SAFE OPIOID PRESCRIBING IN PRIMARY CARE THROUGH IMPLEMENTATION OF EVIDENCE-BASED GUIDELINES

by

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ABSTRACT

MICHELLE (MIMI) STARNES. Safe opioid prescribing in primary care through implementation of evidence-based guidelines. (Under the direction of DR. ALLISON BURFIELD)

Many people are affected by chronic pain. The use of opioids for pain has resulted in an increase in the number of opioid-related overdose deaths. The Center for Disease Control (CDC) created opioid prescribing guidelines to help providers safely prescribe opioids for chronic pain. The purpose of this project was to create an electronic medical record (EMR) template and urine drug test (UDT) alert to increase the providers' adherence to the CDC opioid guidelines in a small, hospital-owned, family practice clinic. A pre/post implementation chart review tool was used to evaluate the medical records of 60 patients prescribed chronic opioids. The tool was used to determine if providers were adhering to the guidelines. Measures included the number of patients who completed an annual UDT, signed a controlled substance agreement (CSA), documented pain diagnosis, quarterly office visits, and if providers reviewed the prescription drug monitoring program (PDMP) every 3 months. Adherence improved in the post-implementation data compared to pre-implementation. There were statistically significant increases in CSA ($p<.001$), PDMP reviewed ($p=.000$), annual UDT ($p=.005$), and quarterly appointments ($p=.006$). Although not statistically significant, there was an increase in documented pain diagnosis ($p=.492$). Implementation of an EMR template and UDT alert led to an increase in provider adherence to opioid prescribing guidelines.

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DEDICATION

I dedicate this project to my family, specifically my mom. She has always been my number one cheerleader and believed in me even when I didn't believe in myself. She is my role model and mentor and has taught me what it means to be a caring and compassionate provider. I want to thank my dad for always helping me take care of my children so I could continue my education. To my sister, Kim Jordan, for always helping with editing my papers. You have a true gift for writing, and I couldn't have completed this project without your help. Last but not least, my three children, Noah, Olivia, and Blair, thank you for being understanding when I had to spend time working on my schoolwork. I hope I have instilled in you the importance of education and to never give up on your dreams.

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LIST OF ABBREVIATIONS

CDC	Centers for Disease Control
CME	Continuing Medical Education
CNCP	Chronic Non-Cancer Pain
COT	Chronic Opioid Therapy
CSA	Controlled Substance Agreement
DNP	Doctor of Nursing Practice
EHR	Electronic Health Record
EMR	Electronic Medical Record
IRB	Institutional Review Board
IT	Information Technology
MME	Morphine Milligram Equivalent
ORT	Opioid Risk Tool
PDMP	Prescription Drug Monitoring Program
UDT	Urine Drug Test

CHAPTER 1: INTRODUCTION

1.1 Background

In 2001, the Joint Commission created standards to address the problem of underassessed and undertreatment of pain. It was at this time that the assessment of pain became known as the fifth vital sign (Baker, 2017). Pharmaceutical companies reassured providers that prescription opioids could be used to treat pain without the risk of addiction. There was an increase in the number of prescriptions written for opioid pain relievers leading to widespread abuse, misuse and diversion, which is utilizing the medication for recreational use or selling it. The Center for Disease Control (CDC) states that prescription opioid misuse costs our economy approximately $78.5 billion a year in costs related to health care, loss of productivity, addiction treatment, and criminal justice (National Institute on Drug Abuse [NIDA], 2019).

There are many people in the United States affected by chronic, non-cancer pain. Many of these people are prescribed opioids. However, there is much controversy regarding the use of opioids for chronic, non-cancer pain. The use of opioids for the treatment of long-term pain has caused an increase in the number of opioid-related overdose deaths (Zgierska et al., 2018). According to Downes, Klepser, Foster, and Nelson (2018), opioid-related deaths in the United States have increased by 200% in the past 18 years. In fact, there are more deaths related to prescription opioids than cocaine and heroin combined.

According to the National Institute on Drug Abuse (2019), misuse occurs when people do not take the opioids as they are prescribed, such as taking a higher dose, taking someone else's medication, ingesting by snorting or injecting, and taking the medication to get high. It is estimated that 1.7 million Americans suffer from substance use disorders related to prescription

opioids. Approximately 29% of patients prescribed opioids for chronic pain will misuse them and 8-12% will develop an opioid use disorder. (National Institute of Drug Abuse, 2019)

1.2 Problem Statement

In North Carolina, the rate of deaths due to opioid overdose is higher than the national average. North Carolina providers have written 61.5 prescriptions for opioids per 100 people in 2018, which is greater than the national average of 51.4 prescriptions per 100 people (National Institute on Drug Abuse, 2020). There is a growing problem not only in North Carolina but nationally. The CDC developed guidelines for prescribing opioids in the United States, which are recommendations for primary care providers that prescribe opioids for chronic, non-cancer pain to help improve the treatment of chronic pain safely and effectively. The CDC recognizes the importance of treating chronic, non-cancer pain but providers need to consider the benefits and risks to prescribing opioids (U.S. Dept of Health and Human Services Centers for Disease Control and Prevention [CDC], 2019). With the growing problem of misuse, abuse, and the overdose of prescription opioids in primary care, there is a need for implementation of a pain management protocol and educating providers of the importance of adhering to the guidelines.

