Addressing Terminal Cancer Pain in Hospice: A Quality Improvement Project

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Abstract

As the worldwide popularity of undertreatment surrounding cancer pain management especially in end of life (EOL) care continues, it is imperative for EOL healthcare clinicians to have the right tool and knowledge base to address such issue. This DNP project is developed with the intent to address the struggle and undertreatment of pain regarding adults experiencing a life-limiting illness (hospice patients). Terminally-ill patients commonly experience distressing symptoms such as pain. The new implementation of the cancer pain protocol can help bridge the gap of sub-optimal treatment surrounding pain control and management in the field of EOL or hospice care. This quality improvement (QI) project aims to improve EOL care practice and patients' outcome through optimal cancer pain management by improving pain levels and providers' compliance with the newly introduced cancer pain protocol intervention at the project site. This was demonstrated through the use of evidence-based research and theoretical framework design of the rapid-cycle improvement technique: Model for Improvement/Plan-Do-Study-Act (PDSA) Cycle to help deliver improvements in the quality and safety of healthcare (Taylor et al., 2014). The cancer pain protocol intervention positively impacted the hospice facility (project site) through reduction of pain rate levels and improvement of providers' protocol compliance as seen at the end of the QI project implementation phase (see data results/analysis).

Addressing Terminal Cancer Pain in Hospice: A Quality Improvement Project

The concept of pain has been widely used since in the early centuries with its own various scientific and ethnological literatures. Many scholars and professional associations have provided their own variations of pain definitions. The widely known definition of pain is popularized by the International Association for the Study of Pain (IASP). IASP promulgated their revised definition of pain as a "mutually recognizable somatic experience that reflects a person's apprehension of threat to their bodily or existential integrity (Cohen et al., 2018, p.2). Pain at the end of life (EOL) remains a great concern and a challenge to many EOL healthcare professionals. During EOL care, healthcare clinicians have the ethical obligation to lessen or palliate the patient's suffering and make them as comfortable as possible (California Hospice and Palliative Care Association, 2019). Hospice care's philosophy is focused on helping the terminally-ill patients to palliate their distressing symptoms and assist in the dying process to have a meaningful, peaceful, and dignified death (CHPCA, 2019). The Medicare Hospice Benefit Program was enacted in 1986 making it available for patients and families to have the option to include hospice services in their Medicaid programs (CHPCA, 2019). Since then, funding in the end of life services was improved, reimbursement rates were increased, and the proliferation of hospice care providers also happened. Terminally-ill patients commonly experience suffering, with cancer-related pain rated as one of the most common distressing symptoms and cancer as one of the largest categories for hospice diagnoses in 2013 (WesleyLife, 2014).

Advanced or end-stage cancer can be optimally treated by EOL providers; however, pain management especially during the EOL remains a challenge or undertreated (Hunnicutt et al., 2016). Recent scientific developments in cancer pain and management including at the EOL

have been made, making this topic significant in the field of nursing and medical hospice practice. More importantly, latest evidence-based guidelines will be explored to help guide hospice providers at the project site, to optimally manage cancer-related pain at the EOL. This DNP project will explore the issue surrounding terminal cancer-related pain symptom management and provide development of an evidenced-base initiative protocol for hospice providers (prescribers and nurses) in the hospice setting.

Background

In literature, it is widely documented that pain at the EOL remains of great concern and many times undertreated (Coyne et al., 2018). Pain in advanced disease is prevalent, especially in advanced malignancy or end-stage cancer disease, and it is a common symptom of cancer disease along with its treatment. In fact, excruciating cancer-related pain is very common affecting 70-80% of advanced malignant disease patients (Harris, 2014). Specialists and experts in the field of pain management in the U.S. and around the world are aware that cancer pain is very complex, challenging, and often sub optimally treated (Pergolizzi et al., 2016).
Patients dealing with a life-limiting illness such as terminal cancer are often faced with distressing and upsetting physical and emotional symptoms. Patients battling with incurable cancer disease are often times admitted to hospice care. A core priority of many hospice organizations is to relieve the patients' suffering such as pain. Hospice healthcare professionals (HCPs) such as prescribers and nurses are ethically obligated to mitigate patients' suffering (American Nurses Association, 2017, as cited in, Coyne et al., 2018). It is important to mention that a core tenant for hospice HCPs is to adequately and appropriately manage pain according to the patient and family's perceptions (Coyne et al. 2018). According to the American Cancer Society (2019), hospice care focuses on promoting the quality of life (QOL) of individuals and

their caregivers who are experiencing a life-limiting illness. Hospice care revolves around providing quality, compassionate, and dignified care for people in the last phases of their incurable disease, to provide comforting care so patients can live with dignity and as fully and comfortably as possible (CHPCA, 2019).

