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Clinical Practice Guideline for the Treatment of Osteoarthritic Pain Among Elderly Patients

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This is to certify that the doctoral study by

Marylie Buckoski

has been found to be complete and satisfactory in all respects,
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Walden University
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Abstract

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Patients

by

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MSN, South University, 2018

BSN, West Visayas State University, 2005

Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

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Abstract

Osteoarthritic (OA) pain is a debilitating condition associated with significant medical, emotional, and economic burdens affecting approximately 27 million Americans and causes billions of dollars for medical expenditures. OA pain is a frequent cause of disability among elderly patients in the United States and requires effective pain management to decrease pain and improve their quality of life. The nurse practitioners (NPs) working in the seven affiliated pain management practices in the Southwest area of the United States, do not consistently follow current evidence-based pain management protocols when providing care for patients with OA pain. The purpose of this DNP project was to develop an evidenced-based pain management clinical practice guideline (CPG) to serve as a resource for nurse practitioners when providing care to elderly patients with OA pain. Knowles adult learning theory provided an understanding of factors that should be considered when developing educational material for nurses. Quality assessment of the CPG was scored by a panel of experts using the Appraisal of Guidelines Research and Evaluation instrument and the results were analyzed using descriptive statistics. The scores for each six domains were 93% and above, with an overall score of 100%, indicating a high-quality guideline. The expert panel identified that CPG overall was well-written, very clear, and will be useful education tool for the stakeholders. The CPG can be use by NPs as a resource to develop plans of care which may reduce pain, influence care outcomes, and improve quality of life for patients with OA. It is therefore recommended that administration disseminate and implement the guideline at the seven practice sites.

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Dedication

I dedicate this doctoral project to my loving and supportive family. First, to my supportive and helpful husband, who always stayed by my side all throughout my graduate studies. Thank you for all your hard work, patience, and encouragement to never give up chasing my dreams. Secondly, to my daughter, for being my inspiration to strive harder and further, for me to enable to provide you a better and greener future. I am so thankful to be your mother and the joy of spending more time with you served as my motivation to keep going. Lastly, to my close family and friends for all their continued love, support, understanding, encouragement, and motivation which greatly contributed to my ability to complete this project.

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Section 1: Nature of the Project

Chronic pain is a debilitating condition associated with significant medical, emotional, and economic burdens. The International Association for the Study of Pain (IASP, 1994) defined chronic pain as pain that persists past the normal time of healing, which may be less than one month, or more commonly, three months. The most frequent pain complaints of patients 65 years old and above are musculoskeletal pain brought about by osteoarthritis (OA; Molton & Terill, 2014). This debilitating chronic pain affects approximately 27 million Americans (American College of Rheumatology/Arthritis [ACR], 2019) and causes billions of dollars for medical expenditures. Hence, evidence-based management of chronic pain is crucial in providing a safe and effective treatment to those patients suffering from OA pain.

Problem Statement

The population of adults age 65 and older is growing. Up to 50% of community-dwelling older adults report pain that interferes with normal function, and at least half of nursing home residents report pain daily (Castillo & Weiner, 2019). An estimated 60%–75% of people over the age of 65 report at least some persistent pain, and this rate is considerably higher for people who are in assisted living facilities or nursing homes (Stompor et al., 2019). Consistent with a greater prevalence rate of chronic medical comorbidities in later adulthood, the most frequent pain complaints among older adults are osteoarthritic back pain, especially in the low back or neck (around 65%), musculoskeletal pain (around 40%), peripheral neuropathic pain (typically due to diabetes or post herpetic neuralgia, 35%), and chronic joint pain (15%–25%; Molton & Terill, 2014). There are approximately 27 million Americans who suffer from OA disease (ACR, 2019).

The economic costs associated with the management of chronic pain, including both the direct healthcare costs and indirect costs, are astronomical in the United States. According to the 2008 MEPS data, the American Pain Society and the Institute of Medicine (IOM) estimated that the total national cost of pain ranged from $560 billion to $635 billion annually in direct treatment costs and lost productivity (IOM, 2011). Although the direct healthcare costs (e.g., medication costs and hospital-based services) were considerable, the indirect costs that accounted for disability compensation and lost work productivity were even higher. It was estimated that the total incremental costs of medical expenditures ranged from $261 billion to $300 billion and the indirect costs that were attributed to lost productivity based on the days of work missed, the annual hours of work lost, and lower hourly wages ranged from $299 billion to $335 billion (IOM, 2011).

In 2013, the total national arthritis-attributable medical care costs and earnings losses among adults with arthritis were $303.5 billion or 1% of the 2013 U.S. gross domestic product (GDP; Centers for Disease Control and Prevention [CDC], 2018). OA is a common degenerative disorder of the articular cartilage associated with hypertrophic changes in the bone and the joints commonly affected are the hands, knees, hips, and spine, but almost any joint can be involved (Sinusas, 2012). Arthritis in general is also a leading cause of disability and a significant cause of reduced quality of life (QoL; Goode et al., 2013). Chronic pain from OA then is one of the most common reasons why older adults seek medical care and has been linked with (a) restrictions in mobility and daily activities, (b) dependence on opioids, (c) anxiety and depression, and (d) poor perceived health or reduced QoL (Dalhlamer et al., 2018).

Treatment modalities used for chronic arthritic pain include medications, regional anesthetic interventions, surgery, psychological therapies, rehabilitative/physical therapy, and complimentary alternative medicine (Muneer, 2016). The ACR foundation came up with a new set of guidelines for the treatment of the OA of the hand, hip, and knee in 2019. In this guideline, the ACR (2019) strongly recommends the use of topical nonsteroidal anti-inflammatory drugs (NSAIDs) in patients with knee OA, NSAID use in all patients with OA, and intra-articular corticosteroid injections in patients with knee or hip OA. Cortisone injection directly to the osteoarthritic spinal joints is recommended for acute flare-ups of low back pain that are not responsive to NSAIDS to rapidly decrease pain and restore function (ACR, 2019).

Researchers have suggested that exercise therapy in general, including stretching and yoga, are good treatments for OA of spine, hips, and knee (Good et al., 2013). Surgery may be needed for certain patients with severe cases of spinal arthritis that leads to instability of the joint (i.e., degenerative spondylolisthesis) or nerve root pinching (i.e., spinal stenosis; Good et al., 2013). Guidelines for the management of chronic pain have been laid out by the CDC (2019) with the recommendations that the following must be taken into consideration for each patient on an individual basis: (a) when to initiate or continue opioids for chronic pain; (b) the opioid selection, dosage, duration, follow-up, and discontinuation; and (c) assessing risk and addressing harms of opioid use.

In seven affiliated private practice sites located in Southwest area of the United States (US), there was no clear written guideline on assessment and management of elderly patients with chronic osteoarthritic pain. Based on my informal review of patient records at some of these sites, there were inconsistencies in following the opioid prescriptive guidelines

established by the CDC and ACR. In addition, many nurse practitioners (NPs) did not recommend interdisciplinary pain management services to their patients as recommended by IOM (2011). Current experiences indicated that there was a lack of implementation of, and non adherence to, evidence-based guidelines among NPs according to ACR (2019). Clearly, there is an urgent need for clinical practice guideline (CPG) for NPs to address the gaps in knowledge and competencies in the care of elderly individuals with OA pain. CPGs are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (U.S. Department of Health & Human Services [DHHS], 2017). These guidelines are not fixed protocols that must be followed but are intended for health care professionals and providers to consider (DHHS, 2017.) Providing evidence-based CPG will standardize and improve the quality of care rendered to OA patients. CPGs based on standardized best practice, have been shown to be capable of supporting improvements in quality and consistency in health care (EMP, 2018).

Purpose Statement

The purpose of this DNP project was to develop an evidence-based CPG from recent evidence-based resources that have the potential to standardize and improve the quality of pain management used by NPs for adults 65 years old and older with OA in an outpatient setting. Specifically, the practice-focused question for this DNP project was: Will an evidence-based CPG related to pain management serve as a guide used by NPs to deliver safe and effective pain management to elderly patients with OA?

Nature of the Doctoral Project

The nature of this project was to develop an evidence-based CPG that would serve as a resource and can be used by NPs to standardize the pain management treatment of patients with OA. The sources of evidence for the development of the CPG were obtained from selected articles relating to practice guidelines on treatment of osteoarthritic pain searched in the databases: Nursing and Medical Source, SAGE Journals, and Thoreau multi database search. CPGs were identified using specific search strategies in various sources, Medline, PubMed, CINAHL, Medscape. The CPG was reviewed and validated by the expert panel utilizing the AGREE II instrument. The key stakeholders comprising of four NPs from the seven practice sites evaluated and validated the content and ensured usability of the developed CPG. The evidenced-based CPG for the treatment of OA pain among elderly patients was proposed to standardize and improve the quality of pain management by NPs in an outpatient setting. The CPG will have the potential to provide NPs with knowledge of interventions for effective pain management in patients with OA.

Significance

OA is the most common type of arthritis, affecting more than 30 million adults in the United States (Cisterna et al., 2016). It is also among the most expensive conditions to treat when joint replacement surgery is required. In fact, OA was the second costliest health condition treated at U.S. hospitals in 2013 (Torio et al., 2016). The pain associated with OA was the most frequent cause of disability among adults in the United States, and the burden is increasing both as the prevalence of OA increases and as patient expectations for treatment rise (AAOS, 2017).

This DNP project served as guide for the NP in delivering most recent evidence-based CPG in treating osteoarthritic pain among elderly patients. Improving the way opioids are prescribed through CPG can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse or overdose from these drugs (CDC, 2018).

Establishing consistent treatment with an evidence-based CPG has the potential to provide NPs with knowledge of interventions for effective pain management in patients with OA (Joshi et al, 2014). A CPG for treating chronic pain would serve as a resource for practitioners to develop plans of care to reduce patient's pain and monitor patient's untoward reactions, dependency, and abusive attitudes towards opioids (CDC, 2019).

The CPG will promote effective and efficient treatment of pain and encourage the adoption of cost-effective interventions in the treatment of chronic pain which will provide more treatment options for the patient (Mazrou, 2013). Providing evidence-based CPG to NPs as a resource in treating OA patients' pain has the potential to improve pain management and reduce costs related to disability (Mazrou, 2013). Providing a standard and best practice through utilizing a guideline will provide increased patient satisfaction with better outcomes and improved QoL (Farooq, 2016). Once a patient is more satisfied with their improvement and the care rendered by the health professionals, they also become more compliant with treatment recommendations (Farooq, 2016).

