Adjuvant Therapy as First-Line Treatment for Chronic Pain: Not Opioids

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There is historical evidence that points to early examples of substance abuse, dating back to as early as the 17th century. The medical community has always struggled with the exploration of drugs that appear to be beneficial to humans, but, because of their euphoric results, have caused addictions, abuse, and even fatalities. One such example is the case of opioids. Opioids are substances that act on opioid receptors in the body, (found especially in the central and peripheral nervous systems and the gastrointestinal tract), producing morphine-like effects.

In healthcare, opioids are primarily used for pain management and anesthesia (Hemmings & Talmage, 2013). In the last few decades, they have become the first-line option for both chronic and acute pain, resulting in overprescribing and, consequently, an overdependence on them. Evidence now shows that there is a direct correlation between the overprescribing of opioids for all sorts of pain, and the opioid epidemic that faces America, (according to statistics from 2017). An estimated 4 million Americans used opioids either as a recreational drug or were dependent on them (United Nations Office on Drugs and Crime [UNODC], 2015). According to Dowell, Haegerich & Chou (2016), prevalence of opioid use and abuse in the US is at an estimated 11.2% of the population. This opioid problem, however, is not just impacting Americans. Globally, an estimated 40 million people, between the ages of 15 and 65 years of age, had used opioids illegally (0.9%) in 2013.

Since the gold standard for pain management continues to be opioids, it is prescribed to as much as 4 % of the US population as long-term therapy (Dowel et al., 2016). While many studies document the overuse and abuse, research should also be done with a broader focus, examining the impact of long-term opioid prescribing practices. According to Ashanti, Tan,

Shanti (2012), clinical pain-control practice relies, almost exclusively, on opioids as the primary analgesics for the management of moderate to severe pain. However, adjuvant analgesics for pain management is becoming increasingly necessary. Adjuvant analgesia such as NSAIDS, muscle relaxers, and physical therapy have been used successfully in pain management, treating chronic pain from diseases like rheumatoid arthritis, fibromyalgia, and other diseases. Therefore, the implementation of adjuvant therapies, in healthcare, can help offset the opioid epidemic.

Background

In the US, opioid abuse has become a serious social issue and is now at epidemic proportions. One of the main contributing factors to the opioid crisis is the overprescribing of opioids by professionals with prescriptive privileges (i.e., physicians, nurse practitioners, and others). The increased prescription of opioids as first-line treatment for all kinds of pain has created an overdependence on the drugs. In 2013, nearly two million Americans abused or were dependent on prescription opioid pain medication (Dowell et al., 2016). In a statement from the Whitehouse Office of National Drug Control Policy, President Trump stated that the opioid epidemic cost the country $78.5 billion in 2013, and two years later, the cost was $504 billion. At this time, abuse of both legal and illegal drugs, often leading to deaths from overdose, is among the primary health concerns in America.

Significance

Between the 1999 to 2014, 160,000 Americans died due to overdosing on opioid pain medications. This DNP project is significant because it not only recognizes the problem but presents a practical solution that will reduce dependency on opioids patients suffering from chronic pain, and it will reduce the effects of long-term opioid therapy.

The traditional management protocol for pain has changed over the years, and many alternative treatments are proving effective. Adjuvant therapies such as chiropractic treatment, yoga, massage therapy, cognitive therapy, exercise, and the use of non-opioids such as Tylenol, and nonsteroidal anti-inflammatory drugs (NSAIDS) are being used successfully.

Problem Statement

Increases in prescriptions of opioid medications for chronic pain have been accompanied by increases in opioid abuse, overdoses, other harms and uncertainty about long-term effectiveness. According to the National Institute on Drug Abuse ([NIDA], 2017), there were 12.5 million Americans who misused prescribed opioids in 2015, alone. Many patients have developed an overdependence on opioids after long-term use. It is possible that prescribing alternatives will reduce the dependency on opioids (Turner et al., 2015). Adjuvant therapies, have been used successfully as first-line treatments of pain. It is being proposed that if a standardized adjuvant therapy protocol is developed to treat patients suffering from chronic pain, there will be a decrease in new cases of opioid-dependent patients. The host site for this project, contains an ideal population for such an implementation. Most of the patients there suffer from chronic pain and are all being treated with opioids as first-line treatment, receiving no recommendation for alternatives, such as yoga, exercise, swimming, and chiropractic care.

Project Question

In patients suffering from low to mild chronic pain, do adjuvant therapies, when compared to current pain management practices, decrease overprescribing of opioids?

Purpose Statement

The purpose of this DNP project is to implement a new pain management guideline for medical staff, the *Adjuvant Therapy Protocol (ATP*). This protocol has been developed for use in

clinics and health centers as first-line treatment for adults with mild to moderate chronic pain. The aim of the ATP is to reduce the risk of overprescribing opioids for chronic pain by clinical staff, which will potentially result in a reduction of addictive incidents and the overall prevalence of opioid dependency, as well as, the effects of long-term opioid therapy.

Project Objectives

The following are the objectives of the Adjuvant Therapy Protocol (ATP).

1. Create a pain management protocol intervention for mild to moderate pain using Tylenol, nonsteroidal anti-inflammatory drugs (NSAIDS) (i.e., ibuprofen), and adjuvant therapy (such as exercise) as the first-line treatments.
2. Implement this ATP for patients with mild to moderate chronic pain, using the adjuvant therapies as the first-line treatment, rather than opioids, the original standard therapy. (This quality intervention pilot project will last for six months.)
3. Evaluate changes in pain management practices through chart audits

Search Methods

The Databases CINAHL, PubMed, Medline, Science Direct, Touro University's Jay Sexter Library, and governmental websites, including the Food and Drug Administration, the US Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Guideline Clearinghouse, were searched. The following key words were used: opioids, opioid therapy, opioid addiction and abuse, opioid dependency, adjuvant therapy, chronic pain treatment, and first line treatment for chronic pain. The search yielded 20 articles that were directly related to the topic; of those 20 articles, 15 were selected, and then further narrowed down to 10 articles. An inclusion criterion was the search of peer-reviewed articles that dealt explicitly with the topic under study, which is a proposal for adjuvant therapies as first-

line treatment for low to medium chronic pain, instead of opioids in health centers. Exclusion criteria were articles that were not peer-reviewed, did not address the issue of the overprescribing of opioids for various types of pain management, and articles that were not related to adjuvant therapy as first-line treatment for pain management. Articles relating to pain management for cancer were also excluded.

Literature Review

The purpose of this literature review is to broaden the foundation of support for the use of adjuvant therapy as first-line treatment for chronic pain. The objective is to establish a theoretical foundation that demonstrates the need for the intervention, its significance and relevance to patient care, pain management, and the nursing profession.

The articles reviewed have a recurring theme that the use of opioid narcotics is at the epidemic stage and something must be done. Opioids belong to a class of drugs that include: the illegal drug- heroin, synthetic opioids such as fentanyl, and pain relievers available by prescription, such as oxycodone (OxyContin), hydrocodone (Vicodin), codeine, and morphine (NIDA, 2017; White, 2017). In healthcare, unfortunately, for years, there was resistance to the idea of adjuvant therapies as treatment. With the current attention to the opioid epidemic, however, adjuvant therapies have been looked at with renewed interest as first-line pain management (National Institute on Drug Abuse [NIDA], 2017). Adjuvant therapies include medications that are not the typical treatment protocol for pain management, but have been effective in many cases, and are used as alternatives to opioids (White, 2017). Adjuvant pain medications often include: muscle relaxants, sedatives, antidepressants, anti-seizure medications, and other forms of therapy as well, such as yoga, exercise, and mindfulness. Many physicians in

perioperative care as well as chronic pain caregivers, are turning towards the use of nonopioid analgesic drugs.

Dowell et al. (2016) suggests that if the benefits do not outweigh the harms of continued opioid therapy, then clinicians should optimize other therapies and work with patients to taper opioids, lowering dosages, or to taper and promptly discontinue opioids**.** These guidelines suggest that the use of opioids should only be for necessity, and the shorter the duration, the less potential for overdose and addiction (Dowell et al., 2016). Furthermore, **c**linicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy checking for chronic pain or dose escalation (Dowell et al., 2016). Clinicians should evaluate benefits and harms of continued therapy with patients every three months or even more frequently.

Impact of the problem. The opioid dependency has reached crisis proportions. According to the American Society of Addiction Medicine ([ASAM], 2016), opioid addiction is driving accidental deaths from drug overdose in the US. There were over 20,000 deaths directly related to prescription pain relievers. In 2015, lethal drug overdose led to more than 52,000 deaths (Ueberall, 2015; ASAM, 2016).

Addressing the problem with current evidence. The risk of opioid use outweighs the rewards. Potential side effects of opioids include overdose, depression, and addiction, plus the terrible withdrawal symptoms when opioid use is stopped. Due to these high risks, it is believed that opioids should not be considered first-line or routine therapy for chronic pain (Dowell, et al., 2017; CDC, 2016).

The CDC (2016) resolves that long-term opioid use must begin with treatment of acute pain. Under such conditions, clinicians should prescribe the lowest effective dose of immediate-

release opioids and should prescribe no greater quantity than that 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 (Recommendation category: A; evidence type: 4) (CDC, 2016).

Nonpharmacologic therapy. According to the CDC (2017), nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should opt for opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient (CDC, 2017). If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (CDC, 2017).

Prior to initiating opioid therapy for chronic pain, clinicians ought to collaborate with patients to establish goals of treatment, one of which should include the discontinuing of opioid therapy if it becomes clear that the benefits will 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 (CDC, 2017).

Opioids therapy. Methadone and buprenorphine have been used often as part of opioid therapy (CDC, 2017). According to the CDC (2017), prior to starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and establish patient and clinician responsibilities for managing therapy. In these situations where opioids are prescribed, the CDC recommends that patients receive the lowest effective dosage, and opioids be combined with nonopioid treatments, such as physical therapy (CDC, 2017).

