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Non-Opioid Pharmacologic Agents in the Treatment of Non-Cancer Chronic Pain in the Outpatient Setting

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A DNP project submitted in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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Approval Page

This is to certify that the DNP Project Final Report by

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has been approved by the DNP Project Team on

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Abstract

Opioid prescription related overdose deaths have increased substantially with evidence demonstrating only modest short-term benefits in chronic pain and thus represents the need to identify alternative treatments to opioids. A needs assessment performed for a federally qualified community health center revealed patients presently taking non-opioid pharmacologic agents in the treatment of chronic non-cancer pain (CNCP) needed additional education in managing multiple non-opioid medications. A targeted approach at improving patient experience and population health supporting the quadruple aim was undertaken with this project.

Purpose

The purpose of this quality improvement project consisted of performing medication management visits for 28 referred patients with CNCP encompassing a focused review of all non-opioid pharmacologic agents being taken with tailored patient education completed. This alternatives to opioids region of need was targeted in support of maximizing the use of non-opioid pharmacologic agents in the first line treatment of CNCP**.**

Interventions and Setting

Over the course of four weeks in a federally qualified community health center, twenty-five patients had completed medication management visits via telehealth, initially referred by their healthcare provider as patients in need of further non-opioid chronic pain medication management education. Each visit consisted of an introduction, visit goals overview, consent to proceed, focused review of all non-opioid pharmacologic agents taken for CNCP, tailored individualized education, and a post visit survey.

Evaluation

A high incidence of polypharmacy was noted with most patients taking multiple non-opioid pharmacologic agents for CNCP with a low incidence of patients taking these medications as prescribed. The outcome measurement comprises patient knowledge based on the survey questions and a majority of the patients self-scored as agreed or strongly agreed following the visits concerning awareness of medication indicated for pain, confidence on how to take the prescribed medication and side effect profile familiarity.

Discussion

Improvement opportunities continue to exist in supporting chronic pain patients, particularly in the first line treatment setting to maximize therapies and response. This project has great potential for sustainability and improvement in patient knowledge surrounding medication administration to enhance the first line non-opioid pharmacologic treatment of CNCP in all outpatient settings.

Problem Identification and Evidence Review

As a nation, opioid prescriptions for chronic pain have increased substantially with approximately 35% of all opioid overdose deaths in 2017 attributed to prescription medications (AHRQ, 2019). Opioid evidence shows only modest short-term benefits for chronic pain, thus, there is a need to identify alternative treatments to opioids (AHRQ, 2019). Centers for Disease Control and Prevention (CDC) 2016 guidelines for prescribing opioids for chronic pain recommends nonopioid therapy as preferred treatment for chronic pain (Dowell, Haegerich, & Chou, 2016). Quality improvement initiatives are needed in the management of chronic pain, opioid prescriptions, and alternative modalities supporting the Connecticut opioid education initiative and the 2011 Institute of Medicine (IOM) report.

Description of Local Problem

Patients with chronic pain may not be aware of the various options for treatment and lack of knowledge of the alternative pain treatments is directly inhibiting the ability to participate in a shared decision-making process. There are limited methods to facilitate increased awareness for prescribing care practitioners at the project site, a federally qualified community health center, of the availability of non-opioid pharmacologic agents in treating chronic pain. A further needs assessment revealed patients presently taking non-opioid pharmacologic agents in the treatment of chronic non-cancer pain needed additional education in managing multiple non-opioid medications. Targeting this area of need for improvement, can result in increasing patient knowledge in managing current non-opioid medications to maximize the duration of first-line agents in the treatment of chronic non-cancer pain.

Organizational Priority

This project has the support of the sites Medical Director, Behavioral Health APRN, and Primary Care APRN. In addition, this project is supported by the Alternative to Opioids for Pain (ALTOP) grant and in partnership amongst Sacred Heart University Davis Henley College of Nursing (SHU DHCON) and the practice site, a federally qualified community health center, to maximize the use of non-opioid pharmacologic agents in the first line treatment of chronic non-cancer pain**.**

Focused Search Questions

In primary care patients with different etiologies for chronic pain (P) how do non-opioid pharmacologic agents (I) compare to usual pharmacologic care (C) affect the treatment (O)?

External Evidence

A retrospective cohort study in patients with chronic non-cancer pain (CNCP) included 22,912 new episodes of prescribed therapy for both long-acting opioids and controlled medications (Ray et al., 2016). Long-acting opioids compared with alternatives included significantly increased risk of all-cause mortality, including deaths from overdose, with a modest absolute risk difference (Ray et al., 2016). Narrative RCTs reviewed examined 271 trials and concluded greater research is needed to determine effective mechanism-based treatments for CNCP (Nicol, Hurley, & Benzon, 2017). The literature supports thorough provider consideration of harms and benefits of treatment when counseling patients regarding therapies for chronic pain.

Internal Evidence

Cochrane review examined sixteen reviews offering quantitative data investigating opioid agents and associated adverse events used in the treatment of CNCP (Els et al., 2017). Results

included significantly increased risk of experiencing any adverse event (AE) with opioids compared to placebo (risk ratio (RR) 1.42, 95% confidence interval (CI) 1.22 to 1.66) as well as with opioids compared to a non-opioid active pharmacological comparator, with a similar risk ratio (RR 1.21, 95% CI 1.10 to 1.33) (Els et al., 2017). Additional systematic review of RCT data in opioids for CNCP revealed potential opioid benefit, however, magnitude is likely to be small (Busse et al., 2019). Long-term opioids prescribed to patients with chronic pain have limited benefits and non-opioid pharmacologic alternatives should be considered (Tauben & Stacey, 2021).