Cancer pain and breakthrough pain is not uncommon, especially in its advanced stages. There is a wide array of treatment options to combat pain, and the more reason hospice clinicians need to fully understand pain management and the different pain control options for cancer-related pain symptoms (Pergolizzi et al., 2016). In fact, the World Health Organization (WHO) declared pain management or pain control to be one of the fundamental human rights (Pergolizzi et al., 2016). However, repeated studies and literatures have shown of undertreatment and struggles in cancer-related pain management, especially during EOL. A recent retrospective national study by Tenor et al. (2018) concluded that significant unmet needs in EOL care remain and continued efforts are critically needed to improve the quality of EOL care. Unfortunately, despite huge investment in EOL such as hospice and palliative care services, trends between the year of 2000 and 2009 points to more days in intensive care unit in the last month of life, late referrals to hospice care, and more repeat hospital admissions in the last 90 days of life (Tenor et al., 2018). As a standard practice of cancer pain management, national and international healthcare organizations such as WHO recommends for EOL clinicians to have an integrated or multi-modal approach, utilize strong opioids as the mainstay of analgesic therapy in moderate-severe cancer-related pain (being oral morphine as the opioid of first choice), and to conduct a full and thorough assessment of physical and non-physical suffering (Fallon et al., 2018).However, despite existing guidelines and availability of opioids in EOL care, undertreatment continues to be an issue (Fallon et al., 2018).

Problem Identification

Despite existing therapeutic advances and interventions on pain and cancer pain, it is widely known that under-treatment still exists (Hunnicutt et al., 2016). Multiple literatures have noted the ongoing struggle and challenge to optimally manage cancer pain and EOL pain symptoms. In a study employing interviews, patients' loved ones reported that the patient continued to experience an unmet need for pain management during the EOL period by 25.2% (Teno et al., 2015, as cited in Coyne et al., 2018). Severe cancer-related pain is commonly experienced by patients affecting about 70-80% of patients with advanced malignant disease (Harris, 2014). Similarly, the largest previous study on hospice and pain management in nursing homes using data from 1992 to 1996 found that undertreated pain was 15% in hospice patients and 23% in non-hospice patients (Shield et al. 2005, as cited in Hunnicutt et al., 2016). The chosen project site (a local home hospice facility in Las Vegas) admits to the same challenge of suboptimal treatment of EOL cancer pain by their hospice clinicians. Upon assessment, the stated local hospice facility has no current protocol of EOL cancer pain management to guide their hospice prescribers and nurses.

Cancer pain prevalence ranges from about 30% in its early stages to around 80% in its terminal stages, although it has a fair amount of frequency of about 50% at any given stage (Petracci et al., 2016). HCPs' assessment and treatment represent the two primary steps for cancer pain management, being pain intensity as the basic parameter to be evaluated (Petracci et al., 2016). Hospice HCPs also need to acknowledge possible existing barriers that may be contributing to why appropriate and optimal pain management remains a challenge during the EOL. EOL providers have an ethical responsibility to relieve pain and suffering (American Nurses Association, 2017, as cited in, Coyne et al., 2018). They should also recognize that the

provision of medications to mitigate suffering is consistent with the accepted ethical and legal principles of EOL care. Finally, EOL HCPs should be aware that evidence suggests that the risk of hastening death by opioid administration is minimal, especially when an established guideline and protocol is being followed (Coyne et al., 2018). The ethical tenets of beneficence, nonmaleficence, autonomy, and justice still guide the surrounding practice of nursing and medical EOL care (Coyne et al., 2018). It is clear that through this project presentation and the strong existing literature on EOL cancer pain management, that it will contribute to the nursing leadership profession and to the improvement of EOL or hospice care practice to improve cancer-related pain management and patients' QOL. It is important to note the purpose of this project to implement a quality improvement (QI) evidenced-base protocol for hospice HCPs in the project site, with the goal of improving pain level and pain symptom management at the EOL. The QI protocol to be implemented at the hospice project site is based from the National Comprehensive Cancer Network (NCCN), an approved national clinical practice guideline (CPG) recommended by national counsel.