Methadone. Methadone treatment reduces and/or eliminates the need for illegal opiates and provides patients with an opportunity for better health outcomes. The main benefits of

methadone maintenance are relief of narcotic craving, blocking of the euphoric effects associated with opiates, and a reduction of withdrawal symptoms (CDC, 21017). Methadone maintenance has been found to be medically safe and non-sedating. However, methadone toxicity has been shown to be associated with specific phenotypes of CYP2B6, (an enzyme in humans that metabolizes substances such as nicotine), therefore caution is advised (CDC, 2017)

Buprenorphine. Buprenorphine sublingual preparations have been widely utilized to manage dependence on substances such as heroin, oxycodone, morphine, and other opioids (CDC, 2017). This was approved by the Federal Drug Administration (FDA) nearly two decades ago (CDC, 2017). Some formulations of buprenorphine include the opiate antagonist naloxone to discourage users from crushing the tablets and injecting them, instead of using the sublingual (under the tongue) route of administration (CDC, 2017). Medications such as buprenorphine, when utilized in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid dependency. There is evidence to substantiate the efficacy and safety of Buprenorphine when taken as prescribed (Substance Abuse and Mental Health Services Administration [SAMHSA], 2018).

Synthesis of Evidence

Most of the literature retrieved were qualitative, systematic reviews, cohort studies, and randomized control trials (RCTs). The topic lends itself to implementing a quality improvement protocol, and so it is important to perform a needs assessment. In a qualitative systemic review, George, Menon, Gupta, and Tan, (2013) noted that the use of opioids in chronic non-cancer pain (CNCP) is controversial, as it presents both benefits and risks. On the other hand, there is currently no available data on the incidence, prescription pattern, functional outcomes and adverse effects of opioids in patients with

Out of the 1,389 new patients who visited the center, 42 (3.0%) with CNCP received strong opioids for more than three months a year. The most commonly prescribed opioid was methadone (42.9%). The principal diagnosis for opioid prescription was spinal pain (38.1%). Ten patients had severe side effects. Fifteen patients saw improvement in activities of daily living scores.

Significance of Evidence to the Profession

Primary healthcare professionals such as physicians and nurse practitioners continue to find the management of chronic pain to be a challenge. The use of opioids has long been the go-to option to treat various types of chronic pain, from low to moderate. Over time, many patients become addicted to prescribed opioids (Tetrault & Butner, 2015). While the long-term effect of opioids for chronic pain is unknown, there is enough evidence to demonstrate that opioid-use is linked to drug addiction, opioid-use disorder, and overdose.

In the literature researched, there were 12 recommendations with nonopioid therapy as the preferred treatment for chronic pain. Nonetheless, if opioids must be used to treat chronic pain, the lowest dosage should suffice, along with assessment every three months, a reassessment in case where there is any increase in dosage to 50 morphine milligram equivalents or more, and a termination date. (category A recommendation) (CDC, 2016; Dowell, Haegerich, & Chou, 2016).

Overall, the literature provides strong evidence that opioids should be carefully scrutinized before prescribing them for long-term use. In addition, exploration of other forms of pain management protocols for chronic pain should be considered.

Theoretical Framework

Nursing relies on theoretical concepts developed within the discipline, as well as concepts from other disciplines which influence nursing practice (Moran, Brunson, & Conrad, 2017). A framework is an abstract, or logical structure, of meaning that gives support to study or research (Grove, Burns, Grey, 2013). In other words, the theoretical framework represents the ideas that support the phenomenon being researched.

Within a theoretical framework is all the ideas and concepts that are the underpinnings of the research project. Middle range theories are widely used in quantitative research because they describe concrete, practical evidence (Liehr, & Smith, 2014). There are a number of theories that can establish a framework for implementation of new protocols, such as the Lippit's *Change Theory.* The middle range theory that sets the theoretical framework for this research project, however, is the Donabedian Model, utilizing structure, process, and outcomes.

Tenets of the Donabedian Model

The Donabedian model has been used successfully to implement qualitative changes in various settings (Donabedian 1988). It was developed and published over 50 years ago by Avedis Donabedian (Ayanian, & Markel, 2016). While the Donabedian model is widely known for three standards, namely, structure, process, and outcomes, proposed to evaluate the quality of healthcare, Donabedian is also known for his later works. These included the seven pillars of healthcare: efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity, which are still influencing quality healthcare over 50 years later (Ayanian, & Markel, 2016).

Efficacy- The ability to improve care.

Effectiveness- The degree to which attainable health improvements are realized.

Efficiency- The ability to obtain great health at the lowest cost possible.

Optimality- This refers to a balance of cost and benefits.

Acceptability- Patient preferences regarding accessibility, as well as the relationship between the patient and the practitioner, the amenities, the effects of care, and the cost of care.

Legitimacy- Conformity to social preferences concerning all the previously mentioned pillars.

Equity- Equity is fairness or equality in the distribution of care and its effects on healthcare. Consequently, healthcare professionals must consider the preferences of patients, as well as social preferences, in assessing and assuring quality service and care.

According to Moran, Burson, & Conrad (2017), combining the Donabedian Model (staff -centered) with the theory of caring (patient-centered) will benefit both the patients and the practice site. Change is always a challenge as noted by Ash and Miller (2016). Even necessary change can be met with strong resistance; therefore, it is necessary to have a conceptual plan. The Donabedian Model fits this project implementation strategy, adequately. The premise of the model is that change is a process. Described below are: structure, process, and outcome, important steps in any quality improvement project (Donabedian, 1988; Lawson & Yazdany, 2012).

Structure

Structure refers to the setting where the project will be implemented, and who will be involved. Structure includes the physical facility, equipment, and human resources, as well as organizational characteristics, such as staff training and payment methods. These factors are important because they impact the service patients receive. Structure is often easy to observe and measure (Donabedian, 1988; Lawson & Yazdany, 2012).

Process

Process refers to what will be done, and how it will be done. It is the plan of action. Process includes diagnosis, treatment, preventive care, and patient education, but may be expanded to include actions taken by the patients or their families (Lawson & Yazdany, 2012). Process sometimes includes how care is delivered, or interpersonal processes. According to Donabedian, the measurement of process is nearly equivalent to the measurement of quality of care because process contains all acts of healthcare delivery (Lawson & Yazdany, 2012).

Outcome

Outcome describes what will be measured, reviewed or assessed at a site. Outcome notes all the effects of healthcare on patients or populations, including changes to health status, behavior, or knowledge, as well as patient satisfaction and health-related quality of life. Outcomes are sometimes seen as the most important indicators of quality because improving patient health status is the primary goal of healthcare. However, accurately measuring outcomes that can be attributed exclusively to healthcare is very difficult (Donabedian, 1988; Lawson & Yazdany, 2012).

Application of the Donabedian Model to Nursing Practice

Presently, it is presumed that the opioid epidemic is partly sustained by the overprescribing of opioids by healthcare professionals such as doctors, nurse practitioners, and other clinicians. To effectively reduce the dependency of patients with chronic pain, who are currently receiving opioids, there has to an examination of current practices, and a commitment to change. In the past two decades, there has been an increased focus on quality of healthcare and better patient outcomes. In addition, the nursing profession has been called upon to take

leadership roles in guiding policies and healthcare service due to the close relationships fostered with the patients.

As a result, nurses are taking on these leadership roles as administrators and are even opening their own practices, whereby they are in control of healthcare delivery. Conversely, with the new accessibility of information, patients have also become more demanding of quality service and better healthcare outcomes. This is where a theoretical framework such as the Donabedian Model can be utilized in the healthcare setting to improve the quality of service being delivered to the patients.

There are three areas that are important, and based on the Donabedian model, the goal is for all three (structure, process, and outcomes) to be working in unity (Ayanian, & Markel, 2016). The Donabedian model is often used in personnel development, where the staff is trained/taught by the project leader to introduce new first-line therapies for individuals who suffer from mild to moderate chronic pain (Ayanian, & Markel, 2016).

The purpose of this project is to implement this new pain management guideline (the *Adjuvant Therapy Protocol) (ATP*) to be used in clinics and health centers as first-line treatment for management of chronic pain. The aim of the ATP is to reduce the risks of overprescribing of opioids by clinical staff. This ATP will potentially result in a decrease in incidents and prevalence of opioid dependency, as well as reduce the effects of long-term opioid therapy.

Application of Donabedian Model to Healthcare Sites

The Donabedian model asserts that there is a casual relationship or correlation between structure, process, and outcome, the three essential standards in assessing quality healthcare. Thus, if there is quality in one area, for example structure, then the other two areas would assumedly be operating at a quality level. That is to say, if there are faults in one area, like the

process, which could include the service deliveries, then patient outcomes might not be satisfactory as well. According to Guerts et al. (2017), chronic pain is a major economic and social health problem. Over 80 percent of chronic pain patients are unhappy with their pain management. The staff meeting patients' expectations, then, is likely to produce greater satisfaction with care (Guerts et al. 2017).

Structure: This could refer to a hospital, an Emergency Room, a clinical, a private office, or even in the confines of a home. It also implies the product or service being offered and features of the system, including the service provider, and the patient (Ayanian, & Markel, 2016; Donabedian, 2005). Health clinics and private practices are usually small in size, and patients tend to have long waits. Determining how long patients are waiting by conducting a survey can impact structure and the process. Patients experiencing mild to moderate pain should not have long wait time.

Process: Process is two-fold and refers to the activities that occur between healthcare professionals, and then between the healthcare professionals and the patients. It is inclusive of both the technical and interpersonal aspects. Using this Donabedian model, and in particular the process standard, patients who are now receiving opioids as first-line therapy will have the opportunity to explore other first-line options because the personnel (medical staff) would be trained and equipped to deliver adjuvant therapies such as Chlorzoxazone (muscle relaxer) and provide or recommend other forms of therapy such as yoga, physical exercise such as swimming and walking, and chiropractic care (CDC, 2017).

