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Applying Clinical Guidelines to Curtail Opioid Overprescribing in Primary Care

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Walden University

College of Health Sciences

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Glenda Le Flore

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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2016

Abstract

Applying Clinical Guidelines to Curtail Opioid Overprescribing in Primary Care

by

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Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

May 2017

Abstract

The purpose of this scholarly project was to evaluate an evidence-based quality improvement program implemented in 2016 in a clinical practice setting to curtail overprescribing of opioids for noncancer pain management. In 2001, the National Pharmaceutical Council and The Joint Commission on Accreditation and Hospital Accreditation initiated a standard of practice for opioid use in noncancer pain management that resulted in opioid overprescribing and a 200% increase in opioid-related deaths and incalculable societal costs. Primary care providers including nurse practitioners issue the greatest number of opioid prescriptions; therefore, to address the problem of opioid overprescribing, the 2016 Centers for Disease Control and Prevention guidelines for opioid administration were implemented as a quality improvement program in a primary care setting with 10 providers. Lewin's change model was the vehicle for change and included an ongoing audit developed for tracking provider prescribing rates. The project sought to determine if adoption of the opioid administration guidelines reduced the prescribing rates in a clinical practice setting and thereby justify expanding the program to other primary clinic sites. A pre- post-single group comparison was conducted of prescribing rates from May 15, 2015 prior to implementing the guidelines and December 19, 2016 after the guidelines were in place. Analysis from *t* tests indicated a 41% ($p < .01$) reduction in prescribing rates. The project promotes positive social change through the decreased individual and societal cost of opioid-related deaths.

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Dedication

First and foremost, I would like to thank my God who sustains me and to whom I credit all things positive wrought from my hands. It is He who generates the ability and desire within me to engage in a purpose-driven life. Throughout this process, I was concerned regarding my ability to work and attend school full-time, as well as fulfill my commitment to my family and others. I am thankful to have seen this process to its completion.

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I would like to express my gratitude to my wonderful and supportive husband Robert Stewart for his unwavering support during my sleepless nights and overwhelming days. Thanks to my sons for being such loving children and wonderful boys. I would also like to thank my parents for the work ethic that they exemplified. They were truly overcomers. I would like to thank Dr. Eric Walsh, the best practicum instructor and mentor to ever exist, for his confidence in my abilities and his sage advice on professionalism. He is truly a motivational man walking in his purpose. An additional source of inspiration has been the U.S. Surgeon General Vivik Murthy, whom I had the pleasure of meeting. He was leading the fight to “Turn the Tide” on opioid-related morbidity and mortality. Finally, I would like to thank the staff at Bakersfield Family Medical Center for the educational opportunity of a lifetime. The professional growth attained while attending my practicum was invaluable. I could not have imagined a more professionally rewarding experience.

I would finally like to thank Walden University and Dr. Janice Long in particular for guidance throughout this journey in professional and academic growth.

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Section 1: Overview of the Project

Introduction

My aim in this project was to evaluate a quality improvement program that had the potential to address the well-documented problem of opioid overprescribing in primary care practice resulting in poor patient outcomes (Manchikanti et al., 2012; Paulozzi, Mack, & Hockenberry, 2014). The literature review method that I chose to guide the program included relevant literature identified through searches of MEDLINE, Agency for Health Research Quality (AHRQ), Health Resources and Services Administration (HRSA), Google Scholar, and PubMed. Also included were required and recommended readings from the Walden University Doctorate of Nursing Practice Program. I researched the terms *quality improvement*, *opioids*, *opioid addiction*, *overprescribing*, *opioid epidemic*, *opioid guidelines*, and *opioid recommendations*.

The program incorporated a multidisciplinary team of stakeholders to apply a systematic approach to a practice change (HRSA, 2016; Joshi, 2014). A team-based approach helps organizations to achieve significant and lasting quality improvements (HRSA, 2016). This program was designed to effect a permanent change in the approach to the treatment of pain. The organization anticipated that the program would have ongoing quality improvement support through peer review and monitoring systems to ensure that the change is implemented and remains in effect after the initial implementation phases (AAFP, 2016; Joshi, 2014). In Section 1 of this project, I cover the problem of opioid misuse, the purpose of the program, the nature of the program, the program's significance, and a summary.

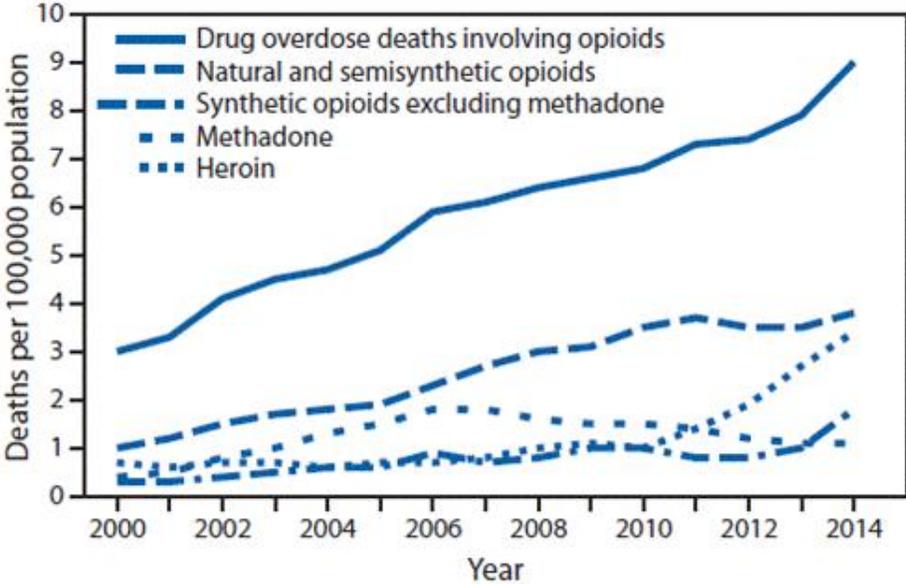
The Problem

My aim in this project was to determine if this implemented evidence-based program would curtail opioid overprescribing in primary care. I used the Centers for Disease Control and Prevention [CDC] (CDC, 2016a) clinical guidelines as the main instrument of change for the program. Advanced practice nurses, as primary care providers (PCPs), are equipped to take on leadership roles in countering the current opioid overprescribing trend through the application of evidence-based practice guidelines (American Association of Colleges of Nursing, 2006). Prescription opioid disorders are a significant national public health problem as well as a patient safety concern (CDC, 2015a). CDC (2015b) national vital statistics have indicated that, since 2001, the number of opioid prescriptions for the treatment of noncancer, nonpalliative care pain has increased exponentially (CDC, 2016b; Manchikanti et al., 2012). Unfortunately, along with this increase in opioid use for the treatment of noncancer pain, the prevalence of opioid misuse, abuse, disorders, diversion, and deaths has grown (CDC, 2015a; Health and Human Services [HHS], 2016). This alarming trend has mandated the attention of the CDC, as well as other governmental and health care organizations (Time Inc., 2016; White House Statements and Releases, 2016). This problem has now advanced to the stage of an epidemic (CDC, 2016b).

Given that a 200% increase in opioid related deaths was registered between 2000 and 2014, there was a need to evaluate and modify the way that PCPs treat pain (see Figure 1). The reversal of this trend required a new approach to the treatment of pain due to negative patient outcomes (CDC, 2015a, 2015b). The escalating use of therapeutic

opioids reflects a lack of understanding of the addictive nature of this substance (Manchikanti et al., 2012); National Pharmaceutical Council [NPC], 2001). Dependence can occur in as little as 1 week (NPC, 2001). Thus, my aim in this project was to evaluate this informed practice change through utilizing evidence-based guidelines directed toward PCPs and the way they treat pain.

Figure 1
Drug Overdose Deaths Involving Opioids by type of Opioid
2000 to 2014



Reproduced from Centers for Disease Control. Multiple cause of death data on CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC. Accessed 12/1/2016 from <http://wonder.cdc.gov/mcd.html>

Figure 1. Drug overdose deaths involving opioids by type of opioid 2000–2014 (with permissions).

To address the problem of opioid prescribing locally, the State of California passed legislation requiring health care providers to access the state database to obtain a patient drug monitoring report prior to prescribing any Schedule II drugs (American

Insurance Association [AIA], 2016). This online database alerts prescribers of patients attempting to “‘doctor shop’ in order to obtain controlled substances” (AIA, 2016). The governor of California responded to the epidemic of opioid deaths facing the State of California and the nation (AIA, 2016; Harris, 2015). This mandate is one of the recommendations found in the CDC (2016a) guidelines.

In addition, PCPs have now come under legal jeopardy for opioid prescribing practices (CDC, 2016b). There may be legal implications for failure to adhere to responsible practice guidelines. The implications of not addressing the practice problem include the potential for governmental and patient litigation (Gerber, Girion, & Queally, 2015; McMullen & Howie, 2011). Once a standard has been established by a credible and validated oversight agency, the potential for litigation is introduced. Such litigation has already occurred in the State of California, whereby a physician was convicted of second-degree murder due to reckless opioid prescribing practices (Gerber et al., 2015). The legal and financial implications of operating below an established industry standard were established with this precedent. Suboptimal care in light of the new standard may be viewed as malpractice (Mosby, 2009).

