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Implementation of an Opioid Risk Assessment Tool in an Acute Pain Service

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Dedication

This project is dedicated to God, my family “the village”, and the people who have lost their lives from an opioid-related overdose. The fight to end the opioid epidemic continues.

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Abstract

The U.S is currently experiencing a deadly opioid epidemic, as demonstrated by the prevalence of opioid misuse and overdose-related deaths. Over the last two decades, opioid overdose has claimed the lives of more than 700,000 Americans; deaths increased by 200% from 2000 to 2014 (National Institute of Health, 2020), and totaled 67,367 in 2018 alone (CDC, 2020). Therefore, healthcare providers collaborating with other stakeholders must continue to explore and apply appropriate risk assessment tools to mitigate this crisis, such as a systematic method of risk stratification. This quality improvement project aims to improve current opioid risk screening practices conducted by acute pain services (APS) by introducing an opioid risk assessment tool, the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score, into clinical practice. The DIRE Score was designed to be utilized in clinical practice and expected to substantially change providers' prescribing decisions. Purposive sampling was used to recruit the participants (N=11), APS providers from a metropolitan hospital in Atlanta, Georgia. Data was collected retrospectively, utilizing the DIRE Score and 9-weeks rounding sheet, before and during the 10-week project implementation. Lastly, a post-implementation questionnaire survey provided feedback about the DIRE Score. This research demonstrated no statistically significant relationship between provider's initial and final plans to initiate long-term opioid therapy or refer patients to addiction specialists. However, there was a statistically significant relationship between patients' risk level and their providers' decision to initiate long-term opioid therapy or refer patients to addiction specialists. The percentage of long-term opioid therapy methods initiated during the ten weeks of project implementation decreased from pre- to post-assessment. The providers' utilization of the DIRE Score increased, and the majority of providers perceived the DIRE Score to be an easy, helpful guide for making the difficult decision to authorize long-

term opioid therapy, validating their initial assessment and interventions. The DIRE Score helps to promote patients' safety and supports the safe prescription of long-term opioids.

Keywords: DIRE Score, opioids, DIRE, long-term opioid therapy, addiction specialist, opioid risk assessment tool, Acute Pain Service

Chapter I: Introduction and Background

Chronic pain constitutes a societal burden. Over 100 million Americans suffer from chronic pain, resulting in national health care costs of over $600 billion and the loss of workers' productivity (Harle et al., 2015). Dowell et al. (2016) estimated that 20% of patients that visited a physicians' office complaining of noncancer pain symptoms or a pain-related diagnosis received an opioid prescription. In 2012, providers wrote more than 259 million prescriptions for opioids, defined as medicines that contain chemicals used to relax the body and relieve pain (National Institute on Drug Abuse (NIDA), 2019).

Butler et al. (2014) found that the rise in the number of written opioid prescriptions was due to a new awareness of undertreated pain, and this uptick in opioid prescriptions led to an increase in opioid use disorder (OUD). In 2016, 11.8 million people aged 12 and over reported improperly using opioid prescriptions in the United States, accounting for 4.4% of the population (Ahrnsbrak et al., 2016). In addition, 953,000 people received treatment for the misuse of opioid pain relievers in 2017 (Center for Behavioral Health Statistics and Quality, 2018).

Opioid abuse presents serious risks, including overdose and death. Deaths from opioid overdose increased by 200% between 2000 and 2014 (National Institute of Health, 2020), and in 2018, there were 67,367 drug overdose deaths in the U.S. (CDC, 2020). Therefore, healthcare providers must collaborate with other stakeholders to explore and apply appropriate risk assessment tools to mitigate this crisis.

Background Information

Since 1999, opioids have claimed the lives of more than 700,000 Americans; currently, this amounts to an average of 130 deaths per day (Tawil, 2019). In 2017, facing annual deaths of about 47,600 people, the United States government confirmed the opioid crisis as a public health

emergency (Borsari & Read, 2019). In 2009, the Center for Disease Control and Prevention (CDC) reported that 1.2 million emergency department visits were related to the misuse or abuse of opioids (2011). According to results from the 2017 National Survey on Drug Use and Health, an estimated two million Americans misused prescription pain relievers for the first time within the past year, which averages approximately 5,480 initiates per day (National Institute on Drug Abuse, 2018). Zgierska et al. (2018) proposed that, to end the opioid crisis and reduce the rate of opioid misuse, providers should not start at-risk patients on opioid therapy.

A systematic review of chronic opioid treatment for chronic noncancer pain by Chou et al. (2009) strongly recommended conducting screenings of patients' history and risk levels for substance abuse, misuse, and addiction before initiating chronic opioid therapy. Furthermore, the review suggested that healthcare providers in inpatient practices must do their part to mitigate opioid use disorder (OUD); inpatient clinical practices play a pivotal role in delivering healthcare services, especially pain management (Chou et al., 2009).

As a translational clinical research project (TRCP), the primary investigator (PI) implemented the utilization of an opioid risk assessment tool into an acute care pain management group, the acute pain service (APS). When a patient's provider places a pain management consult, APS providers assess the patient and formulate a pain regimen. This assessment currently does not include the use of a validated opioid risk assessment tool to screen patients for compliance, or for their risk for opioid abuse and/or misuse. Given the current state of the opioid epidemic, screening chronic pain patients for opioid risk levels and aberrant drug behaviors before they start long-term opioid therapy is paramount.

Problem Statement

Opioids can depress the areas of the brain that control breathing, heart rate, and body temperature, causing them to stop functioning. If started on long-term opioid therapy without proper supervision or screening, patients who are high risk for opioid abuse and/or misuse could overdose on their prescribed opioids and die. Stakeholders such as the Center for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the American Pain Society, and the American Academy of Pain Medicine have highlighted the importance of assessing patients for risk of opioid abuse to ease the ongoing opioid epidemic (Dowell et al., 2016). Belgrade et al. (2016) developed an opioid risk assessment tool, the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score (see Appendix A) and stressed the need to identify a strategy for selecting patients who are the most likely to comply with, and benefit from, prescribed opioids. Dr. Jerome Adams, the former United States Surgeon General, emphasized the importance of behavioral health and risk factor assessments when prescribing opioids; providers that prescribe opioids for pain management should use these tools and assessments to help inform their treatment decisions (Substance Abuse and Mental Health Services Administration, 2018). When used in combination with a standardized clinical examination, validated risk assessment tools have been shown to improve the ability to detect opioid misuse; they have similarly improved providers' ability to detect aberrant behaviors in patients, such as soliciting opioids from other providers, forging prescriptions, and using additional opioids on top of those prescribed to them (Ducharme & Moore, 2019). These tools support providers in pinpointing at-risk patients' aberrant drug behaviors.

However, the APS does not routinely screen patients using an opioid risk assessment tool (ORAT) before starting long-term opioid treatment. This project sought to implement an ORAT,

specifically the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score, in clinical practice. In addition to a comprehensive assessment, consistent usage of the DIRE Score could provide the APS with a standardized approach for assessing the risk of opioid-related harms before prescribing long-term opioids. The DIRE Score could also support clinical decisions to initiate long-term opioids or refer patients to an addiction specialist.

Clinical Questions

The DNP project sought to answer the following questions:

Clinical Question 1: What are providers' initial and final plans for initiating long-term opioid use in acute pain service patients?

Clinical Question 2: What is the relationship between providers' initial plans for initiating long-term opioid use in acute pain service patients and their final plans for initiating long-term opioid use?

Clinical Question 3: What is the relationship between patients' risk level and providers' final plans for initiating long-term opioid use?

Clinical Question 4: What are providers' initial plans and final plans for referring acute pain service patients to an addiction specialist?

Clinical Question 5: What is the relationship between providers' initial plans for referring acute pain service patients to an addiction specialist and their final plans for referring acute pain service patients to an addiction specialist?

Clinical Question 6: What is the relationship between patients' risk level and providers' final plans for referring acute pain service patients to an addiction specialist?

Clinical Question 7: What percentage of the total number of patients were started on long-term opioids before and during the project implementation according to the acute pain rounding sheet?

Clinical Question 8: What is the providers' utilization of the DIRE Score at two, four, six, eight, and ten weeks?

Clinical Question 9: What are providers' perceptions regarding the DIRE Score after ten weeks of utilization?

The Purpose of the Project

This project aimed to implement the DIRE Score in an acute pain service. Screening patients hospitalized with acute or chronic noncancer pain for the risk of opioid abuse before initiating long-term opioids could help mitigate opioid abuse and misuse after they are discharged. Providers can use this tool to improve patient assessments, thus minimizing risk and maximizing benefits, especially for those on long-term opioid therapy. The study's primary desired outcome was for providers to adopt a standardized screening approach using a validated tool to assess risks before starting long-term opioid treatment on patients. The goal of these measures is to promote patient safety and ease the ongoing opioid epidemic. Patients deemed inappropriate for long-term opioid therapy will be identified based on risk assessment scores, and providers will make appropriate recommendations or referrals before the patient leaves the hospital.

Needs Assessment

The principal investigator (PI) initiated a needs assessment with acute pain services (APS) to identify potential enhancements to quality improvement measures. The site for this project was a hospital in metro Atlanta, in which APS practiced. When a patient's provider places a pain management consult, APS providers perform a focused exam of patients' history and physical state and, with that information, formulate a pain management plan. This approach does not include the use of a validated opioid risk assessment tool to screen patients for

compliance or their risk for opioid abuse and/or misuse, which is vital in light of the continuing opioid epidemic.

Following an interview with the APS manager, the PI identified the need to improve screening and assessment methods for opioid prescription using systematic practices. The PI further discussed implementing the DIRE Score during a staff meeting, in which providers were receptive. They verbalized the importance of using a risk assessment tool as the standard of practice, which can help validate their decisions when initiating long-term opioid therapy, especially long-term opioid analgesics such as Fentanyl, OxyContin, and MS Contin.

The APS typically gets contacted for a pain management consultation by another provider. For instance, a patient admitted to the hospital because of uncontrolled chronic back pain is now in acute pain. The APS can either initiate a new therapy, resume previous home therapy, or modify existing treatment. Patients believed to be at risk for opioid misuse are not accepted for pain management treatments conducted by the APS. Rather, they recommend that patients follow up with an addiction specialist and continue to communicate with their pain management providers.

The CDC guideline for prescribing opioids recommends that providers evaluate risk factors for opioid-related harm and incorporate risk mitigation strategies into the management plan both before starting opioid therapy and periodically during its continuation (Dowell et al., 2016). Similarly, a systematic review of chronic opioid therapy for chronic noncancer pain by Chou et al. (2009) strongly recommended that providers assess patients' history, physical health, and their risk of substance abuse, misuse, or addiction before initiating chronic opioid therapy. It is the assumption of this project that patients who are prescribed long-term opioids without an

objective measure of the risk, or a standardized risk assessment tool, are deemed low-risk according to providers' subjective judgment.

Operational Definitions

A review of precise operational definitions and concepts is an essential component of this study. The relevant terms in this research project are:

Initial plans for long-term opioid use (LTO)-PRE-DIRE Score - providers' decision to initiate long-term opioids before using the DIRE Score.

Initial plans for a referral to an addiction specialist (RAS)-PRE-DIRE Score – providers' decision to recommend a referral to an addiction specialist before using the DIRE Score.

Final plans for long-term opioid use-(LTO)-POST-DIRE Score – providers' decision to initiate long-term opioids after using the DIRE Score.