Outcomes: Outcomes are the measures that are used to determine the end results, the quality improvement or the endpoint. Outcomes would be focused on the patients' success with

pain management services. The effectiveness of the adjuvant treatments or the discontinuing of opioids, if there no further need for them or if is no improvement.

Application of Donabedian Model to Project

In the following project, the goal is to reduce the overprescribing of opioid narcotics for chronic pain management and understanding the goal of providing adjuvant therapies and quality service, using the triad of structure, process, and outcomes to measure and guide. The host site is an outpatient clinic that treats patients mostly for mild to moderate chronic pain (mainly due to arthritis and lower back pain). Understanding the outcomes, at this site, is most apropos as it has implications of the balance of all three. The Donabedian model is often used when the goal is quality improvement.

In implementing the new protocol, a change in the process should impact outcomes of patients. Process is the aspect of the triad that will be used to implement this project. Using the Donabedian Model, and the standard of process, personnel will be trained to administer the new protocol. Project leader will train staff in the pre-implementation phase to utilize adjuvant pharmacological treatments (i.e., methadone) and non-pharmacological therapies such as pregabalin (Lyrica), chiropractic help, yoga, and physical exercise as first-line therapy for chronic pain. The treatment will be for 7 days initially, at which time patients will be asked to return for follow-up. Project leader will teach staff how to engage patients in the process through patient education. Staff will be taught how to guide patients in assessing their pain levels. For example, they will be asked to describe their pain as dull, sharp, piercing, so they are able to give a more precise description of their pain. The project leader will utilize the process standard through staff development, creating unique learning experiences for the staff using a Power Point presentation as well as brochures.

Establishing a process of staff development, guided by the Donabedian model, will provide the medical team with the opportunity to introduce this new protocol, as part of their efforts to improve the quality and impact of their healthcare services (structure) and patient outcomes. It is typical of the Donabedian model that change in one area often leads to change in another area, until all three (structure, process, outcomes) are working harmoniously.

The data will be collected by the project lead, and volunteer staff, and stored in a locked cabinet onsite. Only the project lead will have access during the duration of the implementation (Slyer, & Lewin, 2012). Under the Health Insurance and Portability Accountability Act (HIPAA), the researcher has a responsibility to protect the data collected (Centers for Medicare and Medicaid, 2018). All safety measures will be taken, such as using color codes, redacted names, and special identification, such as numbers, to refer to participants. (Agency for Healthcare Research Quality, 2018). All data collected during the implementation will be destroyed 6 months after the project has been implemented.

Project Design

This is a quality improvement (QI) project. According to Moran et al. (2017), DNP projects use a variety of approaches including quality improvement, or program and policy evaluations. The Donabedian model of influencing or adjusting structure, process and outcomes is the method that will be utilized in the implementation phase of the project (Ayanian & Markel, 2016). This design is suited because the project lead will not administer any treatment directly to the patients but will be teaching the new QI operation to the nursing and medical staff who will be administering the protocol to the patients at the practice site.

The project has the following phases: 1) identification of participants; 2) teaching and training of participants 3) the implementation of the new protocol by the participants, occurring

after the teaching, reinforcement, and demonstrations; 4) data collection and analysis; 5) evaluation; and 6) dissemination of the results to the stakeholders (practice site staff, board members).

Phase 1

In this phase, project leader will be at the practice site for introduction to the participants and to answer any questions before the training and education begins.

Phase 2

During this phase there will be an oral quiz to gauge the knowledge level of the staff on evidence-based guidelines for chronic pain management. Project leader will present the power point presentation to the participants in the project. There will be different learning materials in addition to the power point presentation. Participants will work in groups to demonstrate how to administer the protocol. After the presentation and training, project leader will give an oral quiz to assess whether staff had benefitted from the training session.

Phase 3

The practitioners will measure patient pain levels as part of their documentation. This will be accomplished through the Numeric Pain Scale and the PEG scale. (See Appendix A) Each day, the project leader will collect the data and enter it into an Excel spreadsheet.

Phase 4

At each session with the patient, the practitioner will administer the new protocol and will document their first-line treatment on the chart. Any opioid prescriptions made will be recorded in the EHR, to which the project leader has been given access. This is to determine the opioids prescribing rates. Each day, project leader will collect the data and enter it into Excel spreadsheet.

Population of Interest, Stakeholders and Setting

Population of Interest

The population of interest is the medical healthcare providers at the practice site. That number includes eight registered nurses (RNs), 17 nurse practitioners (NPs) and 15 medical doctors (MD) for a total of 40 participants in the project. The medical professionals were chosen for the project because they all utilize opioids as first-line treatment for pain management therapy at the clinic. These medical professionals all operate their own private practices at the site. The new protocol will be administered by the staff (participants) to their patients who are currently receiving opioids as first-line treatment for mild to moderate chronic pain. Another reason for selecting this population of interest is that they possess the power to take this innovation and to educate themselves, effectuating the protocol for this QI project.

Stakeholders

According to Harris, Croot, Harris, and Springett (2016), when conducting a project most of the engagement is during the selecting of the participants or disseminating the results. If stakeholders can be identified at the beginning of the project, they can add valuable expertise to project leader so that the design and other aspects of the study can perform optimally. Organizational changes, quality improvement projects, and systems changes can be challenging if the key stakeholders are not identified early so they can contribute their support to the study (Harris, et al., 2016).

One of the important aspects when deciding on a project or innovation is to identify and reach out to the key stakeholders (Moran et al., 2013). Stakeholders are those who have an interest in the project and the project outcome. The perspectives of the stakeholders are important because whether it is on the micro level or the macro level, they have unique

perspectives to add. According to Moran et al., (2013) when considering stakeholders, patients colleagues, and community leaders should be included. This is relevant, especially when it comes to community leaders.

The primary stakeholders for this project are the medical staff (physicians and nurse practitioners) at the practice site, the director, managers and administrators, board of directors, and the managers at the site, MDs, and the NPs. Other major stakeholders include the community board, community leaders, residents, and patients of the clinic. Even though the project lead will not be directly working with the patients but will be educating the medical staff on implementing the new protocol, it is important to have the stakeholders informed and onboard. Several educational opportunities will be available to ensure reinforcement of the protocol.

Sustainability will result from educating the stakeholders about the opioid epidemic, and the benefits to be gained from non-opioid therapy. There will also be less addictions, and less incidents of overdosing of patients. The stakeholders, and a member of the local community board. The reason for collaborating with the stakeholders is to get the input of those who have a vested interest in the advancement of the site and the services it provides to the community.

Even though the project leader will not be working directly with the patients, it is still important for the stakeholders to meet the project leader and be informed of the project plan of operation and end-goals. The community board is a strong supporter of the clinic, and they appreciate it being in their community because it reduces the number of persons doing drugs in the park and the housing complex. They also need to be aware of any new services that are being offered so their community residents can benefit.

Setting

The setting for this project is a not-for-profit (501c) community health clinic in New York City. The total number of staff at the practice site is 48, including medical, clerical and support staff. The clinic serves a low socio-economic community. The organization receives about 80 percent of its funding from the federal, state and city government. The remaining 20 percent of funding comes from endowments, voluntary contributions, and an annual fund-raising gala in November of each year. The clinic is run by an administrator and a board. The main service provided is chronic pain management. Ancillary services include health screenings, and mental health services.

The practice site is one of eight locations in the city. However, the protocol is only being implemented in one. This is the one where the practice site of the project leader. The site administrator was identified as one of the primary stakeholders at the beginning of the project, and when there was some reluctance on the part of some board members to fully support the project and be collaborative, the administrator utilized her influence to get them onboard. This project was approved by the practice site administrator and all medical staff at the site located in the Bronx are participants.

Variables. The project's independent variable is opioid prescriptions, and the dependent variables are the use and success of alternatives like pharmacotherapy (NSAIDS) and non-pharmacotherapy treatments (such as yoga and physical activity).

Recruitment Methods

Clinic Staff

Since this is a practice change initiative, or a quality improvement project, all practitioners responsible for prescribing medication (MDs/NPs) will be part of the protocol

training. The project leader will be at the site regularly to update staff and train them. The project is impacting all staff at the site, as this is an organizational change innovation that has been approved by the site's administrator. The inclusion criteria are all the healthcare practitioners at the site who provide pain management treatment and patient care. Exclusion criteria are all non-healthcare practitioners, such as clerical and administrative staff not providing patient care. According to Moran, et al. (2017), the project can be an organizational change or systems change (Moran et al., 2017). Change in one area usually impacts another area.

Recruitment of participants is an important part of any project. Depending on the nature of the study, it might be difficult to recruit participants. Wise et al. (2016), noted that not having sufficient time to recruit participants can create delays in the implementation of the study (Wise et al, 2016). Employing different recruitment methods such as advertisements, social media, and clinical settings are some ways of identifying participants, especially in the cases where diseases are being studied (Wise et al., 2016).

For this project, participants will be recruited face to face by the project site's director. The new protocol will be an organizational change, approved by the director, and all medical practitioners have been approved by the director to participate in the project. The direct participants are the staff who will be trained to administer the adjuvant therapy protocol, and no more than minimal risk can be expected to the participants. The main objective of this project is to evaluate changes in pain management protocol through chart audits.

Tools/Instruments

According to Bastos, Duquia, González-Chica, Mesa, and Bonamigo (2014), the selection of instruments that will be used to collect data is a crucial step in the research process. Validity and reliability of the collected data and their potential comparability with data from

previous investigations must be prioritized during this phase (Bastos et al., 2014). Subsequently, tools selected are valid and reliable tools that are widely used in data collection and analysis. According to Leung (2015), validity refers to the extent to which a tool measures what it is designed to measure. If the appropriate tool is not used, the validity of the study could be in question. Reliability refers to the consistency of the tool, regardless of who is utilizing it or where it is being used (Leung, 2015). Both concepts assure that results are stable and replicable.