Evidence Appraisal, Summary, and Recommendations

A total of 16 articles met the criteria for inclusion in this evidence review with mainly evidence level two ratings. In order to select the article to include in the review, it had to evaluate a non-opioid pharmacologic agent for a specific type of pain in the outpatient setting. Appendix A displays the pertinent information from each of these reviews. Systematic reviews in the Cochrane database (n=14) identified studies of long-term opioid use for chronic non-cancer pain (CNCP) and this quality evidence demonstrated side effects can occur in patients with CNCP who use opioid medicines for greater than two weeks. The evidence ranged in chronic pain conditions treated with opioids, however, these conditions were also found to have efficacious non-opioid therapies listed. Randomized control trials did not support opioid therapy for treatment of moderate to severe chronic pain conditions of varying forms.

Based on this evidence review and synthesis, there is evidence supporting the CDC guidelines in using non-opioid pharmacologic treatments in the first line setting for CNCP. There are various effective opioid alternative pharmacologic therapies to treat common chronic pain conditions. Providers should council the patient and strongly consider, an opioid alternative

pharmacologic agent in the treatment of CNCP shown to be effective for decreasing pain, potential drug related toxicity, improving physical function, and/or quality of life compared to the opioid counterpart.

Phase 2: Project Planning

Project Goals

1. Identify non-opioid pharmacologic treatments for chronic non-cancer pain management.
2. Identify 25 to 30 patients with chronic non-cancer pain currently taking non-opioid pharmacologic agents for chronic non-cancer pain management.
3. Schedule and perform a medication management visit, in person or via telehealth with each identified patient which will include a focused review of all non-opioid pharmacologic agents utilized by the patient for chronic non-cancer pain.
    a. Education will be tailored to individual patient needs.
    b. Educational information handouts provided post visit, reinforcing individual patient medication touch points utilizing literacy-level appropriate materials.
    c. A post visit survey will be completed with each patient.
4. Disseminate information on completed medication management visits in patients presently using non-opioid pharmacologic treatments for chronic non-cancer pain to SWCHC project partners.

Framework

The 4C approach to quality improvement will guide this project. The steps in the 4C model are:

- Center: identify the issue, identify/set goals

- Collaborative Groups: assemble a team to work on the project that includes members that will be impacted by the change
- Change: implement the change using implementation strategies
- Celebration: celebrate and acknowledge improvement efforts (McGonigal, 2017)

Context

The practice site is a federally qualified health center that provides medical, dental, behavioral health services, health education, disease prevention programs, community outreach, homeless health program, and registration services to individuals and families in the Greater Bridgeport area. The practice site has a total of seven primary care clinics located throughout the city of Bridgeport and is a covid-19 testing center (SWCHC, 2022).

Key stakeholders

Key stakeholders include the practice sites prescribing providers of patients referred for medication management. The project team includes lead program staff such as the chief medical officer, QI director, behavioral health provider, primary care provider, and project manager for the Alternatives to Opioids for Pain (ALTOP) Grant. Dorothy Esposito, DNP MSN/ed, APRN, FNP-BC is the academic partner, DNP project faculty advisor, and evidence-based practice expert.

Practice change/Intervention

The proposed intervention will begin with the identification and referral of 25 to 30 patients with chronic non-cancer pain presently taking non-opioid pharmacologic agents for chronic non-cancer pain management. The patients will be identified by the referring provider as patients in need of further non-opioid chronic pain medication management education. Medication management visits will be performed either in clinic or via telehealth. The

implementation process for each medication management visit will begin with an introduction, visit goals overview, and consent to proceed with the visit. The DNP student will perform the medication management visit inclusive of the post visit survey (Appendix B), a focused review of all non-opioid pharmacologic agents utilized by the patient for chronic non-cancer pain and offer individualized patient education with appropriate literacy level handouts provided reinforcing individual patient medication touch points following the visit. Written and verbal summaries on individual medication management visits will be afforded to the referring provider. Real-time collaboration with the referring provider will also be utilized as appropriate.

The target goal will be for 90% of all patients referred to have completed medication management visits. The DNP student will review the ongoing and completed results of the medication management visits with the ALTOP team at the monthly meetings as well as provider emails and onsite communications. A summary of lessons learned will be developed by the DNP student and used to inform any future changes.

Possible Barriers to Implementation

The most common barriers to implementation may certainly include a lack of time for busy primary care providers in a community health center to consider patient referral and resistance to change due to culture or practice. Barriers to sustainability may include again a lack of time for provider referral, provider time constraints for ongoing dialogue with the DNP student, and patient scheduling limitations due to the pandemic and staffing shortages. Strategies to address these barriers include limiting the provider referral base to two providers with an ample chronic pain patient population base and simplifying the referral and communication feedback loops. These support mechanisms should encourage the two providers to utilize the DNP project medication management visits to educate their referred patients on the use of non-

opioid pharmacologic agents in the treatment of chronic non cancer pain and maximize the first line of treatment.

Sustainment

Ongoing project change can be sustained by communicating updated data on medication management visits aimed at maximizing the patients use of non-opioid pharmacologic agents in the treatment of their non-cancer chronic pain. Revisions to the project will be made based off stakeholder responses to enhance sustainability. In addition, celebrating provider success will take place on a regular basis throughout the project.

There is an opportunity for the intervention developing into a billable service for the practice site. Evolving this into a billable service could support the sustainment of this type of intervention and care needed in maximizing the duration of first line non-opioid pharmacologic treatment of chronic non cancer pain patient population. Services would either be administered via the qualified provider or directly supervised by the referring provider, and this would remain a sustainability goal for the practice site post project completion.