1.3 Purpose of the Project

The purpose of the DNP scholarly project was to use an Electronic Medical Record (EMR) template for opioid prescribing as well as Urine Drug Test (UDT) alert to increase providers' adherence of the CDC guidelines for prescribing opioids for chronic non-cancer pain in primary care. The scholarly project will improve documentation for pain management in the Electronic Medical Record (EMR) by developing EMR templates that document the utilization of the Prescription Drug Monitoring Program (PDMP) every 3 months, obtain UDT at least annually, screen patients annually using opioid risk screener tool, and obtain patient contracts

yearly. A pre- and post-chart review with data analysis was used to determine the effectiveness of the EMR template and UDT alert after 3 months.

1.4 Clinical Question

In primary care providers prescribing chronic opioids for non-cancer pain, does implementing EMR templates and alerts for opioid prescribing guidelines compared to no EMR templates and alerts for opioid prescribing guidelines, increase providers adherence to following CDC opioid prescribing guidelines?

1.5 Project Objectives

The objectives of this scholarly project were to: (1) assess the adherence to CDC opioid prescribing guidelines before implementation of an electronic medical records (EMR) template and urine drug test (UDT) alert through pre-implementation chart review; (2) develop an EMR template for documenting a diagnosis of chronic opioid use, documenting the prescription drug monitoring program (PDMP) access, opioid patient agreements, and developing an EMR alert for urine drug test (UDT); (3) implement education for primary care providers and medical office assistants regarding the CDC opioid guidelines and the EMR templates and alerts; and (4) complete post-implementation chart review to determine if the use of an EMR template and UDT alert will increase adherence to CDC opioid prescribing guidelines.

CHAPTER 2: LITERATURE REVIEW

2.1 Search Terms

A comprehensive literature review was performed. The literature searches were completed using CINAHL, PubMed, and EBSCO. Keywords used during the search included opioid prescribing, primary care, chronic opioid therapy, opioid guidelines, and provider adherence. Inclusion criteria for the literature search included articles from 2014-2020. The articles had to be peer-reviewed in the English language. Articles were excluded if they dealt with acute or cancer pain. The search yielded 169 articles. Each article was reviewed and 16 were utilized for this quality improvement project. All levels of evidence were accepted; however, there were no level 2 articles found.

2.2 Review of Literature

There is much controversy regarding the use of opioids for chronic, non-cancer pain due to the increasing numbers of opioid abuse, misuse, and overdose (Krebs et al., 2014) The Center for Disease Control (CDC) released opioid prescribing guidelines in 2016 to help providers safely prescribe opioids for pain and decrease the number of adverse events. (McCalmont, Jones, Bennett, & Friend, 2018)

2.3 Multi-Component Interventions

According to Lasser et al. (2015), primary care providers prescribe the majority of opioids for chronic pain, however it was noted that few of the providers follow guidelines. In the study by Lasser et al. (2015), using multi-component interventions such as nurse care managers, patient registry, provider education, and electronic tools will increase provider adherence to opioid prescribing guidelines. Secondary outcomes would be a decrease in opioid abuse and diversion (Lasser et al., 2015). Liebschutz et al. (2017), conducted a randomized clinical trial to

determine if primary care providers receiving multi-component interventions would increase provider adherence to opioid prescribing guidelines and decrease opioid misuse. Results indicate significant differences between the control group only receiving access to an electronic decision tool to assess opioid misuse risk, and the intervention group in the adherence of guidelines. Liebschutz et al. (2017) describe limitations to the study as being unable to evaluate the patients' experiences using the electronic health record (EHR), such as the impact on pain control, patient's functionality, and disability.

A common agreement exists among best practice guidelines for opioid prescribing. They include urine drug test (UDT), controlled substance agreements (CSA), and limiting the number of opioids prescribed (Razouki, Khokhar, Philpot, & Ebbert, 2018)**.** In the project by Downey et al. (2017), an opioid prescribing protocol was implemented that included the use of CSA, annual UDT, PDMP review before prescribing and refilling opioids, and quarterly office visits. Nurses were used to discuss and explain the CSA to the patients before seeing the provider. The nurse also reviewed the PDMP prior to the scheduled visits.

Patchett et al. (2019) developed a quality improvement project to standardize opioid prescribing. This project preceded the 2016 CDC opioid prescribing guidelines. The intervention was a standard order set for the EMR that included an opioid risk tool (ORT) interactive form, documentation of controlled substance agreement, at least one UDT annually, and quarterly face-to-face visits with the provider. Patients were also mailed a letter explaining the new opioid prescribing protocol. After implementation of the project, CSA completion increased and UDT were completed more frequently. Patchett et al. (2019) felt the most impactful process was the letters sent to the patients describing the process. Wong et al. (2019) created EMR templates to standardize documentation of COT. The template included documentation of pain, treatment

history, any relevant diagnostic imaging, functional status, ORT, annual UDT, annual CSA, and goals of treatment. The creation of the EMR template increased adherence to opioid guidelines and decreased the total dose of opioids prescribed.

2.4 Benefits with Implementation of Guidelines

According to Kroenke et al. (2019), potential benefits to opioid prescribing guidelines include fewer opioid-naïve patients on long-term opioids and patients on COT receive lower doses. The survey used by Provenzano et al. (2018), showed 50% of respondents used pain assessment scales, however more than 68% of providers did not use opioid risk assessment tools. Providers felt challenges in following opioid guidelines were patients' resistance to using non-pharmacological treatment. According to Provenzano et al. (2018), more provider and patient education is needed to enhance understanding of opioid prescribing guidelines.