Summary

The purpose of this DNP project was to develop an evidence-based CPG from recent evidenced based resources that have the potential to standardize and improve the quality of pain

management used by nurse practitioners for older adults with OA in an outpatient setting. It is hoped that this CPG will provide NPs with knowledge of interventions for effective pain management in patients with OA. Providing the evidence-based CPG to NPs for treating OA patients may have positive patient outcomes such as improved pain management and reduced costs related to disability (Mazrou, 2013), thus increasing patient satisfaction with better outcomes and improved QoL (Farooq, 2016).

Section 2 included the background and context of the project, appropriate theories and models that guided the development of the CPG, the project's significance to nursing practice, and the role of the DNP student.

Section 2: Background and Context

Chronic pain is a debilitating condition that is associated with significant medical, emotional, and economic burdens, especially for patients 65 years of age and older. There was no clear written guideline on assessment and management of elderly patients with OA pain in seven affiliated private practices located in the Southwestern United States. The purpose of this DNP project was to develop an evidence-based CPG that has the potential to standardize and improve the quality of pain management used by NPs in treating older adults with OA in an outpatient setting. Specifically, the practice-focused question for this DNP project was: Will an evidence-based clinical practice guideline related to pain management serve as a guide to be used by NPs to deliver safe and effective pain management to elderly patients with OA? Providing an evidence-based CPG for use by NPs in treating OA patients has the potential to yield positive patient outcomes such as improved pain management and reduced cost related to disability (Mazrou, 2013). In this section, I will provide an overview of key aspects of the project, including the concepts, models, and theories underpinning it; its relevance to nursing practice; the local background and context; and my role as the DNP student.

Concepts, Models, and Theories

A framework or model facilitates a systematic translation of new knowledge into practice and enhances the chances of successful implementation (White et al., 2016). It can provide a skeletal set of variables applicable for all types of individuals, groups, and a wide variety of situations (Rycroft-Malone & Bucknall, 2010). Subsequently, the process of learning is derived from educational, psychological, and research-based theories, and the main purpose is to gain knowledge, understanding, or skills through experience; learning is fundamental to human

development (Merriam, 2001). Nurses, for example, spend a significant amount of their time and energy involved with learning and teaching, whether acquiring new information as part of their professional and continuing education or instructing others in health care. Advanced practice nurses are concerned with teaching and learning in numerous ways that would improve the quality of care rendered to their patients and the society. The theory and model selected for the development of this CPG were the adult learning theory and the Appraisal of Guidelines Research and Evaluation II (AGREE II) model.

Adult Learning Theory

Malcom Shepard Knowles proposed andragogy, also known as adult learning theory, in 1968. Knowles recognized that there were many differences in the ways that adults learn as opposed to children. His thoughts surrounding andragogy sought to capitalize on the unique learning styles and strengths of adult learners (Merriam, 2001). The theory of andragogy included five assumptions that educationalists should make about adult learners:

- Self-concept: Because adults are at a mature developmental stage, they have a more secure self-concept than children (Merriam, 2001). This allows them to take part in directing their own learning.

- Past learning experience: Adults have a vast array of experiences to draw on as they learn, as opposed to children who are in the process of gaining new experiences (Merriam, 2001).

- Readiness to learn: Many adults have reached a point in which they see the value of education and are ready to be serious about and focused on learning (Merriam, 2001).

- Practical reasons to learn: Adults are looking for practical, problem-centered approaches to learning. Many adults return to continuing education for specific practical reasons, such as entering a new field (Merriam, 2001).

- Driven by internal motivation: While many children are driven by external motivators—such as punishment if they get bad grades or rewards if they get good grades—adults are more internally motivated (Merriam, 2001).

Based on these assumptions about adult learners, Knowles discussed four principles that educators should consider when teaching adults.

1. Because adults are self-directed, they should have a say in the content and process of their learning (Merriam, 2001).

2. Because adults have so much experience to draw from, their learning should focus on adding to what they have already learned in the past (Merriam, 2001).

3. Because adults are looking for practical learning, content should focus on issues related to their work or personal life (Merriam, 2001).

4. Additionally, learning should be centered on solving problems instead of memorizing content (Merriam, 2011).

I used the first three principles to guide the development of the proposed CPG. The NP participants had an input in the development of the content of the practice guideline based on knowledge at hand, literature reviews and professional experiences. During development of the guideline, expert panels, including two practicing physicians from the specialty practice site and a nursing professor with doctorate degree from Walden University, evaluated the content and made recommendations to ensure the validity of the content and its usability. The CPG was

intended to be a resource that NPs can follow in delivering comprehensive, safe, and effective pain management to patients with osteoarthritic pain.

The Appraisal of Guidelines Research and Evaluation (AGREE) II Model

CPGs are recommendations based on a summary of current best evidence that are systematically developed to assist practitioners to improve patient care (Barham et al., 1997). They are used in evidence-based medicine to help synthesize clinical experience and the best current scientific data when creating individualized patient-care plans. To ensure quality, guidelines must be developed in a systematic manner. As a result of the 2008 Medicare Improvements for Patients and Providers Act, the Institute of Medicine (IOM, 2011) published standards for guaranteeing CPG dependability. These standards included establishing transparency and evidence foundations for rating the strength of recommendations (IOM, 2011). CPG management involved different steps and required participation from different sectors such as a multidisciplinary guideline-development group (GDG) as well as consumers and patients (Moores et al., 2013). In addition, important clinical topics were identified using the Patient–Intervention–Comparison–Outcome (PICO) model, systematic literature searches and syntheses performed, recommendations were drafted using a structured evidence evaluation, and continued updates and revisions should be performed post publication (Cruz et al., 2013).

I utilized the AGREE II framework to guide the development of the CPG and to assess the quality of the guideline developed. The AGREE II is both valid and reliable and includes 23 key items organized within six domains (Walden University, 2019). The six domains are:

- Domain 1: Scope and purpose, which is concerned with the overall aim of the guideline, the specific health questions, and the target population;

- Domain 2: Stakeholder involvement focuses on the on the extent to which the overall aim of the guideline was developed by the appropriate stakeholders and represents the views of its intended users;

- Domain 3: Rigor of development relates to the process used to gather and synthesize the evidence and the methods to formulate and update recommendations;

- Domain 4: Clarity of presentation concerns the language, structure, and format of the guideline;

- Domain 5: Applicability pertains to the likely barriers and facilitators to implementation, strategies to improve uptake, and cost implications of applying the guideline; and

- Domain 6: Editorial independence is concerned with the formation of recommendations not being unduly biased with competing interests.

For a guideline to receive high AGREE scores, there must be a clear link between the proper collection and use of research evidence by qualified professionals and the development of trustworthy recommendations made in the guideline (Walden University, 2019). The higher the AGREE scores, the more confident users can be that the guideline developers used an evidence-based approach to reach their recommendations (Bouwen et al., 2010)

This system allows clinicians to evaluate more effectively the quality of clinical evidence and the applicability of current recommendations to the care of their patients (Guyatt et al., 2008). It is vital that health care practitioners critically evaluate CPGs to make well-informed decisions regarding treatment recommendations and formulary management (Cruz et al., 2015).

Relevance to Nursing Practice

CPGs are defined as a set of recommendations based on scientific evidence and designed to assist both healthcare professionals and users in selecting the most suitable diagnostic and/or therapeutic options to address a specific clinical condition (IOM, 2011). Although the implementation of CPGs has not been fully demonstrated to improve health outcomes (Brusamento et al., 2012), health professionals generally accept that clinical care must be evidence based and understand that CPGs are among the best means available to translate scientific evidence into clinical practice (IOM, 2011). Despite NPs' belief in evidence-based practice (EBP), current health care assessments indicate variability in clinical decisions with a low level of adherence to CPG recommendations (Brusamento et al., 2012). Many factors have been identified that could influence CPG implementation. These factors could act as either a barrier or an enabler in areas such as professional behavior and attitudes, patient characteristics, the professional-patient relationship, the organizational context, the guideline itself, and the wider environmental factors (Brusamento et al., 2012).

NPs' care should be evidence-based and would address patients' health needs rather than respond exclusively to patients' demands (AACN, 2006). CPGs seem to be the best available tool to this end. Allowing evidence-based medicine and CPGs to be incorporated into clinical practice is imperative in easing the management pressure on professionals and improving local leaders' participation in their design (Gene-Badia et al., 2016). The CPG can also be a part of an incentive scheme (i.e., pay-for-performance) laid out by the management structure. It can be part of a comprehensive information system and is sometimes continuously monitored. Hence, compliance with CPGs is used as a key indicator of professionals' performance in many health

care organizations (Hardy, 2019). This use turns it into a control mechanism to monitor

professional activities which serves as quality measure outcome in a practice setting. The result

of a standardized approach as set forth in a CPG may assure that all relevant information

regarding treatment plan, patient preference, and patient need is communicated between care

providers. The development of a CPG with the focus on improving communication between

healthcare providers during transitions of care could improve patient safety and satisfaction if

implemented (Hardy, 2019).

This project emphasized Essentials I, II, III, and VI of the American Association of

Colleges of Nursing (AACN) Essentials of Doctoral Education for Advance Nursing Practice

published in 2006, which are (a) Essential I: Scientific Underpinning for Practice prepares the

DNP graduate to use multidisciplinary theories and concepts to develop and evaluate new

nursing practices; (b) Essential II:Organizational and Systems Leadership for Quality

Improvement and Systems Thinking prepares the DNP graduate to lead organizational initiatives

that focus on improving both patient safety and the quality of care delivered to meet the needs of

the community served; (c) Essential III:Clinical Scholarship and Analytical Methods for

Evidence-Based Practice prepares the DNP graduate to critically analyze current relevant

literature resulting in the creation, implementation, and evaluation of quality improvement

initiatives focused on improving healthcare outcomes; and (d) Essential VI:Interprofessional

Collaboration for Improving Patient and Population Health Outcomes prepares the DNP graduate

to lead inter professional teams in the creation of scholarly products to include clinical practice

guidelines (AACN, 2006).

Local Background and Context

The setting of this doctoral project was a private pain management clinic with seven centers spread throughout the Southwest region of the United States. There were five NPs who assessed and determined interventional procedure option for treatment of pain for patients and three medical doctors who performs radiographic interventions for pain management at the practice sites. The clinic offered multimodal treatment to patients with acute, sub-acute, and chronic pain of various etiologies such as musculoskeletal disorders (i.e., OA of the major joints: shoulders, hips, knees, and spine), spinal stenosis, spinal fractures, headaches, neuropathies, complex regional pain syndrome, and other non-cancer-related pain. The pain clinic also offered interventional procedures for osteoarthritic pain such as such as joint steroid injections, trigger point injections, epidural steroid injections, radiofrequency ablations of nerves, and nerve blocks. Procedures for device implants such as interspinous spacers for spinal stenosis and spinal cord stimulator were also performed at the surgery center. Other procedures offered were kyphoplasty and vertibloplasty for spine vertebral fractures.

