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PROVIDER BASED INTERVENTIONS TO MITIGATE RISK FOR

OPIOID PAIN MEDICATION ABUSE AMONG ADULT

PATIENTS IN A PRIMARY CARE SETTING

by

Sheree Lamara Conley-Donaldson

A Capstone Project Submitted to the Graduate School and the Department of Systems Leadership and Health Outcomes at The University of Southern Mississippi in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

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ABSTRACT

PROVIDER BASED INTERVENTIONS TO MITIGATE RISK FOR OPIOID PAIN MEDICATION ABUSE AMONG ADULT PATIENTS IN A PRIMARY CARE SETTING

by Sheree Lamara Conley-Donaldson

May 2017

Mental and substance use disorders are predicted to exceed all physical disease processes causing major disability by 2020. Misuse and overdose of opioid pain medications is a significant public health concern in the United States. Approximately 1 in 4 patients receiving prescription opioids in primary care settings struggle with misuse. Half of all opioid prescriptions are written by primary care providers, including nurse practitioners. The purpose of this DNP project was to determine if nurse practitioner providers are implementing evidence-based practice guidelines including screening, brief intervention, and referral to treatment (SBIRT) to mitigate risk of prescription opioid pain medication misuse and abuse among patients who request a prescription for opioid pain medication. Nurse practitioner providers were instructed on current evidence-based opioid guidelines to include conducting a comprehensive assessment and screening for opioid misuse/abuse, brief intervention, and referral for behavioral health/addiction services treatment based on risk level scoring. There was a total of 9 out of 12 or 75% of patients age 18-25 that presented requesting an opioid pain medication. There was an even sex distribution, including 6 males (50%) and 6 females (50%). After implementing screening, brief intervention, and treatment, eight (66%) patients were identified as low risk; two (17%) patients were identified as moderate risk, and 2 (17%) patients were

identified as high risk for opioid abuse. The two (17%) patients identified as high risk received brief intervention and were referred for treatment. This project identified the risk level for opioid pain medication misuse/abuse. Implementing evidence-based guidelines for prescribing opioid pain medications and SBIRT in the clinical setting conjunctly with other validated screening tools could prove to be quite effective in combating misuse/abuse of opioid pain medication based on results of the project.

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DEDICATION

Special recognition to my husband Robert (Joe), Sr. and our children Jamal, Reagan, and RJ for their encouragement, prayers, and understanding during this journey. I dedicate this work to them as well as family, friends, and members of the community who have shown endless support of my efforts.

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LIST OF ABBREVIATIONS

AAPM	American Academy of Pain Medicine			
AGNP	Adult-Gerontological Nurse Practitioner			
APRN	Advanced Practice Registered Nurse			
APS	American Pain Society			
BNI	Brief Negotiated Interview			
BNI-ART	Brief Negotiated Interview and Active Referral to Treatment			
CCNC	Community Care of North Caroline			
CDC	Centers for Disease Control and Prevention			
CMS	Centers for Medicare and Medicaid Services			
CSPA	Controlled Substance Prescriptive Authority			
COT	Chronic Opioid Therapy			
DAST	Drug Abuse Screening Test			
DEA	United States Drug Enforcement Agency			
DIRE	Diagnosis, Intractability, Risk Efficacy instrument			
DNP	Doctor of Nursing Practice			
DSM	Diagnostic and Statistical Manual for Mental Disorders			
EMR	Electronic Medical Record			
ER	Extended Release			
FDA	United States Food and Drug Administration			
FLO	Feedback, Listening and understanding, and exploring Options			
FNP	Family Nurse Practitioner			
FQHC	Federally Qualified Health Center			

FRAMES	Feedback, Responsibility, Advice, Menu of strategies,	
	Empathy and Self-efficacy	
ICD	International Classification of Disease	
IR	Immediate Release	
IT	Internet Technology	
LA	Long Acting	
MAT	Medication Assisted Treatment	
MSBN	Mississippi Board of Nursing	
MSDH	Mississippi State Department of Health	
NMPOU	Nonmedical Prescription Opioid Use	
NP	Nurse Practitioner	
NPV	Negative Predictive Value	
ORT	Opioid Risk Tool	
OUD	Opioid Use Disorder	
РСМН	Patient Centered Medical Home	
РСР	Primary Care Provider	
PMP	Prescription Monitoring Program	
PPV	Positive Predictive Value	
REMS	Risk Evaluation and Mitigation Strategy	
SAMSHA	Substance Abuse and Mental Health Service	
	Administration	
SBIRT	Screening Brief Intervention and Referral to Treatment	
SOAPP	Screener and Opioid Assessment for Patients with Pain	

- US United States
- *WIC* Women, Infants, and Children

CHAPTER I - INTRODUCTION

Mental and substance use disorders are predicted to exceed all physical disease processes causing major disability by 2020 (Crowley & Kirschner, 2015). A drastic increase in prevalence of opioid use disorder (OUD) has been linked to an increase in opioid pain medication prescriptions (Centers for Disease Control and Prevention [CDC], 2016). In 2013, 249 million prescriptions for opioids were written by healthcare providers to treat chronic pain (CDC, 2016). Individuals that are prescribed opioids for chronic pain are at risk for misuse, abuse, addiction, overdose, and death if they take opioid pain medications for nonmedical reasons (Katz, El-Gabalawy, Keyes, Martins, & Sareen, 2013). Nonmedical prescription opioid use (NMPOU) leads to adverse health outcomes and has thereby become a major public health concern (CDC, 2016). There are mental and physical factors which may be used to predict OUD. Researchers found prevalence of OUD in patients with comorbid mental disorders and physical conditions (Katz et al., 2013).

Patients at risk for misuse and overdose of prescription opioid pain medications frequent primary care settings. Half of all opioid prescriptions are written by primary care providers, including nurse practitioners. Safe prescribing practice models for chronic pain management have been developed for prescribing opioids (CDC, 2016; Hudspeth, 2016a; Hudspeth, 2016b). Approximately one in four patients receiving prescription opioid pain medications in primary care settings struggle with misuse. Routine screening for anxiety/depression and substance use disorders in primary care settings is imperative to mitigate the risk for adverse health outcomes (CDC, 2016). This project focuses on identification and prevention of opioid use disorder, through screening and referral for

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treatment, in patients requesting a prescription opioid pain medication in a primary care clinic.

Background

Misuse and overdose of opioid pain medications is a major public health concern in the United States (U.S.). Approximately 1 in 4 patients receiving prescription opioids in primary care settings struggle with misuse of opioid pain medication. More than 40 people die from prescription opioid overdoses per day (CDC, 2016). Greater than 165,000 deaths from overdose related to prescription opioids have occurred since 1999 and more than 14,000 individuals died in 2014 alone (CDC, 2016).

Significance

Cost of Opioid Misuse

Misuse and abuse of prescription pain medication alone has cost the nation around \$53.4 billion annually in lost productivity, medical costs, and criminal justice costs. Health care dollars are being allocated for prevention and treatment of opioid use disorder. Reimbursement will be determined by implementing new measures including tracking of high-dose opioid use from four or more providers and pharmacies by non-cancer patients using the prescription monitoring program (PMP) (CMS, 2015). Medicare uses PMP to track opioid prescribers. A new strategy is being developed to report physicians who may be prescribing opioids inappropriately. Centers for Medicare and Medicaid Services (CMS) has launched an attack on the opioid epidemic (CMS, 2017a). The Medicare population has the one of the highest and fastest growing rates of OUD. This is concluded to be due to no systemic policy of screening for opioid misuse. possibility of supporting and strengthening primary care in efforts to improve quality and reduce costs. The CMS strategy includes four priority areas. Prescribers are advised to (1) implement more effective person-centered strategies to reduce risk of misuse and (2) expand screening, diagnosis, and treatment of OUD. Practitioners are also encouraged to (3) increase the use of evidence-based practices for acute and chronic pain management. Improper prescribing is a contributory factor to misuse and overdose of opioid pain medications; (4) naloxone use, distribute, and access should be expanded when clinically necessary (CMS, 2017a).

Governmental agencies are combining forces to combat the problem of opioid prescription drug overdose. The aim is to prevent misuse, treat dependence and ultimately save lives. The extent of the problem has progressed from local and regional perspectives to a national awareness. The United States Food and Drug Administration (FDA) (2012) has joined the effort to decrease prescription opioid misuse. Public health officials are collaborating with prescribers, state and local partners to ensure safe use and disposal of opioid medications. In February 2016, the FDA received a citizen petition from several local and state public health officials in addition to other stakeholders requesting changes to existing labeling for opioid analgesics. The FDA supports stronger warning labels and misuse deterrents (FDA, 2016). Opioid warning labels require boxed warnings, which are the FDA's strongest warning. The labels note that opioids carry serious risks of misuse and abuse, addiction, overdose and even death (CDC, 2016). *Chronic Pain*

The International Association for the Study of Pain (IASP) (2016) defines chronic pain as pain which persists beyond three months (p. 11). Millions of United States

citizens, one-third of the population, in fact, are affected by chronic pain. Chronic pain prevalence in the United States (US) is estimated to be greater than 30 million citizens. Around 25 million of these individuals have moderate to severe pain. Chronic pain has been shown to be greatly comorbid with other medical conditions (IASP, 2016).