The societal costs of prescription opioid dependence, abuse, and misuse have been evaluated and are grouped into three categories: health care, workplace, and criminal justice (Birnbaum et al., 2011). According to Birnbaum et al. (2011),

Total US societal costs of prescription opioid abuse were estimated at \$55.7 billion in 2007 (USD in 2009). Workplace costs accounted for \$25.6 billion (46%), health care costs accounted for \$25.0 billion (45%), and criminal justice

costs accounted for \$5.1 billion (9%). Workplace costs were driven by lost earnings from premature death (\$11.2 billion) and reduced compensation/lost employment (\$7.9 billion). Health care costs consisted primarily of excess medical and prescription costs (\$23.7 billion). Criminal justice costs were largely comprised of correctional facility (\$2.3 billion) and police costs (\$1.5 billion). (pg.1)

These costs were anticipated to continue to rise with increasing prescribing rates (Birnbaum et al., 2011). Consequently, I sought to evaluate a program aiming to address the practice challenge of excessive opioid prescribing and to advance patient safety and health care delivery quality in primary care (AACN, 2006). I evaluated the quality improvement program through the capture of prescribing patterns obtained using information technology (IT) as described by HRSA (2016). By using prescribing rates sourced from the electronic health records (EHRs) or billing records, the process was not only more efficient but theoretically proved to be more accurate than manual counting methods (HRSA, 2016). This method provided evidence by capturing the prescribing rates obtained before and after the program implementation. This technique assisted in evaluating the program's ability to curtail the overprescribing of opioids for noncancer pain.

Purpose

The purpose of the project was to evaluate a program that addresses a primary care practice gap. This gap is proposed to stem from the underuse of the CDC opioid prescribing guidelines resulting in overprescribing. PCPs express concerns regarding

opioid pain medication misuse. However, they emphasize that they are overwhelmed by treating patients presenting with chronic pain, as well as cite concerns with addiction and report being inadequately prepared for prescribing opioids (Jamison, Sheehan, Scanlan, Matthews, & Ross, 2014). According to the CDC (2015b), PCPs are prescribing opioids at increasing rates and are not adhering to current evidence-based clinical guidelines (CDC, 2016b; Cheatle, Comer, Wunsch, Skoufalos, & Reddy, 2014). To bridge the current practice gap, this program was based on the CDC (2016a) standardized guidelines and clinic policy, and it employed an evaluation tool to monitor implementation of the

Figure 2

Primary Care Prescribing Criteria

1. Patient risk assessment. Clinicians should consider opioid therapy only if the expected benefits for both pain and function are anticipated to outweigh the risks to the patient. Clinicians should evaluate the risk factors for opioid-related harms. Screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids are recommended.
2. Obtain a patient/provider pain contract. This contract will include the patient and provider criteria for use, discontinuance, and disclosures regarding the addictive nature of the substance. Experts agree those are essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.
3. Obtain initial and random encounters drug screens. Experts agree that prior to starting opioids, and periodically during opioid therapy, clinicians should use urine drug testing to assess for the use of the prescribed opioids as well as other controlled substances. This includes illicit drugs that increase risk for overdose when combined with opioids, including non-prescribed opioids, benzodiazepines, and heroin.
4. Obtaining a CURES or patient drug monitoring report to assess opioid use patterns. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether or not the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
5. Discussing the expected duration of treatment and outcomes. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

Reproduced from Primary Care Prescribing Criteria Centers for Disease Control, 2016 CDC Guideline for prescribing opioids for chronic pain. *MMWR: United States*. Accessed 12/1/2016 <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

practice change. To determine the effectiveness of the program implemented at the practice site, I used the evaluation tool to assess for the continued application of the CDC guidelines in the primary care practice (See Figure 2 Prescribing Criteria). The findings revealed that this program assisted in curtailing prescribing rates by this approach to bridging the practice gap (CDC, 2016b). The CDC has issued 12 recommendations for safe opioid prescribing (CDC, 2016a).

The purpose of this scholarly project was to evaluate a quality improvement program and assess its potential to address the current practice gap of overprescribing in a primary care practice in central California. The aim of implementing this program was to address the growing problems of opioid abuse and dependence, along with related deaths and disorders affecting the practice and this primary care community (CDC, 2016a; HHS, 2016). As a quality improvement initiative, the current program was initiated to assist the organization in meeting the state mandates and applying the CDC recommendations for the safe prescribing of opioids (AIA, 2016; CDC, 2016a; Harris, 2015). Since July 1, 2016, all providers in the State of California have been required to enroll in the State Drug Monitoring Program (Harris, 2015). In addition, all providers are now required to obtain a Patient Drug Monitoring Report (CURES), prior to prescribing opioids (AIA, 2016).

The risk manager at the facility where this doctoral project took place has identified the need for a practice change due to an increase in the number of drug-seeking patients, increased opioid-related patient morbidity and mortality, as well as

organizational liability. There have been threats of litigation from the families of patients who received and became addicted to opioids.

Chart audits revealed a marked discrepancy between evidence-based CDC safe opioid prescribing recommendations and the current prescribing practices in this primary care setting (Cheatle et al., 2014; Lasser et al., 2014). The prescribing practices in the local primary care settings were consistent with the CDC findings, whereby primary care clinicians overprescribe opioids to manage pain, including chronic pain (CDC, 2016b; Cheatle et al., 2014; Chou, 2016). As in many similar primary care settings, few of the clinicians in the local clinic where this project took place adhere to the current CDC clinical guidelines or recommendations for safe opioid prescribing (CDC, 2016b). This was evidenced through peer review chart audits, which confirmed existence of a practice gap with poor patient outcomes (CDC, 2016a).

Nature of the Project

This project was the evaluation of an evidence-based systematic primary care quality improvement program. I developed it according to a problem-solving evaluation design as outlined by Grove, Burns, and Gray (2014). The particular problem of opioid overprescribing in primary care practice and the underuse of clinical guidelines resulted in a practice gap that was addressed by the program. According to Groves et al. (2014), “Evaluation projects are conducted with minimal application of the rigor and control required with research” (p. 82). This project involved comparing the appropriate indices, retrieved from the EHRs, before and after the use of the CDC (2016a) clinical prescribing recommendations. The postintervention indices were compared with the preintervention

indices to determine the effectiveness of the program in terms of measurable behavioral changes that influenced the provider prescribing rates. My goal in this project was to assess the program's ability to bridge the practice gap through measuring and comparing the prescribing rates.

Given that PCPs are the leading prescribers of opioids, they were the population targeted for participation in the program (CDC, 2016b). Moreover, as this facility is the second largest primary care practice in central California, the results of the evaluation project may hold significance for other health care providers. As a problem-solving project, the findings yielded by the program evaluation will be relevant to this specific health care agency. Essentially, the program was an attempt to address the prescription opioid problem with standardized evidence-based practice (Grove et al., 2014). The risk manager at this facility had identified overprescribing as an organizational problem and has sought to bring its PCPs in line with the new CDC standards of care. Whether this program could achieve the goal was in question.

PCPs are estimated to prescribe more than 50% of all opioid prescriptions nationally (CDC, 2016b). Consequently, they have the greatest influence over the sheer volume of prescriptions being written for the treatment of pain. Hence, interventions to address the problem of overprescribing needed to be inclusive of this stakeholder group. In fact, in 2012, health care providers issued 259 million opioid prescriptions (Paulozzi et al., 2014). Given this information, the necessity of effecting change in prescribing practices is evident (Liu, 2013). The purpose of this project was to evaluate a program

incorporating evidence-based change to alter the practice gap in opioid prescribing in this primary care practice setting.

The First Phase of Program: Methodology

The first phase of the program began with unfreezing the current prescribing patterns among the PCPs within the Family Medical Group (Lewin, 2008). Unfreezing was supported through peer review (see Appendix A), the evidence-based guidelines, policy change (see Appendix B), and identified prescribing rates. As a part of the program, the risk manager was included and presented deidentified case studies for providers to review and assess. The multidisciplinary process of unfreezing was evidence based and incorporated literature relevant to and supporting the need for change. Upon project approval, the quality improvement (QI) manager collected baseline indices for this period from the EHR. These indices related to opioid prescribing rates for PCPs preprogram. I extrapolated the EHR data retrospectively for the project purposes to evaluate the preprogram prescribing patterns and rates.

This phase included a PowerPoint presentation that addressed PCPs and stakeholders (see Appendix C). The presentation commenced with a summary of the old standards as introduced by NPC & Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (2001). The program identified the basis for the current prescribing practices as well as the reasons for the need to cease the current prescribing trends. According to the NPC & JCAHO (2001),

This has evolved into the present stage, with the introduction of pain management standards by JCAHO in 2000, an increased awareness of the right to pain relief,

the support of various organizations supporting the use of opioids in large doses, and finally, aggressive marketing by the pharmaceutical industry. (pg.1)

These positions were based on unsound science and blatant misinformation, and they were accompanied by the dangerous assumptions that opioids are highly effective and safe and devoid of adverse events when prescribed by physicians (CDC, 2016a; Manchikanti et al., 2012). This information provided the rationale and the foundation for the inception of the problem and the current provider dilemma it has created, thus confirming the need for change. Although providers may not have intended to initiate the addiction process, their reliance on the old protocol for opioid prescribing has contributed to this adverse effect (Chou, 2016; Chou et al., 2009).

To unfreeze current practices, the management deemed a punitive approach to this practice problem inappropriate. This perspective aligned with the findings of analyses pertaining to the influence of medical standards on this practice issue (NPC & JCAHO, 2001). To ensure greater stakeholder support for these proposed changes, full disclosure of the inception of the problem was required for a better transition into provider acceptance of the new recommendations (Joshi, 2014). Thus, the Just Culture Model promoted by the American Nurses Association (2010) was applied to move from a punitive approach to one that focuses on change. According to the American Nurses Association (2010), as the Just Culture Model provides a better approach to problem solving, it should be used as an alternative to a punitive system. The Just Culture Model seeks to create an environment that encourages individuals to report mistakes and is widely used in the aviation industry (Understand Just Culture, 2016). The aim is to better

understand the precursors to errors to eliminate the system issues (Understand Just Culture, 2016). Adoption of this model encourages a two-way dialog and feedback to promote behavioral changes (Understand Just Culture, 2016).