Final plans for a referral to an addiction specialist (RAS)-POST DIRE Score – providers' decision to recommend a referral to an addiction specialist after using the DIRE Score.

Summary

Mitigating the opioid misuse epidemic cannot be overemphasized given the loss of lives and attendant resources. Stakeholders have recommended a systematic approach to screen patients to minimize the potential for OUD by identifying aberrant drug behaviors. Since inpatient clinical centers with hospital privileges provide pain management services, clinicians must adopt standardized screening tools in these centers. This chapter highlighted the background, problem statement, clinical questions, and needs assessment of the proposed

project. In the next chapter, an in-depth literature review described the foundations of knowledge of the project.

Chapter II: Review of the Literature and Conceptual Framework

Review of the Literature

A comprehensive literature search was performed using select databases such as CINAHL®, MEDLINE®, ProQuest Central®, Academic Search Complete, and Google Scholar®. The search terms used to find articles included 'opioid risk tools,' 'clinical decision making,' 'risk assessment tools,' and 'opioid misuse behaviors,' used both separately and in conjunction. The literature consisted of clinical studies, cross-sectional studies, surveys, and interviews.

Opioid Misuse Behaviors

Patients who abuse opioid prescriptions exhibit several aberrant drug behaviors. According to Ferrari et al. (2014), an aberrant drug behavior is any medication-related behavior that departs from strict adherence to the prescribed therapeutic plan of care. Examples of aberrant behaviors include using additional opioids outside of those prescribed, forging a prescription, soliciting opioids from other providers, reporting lost or stolen prescriptions, requesting early refills, overdose, and death (Webster & Webster, 2005).

Fleming et al. (2008) conducted a large-sample study (n=904) to determine the frequency of aberrant drug behaviors and their relationship to substance abuse disorders. These patients received opioids for chronic pain from 2002 to 2004 in 235 primary care physicians in eight Wisconsin counties. Participants completed nine written questionnaires and five interview-based surveys. Twelve aberrant drug behaviors in the questionnaire included: (1) purposely over-sedated oneself with opioids, (2) felt intoxicated from opioids, (3) had a motor vehicle accident

while taking opioids, (4) requested an early refill, (5) increased opioid dosage without physician consent, (6) lost or had opioids stolen, (7) tried to obtain opioids from more than one clinician, (8) successfully obtained opioids from more than one clinician, (9) used opioids for purposes other than that prescribed, (10) used alcohol to deal with pain, (11) missed an appointment for a pain condition, and (12) hoarded opioid medication. The study concluded that 80.5% of the patients reported one or more lifetime aberrant drug behaviors, the most frequent being requesting early refills (41.7%), increased dose without physician consent (35.7%), and felt intoxicated from opioids (32.2%). A logic model found that subjects who reported four or more aberrant behaviors were more likely to have a current substance use disorder.

Screening tools help providers detect whether a patient is currently addicted to or abusing prescription medications. Several studies concluded that opioid screening tools were useful for predicting and detecting aberrant behaviors (Webster & Webster, 2005; Larance et al., 2015; Moore et al., 2009; Jones et al., 2015; Varney et al., 2018). Larance et al. (2015) completed a cross-sectional study that developed a brief scale, the Opioid-Related Behaviors In Treatment (ORBIT), which identifies and quantifies recent aberrant behaviors among diverse populations receiving long-term opioid treatment. Four hundred twenty-six patients, recruited from 57 retail pharmacies in two Australian jurisdictions and four pain clinics, were prescribed opioids for a minimum of three months or longer. They completed a 40-item opioid-related survey that included one item per identified aberrant behavior or related matter. The survey created a 10-item scale that showed validity, acceptable test-retest reliability, and adaptability to both clinical and research settings to monitor patient progress. The Pearson's correlation was $r = 0.80$, $p < 0.01$; in terms of internal consistency, Cronbach's alpha = 0.89. The study concluded that the ORBIT would help prompt clinical decisions and aid in the detection of aberrant behavior.

Moore et al. (2009) completed a comparative study that employed different opioid risk-assessment tools to determine how accurately these measures were in predicting the risk of aberrant drug-related behavior. The convenience sample included 48 patients who attended a pain clinic in Knoxville, TN after their opioid treatment was halted due to aberrant drug-related behavior. Participants completed a standard packet of questionnaires, including SOAPP®, ORT, and DIRE Score, and underwent a semi-structured clinical interview with the staff psychologist before receiving opioid analgesics for pain management. They were also required to attend regular appointments, provide urine samples, and adhere to proper medication and clinical guidelines. At the end of the study, the analysis compared the sensitivity of each self-reported measure with the results of the clinical interviews to predict the likelihood of discontinuance because of aberrant drug-related behavior. The results showed that the sensitivity score was 0.77 for the clinical interview, 0.72 for SOAPP, 0.45 for the ORT, and 0.17 for DIRE Score. When the results of the clinical interviews and SOAPP questionnaires were combined, sensitivity increased to 0.90, which demonstrated that these measures were the most effective at predicting discontinuance of opioid therapy due to aberrant drug-related behaviors.

Similarly, Jones et al. (2015) completed a comparative study of a new patient-completed risk tool known as the Brief Risk Questionnaire. The study compared it with a structured clinical interview and two risk assessment tools, ORT and SOAPP®-R, to predict aberrant behavior at a six-month follow-up. The 454 pain-clinic patients were given a packet that contained the BRQ, the ORT, and SOAPP®-R. They also received other assessment tools, such as the Distress Thermometer, the Zung Depression Scale, the Zung Anxiety Scale, the Pittsburgh Sleep Quality Index, the Pain Catastrophizing Scale, and a clinical interview. Researchers gathered information by reviewing patients' medical records, the disposition of the cases at the six-month follow-up,

and the presence or absence of aberrant behavior during this period. The study concluded that the BRQ could better predict future aberrant drug behavior than the ORT and SOAPP®-R, and it could be a useful tool for conducting opioid risk assessments.

Varney et al. (2018) conducted a prospective observational study of adult patients consisting of uniformed members, retirees, and family members over 18 years of age seeking treatment in a high-volume emergency department. The study, designed to determine if validated tools such as the SOAPP®-R, COMM, and provider's gestalt therapy could identify patients at risk for prescription opioid misuse through their pharmacy records, recruited 163 patients via convenience sampling. The study concluded that providers could use gestalt and validated patient self-assessment tools to identify at-risk patients.

Webster and Webster (2005) completed a study to provide clinicians with a brief screening tool that could be used to predict which individuals may develop aberrant behaviors when prescribed opioids for chronic pain. One hundred eighty-five patients were recruited from a pain clinic from January 2000 to May 2001 and asked to complete the ORT, which consists of five items: family and personal history of alcohol, illegal drug and prescription substance abuse, age, history of pre-adolescent sexual abuse, and specific mental disorders. Patients received scores of 0-3 (low risk), 4-7 (moderate risk), or > 8 (high risk), which indicated their probability of displaying opioid-related aberrant behavior. The study concluded that 17 out of 18 patients in the low-risk category (94.4%) did not display aberrant behavior; however, 40 out of 44 (90.9%) patients in the high-risk category did so.

These studies have shown that opioid risk assessment tools help detect aberrant behaviors. The ORT and the BRQ both demonstrated validity and accuracy in predicting whether patients were high- or low-risk for opioid-related aberrant behavior. Using these tools, providers

can modify patients' treatment plans according to their individual risk profiles, allowing more accurate identifications of high-risk patients and more appropriate recommendations or referrals to an addiction specialist.

Risk Assessment Tools

The national standard for chronic pain care now requires that patients undergo risk stratification before beginning opioid therapy (Jones et al., 2015). Validated screening tools should be used to accomplish this assessment. There are three types of risk assessment instruments designed to detect different dangers: opioid misuse before initiating long-term opioid therapy, signs of misuse in patients currently using opioids, and lastly, non-opioid general substance abuse. Providers can use various risk assessment tools to conduct risk stratification, such as the Diagnosis, Intractability, Risk, Efficacy (DIRE) Score, the Opioid Risk Tool (ORT), the Screener and Opioid Assessment for Patients with Pain® (SOAPP®) and its revision the (SOAPP®-R), the Screening Instrument for Substance Abuse Potential (SISAP), the Opioid Compliance Checklist (OCC), the Opioid-Related Behaviors in Treatment (ORBIT), the Pain Medication Questionnaire, the Brief Risk Interview© (BRI)©, and the Brief Risk Questionnaire (BRQ). Providers can also use the Alcohol Use Disorders Identification Test (AUDIT) to screen non-opioid general substance abuse. Tools such as the DIRE Score and PDAT are clinician-rated instruments, while tools such as the ORT, SISAP, and SOAPP®-R are patient self-assessment instruments (Cheattle, 2019).

Greene et al. (2017) conducted a study on 1,538,120 patients receiving opioids to identify factors that increase the likelihood that a patient will engage in opioid-related risk behaviors; researchers used INSPECT and the Prescription Drug Monitoring Program (PDMP) to conduct this study for the state of Indiana. The PDMP is a statewide electronic surveillance program that

collects pharmacy information each time a controlled substance is dispensed. It can be used as both a screening tool and a clinical tool that assists and supports the decision-making process for patients receiving opioids. Four risk behaviors were identified: patients receiving > 90 milligrams of morphine or equivalent, having >4 opioid prescribers, obtaining opioids from >4 pharmacies, and using benzodiazepines. The result showed that 18.4% engaged in one, 5.3% engaged in two, 1.6% engaged in three, and 0.4% engaged in all four risk behaviors: about one-fourth of all patients consuming opioids engaged in one or more risk behaviors. The use of the PDMP as a screening tool helped identify opioid users at high risk for misuse.

Oliva et al. (2017) conducted a quality improvement project to develop a clinical decision support tool to help identify patients at greater risk for overdose or suicide-related events in the Veteran Health Administration (VHA). The Stratification Tool for Opioid Risk Mitigation (STORM) tool was designed to combine data elements to calculate risk scores using risk-mitigation strategies. The study included patients with active short- or long-acting opioids analgesic prescriptions from the VHA. Researchers retrieved data from 1,135,601 participants from the electronic medical record (EMR) and used a predictive model to classify patients based on risk for overdose/suicide-related adverse events, which allowed high-risk patients to be identified. The area under the curve (AUC) for the STORM tool was reasonably accurate at > 0.81. The study concluded that clinical informatics could leverage EMR extracted data to identify patients at risk for overdose/suicide-related events and provide clinicians with information to mitigate risk.

Kavukcu et al. (2015) conducted a cross-sectional study of 36 physicians working at a family health center with the goal of enhancing primary care physicians' knowledge, attitudes, and practices about opioid use through education on risk assessment. The researchers surveyed

participants on patients' risk assessment in both intervention and control groups; the intervention group received education about assessment for the risk of opioid use, but the control group did not. The survey was repeated after six months, and the intervention group underwent a core examination. The results showed that 61% of family physicians reported concern and hesitation in prescribing opioids due to known risks, such as overdose, addiction, dependence, or diversion, and agreed that family physicians should apply risk assessment before prescribing opioids for chronic noncancer pain.