The burden of dealing with chronic pain can diminish a patient's psychological well-being. The ability to maintain gainful employment, relationships with significant others, and social activities may be limited; this can result in feelings of anxiety or depression. Daily activity and quality of life are significantly lowered. Consequently, Americans receive disability insurance primarily for pain. Stigma can also result from patient encounters with healthcare providers who are not properly trained in the management of chronic pain. Evidence reveals 40% to 70% of persons with chronic pain are not receiving adequate medical treatment. Concerns for both over and under treating in this population have been raised (IASP, 2016).

An estimated 5 to 8 million Americans use opioids for long-term management of their chronic pain. Long-term, defined as greater than three months, opioid therapy for chronic pain in adult patients is associated with increased risk of misuse and overdose. Consequently, higher doses are associated with higher risks (Chou et al, 2015). While some patients experience significant pain relief from opioids without adverse effects, benefits and risks must be weighed. Many problems have been caused by the vast number of opioids prescribed leading to their illicit use by the public (Reuben et al, 2015).

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Opioid Pain Medications

Prescription opioids are very potent pain medications and include oxycodone, hydrocodone, and morphine among others (U.S. Food and Drug Administration, 2016). Prescription opioid pain medications are used for severe pain, can have serious side effects if not used correctly, and are often misused by patients. Patients may take higher doses than prescribed to experience a state of euphoria and patients may also divert medications to friends or relatives (McDonald & Carlson, 2013).

Opioid pain medications are scheduled drugs, or controlled substances, which are regulated by the Food and Drug Administration. Scheduling classes are in place to prevent misuse and abuse. Schedule I controlled substances are not used in medical settings in the U.S. Schedule II has accepted medical use. Schedule II controlled substances have a high potential for abuse and require a written and signed prescription that may not be refilled. Examples of Schedule II opioid prescription medications are fentanyl, hydrocodone, methadone, and oxycodone. Most commonly abused opioids are hydrocodone and oxycodone (U.S. Food and Drug Administration [FDA], 2016). Schedule III substances may lead to moderate physical dependence or high psychological dependence. Buprenorphine is a Schedule III opioid substance used for medicationassisted treatment (MAT) of OUD. Schedules IV and V have the lowest abuse potential.

Next, there are two main categories of opioid pain medications—immediate release (IR) and extended-release/long-acting (ER/LA). IR are the most often prescribed type of opioid and is used for breakthrough pain. ER/LA are opioids used for prevention of baseline pain by maintaining a constant level of drug for 8-72 hours. The FDA (2012) approved a Risk Evaluation and Mitigation Strategy (REMS) for ER and LA opioid medications. REMS is a strategy to allow patient access to ER/LA opioid pain medications through safe prescribing and reduction and management of risks for adverse patient outcomes. Inappropriate prescribing leads to risk for misuse and abuse and potential serious adverse patient outcomes including addiction, unintentional overdose, and death (FDA, 2012, 2016).

Table 1

Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
No accepted	Codeine	*Buprenorphine	No opioids	Codeine (not
medical use in	Fentanyl		identified in	more than
US	Hydrocodone		this class	200mg/100 ml)
	Meperidine			and opium
	*Methadone			preparations
	Morphine			(not more than
	Oxycodone			100 mg/100
				mg or ml)

Note: *Used in medication-assisted treatment (MAT) of Opioid Use Disorder (OUD)

Opioid Misuse, Abuse and Addiction

Misuse involves the use of prescription medication in a way which is against

directions (American College of Preventive Medicine, 2016). Misuse can be grouped

into several categories:

- Not taking the medication as prescribed
- Bingeing
- Injecting, crushing, snorting
- Diversion
- Aggressive behavior

The American College of Preventive Medicine (2016) states abuse is selfadministration to alter one's state of consciousness or to "get high." Moreover, addiction is a primary, chronic, neurobiological disease, with genetic, psychological, and environmental factors. Addiction is characterized by 4 C's impaired control, compulsive use, continued use despite harm and craving (American College of Preventive Medicine, 2016). Tolerance and withdrawal are signs of physical dependence. Tolerance is defined as a reduction in effect requiring increased dosages to produce desired effect. Withdrawal symptoms to assess for are rapid heartbeat, agitation, insomnia, diarrhea, sweating, and runny nose (Paone, Dowell, & Heller, 2011).

Self-medication describes use of a drug without consulting a healthcare professional to alleviate stressors or disorders such as depression and anxiety (Shapiro, Coffa, & McCance-Katz, 2013). Non-medical use is intentional or unintentional use of legitimately prescribed medication in an un-prescribed manner for its psychic effect. Individuals also often share their unused opioid prescription pain medications, unaware of the dangers of nonmedical prescription opioid use (NMPOU). NMPOU leads to abuse and addiction characteristic of OUD (CMS, 2016).

Opioid Use Disorder (OUD)

The Diagnostic and Statistical Manual for Mental Disorders (DSM-5) states substance use disorder is evident when the repetitive use of alcohol and/or drugs causes debilitation and failure to carry out activities of daily living involving home, school, or work. For opioid use disorder, specifically, 2 of 11 criteria must be met over a 12-month period (APA, 2013). Criteria include:

- individuals with OUD often take opioids in larger amounts or over longer periods of time than prescribed;
- (2) they may possess a strong desire or have failed efforts to control opioid use; activities to obtain, use or recover from opioids is carried out;
- (3) individuals experience craving or urge to use opioids;
- (4) recurrent opioid use results in a failure to fulfill major role obligations;
- (5) there is continued opioid use despite problems;
- (6) important tasks are given up;
- (7) physical hazards are posed due to use;
- (8) individuals with OUD persistently use opioids even with knowledge of physical or psychological complications caused by the substance;
- (9) tolerance is reached; and
- (10) withdrawal symptoms manifest. (American Psychiatric Association, 2013).

OUD has had an impact on special populations—adolescents, women, and individuals ages 16-45. Through research efforts, misuse of prescription drugs has been shown to affect young adults most, especially age 18 to 45 (CDC, 2016). In 2014, 467,000 adolescents were current nonmedical users of opioid prescription pain medications, with 168,000 having an addiction (CDC, 2016). Women are more like to have chronic pain and may become more dependent on prescription opioids more quickly than men leading to OUD. Between 1999 and 2010, 48,000 women died of prescription pain reliever overdoses (CDC, 2016). Patients that request prescription opioid pain medications from primary care providers must be evaluated for risk of opioid pain medication misuse/abuse. Screening for risk of opioid pain medication misuse/abuse may alert providers of possible opioid use disorder and help stratify patients per risk level.

Prescribing

Primary care providers (PCPs), including nurse practitioners (NPs), manage chronic pain and prescribe opioid pain medications. Currently, 49 of 50 states allow NPs to prescribe controlled substances, including opioid pain medication. Nurse practitioners may be granted controlled substances prescriptive authority through the state board of nursing. Prescribing habits correlate with misuse, and misuse leads to problematic opioid-related behavior including opioid use disorder (OUD) and accidental overdose; therefore, screening for risk for misuse, abuse, and OUD prior to prescribing opioid pain medications is recommended (CMS, 2017a).

Screening

Mitigation strategies to prevent OUD involve screening and lack thereof results in missed treatment opportunities (Bowman, Eiserman, Beletsky, Stancliff, & Bruce, 2013). The Opioid Risk Tool (ORT) is a self-reported screening tool utilized with patients 16 years of age and older in primary care settings to assess risk for opioid abuse (National Institute of Drug Abuse, 2015). Patients with high risk have increased likelihood of opioid use disorder and may require referral for treatment.

Needs Assessment

State Level

The state of Mississippi is a leading prescriber of prescription opioid pain medication, ranked 5th in prescribing opioids nationally. In 2012, an equivalent of 1.2 opioid prescriptions for each citizen were prescribed (Mississippi State Department of Health, 2016). Hydrocodone is the most commonly prescribed opioid in Mississippi. In July 2016, 145,846 prescriptions equal to 8,343,259 dosage units were written (MSDH, 2016). Mississippi has the 30th highest national unintentional drug overdose mortality rate (Levi, Segal, & Miller, 2013).

All providers are required to use the Mississippi prescription drug monitoring program (PMP) when prescribing controlled substances (Mississippi Board of Medical Licensure [MBOML], 2013: Mississippi State Board of Nursing [MSBN], 2016) to decrease the number of opioid pain medications prescribed and unintentional drug overdose. The PMP tracks the number of drug units prescribed, the number of providers prescribing controlled substances for a patient, and the pharmacies used by the patient to fill prescriptions for controlled substances. In the state of Mississippi, NPs have prescriptive authority after meeting all MSBN requirements and may prescribe any schedule of controlled substance after completion of 720 hours of monitored practice and registration with the U.S. Drug Enforcement Agency (DEA) (MSBN, 2016). The MSBN monitors inappropriate opioid prescribing practices by APRN with CSPA.

Local Level

While working as a family nurse practitioner (FNP) in the internal medicine department of a primary care clinic, several patients have presented with complaints of chronic pain. These patients request prescriptions for opioid pain medications often reporting allergies to or ineffectiveness of non-opioid pain medications. Similar encounters have been verbalized by other providers including physicians and nurse practitioners. Each provider expressed lack of discernment with this group of patients. As a student in a Doctor of Nursing Practice (DNP) degree program, completion of a DNP project is a requirement for the degree. In my role as a nurse practitioner provider at the primary care clinic and project director for this DNP project, a needs assessment of the recognized practice problem was conducted to determine the extent of the problem in the clinical practice setting. A chart review was conducted in collaboration with executive staff and members of the internet technology (IT) department in efforts to gauge an estimate of patients currently being treated for pain-related diagnoses. A retrospective review of the previous 30 calendar days revealed a total of 66 initial and established patient encounters with a diagnosis of chronic pain and documentation of prescribing an opioid pain medication. There were 32 (48%) males and 34 (52%) females identified in the chart review and twenty-six (39%) patients were between the ages of 16-45. The most common ICD 10 diagnoses were M54.5 (low back pain) and M79.7 (fibromyalgia). Only 20 (30%) patients seen were prescribed an opioid. Seven (11%) patients had a history of substance-related disorders with no documentation of a risk assessment performed. The majority of the patients 45 (68%) were seen by NPs.

