk-assessment should be completed to assess for the risk of opioid misuse and abuse. Selecting an ORAST that meets the specific needs of the clinic is imperative in order to make positive social change. According to Sehgal, Manchikanti, and Smith (2012), individuals with complaints of chronic pain and co-occurring substance abuse disorders, and/or mental illness are at a higher risk for opioid misuse and abuse. This clinic serves a patient population that is known to have a history of aberrant behaviors, physical and/or sexual abuse, psychological illness, and/or a family history of substance abuse (S. Cole, personal communication, April 21,2017). The providers within the clinic need an ORAST that is validated in patients with complaints of pain, has a high degree of sensitivity and specificity, can be self administered by the patient versus provider administered, is easy

for patients to comprehend, is simple for providers to score, identifies co-existing substance abuse and mental illness conditions and would take less than two minutes to administer and score so it does not impede workflow.

Recommending an Opioid Risk-Assessment Screening Tool

The purpose of this DNP project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Currently, providers within the inner-city, ambulatory care clinic, in the northeast of the United States continue to prescribe opioids without first completing a comprehensive opioid risk-assessment on patients with complaints of pain.

The providers within the clinic need an ORAST that is validated in patients with complaints of pain and has a high degree or sensitivity and specificity (S. Cole, personal communication May 19, 2017). According to Passik, Kirsh, and Casper (2008), until recently few opioid risk-assessment screening tools were validated for opioid related risks for patients being considered for opioid management. Failing to use an ORAST that is validated or does not have a high degree of sensitivity and specificity can calculate potentially inaccurate results. Additionally, the clinic needs an ORAST that can completed by the patient, is easily scored by the provider and would take less than two minutes to administer and score so it does not impede workflow (S. Cole, personal communication May 19, 2017). According to Passik, Kirsch, and Casper (2008), finding an ORAST that can be incorporated into a practice setting is a struggle for many clinicians. With limited resources, to include limited staffing, it was important to find an ORAST that would not disrupt workflow otherwise there may be an increased potential

for decreased adherence amongst providers using the selected ORAST and the policy formulated to guide its use. Finally, this inner-ambulatory clinic has a serves a patient population that is known to have co-occurring substance use disorders and mental illness (S. Cole, personal communication May 19, 2017). Therefore it is important for the selected ORAST to identify co-existing substance abuse and mental illness conditions. According to Sehgal, Manchikanti, and Smith (2012), individuals with complaints of pain and have co-occuring substance use disorders and/or mental illness are at a higher risk for opioid misuse and abuse. Failing to have an ORAST that appropriately screens the specific patient demographic of this inner-city ambulatory clinic for the potential risk of opioid misuse and abuse may not allow for providers to accurately determine the potential risk for opioid misuse and abuse. Ultimately this may put the patient at increased risk if the provider prescribes a patient opioids without factoring in the impact of either co-occuring substance abuse disorders or mental illness on the patient's potential risk for opioid misuse and abuse. Based on the needs of the clinic the following inclusion and exclusion criteria were identified for an ORAST.

Inclusion Criteria

- Can be utilized prior to initiating prescription opioid medications
- Is validated in patients with complaints of pain
- Has a high degree of sensitivity and specificity
- Can be self administered by the patient
- Can be easily scored by the provider
- Take less than two minutes to administer and score

- Identifies co-existing substance abuse and mental illness conditions

Exclusion Criteria

- Can not be utilized prior to initiating prescription opioid medications
- Is not validated in patients with complaints of pain
- Does not have a high degree of sensitivity and specificity
- Cannot be self administered by the patient
- Cannot be easily scored by the provider
- Take greater than two minutes to administer and score
- Does not identify co-existing substance abuse and mental illness conditions

Eliminated opioid risk-assessment screening tools. After critically reviewing and appraising the literature, and the inclusion and exclusion criteria of an ORAST based on the needs of the clinic, it was determined that the SISAP, DIRE, and SOAPP-R would not be the best fit for the clinic or meet the providers' needs. The SOAPP-R was eliminated, as it is a 24-item tool, requiring five minutes to be completed by the patient and scored by the provider. This would be time consuming, potentially hinder workflow, and be less likely to be successfully implemented into practice. Additionally, it has been found to be less specific and have less sensitivity then the original SOAPP (Passik et al., 2008). The DIRE was eliminated as it lacked prospective validation (Passik et al., 2008). Failing to use a validated tool may not allow for accurate information to be obtained. Providers need to be assured that they can rely on the information obtained from the selected ORAST so they can feel confident in the individualized plan of care they are developing specific to prescription opioid medications. The SISAP was eliminated

because it does not assess for co-existing mental health conditions. This inner-city clinic serves a large mental health patient population. Additionally, mental health illnesses have been found to increase the potential risk of opioid misuse and/or abuse (Passik et al., 2008). Finally, the SISAP was not validated in patients with complaints of pain.