Salinas et al. (2012) conducted a study utilizing a nationally distributed case vignette survey of primary care physicians (PCP), pain specialists, and pharmacists, in addition to chart reviews and surveys of patients with chronic pain. From March 2011 to May 2011, the study aimed to better understand healthcare professionals' current knowledge, perception, and clinical practice patterns regarding the prescription of long-acting opioid therapy to patients with chronic pain. The study results showed that many PCPs are inadequately performing opioid risk assessments. Also, the accuracy of opioid risk assessments can vary, which can result in PCPs misestimating patients' risk level, further establishing the importance of standardized opioid risk assessment tools.

Validity of Risk Assessment Tools

Belgrade et al. (2006) completed a retrospective analysis to test the DIRE Score's validity, and predicted that chronic pain patients would have effective analgesia and long-term opioid maintenance treatment. The DIRE Score consists of four factors: Diagnosis, Intractability, Risk, and Efficacy. The risk subcategories, psychological state, chemical health reliability, and social support, are rated separately and then added together to form the DIRE Score, which is used to determine if a patient is suitable for long-term opioid analgesia. DIRE Scores were then

assigned to 61 cases from the pain center's database, and the cases were abstracted into vignettes, which six physicians scored. Researchers conducted repeat scoring for 30 new vignettes after two weeks. The study concluded that the DIRE Score's internal consistency was high (Cronbach's alpha = .80). The sensitivity was 94% and specificity was 87%. The intraclass correlation was 0.94 for interrater reliability and 0.95 for intra-rater reliability.

Reliability: Based on the retrospective study of Belgrade et al. (2006), the internal consistency of the DIRE Score has a Cronbach alpha of .80. This study tested the reliability and validity of the DIRE Score, with three outcomes measures: the global impression of the efficacy of opioid analgesia, the global impression of compliance with prescribing process, and disposition with regards to the continuation of opioids at the last clinical contact. The DIRE Score's sensitivity and specificity for predicting patient compliance to long-term opioid therapy were 94% and 87%, respectively. When analyzing efficacy, the specificity and sensitivity were 76% and 81%, respectively, and lastly, for disposition, the specificity and sensitivity were 73% and 85%, respectively (Belgrade et al., 2006). The intraclass correlation was 0.94 for interrater reliability and 0.95 for intrarater reliability (Terry, 2018).

Validity: According to Belgrade et al. (2006), the validity of the factors making up the DIRE Score was strong. This conclusion was based on feedback from clinicians who had used the tools in their practice. When the chi-square test was used for trends, all factors except for diagnosis showed a significant relationship ($P<0.001$) with compliance. Intractability was the only factor that did not show a significant association ($P <0.05$) with efficacy. Other than diagnosis, all factors showed a significant relationship with the disposition ($P< 0.05$) (Belgrade et al., 2006).

Similarly, Ferrari et al. (2014) conducted an observational, prospective, longitudinal study to evaluate the predictive validity of the PMQ and the DIRE Score in chronic pain patients. Seventy-five patients were recruited from a pain management unit of San Bortolo Hospital in Vicenza and Sant'Antonio Hospital in Padua. Researchers followed them between December 2009 and January 2012, and evaluated all patients' risk of opioid misuse using the PMQ (patient-completed) and the DIRE Score (filled out by a multidisciplinary team). The patients also went through medical and psychological screening at two, four, and six months. The study concluded that the PMQ demonstrated good internal consistency (Cronbach's alpha = 0.77) and test-retest reliability (r = 0.86). Researchers found significant correlations between higher PMQ scores and the number of aberrant drug behaviors detected at two, four, and six-month follow-ups ($P< 0.01$). The DIRE Score also demonstrated good predictive validity, as significant correlations were found between a lower total DIRE Score (higher risk of opioid misuse) and a higher number of aberrant drug-related behaviors detected at two months ($r = -0.37$; $P < 0.01$), four months ($r = -0.35$; $P< 0.01$), and six months ($r = -0.34$; $P< 0.01$).

Jamison et al. (2016) conducted a study to assess the efficacy of the Opioid Compliance Checklist (OCC) for monitoring opioid adherence among chronic pain patients in multiple primary care centers who were prescribed long-term opioid therapy. Researchers recruited 177 chronic pain patients from eight primary care centers, who completed pre-and post-study measures, as well as the OCC, once a month for six months. Patients were classified on the Drug Misuse index based on urine toxicology screens, physicians' misuse behavior ratings, and self-report questionnaire results. Three items from the OCC were most predictive of opioid misuse, which researchers determined by measuring and analyzing the area under the curve (AUC= .861). Patients that scored lower on the OCC showed greater compliance with their

opioid medication. The OCC seems to be a reliable and valid screening tool to help detect current and future aberrant drug-related behavior and nonadherence among chronic pain patients in primary care. Validated screening tools like the DIRE Score, PMQ, and OCC have been successfully used to identify patients at risk for opioid misuse.

Clinical Decisions

The literature shows that screening tools can help identify opioid abuse. Consequently, several studies have focused on both how providers approach the patient screening process with or without standardized tools and their level of confidence about their opioid risk assessment decisions (Harle et al., 2015; Pearson et al., 2017). Studies by Webster and Webster (2005), Larance et al. (2015), Moore et al. (2009), Jones et al. (2015), and Varney et al. (2018) have shown that using opioid risk assessment tools helps detect aberrant behaviors, supports decision making, and boosts providers' confidence levels when deciding to initiate opioid therapy.

Harle et al. (2015) conducted an in-depth interview with 15 family and general medicine physicians to understand how providers view their decisions to prescribe opioids for chronic noncancer pain (CNCP). The study revealed that providers often rely on their own individual assessment of patients' risk level for aberrant drug-related behaviors, such as opioid abuse, despite recognizing that they may make inaccurate assessments. Some physicians even actively avoid the chronic pain management field because of their concerns about opioid risks. The researchers proposed that clinical leaders, educators, and policymakers should continue to create and disseminate evidence-based education on chronic pain and opioid risk assessment.

Pearson et al. (2017) conducted an Opioid Therapy Provider survey to investigate the association between provider confidence in managing chronic pain and their practice behaviors and demographics. The survey was offered to 103 providers (physicians, physician assistants,

nurse practitioners, and other prescribing providers) that attended the Mayo Clinic Opioid Conference: Evidence, Clinical Considerations, and Best Practice. The survey results showed that 60.8% of the respondents did not feel confident managing patients with chronic pain. The providers' confidence was positively correlated with: following an opioid therapy protocol ($P=0.001$), the perceived ability to identify patients at risk for opioid misuse ($P=0.006$), and using a practice-based approach to improve their comfort level ($P<0.001$). The study concluded that providers' confidence was associated with a protocolized, consistent, practice-based approach towards managing opioids and their perceived ability to correctly identify patients at risk for opioid misuse.

Conceptual Framework

Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) was used as the theoretical framework for this project. RE-AIM was initially developed in 1999 by Russell Glasgow, Shawn Boles, and Thomas Vogt, as a framework for the consistent reporting of research results. It was later used to organize reviews of existing literature on health promotion and disease management in different settings (Glasgow et al.,1999). The following questions guided the implementation process:

1. How do I reach the targeted population?
2. How do I know my intervention is effective?
3. How do I develop the institutional support to deliver my intervention?
4. How do I ensure the intervention is adequately delivered?
5. How do I incorporate the intervention so it is delivered over the long-term?

The five-dimensional RE-AIM framework was instrumental in guiding the implementation of this project.

Reach refers to the targeted audience or individuals willing to participate in a given intervention. The PI reached out to 11 acute pain service providers, targeted because they provide pain management in an acute care setting, and 11 agreed to participate.

Effectiveness is an intervention's impact on essential outcomes, including potential adverse effects. The overall goal is to mitigate the opioid crisis by equipping providers who prescribe opioids with an objective method to screen patients before initiating long-term opioid therapy. Positive feedback attained from the post-implementation survey about the use of the DIRE Score showed that it was implemented effectively.

Adoption refers to the proportion and representativeness of settings and intervention agents who are willing to initiate the program. Eleven nurse practitioners received education via a PowerPoint® presentation, and they began screening with the tool for ten weeks.

Implementation involves the intervention agents' fidelity to the adaptations of intervention and its associated strategies for implementation. Over a ten-week period, the APS providers used the DIRE Score to screen patients who required pain management before deciding to either initiate long-term opioid therapy or refer patients to an addiction specialist.

Maintenance is the extent to which a program is integrated into an organization's routine practices and policies. This project implemented an opioid risk assessment tool in an acute pain service so that providers could use it to screen patients requiring opioid therapy in their clinical practice. Incorporating the DIRE Score into the electronic health record will make the DIRE Score easily accessible to all providers and promote routine use in the future.

It was utilized in different stages to evaluate the success of the project, as shown by Figure 1.

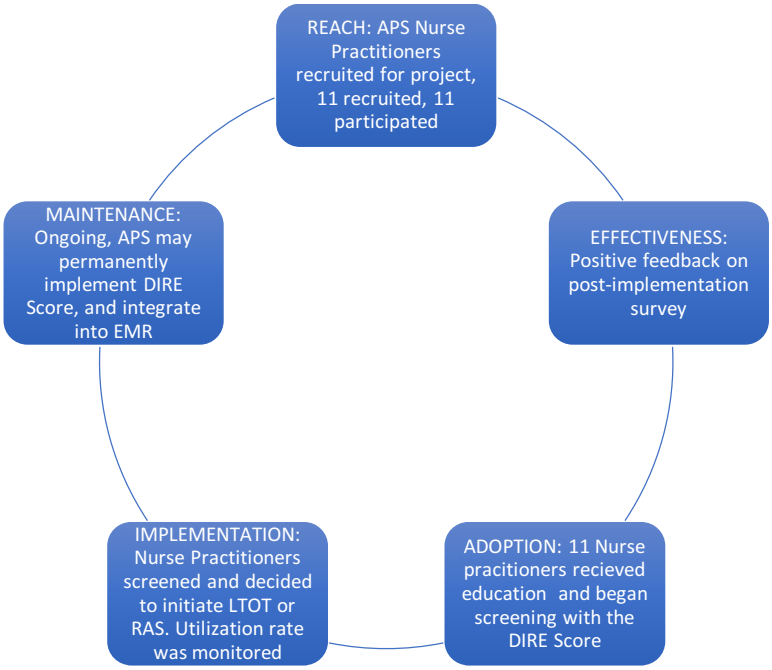

Figure 1.

Application of the Reach, Effectiveness, Adoption, Implementation, Maintenance Framework.

The study by Strand et al. (2020) also used the RE-AIM model to evaluate an opioid and Naloxone education program, which identified strengths in the areas of efficacy, adoption, and maintenance, and highlighted the need for improvement in the areas of reach and implementation. Similarly to this project, studies focused on changing individual behavior have also used RE-AIM as their framework (King et al., 2010). RE-AIM has also been used in the study of diverse health areas to plan and assess progress, report results, and review existing literature (Gaglio et al., 2013).

Summary

The literature review detailed in this chapter showed that patients who abuse their opioid prescriptions also show aberrant drug behaviors. Providers can use validated screening tools to identify such aberrant behaviors and inform their judgment to recommend long-term pain

management regimens for patients. Using opioid risk assessment tools can support providers' decision making and boost their confidence levels when deciding to initiate opioid therapy.

This project introduced a validated screening tool, the DIRE Score, in an APS group to support providers in screening patients. The project also shows the utility of the RE-AIM theoretical framework for instituting organizational change. The next chapter discusses the project's methodology, design, and ethical considerations.