Misuse of prescribed opioid pain medication is a problem pertinent to primary care. Misuse may be prevented through proper prescribing consistent with evidence-base practice recommendations for conducting a comprehensive assessment that includes screening for risk of opioid pain medication abuse/misuse (CMS, 2017a). This DNP project explores the PICOT question: "In patients 18-45 years of age, who present to a primary care clinic requesting a prescription for opioid pain medication, will screening by nurse practitioners identify patients at risk for opioid abuse leading to appropriate intervention or referral?"

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The DNP project will focus on nurse practitioner providers in a designated federally qualified health center (FQHC) and patient-centered medical home (PCMH) primary care clinic in southeastern Mississippi. A FQHC is an organization which qualifies for enhanced reimbursement from Medicare and Medicaid (CMS, 2017b). A PCMH is a model in which treatment is facilitated by primary care providers to coordinate needed care (NCQI, 2017). This DNP project will ask the question; find the evidence; appraise; act; evaluate and reflect (Schaffer, Sandau, & Diedrick, 2013) to ensure mitigation of risks related to opioid abuse. Proposed mitigation strategies include NPs implementing an opioid abuse/misuse risk assessment screening tool in practice and providing evidence-based interventions and referrals to hopefully, prevent OUD. Outcomes extend beyond improved patient outcomes but also hopefully, promote better prescribing practices by NP providers, and decreased health care costs.

Relevant Review of the Literature

Databases accessed for this review of literature include CINAHL, MEDLINE, PsycARTICLES, and evidence-based treatment guidelines. Key terms used in the review of literature were chronic pain, evidence-based practice, risk mitigation strategies, identification, opioid pain medication, opioid use disorder, abuse, misuse, prevention, primary care, and screening. The proposed aim of this DNP project is to determine if nurse practitioners in a primary care setting are implementing evidence-based practice guidelines to mitigate risk of prescription opioid pain medication abuse among patients who request a prescription for opioid pain medication.

Management Strategies

In March 2016, the Centers for Disease Control and Prevention released guidelines to provide recommendations for providers who prescribe opioid pain medications. The guidelines are not intended for chronic pain related to active cancer treatment, palliative care, and end of life care. Initiation, selection, dosage, duration, follow-up, discontinuation, assessing risk and addressing harms of opioid use are addressed through twelve recommendations.

- Non-pharmacologic treatment is preferred. If pharmacologic treatment is warranted, non-opioid treatment should be initiated with or without opioid pharmacologic therapy as appropriate.
- Providers should establish treatment goals with each patient prior to initiation of treatment. Goals for pain and function should be realistic. If there is clinically significant improvement in pain and function which outweighs risks to patient safety, opioids may be continued.
- Known risks should be discussed with all patients prior to starting therapy as well as periodically. Patient and provider responsibilities should be outlined (CDC, 2016).
- Immediate-release opioids should be prescribed when starting therapy instead of extending release/long-acting opioids.
- Lowest effective dose should be prescribed at start.
- No greater quantity than necessary for the anticipated duration of severe pain should be prescribed. Three days or less will often suffice. Rarely, greater than seven days is needed for acute pain (CDC, 2016).

- Benefits and harms should be evaluated within the first four weeks especially before dose escalation. The goal is to taper opioids to lower doses or discontinue all together is deemed safe.
- Consideration of offering naloxone is indicated for patients with increased risk of overdose such as a history of substance use disorder; higher opioid dosages; concurrent benzodiazepine use; or history of overdose.
- Providers should review patients' Prescription Monitoring Program (PMP) when starting opioid pain medications and periodically during treatment for chronic pain (CDC, 2016).
- Use of urine drug testing is also recommended when starting opioid pain medications as well as periodically during treatment, at least annually.
- Clinicians should avoid prescribing opioid pain medication to patients currently taking benzodiazepines.
- Providers should offer or arrange evidence-based treatment for patients with opioid use disorder (CDC, 2016).

The American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) comprised a panel to develop an evidence-based guideline on chronic opioid therapy (COT) for individuals with chronic pain (Chou et al., 2009). The investigators reviewed 8,034 abstracts. A total of 14 systematic reviews and 57 primary studies were included in the report of evidence. The expert panel recommends clinicians first obtain appropriate diagnostic tests for evaluation of any underlying conditions. Consideration of the effectiveness of non-opioid therapy should precede COT. Reliable evidence on methods to assess potential benefits of COT is limited. Screening tools for the assessment of potential risks of COT are helpful for risk stratification. More validation studies are needed however to explore outcomes. The ORT has been shown to have construct partial validity. The strongest factor predictive of drug misuse after initiation of COT is a personal or family history of alcohol or drug abuse. Patients should receive informed consent and participate in their opioid manage plans. Initiation and titration of COT follow. An initial trial typically lasts from several weeks to several months. Proceeding beyond this time frame warrants careful consideration of trial outcomes. Clinicians should monitor and reassess patients on COT periodically. Urine drug screens, as well as other information to determine adherence, are useful, but quality of evidence regarding these measures is low as well. When pain is accompanied by comorbidities, clinicians should integrate or refer for therapies that target psychosocial factors. Cognitive-behavioral therapy is consistently shown to be effective for chronic pain. Functional restoration and specific behavioral interventions in addition to pain education have been shown to improve strength. Interdisciplinary or multidisciplinary pain management and rehabilitation approaches are recommended for high-intensity chronic pain patients at high risk for opioid use disorder to coordinate physical, vocational, and or psychological components of care (Chou et al, 2009).

Prevention, assessment, and treatment of chronic pain is challenging. Insufficient evidence exists that pain relief is sustained or function is improved when opioids are prescribed for chronic pain (Paone et al., 2011). To prevent misuse providers should avoid prescribing opioids for chronic pain unless other pharmacological and or nonpharmacological approaches have been ineffective. Also, whenever possible, opioids should not be prescribed in patients taking benzodiazepines because of the risk of fatal respiratory depression (Paone et al., 2011). Chronic opioid therapy (COT) to treat pain, aside from severe acute pain or chronic malignant pain, remains a topic of controversy. Selection of patients for an opioid trial should follow weighing of potential benefits and risks of COT (Paone et al., 2011).

Management of Pain by Healthcare Professionals

Pain is one of the most common reasons for health care visits; however, most health professionals' educational programs do not adequately prepare them to effectively manage pain. Core competencies such as basic knowledge, assessment, team-based care and cultural competency are integral. The National Pain Strategy recommends strengthening evidence base for pain prevention strategies, assessment tools, and outcome measures. Rigorously researched efforts are warranted. This is particularly relevant to primary care. Improvements in self-management strategies in patients with chronic pain are also necessary. Treatment should start with a comprehensive approach. Plan of care should address biological, psychological and social aspects (The Interagency Pain Research Coordinating Committee, 2015).

Researchers note no single practice change in prescribing behavior alleviates all risks. Still, regular monitoring and reassessment provide opportunities to minimize the risks associated with long-term opioid use by allowing for the tapering and discontinuing of opioids among patients who are not receiving a clear benefit or among those who are engaging in practice that increase the risk of overdose (Volkow & McLellan, 2016). Examples of such practice are consumption of high doses of alcohol, concurrent use of benzodiazepines, and poor adherence to opioid medication regimen. Prevention of drug diversion, reduction of risk of overdose, and minimization of the risk of addiction are presented as goals. Recommendations to achieve this involves increased use of evidencebased prescribing and management practices. The extended prescription of opioids for the treatment of chronic pain has questionable benefits, and the risks of overdose increases with higher doses. There is also a call for increased research on pain. Discovery-oriented research has been recommended to identify potent non-opioid analgesics and other pain treatment strategies (Volkow & McLellan, 2016).

Screening for Opioid Misuse/Abuse Risk

Clinicians need to identify patients at risk of misusing prescribed opioids in order to safely monitor therapy. Opioid misuse carries the risk of development of addiction, overdose, and death (Claxton & Arnold, 2011). Providers must balance each patient's pain and risk levels. Patients with higher risk should be monitored more intensely than patients with lower risk. Risk factors for misuse may be grouped into three categories (1) biological, (2) social, and (3) psychological. Biological risk factors are family history of drug abuse and male gender. Poor social support and history of drug-related criminal chargers are social risk factors. Finally, psychological risk factors include personal history of substance abuse, preadolescent history of sexual abuse, and comorbid psychiatric illness. Personal history of substance abuse includes alcohol or tobacco. Examples of comorbid psychiatric illnesses are major depression, bipolar disorder, and personality disorder (Claxton & Arnold, 2011).