The setting of the project made the project feasible because the administrator/founder of the practice identified the need for a practice guideline and was supportive of the development and implementation of the guidelines in all seven practice centers. The administrator/president of the practice site, who is a physician, has the authority and granted the final approval for the CPG implementation in all practice sites once developed and published.

Definition of Terms

The following terms were used throughout this project:

Chronic pain: A type of pain that persists past the normal time of healing, which may be less than one month, or, more commonly, three months (IASP, 1994).

Clinical practice guideline (CPG): Statements that include recommendations intended to optimize patient care and that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (IOM,2011).

Evidence-based practice (EBP): The conscientious use of current best evidence in making decisions about patient care. It is a problem-solving approach to clinical practice and administrative issues that integrates a systematic search for and critical appraisal of the most relevant evidence to answer a pressing clinical question; one's own clinical expertise and patient preferences and values (Melnyk et al., 2014). The EBP process is a method that allows the practitioner to assess research, clinical guidelines, and other information resources based on high quality findings and apply the results to practice (AMSN, 2020).

Nurse practitioner (NP): Clinicians who blend clinical expertise in diagnosing and treating health conditions with an added emphasis on disease prevention and health management (AANP, 2020). NPs bring a comprehensive perspective and personal touch to health care (AANP, 2020).

Osteoarthritis (OA): The most common form of arthritis and known as degenerative *joint disease* or *"wear and tear" arthritis*. It occurs most frequently in the hands, hips, knees, and spine (CDC, 2020). With OA, the cartilage within a joint begins to break down, and the underlying bone begins to change. These changes usually develop slowly and get worse over time (CDC, 2020).

Role of the DNP Student

   I am an NP employed at the practice site, specializing in pain management. According to

the American Association of Nurse Practitioners (2020), NPs are licensed, autonomous clinicians

focused on managing people's health conditions and preventing disease. In the development of

this project, I performed various roles such as: researcher, leader, and evaluator.

   As a researcher, I did literature review to identify the evidence that will support the need

of the guideline in the practice site. I also conducted informal interviews with the NPs and the

administration to determine the need of the guideline at the practice site. This interview revealed

that there was currently no written guideline available for the treatment of OA. As a leader, I

coordinated with the administration and performed a needs assessment with various staff to

collect the information necessary in the development of the guideline. As an evaluator, while

treating patients, I noticed that the documentation of opioids prescribed were not consistent with

the CDC and ACR guidelines. I also was able to determine the most recent and appropriate

evidence using different tools available, with the guidance of my preceptor and my project

mentor in developing the CPG. In addition, I reviewed the results of expert panel and

stakeholder's/end-user's formative evaluations and determined the validity and usability of the

guideline. The development of this project emphasized Essentials VI of the AACN's Essentials

of Doctoral Education for Advance Nursing Practice published in 2006: Interprofessional

Collaboration for Improving Patient and Population Health Outcomes prepares the DNP graduate

to lead interprofessional teams in the creation of scholarly products to include clinical practice

guidelines (AACN, 2006). My motivation in developing this project was to improve the quality

of care rendered by the NPs in my practice setting and to deliver safe and effective care or

treatment to patients with OA pain. In completion of this project, I fulfilled the prerequisite required for the DNP degree.

CPGs are an important instrument for knowledge translation. Ideally, CPG was based on valid scientific evidence, critical assessment of that evidence, and objective clinical judgment that relates the evidence to the needs of practitioners and patients (Detsky, 2006). Since these judgments were a human endeavor, they naturally leave room for error and bias. The most significant problem in the development of sound CPGs was the lack of research that can be used to guide the development of comprehensive recommendations on clinical practice (Detsky, 2006). Another major issue that may affect the validity of the CPG was my professional experiences and the inherent influences from my personal experiences which may affect treatment recommendations due to my personal preferences (Detsky, 2006). I maintained awareness of how my own cognitive and affective biases might affect the outcome of the CPG (AMA, 2018). As an Asian individual, my personal view was that treatment of pain does not necessarily need a pain medication especially opioids unless the pain becomes unbearable and other treatment options failed. In improving the validity of the guideline, all sources of biases were recognized. To avoid these biases, the expert panel and the stakeholders reviewed the guideline's content validity and applicability.

Summary

The purpose of this doctoral project was to develop an evidence-based CPG for the treatment of osteoarthritic pain among elderly patients. The theory and model selected for the development of this CPG were the adult learning theory and the appraisal of guidelines research and evaluation (AGREE) II model. The adult learning theory principles by Knowles supported

and guided the development of the proposed CPG incorporating the input from the NPs. The

AGREE II model allowed the expert panel to evaluate more effectively the quality of clinical

evidence and the applicability of current recommendations to the care of patients with OA pain,

and to make well-informed decisions regarding treatment recommendations and formulary

management (Cruz et al, 2015). In the next section, I described the sources of evidence, ethical

protections, and the analysis and synthesis of the evidence that will be utilized for the

development of the CPG.

Section 3: Collection and Analysis of Evidence

Osteoarthritic pain especially of the lower back is the most frequent pain complaint among older adults and is associated with disability, reduced quality of life, and high economic costs (Goode et al, 2013). In 2013, the total national arthritis-attributable medical care costs and earnings losses among adults with arthritis were $303.5 billion or 1% of the 2013 US Gross Domestic Product (CDC, 2018). NPs in the facilities do not always follow recommended interdisciplinary pain management services as suggested by IOM (2011) and the opioid prescriptive guidelines established by CDC and ACR. The purpose of this DNP project was to develop an evidence-based CPG from recent evidence-based resources that have the potential to standardize and improve the quality of pain management used by NPs for older adults with OA in an outpatient setting.

This doctoral project was conducted in a private pain management clinic composed of seven centers spread throughout the Southwest region of the United States. The setting of the project was feasible since the administrator/founder of the practice identified the need of a practice guideline and was supportive of the development and implementation of the guidelines in all seven practice centers. This section presents the practice-focused question, sources of evidence methodology, and analysis and synthesis.

Practice-Focused Question

At the current clinical practice sites, there was no existing written guideline on the treatment for OA pain among elderly patients. Inconsistencies in following the opioid prescriptive guideline established by the CDC and ACR were also identified. Some of the NPs did not recommend interdisciplinary pain management services to their patients as recommended

by IOM (2011).   The practice-focused question was: Will an evidence-based clinical practice guideline related to pain management serve as a guide to be used by NPs to deliver safe and effective pain management to elderly patients with OA? Creating an evidence-based CPG will fill the gap in practice by providing NPs with a standardized procedure that they can use to improve the quality of their pain management practices to patients with OA. A standardized guideline based on the recommendations of different medical organizations, has the potential to decrease the pain of patients with OA and increase their QoL.

Sources of Evidence

I used two sources of evidence to develop the CPG, literature review and informal communication with the facility personnel. Selected articles relating to clinical guidelines on treatment of osteoarthritic pain were searched using the keywords: *clinical practice guideline, pain management, osteoarthritis, treatment of osteoarthritis, and chronic pain*. I combined each search term from each category with the Boolean operator AND to yield multiple search term combinations. For example, one search term combination I used was elderly adult AND chronic pain AND treatment   AND guidelines. These search term combinations were entered in electronic databases including Cochrane Library, CINAHL, and PubMed (including MEDLINE and PubMed Central), all of which were accessible through the Walden University Library and Google scholar. I placed the following search restrictions on my electronic database searches full text only; published after 2010; academic journals; osteoarthritis as subject and major heading; English language; age 65+; and USA.

There were no available written guidelines on the management of OA pain at the practice site and per informal conversations with the administrator of the practice site and NPs, they all

agreed that there was a need of a practice guideline to standardize the treatment for OA pain. Moreover, two practicing physicians from the practice sites and a professor from Walden as member of the of expert panel reviewed the content validity and the NPs reviewed the applicability of the CPG. The evidence obtained from the literature and standards of practice from different professional organizations were utilized to develop the evidence-based CPG. This CPG will be used as a resource to guide NPs with the most EBP standard of care for managing the pain of patients with OA.

Approach or Procedural Steps

After approval of Walden University IRB (approval # 09-15-20-0629674), the following steps, as described in the Walden University Manual for Clinical Practice Guidelines Development, were used to develop the CPG for treatment of osteoarthritic pain among elderly patients ages 65 years and older:

1. Reviewed current available evidenced based practice guidelines from different sources and articles regarding treatment of OA pain in elderly patients.

2. Reviewed the search results to determine whether they are relevant to the problem question, and then modify the search strategy if necessary. Search engine tools such as Zotero and Covidence was utilized in recording, tracing, organizing, and analyzing the literature gathered.

3. Categorized the levels of evidence using the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) framework.

4. Synthesized the evidence from the articles obtained from the review of the literature.

5. Developed a draft of the evidence-based CPG.

6. Stakeholders/end-users, identified by the administration, evaluated the guideline's usability.

7. Revised guideline based on the stakeholders' recommendations.

8. Expert panel completed a formative evaluation of the guideline's content validity using the AGREE- II instrument.

9. Revised the guideline based on the expert panel's recommendations.

10. Developed the final evidence-based CPG.

11. Disseminated the final report to the Administrator.

Ethical Protections

The aim of this project was to develop an evidence-based CPG from recent evidenced based resources that have the potential to standardize and improve the quality of pain management used by nurse practitioners for older adults with OA in an outpatient setting. The focus of the project was to develop a CPG which can be utilized for quality improvement; the project did not require an approval from the facility IRB. There were no patients included in this project since the guideline was developed for the NPs of the pain clinics. No identifiers of the experts and stakeholders involved in the evaluations of the CPG were collected. In addition, their names or the names of the facility was not identified in any written document about this project. Only the location based on the region in the U.S. was used to identify the facility.   The data collected from the expert panel and stakeholders' review were kept in a locked file cabinet in my home. I will destroy the documents after five years as required by Walden IRB. This DNP project supported the American Nurses Association (2015) Code of Ethics provision of

Professional Responsibility in Promoting a Culture of Safety. The written report of the results of the project did not identify the facility by name.