Opioid risk-assessment screening tool to be recommended. The Opioid Risk Tool (ORT) is the most appropriate ORAST for this ambulatory outpatient clinic because it will meet the needs of the clinic and provides an assessment that will meet the recommendation from the CDC (.2016). My recommendation of selecting the ORT was presented to the DNP project team for their review and input after IRB approval was obtained. The ORT provides excellent discrimination between patients at high risk versus low risk for opioid misuse and/or abuse prior to initiating opioids (Passik et al., 2008). This clinic serves a patient population that is known to have a history of aberrant behaviors, physical and/or sexual abuse, psychological illness, and/or family history of substance abuse (S. Cole, personal communication, April 21,2017). The ORT consists of five items, which include family history of substance abuse, personal history of substance abuse, age, history of preadolescent sexual abuse, and psychological abuse. The ORT will allow for patients that have history of psychological illness, physical or sexual abuse, and substance abuse history to be appropriately screened for risk of opioid misuse and abuse. Additionally, the ORT takes less than one minute to be completed by the patient and scored by the provider, and has been validated in patients with complaints of pain (Passik et al., 2008). The use of the ORT should not impede provider workflow, and may help to

ensure the information collected from the ORT is accurate. As a result, the providers may feel more confident in relying on the selected ORAST.

Ethical Considerations

Ethics approval was requested from the Walden Institutional Review Board (08-04-17-0386824), which included the pre-approved site Agreement and the Disclosure to Expert Panelist Form for Anonymous Questionnaires. Names of partner organizations were changed, geographic location generalized, and data was not collected from patients or patients' family members. It was ensured that no proprietary, sensitive or confidential information was disclosed in this doctoral project document, and all organization's policies were complied with. Based on the IRB requirements all data collected for this DNP project, each team members anonymously completed AGREE II Instrument and summative evaluation, will be stored in a locked cabinet for five years.

Analysis and Synthesis

This DNP project plan used a Plan-Do-Study-Act (PDSA) approach to complete an integrated literature review on pain management with critical appraisal of the strength of the evidence. An appropriate ORAST was identified as a part of the initial literature review and was then recommended to the project team after obtaining Walden IRB and site approval. The DNP project team consisted of the medical director and one resident from each of the 10 primary care teams. The team was convened to study and analyze the evidence from the literature on the four opioid risk-assessment screening tools based on the inclusion and exclusion criteria that was previously identified. The project team then developed a policy to guide the use of the selected ORAST within the clinic. Team

members were then asked to complete the AGREE II Instrument and provide a summative evaluation of the DNP student's leadership in project planning and implementation. Prior to making this request all team members were provided the Disclosure to Expert Panelist Form for Anonymous Questionnaires (Appendix B), a complete Opioid Risk Tool (Appendix A), and a detailed explanation of the AGREE II Instrument.

Summary

Section 3 restated the problem and purpose for this DNP project, as well as depicted the practice – focused question, sources of evidence, and the methodologies that would be utilized to analysis and synthesize the data that will be obtained. Section 4 will report the findings and implications of the data, describe proposed recommendations, summarize the contribution of the Doctoral project team, and discuss the strengths and weaknesses of the project.

Section 4: Findings and Recommendations

The practice problem in this DNP project was that providers failed to consistently assess patients with complaints of pain for risk of opioid misuse and/or abuse prior to initiating opioid medication. The practice-focused question was as follows: "Will the introduction of an opioid risk-assessment screening tool and the policy to guide provider use help in identifying patients at risk for opioid misuse and/or abuse?"

The purpose of this DNP project was to identify and introduce an ORAST and then develop a policy to guide providers in its use in an ambulatory care clinic. Currently, providers within the inner-city, ambulatory care clinic, in the northeast of the United States continue to prescribe opioids without first completing a comprehensive opioid risk-assessment on patients with complaints of pain.

The sources of evidence used to address the practice-focused question were the PubMed, Ovid, Medline and the CDC databases. The following keywords were used: *addiction assessment tool* and *compliance*, *predicting aberrant behavior* and *opioids*, and *opioid prescribing*. I used Boolean operators AND and OR to optimize the results. The scope of the review included literature sources between 2006 and 2017 as well as primary resources prior to 2010. The strategy utilized to obtain the evidence needed to complete this doctoral project included completing an integrated literature review and critically appraising the strength of evidence to recommend an ORAST to clinic providers. The recommended ORAST was presented to the team. Together with the team a policy was developed based on the needs of the clinic. The ORAST and policy to guide provider use was then presented to and evaluated by the team using the AGREE II Instrument. Team

members were then asked to provide a summative evaluation of the DNP student learning leadership within the project.

Doctoral Project Team

The doctoral project team included the stakeholders that have been identified for the doctoral project. The stakeholders that were selected for the purpose of this DNP quality improvement project were the medical director and one resident from each of the primary care teams. The medical director selected one resident from each of the 10 primary care teams. Stakeholder criteria for selection included availability to attend all meetings, provide feedback on the selected ORAST and the developed policy guiding its use, and the willingness to serve as a positive social change agent within the clinic. In total there were 11 stakeholder team members. The residents were notified about this doctoral project and requested to participate by the medical director. All 11 team members participated by attending two round table discussions that were held in the resident conference room. All 11 team members voted and completed an AGREE II Instrument and summative evaluation.