Screening Tools for Opioid Misuse/abuse

Common screening tools for opioid misuse in patients with chronic pain are Screener and Opioid Assessment for Pain Patients (SOAPP) and the Opioid Risk Tool

(ORT). However, these tools have not been fully validated. The SOAPP predicts risk for possible aberrant drug behavior using a 14 item self-report. Responses are based on a 5point Likert scale. With 7 as a cutoff score, the test has sensitivity of 91%, specificity of 69%, positive predictive value (PPV) of 71%, negative predictive value (NPV) of 90% (Claxton & Arnold, 2011). The ORT is a 5 item yes or no tool which predicts the probability of opioid misuse or abuse among patients being considered for opioid therapy for chronic pain. Patients are categorized as low, medium, and high risk. Sensitivity and specificity for patients who score at least medium risk are 99% and 16% respectively. The tool is best applied in primary care settings. Clinicians must be aware these screening tools have been used in studies to identify high-risk patients. The tools are not diagnostic of substance use disorders or to accurately identify patients who should not be prescribed opioids for chronic pain (NIDA, 2015). Furthermore, they do not assess the risk of diversion of drugs. Regardless of if a provider chooses to use a tool, a thorough history is crucial to identify patients who require closer assessment, monitoring and or referral (Claxton & Arnold, 2011).

Evidence supporting risk assessment tools for identification and prevention of opioid use disorder is inconsistent. Standardized tools lack sufficient sensitivity and specificity (Shapiro et al., 2013). Still, screening is paramount assuming all patients are at risk. Fundamental comprehensive clinical assessment is necessary for all patients taking opioids for management of chronic pain. Evaluation should include (1) pain intensity appraisal; (2) functional status; (3) quality of life and (4) known risk factors for potential harm. Known risk factors are (a) medical comorbidity, (b) history of substance use disorders or current substance use, (c) mood disorders and (d) concurrent use of

medications with potential drug-drug interactions. Patients at highest risk for harm should have more structured monitoring during follow-up visits at regular intervals (Reuben et al., 2015). A comprehensive assessment, evaluation of risk, screening, brief intervention and referral to treatment are indicated in the clinical setting when managing patients presenting with complaint of chronic pain.

Screening, Brief Intervention, and Referral to Treatment (SBIRT)

The SBIRT model was developed following an Institute of Medicine recommendation which solicited community-based screening for health risk behaviors. SBIRT consists of three major components. The first component is screening. Screening

A healthcare professional assesses a patient for risky substance use behaviors using standardized screening tools. Screening provides a quick method of identifying patients who use substances at at-risk levels in addition to those who may already experience substance use-related issues. A brief one to three question prescreen is administered. If an individual screen is positive, a longer screening is given. Screening can occur in any healthcare setting (Substance Abuse and Mental Health Services Administration [SAMHSA], 2016).

Suggested screening tools are the drug abuse screening test (DAST), a sensitive screening tool for drug abuse. The ORT has been validated and fits recommendations for a longer screening tool. Utilizing the SBIRT model in a study of more than 499, 000 patients using the DAST, 22.7% of patients were identified as high-risk users or had a current substance use disorder. There was a 67.7% decline in reported illicit drug use at follow-up (McCance-Katz & Satterfield, 2012). Those who received specialty

experienced great improvements in general and mental health; employment; housing status; and criminal behavior.

Opportunities for early intervention involving at-risk substance users include primary care centers, emergency rooms, trauma centers, and other community health settings. Screening assesses severity of and identifies the appropriate level of treatment. The Center for Substance Abuse Treatment/Substance Abuse and Mental Health Services Administration has launched a training program to foster SBIRT clinical skills in support of innovations and implementation of SBIRT. In addition, reimbursement billing codes exist for providers that implement SBIRT. Current procedural terminology or CPT codes used are: CPT 99408 for alcohol and or substance abuse structured screening from 15-30 minutes and CPT 99409 for alcohol and substance abuse structured screening exceeding 30 minutes commercial insurance billing purposes; G0396 and G0397 codes may be used for Medicare for alcohol and/or substance use (not tobacco) structured assessment and brief intervention 15-30 minutes and greater than 30 minutes, respectively; and H0049 and H0050 may be used to bill for Medicaid alcohol and/or drug screening (McCance-Katz, & Satterfield, 2012; SAMHSA, 2016).

Brief Interventions

Brief interventions are evidence-based practice designs aiming to motivate individuals at risk of substance abuse to make behavior changes. A healthcare professional engages a patient in a short conversation, providing feedback and advice. Brief intervention can also be used for at-risk patients to become more receptive to utilize referral services. In primary care settings, brief interventions consist of 5 minutes of brief advice. The interventions are ideal to treat problematic or risky substance use—not intended to treat individuals with serious substance dependence. Cognitive behavioral therapy and motivational interviewing, or a combination of the two, are the two most common behavioral therapies used in SBIRT programs (SAMSHA, 2016). Brief intervention without cognitive behavioral therapy will be used for this project.

FLO and BNI are acronyms for two common forms of motivational interviewing. Each will be discussed in this section. Brief Negotiated Interview and Active Referral to Treatment (BNI-ART): Provider Training Algorithm (Appendix A) is a flowchart created by the Boston University School of Public Health which includes brief screening questions health practitioners can ask during brief intervention. Steps includes a listing of questions and responses that a health provider can use during a brief intervention. With BNI, providers raise the subject, provide feedback, enhance motivation, and negotiate and advise. The tool focuses on; building rapport initially; then raising the subject and discussing daily life; discussing pros and cons of use; asking permission; giving information, and eliciting reaction; discussing readiness to change, and reinforcing positives; creating an action plan; and identifying strengths. The final stage is prescription for change which involves writing down an action plan and sealing the deal. Patients are provided handouts and follow-up to discuss progress is suggested (SAMSHA, 2016).

The FLO Model includes providing F-feedback, L-listening and understanding, and exploring O-options. FLO is often reinforced with S.E.W. S-summarize patient's statements in favor of change. E-emphasize their strengths. W-what agreement was reached? (SAMSHA, 2016).

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Referral for Treatment

Referral is provided for patients who screen high risk and need additional services. Referral to treatment is critical yet often underutilized (SAMSHA, 2016). The process consists of assisting with accessing specialized treatment. Community Care of North Carolina (CCNC) has developed a set of three referral forms in partnership with other stakeholders to orchestrate easier consultation and follow-up. These are Bridging the Gap Between Primary Care and Behavioral Health-Referral Forms (SAMSHA, 2016). An in-house referral form will be used for this project.

In summary, the review of literature shows that implementing SBIRT (SAMSHA, 2016) and other evidence-based practice recommendations (CDC, 2016) are effective in minimizing the risk for misuse of opioid pain medication. Opioid therapy for chronic pain is associated with increased risk of misuse and overdose as well as other physical conditions (CDC, 2016). Experts suggest inappropriate prescribing contributes to misuse of prescription opioid pain medication (Shapiro et al., 2013). The American Pain Society (APS) (2016) states a reliable instrument for identifying aberrant drug-related behaviors could be valuable for ongoing monitoring of risks and benefits of chronic opioid therapy. ORT should be used with other combined strategies. The APS and American Academy of Pain Medicine (AAPM) (2016) recommend coordination of care when the services of other health care professionals are needed. Coordination of care also minimizes misuse of opioid pain medications. Prescribers should make referrals as needed. The American Society of Addiction Medicine (ASAM, 2016) recommends a combination of psychosocial interventions and medications for the treatment of opioid use disorder. A table summarizing the ROL can be found in Appendix B.

Using the Iowa Model of evidence-based practice (Titler et al., 2001), this DNP project will ask the question; find the evidence; appraise; act; evaluate and reflect to ensure mitigation of risks related to opioid misuse (Schaffer, Sandau, & Diedrick, 2013). This DNP project will ask the question are providers utilizing evidence-based guidelines which include implementation of SBIRT prior to prescribing opioid pain medication. Finding and appraising of the evidence was carried out through relevant review of literature. Acting will require education of the providers on prescription opioid drug misuse and the importance of utilizing evidence-based guidelines in practice. In addition, SBIRT will be implemented over a 4-6-week period with all initial encounters involving patients requesting a prescription for an opioid pain medication. Evaluation and reflection is necessary to ensure mitigation of risks related to opioid misuse (Schaffer et al., 2013). Specifically, the project will evaluate whether implementing SBIRT in conjunction with evidence-based guidelines by nurse practitioner providers mitigates the risk for prescription opioid pain medication misuse and abuse among patients requesting a prescription for opioids in a primary care setting.

Conceptual Framework

The conceptual framework used for this project is the SBIRT Program Matrix. This framework is used for program implementation and evaluation. SBIRT Program Matrix has five components: (1) SBIRT services; (2) performance sites; (3) provider attributes; (4) patient/client populations; and management structure and activities. Implementation outcomes include but are not limited to program adoption, fidelity, costs, and grant compliance (Del Boca, McRee, Vendetti, & Damon, 2017). SBIRT services includes risk factors, instruments, approaches, procedures. Examples are pre-screening,

screening, brief intervention, referral to treatment, brief treatment, and added services. Participating providers will offer SBIRT services using the five components of this model at a rural health primary care clinical site. Screening with the ORT for those with a positive preliminary screen will be carried out. Brief intervention and referral to treatment will be implemented for high-risk patients. The performance site is a federally qualified health center and patient-centered medical home. The NP provider attributes include management of patient population through knowledge and structured skills obtained from appropriate educational tools and resources. Additional provider attributes include personal characteristics, clinical training, educational attainment, self-efficacy, treatment philosophy, and counseling experience. For this project, patient/client population presenting requesting an opioid prescription will be assessed for risk status, demographic characteristics, and physical and mental health. Management structures and activities include evidence-based protocols; coaching and staff evaluation; program evaluation and dissemination; as well as facilitative administrative supports, systems interventions and sustainability planning are all necessary components of SBIRT program implementation and evaluation (Del Boca et al., 2017).