2.5 Provider Challenges/Barriers

Due to poor adherence to opioid prescribing guidelines, Krebs et al. (2014) used interviews to understand providers' and patients' viewpoints on opioid prescribing practices. The study also looked at possible barriers to following opioid prescribing guidelines. Krebs et al.'s (2014) qualitative study used semi-structured interviews with 14 primary care providers and 26 of their patients being treated with long term opioids. Results of the study indicate three barriers to guideline adherence. Providers stated time management and lack of resources was a barrier. The second barrier was providers felt they knew their patients well enough that they did not need to follow guidelines, and the third barrier was providers thinking opioid monitoring was more for law enforcement and could affect the patient-provider relationship.

McCalmont, Jones, Bennett, & Friend (2018) used a cross-sectional investigation to survey providers. The study looked at how familiar providers were with the 2016 CDC opioid

prescribing guidelines, as well as adherence. The authors of the study questioned the providers regarding amount of continuing medical education (CME) and the relationship of comfort in pain management, confidence in opioid conversions, and adherence to guidelines. The results indicated that increased number of CME hours was associated with increased adherence to guidelines. McCalmont et al. (2018) noted that there were limitations to the study due to incomplete responses by providers and the possibility that respondents may have already been confident and adherent to the CDC guidelines.

Desveaux, Saragosa, Kitbulegoda, and Ivers (2019) examined provider perceptions of opioid prescribing and potential barriers. Based on interview results, providers felt pressure adhering to opioid guidelines while trying to manage patients' pain symptoms. Providers felt the opioid crisis is due to prescribers being told that chronic pain was undertreated and therefore more opioids were being prescribed. This led to many patients being on chronic, opioid therapy and now many of the patients are resistant to change. Providers are conflicted with helping patients and doing the right thing. This causes frustration among providers, due to the inability to treat pain without opioids because of a lack of pain management resources available (Desveaux, Saragosa, Kithulegoda, & Ivers, 2019).

According to Razouki, Khokhar, Philpot, and Ebbert (2018), providers reported a high level of confidence in their ability to care for patients with chronic, non-cancer pain (CNCP), however due to the opioid crisis, providers are more reluctant to prescribe opioids. Providers that felt highly confident in treating patients with CNCP were more likely to follow opioid prescribing guidelines. Providers reported tension with patients when treating chronic pain due to the strict opioid prescribing guidelines and increased concern regarding opioid misuse, addiction, and dependence. Studies show that implementing components related to safe prescribing

guidelines could possibly increase provider adherence and reduce patient misuse (Downey et al. 2017).

There are many challenges with the implementation of opioid prescribing guidelines. The CDC guidelines were not meant to be prescriptive; however, they have been implemented without flexibility in many cases (Kroenke et al. 2014). According to Wong et al. (2019), challenges include effectively managing pain, inadequate training in pain management, lack of confidence in prescribing opioids and concerns regarding abuse and addiction of opioids. Downey et al. (2017) feel guidelines are not consistently implemented because it consumes time and interrupts providers' normal clinical workflow.

2.6 Theoretical Framework

The theoretical framework that guided this quality improvement project was the Plan-Do-Study-Act (PDSA), which involves implementing a change and continuous cycles of quality improvement (Gawlinski and Rutledge, 2008). The Plan-Do-Check-Act (PDCA) model was first introduced in 1939 as a straight-line process by Walter Shewhart. He later modified the model into a cyclical concept, also known as the Shewhart cycle. Edward Deming modified Shewhart's model emphasizing the importance of continuous collaboration among the four steps. The PDCA model was later changed to the PDSA cycle which emphasized the study step (S) as a learning process to determine what works and what needs to be changed. (Moen and Norman, 2010)

The "Plan" was to assess providers' adherence to the CDC's opioid prescribing guidelines through a pre-implementation chart review. The "Do" was to create opioid prescribing template, urine drug tests alert in the electronic medical records (EMR) and educate the providers on the use of the EMR template and alert. The "Study" was evaluating and analyzing if the providers were adhering to the CDC opioid prescribing guidelines. The "Act" was to

evaluate if further provider education was needed to increase provider adherence to the CDC guidelines.

CHAPTER 3: METHODOLOGY

3.1 Setting

The setting for the quality improvement project was a hospital owned primary care practice in Hickory, North Carolina. The practice consists of four providers, ancillary staff, front desk personnel, and a practice coordinator. The primary care office treats approximately 900 patients per month for various chronic and acute conditions.

3.2 Population

The participants for this project were the primary care providers and ancillary staff, such as medical office assistants. The primary care providers included in the project have treated patients 18 years of age and older for chronic, non-cancer pain (CNCP) on chronic opioid therapy (COT) for at least three months. The primary care providers included two physicians, one physician assistant, and one nurse practitioner.

3.3 Intervention

The first step before implementing the evidence-based guidelines into practice, was to work with the information technology (IT) department to create a template (Appendix A) for the electronic medical records (EMR) for the providers to use when prescribing COT. There was also an alert added to the EMR for annual urine drug tests (UDT) (Appendix B). The template provided guidance for the providers including dates of last pain contract signed, prescription monitoring website checked, last urine drug screen, proper pain diagnosis, and the morphine milligram equivalent (MME) daily dose of the opioid.

The project was approved by the Institutional Review Board (IRB) at Catawba Valley Medical Center (Appendix C) and The University of North Carolina at Charlotte (Appendix D) as a quality improvement project. Patients' medical records were randomly selected based on

patients receiving long-term opioids (greater than three months) for chronic, non-cancer pain. No identifying information was included in the record. A data collection spreadsheet (Appendix E) was used when reviewing and collecting data from the electronic medical records. The electronic medical records were reviewed to determine if any of the guideline components, UDT, signed agreement, pain diagnosis, quarterly appointments, and review of PDMP website, had been completed before the providers and clinical staff have been trained.