Stakeholder Process and Policy Development

The stakeholder team included the medical direct and one resident from each of the ten primary care teams (n =11). The residents were asked to participate by the medical director. All 11 team members participated by attending two round table discussions. During the first discussion my recommendations and the information obtained from my comprehensive literature review, which included recommended guidelines for opioid medications were presented to the stakeholder team to include a

presentation of each of the four opioid risk-assessment screening tools. The stakeholder team discussed the information presented to include what they felt the pros and cons were of each ORAST and how ORAST would help or hinder their present practice. The consensus of the team was the SOAPP-R was too long and would not be feasibly implemented into their daily practice. Additionally, the DIRE did not make the team feel like they could rely on the tool as it lacked prospective validation. In terms of the SISAP, the team was concerned that it did not assess for co-existing mental health conditions especially since a large percentage of their patient population has mental illness, and the literature has suggested that mental illness can increase risk for opioid misuse and abuse. Finally, the team consensus in regards to the ORT was it seemed to be the best fit for their present patient population and workflow because it was quick to administer and score, was accurate, and screened for mental illness. Thereafter, my recommendation of the Opioid Risk Tool (ORT) as being the most appropriate ORAST for this clinic was voted upon by all team members, and policy guiding the use of the ORT began to be created with all 11 team members. Voting was done by simply going around the table and having each member say “yes” they agreed or “no” they did not. There was no anonymity in the voting process. This was identified as a limitation of the DNP project, which will be later discussed.

Collaborating amongst team members to formulate the policy to guide the use of the ORT was done in open dialogue using the domains of the AGREE II Instrument as structure to guide the conversation and CDC guidelines to inform the policy structure. All stakeholders spoke openly about their interpretation of the information presented as well

their opinions, experiences, and perspectives interchangeable until a consensus was reached on the policy to define the use of the ORT in the clinic. The medical director, as part of the project team, participated fully in this process with the rest of the team members. Given his role within the clinic he served as an expert in policy content. The medical director's interactions with the group appeared to be very supportive and not authoritative. There did not appear to be any bias from the group due to his presence.

I took notes throughout the meeting as a means to document team communication on points to be included in the policy. The notes revealed that the stakeholder team wanted a policy that required the ORT to be utilized prior to initiating any/all opioid medication amongst the residents for patients with complaints of pain. Additionally, notes indicated that the stakeholder team wanted a policy that allowed for greater learning opportunities regarding pain management than the clinic presently offered. Overall the team felt that their knowledge about prescription opioid medications and pain management was lacking and there was little opportunity to improve. The team believed that a policy requiring the residents to discuss the plan of care with their attending would facilitate an opportunity for them to develop their knowledge base on pain management and prescribing opioid medications. Thirdly the stakeholder team liked how the ORT scored patients as low, moderate, or high risk for opioid misuse and/or abuse but they did not want a policy to dictate the care that was provided solely based on risk assessment. Instead they wanted to be able to have a policy that allowed for the information obtained from the ORT to be presented by residents to their attending so together a comprehensive plan of care based on recommended guidelines could be created, documented, and

implemented. Based on the stakeholder meeting, I composed a formal policy to recommend to the team that would guide the use of the ORT (Appendix E).

During the second round table discussion the final policy based on the stakeholder team's input was presented to the all 11 members of the stakeholder team for the review and feedback. All 11 team members were asked to anonymously complete the AGREE II Instrument (Appendix C) and summative evaluation (Appendix D). Prior to this request all team members were provided the Disclosure to Expert Panelist Form for Anonymous Questionnaires (Appendix B), a complete Opioid Risk Tool (Appendix A), and detailed explanation of the AGREE II Instrument. I then utilized simple descriptive statistics to determine what percentage of the stakeholder team rated each of the domains in the AGREE II Instrument (Table 1) and each of the items in the summative evaluation (Table 2). The stakeholders' completed summative evaluation and the AGREE II Instrument were kept anonymous and placed in an envelope after their completion. Evaluation of the results did not take place until after the meeting. None of the team members filled out any of the comment sections in the AGREE II Instrument. So in areas that were rated as *mostly agree* or *strongly agree* on the AGREE II Instrument, or *agree* versus *strongly agree* on the summative evaluation there was no ability for recommendations to be reviewed and incorporated into further revisions. The medical director will be the end decision maker as to whether the selected ORAST and policy developed will be implemented in the clinic setting. Implementation of the selected ORAST and the policy guiding provider use will not be completed until after graduation.

Findings and Implications

The finding of this DNP project in regards to the results of the AGREE II Instrument and summative evaluation will now be discussed. The implications of the project results, including the potential for social change, the strengths and limitations of the project, and future recommendations will be identified.