During this phase, a forum for dialogue allowed clinicians to discuss their attitudes regarding prescribing opioids without fear of reprisal (Joshi, 2014; Understand Just Culture, 2016). In addition, in the unfreezing phase, open provider dialogue allows barriers to be identified. According to Manchikanti et al. (2012), “The obstacles that must be surmounted are primarily inappropriate prescribing patterns, which are largely based on a lack of knowledge, perceived safety, and inaccurate belief of under-treatment of pain” (p. ES10). This saved time during the implementation phase, as there were fewer unidentified or unresolved barriers to impede the change implementation (Joshi, 2014).

The anticipated legal barriers for providers were addressed during this phase. The real potential for litigation had been identified as a barrier to changing provider’s current opioid prescribing practices (Hoffmann & Tarzian, 2003). This dialogue was especially relevant, as providers have been successfully sued based on previous standards of care (Hoffmann & Tarzian, 2003). Providers who were accustomed to issuing prescriptions for controlled substances for commonly occurring noncancer pain may have resisted the mandate to make the practice adjustments due to fear of potential litigation (Hoffmann & Tarzian, 2003). The new precedent for litigation was presented based upon a recent case, whereby a physician was tried and convicted of second-degree murder for overprescribing (Gerber et al., 2015). The new practice standards have been upheld by the legal system with this conviction (Gerber et al., 2015).

The Second Phase Program: Data Collection

The second phase of change, as described by Lewin, involved the adoption and application of evidence-based clinical guidelines in primary care (Lewin, 1947, 1951, 2008; McEwen & Wills, 2014). To determine whether the change occurred, an assessment was required. The evaluation of the clinical guidelines use included a peer review and policy implementation (see Appendix B). I evaluated five provider charts monthly using a tool to assess provider policy adherence. The QI manager was responsible for assigning the EHRs for the monthly peer reviews. To obtain the necessary support from the stakeholders, it was important to engage them during all stages of care management program development. Peer review was an effective tool for monitoring the adoption and continuance of the practice change (AAFP, 2016; Chan, 2014). According to the AHRQ, the target population involvement in the rudimentary phases of change is essential for successful program design, as it helps ensure long-term support for the program. During the implemented change process, seeking feedback from the PCPs was necessary. Peer review served as a vehicle to provide that feedback without fear of reprisal or litigation (AAFP, 2016). It was important to include strategies that encouraged the involvement of stakeholders to establish collaborative relationships and promote an ongoing two-way dialog (Joshi, 2014).

I evaluated the overprescribing rates upon practical application of the clinical guidelines. The assessment included the extent to which prescribers used risk stratification, pain contracts, random drug testing, patient drug monitoring reports, and other recommended strategies prior to issuing prescriptions. This initiative also included

assessing the number of opioid prescriptions for alterations (CDC, 2016a). When providers consider factors other than self-reporting of pain, they are more responsible in their prescribing practices in primary care setting (CDC, 2016a). According to the U.S. surgeon general, self-reporting as the primary criterion for pain treatment excludes some crucial factors that may result in addiction, such as multiple prescribers, abuse, misuse, and diversion (Time Inc., 2016). According to the program, opioid prescribing rates decreased once these factors were considered.

The Third Phase Program: Analysis

The third phase of refreezing, as described by Lewin (1947, 1951, 2008), involved ongoing peer evaluation of the program implementation to operationalize the new prescribing practice. The aim was to deter providers from returning to old prescribing patterns. The peer review approach has been identified as an appropriate learning and evaluation tool in the clinical setting (Chan et al., 2014). According to American Academy of Family Practice (AAFP, 2016), an effective peer review is an essential part of improving the quality of health care delivery (see Appendix A). Peer review, when performed effectively, leads to improvements in the quality and safety of patient care, while also enhancing clinical performance (Chan et al., 2014). Peer review was used because it provided the QI Manager with the data that could be analyzed to assess the degree to which the program was being successfully implemented (AAFP, 2016). It also provided the medical director with the information required to direct the providers in the quality improvement practice change (AAFP, 2016).

Significance

This project holds significance to nursing staff as well as all primary providers by providing insights and guidance in clinical decision making. Nurses, as a part of the opioid overprescribing problem, take on a leadership role in providing evaluation of a quality improvement program targeted at the problem of overprescribing in primary care practice (ACCN, 2016; CDC, 2016a, 2016b). It remained to be determined if the program that used the CDC clinical guidelines can curtail overprescribing when applied in a systematic approach. The direct and positive correlation between death rates and the opioid prescribing practices in primary care has negatively affected society (Birnbaum et al., 2011). It remains to be determined if the trajectory may be altered with the implementation of this program.

Summary

The opioid epidemic was created by a faulty standard of practice initiated by a National Certifying Agency (Manchikanti et al., 2012; NPC & JCAHO, 2001). This epidemic is currently provider driven (CDC, 2015c, 2016b). This practice has resulted in a 200% increase in opioid-related deaths (CDC, 2015b, 2016b, 2016d). I sought to evaluate a program that was directed toward curtailing the practice problem through introduction of and adherence to evidence-based clinical guidelines. This program, referred to by Joshi (2014) as a high-impact intervention program, is aimed to address a prevalent health problem. The aim of the current project was to evaluate an implemented systematic approach to change opioid prescribing practices based on Lewin's change

model, which allowed operationalizing the program in three phases (Lewin, 1951, 2008).

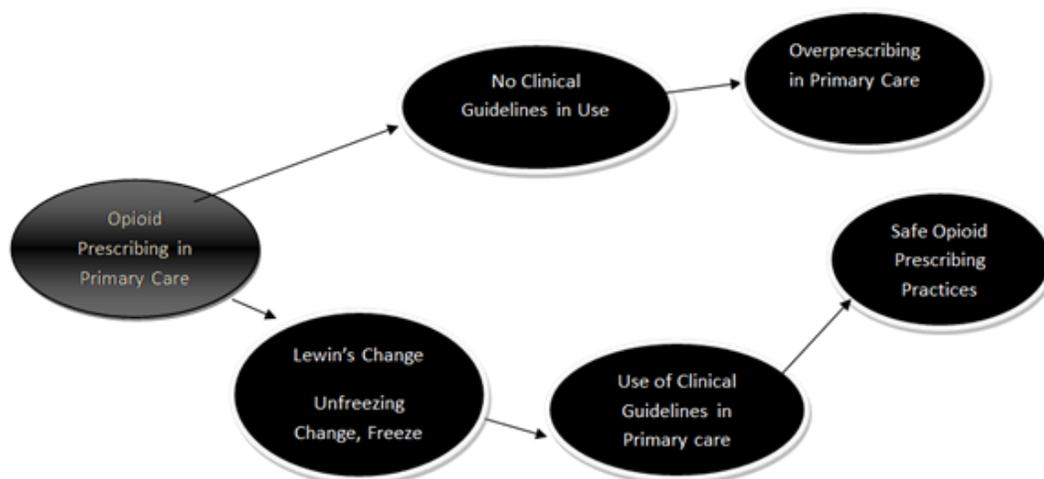
This systematic program was directed towards facilitating an organizational practice delivery change to improve patient outcomes (AACN, 2006).

Section 2: Background and Context

Introduction

The problem of opioid overprescribing has resulted in an increase in addiction, misuse, dependence, and deaths (CDC, 2016; HHS, 2016). The CDC has developed clinical guidelines to address this health problem and curtail opioid prescribing (CDC, 2016a). This practice problem provided the opportunity for nursing staff to take on a leadership role in developing a systematic program and determine its effectiveness in addressing the current opioid epidemic (AACN, 2006; CDC, 2016b). A review of pertinent literature has revealed a practice gap, in that few providers use current clinical guidelines when prescribing these medications (Cheatle et al., 2014; Lasser et al., 2015). As a part of this scholarly project, I evaluated a program that incorporated the new evidence-based CDC clinical guidelines in terms of its ability to address this practice gap (CDC, 2016a). In the next section, I will provide an overview of the program's conceptual model that was previously operationalized in the phases, in addition to delineating its relevance to nursing practice, the local background, and context, before summarizing the discussion. The section will close with the description of my role in the program evaluation.

Figure 3
Conceptual Model of the effects of Clinical Guidelines in Safe Prescribing Practices



My aim in the project was to evaluate an evidence-based program implemented at a primary care site to curtail overprescribing. An additional objective was to determine the effectiveness of the use of clinical guidelines in addressing the problem of overprescribing in primary care (Le Flore, 2016). Through situational relating, I was able to establish the association of the relationships between the concepts of overprescribing and application of the CDC clinical guidelines. The change model developed by Lewin has served as the specific vehicle of change. Its phases included unfreezing, change, and refreezing (Lewin, 1947, 1951, 2008; McEwen & Wills, 2014). I used this model to operationalize the project and define its three phases, including methodology, data collection, and analysis, respectively. The first phase involved providing the foundation for the practice change. The primary changes were effected in the second phase through the application of clinical guidelines. The third phase was designated to continuous provider assessment to ensure that they did not return to the previous prescribing

practices. I communicated the information pertinent to each of these phases to the practitioners through a PowerPoint presentation (see Appendix C).