The tools that will be utilized for this QI project are the Numeric Pain Scale (NPS), Pain Enjoyment General activity (PEG) scale for pain and functioning, demographic data collection tool, CDC's Guideline for Chronic Pain Management Protocol, and the Statistical Package for the Social Science (SPSS). Except for the demographic scale, all other scales and tools are the standard measurements for pain, functioning, and statistical data analysis.

The NPS (See Appendix A) is a segmented version of the visual analog scale (VAS) in which a respondent selects a whole number (0-10) that bests describe the intensity of their pain. It is a 10-item scale which has been widely implemented in primary care settings because of its reliability and validity. This tool will be utilized to assess the patient's pain and severity during the implementation phase of project (CDC), (2017). Also under Appendix A is the Demographic data collection tool (Appendix B) can help determine who is being treated in context of the broader community. It will also be used to determine what is the ethnicity, gender, age, and level of education of the population being served. Different ethnicity has been found to have different tolerance levels for pain.

The pain enjoyment general activity (PEG Scale) (Appendix C) is utilized to assess pain intensity and interference. It is a 3-item tool to assess pain, intensity, interference with enjoyment of life, and interference with general activity. It is validated and is an easy and simple

tool to track functioning and pain (US Department of Health, 2015). Each item is rated zero to ten for a possible 30 points. This tool will be utilized to assess the patient's pain severity and functionality during the implementation phase of project. Since pain can reduce functionality, the PEG scale will be helpful in identifying those patients who have been severely limited in their functioning due to the severity of their pain. Staff will also be given a pretests and a post test to determine knowledge level of chronic pain management and the role of opioids (Appendix D).

Another tool to be used in the project is a power point presentation (Appendix E) on teaching staff how to implement the project will be utilized. This is in keeping with one of the objectives of the project, which is to educate the staff to conduct the screening on the site.

The CDC Guideline for Chronic Pain management is a 12- item guide geared specifically towards reducing the prescribing of opioids as first-line treatment for chronic pain. The guidelines do not recommend opioids as first line treatment for chronic pain, and strongly recommends adjuvant therapies such as non-opioids, and pharmacotherapies (CDC, 2016).

The Statistical Package for Social Sciences (SPSS) software program will be used for all data analysis. It is the standard for data analysis regardless of the nature of the data. It meets both reliability and validity criteria (Schmith & Brown, 2012). Data collected each day will be entered in Excel spreadsheet. All data will be stored on a secure database and protected by a password.

Data Collection Procedures

Demographic data will be recorded, and color coded for classification. When collecting data, all identifying information will be redacted and remain confidential. The information gathered will be the number of patients being treated for chronic, mild to moderate non-cancer

pain, and the number of patients that received education and alternative therapies. The project leader will record whether the demographic data will also be collected and color coded. Participants will be given numbers to maintain anonymity and all documents will be kept onsite, in a locked safe for three years, as per the law (Health and Human Services [HHS], 2018). Additionally, all data collected electronically will be encrypted and stored on password protected, only able to be accessed by the project leader. A pre and post intervention chart review will be conducted by the project leader.

The information gathered will be: the number of patients being treated for chronic, mild to moderate, non-cancer pain, and the number of patients that received education and alternative therapies. Demographic data will also be recorded and color coded for classification. When collecting data, all identifying information will be redacted and remain confidential. Patients will be given numbers to maintain anonymity and all documents will be kept on site, in a locked safe for three years, as per the law (HHS, 2018). Additionally, all data collected, electronically, will be encrypted and stored on password protected, only able to be accessed by the project leader.

A pre- and post-intervention chart review will be conducted by the project lead. All identifying information will be redacted and all information confidential. Each chart will be assigned a number. The information collected will be number of patients who were being treated for chronic mild to moderate non-cancer pain, and the number of patients that received education and alternative therapies. The project lead will record whether the demographic data is selected and whether treatment with opioids for chronic pain is selected on the survey. This data will be recorded onto an Excel spreadsheet.

Participants will provide demographic data including age, gender, marital status, and level of education, and whether they are receiving opioids for chronic pain. No name will be required, and all identifiable information will be redacted to protect the privacy and confidentiality of the participants when disseminating the results of the study. A different color code will be used for each of the demographic data, and participants will be numbered to avoid using names. All paper surveys collected will be locked away in a safe, and only the project lead will have the key. All documents will be kept onsite in a locked safe for three years as per law (U.S. Department of Health and Human Services, 2018). Data collected will be entered into a computer and will be encrypted. The computer will be password protected and will only be accessed by the project lead.

Clinical Staff Knowledge Levels

In the first training session, staff will be given a pre-and a post-test knowledge assessment questionnaire survey. This is to determine whether the training will improve their knowledge of opioid as a treatment for chronic pain management. Staff will be quizzed at intervals during the presentation. An example of the type of question they would be asked is, "What is the recommended first-line treatment for chronic pain?" This quiz will be followed by a brief PowerPoint presentation on the current opioid epidemic. The staff will be introduced to the new protocol and then will have an opportunity to demonstrate its use (working in groups). The staff will take the post-test after the presentation and training. Data will be collected and stored in Excel before exporting to SPSS tool for analysis.

Opiate Prescribing Rates

In keeping with the objective to create a pain management intervention protocol as first-line treatment for chronic pain, teaching the practitioners to implement the adjuvant therapy will

follow and will contribute to the reduction rate of prescribing opiates at the practice site. Opioid-prescribing rates will be gathered from the electronic health record (EHR). Currently, the information reported by the practice site puts the opiate prescribing rate at 85-90 percent. The goal is to reduce that by at least 10 percent in the implementation phase. The project leader has been given approval to access the EHR for this information.

Adjuvant Pain Rating

The objective pertaining to the utilization of the tracking tool by the healthcare practitioners (HCPs) at each encounter in identifying adults receiving opioids for chronic pain. Once participants complete the demographic survey, they will be given the Numeric Pain Rating Scale to determine level of pain at pre-test. HCPs will then begin new protocol of pharmacological and non-pharmacological adjuvant therapies. A pre-test and a post-test will also be administered to the patients by the HCPs utilizing the same Numeric Pain Scale and the PEG scale. Data will be entered into Excel spreadsheet.

Intervention and Project Timeline

Implementation of the project will take approximately five weeks. The proposed timeline for the project is as follows:

Week 1

The project lead will conduct a formal onsite meeting with stakeholders (Director of practice site, all nurses and physicians) prior to the implementation. Staff will receive protocol training (Appendix E). This will be done on day one, with the purpose of reviewing the procedures of the new procedure (protocol). Throughout the implementation phase, the project lead will conduct daily staff huddles in the morning before the staff begins the protocol

implementation each day. Staff will begin the implementation of the protocol with their patients by administering a pretest of both the Numeric Pain Scale and the PEG scale.

The project is based on evidence, and staff huddles (staff gather together for 5 minutes to be briefed on the activities for the day) have been utilized as a part of the PBED model (Plan, Brief, Execute, Debrief), to improve communication and to ensure everyone knows what is to be done, who is to do it, and when it is to be done (Harris, & Roussel, 2017). This might seem excessive; however, it is now a common practice to have brief staff huddles at the beginning of the day so all members of the team can have the most current communication. This eliminates errors and gaps in coverage and ensures all team members are aware of what needs to be done and what each team member is responsible for (Moran, Burson, & Conrad, 2017). The project lead will begin chart audits in this week and continue throughout the duration of project implementation phase. During the implementation phase, the project lead will be engaged in data collection, chart audits, and data entry. Project lead will select all charts of patients who were seen each day for chart audits.

Week 2

The practice site staff will continue with the project implementation each day. The project lead will continue to audit the charts at the end of each day. The data gathered will be entered into Excel spreadsheet daily. Briefs and debriefs will also be conducted by the project lead each morning. The purpose of these is to address anything project related that staff might need clarified at the start of the day and anything that might want to pass on immediately at the end of the day. All days will run in the same manner to maintain an orderly control over the project.

Week 3

The practice site staff will continue with the project implementation each day. The project lead will continue to audit the charts at the end of each day. The data gathered will be entered into Excel spreadsheet daily. During the implementation phase, the project lead will be engaged in data collection, data entry, chart audits, holding briefs and debriefs at the start and end of each day.

Week 4

Practice site staff continues with the project implementation each day. The project lead will continue to audit the charts at the end of each day. The data gathered will be entered into Excel spreadsheet daily. At the end of week four, participants will be given a post-test by the staff.

During the implementation phase, the project lead will be engaged in data collection, data entry, chart audits, holding briefs and debriefs at the start and end of each day.

Week 5

Complete evaluation of the protocol and analysis of the data gathered. The project lead will ask staff to provide feedback on the use of the protocol. They will be given a short survey on the ease of use of the tool. The purpose of this is for sustainability. The project lead will export data collected into SPSS software for analysis and comparison of pre-and post-data indicators. Findings will be written in a report for dissemination to stakeholders.

Ethics and Human Subjects Protection

The following project will focus on the implementation of a QI practice change through the development of a new protocol for treating patients with chronic mild to moderate pain at a local health clinic. There are certain measures that must be taken in order to protect the privacy and confidentiality of patients (Agency for Healthcare Research and Quality [AHRQ], 2014).

According to the HHS (2018), the *Belmont Report* is the framework for ethical principles when working with human subjects. It identifies basic ethical principles and guidelines that address ethical issues which ensures participants are not harmed during the process. Therefore, the project lead has the responsibility to uphold patient confidentiality as defined by a certificate of confidentiality, meeting both ethical and legal obligations (Beskow et al., 2012; National Institutes of Health [NIH], 2018). In order to protect the privacy and confidentiality of the participants and patient charts, several measures will be taken.