Chapter III: Methodology

Methodology

The PI carried out a quality improvement project in an acute pain service to promote patient safety and promote safe prescribing practices. The providers used the DIRE Score to screen patients requiring pain management and considered for long-term opioid therapy. This DNP project sought to answer the following clinical questions:

Clinical Question 1: What are providers' initial plans and final plans for initiating long-term opioid use in acute pain service patients?

Clinical Question 2: What is the relationship between providers' initial plans for initiating long-term opioid use in acute pain service patients and their final plans for initiating long-term opioid use?

Clinical Question 3: What is the relationship between patients' risk level and providers' final plans for initiating long-term opioid use?

Clinical Question 4: What are providers' initial plans and final plans for referring acute pain service patients to an addiction specialist?

Clinical Question 5: What is the relationship between providers' initial plans for referring acute pain service patients to an addiction specialist and their final plans for referring Acute pain service patients to an addiction specialist?

Clinical Question 6: What is the relationship between patients' risk level and providers' final plans for referring acute pain service patients to an addiction specialist?

Clinical Question 7: What percentage of the total number of patients were started on long-term opioids before and during the project implementation according to the acute pain rounding sheet?

Clinical Question 8: What is the providers' utilization of the DIRE Score at two, four, six, eight, and ten weeks?

Clinical Question 9: What are providers' perceptions regarding the DIRE Score after ten weeks of utilization?

Project Design

This descriptive mixed methods quality improvement project introduced an opioid risk assessment tool, the DIRE Score, to the providers at an acute pain service group. The providers utilized the DIRE Score to assess patients for risks of opioid misuse before starting pain management therapy.

Before the Implementation of the DIRE Score

A review of the providers' APS rounding sheet revealed the number of patients initiated on long-term opioids in May and June, nine weeks before implementing the DIRE Score. Providers wrote any modifications to the patient's plan on the sheet, allowing for continuity of care, as they may not see the same patients every day. The PI contacted providers via e-mail to invite them to the research. Informed consent was sent and signed electronically. Also, the PI emailed each participant a PowerPoint® Presentation on how to use the DIRE Score.

DIRE Score Implementation

During project implementation, providers conducted their standard assessment and responded to two clinical decision questions. The two questions were: (1) would you initiate long-term opioids, or, (2) would you recommend a referral to an addiction specialist? Providers then used the DIRE Score on the same patient to assess for opioid misuse risks, computed a score for the patient, and then responded to the same two clinical decision questions previously asked.

After Project Implementation

The PI sent out a post-implementation questionnaire survey consisting of mostly open-ended questions to providers, to obtain their feedback on the DIRE Score. Next, the PI reviewed the APS rounding sheet to assess the number of patients initiated on long-term opioids during the implementation, and entered the data from both tools into SPSS for analysis.

Data Collection

The PI used the APS rounding sheet to obtain the number of long-term opioids initiated, in the nine weeks before and ten weeks during the project implementation, and used the clinical decision questions on the DIRE Score forms to count the total number completed and the patients' DIRE Scores. The PI remained available to provide support throughout the ten weeks of project implementation.

Setting

The PI conducted this project within a specialty group, the acute pain service, which provides in-patient pain management services in a metro Atlanta acute care hospital system, during the global COVID-19 pandemic. Clients are typically surgical patients with acute pain, or those admitted with acute pain and/or a history of chronic pain. The APS typically receives a request for an expert consultation from a provider in a different specialty, for various reasons. For example, when a patient is admitted with acute chronic pain, the APS can initiate a new therapy, resume earlier home therapy or modify existing therapy, increase the dose of a short-term opioid, or start a long-term opioid.

The service has a total of twelve providers, all of whom are nurse practitioners. Six nurse practitioners work full-time, and six work part-time.

Participants

The PI used a purposive sampling strategy to recruit the providers (nurse practitioners) by sending an e-mail asking them to consider taking part in the research project (see Appendix B). The e-mail described the intent, scope, and needs of the project. Eleven providers participated in the project. The study's inclusion criteria consisted of certified NPs, employed in the acute pain service, over 18 years old. Exclusion criteria included nurses who were not in an advanced practice role or employed by the acute pain service. The PI emailed a PowerPoint® presentation on how to use the DIRE Score and provided ongoing support via telephone, e-mail, and text throughout the ten-week implementation period.

Ethical Considerations

An Institutional Review Board (IRB) approval was obtained from Georgia College (see Appendix C), and site approval from Northside Anesthesiology Consultants (see Appendix D), before the commencement of the project. There was no foreseeable physical or mental risk of harm to participating providers. The PI practiced complete disclosure about the project, participation was voluntary, and electronic informed consent forms were signed (see Appendix E). Providers were given the choice to opt-out at any time during the process, and informed that they would experience neither coercion, financial or material incentive, nor consequences from the organization, whether they participated in the project or not.

Data Security

The data for this project included providers' responses from the surveys and the DIRE Scores. Data collected were reported in aggregate; no form of identification linked patient or participant responses, to assure anonymity and confidentiality. The completed DIRE Scores were stored in a locked box, and only the PI had access. Electronic data was stored and encrypted on a

personal password-protected computer that was accessed solely by the PI. Data was analyzed using Statistical Package for Social Science (SPSS ® Version 25). The PI will retain all records for a minimum of three years, in compliance with the Georgia College research policy, and will then shred the paper files and wipe electronic files with professional software.

Measures/Tools/Instruments

Survey Instrument

The PI created the post-implementation questionnaire survey instrument (see Appendix F). It consisted of six items, including five open-ended questions and one close-ended question. These questions were used to obtain data about the providers' feedback after using DIRE Score for ten weeks. Survey Monkey®, an online survey service, was used to host and distribute the questionnaire.

Risk Assessment Instrument

The DIRE Score was selected as the opioid risk assessment tool used in this project. This clinician-rated tool, which takes less than two minutes to administer, is used to screen patients who are potential candidates for long-term opioids, for opioid risks and compliance with the medication regimen (Belgrade et al., 2006). The PI obtained permission from Dr. Miles Belgrade, the DIRE Score creator, to use the DIRE instrument (see Appendix G).

The DIRE Score is a 7-item opioid assessment tool developed in 2006 by Dr. Belgrade, who tested its validity with a retrospective study. The score is made up of four factors: Diagnosis, Intractability, Risk, and Efficacy Score. The assessment, based on a 3-point scale, is performed by the provider. A score of 1 correlates to behaviors indicative of a negative prediction, and a score of 3 indicates appropriateness for treatment with opioids. The categories that make up the DIRE Score are described below.

Diagnosis: the patient is rated according to their condition. A patient with benign chronic conditions with minimal objective findings is rated 1. A patient with a slowly progressive condition with moderate pain is rated 2. A patient with a progressive condition that is concordant with severe pain with objective findings is rated 3.

Intractability: the patient is rated according to the number of pain management therapies they have tried. A patient who has tried few therapies and occupies a passive role in the pain management process is rated 1. A patient who has tried most customary therapies is rated 2. A patient who is fully engaged in a spectrum of therapies with inadequate responses is rated 3.

Risk is made up of four subcategories:

Psychological health: the patient is rated according to their psychological health. A patient with a severe personality disorder or mental illness interfering with care is rated 1. A patient with a moderate personality disorder or mental illness interfering with care is rated 2. A patient with no significant mental illness is rated 3.

Chemical health: the patient is rated according to their chemical health. A patient with active or very recent use of illicit drugs or prescription drug abuse is rated 1. A patient who uses medications to cope with stress is rated 2. A patient with no history of chemical dependency is rated 3.

Reliability: the patient is rated according to their compliance with their healthcare. A patient with numerous medical misuse problems and missed appointments is rated 1. A patient with occasional difficulties with compliance is rated 2. A patient who is highly reliable with medications, appointments, and treatment is rated 3.

Social support: the patient is rated according to their level of social support. A patient with their life in chaos with little family support is rated 1. A patient with a reduction in

some relationship is rated 2. A patient with a supportive family who is involved in work or school is rated 3.

Efficacy: patients are rated according to how effective their regimen has been. A patient who experiences minimal pain relief despite moderate or high doses of opioids is rated 1. A patient who experiences a moderate benefit is rated 2. A patient with good improvement in pain, with stable doses over time, is rated 3.

The total score varies from a minimum of 7 to a maximum of 21. Scores greater than 14 are predictive of good patient compliance and treatment (Ferrari et al., 2014).

Acute Pain Service Rounding Sheet

An acute pain service rounding sheet is a form of a daily written report used by an APS to document a patient's assessment and opioid regimen plan (see Appendix H). Any modifications to the patient's plan are also documented on the sheet. This allows continuity of care as providers may not see the same patients every day. Patients started on long-term opioids were documented on the APS rounding sheet.

Data Analysis

The dependent variable in this project is the number of long-term opioid therapies initiated and the number of patients recommended for referral to an addiction specialist. After data collection, all additional variables were identified, coded, and entered into IBM SPSS® Version 25 for analysis. The following clinical questions were analyzed as follows:

Clinical Question 1: What are providers' initial plans and final plans for initiating long-term opioid use in acute pain service patients? This question was answered using descriptive statistics (frequencies and percentages for each initial and final plan).

Clinical Question 2: What is the relationship between providers' initial plans for initiating long-term opioid use in acute pain service patients and their final plans for initiating long-term opioid use? This question was answered using McNemar's test.

Clinical Question 3: What is the relationship between patients' risk level and providers' final plans for initiating long-term opioid use? This question was answered using McNemar's test.

Clinical Question 4: What are providers' initial plans and final plans for referring acute pain service patients to an addiction specialist? This question was answered using descriptive statistics (frequencies and percentages for each initial and final plan).

Clinical Question 5: What is the relationship between providers' initial plans for referring acute pain service patients to an addiction specialist and their final plans for referring acute pain service patients to an addiction specialist? This question was answered using McNemar's test.

Clinical Question 6: What is the relationship between patients' risk level and providers' final plans for referring acute pain service patients to an addiction specialist? This question was answered using McNemar's test.

Clinical Question 7: What percentage of the total number of patients were started on long-term opioids before and during the project implementation according to the acute pain rounding sheet? This question was answered using descriptive statistics (frequencies and percentages before and during implementation).

Clinical Question 8: What is the providers' utilization of the DIRE Score at two, four, six, eight, and ten weeks? This question was answered using descriptive statistics (frequencies and percentages).

Clinical Question 9: What are providers' perceptions regarding the DIRE Score after ten weeks of utilization? This question was answered using descriptive narratives.

Summary

This chapter described the implementation of this quality improvement project. It described the project design, its setting, the participating providers, and the relevant ethical considerations. The data collection tools were described, as well as the methods for measuring and analyzing each of the nine clinical questions. Chapter 4 will communicate the findings of this study.

Chapter IV: Results

Stakeholders, such as the CDC, recommend that providers who manage pain must adequately screen patients before starting long-term opioid therapy. This quality improvement project aims to improve current opioid risk screening practices in an acute pain service (APS) by introducing the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score, an opioid risk assessment tool, into clinical practice. Purposive sampling was used to recruit the participants (N=11). Data were collected retrospectively using nine weeks of rounding sheets before project implementation, and during the 10-week project implementation using the DIRE Score and rounding sheet. The findings from the project will be discussed in this chapter.

Categories of findings include providers' demographics, relationships between initial plans and final plans to start long-term opioids or refer patients to an addiction specialist, the relationship between patients' risk levels and providers' final plans to initiate opioids or refer to an addiction specialist, and, lastly, providers' utilization of the DIRE Score and its perception.