Appraisal of Guidelines Research and Evaluation (AGREE) II Instrument

According to Walden University (2017), the Appraisal of Guidelines Research and Evaluation (AGREE) II Instrument provides the framework that can be utilized by the DNP to develop clinical practice guidelines and to assess the quality of the guidelines developed. Each member of the stakeholder team (n = 11) was asked to use the AGREE II Instrument (Appendix C) to assess the quality of the evidence of the policy used to formulate the recommendation. The According to the Agree Resource Trust (2013), the AGREE II Instrument is comprised of 23 items which are organized into seven domains. Additionally, there are two global rating items. The seven domains include:

- Scope and Purpose
- Stakeholder Involvement
- Rigor of Development
- Clarity of Presentation
- Applicability
- Editorial Independence
- Overall Guideline Assessment

Scope and Practice assures that the overall objectives of the guidelines, the health questions, and the population to whom the guideline is meant to apply to were specifically described (AGREE, 2013). *Stakeholder Involvement* evaluates the involvement of relevant professional groups in the development of the guideline, if the views and preferences of the target population have been sought, and if the target users of the guideline were are clearly defined (AGREE, 2013). *Rigor of Development* evaluates the details presenting regarding the strategy used to search for evidence (AGREE, 2013). This includes assessing if the methods for formulating the recommendations were clearly described. *Clarify of Presentation* reflects the clear and concise description of the policy (AGREE, 2013). *Applicability* accounts for the degree in which the guideline provides advice on how the recommendation should be put into practice (AGREE, 2013). Finally, *Editorial Independence* assures that the guidelines were not influenced by external interests (AGREE, 2013). The *Overall Guideline Assessment* refers to the overall rated quality of the guideline and recommendations for use (AGREE, 2013).

The AGREE II Instrument uses rates each of the domain on a seven-point scale as 1 = *strongly disagree*, 2 = *moderately disagree*, 3= *disagree*, 4 = *neither agree nor disagree*, 5 = *agree*, 6 *moderately agree*, and 7 = *strongly agree* (Agree Resource Trust, 2013). All 11 team members were asked to complete the AGREE II Instrument (Appendix C) and summative evaluation (Appendix D).

The results of the AGREE II Instrument are summarized in Table 1. Implementation of the ORT and the policy to guide its use will occur after graduation.

Table 1.

Results of AGREE II Instrument

Domain	Agree %	Moderately Agree %	Strongly Agree %
1. Scope and practice	0	36	64
2. Stakeholder involvement	9	55	36
3. Rigor of development	0	45	55
4. Clarity of presentation	0	18	82
5. Applicability	0	18	82
6. Editorial independence	0	9	91

Overall the team agreed on the appropriateness of the components included in the policy and procedure and supporting evidence, and expressed that they felt the policy should be implemented into their practice setting. Simple descriptive statistics were utilized to calculate what percentage of the group rated each domain on the seven-point Likert scale. While 64% of the team members *strongly agreed* on *Scope and Practice* of the policy and procedure, 36% responded *moderately agree*. 36% of the team responded that they *strongly-agreed* on *Stakeholder Involvement* while 55% *moderately agreed* and 9% *agreed*. Thirdly, 35% of the team responded that they *strongly-agreed* on *Rigor and Development,* while 45% *moderately-agreed*. In regards to *Clarity and Presentation* 82% of the team responded that they *strongly-agreed* while 18% *moderately-agreed*. In terms of *Applicability* 82% of the team responded that they *strongly-agreed* while 18% *moderately-agreed*. Finally, 91% of the team *strongly-agreed* while 18% *moderately-*

agreed on *Editorial Independence.* As none of the 11 participants wrote on comments on the AGREE II Instrument that was collected, and responses were kept anonymous I was unable to summarize the variability in rating amongst the team as none of the participants commented on the AGREE II Instrument that was collected. This was seen as a limitation of this doctoral project. Overall all 11 team members scored all domains within the AGREE II Instrument as either *Strongly Agree* or *Moderately Agree.* This concludes that the proposed policy developed with the team guiding the residents' use of the ORT can be recommended for use in practice

Summative Evaluation of DNP

The DNP project team also completed a summative evaluation. The summative evaluation was comprised of 11 items. Each of the 11 items was rated on a five-point scale where five was *strongly agree* to one-*strongly disagree* by each of the DNP project team members. The results of the summative evaluation are summarized in Table 2.

Table 2.

Results of Summative Evaluation

Evaluation Statement	Agree %	Strongly Agree%
1. The selected opioid risk-assessment screening tool is relevant to clinical practice.	36	64
2. The stated problem, purpose and objectives of the DNP project were clearly defined.	36	64
3. Project team members were involved in the policy development and procedure for the use of the Opioid Risk Tool.	36	64

4. Communication was effective regarding policy and procedure development.	36	64
5. The patients that should be screened for risk of prescription opioid misuse and/or abuse using the Opioid Risk Tool were clearly defined.	18	82
6. The recommendations for implementing a practice change by adapting the Opioid Risk Tool are clear and unambiguous.	18	82
7. The policy and procedure will improve patient care.	64	36
8. The Opioid Risk Tool will be useful in identifying patients at risk for prescription opioid misuse and/or abuse with complaints of pain.	45	55
9. This information presented in this DNP project increased your knowledge of prescription opioid misuse and abuse risk assessment in patients with complaints of pain.	45	55
10. The DNP student conducted the study with professionalism.	27	73
11. The DNP student demonstrated leadership skill throughout the process.	9	91