After pre-implementation data collection, the providers and ancillary staff were educated and trained on the EMR pain management template and the various tools that would be used. The guidelines included a face-to-face office visit with patients on chronic opioids every three months. The EMR would indicate the proper diagnosis of the chronic pain, the PDMP would be accessed for each patient on chronic opioids at least every three months and documented, and an UDT would be obtained at least annually. The provider and patient would update the agreement annually and discuss risks and benefits of taking opioids for chronic, non-cancer pain. Providers and clinical staff were shown how to access an opioid dose calculator to determine how many morphine milligrams equivalents (MME) the patient is taking and documented in the EMR.

After implementation, medical records were again randomly selected based on long-term opioid use. The data was analyzed to determine provider adherence with the opioid prescribing guidelines and to determine if further education was needed.

3.4 SWOT Analysis

SWOT Analysis of Implementing Opioid Prescribing Guidelines

STRENGTHS	OPPORTUNITIES
• Support of larger health care system • Strong emphasis on evidence-based practice • Implementing CDC guidelines for chronic opioid prescribing	• Development of EMR templates for opioid prescribing to increase compliance • Prescribing less opioids • Decrease opioid misuse and abuse • Improving patient safety
WEAKNESSES	**THREATS**
• Perceived adverse attitudes • Varying practices among providers • Providers reluctant to prescribe opioids • Accessing data from EMR	• Time constraints on the provider • Dealing with patients that are dependent on opioids • Providers reluctant to change • Reaction from patients • Missed appointments due to Covid • Loss of patients in practice due to not prescribing opioids

3.5 Measurement Tool

A checklist (Appendix E) was used when conducting the chart review to evaluate providers' compliance with the CDC opioid prescribing guidelines (U.S. Dept of Health and Human Services Centers for Disease Control and Prevention [CDC], 2016) Electronic medical records were reviewed for the following items: 1) PDMP accessed; 2) informed consent/patient agreement; 3) urine drug test (UDT) at least annually; 4) documentation of morphine milligram equivalents (MME); 5) documentation of chronic pain diagnosis; and 6) quarterly office visits.

Each item on the chart review checklist was numbered and recorded in an excel spreadsheet. The data were reviewed an analyzed using StataCorp v.16 statistical software (2019).

3.6 Inclusion/Exclusion Criteria

The inclusion criteria for the project were all the providers at Catawba Valley Family Medicine that prescribe chronic opioid therapy (COT) for chronic, non-cancer pain (CNCP). In order to be included in the chart review, the inclusion criteria were male and female patients over the age of 18 years old, being treated for chronic, non-cancer pain with opioids for greater than 3 months. Patients with a diagnosis of cancer or patients treated with opioids for less than 3 months were excluded from the study. All records and data will be kept in a locked filing cabinet in the Doctor of Nursing Practice student's office for a minimum of seven years, as required by the healthcare organization.

3.7 Data Collection Procedures

The pre-implementation data was collected from August 17, 2020 – August 28, 2020 and post-implementation data from December 7, 2020 – December 18, 2020 through a retrospective chart review on a sample of 30 randomly selected charts. Data was collected from the electronic medical records of patients that fit the specified criteria with the assistance of the IT department at Catawba Valley Medical Center. The data from the electronic medical records had no identifiable patient information. Data reports were saved on a secure computer drive at Catawba Valley Family Medicine.

3.8 Data Analysis

Data analysis was conducted using StataCorp V16 statistical software (2019). Descriptive statistics were performed on all pre- and post-intervention variables. Categorical variables were reported as counts and percentages, continuous variables were reported as mean and standard

deviation. Normality was assessed, and Wilcoxon rank sum test for unmatched pairs was performed for non-parametric continuous data (MME) and t-test for parametric continuous data (age). Chi-square (x^2) was performed for dichotomous variables, and Fisher's exact probabilities were reported when cell counts were <5.

CHAPTER 4: RESULTS

4.1 Characteristics of Participants

Demographic data was collected from the medical records on the following items: age and gender. Data was collected on types of pain diagnoses between the pre- and post-intervention groups. These variables were compared between pre- and post-intervention to determine if there were any significant differences between the two groups.

In the pre-implementation group, 36.7% were males and 63.3% were females. In the post-implementation group, 36.7% were males and 63.3% were females. There was no numerical difference in males and females in the pre- and post-groups. The mean age of the participants in the pre-implementation group was 67.7 years (SD 11.7) and the mean age of the post-implementation group was 58.9 years (SD 10.0). There was a statistically significant difference in ages between the two groups (p=.002). The participants' characteristics from both groups are shown in Table 1.