Dissemination Plan

Initial project dissemination includes monthly updates concerning project progress to the ALTOP team. Considering the development of an evidence-based practice (EBP) poster will provide a professional announcement of evidence-based findings with visual data and tables of the most fundamental aspects of this project. A poster presentation is a highly effective method for communicating and internally disseminating the project’s important findings.

Timeline

Nov-Dec 2020

- Complete project proposal draft

Jan-April 2021

- Complete official DNP project proposal and present to practice site stakeholders
- January-April 2021 make revisions to project proposal as needed

May-Aug 2021

- Identify & obtain the required review and approval needed for implementation

Sep-Dec 2021

- Prepare project implementation
- Track any deviations from project plan and make changes if needed

Sep-Mar 2021/22

- Complete medication management visits for referred patients

April 2022

- Present final DNP project
- Submit final DNP project
- Submit executive summary

Resources

Anticipated resources for this project include:

1. People:
    a. Patients, chief medical officer, quality improvement director, project manager for the ALTOP Grant at the practice site, primary care providers in internal medicine, and behavioral health professional.

2. Capital:
    a. Salaries for doing the work if not done as part of job may be required
3. Material:
    a. Educational materials related to the project
    b. Mailing materials inclusive of stamps, envelopes, & paper
    c. Zoom account or alternate virtual meeting platform required

Ethical Merit

This project has been reviewed by the ALTOP grant team and does not require Institutional Review Board approval as deemed a quality improvement project (see Appendix E). Utilizing the differentiating quality improvement and research activities tool answers to questions 1-10 are marked yes (see Appendix E). For questions 11-14 the answers are marked no indicating that this project meets criteria for a quality improvement project, does not qualify as human subjects 'research, and does not have to go through the Institutional Review Board at Sacred Heart University (see Appendix E).

Project Implementation

The project was carried out using the previously selected 4C model and the project began with the primary healthcare provider's identification and referral of patients with chronic non-cancer pain presently taking non-opioid pharmacologic agents for chronic non-cancer pain management. Over the course of four weeks, thirty-eight patients were identified and referred by the earlier identified two providers at the practice site. All thirty-eight patients were identified by the referring provider as patients in need of further non-opioid chronic pain medication management education. Each patient was contacted for medication management visits via

telehealth. Patients were left messages if not initially reached by phone and follow-up phone calls were also performed at varying times of day.

The implementation process for each medication management visit began with an introduction, visit goals overview, and consent to proceed with the visit. A total of twenty-eight patients were reached via telephone and agreed to continue with the medication management visit. Each patient had a completed medication management visit performed by the DNP student. Medication management visits incorporated a focused review of all non-opioid pharmacologic agents utilized by the patient for chronic non-cancer pain, tailored individualized medication education as needed, a post visit survey (Appendix D), and an offer for individualized patient education with appropriate literacy level handouts reinforcing individual patient medication touch points following the visit. Written and verbal summaries on individual medication management visits were afforded to the referring provider following the completion of the medication management visits. Real-time collaboration with the referring provider was also utilized when needed and as appropriate.

Project Plan Deviations

The initial project implementation was targeted for the fall of 2021. Due to extensive project revisions, the project implementation was delayed until February 2022. The initial intent of the project was provider education focused. Feedback elicited combined with the practice site's provider workflow volume changes over the course of the project's development demonstrated a greater area of need for education concerning the directed patient population. Necessary project revisions aimed at focusing the education intervention on the detailed patient population caused a deviation and delay.

Initial implementation barriers included EMR access delays due to new practice site system security training, student re-approval for remote work delays, and several calls with practice site informational technology support over the course of two weeks to reset expired passwords.

Further patient scheduling barriers involved difficulty reaching patients via telephone with the inability to leave messages, whether for a full voicemail box or no voicemail box set up, and unreturned call backs. This represented a deviation from the project plan as the completed medication management visit goal was set for 90% while only less than that of patients were reached.

Evaluation

A target goal was established for 90% of all patients referred to have completed medication management visits. Of the thirty-eight patients referred, a total of twenty-eight had completed medication management visits, representing 74% of the referred population as reflected in Table 1.

Table 1.

Patients Referred for Medication Management Visits n=38

Process Measures. The process measurement included tracking the number of medication management visits performed focusing on non-opioid pharmacologic agents in the treatment of chronic pain. Descriptive statistics collected from the EHR inclusive of demographics, indicated diagnosis for non-opioid medications, number and variety of non-opioid medications, and therapeutic medication classes. Post survey responses were collected and grouped as appropriate for reflection in the qualitative findings. Table 2, 3, and 4 display available data.

Table 2.

Patient Characteristics

Characteristics	Patient completed Visits (n=28)
Age ≥ 18	28
Gender	
Male	8
Female	20
Race	
Asian	1
Black / AA	9
White	17
Declined	1
Ethnicity	
Not Hispanic or Latino	17
Hispanic or Latino	9
Declined to specify/unknown	2
Chronic Pain Location	
Head	2
Neck	2
Back/lower back	11
Hands/Feet	4
Abdominal	1
Knee	3
Whole Body	3
Other	2
Combination > 1 site	28

Table 3.