Simple descriptive statistics were utilized to calculate what percentage of the group rated each of the 11 on a five -point Likert scale. All 11 team members participated. Overall team members recommended implementing the policy into clinical practice. The results

of the summative evaluation reflected that DNP project goals were met and that I lead this DNP project with leadership skills throughout the process. 64% of the team responded that *strongly agree* that the selected ORAST was relevant to clinical practice; the stated problem, purpose and objectives of the DNP project were clearly defined; project team members were involved in the policy development and procedure for the use of the Opioid Risk Tool; and communication was effective regarding policy and procedure development. Of these four items 26% of the team responded *agree*. 82% of the team responded *strongly agree* to the patients that should be screening for risk of prescription opioid misuse and/or abuse using the Opioid Risk Tool was clearly defined, and the recommendation for implementing a practice change by adapting the Opioid Risk Tool was clear and unambiguous. For these two items 18% of the team responded *agree*. 36% of the team responded *strongly agree* to the policy and procedure will improve patient care while 64% responded *agree*. Finally, 55% of the team responded *strongly agree* and 45% responded *agree* to the Opioid Risk Tool would be useful in identifying patients at risk for prescription opioid misuse and/or abuse with complaints of pain. Since the summative evaluation was anonymous and an area for comments was not provided, nor were any left I was unable to determine why some stakeholders responded *agree* versus *strongly agree* to each of the 11 items. This was later seen as a limitation. Overall the results revealed that all 11 participants responded either *agree* or *strongly agree* to each of the 11 items. This concludes that the proposed guidelines can be recommended for use in practice with the support of the stakeholder team.

Potential Implications for Positive Social Change

Through utilization of an ORAST there is a potential implication for positive social change. Implementation of the ORT into this inner-city ambulatory clinic in the northeast has the potential to change prescribing practices with the clinic and create positive social change by allowing for providers to consistently screen patients with complaints of pain for prescription opioid misuse and abuse prior to initiating prescription opioid medications. Provider whom utilize an ORAST prior to initiating prescription opioids have the ability to identify patients that are at risk for prescription opioid misuse and/or abuse. By understanding each patient's risk stratification a plan of care can be developed in order to manage the patient's pain complaints while taking the least amount of risk. For example, a plan of care for patients identified as being at high risk for prescription opioid misuse and/or abuse may include deferring from initiating opioids and trialing alternative therapies, initiating prescription opioids with intensified adherence monitoring, and/or referring to a specialist in pain management. This in turn can assist providers reduce prescription opioid misuse, abuse, exposure, dependence, addiction, opioid related deaths, and the associated economic burden. This can improve the quality and safety of patient care within the clinic amongst patients with complaints of pain.

Strengths and Limitations of the Project

The strengths and limitations of this project were identified. Definite strengths of this DNP project included the enthusiasm and teamwork of the DNP project team, the support of the medical director, and the desire of the residents as a whole to create to

practice change to combat the prescription opioid epidemic. There were several limitations of the project. The implementation of the Opioid Risk Tool (ORT) and the policy guiding its use will not occur until after graduation. The medical director anticipates this to occur in spring of 2018. An additional limitation of this DNP project was the lack of knowledge amongst the residents in regards to current evidence-based guidelines and recommendation in treating pain, prescribing opioids, and the adherence monitoring of prescription opioid medications. According to Nuseir, Kassab, and Almonani (2016), an integral component of effectively diagnosing and managing patients with complaints is a comprehensive understanding of pain management, however providers often reveal a deficit as they are neither knowledgeable nor well educated about pain. In speaking with the DNP project team, the residents reported that their degrees focused very little, if at all on pain and/or pain management and they feel ill prepared to diagnose, treat, and manage patients with complaints of pain both safely and effectively. According to Volkow and McLellan (2016), more than 30% of Americans have some form of either acute of chronic pain. Given the frequency the providers encounter needing to manage pain complaints knowledge continues to be lacking. According to Volkow and McLellan (2016), many physicians admit that they are not confidence in how to safely prescribe opioid medications, how to detect prescription opioid misuse and/or abuse, or how to discuss these problems with their patients. The residents' lack of knowledge may have potentially impacted the development of the DNP project and development of the policy. Another limitation was the absent of anonymity in voting during both round table discussions. It is possible that the residents may have given different responses during

voting and discussions if the medical director was not present. Therefore, potential bias amongst the team in regards to the policy input is possible. Additionally, the participants did not leave any comments on the AGREE II Instrument. This made it impossible to identify why certain team members scored domains differently than others. Finally, it may have beneficial to have an outside pain management expert as part of the stakeholder team however finding a provider who was able to dedicate their time to the DNP project in addition to their professional obligations would have proven challenging.