Analysis and Synthesis

The evidence gathered from the literature were recorded, tracked, organized, and analyzed using two electronic tools: Zotero and Covidence. Zotero is a reference manager that allowed the collection and organization of online research sources into a personal library; the web browser plug-ins were used to save a returned search result from an electronic database to a user's personal Zotero library (Zotero, n.d.). All the saved sources found in Zotero were imported to Covidence for analysis. The Zotero and Covidence browsers are research information system and an an online technology platform which facilitates all stages of a literature review, including title review, abstract review, full-text review, quality appraisal, and data extraction (Covidence, n.d.).

The analysis of the literature was conducted into two stages. First, each paper was categorized according to the level of evidence that it provides as a function of its research design. The JHNEBP framework was used to categorize the levels of evidence which are Level 1 (experimental study or meta-analysis of experiments); Level 2 (quasi-experimental study); Level 3 (nonexperimental study, qualitative study, or meta-synthesis); Level 4 (opinion of nationally recognized experts based on research evidence or expert consensus panel); and Level 5 (opinion of individual expert based on nonresearch evidence) (White et al, 2016) . Second, each paper was appraised for quality, and graded as A (high), B (good), or C (low), again according to JHNEBP.

The result of the analysis was integrated per outcome measure, such as clinically relevant outcomes, patient-reported outcomes, or compliance outcomes. The synthesis of the evidence resulted in a set of statements that formed the draft of the CPG. The usability and applicability of the guideline was reviewed for content validity and usability by the stake holders'/end users. The stakeholders were four nurse practitioners employed at the practice sites. After the review, the practice guideline was revised based on the recommendation and feedback from the stakeholders. The guideline was appraised for its methodological rigor by the expert panel team using the AGREE II instrument. The expert panel team was comprised of two physicians specialized in pain management and my practicum faculty with a doctorate degree in nursing. The guideline was revised per recommendation of the panel. The completed guideline will then be disseminated to the president/administrator of the practice site.

Summary

The purpose of this project was to develop an evidenced based CPG that could potentially standardize and improve the quality of care the NPs render to manage the pain of their patient's with OA through safe and effective approaches. In this section, I provided a detailed description of retrieval of the evidence-based literature related to treatment osteoarthritic pain among elderly patients. I discussed the use of the JHNEBP framework to categorize, appraise for quality, and grade the level of the evidence gathered.

The initial draft of the CPG was appraised for content quality and usability by the stakeholders and end-users. It was revised based on their recommendations. It was further reviewed for content validity and quality by the expert panel and subsequently revised and finalized based on their recommendations. The CPGs are systematically developed statements

which will assist NPs to make sound decisions regarding pain management for patients with OA (IOM, 1990).

In Section 4, I will discuss the literature findings and implications, including the synthesis of the selected studies, and recommendations for establishing a clinical practice guideline in the treatment osteoarthritic pain in a specific population.

Section 4: Findings and Recommendations

The local problem that was addressed in this project was the lack of written guideline on assessment and management of elderly patients with chronic osteoarthritic (OA) pain. The gap in practice identified was the inconsistencies in following the opioid prescriptive guidelines; decreased utilization of interdisciplinary pain management services; and the lack of implementation and adherence to the available EBP guidelines. The practice-focused question was: Will an evidence-based clinical practice guideline related to pain management serve as a guide used by NPs to deliver safe and effective pain management to elderly patients with OA? Using the Adult Learning Theory, the purpose of this project was to develop an evidence-based CPG from recent evidence-based resources that have the potential to standardize and improve the quality of pain management used by NPs for adults 65 years old and older with OA in an outpatient setting (Appendix E). Sources of evidence that were used were found in the Walden library and professional journals. The AGREE II appraisal instrument was used for analysis of results obtained from expert panelists. The instrument was accessed by the expert panel via the AGREE website and data were scored for each domain and reported using appraiser numbers instead of names or other identifying characteristics such as email addresses. Results were analyzed using descriptive statistics.

Findings and Implications

Three expert panelists provided evaluations of the evidence-based CPG. The results showed data from 23 items as well as each of the six domains. A percentage was calculated and reported for each domain. Acceptable scores for each domain were considered 50% and above; however, any domain that scored under 75% was reviewed. High quality guidelines are those

with a Domain 3 score >70% (Brouwers et al., 2010). The lowest domain score obtained was above 90%. The results are presented in table 1.

Table 1.

EBCPG AGREE II Appraisal of the Six Domains

Domains	*Percentage*
1- Scope and Purpose	100%
2.-Stakeholders Involvement	95.2%
3- Rigour of Development	97.6 %
4- Clarity of Presentation	100%
5- Applicability	97.6 %
6- Editorial Independence	92.9%

Domain one and four scored 100%, domain two scored 95.2%, domain three and five scored 97.6 %, and domain six scored 92.9.%. The overall guideline assessment scored by the three expert panelists was 100%. The AGREE II instrument included an area where the expert panel reviewer could comment, if needed. One of the reviewers commented about "having a detailed advice or tools on how the CPG recommendations can be applied into practice." Three other reviewers commented that the CPG overall was "well-written, very clear and will be a useful education tool for the stakeholders." One unanticipated event was the difficulty of some expert panelist to register and access the AGREE II website. To facilitate completion of the evaluation, I sent them an electronic copy which they completed and returned via email.

Implementation of the evidence-based CPG will provide an educational tool to NPs to effectively treat patients with OA pain. The development of this evidence-based CPG has the potential for positive social change for NPs and patients. NPs will have a resource to use as a guide to develop plans of care that have the potential to reduce patient's pain, monitor patient's untoward reactions, dependency, and abusive attitudes towards opioids (CDC, 2019). Effective management of OAs patients pain have the potential to decrease their suffering and increase their QoL.

Recommendations

The CPG was developed to address the gap in practice related to inconsistencies in following the opioid prescriptive guidelines; decreased utilization of interdisciplinary pain management services; and the lack of implementation and adherence to the available evidence-based practice guidelines. The evidence-based CPG providing the most recent evidenced based treatment guideline for OA pain has the potential to standardize the practice of the NPs and improve quality of care rendered to those patients. A guideline has the potential of influencing care outcomes, when effectively disseminated and implemented. I therefore make the following recommendations for implementation:

- Implement the CPG in the organization's seven practice sites. Develop a PowerPoint presentation to educate the NPs about the CPG. This can be presented virtually using meeting apps such as google meet or zoom. The guideline can be presented in approximately one hour allowing time for the NPs to ask questions at the end of each session. This process can be repeated every week for three consecutive weeks to increase

the opportunity for all NPs to attend a session. Administering a pre- and posttest at each

session will help to determine the NPs knowledge gained from the educational activity.

- Provide each of the seven practice sites with a printed copy of the guideline. This can be

  kept in the NPs offices. In addition, an electronic format of the CPG can be made

  available on the mainframe computers at the different practice sites.

- Evaluate compliance to the CPG treatment recommendations, by the practicing

  collaborative physicians, in the yearly performance evaluation of the NPs.

- Reevaluate the CPG every three years or when new recommendations for OA pain

  treatment are published.

- Cost considerations: cost related expenses are very minimal such as cost for printing

  paper, and folders for the CPG that will be kept in the NPs offices. The time allocated for

  the the learning activity will be taken from the administrative time of the NPs allotted for

  continuing educational activities and meetings.

Contribution of the Doctoral Project Team

The individuals who participated as the expert panel, which provided formative

evaluation of the CPG, consisted of one DNP practicum professor who is a nurse practitioner

specialized in neuroradiology and interventional radiology and, two physicians who specialized

in interventional pain management and anesthesiology. The panel of experts were contacted via

email, mobile call, and messaging system (text messages). They all agreed to be part of the

expert panel. The panel received the expert panel packet via email. There were questions

regarding how to register in the AGREE II site, as well as delays when attempting to register due

to logon name and password issues. Some of the expert panelists encountered issues with

accessing the website. I downloaded AGREE II tool, converted it to an electronic form, and emailed it to the expert panelists. The AGREE II site assigned the panelists random numbers for anonymity. When reviewing feedback from panelists, their identifying information was removed and replaced by numbers so that there was no way to connect the information on the questionnaire to the individual expert. The appraisal instruments were scored and described using descriptive statistics. The scores for each six domains were 93% and above. The panel recommended that the project could be used as resource material for NPs at the local pain clinic practice sites as written. The evidence-based CPG will be disseminated to the administrator of the pain clinic practice sites.

The organization focuses on congruent care practices, which means all practice sites uniformly use the same policies, procedures, and practice guidelines. The company has seven practice clinics with five practicing NPs and three physicians who all work together when deciding to implement a new guideline in the health care system. Presenting this project as an NP will result in working directly with the president of the company and two other physicians at the practice site. My plan is to work with the president of the company to obtain permission to implement the CPG for the NPs at the seven practice sites. In fact, prior to CPG development, I have already obtained an approval from the president of the company regarding the project. Two of the three physicians in the pain management practice were also members of the expert panel who evaluated the CPG.

<div align="center">**Strengths and Limitations of the Project**</div>

Strengths of the project directly relates to positive feedback and recommendation to implement CPG by the expert panel members. The member of the expert panel and stakeholders

expressed their beliefs that the guideline would be beneficial for NPs decision-making in treating

OA pain. The evidence-based CPG has the potential to improve NP's knowledge and awareness

in providing safe and effective treatment to patients with OA pain. This CPG can be used in an

outpatient setting in different specialties: pain management, orthopedic/rheumatology, and

primary care. Transferability is a strength. Although one panel member commented that the cost

of implementation was not addressed. The cost was not included in the CPG; however, this was

addressed in the recommendations for implementation. One of the limitations identified was that

some of the expert panelists were challenged to use the AGREE II site. It is recommended that

for future projects, the AGREE II instrument is downloaded and placed in Survey Monkey. This

site is more user friendly for the expert panel.

Summary

The findings and implications for this project were centered around the use of and

analysis of the AGREE II tool instrument by the expert panel. A descriptive statistic was utilized

to calculate the rate of each domains and over all assessment of the CPG. The panel favored the

use of the CPG and provided recommendations that the CPG is well written, comprehensive, and

well researched. A detailed recommendation to address the gap in practice and the

implementation plans were also set. In Section 5, I will provide a self-analysis and summary of

the project including challenges, solutions, and insights.

Section 5: Dissemination Plan

This project will be disseminated to the administrator of the seven practice sites and I will have the ability to present the CPG to my organization as a practicing NP. There are many steps involved when presenting a new guideline for implementation within my organization. An educational activity will be prepared for the NPs and copies both printed and digital of the CPG will be made available at the seven practice sites. The CPG will be a resource tool to be used by the NPs in treating OA pain among elderly patients in the seven pain management clinics in the Southwest part of USA.