Relevance to Nursing Practice

The overprescribing problem exists in nursing practice, and in particular among advanced practice nurses who furnish controlled substances. The opioid overprescribing practice problem is not solely a physician concern. In a study conducted by Chen, Humphreys, Shah, and Lembke (2016), the authors wrote:

The researchers examined Medicare prescription drug claims data from 2013 for 808,020 individual prescribers, including physicians, nurse practitioners, physician assistants, and dentists. From an analysis of total claims, it was determined that in 2013, most opioids were prescribed by healthcare providers in family practice (15.3 million prescriptions) and internal medicine (12.8 million), followed by nurse practitioners (4.1 million) and physician assistants (3.1 million). (p. 260)

The authors further noted, “Efforts to curtail national opioid overprescribing must address a broad swath of prescribers to be effective” (Humphreys et al., 2016, p. 259). The onus of the opioid crises belongs to more than one select group of practitioners.

Given that a significant number of nurse practitioners are writing opioid prescriptions, they are compounding this problem. Consequently, they should also be involved in any remedial initiatives (Chen et al., 2016). This practice problem presented me with an opportunity to take on a leadership role by evaluating the implementation of practice changes necessary to curtail overprescribing within health care organizations

(AACN, 2006). Currently, several organizations, including the American College of Physicians and the World Health Organization, have developed guidelines for prescribing opioids for the treatment of pain (Chou, 2009; McMullen, 2011). Those guidelines were attempts to curtail prescribing as well. However, this program was identified because it used the CDC (2016a) guidelines which have its focus on PCPs.

Local Background and Context

A review of the scholarly evidence reveals the existence of a significant opioid prescribing problem in the United States, as well as delineates some adverse consequences for patient health and safety (CDC, 2014, 2015a, 2016a, 2016b, 2016c; HHS, 2016; Manchikanti et al., 2012). Opioid abuse is such a serious public health concern that it is deemed a national epidemic by the CDC (2016b) and HHS (2016). In 2015, the CDC launched the Prescription Drug Overdose: Prevention for States Program, as a part of which \$20 million was provided to all US states to support strategies aimed at improving prescribing practices. This effort was designed as a means of preventing prescription opioid-related deaths (White House Statements and Releases, 2016).

From 1999 to 2014, it was estimated that more than 165,000 deaths in the United States were associated with opioid use (CDC, 2016d). Drug overdose deaths are the leading cause of injury death in the United States (CDC, 2016b; HHS, 2016; Manchikanti et al., 2012). According to HHS (2016), “President Obama released his first National Drug Control Strategy, which emphasized the need for action to address opioid use disorders and overdose, while ensuring that individuals with pain receive safe, effective treatment” (as cited in Pratt, 2016, p. 1). The current statistics show that opioid overdose

results in 44 deaths daily (CDC, 2016b). In 2016, the National Institute on Drug Abuse (NIDA) also reported, “The current epidemic of prescription opioid abuse has led to increased use of heroin, which presents similar dangers” (as cited in Pratt, 2016, p. 1). HHS (2016) estimates indicate that 450 individuals transition from prescribed opioids to heroin daily. Such high prevalence of opioid-related disorders is causing fracturing of homes, communities, and societies, resulting in billions of dollars lost in productivity (Birnbaum et al., 2011). In 2014, more than 10,500 individuals died from heroin overdose (HHS, 2016).

Since 1999, the amount of opioid prescription drugs prescribed and sold in the United States has nearly quadrupled (Manchikanti et al., 2012). According to Agarin, Trescot, Agarin, Lesanics, and Decastro (2015), “The Federation of State Medical Boards undertook the development of model guidelines aimed at encouraging state medical boards, its licensees, and other health care regulatory agencies to adopt policies promoting adequate treatment of patients using opioids when appropriate” (p. E307). This policy resulted in increased availability of opioids. Yet, empirical evidence suggests that the amount of pain that Americans report has not changed (CDC, 2016a; HHS, 2016). This discrepancy between opioid use and perceived effectiveness is an indication that clinicians are overprescribing.

Overprescribing results in more opioids available for abuse and consequently more deaths due to overdose (Agarin et al., 2015). According to CDC (2016b), “Health care providers wrote 259 million prescriptions for opioid pain medications in, 2012. That is enough for every American adult to have a vial of pills” (p. 1). Statistics indicate that,

as the availability and use of opioids analgesics increased, so did the number of fatalities (Agarin et al., 2015; CDC, 2011). This finding indicates that far too many opioids are available for public consumption (Agarin et al., 2015). Hence, prevention of opioid-related health disorders and addiction can prove the most appropriate strategy for effecting change (CDC, 2016a).

The CDC responded to this epidemic with Opioid Prescribing Recommendations (CDC, 2016b). These guidelines were developed using the GRADE systematic review of the best evidence available. The GRADE (Grading of Recommendations Assessment, Development, and Evaluation) system was informed by the recommendations from leading experts in the pain management field (CDC, 2016a). Implementing the new CDC guidelines has the potential to mitigate the growing prevalence of overprescribing, thus avoiding the potential for abuse, dependence, disorders, addiction, and overdose.

Role of the DNP Student

The role of the doctorally prepared nurse student in this project pertained to evaluating this quality improvement program for primary care practice. For this project, the DNP student was assigned to evaluate a practice-focused program that had a specific practice application-oriented goal (AACN, 2006). As an evolving expert in the science practice application, the DNP student selected and evaluated measures of appropriate indices for this quality improvement program. It was determined that the program implemented for the improvement of patient care delivery and patient outcomes met its practical objectives. The DNP student sought to provide leadership for the staff members working in other disciplines in the evaluation of a systematic approach to address this

professional challenge (AACN, 2006). This included collaborating with experts and practitioners in other disciplines to bring about appropriate conclusion (AACN, 2006). It also involved directing staff members working in other disciplines to assist in the evaluation process and incorporate their expertise. This type of leadership acknowledged the value in other disciplines in terms of perspective, expertise, and skills these individuals contributed to the problem solving process (Joshi, 2014).

This project required data collection and analysis from the EHR, which was conducted in collaboration with the Quality Improvement Manager (AHRQ, 2014). The DNP student provided the QI Manager with the appropriate health IT methodology to collect the data necessary to accurately measure opioid prescribing rates. This data was needed to retrospectively evaluate the baseline prescribing rates prior to the program implementation, as well as the prescribing rates recorded after the program was implemented. The data was analyzed to determine the effectiveness of the program in curtaining prescribing rates.

The data was retrieved from the medication registry within the EHR. This database allows for the retrieval of the number of opioids being prescribed at any given date or within a date range. This approach ensured greater accuracy in evaluating the prescribing rates (Joshi, 2014). The value of this program evaluation project relates to the ability to replicate the program should it be determined effective (Grove et al., 2014). In addition, this program could serve as a blueprint to effect organizational change within multiple primary care practices.

Summary

This project sought to evaluate a program implemented to curtail the iatrogenic opioid overprescribing practices in primary care via the medication registry of the EHR. The program was based on Lewin's conceptual model to operationalize the change in three phases. The CDC (2016a) clinical guidelines provided the structure for the program. The aim was to determine whether this evidence-based project has achieved the set objective of curtailing prescribing rates. This was measured by evaluating the EHR data to determine whether any changes to prescribing were noted following program implementation.

Section 3: Collection and Analysis of Evidence

Introduction

It remains to be determined if adherence to the CDC (2016) evidence-based guidelines can curtail opioid overprescribing in primary care. The standard of care that allowed clinicians to prescribe opioids based on subjective reports of pain has resulted in poor patient outcomes (CDC, 2016; HHS, 2016; Time Inc., 2016). Since the initiation of this standard set by the NPC & JCAHO in 2001, a 200% increase in opioid-related deaths has been recorded (CDC, 2015b, 2015d; HHS, 2016; Manchikanti et al., 2012; Time Inc., 2016). PCPs are the leading prescribers of opioids for chronic pain, yet few PCPs follow standard practice guidelines regarding assessment and monitoring (Cheatle et al., 2014; Lasser et al., 2015). The effectiveness of adhering to CDC 2016 Clinical Guidelines for Opioid Prescribing in curtailing the current prescribing rates among PCPs has not been assessed to date (CDC, 2016; Lowe, 2016). It also remained to be ascertained if application of these guidelines would improve patient outcomes in terms of dependence, addiction, abuse, and deaths (CDC, 2016). The development and use of a program to improve patient outcome by curtailing opioid prescribing in primary care was needed.

An advantage of implementing this program at the selected primary care practice stemmed from the staff's collaborative approach and willingness to counter the practice problem through implementation of evidence-based solutions. In this collaborative interaction, each party's concerns and perspectives were valued and addressed, and different perspectives were coalesced or overcome (Thomas, 1976). In addition, the

collaborative was favorable toward having an advanced practice nurse take on a leadership role in the planning and implementation of systematic changes in health care for better patient outcomes (AACN, 2006). Although the value of the other disciplines cannot be underestimated, the overall objective of this project was to assert nursing leadership to improve patient and societal health. It served to further provide evidence of the essential role of nursing staff in health care quality improvement (Joshi, 2014).

The chief executive officer, medical director, risk manager, and quality improvement manager endorsed support for the implementation of an evidence-based and recently partially legislated opioid curtailment program (AIA, 2016). The interdisciplinary collaboration was a prudent strategy for positive outcomes in health care (Joshi, 2014; World Health Organization, 1999). By addressing the practice problem through evidence-based guidelines, providers and all stakeholders improved patient safety and health care delivery (Vega & Bernard, 2015). The initiative put the patient at the center of the health care team's focus and allowed all health professionals, with the patient, to collaboratively provide input, be part of the decision making, and improve outcomes (Vega & Bernard, 2015). Again, the interdisciplinary collaboration assisted with the logistics of the program as well as enhancing organizational performance (Institute of Medicine, 2015). In the remaining sections of this project, I will provide an overview of the opioid overprescribing epidemic, the multidisciplinary program for countering the problem, and a system to evaluate the effectiveness of the program. I will detail the collection and analysis of the evidence in the next segment.