Recommendations

An ORAST, the Opioid Risk Tool (ORT), was introduced to this inner-city ambulatory care clinic and the policy developed during this project guiding its use will be implemented after graduation. The medical director is very supportive of implementing this practice change, and anticipates being able to do so in spring of 2018. The gap in practice was that, despite guidelines that recommend evaluating risk factors related to opioids prior to the initiation of opioid medication, providers continued to prescribe them without consistently assessing the patients. The Opioid Risk Tool (ORT) has been determined by the stakeholder team and myself to be the most appropriate ORAST for this ambulatory outpatient clinic. Overall the ORT provides excellent discrimination between patients at high risk versus low risk for opioid misuse and/or abuse prior to initiating opioids (Passik et al., 2008). This clinic serves a patient population that is known to have a history of aberrant behaviors, physical and/or sexual abuse, psychological illness, and/or a family history of substance abuse (S. Cole, personal communication, April 21,2017). The ORT consists of five items, which includes family

history of substance abuse, personal history of substance abuse, age, history of preadolescent sexual abuse, and psychological abuse. The ORT will allow for patients that have history of psychological illness, physical or sexual abuse, and substance abuse history to be appropriately screening for risk of opioid misuse and abuse. Additionally, the ORT takes less than one minute to be administered by the patient and scored by the provider, and has been validated in patients with complaints of pain (Passik et al., 2008). This will not impede provider workflow, and will ensure the information collected from the ORT is accurate so the providers will feel more confident in relying on the selected ORAST.

The policy to guide the use of the ORT has been developed and will be used amongst the residents in their primary care teams after graduation (Appendix E). The time frame in which this will occur will be decided by the medical director. The recommendation of the stakeholder team was to implement the ORT as an ORAST in their practice setting to screen all patients with complaints of pain for opioid misuse and/or abuse prior to initiating opioid medications. According to the CDC (2016), reported evidence-based guidelines include evaluating risk factors related to opioid use prior to initiation of opioid medication. An ORAST has the potential to identify those patients at risk for opioid misuse and/or abuse. The residents will be responsible for ensuring the completed ORT is scanned into the respective patient's electronic health record. The residents will present the score obtained from the ORT (three or lower is low risk, four to seven is moderate risk, and eight or higher is high risk) to their attending. Collaboratively the resident with their attending will develop a customized,

comprehensive plan of care to based on recommended guidelines to manage the patient's pain. According to Jovey (2012), in patients that have a risk of opioid misuse and/or abuse a provider and a patient may choose to undergo a cautious trial of opioid medications. The higher the level of risk stratification, the more intense the adherence monitoring should be. According to Jovey (2012), a patient that is found to be at high risk for opioid misuse and/or abuse requires a plan of care that includes more monitoring, structure, and assessment. Each of the10 residents really felt that their knowledge base differed amongst each other however despite experience level all of the residents verbalized that they really did not feel knowledgeable in pain management or safe opioid prescribing. According to Hashemi, Akbari, Razavi, Niaki, and Khameneh, (2015), residents often have differing degrees of inadequate knowledge and attitudes of pain management and safe opioid prescribing. As pain is a complaint that surfaces in many aspects of medicine incorporating pain management into curriculum could help to improve the quality and safety of care in patients with complaints of pain. According to Hashemi et al. (2015), medical schools should increase education programs and integrate education and clinical training for pain management. Both the residents and the medical director expressed wanting to use the policy's design as an opportunity for teaching to increase aptitude for pain management rather than an algorithm for patient care. This will address the need for further resident education on pain management.

The plan of care agreed upon by the resident and their attending is to be documented in the patient's electronic medical record. Post implementation of the ORAST and the policy to guide its use it was recommended to the medical director that a

three-month reassessment be completed. Retrospective chart reviews should be completed amongst patients that were initiated opioid medications during the three-month post implementation time period to analyze if the ORT was utilized and the policy to guide its use was followed. This would inform the level of compliance in regards to the practice change amongst the residents and the success of the DNP project. This information should then be disseminated to the project team to inform them of the success of the practice change and allow for revisions to be made if indicated.

Recommendations for future projects include enhancing the resident program within this inner-city ambulatory care clinic by providing greater learning opportunities in regards to pain management. Additionally, projects that outline algorithms that guide the plan of care of patients with complaints of pain based on risk stratification may also prove useful.

Summary

Section 4 reported the findings and implications of the data, described the proposed recommendations, summarized the Doctoral project team, and discussed the strengths and weaknesses of the project. Section 5 will identify the plan for dissemination and provide an analysis of self.

Section 5: Dissemination Plan

Introduction

Implementation of the chosen ORAST, the Opioid Risk Tool (ORT), and the policy guiding its use will be implemented after graduation. The medical director will decide as to when the implementation of the ORT and the policy guiding its use will be introduced to the primary care residents within the clinic. The results of this project would be appropriate for other audiences and venues, for example professional publications and presentations to other inner-city ambulatory clinics with similar patient populations.

Analysis of Self

In the following sections I will analyze myself across several domains related to developing this DNP project. I will also discuss the completion of the project, challenges and solutions, and insights gained.