DNP Essentials

The project aims to implement a change in prescribing practices of NP primary care providers at a primary care health center in efforts to mitigate the risk of misuse of prescription opioid pain medications in patients requesting a prescription for opioid pain medication. DNP essentials and competencies (American Associations of Colleges of Nursing, 2014) are fulfilled upon completion of this DNP project (Appendix C).

Evaluation Plan

The logic model (Appendix D) demonstrates how the project director will evaluate outcomes. The project director used the SBIRT tool to provide training to stakeholders. Stakeholders in this study are identified as nurse practitioner providers who treat patients that present requesting prescriptions for opioids with the potential for opioid misuse if opioid pain medication is prescribed. The project director (PD) trained the providers and administrators on the risk as well as appropriate use of the SBIRT algorithm with incorporation of ORT. The providers then implemented the use of the tool in the clinical setting. The PD will evaluate adherence to the training and fidelity to use of the instrument by analyzing administration of the tool in the clinical setting, use of intervention after assessing risk, and whether an opioid was prescribed. The analysis will reach the medium-term goals with the idea that the accurate implementation of the tool and following risk assessment protocols could potentially lead to a reduction in opioid misuse and abuse.

Assumptions

The assumption is once educated providers change their prescribing habit and adopt evidence-based practice recommendations, the risk of patients misusing prescription opioid pain medications will be lowered. Patients will have improved overall health outcomes, and costs will be lowered for insurers and consumers alike.

Purpose of the DNP Project

The purpose of the DNP project is to determine if nurse practitioner providers are implementing evidence-based practice guidelines including Screening, Brief Intervention, and Referral to Treatment (SBIRT) (McCance-Katz & Satterfield, 2012) to mitigate risk of prescription opioid pain medication misuse and abuse among patients who request a prescription for opioid pain medication.

CHAPTER II - METHODS

The purpose of this DNP project was to determine if nurse practitioners (NPs) in a primary care setting were utilizing screening, brief intervention, and referral for treatment (SBIRT), prior to prescribing opioid pain medications for patients seen on an initial visit requesting a prescription for opioid pain medication. The desired outcome was to mitigate the risk for opioid pain medication misuse or abuse while providing appropriate chronic pain management.

Setting

The setting was a patient-centered medical home (PCMH), designated as a federally qualified health center (FQHC) located in rural Mississippi. The clinic serves pediatric to geriatric patients. Most of the patient population receives Medicare and/or Medicaid benefits; a sliding scale fee is offered to eligible patients who are uninsured, and private insurance is also accepted at the facility. Services offered include internal medicine; pediatrics; women's health; women, infants and children (WIC); dental; vision; pharmacy; and social services.

There are four clinic locations: Site 1 (main clinic), Site 2, Site 3, and Site 4 (satellite clinics). There are five NPs on staff at the main clinic—3 full-time, 1 part-time, and 1 that works as needed (prn). Both Sites 2 and 3 are staffed by 1 full-time NP each but were excluded from the project. Site 4 is only staffed by medical doctors and was excluded from the project. The DNP project was only conducted with the five full-time nurse practitioners that see patients age 18 to 45 years of age at the main clinic-Site 1.

Population

Participants included nationally certified adult-gerontological and family nurse practitioners, AGNPs (N=2) and FNPs (N=3). The full-time NPs are licensed to practice in the state of Mississippi and work at the primary care main clinic setting. All five of the participants completed 720 hours of monitored practice as required by the Mississippi Board of Nursing (MSBN, 2016) deeming them eligible for controlled substance prescriptive authority (CSPA). The majority of patients between the ages of 18-45 years of age with a diagnosis of chronic pain are seen by nurse practitioners; therefore, nurse practitioner prescribers were the targeted populations for the DNP project.

Design

The design was descriptive in nature. The protocol describes the implementation of SBIRT in patients requesting a prescription for an opioid pain medication seen by NPs in a primary care setting. The primary project outcome was identification of risk for opioid misuse or abuse in patients, while secondary or long-term outcomes include reduction in misuse of opioids, better prescribing practices, healthcare cost reductions, and improvement in public health and safety.

Procedures

Education Session

The project director is a full-time FNP employee, with CSPA, at a primary care clinic in southeastern Mississippi. In a one-on-one educational session, NP providers were educated by the project director on current evidence-based opioid guidelines to include conducting a comprehensive assessment and screening for opioid misuse/abuse, brief intervention, and referral for treatment (SBIRT) (CDC, 2016; SAMHSA, 2016).

The educational session covered the most common pain diagnoses seen in the clinic; conducting a comprehensive assessment, and implementation of SBIRT. The project director defined chronic pain and all applicable ICD-10 diagnosis codes, excluding active cancer; palliative; or end-of-life-care. Participants were educated on how to conduct a comprehensive assessment based on evidence-based guidelines (CDC, 2016) and implement Screening, Brief Intervention, and Referral for Treatment (SBIRT) (SAMSHA, 2016). NP participants were also instructed to use the prescription monitoring program (PMP). Education was provided on known risk factors such as illegal drug use; prescription drug use for nonmedical reasons; history of substance use disorder or overdose; and mental health conditions.

Screening in SBIRT was modified to use a screening tool that identifies risk for opioid use or misuse rather than the longer screening for substance use-DAST. The participants were also educated regarding use of the Opioid Risk Tool (ORT) developed by Lynn R. Webster, MD (Appendix E). The tool is a self-report screening tool to assess risk for opioid abuse or misuse in individuals, age 16 to 45 (National Institute on Drug Abuse [NIDA], 2015). The ORT addresses family as well as personal history of substance abuse—alcohol, illegal and prescription drugs. History of preadolescent sexual abuse and questions regarding psychological disease are included. Providers were advised to read the tool to the patient when administering the tool and assigning points based on patient's responses. Points were assigned based on male or female sex. Points were then summed up by providers to note mild, moderate, or high risk. The ORT has been validated in both males and females with a diagnosis of chronic pain. In a preliminary study, a high degree of sensitivity and specificity was shown using a c statistic for validation. Excellent discrimination was displayed, c=0.82 male and c=0.85 female. Patients categorized as high-risk are at increased likelihood of developing opioid use disorder (OUD) (NIDA, 2015).

Providers were informed on brief interventions to implement and referral for treatment based on scoring of the ORT. Brief interventions should be utilized for patients identified as mild to moderate risk prior to prescribing opioid pain medication. Providers were instructed on using a brief negotiated interview (BNI), motivational interviewing for a period of 5 minutes (SAMSHA, 2016). Patients identified as high risk were referred for behavioral health/addiction services in addition to brief intervention. A list of referral sites in the surrounding area was provided for providers.

Consent

After the educational session, providers were asked to participate in the proposed project. Providers were informed of the project and informed consent for participation was obtained from all providers willing to participate in the project. All practitioners were made aware of the option to opt out of the project. For those participants willing to participate in the project after being invited and having received the informed consent statement, data collection tools were provided. An overview of completing the data collection tools after implementing SBIRT was provided for participating providers. *SBIRT Implementation*

Participants were instructed on implementing SBIRT in patients that presented for an initial visit requesting a prescription for an opioid pain medication over a 4 to 6week interval in a primary care clinic in rural southeastern Mississippi. Participants implemented SBIRT on all new patients meeting criteria, age 18-45 and requesting a prescription for an opioid pain medication. Based on the review of literature (NIDA, 2015) which noted young adults age 18-45 at highest risk for misuse, patients less than 18 years of age or older than 45 years of age were excluded. Pregnant patients are also excluded due to vulnerability

Before prescribing opioid pain medications, providers were informed to conduct a comprehensive assessment based on evidence-based guidelines (CDC, 2016) on any individuals meeting inclusion criteria during an initial visit requesting pharmacological treatment with an opioid pain medication. Prescreen data was collected by participating NP providers to identify patients' risk for OUD. A comprehensive assessment included a risk assessment and interventions, including referral for treatment for opioid use disorder, and was provided based on the results or the risk assessment (SAMSHA, 2016) (Appendix F). Patients were first asked about past drug use to determine whether additional screening was necessary: In the past year, how many times have you used illegal drugs and/or prescription drugs for nonmedical reasons (prescreen)? If the risk screen was negative, participants followed evidence-based guidelines (CDC, 2016) but did not report on negative screens. If the preliminary screening was positive, risk level was determined further through the Opioid Risk Tool (ORT) which was provider administered. Participants provided brief intervention as needed. Brief intervention consisted of 5 minutes of motivational interviewing to assess readiness for positive behavioral change. All patients received screening and/or brief intervention depending on risk level. Brief intervention was utilized for patients identified as mild, moderate, or high risk prior to prescribing opioid pain medication. This project focused on motivational interviewing (BNI) for a period of 5 minutes (SAMSHA, 2016). Patients

identified at mild or moderate risk were treated according to the CDC (2016) guidelines for prescribing opioids for chronic pain. Only patients at high risk received referral for treatment. Patients at high risk were referred to local behavioral health/addiction services.

Data Collection

A data collection tool, the ORT, BNI, and list of referral sources was provided to participants. Participants administered and documented results of the ORT and BNI during patient visits. Data was documented on a data collection tool by NP providers. Patients were categorized on the data collection tool by age group; sex; level of risk for opioid abuse (low: 0-3, moderate: 4-7, or high >8); and brief intervention treatment (yes or no) with prescription for opioid treatment (yes or no); or referral for treatment (yes or no).