Analysis of Self

My nursing career started after being a registered nurse in an adult intensive care unit. I found a passion for educating and making sure that the patient obtained the best possible treatment for their diseases. I felt an obligation and believed it was my responsibility to acquire the knowledge needed to provide the best care to my patients. This sense of duty led to me to earn my MSN as a certified family nurse practitioner, and now my DNP. Providing my patients with the best care by knowing how to make changes that are centered around them is very important. Rules and guidelines that help to provide evidence-based patient centered care uniformly are appreciated by practitioners and patients, which is why I chose to develop this CPG.

Practitioner

As an NP in pain management, I have identified issues that needed urgent attention such as the inconsistent approach of the NPs in treating OA pain among elderly patients. After going through the experience of completing this project, it provided me with an appreciation of how

important it is to have nurses at all levels of education, especially those with higher levels of education and other member of the health care team such as the physicians. When looking for my panel of experts, I needed to consider their education levels and ability to use and understand the appraisal instrument adequately. My end goal is to find a part-time faculty position teaching online, participate in conferences as a lecturer, conduct quality research/studies, and continue to work as an NP at my current practice site.

Scholar

The path to my DNP has been one filled with great experiences. As a scholar, I focused on my courses which provided me with the knowledge to utilize evidence-based information to develop this guideline. Through this journey, I learned to look at the work I do in a different light. I was able to identify problems; research current literature regarding the problem; devise a plan; and implement and evaluate changes. The education I received has helped me to see a way to help change nursing to align with current recommendations and evidence-based research.

Project Manager

As the project manager, I was able to manage the project and the expert panel members. I researched literature that helped support my project. I was then able to identify professionals who would be able to perform an appraisal of the project using the selected instrument. I found that in my search for panel members, I considered their education level, position, and involvement with patient care. I found that panelists were eager to help but were busy and took longer than expected to complete the appraisal. I found that being a project manager was stressful but gratifying, as the result will be beneficial to practitioners and patients.

Challenges, Solutions, and Insights Gained

The challenges faced during the process of completing this project were both personal and academic. Managing my time with the requirements of the program and my responsibilities with work and family were challenging. Working on my project, tending to my family, and my job were priority. There were personal issues that arose during the entire course of my study, i.e., death in family, sickness, and the COVID 19 pandemic which brought a lot of changes and delays in how things are done, not only at the practice site, but in almost all industry. The biggest academic challenge was completing the revisions that were needed to ensure that my project was well-written. Another challenge involved using the AGREE II website for the first time and engaging my expert panelists of how to use the website. I learned so much through this experience and understand how invested one needs to be when proposing a change in practice.

Summary

Searching through the literature was a tedious task, especially selecting the best evidence for the EBCPG and synthesizing the evidence since there are numerous published guidelines for treatment of OA and chronic pain. As a scholar, I identified the need for this guideline in my practice site. Working through challenges involving review of literature, writing a guideline, and having an appraisal completed by a diverse panel of experts required a tremendous amount of time and effort. Patient-centered care is imperative, and our duty as professionals is to deliver the best, safe and effective care to our patients. Creation and implementation of this evidence-based CPG has the potential to standardize NP's practice and improve the quality of care they provide to their patients.

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Appendix A: Expert Panel Packet

Disclosure to Expert Panelist Form for Anonymous Questionnaires

To be given to an expert panelist prior to collecting questionnaire responses—note that obtaining a "consent signature" is not appropriate for this type of questionnaire and providing respondents with anonymity is required.

Disclosure to Expert Panelist

You are invited to take part in an expert panelist questionnaire for the doctoral project that I am conducting.

Questionnaire Procedures

If you agree to take part, I will be asking you to provide your responses anonymously, to help reduce bias and any sort of pressure to respond a certain way. Panelists' questionnaire responses will be analyzed as part of my doctoral project, along with any archival data, reports, and documents that the organization's leadership deems fit to share. If the revisions from the panelists' feedback are extensive, I might repeat the anonymous questionnaire process with the panel of experts again.

Voluntary Nature of the Project

This project is voluntary. If you decide to join the project now, you can still change your mind later.

Risks and Benefits of Being in the Project

Being in this project would not pose any risks beyond those of typical daily professional

activities. This project's aim is to provide data and insights to support the organization's success.

Privacy

I might know that you completed a questionnaire, but I will not know who provided which responses. Any reports, presentations, or publications related to this study will share general patterns from the data, without sharing the identities of individual respondents or partner organization(s). The questionnaire data will be kept for a period of at least 5 years, as required by my university.

Contacts and Questions:

If you want to talk privately about your rights in relation to this project, you can call my university's Advocate via the phone number 612-312-1210. Walden University's ethics approval number for this study is (Student will need to complete Form A in order to obtain an ethics approval number).

Before you start the questionnaire, please share any questions or concerns you might have.

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Appendix B: AGREE II Instrument

Domain 1. Scope and Purpose

1. The overall objective(s) of the guideline is (are) specifically described.

2. The health question(s) covered by the guideline is (are) specifically described.

3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.

Domain 2. Stakeholder Involvement

4. The guideline development group includes individuals from all the relevant professional groups.

5. The views and preferences of the target population (patients, public, etc.) have been sought.

6. The target users of the guideline are clearly defined.

Domain 3. Rigor of Development

7. Systematic methods were used to search for evidence.

8. The criteria for selecting the evidence are clearly described.

9. The strengths and limitations of the body of evidence are clearly described.

10. The methods for formulating the recommendations are clearly described.

11. The health benefits, side effects, and risks have been considered in formulating the recommendations.

12. There is an explicit link between the recommendations and the supporting evidence.

13. The guideline has been externally reviewed by experts prior to its publication.

14. A procedure for updating the guideline is provided.

Domain 4. Clarity of Presentation

15. The recommendations are specific and unambiguous.

16. The different options for management of the condition or health issue are clearly presented.

17. Key recommendations are easily identifiable.

Domain 5. Applicability

18. The guideline describes facilitators and barriers to its application.

19. The guideline provides advice or tools on how the recommendations can be put into practice.

20. The potential resource implications of applying the recommendations have been considered.

21. The guideline presents monitoring or auditing criteria.

Domain 6. Editorial Independence

22. The views of the funding body have not influenced the content of the guideline.

23. Competing interests of guideline development group members have been recorded and addressed.

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Appendix C: Johns Hopkins Nursing Evidence Level and Quality Guide

Levels of Evidence Johns Hopkins Nursing Evidence Based Practice

Evidence Levels	Quality Guides
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	**A High quality**: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi experimental, or quasi-experimental studies only, with or without meta-analysis	**B Good quality**: Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
Level III Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis Qualitative study or systematic review with or without a meta-synthesis	**C Low quality or major flaws**: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

Evidence Levels	Quality Guides
Level IV Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence Includes: Clinical practice guidelines Consensus panels	**A High quality**: Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **B Good quality**: Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **C Low quality or major flaws**: Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years

Evidence Levels	Organizational Experience
Level V Based on experiential and non-research evidence Includes: Literature reviews Quality improvement, program or financial evaluation Case reports Opinion of nationally recognized experts(s) based on experiential evidence	**A** <u>High quality</u>: Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence **B** <u>Good quality</u>: Clear aims and objectives; consistent results in a single setting; formal quality improvement or financial or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence **C** <u>Low quality or major flaws</u>: Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial or program evaluation methods; recommendations cannot be made **<u>Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference</u>**: **A** <u>High quality</u>: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field **B** <u>Good quality</u>: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions **C** <u>Low quality or major flaws</u>: Expertise is not discernable or is dubious; conclusions cannot be drawn

Dang, D., & Dearholt, S. (2017). *Johns Hopkins nursing evidence-based practice: model and guidelines.* 3rd ed. Indianapolis, IN: Sigma Theta Tau International. www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html

Appendix D. Clinical Practice Guideline for Treatment of Osteoarthritic Pain Among

Elderly Patients

Objective

The purpose of this Doctor of Nurse Practice (DNP) project is to develop an evidence-based clinical practice guideline (CPG) from recent evidence-based resources that have the potential to standardize and improve the quality of pain management used by nurse practitioners (NPs) in treatment for adults 65 years old and older with Osteoarthritis (OA) in an outpatient setting.

Problem Statement

Will an evidence-based clinical practice guideline related to pain management serve as a guide to be used by NPs to deliver safe and effective pain management to elderly patients with OA?

Target Population

This CPG is created to serve as a guide for nurse practitioners in different pain clinic practice sites in delivering safe and effective pain management to elderly patients with OA.

Guideline Monitoring

The guideline should be reevaluated every three years or when new recommendations for OA pain treatment are published. Barriers to the application of this guideline should be addressed as they arise by the practitioner and before implementation. Barriers may be related to NP's knowledge (e.g., lack of awareness and lack of familiarity), barriers that affect NP's attitude (e.g., lack of agreement, lack of motivation) and external barriers (e.g., patient factors such as insurance coverage and resources)**.**

Introduction

OA is the most common form of arthritis, affecting an estimated 302 million people worldwide and is a leading cause of disability among older adults (Kolansinki et al., 2020). The most affected appendicular joints are the knees, hips, and spine characterized by pathology involving the whole joint, including cartilage degradation, bone remodeling, osteophyte formation, and synovial inflammation, that leads to pain, stiffness, swelling, and loss of normal joint function (Kolasinski et al., 2020). Spondylosis is a general term referring to age-related wear and tear that affect elements of the cervical, thoracic and lumbar spine over time; areas affected include the intervertebral disks, facet joints, and other connective-tissue structures (Theodore, 2020).

Pain in OA is not simply attributable to the structural changes in the affected joint, but the result of interplay between structural change, peripheral and central pain processing mechanisms and neuroplastic changes in the nociceptive system, such as peripheral and central sensitization that facilitate the pain process (Clauw and Hassett, 2017; Villafañe, 2018). Despite conflicting evidence, several authors have concluded that a possible explanation for chronification of pain in the knee, hip, low back pain, shoulder, and hand, in the absence of concomitant worsening in joint degeneration, can be explained by central sensitization (Villafane, 2018). OA pain may also be aggravated by general factors such as metabolic changes and diabetes mellitus, genetic and psychological factors. The weight of such factors may determine the pain pattern in individual patients (Villafane,2018).

This CPG will serve as a guide for NPs and patients in engaging shared decision-making that accounts for patients' values, preferences, and comorbidities treatment decisions for the

management of OA pain. The level of evidence was categorized according to the Levels of

Evidence Johns Hopkins Nursing Evidence Based Practice (Appendix A).