Sample Characteristics

The study participants consisted of 11 providers from the APS who provided pain management for a metro Atlanta hospital. All providers completed the informed consent and agreed to participate in the project. All 11 providers were female (100%) and held a master's level of education (100%). Six (54.54%) of the providers worked full-time, while five (45.45%) worked on a per diem basis. Specific demographic data, such as age, race, and years of experience, were not collected in order to protect confidentiality. Table 1 summarizes the demographic characteristics of the sample population.

Table 1

Sample Characteristics

Characteristics	n	%
Gender		
Male	0	0
Female	11	100
Level of Education		
MSN/NP	11	100
Work Status		
Full time	6	54.54
Per Diem	5	45.45

N=11 providers

The Statistical Package for Social Sciences (SPSS)® version 25 software was used for data entry and analysis. All data entries were verified twice. Data analysis began with an evaluation for missing data and standard data cleaning. No missing data or outliers were identified. Data were assessed for the need for manipulation, and it was determined no manipulation was necessary. The normality test was assessed for all interval/ratio (I/R) variables of the DIRE Scores using Fisher's exact test for skewness and kurtosis. Total scores (I/R) variables were normally distributed with skewness of -0.24 (SE= 0.33) and kurtosis of -0.63(SE= 0.65).

DIRE Score Instrument

The DIRE Score was used to screen patients who were being considered for long-term opioid management. The Cronbach alpha for the DIRE Score in this study was .80, indicating adequate internal consistency and exactly matching that of the original study. Table 2 displays

descriptive statistics for the DIRE Score instrument and internal consistency reliability coefficients for the DIRE Score factors and subcategories.

The providers evaluated 51 patients (*N*=51) using the DIRE Score opioid risk assessment tool. The mean total score from the DIRE Score was 15.63 (3.2). The most frequently observed diagnosis category was "slowly progressive condition" (*n* = 23, 45%); the most frequent intractability categories were "most customary treatments have been tried" and "patient fully engaged in a spectrum of appropriate treatments" (n=23, 41%). The most frequently observed psychological category was "personality or mental health interferes moderately" (*n* = 31, 61%), that of chemical category was "no CD history" (*n* = 29, 57%), and the most frequent reliability categories were "highly reliable patient with meds" and "appointments & treatment" (*n* = 22, 43%). The most frequently observed social support category was "reduction in some relationships and life roles" (*n* = 25, 49%), and that of efficacy was "moderate benefit with function improved in a number of ways" (*n* = 24, 47%). Table 2 displays descriptive statistics for the DIRE Score instrument.

Table 2

Descriptive Statistics for the DIRE Score Instrument

DIRE Score	n	%	Mean	SD	Range	Cronbach alpha
Diagnosis			2.12	0.74	1-3	.80
1 = "Benign chronic condition"	11	21.6				
2 = "Slowly progressive condition"	23	45.1				
3 = "Advanced condition"	17	33.3				
Intractability			2.24	0.73	1-3	.81
1 = "Few therapies have been tried"	9	17.6				

DIRE Score	n	%	Mean	SD	Range	Cronbach alpha
2 = "Most customary treatments have been tried"	21	41.2				
3 = "Patient fully engaged in a spectrum of appropriate treatments"	21	41.2				
Risk(P+C+R+S)			9.37	2.18	4-12	.77
Psychological			2.31	0.72	1-3	.78
1 = "Serious personality dysfunction or mental illness interfering with care"	2	3.9				
2 = "Personality or mental health interferes moderately"	31	60.8				
3 = "Good communication with clinic"	18	35.3				
Chemical			2.39	0.77	1-3	.72
1 = "Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse"	9	17.6				
2 = "Chemical coper"	13	25.5				
3 = "No CD history"	29	56.9				
Reliability			2.27	0.72	1-3	.75
1 = "History of numerous problems: medication misuse, missed appointments, rarely follows through"	8	15.7				

DIRE Score	n	%	Mean	SD	Range	Cronbach alpha
2 = "Occasional difficulties with compliance, but generally reliable"	21	41.2				
3 = "Highly reliable patient with meds, appointments & treatment"	21	43.1				
Social Support			2.39	0.60	1-3	.77
1 = "Life in chaos. Little family support and few close relationships. Loss of most normal life roles"	3	5.9				
2 = "Reduction in some relationships and life roles"	25	49.0				
3 = "Supportive family/close relationships. Involved in work or school and no social isolation"	23	45.1				
Efficacy Score			1.90	0.72	1-3	.79
1 = "Poor function or minimal pain relief despite moderate to high doses"	16	31.4				
2 = "Moderate benefit with function improved in a number of ways"	24	47.1				
3 = "Good improvement in pain and function and quality of life with stable doses over time"	11	21.6				

[a]N= 51 number of DIRE Score forms completed by the providers

Summary

Results by Clinical Question

Clinical Questions

Of the 51 patients in the sample, 13 scored between 7-13 (not a suitable candidate for long-term opioids), while 38 scored 14-21 (may be a good candidate for long-term opioid management).

Clinical Question 1: What are providers' initial plans and final plans for initiating long-term opioid use in acute pain service patients?

Descriptive statistics were used to analyze the initial plans to start long-term opioids (pre-DIRE Score) and the plans to initiate long-term opioid use after the DIRE Score (post-DIRE Score). The providers completed 51 DIRE Score forms (*N*=51).

Findings revealed that the providers decided not to initiate long-term opioids on 33 (64.7%) patients pre-DIRE Score and 34 (66.7%) patients post-DIRE Score. Comparably, the providers decided to initiate long-term opioids on 18 (35.3%) patients pre-DIRE Score and 17 (33.3%) patients post-DIRE Score. Table 3 presents the findings of the descriptive statistics.

Table 3

Descriptive Statistics for Providers' Plans for Initiating Long-Term Opioids

	n	%
Initial plans (LTO PRE-DIRE Score)		
No	33	64.7
Yes	18	35.3
Final Plans (LTO POST-DIRE Score)		
No	34	66.7
Yes	17	33.3

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 2: What is the relationship between providers' initial plans for initiating long-term opioid use in acute pain service patients and providers' final plans for initiating long-term opioid use?

A McNemar's test was completed to determine the change in providers' decisions to initiate long-term opioid treatment between the initial plan (pre-DIRE Score) and post-DIRE Score. According to the results, the percentage of decisions to initiate long-term opioid treatment before and after using the DIRE Score was not significantly different ($p > 0.05$). The providers decided to initiate 16 (31%) patients on long-term opioid treatment pre-DIRE Score and 17 (33%) post-DIRE Score (N=51). Similarly, they decided against long-term opioids on 32 patients (67.7%) before the DIRE Score and the same number after. Two (3.9%) patients placed on long-term opioid treatment pre-DIRE Score were taken off post-DIRE Score. Table 4 presents the results of McNemar's test.

Table 4

Frequencies and McNemar's Test Results for Providers' Plans for Initiating Long-Term Opioids

		Final Plans for long-term opioids use - POST-DIRE Score		Total	p-value
		No	Yes		
Initial plans for long-term opioid use-PRE-DIRE Score	No	32	1	33	> 0.05
	Yes	2	16	18	
Total		34	17	51	

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 3: What is the relationship between patients' risk levels and providers' final plans for initiating long-term opioid use?

McNemar's test was used to determine whether there was a relationship between patients' risk levels and providers' final plans to initiate long-term opioid use. Findings revealed a statistically significant relationship ($p < 0.05$). Patients with high DIRE Score risk levels were less likely to be initiated on long-term opioids. Twelve (23.5%) patients with high DIRE Score risk levels were not initiated on long-term opioids; one (2%) patient with a high DIRE Score risk level was initiated on long-term opioids. Comparably, patients with low DIRE Score risk levels were more likely to be initiated on long-term opioids. Twenty-two (43.1%) patients with low DIRE Score risk levels were not initiated on long-term opioids; 16 (31.4%) patients with low DIRE Score risk levels were started on long-term opioids. Table 5 presents the results of McNemar's test.

Table 5

Frequencies and McNemar's Test Results for Patients' Risk Levels and Providers' Plans for Initiating Long-Term Opioids

		Final plans for long-term opioid use - POST-DIRE Score		Total	p-value
		No	Yes		
Risk Level	High	12	1	13	$p < 0.05$
	Low	22	16	38	
Total		34	17	51	

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 4: What are providers' initial plans and final plans for referring acute pain service patients to an addiction specialist?

Descriptive statistics were used to determine the clinician's initial plans for referring APS patients to an addiction specialist (pre-DIRE Score) and their final plans for referring APS patients to an addiction specialist (post-DIRE Score). A sample of 51 DIRE Score forms were completed (N=51).

The results show that the providers decided not to refer 38 (74.5%) patients to an addiction specialist pre-DIRE Score and 39 (76.5%) patients post-DIRE Score. Comparably, the providers decided to refer 13 (25.5%) patients to an addiction specialist pre-DIRE Score and 12 (23.5%) patients post-DIRE Score. Table 6 presents the findings of the descriptive statistics.

Table 6

Descriptive Statistics for Providers' Plans for Referring APS Patients to an Addiction Specialist

	n	%
Initial plans (RAS PRE-DIRE Score)		
No	38	74.5
Yes	13	25.5
Final Plans (RAS POST-DIRE Score)		
No	39	76.5
Yes	12	23.5

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 5: What is the relationship between providers' initial plans for referring acute pain service patients to an addiction specialist and their final plans for referring acute pain service patients to an addiction specialist?

McNemar's test was performed to determine the changes in providers' decisions to refer patients to an addiction specialist between the initial plan (pre-DIRE Score) and after the use of the DIRE Score. Findings revealed no statistically significant relationship ($p > 0.05$). The

providers chose to refer 12 (23.5%) patients to an addiction specialist both pre- and post-DIRE Score (N=51). They chose not to refer 38 (74.5%) patients pre-DIRE Score and 38 (74.5%) post-DIRE Score. One (2%) patient chosen for referral pre-DIRE Score was changed to no referral post-DIRE Score. Table 7 presents the results of McNemar's test on Clinical Question

Table 7

Frequencies and McNemar's Test Results for Providers' Plans for Referral to an Addiction Specialist.

		Final plans for referral to an addiction specialist-POST-DIRE Score		Total	p-value
		No	Yes		
Initial plans for referral to an addiction specialist-PRE-DIRE Score	No	38	0	38	p> 0.05
	Yes	1	12	13	
Total		39	12	51	

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 6: What is the relationship between patients' risk levels and providers' final plans for referring acute pain service patients to an addiction specialist?

McNemar's test was used to determine a relationship between patients' risk levels and providers' final plans for referring acute pain service patients to an addiction specialist, and it was found to be statistically significant ($p < 0.05$). Patients with high DIRE Score risk levels are more likely to get a referral to an addiction specialist. Ten (19.6%) patients with high DIRE Score risk levels were referred to an addiction specialist; three (5.9%) patients in this category

were not referred. Similarly, patients with low DIRE Score risk levels were less likely to get a referral to an addiction specialist. Thirty-six patients (70.6%) with low DIRE Score risk levels were not referred to an addiction specialist; only two (3.9%) patients in this category were referred. Table 8 presents the results of McNemar's test.

Table 8

Frequencies and McNemar's Test Results for Patients' Risk levels and Providers' Plans for Referral to an Addiction Specialist.