Practice-Focused Questions

The previous opioid prescribing standard has resulted in an increase in opioid-related disorders and fatalities (Agarin et al., 2015; CDC, 2015b, 2015d, 2016a; HHS, 2016; Manchikanti et al., 2012). Efforts to increase opioid use and a campaign touting the alleged under-treatment of pain continue to be significant factors in the escalation of this nation-wide problem (Agarin et al., 2015, NPC, 2001). I sought to determine if the application of the CDC Clinical Guidelines for Opioid Prescribing (CDC, 2016) would curtail primary care provider prescribing rates. These clinical guidelines aimed to specifically address the overprescribing practices by providers, which have resulted in the current epidemic in the health care setting. Although it remained to be determined whether the implementation of the guidelines would be effective in curtailing opioid prescribing, it was clear that the old prescribing patterns were too harmful to continue (Aragrin et al., 2015; CDC, 2011, 2016b).

According to the AIA (2016),

California has taken an important step in preventing prescription drug and opioid abuse by passing SB 482 into law. The CURES database will be critical to helping doctors prescribe medication responsibly and appropriately given each patient's medical history. We applaud the legislature and Governor Brown for ensuring patient and public safety by passing this life saving measure. (p. 1).

This mandated component of the CDC guidelines provided impetus for clinicians to adhere to and give consideration to the recommendations.

The purpose of this scholarly project was to evaluate a program developed and implemented to alter the current practice gap of overprescribing in a primary care practice in central California. This intervention was implemented in the form of a systematic quality improvement program using multidisciplinary approach to curtail overprescribing. The terms *physician, clinician,* *nurse practitioner,* and *physician assistant* are used interchangeably in the following discussions, as they all relate to PCPs.

Definitions

The key terms for this project include overprescribing, primary care provider/clinician, patient, curtail, and opioids. For the purposes of the project, overprescribing refers to “the unnecessary use of drugs (to prescribe excessive or unnecessary medication that is not beneficial for patients)” (Rambhade, Chakarborty, Shrivastava, Patil, & Rambhade, 2012, p. 68). The term “*primary care provider*” refers to “clinicians involved in the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community” (Rambhade et al., 2012, p. 68). The term “clinician” or “provider” refers to “an individual who uses a recognized scientific knowledge base and has the authority to direct the delivery of personal health services to patients” (Rambhade et al., 2012, p. 68). The term “patient” refers to “an individual who interacts with a clinician either because of illness or for health promotion and disease prevention” (Rambhade et al., 2012, p. 68). The term “opioid” pertains to “any morphine-like synthetic narcotic that produces the same effects as drugs derived from the opium poppy

(opiates), such as pain relief, sedation, constipation and respiratory depression” (Gale Encyclopedia of Medicine, 2016, p.1). Finally, “curtail” is defined as “to make less by or as if by cutting off or away some part” (Merriam-Webster, 2016, p.1).

Exclusions

Patients with a cancer diagnosis or terminal illness were not included in either the data collection for the program or the project. Patients in hospice care were also excluded from the data collection, as were patients receiving opioids from providers (pain management) outside of the primary care practice.

Inclusions

Patients receiving opioid agonists were included in the data collection for the project and the program. All providers in the primary care clinic—i.e., primary care physicians, nurse practitioners, physician’s assistants, internal medicine physicians, and doctors of osteopathic medicine—were included in both the program and the project.

Sources of Evidence

To evaluate the effectiveness of this program, specific practice-related data were collected. The participants for the data collection for this project were the Quality Improvement Manager because of her role within the organization (AHRQ, 2014). The QI Manager is expert in data retrieval and collection (AHRQ, 2014). Data is the cornerstone of Quality Improvement, as according to HRSA (2016), “It is used to describe how well current systems are working; what happens when changes are applied and to document successful performance” (p.1).

Protections

This project proposal was approved by the Walden Internal Review Board (IRB) and the IRB approval number for this study is 02-06-17-0588593. According to Grove et al. (2014), the participants in the project were protected according to the ethical principle of beneficence. In addition, no provider names were associated with the statistical data collected. The providers were protected from harm, as overall group prescribing rates were obtained and no individual PCPs were associated with the data. This project was conducted as an organizational quality improvement project. All data was provided by the organization's Quality Improvement Manager at the direction of the doctoral student.

Procedures

The QI Manager took on the task of data collection from the EHR under the direction of the DNP student. The Quality Improvement Manager's first task was to extrapolate data regarding the total number of opioid prescriptions being written prior to the intervention program. The de-identified data was extrapolated retrospectively from the medication prescriptions registry within the EHRs. The EHR has the ability to capture data related to the number of opioid prescriptions being written within the primary care practice at any given time. This data allowed the researcher to arrive at the exact number of patients receiving opioids at any given point prior to and following program implementation. This first measurement served as the baseline data set for the DNP project.

The primary care practice staff, comprising of family practice physicians, internal medicine physicians, physician's assistants, and family practice nurse practitioners, had their prescribing rates evaluated retrospectively. The rate represented prescribing rates

prior to the intervention of the program and 5 months prior to the release of the CDC (2016a) guidelines. After this number was obtained, an additional measurement of the numbers of patients being prescribed opioids 5 months after the introduction of the program was obtained. The difference in these two rates determined the effectiveness of the program.

Opioids are natural or synthetic chemicals that bind to receptors in brain or body (HHS, 2016). Common opioids include heroin and prescription drugs, such as oxycodone, hydrocodone, and fentanyl (HHS, 2016). The list of opioids for data collection included hydrocodone, oxycodone, hydromorphone, and fentanyl, as well as other schedule II opioid agonists in the EHR. The prescribing rates for opioid agonists were captured when the data was retrieved for both instances.

Analysis and Synthesis

The retrospective point in time data technique served as the data collection method for comparison purposes. The first set of data was collected on May 1, 2015, five months prior to the initiation CDC clinical guidelines. The second set of data was collected on December 19, 2016, five months after the program was introduced. The comparison of the two data sets allowed the effectiveness of the intervention to be measured (Grove, et al, 2013).

Additionally, for continuous quality improvement, the QI Manager was advised by the Risk Manager to obtain the prescribing rates monthly to provide continuous monitoring of opioid prescribing rates for the practice following the project completion.

These rates served to determine the effects of the project over time and to identify and address changes in prescribing patterns.

Assessment of Program Implementation

To assess provider use of the guidelines within the program, the QI Manager assisted in peer review. This assessment was associated with the program and was not a part of the evaluation project. Each month, the QI Manager was to select five EHRs encounters per provider for peer review. This represented a sampling of the provider EHRs and included those for patients which are currently being prescribed opioids. Providers had their information de-identified so as to preserve provider confidentiality. Providers were assessed for the prescribing criteria contained within the peer review template (See Figure 4). The scores reflected the degree of compliance with the criteria, whereby the score of 5 denoted full compliance, and 0 indicated non-compliance. The findings were distributed to providers confidentially for quality improvement purposes, while allowing each individual to discuss the results with the Quality Improvement Team.

Figure 4 PEER CHART REVIEW

Today's Date:						
Provider Review:		Audited Charts' #				
		Date	Date	Date	Date	Date
Please Review these Progress Notes on the date of:		Chart #	Chart #	Chart #	Chart #	Chart #
Description	Questions					
Risk Assessment Provider has indicated He/She has assessed the patient for Risk Behaviors or Conditions	1 History of Substance Abuse					
	2 History of Mental Illness					
	3 History of Diversion					
	4 History of Overdose					
Pain Contract	5 There is a pain contract accompanying					
Drug Screen	6 Documented drug screen on chart.					
Discussed Length of Therapy and Goals	7 Length of therapy and goals are documented.					
Cures Report	8 Results of cures report documented					

Reproduced from Primary Care Prescribing Criteria Centers for Disease Control, 2016 CDC Guideline for prescribing opioids for chronic pain. MMWR: United States. Accessed 12/1/2016
<http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

The quality improvement team consisted of the Medical Director, the Quality Improvement Manager, a Nurse Practitioner, and Risk Management. The team reviewed the monthly prescribing rates along with the peer review findings. They examined the results and discussed the findings. Providers who were non-compliant had the

opportunity to present their barriers to compliance without fear of reprisal. They were advised and coached to remove incentives to engage in negative behaviors (Understand Just Culture, 2013). This approach was consistent with the Just Culture Model for behavioral changes (Understand Just Culture, 2013). However, egregious errors in opioid prescribing safety needed to be addressed by the team. These errors, having been considered a conscious disregard to safety, have been determined to be reckless. This behavior may result in punitive deterrents if determined appropriate by the organization (Understand Just Culture, 2013). The collaborative effort of this team was expected to alter these undesired behaviors. This quality improvement program resulted in increased accountability for the providers making choices related to opioid prescribing practices.

Purpose of Data Collection and Analysis

The data obtained through peer review was analyzed to assess provider use of the guidelines. The findings yielded indicated the extent to which the gap in practice was bridged. To determine whether the guidelines are being implemented in the primary care practice, there needed to be support to confirm their use. Peer review helped identify the gap in practice, whereby providers are not adhering to the CDC primary care practice guidelines (Cheatle et al., 2015; Lasser et al., 2014). Further, there needs to be ongoing assessment to determine if the change is sustained or if providers have returned to old prescribing standards. Ongoing assessment will be needed to ensure that the organization continues to adhere to the process after the project ends (Joshi, 2014). The peer review portion of the program is primarily a tool for the QI manager to determine whether specific providers are adhering to the program policies and expectations.