The project will be conducted at a health clinic located in New York City. Although the project lead will conduct a chart review, which will contain patient data, the information extracted will contain no patient identifiers and will only be utilized for QI purposes. All collection of data will be the sole responsibility of the project lead. The director of the clinic has already granted permission to the project leader to implement the project in this setting. An institutional review board (IRB) approval will not be needed by the health clinic. Based on the IRB guidelines, this project meets exempt status because there is no more than a minimal risk to the patients. There will be no compensation to the participants who will participate in this project. The data collected will be stored in a locked file cabinet on site. Only the project lead will have access to it. This is to ensure safety and confidentiality of the participants and prevent tampering of the data.

Plan for Analysis/Evaluation

The data collected by project lead will be inputted into an Excel spreadsheet. This data will then be copied over into the statistical package for the social sciences (SPSS) software for analysis. A t-test of differences will be run to ascertain whether there was a difference between

baseline test and post-intervention of new pain protocol. The results will be used to run comparisons among the types of adjuvant therapies to determine which ones were effective.

The project will be evaluated by getting feedback from the staff. The project will be evaluated by getting feedback from the staff. They will complete a brief survey on whether they felt the adjuvant therapy protocol was effective, in what areas it was and which areas it was not. The project lead will also hold exit meetings with the staff according to disciplines to get feedback on the sustainability of the project. Staff will conduct a survey of their patients to get their feedback.

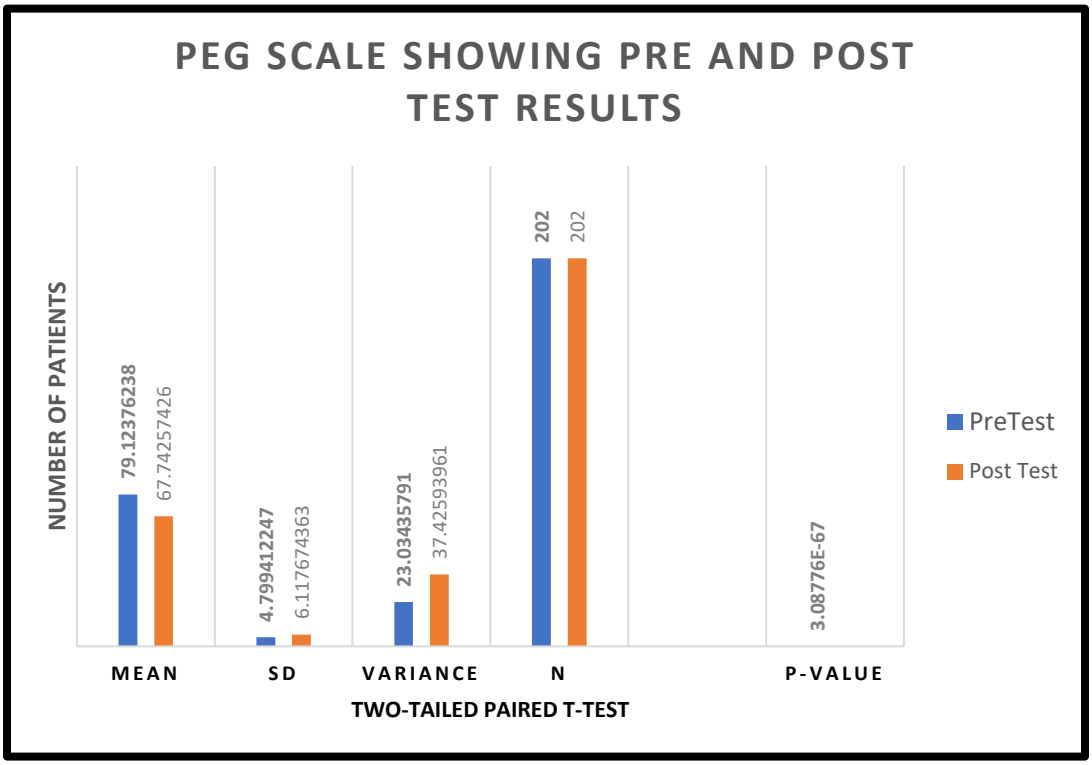
Statistical Analysis

The implementation of the clinical practice guidelines for the reduction in the overprescribing of opioids for the treatment of chronic pain occurred successfully resulting in an increase in the utilization of adjuvant therapies that were not previously explored as first-line treatment of chronic mild to moderate pain.

The pre-test and post-test of the pain enjoyment and general activity (PEG) scores were analyzed using Excel's data analysis to determine whether there was a significant change in the pain level at baseline compared to post implementation period (post-test).

A two-tailed paired t-test was utilized. The data showed significant difference between the pain levels at baseline (79.12%) and post-implementation (67.74%) with p-value (p-0.30). There was a high confidence that the scores were highly significantly different. The results demonstrated the pain level decreased over the duration of the implementation phase (See Figure 1).

Figure 1.



Numeric Pain Scale

Statistical analysis was also carried out to compare the pain levels at baseline based on the four-item numeric pain scale (NPS). Pain levels at baseline and after the implementation within each group were assessed using Excel data analysis. A paired t-test was used to test the significance between baseline (pretest) pain scores (NPS) and post-test scores after the new protocol. The average NPS score at baseline was 5.9% compared to 3.3% at the end of the implementation phase (Figure 2). A combination of pharmacological and non-pharmacological therapies were utilized for patients who were on opioids as first-line therapy. Chlorzoxazone (muscle relaxer), yoga, walking, and chiropractic care were the most frequently prescribed by the participants (See Table 1). There were more prescriptions written for adjuvant therapies as first line treatment during the implementation of this project than previously prescribed (Table 1).

Figure 2.

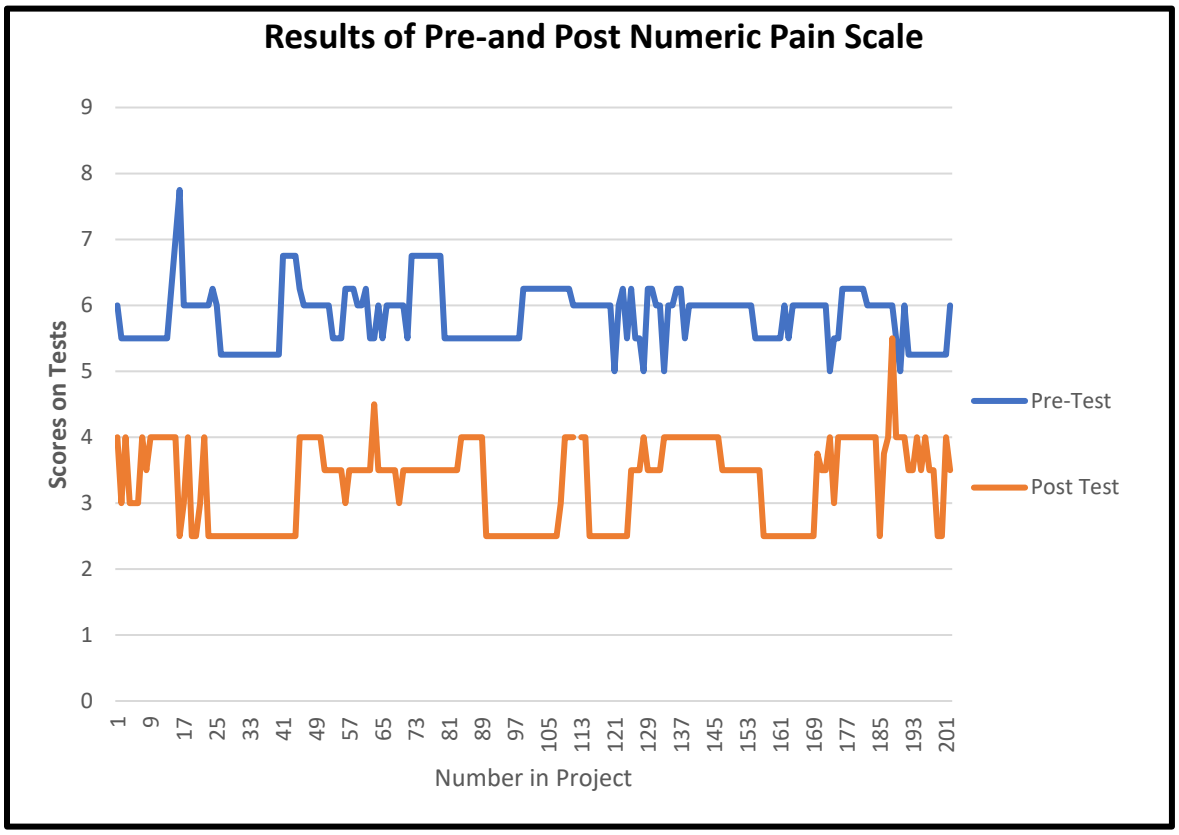


Chart showing pre-test and post test results for NPS

Prior to implementation, all patients received opioids as first-line therapy for chronic pain management. During the implementation phase, opioids were tapered and combined with adjuvant therapies (Table 1) for returning patients. New patients received adjuvant therapy (pharmacological and non-pharmacological therapies as first line treatment for chronic pain). Pharmacological and non-pharmacological therapy prescribed as first-line treatment during the project implementation phase. A total of 202 charts were audited.

Table 1.