As a Practitioner

This DNP project allowed me to transition as an expert within my field as a nurse practitioner. Having the opportunity to experience being a leader within a multidisciplinary team in order to analyze and synthesize literature, disseminate findings, and pose recommendations allowed me help improve the health outcomes of others by putting evidence based guidelines into practice. Creating positive social change within communities is a fundamental component of my long-term professional goals.

As a Scholar

This DNP project has allowed me to develop and apply new skills. Additionally, it has improved my ability to analyze and synthesize literature to identify gaps in practice and then devise interventions to improve the healthcare of others based on their specific needs. Healthcare is constantly evolving and in order for population health outcomes to improve research findings need to be put into practice. This DNP project has equipped me with the tools necessary to do this in a variety of settings so I may be an agent for positive social change.

As a Project Developer

This DNP project and related coursework allowed me to develop and apply skills learned in order to utilize theoretical frameworks to implement a practice change to address a practice problem. One specific skill that I was able to apply was my leadership skills as this project has allowed me the opportunity to identify an objective and path to achieve those objectives. This project has also allowed me to develop and apply management skills while focusing on the implementation of the project while controlling, arranging, and directing resources. This DNP project has also allowed me to become an effective team leader and agent for social change. I believe that this DNP project has helped prepare me to work within the highest level of my degree.

Project Completion

Utilization of an ORAST can change the prescribing practices of clinic providers and create positive social change. It can do so by reducing the amount of opioids that are prescribed, identifying patient at risk for prescription opioid misuse and abuse, tailoring

adherence monitoring to each patient's risk stratification according to policy. If this is done, it will reduce opioid misuse, abuse, dependence, addiction, opioid-related deaths, and the associated societal economic burden.

The goal of this project was to setup the framework to have 100% of the primary care providers utilize the selected ORAST prior to initiating opioid treatment. Through completing a systematic and comprehensive review of the literature the Opioid Risk Tool (ORT) was selected as the ORAST that best fit the needs of the clinic. Through collaborating with the project team a policy to guide the use of the ORT was created. Implementation will be completed after graduation. This DNP project has successfully met its goals.

As with any project there are challenges that can be identified. The greatest challenge that this DNP project was faced with was the lack of knowledge amongst the residents in terms of pain management. Although they had varying degrees of experience, all expressed feeling ill prepared to both effectively and safely manage patients with complaints of pain. Another limitation of this DNP project was the available resources of this inner-city ambulatory clinic. As the primary care needs of the clinic are divided amongst 10 resident based primary care teams, the residents may rotate from team to team based on staffing needs. Additionally, there is constant turnover as residents complete their residencies, change programs, or are given other assignments. Due to the constant resident rotation and turnover patients are often confronted with seeing a multitude of providers, which inhibits building a patient-provider relationship as well as continuity of care. Additionally, at this time this clinic meets the needs of its primary care

patients by solely utilizing residents. A limitation was the inability to better utilize an interdisciplinary approach. This DNP project has allowed me to develop and strengthen my leadership skills. I have learned how important selecting and involving a stakeholder team to be apart of a practice change can be. Without their involvement this DNP project would be destined to fail. As a leader I have learned the importance of identifying clear objectives and a path to achieving them, while creating an environment that supports translation of evidence into practice to support positive social change.

Summary

Through my scholarly journey that has lead me to the completion of this doctoral project I sincerely feel that positive social change will occur with implementation of the recommended practice change. One consistent method to assessing patients for prescription opioid misuse and abuse is to screen with an ORAST. The Opioid Risk Tool (ORT) has been the selected ORAST to be adapted by this inner-city ambulatory clinic. The policy to guide its use will be implemented after graduation. The medical director will be the final decision maker in determining when the policy to guide the use of the ORT will be implemented. The medical director supports the recommended practice change to include the selection of the ORT as clinic's ORAST and the policy designed to guide its use. He anticipates being able to implement the policy by spring of 2018. It is recommended that data is gathered three-months post implementation on the ORT and the policy to guide its use in order to determine if residents are adherent to the practice change so this information can be disseminated to the team, and further revisions can be made if indicated.

Implementation of the ORT into this inner-city ambulatory clinic in the northeast has the potential to change prescribing practices within the clinic and create positive social change by reducing the amount of opioids that are prescribed, and tailor adherence monitoring specifically to each patient's risk stratification through a policy to guide the providers in the use of the tool. Limiting the amounts of opioids that are prescribed and identifying patients at risk for opioid misuse and abuse prior to initiating opioids management may decrease opioid misuse, abuse, dependence, addiction, exposure, opioid related deaths, and the associated economic burden.

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Appendix A: Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16 – 45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring Totals		

Questionnaire developed by Lynn R. Webster, MD to assess risk of opioid addiction

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Appendix B: Opioid: Disclosure to Expert Panelist Form for Anonymous Questionnaires

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Appendix C: AGREE II Instrument

AGREE II-Global Rating Scale (AGREE II-GRS) Instrument

Instructions: For each item, please choose the response on the 7 point scale which best characterizes the clinical practice guideline.