Ethical Protection of Human Subjects

There were minimal risks of harm to participants associated with this project. The project consisted primarily of participants, nurse practitioners (NP) providers, documenting screening, brief intervention, referral for treatment on a data collection tool. Data documented was reported in the aggregate, no single person was identified. Data was anonymous via de-identification and was protected using coding, and cannot be associated with individual subjects; therefore, loss of privacy and breach of confidentiality was not a risk. Although the project director knows who the providers \were, the association of providers to which data was accessible, only by listing the first initial of the provider's last name. The project director will made weekly follow-ups to answer any questions and ensure fidelity of procedure.

The project consisted of data with no identifying information. Data was recorded on the ORT and other data collection tools by the trained data collectors so that subjects could not be identified, directly, or through identifiers linked to the subjects. To ensure confidentiality and anonymity, subjects' information was stored using codes assigned on the data collection form. Data on the data collection tool was stored under double locks in the office files of the data collector at the clinic. The data collector was the only person who had access to the double locked office file. The data collection tools were placed in an envelope by the data collector to be given to the project director (PD) on a weekly basis for analysis and completion of the project. The project director provided any assistance necessary to ensure efficiency of data collection.

Information on the data collection tool was entered in an Excel spreadsheet by the project director to maintain confidentiality. Data was recorded and summarized by the Project Director so that subjects could not be identified, directly, or through identifiers linked to the subjects. Electronic data wad stored on a password protected computer. Confidentiality was protected by placing all physical data collected in a locked file box that was kept in the office of the PD and only the PD had access to the locked file box and drawer. All collected data forms will be destroyed by shredding after completion of the project 6 months post-graduation from the DNP degree program.

Participation in the DNP project was completely voluntary without risks or incentives and any participant had the option to decline participation at any time without penalty. Providers who agreed to participate may have feared occupational consequences if they did not participate, but were assured of no consequences for nonparticipation on the consent given prior to participation. Other inconveniences that the NP participants may have experienced were time constraints in implementing a component of an evidence-based guideline into daily practice.

Potential benefits participants may have gain as a result of participation in the project were improved evidence-based prescribing practice to minimize the risk for opioid pain medication misuse/abuse among patients seen by NPs in a primary care setting. In addition to identification of risk for opioid misuse or abuse and reduction in misuse of opioids, additional benefits included healthcare cost reductions and improvement in public health and safety.

Data Analysis

The project director evaluated use of evidence-based practice recommendations for SBIRT to include outcome categories of risk assessment screening for opioid abuse/misuse; brief intervention and referral. Data was retrieved through data collection tools provided to providers to answer the PICOTs question: "In patients 18-45 years of age, who present to a primary care clinic requesting a prescription for opioid pain medication, will screening by nurse practitioners identify patients at risk for opioid abuse leading to appropriate intervention or referral?" Data was stratified based on age (18-25), (26-35), (36-45); sex (male or female), risk level (low, moderate, high), opioid therapy initiated (yes or no), brief intervention (yes or no) and referral (yes or no). Patient follow-up information was not included in this project. Data was analyzed using descriptive statistics.

CHAPTER III - RESULTS

The purpose of this DNP project was to determine if nurse practitioners in a primary care setting are implementing evidence-based practice guidelines (CDC, 2016) to mitigate risk of prescription opioid pain medication abuse among patients who request a prescription for opioid pain medication. During the 4 week period of data collection, beginning February 1st and ending March 1st, 12 patients were identified that met criteria for inclusion in the study. Two NP providers participated in data collection for the study and saw 100% of the patients.

The ORT revealed 42% (5) of patients had a family history of alcohol abuse; 17% (2) patients had a family history of illegal drug abuse, and 0.08 % (1) patient had a personal history of illegal drug abuse. 25% (3) of patients had a history of preadolescent sexual abuse, while17% (2) of patients had a history of attention deficit disorder (ADD), obsessive compulsive disorder (OCD), bipolar, and/or schizophrenia and 42% (5) of patients had a history of depression. There were several identified risk factors for which none of the patients reported having, such as, family history of prescription drug abuse, and personal history of alcohol abuse. All descriptive data are represented in Table 2.

Table 2

Descriptive Statistics

					Std.
	Ν	Minimum	Maximum	Mean	Deviation
age	12	1	3	1.50	.905
sex	12	1	2	1.50	.522
Risk level	12	1	3	1.50	.798
intervention	12	1	2	1.83	.389
referred	12	1	2	1.83	.389
Opioid prescribed	12	2	2	2.00	.000
FH alcohol	5	1	3	1.80	1.095
FH illegal drugs	2	3	3	3.00	.000
FH Rx drugs	0				
PH alcohol	0				
PH drugs	1	4	4	4.00	
PH Rx drugs	0				
age1645	12	1	1	1.00	.000
PA Sex Abuse	3	0	3	1.00	1.732
ADD_OCD_ETC	2	2	2	2.00	.000
depression	5	1	1	1.00	.000
Score totals	12	1	9	3.58	2.999
Valid N (listwise)	0				

The largest portion of the sample based on age group was age 18-25 comprising 75% (9) of the total sample size. The remainder of the study sample was composed of 36-45 year old making up 25% (3). No patients in the sample fell into the 26-35 age range. The sample was split evenly between males and females. 66% (8) of patients were identified as low risk scoring 0-3--everyone scored at least 1 due to age criteria of 16-45 for use of the ORT. The average score for the low-risk category was two). 17% (2) of patients were identified as moderate risk scoring between 4 and 7. Lastly, 17% (2) of patients were identified as high risk. These data are represented in Table 2 below.

Table 3

Risk Level

				Valid	Cumulative
		Frequency	Percent	Percent	Percent
Valid	low	8	66.0	66.0	66.0
	moderate	2	17.0	17.0	83.0
	high	2	17.0	17.0	100.0
	Total	12	100.0	100.0	

Brief intervention was not performed for any of the low to moderate risk patients. Brief intervention and referral for treatment was performed in high-risk patients as indicated in Table 3.

Table 4

		interve	intervention		
		yes	no	Total	
Risk level	low	0	8	8	
	moderate	0	2	2	
	high	2	0	2	
Total		2	10	12	

Risk Level Intervention Cross Tabulation

CHAPTER IV – DISCUSSION

This DNP project was designed to implement a change in prescribing practices of nurse practitioner (NP) healthcare providers at a primary care health clinic in efforts to mitigate the risk of misuse of prescription opioid pain medications in patients requesting a prescription for opioid pain medication. Misuse of prescribed opioid pain medication is a problem pertinent to primary care and may be prevented through proper prescribing consistent with evidence-based practice recommendations. NP practitioner providers were educated on conducting a comprehensive assessment that includes screening for risk of opioid pain medication abuse/misuse (CMS, 2017a). Education was also provided on known risk factors for opioid misuse and abuse such as illegal drug use; prescription drug use for nonmedical reasons; history of substance use disorder or overdose; and mental health conditions. Risk level for misuse and abuse of opioid pain medication was identified through screening using the Opioid Risk Tool (ORT) for those patients with a positive preliminary screen. Brief intervention and referral to treatment was conducted for patients identified as high risk for opioid misuse.

Screening, Brief Intervention, and Referral for Treatment (SBIRT)

The SBIRT model was developed to screen for health risk behaviors in community-based settings. Risk factors for opioid misuse may be grouped into three categories (a) biological, (b) social, and (c) psychological (Claxton & Arnold, 2011). A priority area within the CMS (2017a) person-centered strategies to decrease opioid misuse is to expand screening, diagnosis, and treatment of opioid use disorder. Screening was conducted to identify risk for opioid misuse/abuse and interventions were provided to prevent opioid use disorder. Biological and psychological factors that predict OUD were considered when NP participants administered the Opioid Risk Tool (ORT) to those patients with a positive preliminary screen. Opioid use disorder (OUD) has been found in patients with comorbid mental disorders and physical conditions; therefore, assessing the psychosocial components of the ORT and conducting a comprehensive assessment are essential in primary care settings (Katz et al., 2013).

Another priority in the CMS (2017a) opioid misuse strategy is prescribers are to increase the use of evidence-based practices for acute and chronic pain management. After screening for opioid misuse/abuse risk, treatment should start with a comprehensive approach. The plan of care should address biological, psychological and social aspects (Interagency Pain Research Coordinating Committee, 2015). When pain is accompanied by comorbidities, clinicians should integrate or refer for therapies that target psychosocial factors. Two (17%) of patients received brief intervention, motivational interviewing, and were referred for treatment. Pain management and rehabilitation approaches are recommended for patients with chronic pain that are identified as high risk for opioid use disorder to coordinate physical, vocational, and or psychological components of care (Chou et al., 2009).

Prescribing Practices

Safe prescribing models for chronic pain management have been developed for prescribing opioids. (CDC, 2016). The NP participants exercised healthy prescribing habits as evidenced by not prescribing any opioid therapy in the 12 patients that presented requesting a prescription for an opioid pain medication. Prescribing practices are directly correlated with patient risk--healthy prescribing habits leading to lower risk and unhealthy prescribing habits are associated with higher risk (CDC, 2016). Data reveals implementation of evidence-based guidelines since most patients were low risk, and no opioids were prescribed. Implementation of best practice was desired due to recommendations against initiating pharmacological therapy with opioids unless other pharmacological and nonpharmacological therapies have been ineffective previously (CDC, 2016; Paone et al., 2011). The assumption is once educated providers change their prescribing habit and adopt evidence-based practice recommendations, the risk of patients misusing prescription opioid pain medications will be lowered.