		Final Plans for Referral to an addiction specialist -POST-DIRE Score		Total	p-value
		No	Yes		
Risk Level	High	3	10	13	p< 0.05
	Low	36	2	38	
Total		39	12	51	

N= 51: Number of DIRE Score forms completed by the providers

Clinical Question 7: What is the percentage of the total number of patients started on long term opioids before and during the project implementation, according to the acute pain rounding sheet?

Descriptive statistics were used to analyze the percentage of the total number of patients started on long-term opioids before and during the project implementation. A total sample of 221 patients were evaluated for pain management by the APS providers. Findings revealed that 114 (51.6%) patients were evaluated for pain management nine weeks before the project

implementation, and 46 of those (62.2%) were started on long-term opioids. During the ten weeks of the project implementation, 107 (48.4%) were evaluated for pain management, and 28 (37.8%) were started on a long-term opioid. Table 9 and Table 10 present the findings of the descriptive statistics.

Table 9

Descriptive Statistics for Number of Long-Term Opioids

Long-Term Opioids	N	%	Sum(n)	%
Before Project Implementation	114	51.6	46	62.2
During Project Implementation	107	48.4	28	37.8
Total	221	100	74	100

N= 221 Total number of patients evaluated, n= 74 actual long-term opioids started on patients

Table 10

Descriptive Statistics for Number of Long-Term Opioids, by week

	N	*%*	*Cumulative %*	Sum (n)	% Total sum
Weeks					
Before Project Implementation					
Week 1	8	3.7	3.6	5	6.8
Week 2	15	6.9	10.4	7	9.5
Week 3	17	7.8	18.1	8	10.8
Week 4	5	2.3	20.4	2	2.7
Week 5	13	6.0	26.2	6	8.1
Week 6	12	5.5	32.7	5	6.8
Week 7	15	6.9	38.5	3	4.1
Week 8	24	11.0	49.3	8	10.8
Week 9	5	2.3	51.6	2	2.7

	N	*%*	*Cumulative %*	Sum (n)	% Total sum
During Project Implementation					
Week 10	7	3.2	54.8	2	2.7
Week 11	5	2.3	57.0	1	1.4
Week 12	13	8.1	62.9	6	8.1
Week 13	3	1.4	64.3	0	0.0
Week 14	14	6.4	70.6	4	5.4
Week 15	12	5.5	76.0	0	0.0
Week 16	24	11.0	10.9	8	10.8
Week 17	8	3.7	90.5	1	1.4
Week 18	13	6.0	96.4	3	4.1
Week 19	8	3.7	100.0	3	4.1

N= Total number of patients evaluated for pain management. n= number of long-term opioids initiated

Clinical Question 8: What is the providers' utilization of the DIRE Score at two, four, six, eight, and ten weeks?

Descriptive statistics were used to determine the providers' utilization of the DIRE Score at two, four, six, eight, and ten weeks of the project implementation. Findings revealed that at week two, six DIRE Score forms were utilized. At week eight, 15 DIRE forms were utilized, and at the final checkpoint, ten weeks, 21 DIRE Score forms were utilized. One hundred and seven patients were evaluated in ten weeks, and the providers completed 51 DIRE Score forms, which is almost half of the total number of patients assessed for pain management. Tables 10 and 11 present the findings for Clinical Question 8.

Table 10

Descriptive Statistics of Providers' Utilization Rate of the DIRE Score: Forms Completed

Weeks Interval	N	% of Total N	% of Total Sum

Week 1 through 2	6	11.8	1.7
Week 3 through 4	2	3.9	2.2
Week 5 through 6	7	13.7	10.1
Week 7 through 8	15	29.4	31.3
Week 9 through10	21	41.2	54.7
Total	51		

N=51 completed DIRE Score forms.

Table 11

Descriptive Statistics of Providers' Utilization Rate of the DIRE Score: Patients Evaluated

During Project Implementation	N	%	n	%
Week 1	7	3.2	6	11.8
Week 2	5	2.3	0	0
Week 3	13	5.9	0	0
Week 4	3	1.4	2	3.9
Week 5	14	6.4	6	11.8
Week 6	12	5.5	1	2.0
Week 7	24	11.0	8	15.7
Week 8	8	3.7	7	13.7
Week 9	13	6.0	14	27.5
Week 10	8	3.7	7	13.7
Total	107		51	

N= Total number of patients evaluated. n= number of DIRE Score forms completed

Clinical Question 9: What are providers' perceptions regarding the DIRE Score after ten weeks of utilization?

Descriptive narratives were used to qualitatively analyze providers' perceptions regarding the DIRE Score after ten weeks of utilization. The PI asked providers for their opinions of DIRE Score as an opioid risk assessment tool. Responses revealed that half of the

providers indicated that it was "helpful," while one-fourth indicated it was "easy," and it "served as a guide." One provider said:

> I think the DIRE prompts the provider to consider the deeper aspects of how pain is impacting each patient and provides some guidance on what needs to be included in the care plan.

Although most reviews were positive, one participant thought it did not apply to all patients.

When providers were asked to describe the ease of use of the DIRE, three-fourths thought it was "easy to use." Another description of this dimension was "simple and self-explanatory." Encouragingly, providers found the tool easy to use and adapt into their daily workflow, attributes of feasible implementation. The providers were asked if they had any concerns about its use. Although five providers had no concerns, one provider thought it made them critical of the patient. Another thought it was not inclusive of all patients. Lastly, one provider indicated that limited upfront knowledge of the patients' social or drug history made that aspect difficult to score.

Seven providers chose to continue to use the DIRE Score; only one chose the option to discontinue. The PI asked those interested in continuing to explain their decision. The majority said it was helpful with long-term opioid decisions. Other reasons included that it "takes the some of the guesswork away," is a "great screening tool for long-term opioid prescription," and "helps in deciding if long-acting medications are needed in complicated cases." One provider said, "I think using the DIRE is encouraging for providers, [since it helps] to know that there are tools out there to guide in safe decision making in regards to managing pain."

Summary

At the end of the project implementation, nine clinical questions were analyzed. In terms of the providers' initial and final plans to initiate long-term opioid therapy, findings revealed no statistically significant relationship. However, the results indicated a statistically significant relationship between the patient's risk level and providers' decision to initiate long-term opioid therapy.

Similarly, the providers' initial and final plans to refer patients to an addiction specialist revealed no statistically significant relationship. However, the relationship between a patient's risk level and providers' decision to refer patients to an addiction specialist proved statistically significant.

The percentage of long-term opioids initiated during the ten weeks of project implementation decreased compared to nine weeks before the project implementation. The providers' DIRE Score utilization increased weekly, and most providers thought the DIRE Score was easy to use, helpful, and a guide during long-term opioid decision making.

The last chapter will discuss the study results, as well as its strengths, limitations, and implications for practice, and future recommendations.

Chapter V: Discussion

The Study

This DNP project aimed to provide APS providers with an objective method to screen patients for opioid risks. The project introduced the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score, an opioid risk assessment tool, into the clinical practice. The literature revealed that the use of opioid risk assessment tools can help detect aberrant behaviors, support clinical decision making, and boost providers' confidence levels when deciding to initiate opioid therapy (Webster & Webster, 2005; Larance et al., 2015; Moore et al., 2009; Jones et al., 2015; Varney et al., 2018). This chapter will discuss the sample's demographics, study results, limitations, implications for practice, and recommendations for future study.

Participants in this project were all female providers working in an acute pain service. A U.S. Department of Health and Human Services survey of nurse practitioners in 2012 showed that the NP workforce is largely homogenous in gender, with male practitioners making up only 7% of the survey pool. About 86% of participants were white, 5% were black, and about 84% held a graduate degree (U.S. Department of Health and Human Services, 2014).

The PI educated providers on how to use the DIRE Score. Their decisions to initiate long-term opioid therapy for patients before and after using the DIRE Score were recorded, as were their decisions to refer patients to an addiction specialist before and after using the DIRE Score.

Long Term Opioid Initiation

The providers' initial plans to initiate long-term opioids did not differ from their final plans after using the DIRE Score. The project's findings also indicate no significant relationship in the percentage of providers who decided to start long-term opioid treatment before and after using the tool. These results suggest that, although researchers postulated that the DIRE Score

would substantially assist the providers' clinical decisions, it is more accurate to say that it validated their initial assessments and interventions. The relationship found between patients' risk levels and providers' final plans to initiate long-term opioids echoed the original study used to validate the DIRE Score, which showed that its score demonstrated a strong correlation with compliance with opioid treatment (Belgrade, 2006). Therefore, it was reasonable for providers not to initiate long-term opioid therapy on high-risk patients.

In comparison, patients with low DIRE Score risk levels, those less likely to abuse opioids or refuse to comply with therapy, were more likely to be initiated on long-term opioids. However, providers did not initiate long-term opioids on some patients with low-risk levels, probably because they did not require long-term opioid therapy. Jovey (2012) stated that without risk factors, it is unlikely that an individual will develop an addiction disorder, but will rather take the medication appropriately, as prescribed for pain.

Referral to Addiction Specialist

The providers' plans to refer patients to an addiction specialist did not differ from pre- to post-DIRE Score. The project's findings also indicated no significant changes in providers' decisions to refer patients to an addiction specialist before and after using the DIRE Score. Based on the PI's personal clinical experience, patients referred to an addiction specialist usually displayed aberrant behaviors. Examples of aberrant behaviors include using additional opioids alongside those prescribed, forging a prescription, soliciting opioids from other providers, reporting lost or stolen prescriptions, requesting early refills, and having a history of overdose (Webster & Webster, 2005).

Similarly, Larance et al.'s (2015) study using the Opioid-Related Behaviors in Treatment (ORBIT) scale to detect aberrant behavior also concluded that the ORBIT prompts clinical

decisions and helps providers pinpoint aberrant behavior. The PI's experience as an acute pain provider suggests that when providers recognize these behaviors in their patients, they are likely to refer them to an addiction specialist even without using an opioid risk assessment tool.

The study found a statistically significant relationship between patients' risk levels and providers' final plans for referring APS patients to an addiction specialist. The project's findings indicated that patients with high DIRE Score risk levels were more likely to get a referral to an addiction specialist. High-risk patients were more likely to abuse opioids and needed a higher level of expertise to assess their addiction treatment needs.

In comparison, patients with low DIRE Score risk levels were least likely to get a referral to an addiction specialist. They did not need a referral because they were less likely to misuse opioids and more likely to comply with the opioid regimen. This is similar to Jamison et al.'s (2016) study that assessed the efficacy of the Opioid Compliance Checklist (OCC) and concluded that patients who scored lower on the OCC showed greater compliance with their opioid medication.

DIRE Score Utilization and Providers' Perception

This study used the Effectiveness, Adoption, and Implementation subsets of RE-AIM framework to evaluate whether the DIRE Score could be used to accurately gauge providers' perception. The number of long-term opioids initiated nine weeks before the project's implementation dropped by 24.4% by ten weeks into the project's implementation. This decrease could result from several different factors, such as the number of high-risk or low-risk patients evaluated during those periods, or providers' raised awareness about the risks of long-term opioid therapy exposed by the DIRE Score, leaving them more hesitant to prescribe. Since the rise in opioid use disorder has been attributed to increased opioid prescriptions, decreasing the

number of patients started on long-term opioid therapy could help ease the epidemic by reducing the pool of potential abusers.