However, the data collected from the medication registry pertained to the actual prescribing rates. This data relates to the project objective, which was to determine whether the use of the guidelines is affecting prescribing rates. Providers were expected to adhere to the CDC guidelines to alter the current system, which has led to poor outcomes (CDC, 2016a). This approach was directed toward addressing guideline adherence and prescribing rates. The goal of the program was to determine whether prescribing rates can be curtailed by the use of the guidelines. In order for this to be accurately evaluated, as a part of the assessment of prescribing rates, it was essential to determine whether the guidelines are being applied. In other words, the aim was to align what was believed to be happening from the actual practices (HRSA, 2016).

Summary

The data collected for the evaluation project allowed the previous and current opioid prescribing rates to be evaluated and compared. For this purpose, the prescribing rates were sourced from the practice's EHR medication registry. The data related to opioid agonists was captured in order to determine prescribing rates prior to and following program implementation. This source of information provided measures related to the purpose of this project, which was to determine if the implementation of the program, which uses the CDC clinical guidelines, would curtail prescribing rates in a primary care setting. The retrospective data collection prior to and following program implementation provided the evidence to determine the program's effectiveness. It necessitated the collection of data from the EHR opioid medication registry, which was deemed the most appropriate method for meeting the purpose of the evaluation project (Joshi, 2014).

The data collected for the primary care provider peer review reflected provider compliance with the program. It allowed evaluation of provider adherence to key components of the CDC (2016a) Clinical Guidelines for Opioid Prescribing. This initiative helped to determine if prescribing behaviors have changed and whether the change is being consistently maintained. This data was gathered for quality improvement purposes and not for the purposes of the project.

This program has been implemented in two primary care locations. One of the clinics is located in central California (practicum location) and the other in South Los Angeles (work location). The practicum clinic consists of 10 PCPs averaging 2,300 patient visits per month, and the South Los Angeles Clinic Consists of 12 PCPs averaging 2,800 visits per month. The practicum location was used for the project's retrospective data collection related to the prescribing rates recorded in the EHR medication registry.

Section 4: Findings and Recommendation

Introduction

The problem of overprescribing in primary care practice has resulted in poor patient outcomes, including dependence, abuse, misuse, and death (CDC, 2016a; HHS, 2016). The problem is iatrogenic and needed to be addressed through practice changes (CDC, 2016b). The current gap in practice results from an old faulty standard of practice that did not adhere to the evidence-based CDC (2016a) guidelines. I sought to evaluate a program developed to systematically address this gap by applying these guidelines in primary care. The objective was to determine whether this program could curtail opioid overprescribing practices in a primary care setting.

Exclusions

Patients with a cancer diagnosis or terminal illness were not included in the data collection for the program or the project. Patients in hospice care were also excluded from the data collection, as were patients who were receiving opioids from providers outside of the primary care practice.

Inclusions

All primary care clinicians were included in the program and the project. For these purposes, primary care physicians, nurse practitioners, internal medicine physicians, and doctors of osteopathic medicine were included in the data collection. All noncancer, nonpalliative care patients receiving Schedule II opioid agonists from a primary care provider within the practicum site were included in the measurements.

Methods and Findings for the Project

I collected the data required for the project retrospectively and was sourced from the EHR medication registry. I accessed the medication registry to provide point in time data indicating the number of patients actively being prescribed opioid agonists. This included hydrocodone/norco, oxycodone/percocet, hydromorphone, oxymorphone, and Fentanyl. I collected the first set of data on May 1, 2015, 5 months prior to the release of the CDC (2016) clinical guidelines. I collected the second set of data on December 19, 2016, 5 months after the program was introduced (See Table 1).

Table 1

Active Totals for Premeasurement Dates and Postmeasurement

05-15-2015	1103
12-19-2016	646

Findings and Implications for the Project

As mentioned previously, I collected two sets of point in time data for the project and compared the sets to assess the program's effectiveness. I collected the first set of data on May 1, 2015, 5 months prior to the introduction of the CDC clinical guidelines, and obtained the second set of data on December 19, 2016, 5 months after initiating the curtailment program. The retrospective data collected pertained to all patients who were actively prescribed opioids at the primary care practice on those dates. Using a *t test* to

examine differences between the two datasets, results revealed a 49.24% statistically significant difference ($p < .01$) between the prescribing rates prior to and following program completion, confirming its effectiveness.

DNP Project Data

Upon comparing the two measurements, a significant and a much greater than anticipated decrease (from 1,068 patients to 646) in the number of patients receiving opioids was noted. Owing to this dramatic decrease in the number of patients receiving opioids, the quality improvement and risk managers retrieved records for additional dates to verify the trend. The trends for prescribing rates are listed below.

Table 2

Trend for Opioid Prescribing Rate

Dates	Patients Receiving Opioids
07-12-2015	1068
08-23-2016	821
09-29-2016	738
10-11-2016	722
11-15-2016	594
12-19-2016	646

Recommendations for the Project

After reviewing and analyzing the data for the project that the project team recommended that providers be surveyed to determine the greatest influence in curtailing prescribing rates. Providers should be allowed to share which parts of the program were beneficial and which parts of the program were least helpful in guiding their clinical decision making (Understanding Just Culture, 2013). In addition, we advised that the QI manager continue to retrieve the data from the medication registry monthly to monitor providers' prescribing rates as a means of identifying changes (if any) in prescribing trends (Heath Resources & Services Administration (HRSA), 2016). This will allow QI and risk management to identify the most effective portions of the program and to respond to problems early on before they present major challenges for the organization.

Findings and Implications for the Program

The data for the program was collected through peer review. Five charts per provider were audited for the five criteria in the peer review template. One point was awarded for each of the five criteria or elements present within the chart. Thus, a provider could score a maximum of 25 points.

After a score was obtained for each provider, the information was confidentially disseminated. The providers subsequently met with the program coordinator to discuss the findings in a group setting, ask questions regarding the results, and discuss any concerns related to the program. In the initial peer review, the findings were discussed in a group setting with the understanding that future peer reviews will involve the QI Manager, Risk Manager, and the Medical Director.

The findings indicated that the highest points among all providers were received for having pain contracts, PDMP or CURES reports, and risk assessments in that order. The pain contract was by far the most consistent item found in the EHRs of patients receiving opioids. The lowest scores were associated with discussing the length of therapy, the goals of therapy, and drug screens in that order. Providers in general did not discuss the goals of pain management or the expected length of treatment with their patients. This finding was not surprising, as according to Chou (2016) clinicians as a rule do not continue most medications (with the exception of opioids) that are not proving to be effective in addressing a problem.

Recommendations for the Program

In addition to project data, program data was also collected through peer review in the form of chart audits. The charts selected for the peer review belonged to patients who were currently receiving an opioid agonist. The initial peer review was conducted four months after the initiation of the program. This initiative was a part of the quality improvement assessment. The de-identified findings of the peer review were discussed with the staff.

Upon reviewing the findings of the program, it was recommended that the QI Manager continue peer review quarterly. This will ensure that providers improve on their compliance in this area and do not return to the old standard of practice (Joshi, 2014). Performing this exercise going forward will serve as a reminder to continue adherence to the evidence-based guidelines. The refreezing portion of the program will require continual evaluation. Additionally, ongoing monitoring will serve as continuous quality

improvement for the organization (Joshi, 2014). It is further recommended that providers document the criteria in consistent locations within the chart. This quality improvement recommendation will facilitate the retrieval of the required information for the reviewer.

It is further recommended that the project be replicated in other primary care settings (Joshi, 2014). It has been established that the primary care program can curtail prescribing rates in the primary care setting. Therefore, the benefits of replicating this program include potentially decreasing the negative outcomes for additional primary care patients while providing evidence-based guidelines for clinical decision making in other practices. The purpose benefit of quality improvement programs can be translated to other similar settings (Joshi, 2014).

Strengths and Limitations

The strength of this project rests within its ability to assess and validate a program with the potential to curtail in prescribing patterns in primary care. This project, which evaluates a quality improvement program, was developed according to a problem solving evaluation design as outlined in Grove et al (2013). The data collected for the evaluation project served to evaluate pre and post intervention opioid prescribing rates as well as validate the effectiveness of the program. It identified differences pre and post intervention prescribing rates through EHRs medication registry. The sources of this data were deemed most appropriate for the purposes of the evaluation project (Joshi, 2014). It evaluated the program's ability to produce a positive result in terms of curtailing prescribing rates.

The rigor and stringent controls were not in place for the evaluation of the effectiveness of the treatment or intervention in this project (Grove, et al, 2013). The project involved conducting an evaluation of a program to apply a new standard of care to address a serious health care issue (Grove, et al, 2013). It was conducted in a usual real world clinical primary care environment to evaluate an intervention.

Strengths and Limitations of the Program

The program data reflects provider compliance with the program only in part. It assessed for provider adherence to key components of the CDC (2016) clinical guidelines for opioid prescribing. It has helped to determine that provider prescribing behaviors have changed however many components of the program were not totally adhered to. The findings indicated that the components of the peer review are not being consistently maintained even though prescribing rates declined. This data was for program quality improvement purposes and not for the purposes of the project.