Table 1

Characteristics of Participants

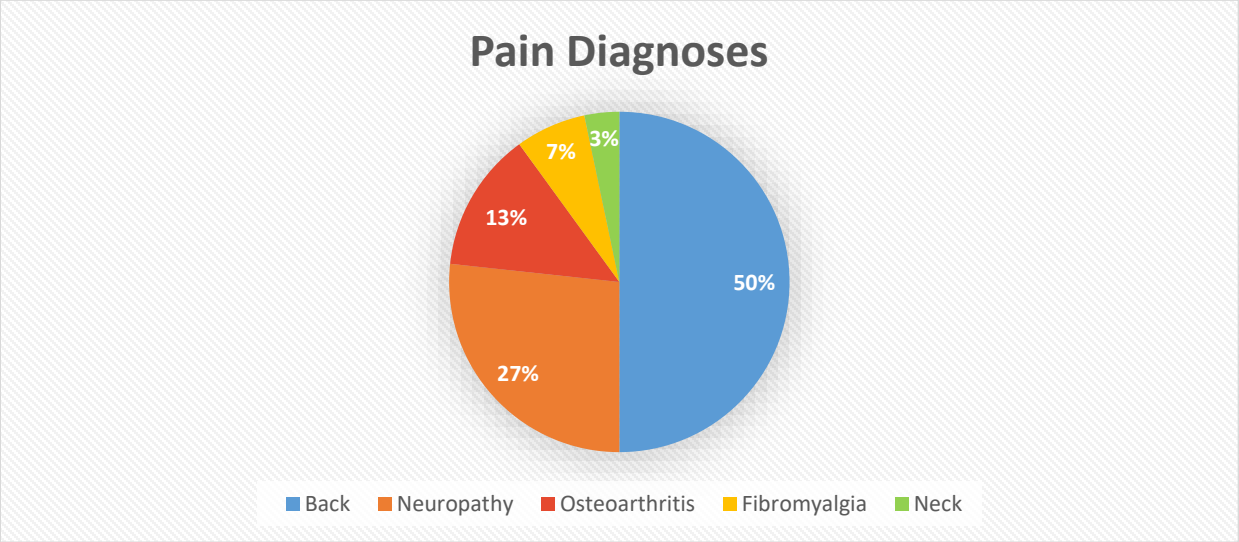
	Pre-Implementation N=30	Post-Implementation N=30	*p*-value
Gender, n (%)			1.0
Male	11 (36.7%)	11 (36.7%)	
Female	19 (63.3%)	19 (63.3%)	
Age, mean (SD)	67.7 (11.7)	58.9 (10.0)	.002*
Diagnoses			
Back Pain	15 (50%)	16 (53.3%)	.796
Fibromyalgia	2 (6.7%)	5 (16.7%)	.424
Neuropathy	8 (26.7%)	3 (10%)	.181
Other	5 (16.7%)	6 (20%)	.739

*Statistically Significant

The majority of patients receiving COT had the diagnosis of back pain, with 50% of the pre-implementation group and 53.3% of the post-implementation group. Other diagnoses included fibromyalgia, neuropathy, and other pain. The category of other pain included migraine, neck, and osteoarthritis. The percentages in the pre-implementation group were 6.7% for fibromyalgia, 26.7% for neuropathy, and 16.7% for other diagnoses. The percentages of different types of pain diagnoses seen in the pre-implementation group is shown in figure 1.

Figure 1

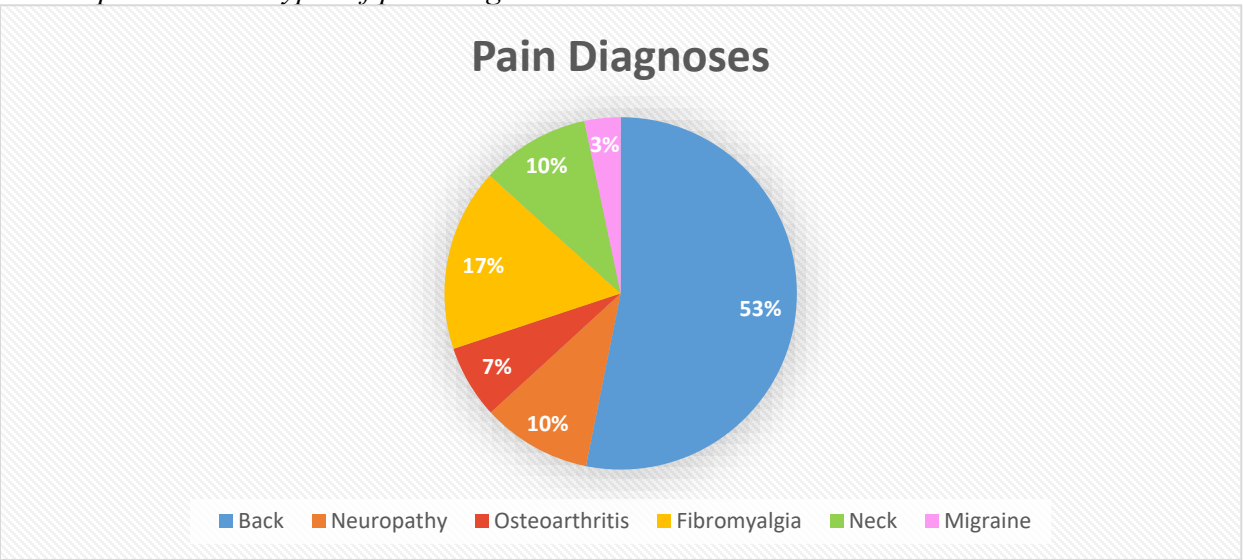
Pre-implementation types of pain diagnoses



In the post-implementation group, 16.7% had fibromyalgia, 10% neuropathy, and 20% other. Figure 3 shows the percentages of pain diagnoses of the post-implementation group. There were no statistically significant differences in diagnoses types between the two groups.