Indicated Diagnosis for non-opioid prescription

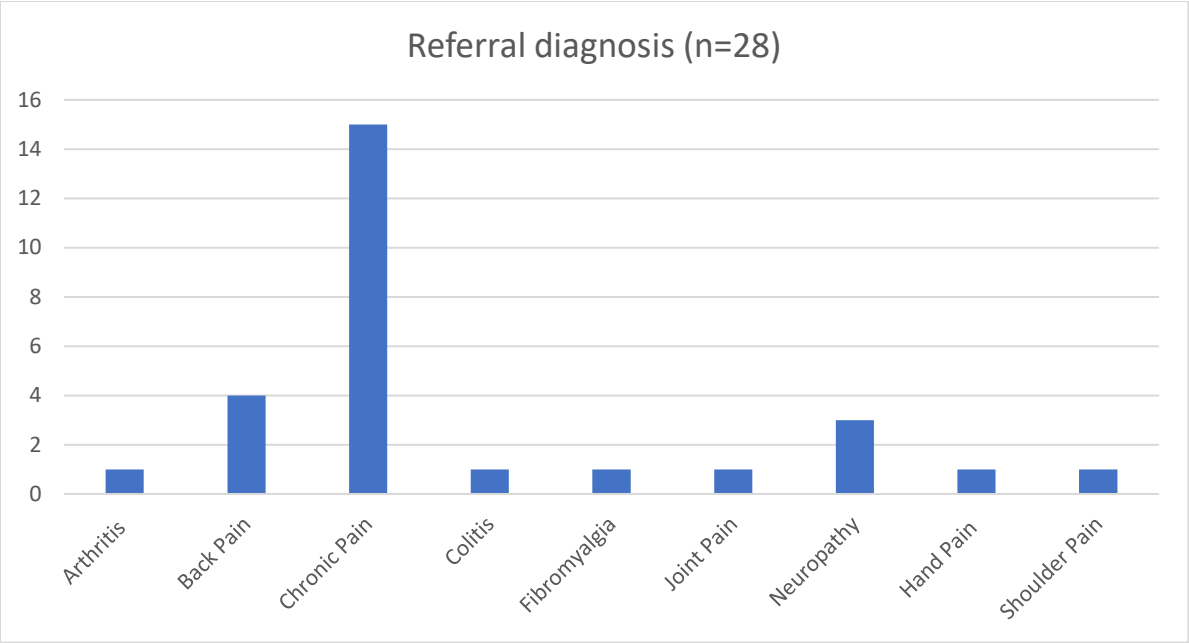
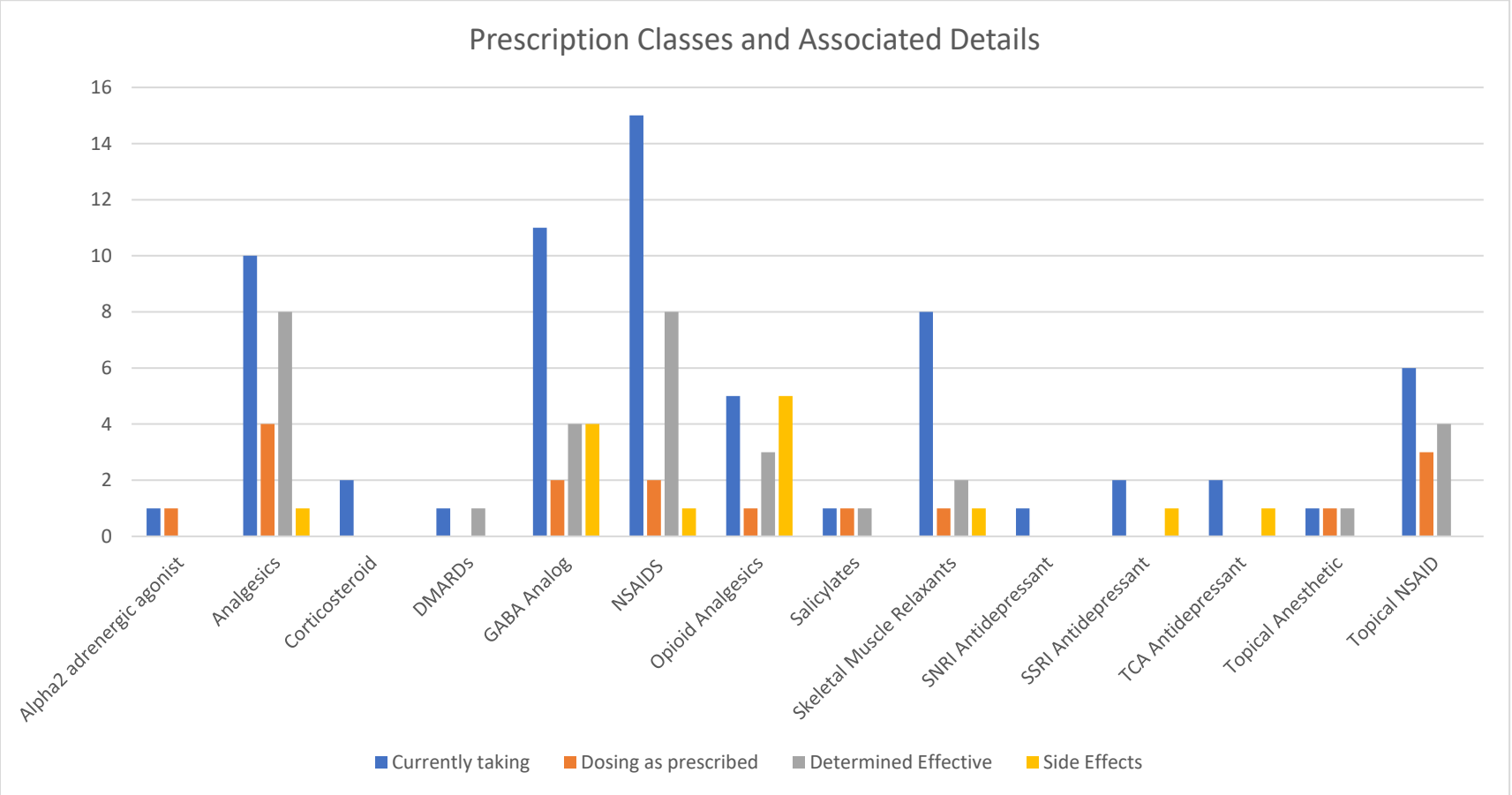


Table 4.