Item	**Description**	Lowest Quality (1)	(2)	(3)	(4)	(5)	(6)	Highest Quality (7)
1. Rate the overall quality of the guideline development methods	Consider: *Were the appropriate stakeholders involved in the development of the guideline?* *Was the evidentiary base developed systematically?* *Were recommendations consistent with the literature?*	☐	☐	☐	☐	☐	☐	☐
2. Rate the overall quality of the guideline presentation	Consider: *Was the guideline well organized?* *Were the recommendations easy to find?*	☐	☐	☐	☐	☐	☐	☐
3. Rate the completeness of reporting.	Consider: *Was the guideline development process transparent and reproducible?* *How complete was the information to inform decision making?*	☐	☐	☐	☐	☐	☐	☐
4. Rate the overall quality of the guideline recommendations	Consider: *Are the recommendations clinically sound?* *Are the recommendations appropriate for the intended patients?*	☐	☐	☐	☐	☐	☐	☐
5. Rate the overall quality of the guideline.		☐	☐	☐	☐	☐	☐	☐

General Questions: Overall Guideline Assessment

Instructions: For each item, please choose the response on the 7 point scale which best characterizes the clinical practice guideline.

Item	Strongly Disagree (1)	Disagree (2)	Disagree Slightly (3)	Neither Agree or Disagree (4)	Agree Slightly (5)	Agree (6)	Strongly Agree (7)
1. I would recommend this guideline for use in practice.	☐	☐	☐	☐	☐	☐	☐
2. I would make use of a guideline of this quality in my professional decisions.	☐	☐	☐	☐	☐	☐	☐

Appendix D: Summative Evaluation

Opioid Risk-Assessment Screening Tool
Summative Evaluation

Circle the numeric response to each question

#	Question	Survey Scale (5) Strongly Agree, (4) Agree, (3) Neural, (2) Disagree, (1) Strongly Disagree				
1	The selected opioid risk assessment-screening tool is relevant to clinical practice.	5	4	3	2	1
2	The stated problem, purpose, and objectives of the DNP Project were clearly defined.	5	4	3	2	1
3	Project teams members were involved in policy development and procedure for the use of the Opioid Risk Tool.	5	4	3	2	1
4	Communication was effective regarding policy and procedure development.	5	4	3	2	1
5	The patients that should be screened for risk of prescription opioid misuse and/or abuse using the Opioid Risk Tool were clearly defined.	5	4	3	2	1
6	The recommendations for implementing a practice change by adapting the Opioid Risk Tool are clear and unambiguous.	5	4	3	2	1
7	The policy and procedure will improve patient care.	5	4	3	2	1
8	The Opioid Risk Tool will be useful in identifying patients at risk for prescription opioid misuse and abuse with complaints of pain.	5	4	3	2	1
9	This information presented in this DNP Project increased your knowledge of prescription opioid misuse and abuse risk assessment in patients with complaints of pain.	5	4	3	2	1
10	The DNP student conducted the study with professionalism.	5	4	3	2	1
11	The DNP student demonstrated leadership skills throughout the process.	5	4	3	2	1

Appendix E: Opioid Risk Tool Policy

Title: Opioid Misuse and Abuse Screening Prior to Opioid Initiation Policy	
Section: Medications	**Number:**
Effective Date:	**Medical Director Signature:**

1.0 Purpose:
To consistently screen patients with complaints of pain for opioid misuse and abuse prior to the initiation of opioid medications. Considering proper opioid prescribing includes assessing the potential risk of opioids in order to reduce opioid misuse, abuse, addiction, dependence, overdose, and exposure (CDC, 2017) all patients with complaints of pain will first be screened using an opioid risk-assessment screening tool prior to being prescribed any/all opioids.

2.0 Policy
This policy will provide guidelines for the use of the Opioid Risk Tool.

3.0 Supportive Data:

4.0 Equipment and Forms
4.1 Opioid Risk Tool (see attached exhibit)

5.0 Procedure: All primary care residents will first screen patients for opioid misuse and abuse using the Opioid Risk Tool (ORT) prior to initiating any/all opioid medications. The completed ORT will be scanned into the patient's electronic medical record. Based on the score obtained from the ORT patients will be ranked as low risk (3 or lower), moderate risk (4 – 7) or high risk (8 or higher) for risk of opioid misuse and/or abuse. The resident will present the completed ORT to their attending and the corresponding patients case to their attending. Collaboratively the resident with their attending will develop a customized, comprehensive plan of care to manage the patient's pain. The plan of care agreed upon by the resident and their attending is to be documented in the patient's electronic medical record.

6.0 Documentation: The completed ORT is to be scanned into the patient's electronic medical record and the resident's and their attending's agreed upon plan of care must be documented into the patient's chart.

7.0 References and Resources:
7.1 Center for Disease Control and Prevention. (2017). Guideline information for providers. Retrieved from
https://www.cdc.gov/drugoverdose/prescribing/providers.html

7.2 Webster, LR., & Webster, RM. (2005). Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. Pain Medicine, 6(6): 432-442. doi: 10.1111/j.1526-4637.2005.00072.x