Figure 2

Post-implementation types of pain diagnoses



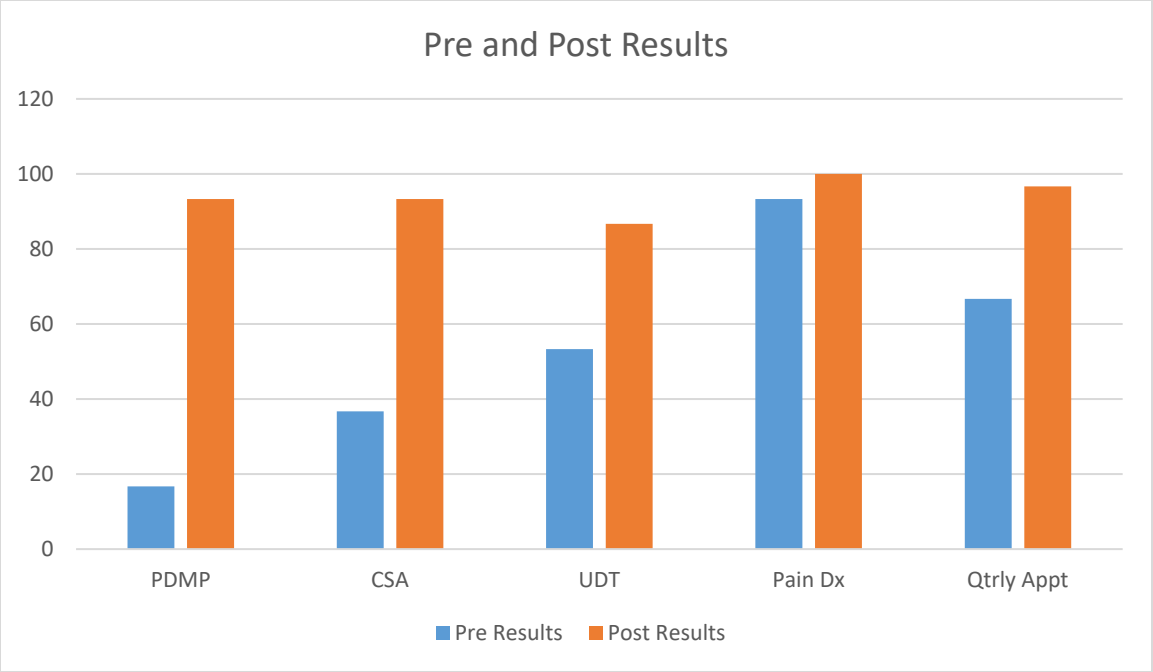
4.2 Project Findings

During the weeks of August 17, 2020 - August 28, 2020, the initial chart review was conducted on 30 patients on chronic opioid therapy. Data was collected from the patients of four providers, which included a medical doctor, a doctor of osteopathy, a nurse practitioner, and a physician assistant. The data collected from each chart included the review of the PDMP website, annual UDT, controlled substance agreement, documented pain diagnosis, documented MME, and frequency of appointments. Data analysis was performed to determine the percentage of patients that met each parameter. Following guidelines implementation, a total of 30 charts were reviewed during the week of December 7, 2020 – December 18, 2020 to determine if there was an improvement in provider adherence to the opioid prescribing guidelines.

Numerical and statistically significant increases were seen in the post group for the PDMP reviewed, signed controlled substance agreement, annual UDT, and quarterly appointments, this is demonstrated in Figure 3.

Figure 3

Difference in Pre- and Post-Implementation Results



A numerical increase in documented pain diagnosis was seen in the post group, but this increase was not significant. While not significant, decreases in the post-intervention group for average Morphine Milligram Equivalents (MME) were observed (p=.075), as shown in Table 2.

Table 2

Pre- and Post-Implementation Results

Variable	Pre-Implementation N=30	Post-Implementation N=30	*p*-value
MME, mean (SD)	48.2 (21.1)	40.3 (18.7)	.075
PDMP Reviewed, n (%)	5 (16.7%)	28 (93.3%)	.000*
Signed CSA	11 (36.7%)	28 (93.3%)	.000*
Annual UDT	16 (53.3%)	26 (86.7%)	.005*
Documented Pain Diagnosis	28 (93.3%)	30 (100%)	.492
Quarterly Appointments	20 (66.7%)	29 (96.7%)	.006*

*Statistically Significant

CHAPTER 5: DISCUSSION

5.1 Limitations

Limitations of this project included a small sample size of 30 patients both pre- and post-intervention. The duration of the intervention was brief, only 3 months, before collecting post-intervention data. This does not give adequate time to implement a new intervention. A longer implementation period may have resulted in fewer opioid prescriptions written. The small, single practice with only four providers limits generalizability to larger health care systems. Another limitation was implementation during the Covid-19 pandemic that resulted in an increase in virtual visits in place of face-to-face visits.

5.2 Implications

In order to treat chronic pain safely and effectively, providers need to increase their adherence to the CDC opioid prescribing guidelines. This project can be easily implemented into all the primary care offices of Catawba Valley Medical Group. Implications for future practice would include monitoring the number of opioid prescriptions written to see if increasing provider adherence to the guidelines will decrease the number of opioids prescribed. There should be bi-annual or annual re-training with the providers of the opioid guidelines and EMR template which could also reinforce greater provider compliance.

5.3 Recommendations

It would be beneficial to expand the project to include additional practices within the Catawba Valley Medical Center organization to determine if provider adherence to the guidelines would improve. Future projects could include creating EMR alerts to notify providers when MME doses equal or exceed 90 MME/day or if benzodiazepines are concurrently

prescribed with opioids. Evidence suggests the risk for opioid related adverse events is higher in patients receiving concurrent benzodiazepines and higher doses of opioids (Sun et al., 2017).