Prescription Classes and Associated Details



Outcome Measurements. The outcome measurement comprises patient knowledge based on the survey questions surrounding awareness of medication indicated for pain, confidence on how to take the prescribed medication and side effect profile familiarity. Data collection includes post visit survey. See Table 5.

Table 5.

Patient knowledge assessments

Survey Questions	Post Visit n=28				
	1	2	3	4	5
1. I know which of my medication(s) to take for different types of pain.	0	1	0	14	13
2. I am confident on how to take my medication(s)s for pain.	0	0	0	17	11
3. I am familiar with the side effects of the medication(s) I take for pain.	0	3	0	16	9

Key: 1= Strongly Disagree, 2= Disagree, 3= Sometimes, 4= Agree, 5= Strongly Agree

Return on Investment. The return on investment (ROI) is utilized to evaluate the financial impact of the project and is generated from the estimated financial value of the practice change subtracted from the estimated actual project costs. The total profit the project is estimated to generate is then divided by the project costs. Total project costs were estimated at $800.00 including provider time for 30-minute visits based on an average annual salary, printing materials, and mailing supplies cost for a total of twenty-five completed patients. The anticipated financial value generated via a billable and service for a sample size of twenty-five patients represents $1950.00. Medicare 2022 reimbursement rates utilizing medication management CPT codes estimated the expected financial return. An estimated ROI of 1.45% is observed.

Dissemination

Implications of Project Results to Organization and Practice Community

Initial project dissemination included monthly updates concerning project progress to the ALTOP team and final project presentation on April 12, 2022. Project results and practice community implications were presented to the organization. Additional evidence-based practice (EBP) poster dissemination involved both the practice site organization and DNP program.

Executive Summary. The executive summary was developed as a highly summarized description of the project. As detailed in Appendix F, the executive summary includes the projects' purpose, methods, results, conclusions, and recommendations for sustainability.

Electronic Poster. The development of an evidence-based practice (EBP) poster was completed and provided within the DNP program as a professional announcement of evidence-based findings with visual data and tables of the most fundamental aspects of this project as demonstrated in Appendix G. A poster presentation is a highly effective method for communicating and internally disseminating the project's important findings.

Practice Organization Presentation. The final project dissemination concluded in an ALTOP meeting project presentation with key stakeholders in attendance from the practice site, and DNP program professors, project, and clinical advisors. Additional DNP program peers were in attendance as well.

Key Lessons Learned

Enhanced patient referrals resulted in limiting the number of providers through project engagement and enhanced feedback loop communication. Ease of referral process and ample patient population also contributed to the robust patient referrals. Barriers in contacting patients via telehealth could have been improved upon by targeting an onsite day for patient visits.

Sustainability Plan

Improvement opportunities continue to exist in supporting chronic pain patients, particularly in the first line treatment setting to maximize therapies and response. This project has great potential for sustainability with practice site leadership support, opportunity for a billable service, and improvement in patient knowledge surrounding medication administration. Several factors in place contributing to the success of this project include the robust chronic pain patient population, dedicated providers, and the organizational support for alternatives to opioids working under the ALTOP grant. The organizational and faculty partnerships strengthened during this project enhance the potential for project sustainability.

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Appendix A

Description of Evidence Search

A search of the subsequent databases was conducted; CINAHL, MEDLINE, and the Cochrane Database of Systematic Reviews. The key words searched included; non-opioid pharmacologic agents, providers, prescribers, clinicians, health care professionals (HCPs), non-opioid medications, chronic pain, prescribing, non-opioid analgesics, and opioid alternative medications. Limits and filters added for all searches pertaining to the aforementioned search terms included, English language, adults (age 18 and over) and published between 2010 – 2020. Inclusion criteria for article selection pertained to non-opioid pharmacologic agents, chronic pain, and may have or have not included prescribing practices. Tables 1 through 3 display the database, search terms and results of search.

PICO question: In primary care patients with different etiologies for chronic pain (P) how does non-opioid pharmacologic agents (I) compare to usual pharmacologic care (C) affect the treatment (O)?

Table A1.

CINAHL Complete Search Terms and Search Results

Search Terms	Number of hits	Number of title & abstract reviewed	Number of full-text articles reviewed	Duplicates	Number of articles selected for this review without duplicates
Non-opioid pharmacologic agents	882				
Providers & Non-opioid medications	3	3			
Prescribers & Non-opioid medications	1	1			
Physicians or doctors or clinicians or HCPs & non-opioid medications	3	3	1		1
Non-opioid medications	64				
Non-opioid medications & chronic pain	22	11	3	11	1
Prescribing non-opioid medications & chronic pain	656	23		1	2
Prescribing practices & non-opioid medications	1				
Non-opioid analgesics & chronic pain	56				2
Chronic pain & opioid alternative medications	7	2			

Table A2. Medline Search Terms and Search Results

Search Terms	Number of hits	Number of title & abstract reviewed	Number of full-text articles reviewed	Duplicates	Number of articles selected for this review without duplicates
Non-opioid pharmacologic agents	1907				
Providers & Non-opioid medications	6				
Prescribers & Non-opioid medications	2			1	
Physicians or doctors or clinicians or HCPs & non-opioid medications	11			3	
Non-opioid medications	52	8		12	
Non-opioid medications & chronic pain	17			13	
Prescribing non-opioid medications & chronic pain	325	25		123	1
Prescribing practices & non-opioid medications	2			1	
Non-opioid analgesics & chronic pain	117	4			
Chronic pain & opioid alternative medications	6			4	

Table A3.