The process was tedious as many of the providers were not consistent in their placement of the pertinent data within the EHR. This process has helped the organization to realize that they need better consistency in documenting and document placement within the EHR. This was an incidental quality improvement finding to be discussed with the stakeholders and providers in the final PowerPoint presentation (Joshi, 2014).

Summary

The results of this project indicated that the program is worth the investments in implementation. Although there are additional costs in terms of provider responsibilities and administrative time, it may be well worth the investment. Considering the current

mortality and morbidity rates, societal costs and lack of provider confidence in prescribing the program has definite value (Birnbaum et al., 2011; CDC, 2016a, 2016b). Ultimately, because the program has the ability to reduce patient and organizational risks associated with opioid overprescribing and opioid disorders the program holds definite value. The evidence of its significance is apparent in the lowered prescribing rates among the target population of PCPs (CDC, 2016a).

Section 5: Dissemination Plan

Organization Dissemination

To disseminate the project findings to the target organization, I presented a final PowerPoint presentation (Joshi, 2014). The primary care staff, the risk manager, quality improvement manager and all stakeholders viewed the PowerPoint presentation. The presentation included the program findings and the project findings. This vehicle was an efficient method of disseminating the information while providing a forum to allow for questions and feedback (Bartsch & Cobern, 2003). This method also seemed appropriate considering these meetings were regularly scheduled for quality improvement purposes.

The program policy and the program peer review guidelines will remain at the facility with risk management and quality improvement to continue the program goals.

Nursing Dissemination

I will utilize a variety of methods to disseminate the project findings. I will send the final project to AANP to determine interest in the subject matter. I contact other nursing journals, as well as Medscape, to ascertain whether or not topic is of interest to their subscribers. I will solicit interest in presenting for the Family Nurse Practitioner Students at the University of California at Los Angeles. I am a clinical instructor for the university and an associate instructor allowing for the opportunity lecture on the topic of opioid use in primary care. I believe the project content will be valuable in providing clinical direction for new providers.

Some of the most effective methods of dissemination in terms of turning the tide of opioid prescribing are through educational programs. That method would provide an evidence-based foundation for current prescribing standards and their implementation. Other methods include presentations at conferences for PCPs, primary care practice updates, and university pharmacology courses as well as online presentations. The aforementioned vehicles for dissemination could serve as efficient methods to disseminate the information to advanced practice nurses as well as the primary care community in general.

Analysis of Self

Throughout the program and project, my focus was on the ability of the program to curtail primary care provider opioid prescribing rates. I found myself so focused on the prescribing rates that I lost sight of the patients at times. In many instances, the medication was inappropriately prescribed. However there are times when opioid medications are needed and this perspective should be factored into prospective future programs. I have to be cognizant of the need for variations in clinical decision making when warranted. It is my desire to continue to take on a leadership role in addressing this provider and societal problem through evidence-based practice. To achieve this goal, I will need to remain adaptable as well as focused and intentional.

Summary

In this project, I evaluated an evidence-based quality improvement program to curtail overprescribing in primary care practice. The program incorporated the new CDC (2016a) clinical guidelines developed expressly for PCPs. After measuring prescribing rates prior to the introductions of the guidelines and postprogram interventions, it was determined that the program was able to curtail overprescribing in primary care practice with a 49.24% change. As a result of these findings, it is the organization's expectation that this program will be replicated in additional primary care practice offices within this organization.

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Appendix A: Peer Review Guidelines

American Association of Family Practice Peer Review Guidelines

For the purposes of this program, the terms Clinician, physician and provider will be used interchangeably due to the participation of Mid-Level Providers (Nurse Practitioners and Physician Assistants). According to the American Association of Family Practice (AAFP, 2014) guidelines, in order for a meaningful peer review to take place, adherence to the following criteria is essential:

1. The primary goal of peer review should reflect enhancing the quality of patient care. Nonetheless, peer review will increasingly address issues of value-driven care. Physicians/Providers should initiate and lead these conversations.
2. Clinical policies for patient care should be established by practicing physicians/providers based upon the best patient-oriented evidence available, balanced with sensitivity to local needs and expectations (See figure 5).
3. Physician departure from clinical policies (e.g., clinical guidelines) should not be interpreted as a prior breach of good medical practice. Patient preference, availability of services, and assessment of individual risks vs. benefits may substantially influence management. Physicians/Providers should have access to the full rationale of peer decisions and opportunity for rebuttal if a negative conclusion is reached.
4. Peer review should include assessment of the quality of care rendered. It should be performed by a physician/provider holding qualifications similar to those of

the physician/provider being reviewed to ensure objectivity and comprehensiveness of assessment.

5. Criteria for care (e.g., hospital admission, transfer, or alternative care site delivery) should reflect severity of illness, social factors, caregiver burden, access to services, and the particular circumstances of each patient.
6. Utilization review provided by a physician/provider should be considered the most valid determinant of the correct diagnostic category. Physician/Provider peers should determine the appropriateness of care, while recognizing and assessing the complexity of factors influencing decision-making.
7. The peer review should be aimed at the improvement of patient care through physician/provider education and health system enhancements. Those performing the peer review should seek to identify potential systematic improvements that the organization could implement to reduce the potential mistakes or adverse events in the future.
8. Due to the need to safeguard public interest, peer review by medical staff, medical societies, medical groups, health plans, and other entities should be confidential, protected, and not subject to disclosure or discovery. Nonetheless, the evidence and clinical decision-making criteria used in developing peer review decisions should be transparent and open to scrutiny. Those subject to peer review should be given the opportunity to provide further information and rebuttal to the peer review outcomes.

Appendix B: Opioid Prescribing Policy

Title: Safe Opioid Prescribing in Primary Care	
Section: Medications	Number:
Effective Date: October 2016	Reviewed Dates: September 2016 Revised Dates:
Manager Signature	Board Approval:

1.0 Purpose:

To address the issue of pain treatment in primary care practice. Considering the increased incidence of opioid related deaths, abuse, disorders, and diversion (CDC, 2016) all schedule 2 drugs will require that steps be followed to insure safe opioid/controlled substance prescribing.

2.0 Policy:

This policy will provide guidelines for prescribing schedule 2 drugs at UMMA Clinic. Opioids are not to be prescribed as the first-line treatment for chronic pain. Patients determined to be opioid dependent, addicted or with opioid disorder should be appropriately referred for behavioral health and/or addiction counseling services.

2.1 This policy will provide guidelines for prescribing schedule 2 drugs at UMMA Clinic. Opioids are not to be prescribed as the first-line treatment for chronic pain.

3.0 Supportive Data:**4.0 Equipment and Forms:**

4.1 Pain Contract (see attached exhibit)

5.0 Procedure:

5.1. A full pain inventory will be obtained on the initial visit. Patient will be assessed for risk factors for drug abuse. These risk factor include, history of abuse, history of overdose, history of diversion, and consideration of mental illnesses.

5.2. A CURES report should be obtained on all patients before prescribing opioids for the treatment of pain (Reports may be scanned or downloaded to the patient chart).

5.3. A pain contract will be signed and agreed to by the patient receiving opioid treatment.

5.4. An initial urine drug screen is to be obtained prior to initiating opioid treatment and periodic drug screens should be obtain to evaluated for multi-substance use or diversion.

5.5. The length of treatment, the goals of treatment, and the addictive nature of the medication is to be disclosed to the patient prior to initiating treatment.

5.6. All patients requiring opioids beyond a 3-month period, or the normal period for expected healing should strongly be considered for referral to pain management.

5.7. The simultaneous prescription of benzodiazepines and opioids should be avoided.

6.0 Documentation:

7.0 References and Resources:

7.1 Centers for Disease Control, (2016). *CDC Guidelines for prescribing opioids for chronic pain*. MMWR: United States. Retrieved from <http://www.cdc.gov/mmwr/volumes/65rr/rr6501e1.htm>

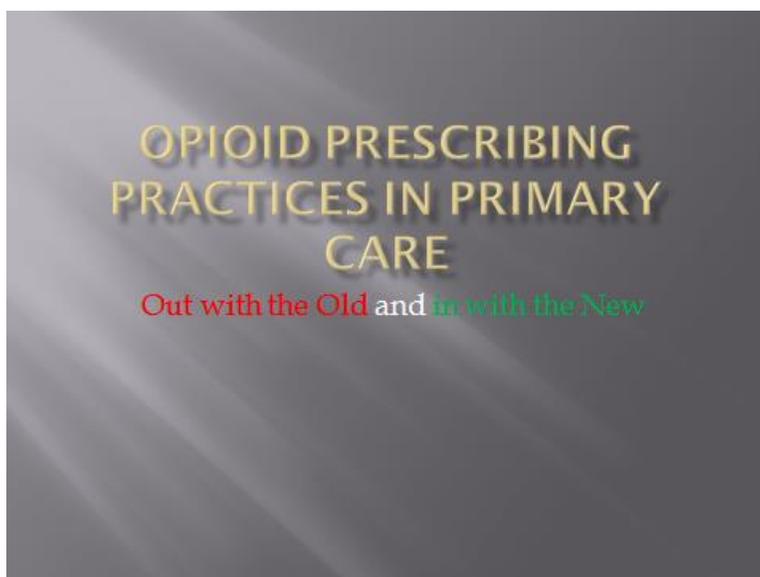
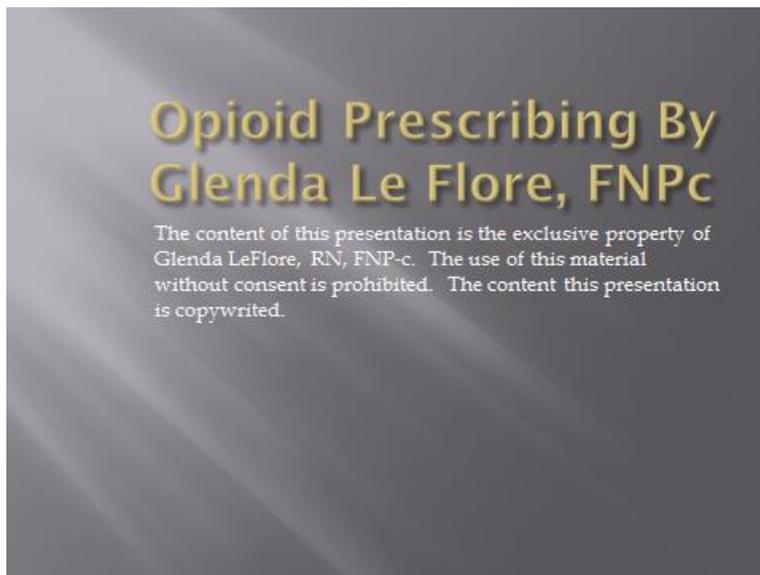
7.2 CURES (Controlled Substance Utilization Review and Evaluation System) website: <https://oag.ca.gov/cures>

7.3 Medical Board of California Prescriber Guidelines for Substances for Pain, (2016). Comparison of Prescribing Guidelines.