5.4 Conclusion

The CDC created opioid prescribing guidelines in 2016 to help providers safely prescribe opioids for patients with chronic, non-cancer pain (McCalmont, Jones, Bennett, & Friend, 2018). Existing literature on opioid prescribing shows that creating EMR templates that include components of the CDC opioid guidelines, is shown to improve provider adherence and decrease the total dose of opioids prescribed (Wong et el., 2019). The CDC guidelines recommend providers review the PDMP website at least every 3 months, obtain a UDT annually, have a signed controlled substance agreement on file, and avoid opioid doses greater than or equal to 90 MME/day (U.S. Dept of Health and Human Services Centers for Disease Control and Prevention [CDC], 2019). Research has shown that following the guidelines minimize the risks of opioid misuse and overdose (Dowell et al., 2017).

This project demonstrated an increase in provider adherence to opioid prescribing guidelines. The data analysis showed a statistically significant increase in controlled substance agreements, PDMP review, annual UDT, and quarterly appointments. Although not statistically significant, there was also an increase in documented pain diagnosis. By improving provider adherence to the opioid prescribing guidelines, patients can be safely and effectively treated for their chronic pain.

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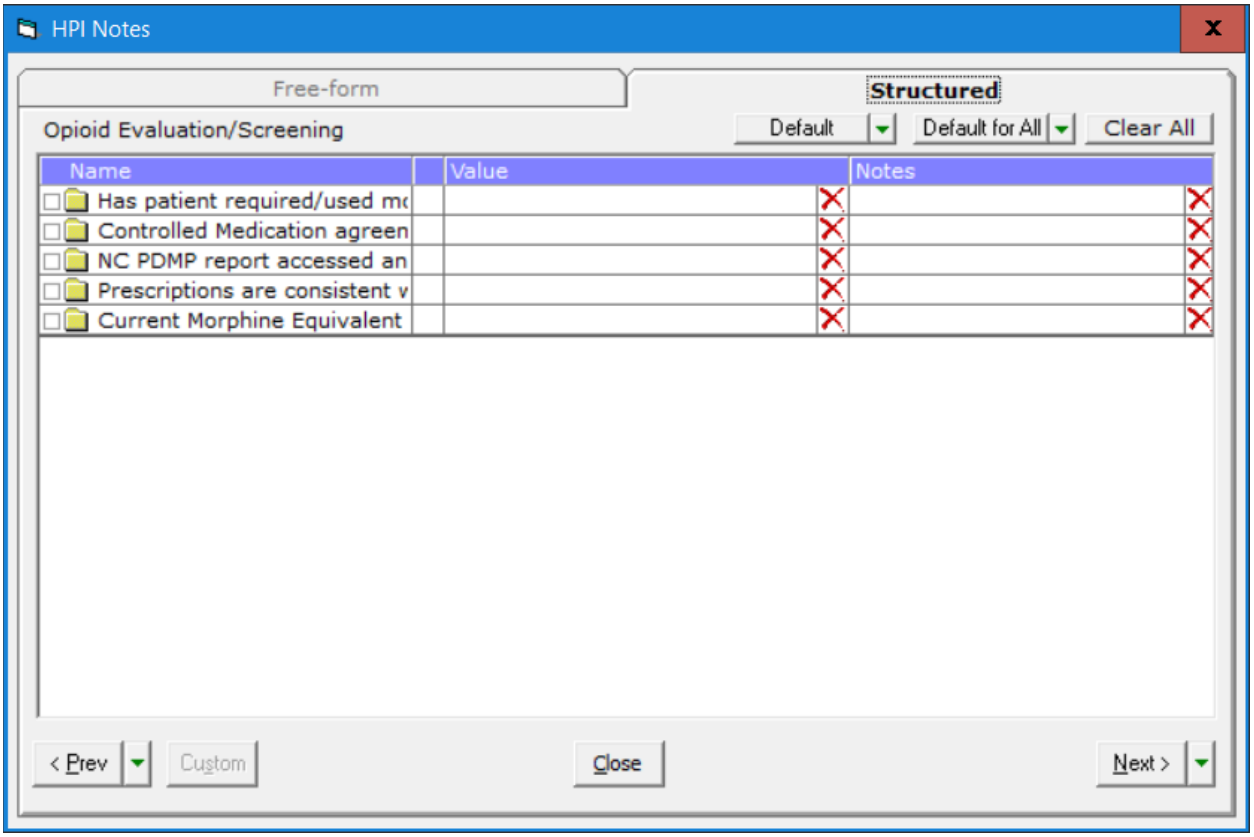
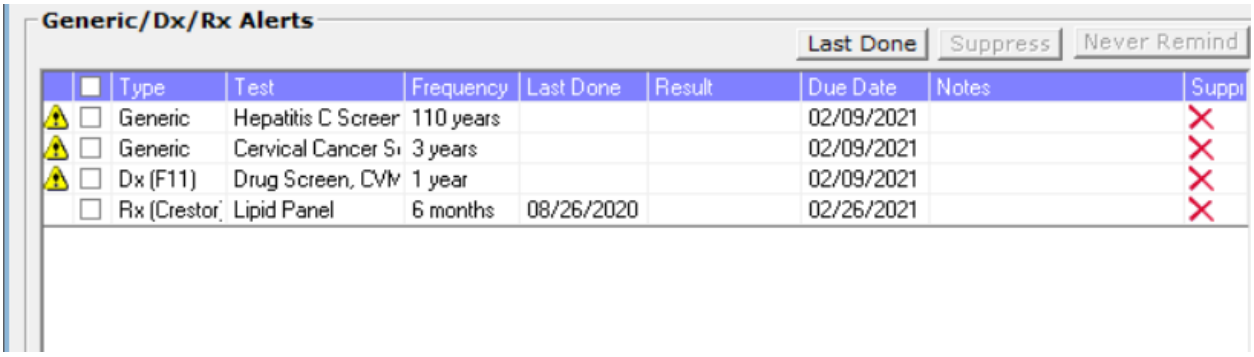
APPENDIX A: EMR TEMPLATE AND UDT ALERT