Cochrane Database of Systematic Reviews Search Terms and Search Results

Search Terms	Number of hits	Number of title & abstract reviewed	Number of full-text articles reviewed	Duplicates	Number of articles selected for this review without duplicates
Non-opioid pharmacologic agents	39	5			3
Providers & Non-opioid medications					
Prescribers & Non-opioid medications					
Physicians or doctors or clinicians or HCPs & non-opioid medications					
Non-opioid medications	2				
Non-opioid medications & chronic pain Prescribing non-opioid medications & chronic pain	1				
Prescribing practices & non-opioid medications					
Non-opioid analgesics & chronic pain	2				
Chronic pain & opioid alternative medications	6	2			2

Appendix B

Search Question in PICO format: In primary care patients with different etiologies for chronic pain (P) how does non-opioid pharmacologic agents (I) compare to usual pharmacologic care (C) affect the treatment (O)?

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
Neuropathic Pain								
1	Arezzo (2008)	Efficacy evaluation in DPN-associated neuropathic pain	Randomized, double-blind, placebo controlled trial II	167, 13 week parallel-group trial across 23 outpatient centers in U.S -pre-existing painful DPN >/=3 months	Endpoint mean pain score (MPS),	11-point scale MPS	• Pregabalin 600mg/d (300mg BID) effectively reduced pain & well tolerated • pregabalin tx pts lower MPS than controls (mean difference -1.28; p<.001)	-significant pain improvement evident @ 1 week & sustained weekly timepoints -this trial important addition to pregabalin & neuropathic pain literature
2	Devi (2012)	Reduction in neuropathic pain severity	Prospective, randomized, open label, comparative study II	152, outpatients Dept. of Endocrinology & Neurology, St. Johns Medical College Hospital Bengaluru	pain severity (3 tx groups) -safety of study medication	11-point VAS (0=no pain – 10=worst possible pain) -recording ADRs	• Head to head comparison for Gabapentin, Pregabalin, Duloxetine w/ all 3 demonstrating significant reduction in pain	-all 3 treatment groups significant reduction in VAS for pain across 12 weeks (P<0.05)

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
3	Kelle (2012)	Compare effectiveness of gabapentin & pregabalin in neuropathic pain due to peripheral nerve injury	Randomized, II	30, Military veterans w/ neuropathic pain r/t peripheral nerve injury -2 groups (Gabapentin vs Pregabalin) -tertiary care hospital	Pain at baseline, 1 week, 1 month, 3 months	11-point VAS (0=no pain – 10=worst possible pain)	• mean reduction in VAS pain statistically significant (P < 0.05) in both groups	- significant reduction in VAS for pain across all timepoints
4	Backonja (2008)	percentage change in NPRS score from baseline to weeks two to eight.	Randomized, II	402, Patient ages 18–90, had had postherpetic neuralgia for at least 6 months, & had average baseline numeric pain rating scale (NPRS) score of 3 to 9.	numeric pain rating scale (NPRS) score	#1 60 min application of 8% capsaicin or low concentration capsaicin control patch. % change in NPRS score from baseline to wks 2 to 8	• pts assigned to 8% capsaicin had significantly > pain reduction in pain during weeks 2 to 8 than those w/ control patch. • Mean changes in NPRS score -29.6% vs -19.9% (difference -9.7%, 95% CI -15.47 to -3.95; p=0.001)	>pain reduction in patients using 8% capsaicin for post herpetic neuralgia
Fibromyalgia								
5	Arnold (2007)	Compare gabapentin vs placebo for efficacy	Randomized, II	150 subjects, in 3 outpatient research centers in the	Brief pain survey (BPI) average pain	Response to treatment was defined as a reduction of >or=30% in this	Gabapentin-treated patients displayed a significantly	≥30% pain reduction (BPI) in Gabapentin treated patients

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
		& safety in treating pain associated with fibromyalgia		U.S., ages ≥18 & met ACR criteria for fibromyalgia	severity score (range 0-10)	score. The primary analysis of efficacy for continuous variables was a longitudinal analysis of the intent-to-treat sample, with treatment-by-time interaction as the measure of effect.	greater improvement in the BPI average pain severity score (P=0.015; estimated difference between groups at week 12=-0.92 [95% confidence interval -1.75, -0.71])	
6	Arnold, 2008	assess the efficacy and safety of pregabalin monotherapy in patients with fibromyalgia	Randomized double-blind, multi-dose, placebo-controlled II (Industry)	745, 84 outpatient research centers across U.S. ≥18y/o, FM class met, baseline pain score of at least 40mm on the 100mm visual analog scale (VAS)	- Brief pain survey (BPI) average pain severity score (range 0-10)	-Pregabalin 600mg/450mg/300mg per day Vs Placebo -BPI-S Avg pain scale 0-10 (NRS), 14 weeks	- All three monotherapy dosing groups demonstrated statistically significant improvement compared w/ placebo treated pts -wkly mean pain scores in all 3 pregabalin tx groups significantly separated from placebo as early as week 1, & significant improvement was sustained until EOT period (week 14), with the	≥30% pain reduction (BPI) in all Pregabalin treated patients