Significance

The project topic is a significant issue in both the medical and the nursing profession in the field of EOL care and cancer pain management. The top five diagnoses in hospice care are cancer, debility unspecified, dementia, heart disease, and lung disease accounting for over 83% of hospice patients (WesleyLife, 2014). More specifically, end-stage cancer diagnosis is the largest category for hospice diagnoses, accounting for 36.9% of hospice patients (National Hospice and Palliative Care Organization, as cited in WesleyLife, 2014). It is the responsibility of EOL prescribers and nurses to be aware and accountable of their essential roles to conduct comprehensive and effective pain symptom management to maintain the hospice patients' QOL

and provide comfort during the dying phase of the patients' life. Having said this, it is in clear significance that optimum management of cancer-related pain symptoms during EOL care is essential for hospice HCPs' to achieve following a standardized and approved initiative protocol.

Problem Question

PICO(T) Format

In adults with terminal cancer disease, does an evidence-based standardized pain management protocol for hospice healthcare providers, compared to current practice, improve patients' pain levels and providers' compliance with pain management guidelines?

P-Adults with terminal cancer disease

I-Evidence based standardized hospice pain protocol

C-Current practice

O- Improving patients' pain levels and providers' compliance with pain management guidelines

Search Methods

The literature review search was guided by the PICO question: in adults with terminal cancer disease, does an evidence based standardized pain management protocol for hospice healthcare providers, compared to current practice, improve patients' pain levels and providers' compliance with pain management guidelines?

A comprehensive search was conducted and the online databases CINAHL, PubMed, Medline, ProQuest, EbsCo, and ScienceDirect along with search engines such as Touro University's Jay Sexter Library, Google, and governmental websites were utilized for this literature review. Searches were filtered from year 2012 to 2020. Key words or search terms used were: hospice, end of life care, cancer pain, cancer pain management, cancer-related pain,

advanced cancer pain guideline, hospice nurses, hospice providers, pain assessment, hospice symptom management, terminal cancer pain management, hospice cancer pain, pain control, opioids management, opioid therapy, cancer and opioids, suboptimal cancer pain treatment, and end of life cancer pain practice guidelines.

Inclusions were comprised of keywords and terms mentioned above including the timeline from 2012 to 2020. The inclusion criteria had to discuss cancer-related pain in EOL and/or hospice settings, cancer pain management during EOL within the U.S. or other parts of the world such as in Europe, suboptimal pain management in EOL or hospice care, hospice homecare pain symptom management, and hospice providers' challenges in pain management (specifically cancer pain). Cancer-related pain management and not just advanced or terminal cancer pain in specifics were acceptable as it can give general information and shed light to cancer pain management in general, especially during literature review. Other search engines were utilized as well such as Google and Google scholar and a review of articles and guidelines from other governmental organizations and national counsel such as the Center for Medical and Medicaid Services, World Health Organization (WHO), and the National Comprehensive Cancer Network (NCCN) were also utilized.

Exclusion criteria were articles and literatures that referenced hospice care in the inpatient setting as this project is based in homecare hospice settings. Timeline outside of 2012-2020 were excluded in the search entry. Articles or resources discussing hospice cancer and cancer in the EOL but not necessarily discussing cancer-related pain is part the of the exclusion criteria. In addition, non-peer reviewed, non-full-text, and not from scholarly journals were also excluded in the filters. Articles discussing cancer pain management in children are also excluded, as the DNP project is strictly for the adult population. Inputting the PICO question in TUN's

Jexter Jay Library and related keywords initially yielded 575 results. After much manipulation in the filters and key terms and accounting of the inclusion and exclusion criteria, the search results were narrowed down to over 100 and 18 of those resources were utilized for this review.