Created by: Glenda Le Flore, RN, MSN, PHN, FNP-c

Appendix C: PowerPoint Presentation

PowerPoint Presentation



Mission Statement

"My mission is to affect change in the current harmful opioid prescribing practices in primary care: by moving from existing standards of prescribing practices and implementing the new Centers for Disease Control Guidelines. I will partner with stakeholders to initiate safer prescribing for a healthier nation one practice at a time".

Objectives

- ▣ 1. Provide a Historical Perspective of the Depth and Breath of the Practice Problem
- ▣ 2. Provide a Rationale for the Practice Change in Primary Care Opioid Prescribing Practices
- ▣ 3. Discuss the Old and New Prescribing Standards of Care and Legal Implications
- ▣ 4. Provide the New Opioid Prescribing Recommendations/Guidelines
- ▣ 5. Identify 5 Essentials for Safe Prescribing

The Old Standard

- In 2000, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) introduced new pain management standards aimed at upholding patients' right to effective assessment and treatment of pain from admission to discharge.

The Principle of The Old

Whatever the cause or the duration of pain, however, the same principle applies: A patient's self-report is the most reliable indicator of the intensity of his pain.

Because pain is subjective and patients undergoing the same procedure can experience markedly different levels of discomfort, it's crucial to believe and respond quickly to a patient who tells you he's in pain.

This standard was set by JACHO and The National Pharmaceutical Counsel

Patient's Report of Pain Was Enough to Prescribe Opioids

According to NPC & JCAHO (2001), the primary reason for 9 of 10 clinic visits is pain related. Additionally, if pain was not managed properly it could result in severe medical complications and delay recovery from surgical procedures or injuries. Further, if pain is undertreated the patient might have difficulty performing activities of daily living and as a result this could affect their quality of life (National Pharmaceutical Counsel, 2001).

Liability

- ❑ In 1999 the Oregon Medical Board disciplined a physician for the under-treatment of pain for several of his patients.
- ❑ Less than 2 years later a California Physician was successfully sued for under-treatment of pain
- ❑ These cases marked a change in the way pain was viewed in the United states
- ❑ Prior to this time opioids were deemed too addictive for general use. They were reserved for cancer patients and for palliative care

What's Behind the Rise in Non-Terminally Prescribed Drugs? There's More to The Story

Pandora's Box Opens

The use of medications once reserved for patients diagnosed with cancer, or some other terminal illness became the treatment for the most commonly occurring health problems.

Norco is commonly prescribed for musculoskeletal pain or injuries, headaches, myalgia and chronic back pain.

The Result

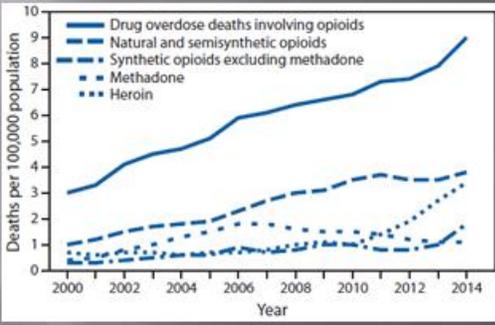
According to the Centers for Disease Control and Prevention (CDC), the United States is experiencing an increased epidemic of drug and opioid overdose deaths.

Since 2000, this number has a 200% increase in deaths involving opioids. More commonly known as painkillers, opioids caused more deaths in 2014 than car accidents (61%).

In his 2016 State of the Union address, President Obama stated that "more Americans now die every year from drug overdoses than they do from motor vehicle crashes ...

•The majority of those overdoses involve legal prescription drugs. In 2012, there were 259 million prescriptions provided by clinicians. A number large enough for every American adult to have a bottle of pills.

•Even though prescription painkiller sales increased since 1999, there has not been an overall change in the amount of pain Americans reports.



Source: National Vital Statistics System, Mortality file

Who is the target Population to Affect Change

Primary care providers are responsible for 50% of all of the opioid prescriptions written (CDC, 2015)

The Practice Gap

Primary care providers (PCPs) are the leading prescribers of opioids for chronic pain. Few PCPs follow standard practice guidelines regarding assessment and monitoring" (Lasser, et al, 2015).

According to Cheadle (2014), a review of the literature indicates there is currently a gap between the evidence and what actually takes place in primary care practice.

The New Standard

- ▣ **Recommendations**
- ▣ The recommendations are grouped into three areas for consideration:
 - Determining when to initiate or continue opioids for chronic pain.
 - Opioid selection, dosage, duration, follow-up, and discontinuation.
 - Assessing risk and addressing harms of opioid use.

The application of The New Clinical Guidelines

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.

CDC developed and published the CDC Guidelines for Prescribing Opioids for

Chronic Pain to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

The Grade System

- Such guidelines are traditionally the result of consensus conferences or expert panels and represent attempts to synthesize – from the best available evidence and expertise – practical guidance on the best possible care. Beyond issuing a guideline, many organizations have felt the need to provide a grading of each guideline's quality, thereby conveying to the reader a sense of the confidence that might be placed in it. This article addresses only the grading of guidelines, not their use or development.

Clinical Guidelines

1
Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate

2
Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety

3

Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy

4

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids

5

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day

6

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed

7
Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids

8
Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present

9

Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months

10

When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs

11

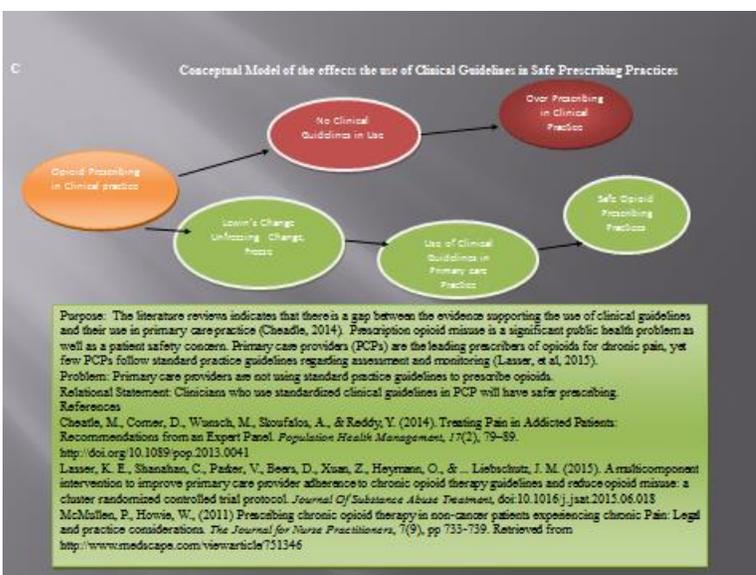
Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible

12

Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder

Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings.



Highlighted Recommendations

- ▣ 1. Risk Stratification
- ▣ 2. Cures Report
- ▣ 3. Drug Screen (Initial and Random)
- ▣ 4. Pain Contract
- ▣ 5. Discuss Addictive Nature of Medication, duration of treatment, goals and discontinuance.

New Rule

- ▣ Federal regulators will issue a final rule to increase from 100 to 275 the number of patients that physicians who prescribe buprenorphine can treat. But some say the number should be far higher.
- ▣ DHHS proposes to eliminate potential financial incentives for doctors to prescribe opioids out of fear that patients will give them low marks in patient experience surveys if they experience a lot of untreated pain after procedures.

Provider Prescribing Criteria

- ❑ 1. Risk Assessment: Is this patient appropriate to receive opioids
- ❑ 2. Pain Management Contract
- ❑ 3. Initial and Random Drug Screen
- ❑ 4. Run a Cures (PDMP) Report before Prescribing
- ❑ 5. Discuss length of treatment (5-7 days) beyond 3 months must be followed by pain management. Discuss addictive nature of the treatment.

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Opioid Prescribing Policy

- ▣ Effective Immediately all providers will be expected to follow the CDC recommended guidelines for safe opioid prescribing:
- ▣ 1. Run a CURES report before prescribing opioids
- ▣ 2. Obtain a pain contract
- ▣ 3. Obtain an initial and random drug screen
- ▣ 4. Perform a risk assessment benefits vs risks
- ▣ 5. Discuss length of treatment (3-7 days) and discuss the addictive nature of the substance.
- ▣ 6. Refer all patient using opioids beyond a 3 months to pain management.