Inclusion Criteria

 1. Adult patients ages 65 and older

 2. Patients with hip, *low back and knee pain due to OA

  * Low back pain is defined as pain of musculoskeletal origin extending from the

  lowest rib to the gluteal fold that may at times extend as somatic referred pain into

  the thigh (above the knee).

Exclusion Criteria

1. Hip, low back and Knee pain due

a. Tumors or neoplasms

b. Infection

c. Metabolic disease

d. Fracture

e. Vascular disease

f. Other inflammatory conditions of joints other than OA

g. Other structural/mechanical defects i.e., torn meniscus, loose body, herniated discs,

spondylolysis and spondylolisthesis, spinal stenosis with neuroclaudication

This treatment guideline will focus on non-surgical treatments for knee, hip, and spine pain due to OA. It is presented in three sections beginning on page 4-24:

Part I: Nonsurgical Treatment Guideline for Knee Pain due to OA

Part II: Nonsurgical Treatment Guideline for Hip Pain due to OA

Part III: Nonsurgical Treatment Guideline for Lower Back Pain due to OA

I.   **Non-Surgical Treatment Guideline for Knee pain due to OA**

Treatment	Recommendation	Level of Evidence/Quality ratings	Comments	Source of Evidence
Participation in self-management programs such as symptom management activities like exercise, relaxation, communication, healthy eating, managing medication and managing fatigue.	Strongly recommended	Level II, III, IV Good- Low	Although effect sizes are generally small, the benefits of participation in self-efficacy and self-management programs are consistent across studies, and risks are minimal.	Safari et al., 2020 Kolansinski et al., 2019 Department of Veteran Affairs / Department of Defense (VA/DOD), 2020 Center for Disease Control and Prevention (CDC), 2019 American Academy of Orthopedic Surgeons (AAOS), 2013
Exercises Tai Chi	Strongly recommended	Level I, III, IV Good	There are some encouraging evidence suggesting that tai chi may be effective for pain control in patients with knee OA. RCT showed improved physical function, depression, medication use, and quality of life and is comparable to physical therapy	Lee et al., 2008 Wang et.al., 2016 Kolansinski et al., 2019 VA/DOD, 2020
Dietary weight management Weight loss for patients with symptomatic osteoarthritis of the knee and a BMI ≥ 25	Strongly Recommended	Level I, II, IV Good	Long-term weight loss between 10–19.9% of baseline body weight has substantial clinical and mechanistic benefits such as significantly improved physical health related quality of life (HRQL), and a clinically important reduction in pain and improvement in function.	Messier et al., 2018 Kolansinski et al., 2019 AAOS, 2013

			Weight-loss interventions may provide small to moderate improvements in pain and disability for OA compared to minimal care.	Robson et al., 2020
Topical NSAIDS	Strongly recommended	Level I, II, IV High	RCTs and systematic reviews showed greater reduction of pain and better outcomes and is recommended for elderly patients and who are at risk for adverse gastric, cardiovascular and renal effects. When selecting a topical NSAID, absorption and bioavailability are important because of heterogeneity among topical drug formulations. Etofenamate have a bioavailability of >20% and evidence for accumulation in synovial tissues, with efficacy demonstrated as improvement in pain and function in real-life studies of OA patients. Diclofenac also shows good efficacy alongside evidence that diclofenac accumulates in the synovium.	Bannuru et al., 2019 Molly et al., 2018 Kolansinski et al., 2020 AAOS, 2013 Rannou et al, 2016

Oral NSAIDS	Strongly recommended	Level I, IV High	Oral NSAIDs remain the mainstay of the pharmacologic management of OA regardless of anatomic location versus over other all available oral medications. * Not recommended for patients with cardiovascular risks and frailty.	Nissen et al., 2016
1. COX 2 inhibitors + PPI	Recommended for patients with higher risk of upper GI bleeding		COX-2 inhibitors have fewer GI adverse effects.	Bannuru et al., 2019 Kolansinski et al., 2020 VA/DOD, 2020
2. NSAIDS + PPI	Conditionally recommended for those without comorbidities		The use of NSAIDs maybe associated with renal insufficiency, hypertension, and cardiac-related events.	Department of Health and Human Services (HHS), 2019 AAOS, 2013
Intra articular (IA) Corticosteroid	Strongly recommended	Level II, IV High	Effective for exacerbation of pain with short term effect. IA corticosteroid injection in knee OA was shown to be safe with no negative impact on structural changes.	Bannuru et al., 2019 Kolansinski et al., 2020 Pelletier et al., 2020
Gait Aids i.e. cane	Strongly recommended.	Level II, IV, V Good	The use of assistive devices has a large impact on ambulation, joint stability, or pain.	Fang et al., 2014 Kolansinski et al., 2020
Tibiofemoral Brace	Recommended	Level I Good IV High	The use of assistive devices has a large impact on ambulation, joint stability, or pain. There is a concern that not all patients will be able to tolerate the associated	Yu et al, 2016 Kolansinski et al., 2020

			inconvenience and burden associated with bracing.	
Patellofemoral brace	Conditionally Recommended	Level I- Good IV- Good	Multidisciplinary non-operative program improved pain and function in persons with tibiofemoral OA. However, wearing a patellofemoral did not appear to provide additional benefits. There is a concern that not all patients will be able to tolerate the associated inconvenience and burden associated with bracing.	Yu et al., 2016 Kolansinski et al., 2020
Kinesiotaping	Conditionally Recommended	Level IV- High V- Good	Permits range of motion of the joint to which it is applied. Literature reviews showed that kinesiotaping is effective in improving pain and joint function in patients with knee OA.	Kolansinski et al., 2020 Melese et al., 2020
Cognitive Behavioral Therapy (CBT)	Conditionally Recommended	Level I, IV Good- High	CBT was inferior to pharmacological treatment for pain in a randomized trial. Limited evidence for pain control in OA. Trials however showed improvement in patient's perception of pain, functional capacity, health related quality of life, negative mood, fatigue and disability conditions other than OA.	Faraenkel et al., 2020 Kolansinski et al., 2020
Yoga	Conditionally Recommended	Level I, IV Good - High	Far less studied but may be helpful in OA through a similar blend of physical and psychosocial factors	Kolansinski et al., 2020

			Yoga is an acceptable and safe intervention, which may result in clinically relevant improvements in pain and functional outcome associated with a range of musculoskeletal conditions such as OA.	Deepeshwar et al., 2018
Thermal intervention (heat and cold)	Conditionally recommended	Level II, IV Good- High	Method of delivery varies considerably in publish reports. Short duration benefit, heterogeneity of modalities.	Uludağ & Kaşikçi, 2018 Kolansinski et al., 2020
Topical Capsaicin cream	Conditionally recommended	Level IV Good - High	Small effect sizes and wide confidence intervals in the available literature.	Kolansinski et al., 2020 VA/DOD, 2020
Duloxetine	Conditionally recommended	Level II, IV Good	Evidence suggests that duloxetine has efficacy in the treatment of OA when used alone or in combination with NSAIDs; however, there are issues regarding tolerability and side effects. May offer Duloxetine as an alternative to adjunct therapy for patients with inadequate response to NSAIDs.	Kolansinski et al., 2020 Wang et al., 2015 VA/DOD, 2020
Tramadol	Conditionally recommended *for patients who have contraindication to NSAIDs, other therapies ineffective	Level IV Good	Clinical trials have demonstrated some symptomatic efficacy, though concerns regarding potential adverse effects remain. If an opioid is being considered, tramadol is conditionally recommended over non tramadol opioids	Kolansinski et al., 2020 AAOS, 2013

	or have no surgical options			
Radiofrequency Ablation of nerve	Conditionally recommended	Level II - High IV High	Systematic review demonstrated geniculate nerve thermal RFA to be a superior nonsurgical treatment of knee OA compared with NSAIDs and IA corticosteroid injections. None of the RCTs reported any serious adverse reactions with geniculate nerve thermal RFA, as opposed to known cardiovascular, gastrointestinal, and renal AEs for NSAIDs and accelerated cartilage loss and periprosthetic infection risk for IA corticosteroid injections. Heterogeneity of techniques and controls used and lack of long-term safety data	Chen et al., 2020 Kolansinski et al., 2020
Acetaminophen	Unable to recommend for or against *	Level II – Low Level IV- Good	* Conditionally not recommended especially to patients with hepatic comorbidities	Kolansinski et al., 2019 VA/DOD, 2020 AAOS, 2013

Acupuncture	Unable to recommend for or against *Symptomatic OA	Level II - Low IV - High	RCT in a single setting study in 2005 showed improvement in knee function for 8-week duration No recent large scale RCT conducted. There is insufficient evidence available.	Witt et al., 2005 HHS, 2019 AOOS, 2013 VA/DOD, 2020
Fish Oil	Unable to recommend for or against	Level I – Good	Recent RCT showed fish oil significantly reduced OA-specific pain) and burden compared with no fish oil treatment; reductions were correlated with improvements in microvascular function and well-being in overweight/obese older adults. No additional benefit of a high-dose fish oil compared with low-dose fish oil. Fish oil appeared to have better efficacy in reducing pain at 2 years. Small scale studies and needs further studies.	Howe et al., 2020 Hill et al., 2016 VA/DOD, 2020
Insoles- lateral and medial wedge	Not recommended	Level IV Good	The currently available literature does not demonstrate clear efficacy of lateral or medial wedged insoles	Kolansinski et al., 2020 AAOS, 2013
Colchicine	Not recommended	Level II, IV Good	Colchicine reduced inflammation and high bone turnover biomarkers but did not reduce symptoms over a 16-week study period.	Leung et al., 2020 Kolansinski et al., 2020