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
							exception of 300 mg/d at week 11.	
7	Branco, 2011	Investigate long term efficacy & safety of milnacipran in tx of FM	Randomized, double-blind, extension study II (Industry)	270, 70 outpatient centers in 11 European countries Pts post 3 month lead in study (double blind Milnacipran tx, placebo controlled) 18-71 y/o, FM dx per ACR criteria	- weekly recall pain (pt. reported avg level of pain over the previous week) based on 1-100 paper Visual Analog Scale (VAS) - Patient global impression of change (PGIC): pt rates impression of overall pain, 7 pt scale	-Weekly recall VAS & PGIC	- Long term extension study shows the beneficial effect of milnacipran in FM at the 3 dosages tested and the maintenance of this effect over a 1-year period. This efficacy was observed for the pain	≥30% pain reduction (improvement in weekly-recall pain VAS score & improved PGIC) in all 3 treatment groups
8	Chappell, 2008	Assess efficacy of duloxetine compared with placebo in FM during 6 month tx phase	Phase-III randomized, double-blind, placebo-controlled, parallel-group II (Industry)	307, 36 outpatient / private practices - centers in Germany, Spain, Sweden, UK, U.S. ≥18 y/o with FM per ACR criteria	- Brief pain survey (BPI) average pain severity score (range 0-10) - Patient global impression of change (PGIC): pt rates impression of overall pain, 7 pt scale	-BPI, if pt did not have >50% reduction at week 13, then blindly escalated to higher dose (120mg) -Pain reduction measured by BPI from baseline to endpoint & PGIC at endpoint	Compared with placebo-treated, pts tx w/ duloxetine had significantly greater AUC of pain relief & experienced greater improvements in BPI least pain score and average interference score.	≥30% pain reduction in both treatment groups -BPI avg pain severity from baseline to endpoint (P=0.053) -PGIC at endpoint (P=0.073)

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
9	Mease, 2008	Evaluate efficacy & safety of Pregabalin for symptomatic pain relief associated w/ FM	Randomized, double-blind, placebo-controlled. II (Industry)	748, 79 research outpatient sites in U.S ≥18, met ACR dx for FM	- Baseline pain intensity, NRS (0-10) - Baseline function/disability: SF-36 physical functioning (0-100)	-pt daily pain rating for previous 24 hrs -"responders" = ≥30% reduction in mean pain score from baseline to endpoint	-pregabalin, statistically significant improvement in endpoint mean pain score and in PGIC response compared with placebo	≥30% pain reduction in all three treatment groups -Pregabalin monotherapy provides clinically meaningful benefit to patients with FM
Osteoarthritis								
10	Baerwald, 2010	Test superiority of naproxen compared w/ placebo in relieving signs & symptoms of Hip OA	Randomized, double-blind, parallel-group, multicenter study. II	810, 105 outpatient centers in U.S, Canada, & Europe ≥40 y/o dx of primary hip OA, +hip pain	-Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain & function subscales	-WOMA pain score -VAS	-well tolerated and promising tx for OA of hip, efficacy statistically greater than placebo	>50% improvement in pain or function
11	Chappell, 2011	Evaluate efficacy & safety of duloxetine in chronic pain tx of Knee OA	Randomized, double-blind, placebo-controlled II (Industry)	256, 21 Outpatient clinical sites, ≥40 y/o dx of OA knee	-baseline pain intensity, BPI average pain (0 to 10) -Weekly 24-hour average pain (0 to 10) -CGI-S (1 to 7)	-BPI 24 hr average pain rating, duloxetine doses increased if <30% pain reduction from baseline at week 7	-pain reduction significantly higher in duloxetine group compared to placebo based on primary efficacy analysis of BPI average pain	≥30% pain reduction from baseline to endpoint
12	Reginster, 2017	Management of symptomatic	Randomized, double-blind,	405, Outpatients, international sites	Pain reduction, change from baseline	Baseline pain intensity, target knee pain (VAS) (0 to 100)	Celecoxib provided a significantly greater reduction	≥40% pain reduction

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
		knee osteoarthritis	placebo controlled II (Industry)	>50 y/o, primary knee OA			in pain after 3 & 6 months	
13	Uchio, 2018	Examine the efficacy & safety of duloxetine in pts. w/ OA knee pain	Randomized, double-blind, placebo controlled II (Industry)	354, 47 outpatient medical centers in Japan 40-<80 y/o, met ACR criteria knee OA pain	Change in BPI severity scales	Baseline pain intensity, BPI severity average pain (0 to 10)	Duloxetine reduced knee knee pain associated with OA	≥30% pain reduction
14	Barthel, 2009	Assessing the efficacy & safety of topical diclofenac sodium 1% gel in mild-mod symptomatic knee OA	Randomized, double-blind, vehicle controlled II (Industry)	492, 64 outpatient centers in U.S. >35 y/o w/ dx of osteoarthritis in 1 or both knees	Pain reduction, change from baseline Pain on movement	Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain subscale Visual analog scale assessing pain on movment (VAS) (0 to 100)	Over a 3-month treatment period, topical tx w/ DSG achieved clinically significant improvements of pain in pts. w/ knee OA	Significant decreases in mean WOMAC pain (P=0.01)
15	Altman, 2015	Evaluating efficacy & safety of low-dose SoluMatrix Meloxicam in pts. w/ OA-related pain	Randomized, double-blind, vehicle controlled II (Industry)	403, outpatient setting >40 y/o, confirmed hip or knee OA	Mean change from baseline in WOMAC pain subscale score at week 12	Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) pain subscale	Meloxicam group experienced significant improvement from baseline in measures of pain.	≥30% pain reduction

Article number	First author year	Purpose	Evidence type, level of evidence	Sample, setting	Major Variables Study and their Definitions	How major variables were measured	Findings that help answer question	Results worth to practice/project, quality of evidence
							Therapeutic option to manage OA related pain	
Low Back Pain								
16	Konno, 2016	Assess efficacy & safety of duloxetine in pts w/ chronic low back pain	Randomized, double-blind, placebo controlled II (Industry)	458, 58 outpatient centers in Japan 20-<80 y/o, LBP for at least 6 months, current NSAID users	Improvement in BPI average pain score from baseline	Baseline pain intensity, BPI average pain (0-10)	Significant improvement in pain from baseline in the Duloxetine group	≥30% pain reduction

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Appendix C

Table C1.