Prescriptions	**Pre-Project Implementation (First-line treatment)**	**Post Project Implementation (First-line)**
Opioids	All patients	0
Opioids/Adjuvants		130
Tylenol		202
Chlorzoxazone		160
Chiropractic Therapy		90
Yoga		80

Table showing a comparison between pre-and post-implementation chronic pain therapy

Documentation and identification of patients who were receiving opioids as first-line treatment was more apparent, and participants were able to introduce the new protocol with ease. The use of the pain management scale and the PEG scales were beneficial in assessing the level of pain, and treatment was provided accordingly. Prior to the implementation of the protocol, opioids were first-line treatment at 100% for all chronic pain management. There were a number of variables that had to be considered for the lower than expected reduction in opioids as first-line treatment over the four-week period. One of the variables was the initial resistance of existing patients to accept combination therapy, which included reduced opioid dosage with the addition of an adjuvant therapy such as Tylenol.

Discussion

Prior to the implementation of the adjuvant therapy protocol for chronic pain management, the facility did not have a formalized protocol for adjuvant therapy in pain

management. By utilizing both the pain management scale and the PEG scale, the practitioners were able to better understand the extent of the pain their patients were having, and thereby better able to prescribe both pharmacotherapy and non-pharmacotherapy, which many patients found beneficial by the third week. Prior to the project implementation, opioids were first-line treatment for all types of pain. The important point not to be overlooked is that post-implementation showed that adjuvant therapies became first-line treatment for chronic pain, and opioids were no longer being used as first-line treatment for chronic pain management. Providers reported some resistance in the beginning, however, after the first week, many patients realized that their self-reported pain intensity was not as severe as they thought. Providers reported being more cognizant that not all patients had the same intensity of pain, and therefore, the treatment should not be the same.

Another important point for discussion was the utilization of the EHR during the project. While the EHR was a preexisting resource for practitioners, during the implementation, the practitioners recognized that they could utilize the EHR to monitor the dosage of opioids that were being prescribed and over what period of time. By participating in the protocol, the practitioners maximized their roles as educators, advocates, and change agents to improve patient outcomes. They were helping the patients become less dependent on opioids as first-line treatment for chronic pain, and they also paid greater attention to the clinical practice guidelines by the CDC.

During the four weeks of implementation of the new adjuvant therapy protocol, the 40 staff attended to and treated 810 patients, which averaged to approximately 40 patients per day. The average patient per staff increased by 50%, which was a bit overwhelming for the participants, especially on days when one or two staff members were absent. This happened

during the first week of implementation. The staff were eager to see the project through, and vacations were delayed by the director to ensure that project was completed in the time allotted.

Staff knowledge was also heightened after the project implementation. Many indicated that they knew very little about pain management and the resources available to providers. Some staff reported that they are going to incorporate the PEG scale especially in their assessment of the patients. While the staff was certainly skilled and competent, the four-week implementation period where everyone was doing the same thing, it made them realize that in order to see improvement in the patients they cannot keep them on opioids when there is clearly no change over at least a six-month period.

Significance to Nursing

The aim of this project was to develop a new protocol using adjuvant therapies as first line treatment for chronic mild to moderate pain. Through collaboration with the medical staff at the practice site, the protocol adhered to the CDC's guidelines for chronic non-cancer pain therapy. Findings supporting the use of these alternative therapies can greatly impact the nursing profession. Awareness of evidence-based guidelines for employing other treatments, versus prescribing opioids can influence future practitioners. With the support of the key stakeholders of the health clinic where project was implemented, the sustainability of the project will be accomplished through collaboration.

The significance of this project was far reaching because of the impact of the opioid crisis. Opioids addiction and fatalities are on the rise in the US and was the expectation that this project would bring an increased awareness to society. Too many people are becoming addicted when opioids are used the first-line treatment for chronic pain (CDC, 2016). In the future, if

alternatives are considered and implemented as was the case in this project, there will be a decrease in opioid addictions and fatalities (CDC, 2016).

Nurse leaders have a critical role to play in bringing attention to the opioids crisis. They are leaders and influencers of the healthcare system, not just of the present, but of the future, by being innovative and finding new ways to help people manage chronic pain without opioids. On April 11, 2018, the United States Senate enacted a bill (S.2680) titled, The Opioid Crisis Response Act 2018, which was aimed at continuing the funding for opioid addiction programs, and to provide funding for continued research on non-addictive pain medication and treatment (US Senate, 2018) was passed. The bill would allocate over $100 billion dollars to addiction treatment over the next 10 years (US Senate, 2018). The DNP prepared nurse leader in particular has the knowledge of clinical prevention and population health (American Association of Colleges of Nursing, 2006). Therefore, DNP nurses can apply for funding to expand or start new programs that would continue to reduce the opioid epidemic. For example, in terms of sustainability for a project such as this, the organization could seek funds to continue the protocol.

Limitations of the Project

. Project limitations included the short time period in which the protocol was initiated and implemented. This model integrates structure, process and outcomes, but due to the short duration of the project (4 weeks), it was not possible to carry out excessive changes in all three areas which the Donabedian model proposes. Nonetheless, changes process did impact structure, and process. A longer time period would have allowed for more data gathering to see whether over a longer period of time, patients who were gradually tapered off opioids as first-line treatment would continue with the adjuvant therapies. Another limitation was the data collection

process. It was done by hand and it took a long time. If this was computerized, the process would be quicker and more data could have been collected and more statistical analysis could have been done with a larger data set. However, this must be put into context, that everything depended on the limited time to start and complete the project.

Areas for Dissemination

The dissemination of the DNP project is important because it speaks for many (those who participated), it established the expertise of the DNP project lead, and it contributes to career goals (Bemker, & Schreiner, 2016). Areas for further dissemination include both internal and external sources such as journals, and repositories. According to Bemker and Schreiner (2016), dissemination of the DNP project is important because it is the accumulation of hard work, and dissemination provides a sense of satisfaction and success.

Dissemination of the DNP project is also significant because it adds to the body of work that exists for others in the profession to utilize and gain insight and valuable learning experience. Subsequently, the DNP project can be disseminated both internally at the practice site, and externally. Internal dissemination can take the form of a poster, a manuscript, a manual, a brochure or in the form of a digital file or power point presentation (Bemker & Schreiner, 2016).

Some areas of dissemination have already been explored and will be pursued immediately, others such as book publishing with Springer Publishers is being explored by DNP project lead. Internally, this project will be disseminated to the director of the site, stakeholders such as staff, the board of the organization, and the local community board. It will take the form of a manual. Dissemination internally will also include a professional seminar for nurses and physicians within the entire organization during nurses week 2019.

External dissemination will include the Doctoral Project Repository. This is an online database that disseminates scholarly doctoral projects for others to see the contribution that DNP nurse leaders are making. The site requires an abstract and the full project to be uploaded to the site. There is a one-time fee of $30.00 that must be paid at the time of submission. This project will also be submitted to Primary Healthcare journal. It relates to the professional healthcare received in the community and is geared towards general practitioners and or practice nurses. It is an Open Access, peer-reviewed academic journal, that aims to publish complete and reliable source of information on discoveries, case reports, and scientific highlights (Primary Healthcare, 2018), which is a scientific journal that also includes a wide range of fields in its discipline. There is no deadline for submission, as they accept manuscripts throughout the year.

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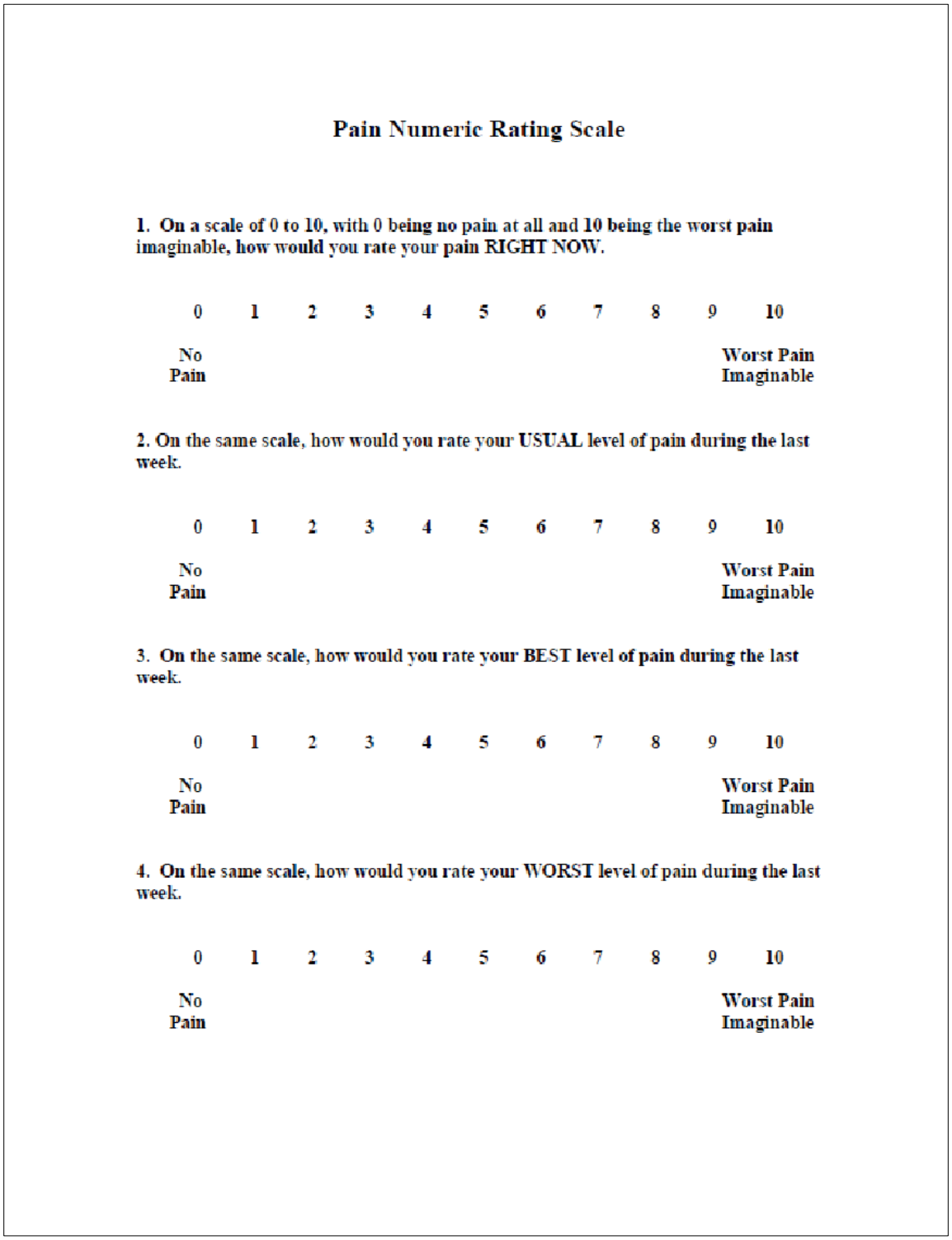
Appendix A