The DIRE Score's effectiveness was evaluated in the RE-AIM framework. Its utilization increased as the weeks passed, indicating promise that providers may be willing to adopt the DIRE Score more permanently in their practices. Providers in the study seemed more compliant in using the DIRE Score when they received frequent reminders. A meta-analysis by Mayer and Fontelo (2017) on the effect of text message reminders for HIV-related compliance supports this relationship.

Providers' perception of the DIRE Score after completing the project was promising, and the influx of positive feedback demonstrated its effectiveness. They recognized that the DIRE Score made them think about important factors that should influence whether a patient is prescribed opioids, such as how pain impacts each patient, their diagnosis, social support, chemical health, reliability, and psychological makeup. They also acknowledged that the DIRE Score was straightforward, easy to use, and helpful in making long-term opioid decisions, especially for complex cases. Similarly, Pearson et al.'s (2017) study concluded that providers' confidence was associated with both a protocolized, consistent, practice-based approach towards managing opioids and the perceived ability to identify patients at risk for opioid misuse. Seven of the eight providers (87.50%) who completed the survey acknowledged that they would continue to use the DIRE Score in clinical practice to screen for and assess the risk of noncompliance, opioid abuse, and opioid misuse in patients requiring pain management.

Providers perceived a similar provider-administered opioid screening tool, the Pain Assessment Documentation Tool (PADT), as equally or identically helpful when compared to the DIRE. Passik (2004) found that the PADT was considered useful in guiding clinicians'

evaluation of possible outcomes of opioid therapy, such as pain relief, patient functioning, adverse events, and drug-related behaviors.

Strengths and Limitations

One of this study's strengths was complete support from the APS director, manager, and providers. All providers participated in the project, which made the implementation and follow-up easy. The projects' small sample size was helpful when it came to educating the providers and gaining their support. This work also introduced a standardized screening tool for risk of opioid regimen non-compliance into an environment with no such guidelines in practice. In keeping with the aims of this project, the DIRE Score will equip providers with the kind of standardized screening approach that is necessary for quality improvement of care.

The primary limitation was the small sample size of 11 providers, which may have affected the study's impact by increasing the possibilities for errors. The on-going COVID-19 pandemic affected the number of DIRE Score forms completed (N=51) in ten weeks. Five out of the 11 providers worked on a per diem basis; as the pandemic caused a reduction in providers' work hours, fewer were available to regularly utilize the DIRE Score.

Also, this study used a homogenous sample of nurse practitioners, making it difficult to replicate with different providers. The limited pool of providers led the PI to employ convenience sampling rather than random sampling to obtain project participants, making the results difficult to generalize to other practices, or to other professionals, such as physicians and pharmacists. Additionally, the providers' repeated use of the DIRE Score opened up the potential for bias as they grew more comfortable over time.

Recommendations for Future Research

Recommendations for further study include using more healthcare providers, such as physicians and physician assistants who deal with pain management, and extending the study's run time and sample size to increase validity. For ease of convenience and reduction in human error, it is recommended that researchers use more advanced technology, such as the free Apple® app version of the DIRE Score to calculate the DIRE Score, collect and analyze data. Further research is needed to determine if the DIRE Score validates other providers' clinical decisions, such as physicians and physician assistants, in inpatient or outpatient settings.

In addition, future research should take the novel approach of using the DIRE Score concurrently with the prescription drug monitoring program (PDMP) to study its validity. By using PDMP, providers can confirm prescription opioids and notice irregularities, like multiple prescriptions by different doctors in the same month, which may prompt them to complete DIRE Score screenings to better guide their patients' treatment plans.

Finally, due to a gap in existing literature, further research using the DIRE Score and other screening tools to detect opioid abuse and/or misuse in acute care settings is recommended. As Harle et al. (2015) proposed, clinical leaders, educators, and policymakers should continue creating and disseminating good evidence-based education on chronic pain and opioid risk assessment.

Implications for Future Practice

The DIRE Score validated providers' initial assessments and interventions, making it a promising tool for objective assessment. If implemented widely, the DIRE Score would promote safe prescribing practices using recommended guidelines, which would increase patient safety. Providers who use the DIRE Score are more likely to identify patients at risk for opioid misuse and refer them to an addiction specialist. Since this early detection of risk may prevent misuse,

overdoses, and deaths, tools like the DIRE Score are essential to mitigating the national opioid crisis.

This project encourages screening patients in acute care settings to determine risk levels and assess their compliance with long-term opioids. Policies for standardized screening in acute care settings could have a global impact. For example, integrating the DIRE Score into the electronic health record will make it easily accessible and allow for automatic scoring for the provider, likely increasing its utilization. Documenting the DIRE Scores in patients' charts to serve as an official record of their risk level is considered a best practice principle. Expanding use of these tools can correct the assumption that opioid abuse occurs mainly in outpatient settings.

Sustainability

The project is sustainable. Performing risk assessment is an essential aspect of pain management because it helps identify patients at risk for opioid misuse, thereby improving patient safety. Providers should perform this risk assessment before starting patients on opioids therapy. With this implementation, providers at the APS may now use the DIRE Score risk assessment tool during pain consultations to assess patients for opioid abuse and/or misuse.

For the DIRE Score to be user-friendly, it needs to be integrated into the EMR so providers can easily access it anytime they need to assess a patient. To achieve this, the stakeholders and the PI can work with the hospital's information technology department to incorporate it into the current EMR. Providers that have access to an iPhone® can download the DIRE Score for free and use it anytime. The PI will perform reviews periodically, at least in the first year, until it is fully integrated into the practice.

The PI disseminated the project results to the APS providers through a PowerPoint presentation. This project will also be shared with the Georgia College community through a virtual poster presentation in the Georgia College Fourth Annual Graduate Research Poster Exhibit & Competition. The purpose of this dissemination is to educate both providers and the general public on the benefits of using the DIRE Score as an opioid risk assessment tool in clinical practice. This could help promote sustainability, change providers' prescribing practices, promote patient safety, and overall have a positive impact on the opioid epidemic.

Summary

This project was designed to improve the current opioid risk screening practices in an acute pain service (APS) by introducing the Diagnosis, Intractability, Risk, and Efficacy (DIRE) Score into clinical practice. This opioid risk assessment tool was introduced based on the assumption that the DIRE Score would substantially change providers' prescribing decisions. After completing the project, the findings revealed that the DIRE Score validated providers' initial plans to initiate long-term opioids or refer patients to an addiction specialist.

A RE-AIM framework was used to evaluate the process through which this project was implemented. The adoption and implementation of the DIRE Score contributed to an increase in the providers' utilization of the DIRE Score. A decrease in the initiation of long-term opioids was noted during the project's implementation, which was one of its direct aims. Implementing the DIRE Score in the APS will bring about a positive change in prescribing practices by allowing providers to screen patients in need of long-term opioids to swiftly detect at-risk patients. Overall, using the DIRE Score will improve patient safety by preventing opioid misuse and even death, thereby mitigating the opioid crisis.

Conclusion

This project consisted of the implementation of the DIRE Score in an acute pain service team in response to the needs assessment of the service. The primary desired outcome was for providers to use a standardized screening approach, guided by a validated tool, to assess risks before starting patients on long-term opioid therapy. The study showed that the DIRE Score validated providers' decisions to initiate long-term opioids or refer patients to an addiction specialist. Future iterations of this area of study might strive to promote patient safety by changing current prescribing practices. Patients for whom long-term opioid therapy would be inappropriate will be identified based on their DIRE Scores, and providers will make the appropriate recommendations or referrals before the patient leaves the hospital. This intervention can prevent opioid-related harms, overdoses, and deaths, and ease the global opioid epidemic.

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Appendices

Appendix A: DIRE Score

Please answer these questions before using the DIRE. Based on your assessment would you

	Yes	No
Initiate Long-term Opioids		
Recommend referral to an addiction specialist		

DIRE Score: Patient Selection for Chronic Opioid Analgesia

For each factor, rate the patient's score from 1-3 based on the explanations in the right-hand column

SCORE	FACTOR	EXPLANATION
	DIAGNOSIS	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain. 2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain. 3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
	INTRACTABILITY	1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process. 2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness). 3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.
0	**R**ISK	(**R** = Total of **P**+**C**+**R**+**S** below)
	Psychological	1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues. 2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder. 3 = Good communication with clinic. No significant personality dysfunction or mental illness.
	Chemical Health	1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse. 2 = Chemical coper (uses medications to cope with stress) or history of chemical dependence (CD) in remission. 3 = No CD history. Not drug-focused or chemically reliant.
	Reliability	1 = History of numerous problems: medication misuse, missed appointments, rarely follows through. 2 = Occasional difficulties with compliance, but generally reliable. 3 = Highly reliable patient with meds, appointments & treatment.
	Social Support	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles. 2 = Reduction in some relationships and life roles. 3 = Supportive family/close relationships. Involved in work or school and no social isolation.
	EFFICACY SCORE	1 = Poor function or minimal pain relief despite moderate to high doses. 2 = Moderate benefit with function improved in a number of ways (or insufficient info – hasn't tried opioid yet or very low doses or too short of a trial). 3 = Good improvement in pain and function and quality of life with stable doses over time.

0 **Total score = D + I + R + E**

Score 7-13: Not a suitable candidate for long-term opioid analgesia

Score 14-21: May be a good candidate for long-term opioid analgesia

NOTES

A DIRE Score of ≤13 indicates that the patient may not be suited to long-term opioid pain management.

Used with permission by Miles J. Belgrade, MD

Please answer these questions after using the DIRE

	Yes	No
Initiate Long-term Opioids		
Recommend referral to addiction specialist		

Appendix B: Participation Letter

Emoshoke Owie August 21, 2020 at 03:25

To: Undisclosed recipients and 11 more...

EO

Participation Invitation Letter

Hello,

My name is Emoshoke Owie. I am a DNP student at Georgia College & State University. I will be conducting a Translational Clinical Research Project entitled *Implementation of an Opioid Risk Assessment Tool in an Acute Pain Service*. As a provider at the Acute Pain Service(APS), I am inviting you to participate in this quality improvement project, which will take place at the APS starting August 28, 2020.

Participation in this project includes viewing a PowerPoint Presentation about the Diagnosis, Intractability, Risk, Efficacy (DIRE). You will be required to answer some clinical decision questions and use the DIRE to evaluate patients requiring pain management for eight weeks. You will also be required to complete an anonymous post-implementation survey.

If you would like to participate in this project, please sign the informed consent that I will send through DocuSign by Tuesday, August 25, 2020, and you will receive a PowerPoint Presentation on how to use the DIRE. Thank you for your time.

Sincerely,

Emoshoke Owie, APRN, FNP-BC

Appendix C: IRB Approval

Institutional Review Board

Office of Academic Affairs

irb@gcsu.edu

http://www.gcsu.edu/irb

DATE: 2020-07-01

TO: Emoshoke Owie

FROM: Sallie Coke, Ph.D., APRN, BC - Chair of Georgia College Institutional Review Board

RE: Your IRB protocol 14210 is Approved for 2020-07-01 - 2021-07-01

Dear Emoshoke Owie,

The proposal you submitted, "Implementation of an Opioid Risk Assessment Tool in an Acute Pain Service," has been granted approval by the Georgia College Institutional Review Board. You may proceed but are responsible for complying with all stipulations described under the Code of Federal Relationship 45 CFR 46 (Protection of Human Subjects). This document can be obtained from the following address:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

The approval period is for one year, starting from the date of approval. After that time, an extension may be requested. It is your responsibility to notify this committee of any changes to the study or any problems that occur. You are to provide the committee with a summary statement. Please use the IRB Portal (https://irb-portal.gcsu.edu/) to request an extension, report changes, or report the completion of your study.