APPENDIX B: CATAWBA VALLEY MEDICAL CENTER IRB APPROVAL

Catawba Valley Med Cnt Institutional Review Board
810 Fairgrove Church Road, SE | Hickory, North Carolina 28602
Office 828-326-3671 | FAX 828-326-3641
https://www.catawbavalleyhealth.org/Site-Search.aspx?C=irb
Chair: Ann Moore, MSN, NPD-BC, CEN

To: Michele "Mimi" Starnes, FNP
Catawba Valley Family Medicine-Viewmont
1205 North Center Street
Hickory, NC 28601

From: CVMC IRB
Date: June 16, 2020
RE: IRB Approval
Study Title: Safe Opioid Prescribing in Primary Care through Implementation of Evidenced-Based Guidelines
Study No.: 2020.02

The above referenced research study was reviewed on 06/16/2020 under 45 CFR 46 in the Code of Federal Regulations and deemed eligible for expedited review under 45 CFR 46.101(b) (1). This research represents **no more than minimal risk** for its subjects. The IRB waives the requirement to obtain informed consent as provided in 45 CFR 46.116(c). This study has been approved for the period of **6/16/2020 to 6/15/2021**. Before the approval expiration date, all research must have ceased, and a study closure request submitted to the IRB. If the research is terminated earlier, notify the IRB within 30 days of ceasing research activity by submitting a study closure request.

This approval includes and is limited to the following:

- IRB Proposal Application Submission 2 Submitted 6/15/2020 and Appendices
- Informed Consent Waiver Request

If additional time is required to complete the research, a request for continuing review must be submitted to the IRB. As the Principal Investigator, it is your responsibility to ensure this request is submitted on or before the study approval expiration date. Although a request may have been submitted prior to this date, all study activity must cease until you have received written confirmation the study approval expiration date has been extended. If you wish to amend the study, you must submit a request to the IRB and receive approval in writing before implementing the proposed modification(s).

Policy RI-20 and the Continuing Review & Study Closure form can be accessed on the Human Subjects Research website http://irb.catawbavalleymedical.org

The CVMC IRB applies 45 CFR 46, Subparts A-D to all research it reviews regardless of funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation.

cc: Kimberly Yates

APPENDIX C: UNCC IRB APPROVAL

OFFICE OF RESEARCH COMPLIANCE
9201 University City Boulevard
319 Cameron Hall
Charlotte NC 28223-0001
(704)-687-1871
Web site: http://research.uncc.edu/
Federalwide Assurance (FWA) #00000649

To: Michelle Starnes

From: Office of Research Protections and Integrity

Date: 7/28/2020
Expiration Date of Approval by External IRB: 6/15/2021
RE: Agreement to Rely on External IRB
External Organization: Catawba Valley Medical Center
Study #: 19-0838

Study Title: Safe Opioid Prescribing in Primary Care through Implementation of Evidence-Based Guidelines

This confirms that an IRB Authorization Agreement with the organization identified above has been executed to rely on their IRB for continuing oversight of this study. This agreement specifies the roles and responsibilities of the respective entities.

Study Description:

The purpose of the DNP scholarly project is to implement evidence-based guidelines for prescribing opioids for chronic non-cancer pain in primary care, based on the CDC opioid guidelines, in order to decrease the amount of opioid misuse and diversion. The scholarly project will improve documentation for pain management in the Electronic Medical Record (EMR) by developing EMR templates that document the utilization of the Prescription Drug Monitoring Program (PDMP) every 3 months, obtain Urine Drug Test (UDT) at least annually, screen patients annually using opioid risk screener tool, and obtain patient contracts yearly. The EMR will be updated to provide alerts to assist the providers in following these guidelines. A pre- and post-implementation chart review with data analysis will be used to determine the effectiveness of the guidelines after 3 months.

It is your responsibility to:

1. Inform the UNC Charlotte IRB about any actions by the external IRB affecting their approval to conduct the study, including suspension or termination of approval.

2. Submit a modification to the UNC Charlotte IRB (via IRBIS) if/when new personnel are added to the study team or the study is modified in such a way that additional institutional approvals are required (e.g., radiation safety, biosafety).

3. Submit a copy of the external IRB approval letter and current approved consent document to the UNC Charlotte IRB (via IRBIS) when the study is renewed; you will continue to receive reminder notices from the UNC Charlotte IRB for renewal, and should provide the external approval and consent documents within 30 days of receipt.

4. Report all Unanticipated Problems protocol violations and unresolved subject complaints to the UNC Charlotte IRB *in addition to the external IRB*. You may submit a copy of the report you submitted to the external IRB; this should be done via the IRBIS UP reporting pathway.

5. Maintain compliance with all other UNC Charlotte policies (e.g., data security, conflict of interest).

APPENDIX D: CHART REVIEW TOOL

Chart	PDMP	CSA	UDT	Dx	Appt	MME	Gender	Age
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Key: 1=yes, 2=no; PDMP=PDMP reviewed; CSA=Controlled Substance Agreement; UDT=Annual Urine Drug Test

Appt=quarterly appointments; MME=Morphine Milligram Equivalents; Gender - 1=Male, 2=Female

Age=age in years