Pain Numeric Rating Scale

1. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your pain RIGHT NOW.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Worst Pain Imaginable

2. On the same scale, how would you rate your USUAL level of pain during the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Worst Pain Imaginable

3. On the same scale, how would you rate your BEST level of pain during the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Worst Pain Imaginable

4. On the same scale, how would you rate your WORST level of pain during the last week.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Worst Pain Imaginable

Childs, J.D., Piva, S.R., Fritz, J.M. (2005). Responsiveness of the numeric pain rating scale in patients with low back pain. Spine 2005;30:1331–4.

PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)

1. What number best describes your pain on average in the past week?

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

2. What number best describes how, during the past week, pain has interfered with your enjoyment of life?

0	1	2	3	4	5	6	7	8	9	10
	Does not interfere									Completely interferes

3. What number best describes how, during the past week, pain has interfered with your general activity?

0	1	2	3	4	5	6	7	8	9	10
	Does not interfere									Completely interferes

Computing the PEG Score.

Add the responses to the three questions, then divide by three to get a mean score (out of 10) on overall impact of points.

Using the PEG Score.

The score is best used to track an individual's changes over time. The initiation of therapy should result in the individual's score decreasing over time.

Source.

Krebs, E. E., Lorenz, K. A., Bair, M. J., Damush, T. M., Wu, J., Sutherland, J. M., Asch S, Kroenke, K. (2009). Development and Initial Validation of the PEG, a Three-item Scale Assessing Pain Intensity and Interference. Journal of General Internal Medicine, 24(6), 733–738. http://doi.org/10.1007/s11606-009-0981-1

Appendix B

Demographic Data Collection Tool (Developed by Beverley Clarke)

Please select the answer by placing an "X" on the line

1. **What is your gender?**

   Male _____ Female_____ Transgender_____

2. **What is your age range?**

   Over 18 years of age _____

   26- 35 _____

   36 –45 _____

   46- 55 _____

   56- 65_____

   Over 65 _____

3. **What is your marital status?**

   Single_____ Married _____ Divorced_____

   Widowed_____ Separated_____

4. **What is your level of education?**

   High School/ Vocational School _____

   Two-year College _____

   Four- year College _____

   Post- Graduate _____

5. **Are you receiving opioids for chronic pain?**

Yes _____

No _____

Appendix C

Damian Family Care Centers, Inc.

Medication Policy and Procedure

Policy:

This policy outlines the guidelines for chronic pain management utilizing both opioids and non-opioids therapy at Damian Family Care Center for the next 4-5 weeks. This facility has a responsibility to keep all prescription drugs in a locked cabinet. These medications should only be made available as prescribed. Please note that for chronic pain, opioids are not first-line or routine therapy **(**Centers for Disease Control and Prevention Guidelines, 2018).

Procedure:

Code	Approved by:	Policy No.
1	**For Initial Patients (New) Clinical Visit**	
	a. Conduct a complete H& P on new patient. b. Assess patient for pain using numeric pain rating scale (NPRS) and PEG scale. c. Enter data into electronic health record (EHR). d. Establish with patients what their treatment goals are before starting treatment. e. Describe known risks and benefits of opioids with patients. f. Prescribe pharmacological therapy such as Buprenorphine, or Methadone, Tylenol. g. Provide appointment for patient to return after 7 days to monitor if adjuvant therapy is working. h. Provide patients with post-test (numeric pain rating scale)	
2	**For Recall Patients (Current)**	
	a. Conduct a complete H& P on new patient. b. Assess patient for pain using numeric pain rating scale (NPRS) and PEG scale. c. Describe known risks and benefits of opioids with patients. d. Begin tapering opioids by 10% and optimize with non-opioid therapy such as acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], tricyclic antidepressants, serotonin norepinephrine reuptake inhibitors, gabapentinoids, cannabinoids. e. Provide appointment for patient to return after 7 days to monitor if adjuvant therapy is working. f. Provide patients with post-test (numeric pain rating scale)	

Appendix D

ClinicalAdvisor

Staff Knowledge Pre-and Post-Test Questionnaire

Demographic Section

1. What is your age?

1.18-25 years

2. 26- 35 years

3. 36-45 years

4. 46- 55 years

5. 56-65 years

6. ≥66 years

2. What is your gender?

1. Male

2. Female

3. What is your ethnicity?

1. African American/Black

2. Caucasian/White

3. Hispanic/Latino

4. Asian

5. Other

4. What type of provider are you?

1. Physician

2. Physician's Assistant

3. Advance Nurse Practitioner (DNP/PhD)

4. Nurse Practitioner (NP)

5. Registered Nurse

5. How many years have you practiced?

1. 0-5 years
2. 6-10 years
3. 11-15 years
4. 16-20 years
5. 21- 25 years
6. 26-30 years
7. ≥31 years

6. How many patients do you see weekly?

1. 0-19
2. 20-39
3. 40-59
4. 60-79
5. 80-99
6. ≥100

ClinicalAdvisor

Knowledge of pain management

Take our quiz to test your knowledge of optimal pain management practices!

1. During the past 2 decades, the opioid epidemic has escalated with adverse consequences. Which of the following factors have contributed to the rise of the opioid epidemic?

   - A. Prevalence of chronic pain
   - B. Healthcare costs
   - C. Limits of physician prescribing
   - D. Both A & B

2. Almost 80% of adults experience lower back pain at some point in their lives. It can be associated with job-related disability and missed workdays. The majority of lower back pain can be mechanical. An example of a mechanical cause of lower back pain is:

- A. Hairline fracture
- B. Sciatica
- C. Ruptured ligament
- D. Dislocated bone

3. Osteoporosis pain, or degenerative joint disease, is a common chronic condition of the joints. The pain can be severe enough to affect an individual's quality of life. The goal of treatment is to decrease pain and improve joint movement. An example of an available treatment is:

- A. Over-the-counter pain relievers
- B. Exercise
- C. Topical treatments (creams, rubs)
- D. All of the above

4. Pain is a common complaint among older Americans. One in 5 older Americans takes a pain reliever. According to the American Geriatrics Society's updated guideline, which class of drugs should be considered rarely and with extreme caution in highly selected individuals due to increased cardiovascular risk?

- A. NSAIDs
- B. Opioids
- C. Anxiolytics
- D. Antidepressants

5. According to the International Association for the Study of Pain, pain can be an unpleasant and emotional experience. Management can be simple or complex and may require a variety of skills and techniques. Which of the following is a technique used for pain management?

- A. Medication management
- B. Psychological counseling
- C. Interventional procedures
- D. All of the above

6. Neuropathic pain can be caused by an increased release of certain neurotransmitters that signal pain. It can also be caused by a nerve's inability to regulate these signals. A common treatment for neuropathic pain can include:

- A. Trazodone
- B. Gabapentin
- C. Levothyroxine
- D. St. John's wort

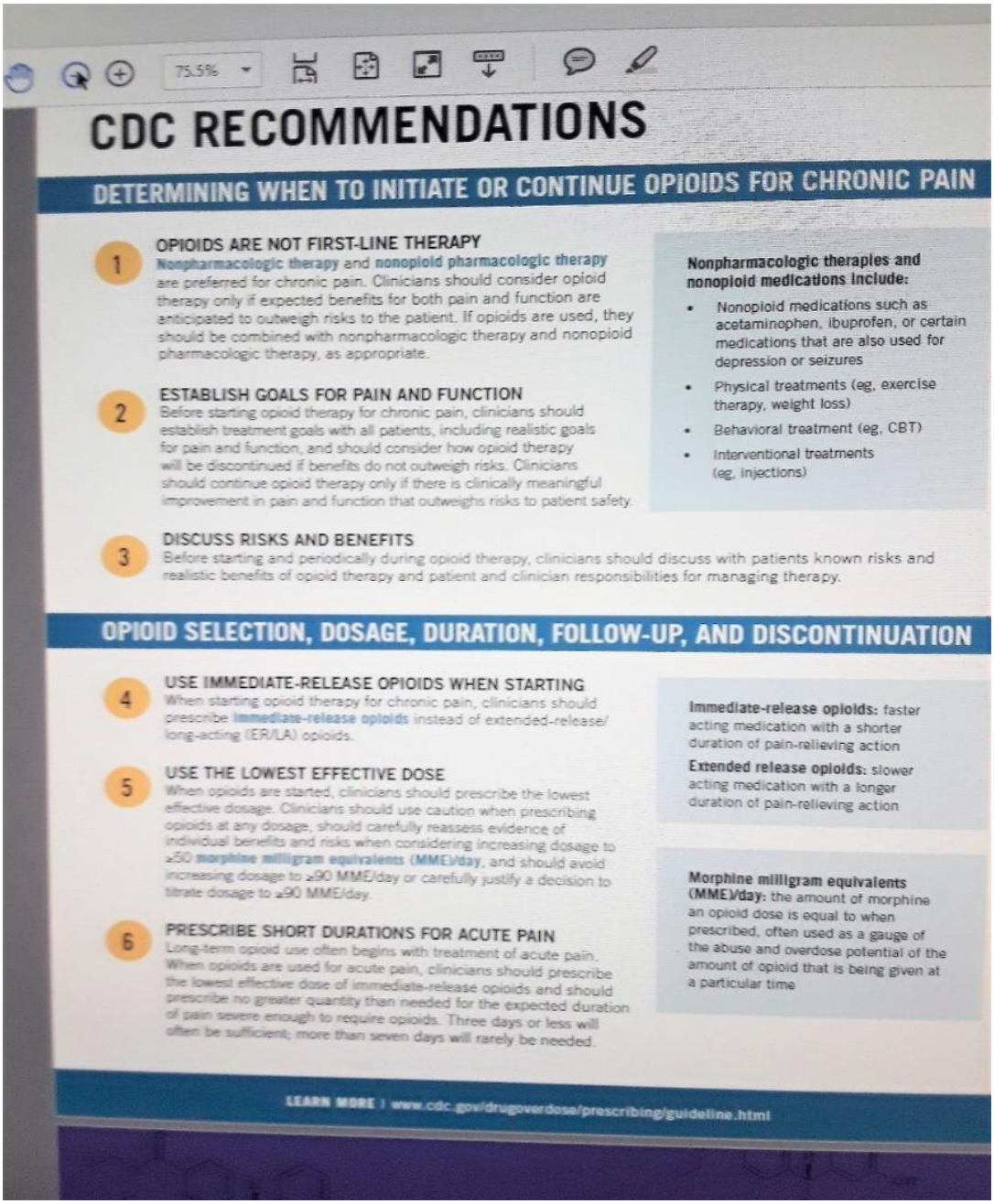
Answers

1. D
2. B
3. D
4. A
5. D
6. B

Appendix E

Power point for Staff Education (Attached)

CDC Recommendations (below)



CDC RECOMMENDATIONS

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

1 OPIOIDS ARE NOT FIRST-LINE THERAPY

Nonpharmacologic therapy and **nonopioid 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 nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

Nonpharmacologic therapies and nonopioid medications include:

- Nonopioid medications such as acetaminophen, ibuprofen, or certain medications that are also used for depression or seizures
- Physical treatments (eg, exercise therapy, weight loss)
- Behavioral treatment (eg, CBT)
- Interventional treatments (eg, injections)

2 ESTABLISH GOALS FOR PAIN AND FUNCTION

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 DISCUSS RISKS AND BENEFITS

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.

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

4 USE IMMEDIATE-RELEASE OPIOIDS WHEN STARTING

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

Immediate-release opioids: faster acting medication with a shorter duration of pain-relieving action

Extended release opioids: slower acting medication with a longer duration of pain-relieving action

5 USE THE LOWEST EFFECTIVE DOSE

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.

Morphine milligram equivalents (MME)/day: the amount of morphine an opioid dose is equal to when prescribed, often used as a gauge of the abuse and overdose potential of the amount of opioid that is being given at a particular time

6 PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN

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.

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

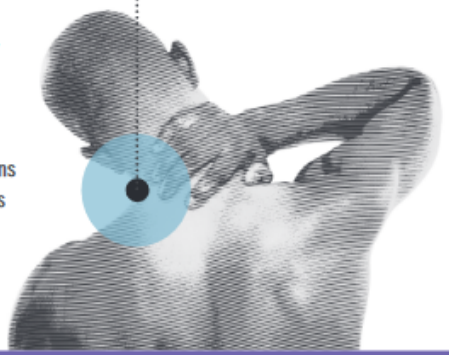
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic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

CLINICAL REMINDERS

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient



U.S. Department of Health and Human Services
Centers for Disease

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

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.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

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.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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Appendix F

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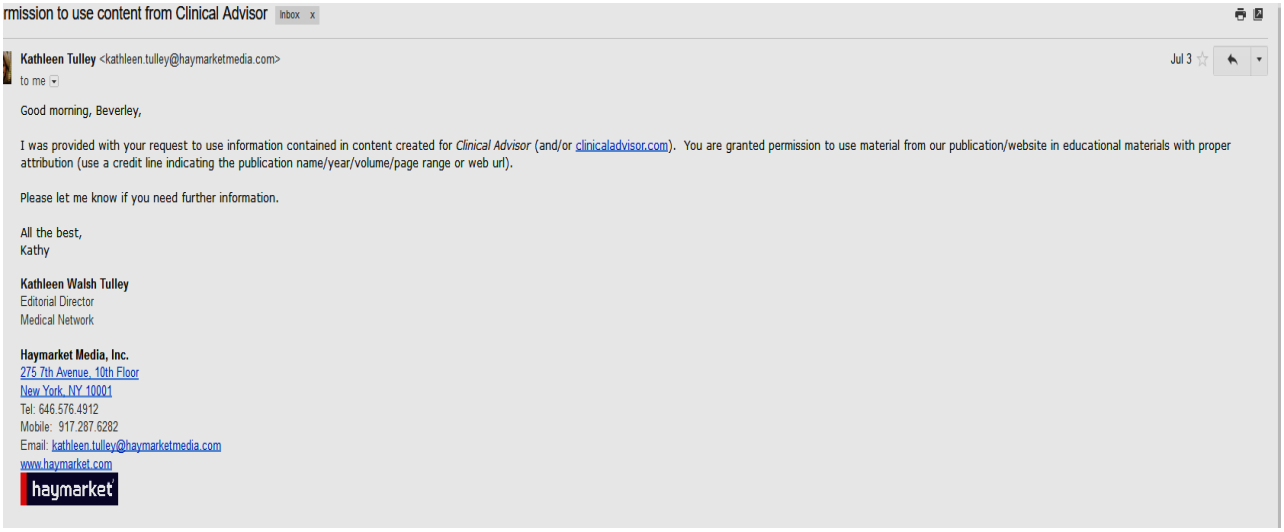

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Kathleen Tulley <kathleen.tulley@haymarketmedia.com> Jul 3

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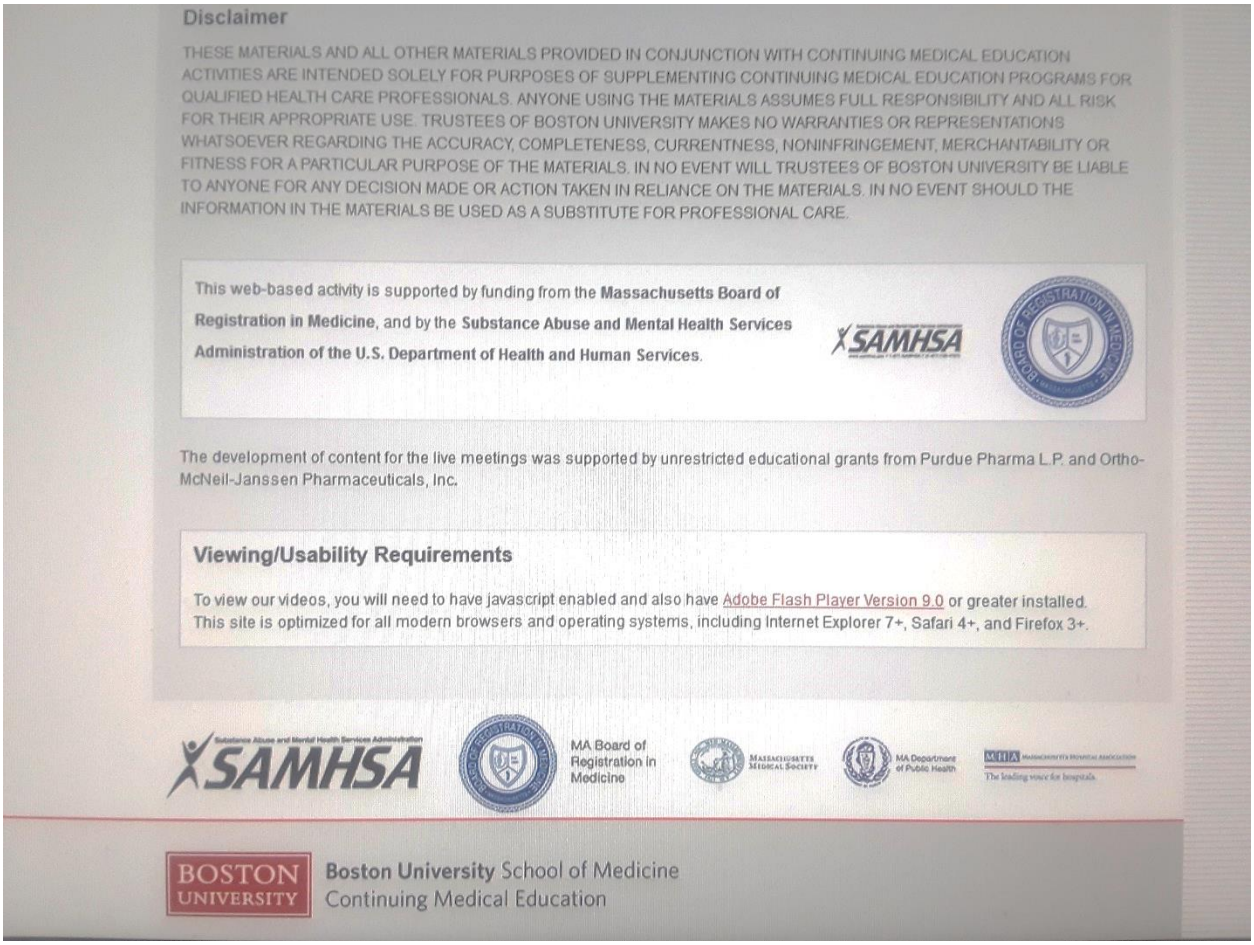

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