			Potential adverse effects and drug interactions, may occur with use of this medication.	
Vitamin D	Conditionally recommended against	Level II IV Good	Number of trials demonstrated small effect sizes with vitamin D treatment, while others have shown no benefit and pooling data across studies	Ong et al., 2018 Pilz et al., 2016 Kolansinski et al., 2020
Massage Therapy	Conditionally recommended against	Level IV, V High	Studies addressing massage have suffered from high risk of bias (4/7).	Nelson & Churilla, 2017 Kolansinski et al, 2020
Opioids, pain patches	Conditionally recommended against in recognition that they may be used under certain circumstances particularly when alternatives have been exhausted. *	Level II -Good Level III- Good IV-High	Very modest benefits of long-term opioid therapy and a high risk of toxicity and dependence. Recent systematic review and meta-analysis suggests that less pain relief occurs during longer trials in the treatment of non-cancer chronic pain	Busse et al., 2018 Kolansinski et al., 2020 CDC, 2018 VA/DOD, 2020 AOOS, 2013
Hyaluronic Acid	Conditionally recommended against	Level II, IV Low	Hyaluronic acid has shown varied results through several clinical trials (Bowman et al. 2018).	Bowman et al., 2018 Kolansinski et al., 2020
Therapeutic Ultrasound (TU)	Not Recommended	Level IV Low	There was little evidence that TU is more effective than placebo for pain treatment in a range of musculoskeletal conditions.	HHS, 2019
Aquatic Exercises	Not recommended	Level IV Good	Aquatic exercise was not recommended for patients who suffered from frailty due to potential risk of accidental injury.	Kolansinski et al., 2020 VA/DOD, 2020

Bisphosphonates, glucosamine, chondroitin sulfate, hydroxychloroquine, and methotrexate,	Strongly recommended against	Level IV High/Good	Efficacy has not been demonstrated and given their risk of toxicity	Kolansinski et al., 2020 VA/DOD, 2020 AOOS, 2013
Platelet rich plasma and tumor necrosis inhibitors and interleukin 1 receptor antagonist	Strongly recommended against	Level IV High/Good	* Efficacy has not been demonstrated and given their risk of toxicity.	Kolansinski et al., 2020 VA/DOD, 2020 AOOS, 2013
Transcutaneous electrical stimulation (TENS) with or without pulsed vibration therapy	Strongly recommended against	Level I, IV Good	RCTs revealed a non-significant pain relief effect. Few trials and absence of adequate data	Iijima et al., 2020 Kolansinski et al., 2020

II. Non-Surgical Treatment Guideline for Hip Pain due to OA

Treatment	Recommendation	Level of Evidence/Quality ratings	Comments	
Participation in self-management programs such as symptom management activities like exercise, relaxation, communication, healthy eating, managing medication and managing fatigue	Strongly recommended	Level II, III, IV Good	Although effect sizes are generally small, the benefits of participation in self-efficacy and self-management programs are consistent across studies, and risks are minimal.	Wainwright et al., 2020 Kolansinski et al., 2010 Department of Veteran Affairs / Department of Defense (VA/DOD), 2020 Center for Disease Control and Prevention (CDC), 2019 AAOS, 2017

Treatment	Recommendation	Level of Evidence	Comments	
Exercise Tai Chi	Strongly recommended	Level I, IV High	RCT showed improved physical function, depression, medication use, and quality of life and is comparable to physical therapy.	Want et al, 2016 Kolansinski et al., 2020 AAOS, 2017
Dietary weight management **Weight loss for patients with symptomatic osteoarthritis of the knee and a BMI ≥ 25**	Strongly Recommended	Level I, IV High	Long-term weight loss between 10–19.9% of baseline body weight has substantial clinical and mechanistic benefits such as significantly improved physical HRQL, and a clinically important reduction in pain and improvement in function (Messier et al., 2018).	Messier et al., 2018 Kolansinski et al., 2020 AAOS, 2017
Oral NSAIDS only 1. COX-2 inhibitors + PPI 2. NSAIDS + PPI	Strongly recommended Recommended for patients with higher risk of upper GI bleeding Conditionally recommended for those without comorbidities *	Level I, II High	Oral NSAIDs remain the mainstay of the pharmacologic management of OA regardless of anatomic location versus over other all available oral medications. * Not recommended for patients with cardiovascular risks and frailty. COX-2 inhibitors have fewer GI adverse effects. The use of NSAIDs maybe associated with renal insufficiency, hypertension, and cardiac-related events.	Nissen et al., 2016 Bannuru et al., 2019 Kolansinski et al., 2020 VA/DOD, 2020 Department of Health and Human Services (HHS), 2019 AAOS, 2017
Ultrasound and imaging guided- Intra articular (IA) Corticosteroid Injection	Strongly recommended to improve function and	Level II, IV High	Ultrasound and imaging guided steroid injection helps ensure accurate drug delivery into the joint. IA corticosteroid injection proved to be an efficacious therapy in both	Kolansinski et al., 2020 Zhong et al., 2019

	reduce pain in the short-term for patients with symptomatic osteoarthritis of the hip.		immediate and delay pain reduction for hip OA patients within 12 weeks.	
Gait Aids i.e. cane	Recommended	Level IV Good	Use of assistive devices has large impact on ambulation, joint stability, or reduction of pain.	Fang et al., 2014 Kolansinski et al., 2020
Cognitive Behavioral Therapy (CBT)	Conditionally Recommended	Level I, IV Good-High	CBT was inferior to pharmacological treatment for pain in a randomized trial. Limited evidence for pain control in OA. Trials however showed improvement in patient's perception of pain, functional capacity, health related quality of life, negative mood, fatigue and disability conditions other than OA.	Faraenkel et al., 2020 Kolansinski et al., 2020
Thermal intervention (heat and cold)	Conditionally recommended	Level II, IV Good, High	Method of delivery varies considerably in publish reports. Short duration benefit, heterogeneity of modalities.	Uludağ & Kaşikçi, 2018 Kolansinski et al., 2020
Duloxetine	Conditionally recommended	Level II, IV Good	Evidence suggests that duloxetine has efficacy in the treatment of OA when used alone or in combination with NSAIDs; however, there are issues regarding tolerability and side effects. May offer Duloxetine as an alternative to adjunct therapy for patients with inadequate response to NSAIDs.	Kolansinski et al., 2020 Wang et al., 2015 VA/DOD, 2020

Tramadol	Conditionally recommended for patients have contraindication to NSAIDs, other therapies ineffective or have no surgical options	Level IV High	Clinical trials have demonstrated some symptomatic efficacy, though concerns regarding potential adverse effects remain. If an opioid is being considered, tramadol is conditionally recommended over non tramadol opioids	Kolansinski et al., 2020 AAOS, 2073
Acetaminophen	Unable to recommend for or against *	Level II – Low Level IV- Good	* Conditionally not recommended especially to patients with hepatic comorbidities	Kolansinski et al., 2019 VA/DOD, 2020 AAOS, 2017
Acupuncture	Unable to recommend for or against *Symptomatic OA	Level II - Low IV - High	RCT in a single setting study in 2005 showed improvement in knee function for 8-week duration. No recent large scale RCT conducted. There is insufficient evidence available.	Witt et al., 2005 HHS, 2019 AOOS, 2017 VA/DOD, 2020
Fish Oil	Unable to recommend for or against	Level I – Good	Recent RCT showed fish oil significantly reduced OA-specific pain) and burden compared with no fish oil treatment; reductions were correlated with improvements in microvascular function and well-being in overweight/obese older adults. No additional benefit of a high-dose fish oil compared with low-dose fish oil. Fish oil appeared to have better efficacy in reducing pain at 2 years.	Howe et al., 2020 Hill et al., 2016

			Small scale studies and needs further studies.	VA/DOD, 2020
Insoles- lateral and medial wedge	Not recommended	Level IV Good	The currently available literature does not demonstrate clear efficacy of lateral or medial wedged insoles	Kolansinski et al., 2020 AAOS, 2013
Colchicine	Not recommended	Level II, IV Good	Colchicine reduced inflammation and high bone turnover biomarkers but did not reduce symptoms over a 16-week study period. Potential adverse effects and drug interactions, may occur with use of this medication.	Leung et al., 2020 Kolansinski et al., 2020
Vitamin D	Conditionally recommended against	Level II IV Good	Number of trials demonstrated small effect sizes with vitamin D treatment, while others have shown no benefit and pooling data across studies	Ong et al., 2018 Pilz et al., 2016 Kolansinski et al., 2020
Massage Therapy	Conditionally recommended against	Level IV, V High	Studies addressing massage have suffered from high risk of bias (4/7).	Nelson & Churilla, 2017 Kolansinski et al, 2020
Opioids, pain patches	Conditionally recommended against in recognition that they may be used under certain circumstances particularly when alternatives have been exhausted.	Level II -Good Level III- Good IV-High	Very modest benefits of long-term opioid therapy and a high risk of toxicity and dependence. Recent systematic review and meta-analysis suggests that less pain relief occurs during longer trials in the treatment of non-cancer chronic pain	Busse et al., 2018 Kolansinski et al., 2020 CDC, 2018 VA/DOD, 2020 AOOS, 2017
Aquatic Exercises	Unable to recommend for or against	Level IV Good	Aquatic exercise was not recommended for patients who	Kolansinski et al., 2020

			suffered from frailty due to potential risk of accidental injury	
Physical Therapy	Unable to recommend for or against	Level I, IV Good	Physical therapy was not beneficial for hip OA in a well-designed trial	Bennel et al., 2014 Kolansinski et al., 2020
Bisphosphonates, glucosamine, chondroitin sulfate, Hydroxychloroquine, and methotrexate,	Strongly recommended against	Level IV Good	* Efficacy has not been demonstrated and given their risk of toxicity	Kolansinski et al., 2020 AAOS, 2017
Platelet rich plasma and tumor necrosis inhibitors and interleukin 1 receptor antagonist	Strongly recommended against	Level IV Good	* Efficacy has not been demonstrated and given their risk of toxicity	Kolansinski et al., 2019 AAOS,2017
Hyaluronic Acid	Strongly recommended against	Level I, IV Good	No benefit of pain relief in several RCTs	Brander et al., 2018 Acuna et al., 2020 Kolansinski et al., 2020 AAOS, 2017
Transcutaneous electrical stimulation (TENS)	Strongly recommended against	Level I, IV Good	RCTs revealed a non-significant pain relief effect	Iijima et al., 2020 Kolansinski et al., 2020

III. Non-Surgical Treatment Guideline for Low Back Pain due to OA of Spine

Treatment	Recommendation	Level of Evidence/Quality ratings	Comments	
Cognitive Behavioral therapy and Physical Therapy	Strongly Recommended	Level I, IV Good	Cognitive behavioral therapy is recommended in combination with physical therapy, as compared with physical therapy alone, to improve pain levels in patients with low back pain over 12 months.	Lamb et al., 2010 Scott Kreneir et al., 2020