Limitations

Only two NP participants implemented SBIRT in 12 patients during the short period for the project. While five NP providers were educated on evidence-based guidelines for prescribing opioid pain medication and SBIRT, patients that met the inclusion criteria for age 18-45 did not present to one provider requesting a prescription for opioid pain medication. The patient population seen by the NP were primarily adults over the age of 45. Two providers were on medical leave for most of the data collection period. Another limitation of the project is that patients may not have been completely honest in responses to the questions on the ORT due to stigma associated with substance misuse and other components of the ORT. For example, all patients denied a family and personal history of prescription drug abuse.

Implications

Practice Implications

While conducting a needs assessment for the DNP project, a retrospective chart review was conducted which revealed seven patients with a history of substance-related disorders with no documentation of a risk assessment performed. After providing education to NP participants, risk assessments for opioid abuse was conducted on the 12 patients seen by the NP participants. Routine screening for anxiety/depression and substance use disorders in primary care settings is imperative to mitigate risk for adverse health outcomes (CDC, 2016). Although no opioids were prescribed by the NP participants, known risks should be discussed will all patients prior to prescribing opioid pain medication and patient and provider responsibilities should be outlined. Immediate-release opioids should be prescribed at the lowest effective when starting pharmacological therapy (CDC, 2016).

The prescription monitoring program (PMP) tracks prescribers who may be prescribing opioids inappropriately (CMS, 2017a). Providers should review the PMP on patients when starting opioid pain medications and periodically during treatment. Experts suggest inappropriate prescribing contributes to misuse of prescription opioid pain medication (Shapiro et al., 2013); therefore, NP participants were also instructed to use the PMP for this project (CDC, 2016). The project did not evaluate whether the NPs accessed and documented use of PMP in the medical record. Accessing the PMP and other evidence-based practice guidelines should be followed when prescribing opioid pain medications.

Implications for Theory

The conceptual framework used for this project is the SBIRT Program Matrix. Participating NPs offered SBIRT services using the five components of the model at a rural health primary care clinical site. The project director outlined program planning, decision making, design, data collection and use during SBIRT program implementation. Implementation outcomes of the SBIRT Program Matrix include but are not limited to program adoption, fidelity, costs, and grant compliance (Del Boca et al., 2017).

Recommendations for adoption of the SBIRT program at the practice site will need to consider not only quality of care but costs and time in implementing SBIRT. Medicare, Medicaid, and commercial insurance reimbursement billing codes exist for providers who implement SBIRT (McCance-Katz & Satterfield, 2012; SAMHSA, 2016). With adoption and implementation of SBIRT, documentation is also essential and SBIRT forms should be scanned into the electronic medical record (EMR).

The fifth component of the SBIRT model, management structures and activities, includes evidence-based protocols; coaching and staff evaluation; program evaluation and dissemination; as well as facilitative administrative supports, systems interventions, and sustainability planning as necessary components of SBIRT program implementation and evaluation (Del Boca et al., 2017). Further evaluation of management structures and activities is warranted. Initial evaluation of implementing the SBIRT model for this project will be disseminated to stakeholders at the practice site where the project was conducted and will be disseminated to interested audiences.

Policy Implications

Further efforts should address each component of the SBIRT matrix, especially in the areas of coordination of care versus integration of care. Although SBIRT program implementation is effective, patients currently receive care from multiple providers at multiple practices sites making the process less seamless than desired. Nurse practitioners can influence practice and policy to mitigate risk for abuse and misuse of opioid pain medications. Utilizing an integrated care approach, dually certified NPs who are family nurse practitioners (FNPs), as well as psychiatric mental health nurse practitioners (PMHNPs), are prepared to provide care to individuals with a pain diagnoses and OUD with little to no fragmentation of care. Providers should offer or arrange evidence-based treatment for patients with opioid use disorder (CDC, 2016).

Coordinated, co-located, and integrated care are three cores of collaboration/integration encompassing six levels. Coordinated care is based on communication involving minimal collaboration (Level 1) and basic collaboration at a distance (Level 2) across separate facilities. Co-location focuses on physical proximity, basic collaboration onsite (Level 3) and close collaboration onsite with some system integration (Level 4). Integrated care requires a practice change aiming for close collaboration approaching an integrated practice (Level 5) and full collaboration in transformed/merged integrated practice (Level 6) (Heath, Wise, & Reynolds, 2013). Screening and assessment vary at each level. Screening and assessment done per separate practice models with separate treatment plans results in patients' physical and behavioral health needs being treated as separate issues. Although patients may be referred, a variety of barriers prevent many patients from accessing care. Close proximity allows referrals to be more successful and easier for patients. There is better follow-up when patients are internally referred. Moreover, the integrated care team approach feels like a one-stop shop. Patients experience a seamless response to all healthcare needs in a unified practice (Heath et al., 2013). Community mental health centers (CMHCs) and Federally Qualified Health Centers (FQHCs) are collaborating to provide integrated primary and behavioral health services, including addiction services (National Council for Behavioral Health, 2016). In the clinical setting where this DNP

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project was conducted, close collaboration onsite with system integration will meet the needs of individuals with a pain diagnoses and opioid use disorder.

Medication-assisted treatment (MAT) is recommended for individuals diagnosed with OUD. MAT, including opioid treatment programs (OPT), combines behavioral therapy and medications in the treatment of substance use disorders. Recent federal legislation, the Comprehensive Addiction and Recovery Act (CARA), provisions include increasing access to preventive services, medication-assisted treatment (MAT), and recovery services. Nurse practitioners with the appropriate education and certification can now be trained to treat OUD. NPs are granted privileges to prescribe buprenorphine in community-based setting after completing training and receiving a waiver to prescribe buprenorphine (SAMHSA, 2017). Since there are limited resources to refer patients for treatment if identified as high risk for opioid abuse, developing an integrated care model would be beneficial in providing care in one setting. NPs at the setting should keep abreast of changes in federal and state laws regarding opioid use disorder prevention and treatment so that qualified nurse practitioners are prepared to meet the need for preventive services, MAT, and recovery services.

Recommendations for Future Evaluation

Screening tools for the assessment of potential risks of opioid therapy are helpful for risk stratification. However, more screening studies are needed to explore outcomes and should be expanded across the lifespan, adolescent to elderly. Tools with construct partial validity include the Screener and Opioid Assessment for Patients with Pain (SOAPP); the Opioid Risk Tool (ORT); and the Diagnosis, Intractability, Risk, and Efficacy (DIRE) instrument. Regardless of the tool used by a provider, a thorough history is crucial to identify patients who require closer assessment, monitoring and or referral (Claxton & Arnold, 2011). The strongest factor predictive of misuse after initiation of opioid therapy is a personal or family history of alcohol or drug abuse. Further evaluation is warranted specifically on the correlation of prescribing practices and risk level identified via validated screening tools since researchers have revealed patients may misuse after only being prescribed one prescription for opioid pain medication (Levi, Segal, & Miller, 2013).

In addition, evaluation of risk for OUD in vulnerable and special populations such as pregnant women are lacking. Most providers report being inadequately trained to effectively treat pain and screen patients for prevention of misuse and abuse (The Interagency Pain Research Coordinating Committee, 2015); therefore, outcome studies that evaluate knowledge and implementation of evidence-based practices for prescribing opioid pain medication should be conducted. Finally, further studies should be performed to identify barriers to SBIRT implementation. Implementation outcomes of the SBIRT framework are adoption; acceptability; appropriateness; feasibility; fidelity; implementation costs; penetration; sustainability; service provision to at-risk populations; and (if applicable) grant compliance (Del Boca et al., 2017). All components of the SBIRT framework require further evaluation. NP participants for the DNP project voiced concern regarding time constraints and costs. However, as mentioned previously, SBIRT interventions are billable for commercial insurance, Medicare, and Medicaid. Again, evaluation should be conducted to assess the cost of adopting, implementing, and sustaining SBIRT and other evidence-based practice recommendations.

Conclusions

Due to the epidemic stemming from misuse of opioid pain medications, the CDC (2016) has implemented evidence-based guidelines to aid in risk mitigation. Implementation of evidence-based guidelines promotes proper prescribing practices which are directly correlated with patient risks (Katz et al., 2013). This DNP project was carried out to evaluate if nurse practitioner providers are utilizing appropriate screening to identify risk for opioid misuse in patients requesting opioid pain medications. Low-risk levels for opioid pain medication misuse was identified among mostly young adults. Young adults are an ideal population to implement interventions to mitigate risk (SAMHSA, 2016). Project outcomes extend beyond improved patient outcomes but also promote better-prescribing practices by NP providers. Implementing SBIRT in the clinical setting conjunctly with other validated screening tools could prove to be quite effective in combating misuse of opioid pain medication.

APPENDIX A – Brief Negotiated Interview Algorithm

BRIEF NEGOTIATED INTERVIEW (BNI) ALGORITHM

1) BUILD RAPPORT Tell me about a typical day in your life. Where does your current [X] use fit in? Help me understand, through your eyes, the good things about

using [X]. What are some of the not-so-good things about using [X]? So, on the one hand [PROS], and on the other hand [CONS].

3) INFORMATION & FEEDBACK Elicit Provide Elicit This Readiness Ruler is like the Pain Scale we use in the hospital. On a scale from 1-10, with 1 being not ready at all and 10 being completely ready, how ready are you to change your [X] use? You marked _____. That's great. That means you are _____% ready to make a change. Why did you choose that number and not a lower one like a 1 or a 2?