Level of Evidence Synthesis Table

Article Number	1	2	3	4	5	6	7	8
Level I: Systematic review or meta-analysis				X	X			
Level II: Randomized controlled trial						X	X	
Level III: Controlled trial without randomization								
Level IV: Case-control or cohort study			X					
Level V: Systematic review of qualitative or descriptive studies								X
Level VI: Qualitative or descriptive study, CPG, Lit Review, QI or EBP project	X	X						
Level VII: Expert opinion								

Table C2.

Outcomes Synthesis Table

Article Number	1	2	3	4	5	6	7	8
Opioid prescriptions	↑	↑ (96%)	ND	+	NE	+	NE	+
Non-opioid prescriptions	NE	NE	ND	+ (control)	+	+	NE	+
Pain intensity	NE	NE	NE	NE	+	ND	NE	NE
Physical functioning improvement	NE	NE	NE	ND	ND (non-opioid/ placebo)	ND	NE	NE
Pain improvement w/ opioids	↓	NE	NE	↑ short duration ↓ long duration	NE	ND	↑ (opioid/ non-opioid combo)	NE
Pain improvement w/ nonopioids	NE	NE	NE	ND	↑	ND	↑	NE
Opioid r/t AEs	↑	NE	↑ (1.90 >risk)	↑	NE	↑	NE	↑

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Appendix D

The following is a script to be completed with the patient post telehealth visit for the chronic pain medication management visit.

For each of the topics listed below, please check the box under the number that indicates your level of knowledge both **before** and **after** completing the medication education visit:
1= Strongly Disagree
2= Disagree
3= Sometimes
4= Agree
5= Strongly Agree

How do you rate your knowledge about the following topics:	Knowledge **AFTER** the Visit				
	1	**2**	**3**	**4**	**5**
Q1. I know which of my medications to take for different types of pain.					
Q2. I am confident on how to take my medications for pain.					
Q3. I am familiar with the side effects of the medications I take for pain.					

Appendix E

Table E1.

Differentiating Quality Improvement and Research Activities Tool

Question	Yes	No
1. Is the project designed to bring about immediate improvement in patient care?	X	
2. Is the purpose of the project to bring new knowledge to daily practice?	X	
3. Is the project designed to sustain the improvement?	X	
4. Is the purpose to measure the effect of a process change on delivery of care?	X	
5. Are findings specific to this hospital/setting?	X	
6. Are all patients who participate in the project expected to benefit?	X	
7. Is the intervention at least as safe as routine care?	X	
8. Will all participants receive at least usual care?	X	
9. Do you intend to gather just enough data to learn and complete the cycle?	X	
10. Do you intend to limit the time for data collection in order to accelerate the rate of improvement?	X	
11. Is the project intended to test a novel hypothesis or replicate one?		X
12. Does the project involve withholding any usual care?		X
13. Does the project involve testing interventions/practices that are not usual or standard of care?		X
14. Will any of the 18 identifiers according to the HIPAA Privacy Rule be included?		X

Adapted from Foster, J. (2013). Differentiating quality improvement and research activities. Clinical Nurse Specialist, 27(1), 10–3. https://doi.org/10.1097/NUR.0b013e3182776db5

Appendix F

Executive Summary

Opioid prescription related overdose deaths have increased substantially with evidence demonstrating only modest short-term benefits in chronic pain and thus represents the need to identify alternative treatments to opioids (AHRQ, 2019). A needs assessment performed for a federally qualified community health center revealed patients presently taking non-opioid pharmacologic agents in the treatment of chronic non-cancer pain (CNCP) needed additional education in managing multiple non-opioid medications. A targeted approach at improving patient experience and population health supporting the quadruple aim was undertaken with this project (Arnetz et al., 2020).

Purpose

The purpose of this quality improvement project consisted of performing medication management visits for 25 referred patients with CNCP encompassing a focused review of all non-opioid pharmacologic agents being taken with tailored patient education completed. This alternatives to opioids region of need was targeted in support of maximizing the use of non-opioid pharmacologic agents in the first line treatment of CNCP**.**

Methods

Over the course of four weeks in a federally qualified community health center, twenty-five patients had completed medication management visits via telehealth, initially referred by their healthcare provider as patients in need of further non-opioid chronic pain medication management education. Each visit consisted of an introduction, visit goals overview, consent to proceed, focused review of all non-opioid pharmacologic agents taken for CNCP, tailored individualized education, and a post visit survey.

Results

The outcome measurement comprises patient knowledge based on the survey questions and a majority of the patients self-scored as agreed or strongly agreed following the visits concerning awareness of medication indicated for pain, confidence on how to take the prescribed medication and side effect profile familiarity.

Conclusions

A high incidence of polypharmacy was noted with most patients taking multiple non-opioid pharmacologic agents for CNCP. Even further problematic, there was a noted low incidence of patients taking these medications as prescribed. The education provided during the medication management visit positively impacted the patient's awareness of taking the medications as prescribed, confidence level of managing multiple non-opioid medications, and familiarity with side effects of these medications.

Recommendations

Improvement opportunities continue to exist in supporting chronic pain patients, particularly in the first line treatment setting to maximize therapies and response. This project has great potential for sustainability and improvement in patient knowledge surrounding medication administration to enhance the first line non-opioid pharmacologic treatment of CNCP in all outpatient settings. The chronic pain medication focused visits can be supported as a billable service furthering justifying the ease of implantation for further success in the management of chronic pain and alternative modalities supporting the Connecticut opioid education initiative and the 2011 Institute of Medicine (IOM) report.

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Appendix G

Evidence Based Poster