Participation in self-management programs such as symptom management activities like exercise, relaxation, communication, healthy eating, managing medication and managing fatigue	Strongly Recommended	Level IV Good	Although effect sizes are generally small, the benefits of participation in self-efficacy and self-management programs are consistent across studies, and risks are minimal	CDC, 2020 Kolansinski et al., 2019.
Yoga Tai Chi Aerobic Exercises	Recommended	Level II/III/IV – Good	It is suggested that, in patients with mild chronic low back pain, yoga and tai chi may offer medium-term improvements in pain and function compared to usual care. The risk-benefit analysis suggests that yoga is generally safe, beneficial, and cost-effective, especially when administered in the group setting. Aerobic exercises is recommended to improve pain, disability and mental health in patients with nonspecific low back pain at short term follow up.	Kolansinski, 2020 Cramer et al., 2015 Scott Kreneir et al., 2020
NSAIDS	Recommended	Level I, IV Good	Provide significant pain relief for inflammation such as in OA.	Birbara et al, 2003 Scott Kreneir et al., 2020
HEAT and Cold	Recommended	Level II or IV Good	It is suggested that the use of heat for chronic low back pain with acute exacerbation results in short term improvement in pain.	Kettenman et al., 2007 Scott Kreneir et al., 2020
Acupuncture	Recommended for short term pain relief and function	Level I, II, IV- Good	Safe and effective treatment for low back pain and risks are minimal	Hempel et al., 2014 MacPherson et al., 2017

Topical Capsicum	Recommended	Level IV Good/High	Recommended treatment for short term basis ,3 months of less	Scott Kreneir et al., 2020
Lidocaine patch	Unable to recommend for or against	Level III- Good IV -Low	Lidocaine patch 5% provided significant improvement in pain and intensity and QOL. RCTs are warranted to further investigate the efficacy and safety.	Gimbel et al., 2005 Scott Kreneir et al., 2020
Opioids	*Conditionally recommended and cautiously limited and restricted to short duration	Level I, IV- High	Cautiously limit and restrict to short duration for the treatment of low back pain Initiation of opioid therapy, when the benefits are deemed by the patient and the clinician to outweigh the risks should be at a low dose and titrated upward to find the lowest dose required to optimally control the pain or improve function and QOL.	CDC, 2016 Lasko et al., 2012 Scott Kreneir et al., 2020 HHS, 2019
Musculoskeletal agents: Baclofen, Tizanidine, Cyclobenzaprine	Unable to recommend for or against	Level IV Good	*Carisoprodol is metabolized to meprobamate, which is both sedating and possibly addictive, so the use of carisoprodol is not recommended, particularly because alternatives are available	HHS, 2019
Mixed topical cream or gel, compounded cream or gel (Diclofenac, Capsaicin, , Bupivacaine)	Unable to recommend for or against	Level I, IV Low	Insufficient evidence to make a recommendation for or against the use. Recent RCT showed that addition of diclofenac to capsaicin added no increased pain relief over capsaicin alone	Predel et al., 2020 Scott Krenier et al., 2020

Smoking Cessation	Unable to recommend for or against	Level III, IV Low	Insufficient evidence to make a recommendation for or against the use	Green et al., 2016
Anti-Depressant - TCAs – amitriptyline, nortriptyline - SNRIs- duloxetine, milnacipran	Unable to recommend for or against	Level I, Good IV - High	Commonly used in various chronic pain conditions with associated risks and adverse reactions. The analgesic actions occur sooner at lower doses than those required for the treatment of depression. Anti-depressants may be useful for managing fatigue and sleep disorders associated with pain. Duloxetine has no statistical benefit on pain or function in chronic low back pain patients at 12 weeks.	Beal et al., 2016 HHS, 2019 Parrot et al, 2008 Scott Krenier et al., 2020
Vitamin D	Unable to recommend for or against	Level I, IV- Good	There is lack of evidence that vitamin D supplementation is an efficacious independent treatment for chronic pain in OA.	Martin & Reid, 2017 Sandoughi et al., 2015 Scott Krenier et al., 2020
Electrical Stimulation TENS	Unable to recommend for or against	Level III, IV/ Low	There is conflicting evidence that transcutaneous electrical nerve stimulation (TENS) results in improvement in pain or function at short- to medium-term follow-up	Macintosh, 2011 Kolansinski et al., 2020\ Scott Krenier et al., 2020
Bracing — Lumbosacral brace — Sacroiliac brace	Unable to recommend for or against	Level IV, V Low	There is conflicting evidence that bracing results in improvements in pain and function in patients with sub acute low back pain	Azadinia et al., 2017 HHS, 2019 Scott Krenier et al., 2020
Anti-convulsant – i.e., Gabapentin, Pregabalin	Unable to recommend for or against	Level III Good- High IV- Good	There is insufficient evidence to make recommendation to use or against anticonvulsant.	Scott Krenier et al., 2020

	for low back pain with or without radiculopathy.		Anticonvulsants, which include gabapentinoids such as gabapentin and pregabalin, may cause significant sedation and have recently been associated with a possible risk of misuse. Ineffective in treatment of low back pain or lumbar radicular pain and have a higher risk for adverse effects	Evoy et al., 2017 Enke et al., 2018 Lyon et al., 2019
Therapeutic Ultrasound	Not recommended	Level I, IV Good	There was little evidence that TU is more effective than placebo for pain treatment in a range of musculoskeletal conditions	Durmus et al., 2013 HHS 2019 Scott Krenier et al., 2020
Laser- cutaneous stimulation for purpose of pain modulation	Not recommended	Level IV Good/High	Laser acupuncture provides no short-term or medium-term benefit over sham treatment for patients with chronic low back pain.	Scott Krenier et al., 2020
Traction	Not recommended	Level I, IV Good/High	Traction is not recommended to provide clinically significant improvements in pain or function	Macintosh, et al., 2011 HHS, 2019 Scott Krenier et al., 2020
Spinal Manipulative Therapy	Not recommended	Level I, IV Good/High	Results is similar outcomes to no treatment, medication or modalities.	Schneider et al., 2015 Dougherty et al., 2020
Massage therapy	Unable to recommend for or against	Level III, IV- Low -Good	Can be effective in reducing myofascial pain only providing short term relief of pain.	Nelson et al., 2017 HHS. 2109
Exercise/physical therapy versus or plus massage	Not recommended	Level IV- Good	Addition of massage to an exercise program provides no benefit when compared to an exercise program alone	HHS, 2019
Steroids Oral and IV	Not recommended	Level I, IV, Good	Use of oral or IV steroids is not effective for the treatment of low back pain.	Eskin et al., 2014 HHS, 2019 Scott Krenier et al., 2020

Interventional Treatment (fluoroscopy guided)				
Thermal radiofrequency ablation	Recommended	Level I, IV, High, Good	Suggested as a treatment for patients with low back pain from the zygapophyseal joints. The relief from these ablations is durable for at least six months following the procedure. Compared with some intraspinal interventional treatments, procedures related to the facet joints can be simpler and carry lower risk.	Nath et al.,2008 HHS, 2019 Scott Krenier et al., 2020
Sacroiliac joint injections (SIJI)	Recommended	Level IV Good	Intra-articular steroid joint injections may be considered in patients with suspected SI joint pain.	HHS, 2019 Scott Krenier et al., 2020
Cooled radiofrequency ablation of the sacral lateral branch nerves and dorsal ramus of L5	Recommended	Level IV, Good	Neuro ablation of nerves supplying SI joint using cooled RF technique has shown promising outcome with long-term benefit	Biswas et al., 2016 Stetlzer et al., 2013 Scott Krenier et al., 2020
Facet Injections	Unable to recommend for or against	Level IV Good	Insufficient evidence to support against the use of steroid injections into the zygopophyseal joint in patients with chronic back pain and a physical exam suggestive of facet mediated pain.	Scott Krenier et al., 2020
Epidural steroid injection	Unable to recommend for or against	Level I, II, IV - Good	There is insufficient evidence to make a recommendation for or against the use of caudal epidural steroid or interlaminar epidural steroid injections for low back pain. Caudal ESI- roughly 20% of patients reported 50% reduction of low back pain after the procedure.	HHS, 2019 Scott Krenier et al., 2020 Benyamin et al., 2012 Southern et al., 2003 Lee et al., 2010

			Interlaminar ESI- roughly 40% of patients reported pain relief at 6 months or greater	
Spinal Cord Stimulation (SCS)	Unable to recommend for or against	Level IV, Low	There is insufficient evidence to make a recommendation for or against the use of spinal cord stimulation as a treatment for low back pain/Currently, SCS is a treatment option for failed back surgery syndrome and neuropathic pain.	Scott Krenier et al., 2020 HHS, 2019
Trigger point injection (dry needling or with use of anesthetic)	Unable to recommend for or against	Level IV Good	Injections to trigger muscles will cause relaxation and lengthening of the muscle fiber, thereby providing pain relief	HHS, 2019 Scott Krenier et al., 2020
Continuous delivery of intrathecal opioids	No recommendation	Level IV Good	Significant side effects, including delayed respiratory depression, granuloma formation, and opioid-induced hypogonadism may occur (HHS, 2019)	HHS, 2019 Scott Krenier et al., 2020

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Appendix A

Levels of Evidence Johns Hopkins Nursing Evidence Based Practice	
Evidence Levels	**Quality Guides**
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	**A** <u>High quality</u>: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi experimental, or quasi-experimental studies only, with or without meta-analysis	**B** <u>Good quality</u>: Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
Level III Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis Qualitative study or systematic review with or without a meta-synthesis	**C** <u>Low quality or major flaws</u>: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

Evidence Levels	**Quality Guides**
Level IV Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence Includes: Clinical practice guidelines Consensus panels	**A** <u>High quality</u>: Material officially sponsored by a professional, public, private organization, or government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **B** <u>Good quality</u>: Material officially sponsored by a professional, public, private organization, or government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise is clearly evident; developed or revised within the last 5 years **C** <u>Low quality or major flaws</u>: Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the last 5 years

Evidence Levels	Organizational Experience
Level V Based on experiential and non-research evidence Includes: Literature reviews Quality improvement, program or financial evaluation Case reports Opinion of nationally recognized experts(s) based on experiential evidence	**A** <u>High quality</u>: Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence **B** <u>Good quality</u>: Clear aims and objectives; consistent results in a single setting; formal quality improvement or financial or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence **C** <u>Low quality or major flaws</u>: Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial or program evaluation methods; recommendations cannot be made **<u>Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference</u>:** **A** <u>High quality</u>: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field **B** <u>Good quality</u>: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions **C** <u>Low quality or major flaws</u>: Expertise is not discernable or is dubious; conclusions cannot be drawn

Dang, D., & Dearholt, S. (2017). *Johns Hopkins nursing evidence-based practice: model and guidelines.* 3rd ed. Indianapolis, IN: Sigma Theta Tau International. www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html