4) READINESS RULER Reinforce positives Ask about lower #

5) ACTION PLAN Identify strengths & supports Write down steps Offer appropriate resources. What are some steps/options that will work for you to stay healthy and safe? What will help you to reduce the things you don't like about using [X]? What supports do you have for making this change? Tell me about a challenge you overcame in the past. How can you use those supports/resources to help you now? Those are great ideas! Is it okay for me to write down your plan, your own prescription for change, to keep with you as a reminder? Will you summarize the steps you'll take to change your [X] use? I have some additional resources that people sometimes find helpful; would you like to hear about them? • Primary Care, Outpatient counseling, Mental Health • Suboxone, Methadone clinic, Needle Exchange, AA/NA, Smoking cessation • Shelter, Insurance, Community Programs • Handouts and information Thank patient Thank you for talking with me today. BNI-ART Institute, www.bu.edu/bniart

APPENDIX B – Review of Literature Table

Authors/ Year	Design/ Sample/ Setting	Framework/ Intervention/ Measures	Goal/ Aim	Outcomes/ Findings
American Academy of Pain Medicine			Screening tools to aid in prevention	Reliable instrument for identifying aberrant drug- related behaviors could be valuable for ongoing monitoring of risks and benefits of chronic opioid therapy
American Pain Society			Treatment approach to prevent and treat misuse/abuse	Recommends coordination of care when the services of other health care professionals are needed
American Society of Addiction Medicine (ASAM) (2016)	Guideline		Coordination/int egration of care	Recommends a combination of psychosocial interventions and medications for the treatment of opioid use disorder.
Centers for Disease Control and Prevention	Systematic review	Analysis of articles	Promote better opioid prescribing practices	12 recommendatio ns for management of chronic pain

(CDC) (2016)				with opioid
(2016)				pain medication
Chou et al (2009)	Report of evidence by expert panel 14 systematic reviews; 57 primary studies	8,034 abstracts	Pathway to prevention of opioid misuse/abuse	Consideration of the effectiveness of non-opioid therapy should precede chronic opioid therapy (COT). Screening tools for the assessment of potential risks of COT are helpful for risk stratification.
Claxton & Arnold (2011)		Analysis of articles		Common screening tools for opioid misuse in patients with chronic pain are Screener and Opioid Assessment for Pain Patients (SOAPP) and the Opioid Risk Tool (ORT).
McCance- Katz & Satterfield (2012)		499,000 patients	Integrate prevention and treatment of substance abuse	A key to using SBIRT in primary care settings Utilizing the SBIRT model, there was a 67.7% decline in reported illicit drug use at follow-up.

National			To provent	Overview of
			To prevent	
Institute on			opioid use	opioid risk tool
Drug			disorder (OUD)	(ORT) and its
Abuse				validation in
(2015)				screening for
				opioid
				misuse/abuse
Paone,	Report		Preventing	To prevent
Dowell,	City health		misuse of	misuse
Heller	information		prescription	providers
(2011)			opioid drugs	should avoid
(/			-F8-	prescribing
				opioids for
				chronic pain
				unless other
				pharmacologic al and or non-
				pharmacologic
				al approaches
				have been
				ineffective.
				Selection of
				patients for an
				opioid trial
				should follow
				weighing of
				potential risks
				and benefits of
				COT.
Reuben et	National			Patients at
al	Institute of			highest risk
(2015)	Health			should have
				more
				structured
				monitoring
				during follow-
				up visits at
				regular
				intervals.
Shapiro,		An effective		Use of
Coffa,		office-based		motivational
McCance-		approach		rather than
Katz		includes a		confrontational
(2013)		coherent		communication
(2013)				
		framework for		is best during

	identification of risk to promote behavioral change	screening, counseling, and treatment to improve patient outcomes.
Substance Abuse and Mental Health Services Administrat ion (SAMHSA) (2016	Comprehensive, integrated, public health approach	The SBIRT initiative is a comprehensive approach used in substance abuse.

APPENDIX C – DNP Essentials

DNP Essentials	DNP Essentials and Competencies Met
DNP Essential I Scientific underpinning for practice	Development, implementation, and evaluation of new practice approaches based on evidence-based clinical practice guidelines (EBCP) and the SBIRT conceptual framework was conducted for the DNP project. The pilot integration of the SBIRT program matrix framework provides an understanding of the conceptual model for program implementation and evaluation.
DNP Essential II Organization and systems leadership for quality improvement and systems thinking	Development and evaluation. Development and evaluation of a new care approach met the current and future needs of the organization, providers, and patients. Accountability for quality health care for the organization and patient safety were met by educating nurse practitioners regarding current EBCP guidelines and validated tools to identify and mitigate risk for opioid misuse and abuse among patients.
DNP Essential III Clinical leadership and analytical methods or evidence-based practice	Leadership skills were exemplified by the project director functioning as a practice specialist/consultant in a collaborative evidence-guided practice. Information technology and research methods were used in the design and evaluation of the project. Critical appraisal of the existing scientific literature was conducted to implement the best evidence for practice. Translation of research into the practice setting was implemented to improve healthcare outcomes.
DNP Essential IV Information systems or technology and patient care technology for the improvement and transformation of healthcare	Utilization of information systems was conducted during the need's assessment to evaluate outcomes of care and quality improvement. Program design, selection, use and an evaluation plan was developed and executed to monitor outcomes of care, including data abstraction. Information systems/technology improvements in the

	practice environment were recommended
	upon evaluation of the DNP project.
DNP Essential V	Patient advocacy and leadership skills
Health care policy for advocacy in	were used in developing and
health care	implementing health policies when
noutifi cure	prescribing opioid pain medications. A
	critical analysis of health policy and
	related issues on prescription opioid pain
	medication misuse/abuse at local, state,
	and federal levels was conducted in
	development and evaluation of the DNP
	project.
DNP Essential VI	Effective communication and
Inter-professional collaboration for	collaborative skills were utilized in the
improving patient and population	development and implementation of the
health outcomes	DNP project. The project director led
neurin outcomes	interprofessional (medical director,
	administrators, staff) and intraprofessional
	(nurse practitioner) teams to create a
	change in healthcare delivery.
	Improvement of population health
	outcomes was met through risk
	identification in efforts to prevent and
	reduce the risk for opioid misuse/abuse
	among patients presenting to the primary
	care clinic requesting a prescription for an
	opioid pain medication.
DNP Essential VII	Aggregate scientific data was analyzed
	related to prescription opioid pain
Clinical prevention and population	medication misuse/abuse. Health
health for improving the nation's	promotion/disease prevention efforts
health	focused on improvement of health status
	and gaps in care for individuals at risk for
	opioid misuse/abuse. The DNNP project
	implemented guidelines and SBIRT to
	prevent misuse and abuse of opioid pain
	medications.
DNP Essential VIII	Conceptual and analytical skills were
Advanced nursing practice	utilized to evaluate the links among
	practice, organization, population, fiscal,
	and policy issues. Advanced levels of
	clinical judgment, systems thinking, and
	accountability were achieved in the
	design, implementation, and evaluation of
	evidence-based care to improve patient

outcomes. The project director guided,
mentored, and supported other nurse
practitioners to achieve excellence in
nursing practice. A comprehensive and
systematic assessment of health and
illness parameters related to opioid
misuse/abuse in the practice setting was
conducted for the DNP project.

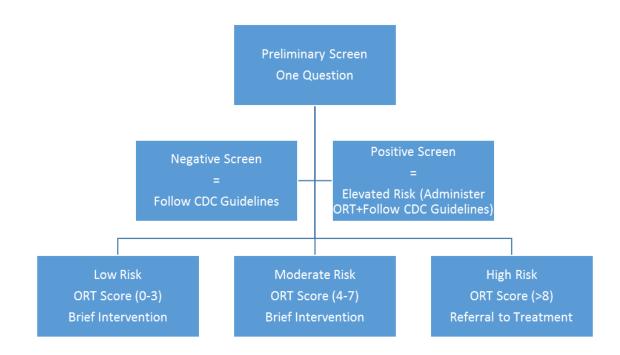
INPUTS	OUTPUTS		OUTCOMES		
Principal investigator Stakeholders SBIRT Tools	ACTIVITIES EBP Guidelines SBIRT Training Implementation Consultation	PARTICIPANTS Providers Patients Administration	SHORT TERM 1)CDC guideline implementati on 2)SBIRT implementati on	MEDIUM TERM	LONG TERM 1)Prevent misuse/ abuse of opioids 2)Prevention of OUD 3)Decrease healthcare costs

APPENDIX D –Logic Model

OPIOID RISK TOOL				
Mark each Item Sco	ore			
Item Score box that applies If Female	If Male			
1. Family History of Substance Abuse Alcohol []	II Male		3	
 Parinity History of Substance Abuse Alcohol [Personal History of Substance Abuse Alcohol [Illegal Drugs [] Prescription Drugs []	2 4 3 4 5	3	3 4 3 4 5
 3. Age (Mark box if 16 – 45) [] 4. History of Preadolescent Sexual Abuse [] 5. Psychological Disease Attention Deficit [] Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia 		1 3 2		1 0 2
Depression []		1		1
TOTAL ———— Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk > 8 Reference: Webster LR. Predicting aberrant behavior validation of the opioid risk tool. <i>Pain Medicine</i> . 200				

APPENDIX E – Opioid Risk Tool (ORT)

APPENDIX F - SBIRT Algorithm



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