Finally, on behalf of IRB, we wish you the best of luck with your study. Please contact GC IRB at any time for assistance.

Sincerely,

Sallie Coke, Ph.D., APRN, BC

Appendix D: Site Permission

[redacted]
Medical Director Acute Pain Services
Northside Anesthesiology Consultants
[redacted]

6/11/2020

Dear GC IRB,

Based on my review of the proposed research by Emoshoke Owie, I give permission for her to conduct the study entitled Implementation of an Opioid Risk Assessment Tool within the Northside Anesthesiology Consultant/Acute Pain Service. As part of this study, I authorize the researcher to invite participants via email to obtain informed consent, use the Diagnosis, Intractability, Risk, Efficacy (DIRE) tool to screen patients requiring opioid therapy, conduct pre-and-post implementation surveys, rounding sheet audits and presentation of the findings. Individuals' participation will be voluntary and at their own discretion.

We understand that our organization's responsibilities include: access to the office space to keep materials, access to the participants, and supervision by Joy Chang, ANP. We understand that the research will include: pre- and -post implementation surveys, pre-and post-rounding sheet audits, and online PowerPoint presentation on how to use the DIRE. We reserve the right to withdraw from the study at any time if our circumstances change.

I confirm that I am authorized to approve research in this setting pending approval from the IRB at Georgia College.

I understand that the data collected will remain entirely confidential and may not be provided to anyone outside of the research team without permission from the Georgia College IRB.
The researcher has discussed the project fully with me and answered any questions I have about the project.

This authorization covers the time period of July 2020 to May 2021.

Sincerely,

[redacted]

Appendix E: Informed Consent

INFORMED CONSENT

Research Topic: Implementation of an Opioid Risk Assessment Tool in an Acute Pain Service.

Principal Investigator:

Emoshoke Owie, APRN, FNP-BC
Georgia College and State University, DNP Student
[redacted]

I, _____, agree to participate in the research *Implementation of an Opioid Risk Assessment Tool in an Acute Pain Service*, which is being conducted by Emoshoke Owie, who can be reached at [redacted]. I understand that my participation is voluntary; I can withdraw my consent at any time. If I withdraw my consent, my data will not be used as part of the study and will be destroyed.

The following points have been explained to me:

1. The purpose of this study is to introduce an opioid risk assessment tool, the Diagnosis, Intractability, Risk, and Efficacy Score (DIRE) into clinical practice that will be used to screen patients to identify patients at risk for opioid misuse when considered for long term opioid therapy.
2. The procedures are as follows: I will need to view a PowerPoint on how to use the DIRE. I will use the DIRE to screen patients being referred for pain management. It will take two minutes to use the DIRE. I will take a post-implementation survey after eight weeks of using the DIRE. The survey may take fifteen minutes to complete.
3. I will not list my name on the post-implementation survey and the DIRE forms. Therefore, the information gathered will be confidential.
4. I will be asked to sign an online consent form. I will print or save for my records.
5. I may find that some questions are invasive or personal. If I become uncomfortable answering any questions, I may cease participation at that time.
6. This research project is being conducted because of its potential benefits, either to individuals or to humans in general. The expected benefits of this study include the availability of a standardized opioid-risk assessment tool that can be used to assess the risks of opioid misuse before prescribing long-term opioids. The tool will also support clinical decision-making when considering patients for long term opioid therapy. To humankind, it will help mitigate the ongoing opioid epidemic by possibly reducing the number of deaths caused by opioid abuse and or misuse when “at-risk” patients are identified and referred to the appropriate specialty.
7. I am not likely to experience physical, psychological, social, or legal risks beyond those ordinarily encountered in daily life or during the performance of routine examinations or tests by participating in this study.

8. My responses will be confidential and will not be released in any individually identifiable form without your prior consent unless required by law.
9. The investigator will answer any further questions about the research should I have them now or in the future (see above contact information).
10. In addition to the above, further information, including a full explanation of the purpose of this research, will be provided at the completion of the research project on request.
11. By signing this form, I am acknowledging that I am 18 years of age or older.

Signature of Investigator Date

Signature of Participant Date

Research at Georgia College involving human participants is carried out under the oversight of the Institutional Review Board. Address questions or problems regarding these activities to the GC IRB Chair, email: irb@gcsu.edu.

Appendix F: Post-Implementation Survey

1. What do you think about the DIRE as an opioid risk assessment tool? 0

2. How would you describe the "ease of use" of the DIRE? 0

3. What concerns do you have about using the DIRE? 0

4. Will you continue to use DIRE as an opioid risk assessment tool? 0

- ◯ Yes
- ◯ No

5. If yes, what are your reasons for continuing to use the DIRE? 0

6. Please provide any additional feedback on using the DIRE? 0

Appendix G: Permission to Use DIRE Score

Gmail Emoshoke Owie [redacted]

Re: Permission to Reprint/Adapt the DIRE score
1 message

Miles Belgrade [redacted] Thu, Mar 19, 2020 at 3:50 PM
To: Emoshoke Owie [redacted]

Dear Emoshoke, Thanks for your interest in using the DIRE Score. You are welcome to use it free of charge in printed and online material for clinical or educational purposes but not for profit. As you indicated, you need to acknowledge me as the copyright owner Miles Belgrade, MD. Did you know that the DIRE Score is available as an Apple App? That is also free. Search for it under DIRE Score opioid

Miles Belgrade, MD

From: Emoshoke Owie [redacted]
Sent: Thursday, March 5, 2020 10:10 AM
To: Miles Belgrade [redacted]
Subject: Permission to Reprint/Adapt the DIRE score

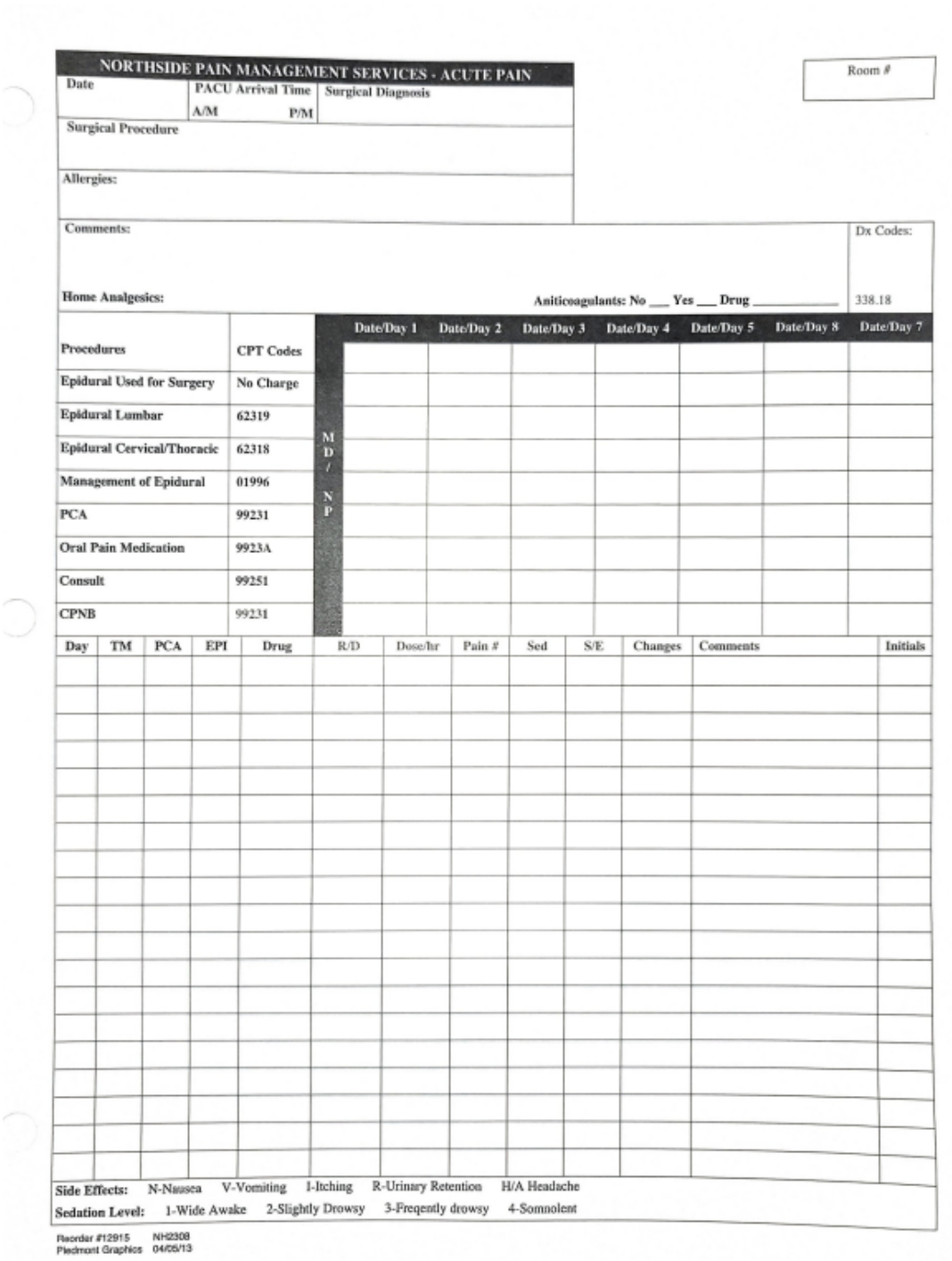
Hello Dr. Belgrade,

I am a doctoral student at Georgia College and State University and currently working on my Translational clinical project (Implementing an opioid-risk assessment tool). I seek your permission to reprint/Adapt the DIRE score to use in my project. I plan to implement the DIRE score as an assessment tool in my clinical practice, which will be used to screen patients with complex pain management that may require long-term opioid therapy. I intend to cite the tool properly in my publication. Thank you for your time, and I am looking forward to hearing from you.

Sincerely,

Emoshoke Owie, DNP-s, APRN, FNP-BC

Appendix H: Acute Pain Rounding Sheet



NORTHSIDE PAIN MANAGEMENT SERVICES - ACUTE PAIN

Room #

Date	PACU Arrival Time A/M P/M	Surgical Diagnosis
Surgical Procedure		
Allergies:		

Comments: Dx Codes:

Home Analgesics: Aniticoagulants: No ___ Yes ___ Drug _____ 338.18

Procedures	CPT Codes	MD/NP	Date/Day 1	Date/Day 2	Date/Day 3	Date/Day 4	Date/Day 5	Date/Day 8	Date/Day 7
Epidural Used for Surgery	No Charge								
Epidural Lumbar	62319								
Epidural Cervical/Thoracic	62318								
Management of Epidural	01996								
PCA	99231								
Oral Pain Medication	9923A								
Consult	99251								
CPNB	99231								

Day	TM	PCA	EPI	Drug	R/D	Dose/hr	Pain #	Sed	S/E	Changes	Comments	Initials

Side Effects: N-Nausea V-Vomiting I-Itching R-Urinary Retention H/A Headache

Sedation Level: 1-Wide Awake 2-Slightly Drowsy 3-Freqently drowsy 4-Somnolent

Reorder #12915 NH2308
Piedmont Graphics 04/05/13