Review of Study Methods

After extensive review of the literature, the review was comprised mainly of RCTs, cohort studies, systematic reviews, quantitative studies, qualitative studies, retrospective, and interviews. A deep evaluation of methodologies in the literature produced emerging themes pertinent to the project topic. Methodologies are all relevant to both the researcher and the proposed DNP project, as experts and scholars in the field of EOL care discussed the significance of EOL cancer pain management and knowledge. It also brought light to the problem of suboptimal treatment in this area, which can trigger hospice HCPs and fellow EOL clinicians and scholars to continue research to help solve the issue and not give disservice to the terminally-ill patients and their loved ones or caregivers.

Review Synthesis

Most of the literatures reviewed were a mixture of quantitative, qualitative, cohort studies, randomized control trials (RCTs), and systematic reviews. Cancer pain management remains a challenge, especially advanced and/or terminal cancer pain during EOL care (Hunnicutt et al., 2016). Although hospice care's priority is to palliate or relieve patients' distressing pain, existing evidence still indicates that pain is often inadequately managed in this specialty setting. Approximately one out of three hospice patients reported uncontrolled pain during their last hospice visit before death (Cea et al., 2016). Unfortunately, despite the available studies and literature regarding cancer pain and EOL care, limited knowledge regarding pain assessment, management practices, and pain-related outcomes in hospice care in the U.S. still

exist (Cea et al., 2016). As a result, optimal potential benefits of hospice care to terminally-ill cancer patients to help improve pain symptoms and QOL may not be fully utilized.

Impact of the Problem

The increasing popularity of hospice care especially in the U.S. has implicated EOL professionals and experts across the discipline to take a deeper look in quality practice gaps. A recent article by Cea et al. (2016) declared limited knowledge regarding pain assessment and management practices, along with types of pain-related outcomes among U.S. hospice patients. Hospice care services are supposed to provide expertise in symptom management, yet many hospice patients struggle with their QOL and experience unpleasant dying process (Cea et al., 2016). The practice gap and prevalence of continuous undertreatment of EOL cancer pain being unacceptably high, negatively impacts the EOL specialty and in alarming hospice HCPs to be up to par of their clinical competence in providing EOL care with regards to pain management and improving hospice patients' QOL (Cea et al. ,2016). Fallon et al. (2018) mentioned cancer pain may in fact be presented as a major global issue of the healthcare system worldwide, with around 14 million new cancer cases and over eight million deaths have occurred worldwide in 2012 based on estimates and incidence projection in 2020 will be over 15 million. Discussions surrounding EOL care, cancer pain and management, and different medication interventions used as death approaches are of great significance (Koivu et al., 2014).

Pain Assessments

Literature has emphasized the importance of thorough and comprehensive pain assessments during EOL care. Complete initial and ongoing pain assessments should be an integral part of cancer pain management. A systematic review in 2014 that utilized the Pain Management Index (PMI) revealed that one-third of patient does not receive appropriate

analgesia proportional to their pain intensity (PI) (Fallon et al., 2018). PI regular self-reporting via a validated pain assessment tool is the first step towards an effective and individualized pain treatment. The most commonly used standardized scales are the visual analogue scale (VAS), the verbal rating scale (VRS), and the numerical rating scale (NRS). A full and thorough pain assessment of physical and non-physical suffering in a routine manner is vital to help improve the appropriate choice of pain therapy (Fallon et al., 2018). Hospice HCPs' competency in identification of pain descriptors (e.g. nociceptive versus neuropathic pain) also helps improves the choice of therapy (Fallon et al., 2018).

For hospice patients with limited communicative skills or cognitive impairment that make self-reporting more challenging, observation of pain-related behaviors and discomfort (objective pain assessments) such as facial expression and body movement is an excellent alternative strategy for pain assessments (Fallon et al., 2018). The comprehensive assessment of all components of pain or suffering such as psychosocial distress should also be considered and evaluated. The NCCN re-emphasized that self-report of pain is the gold standard as part of the comprehensive pain assessment and for clinicians to use an alternative method to obtain pain rate and response for those unable to verbally report pain (NCCN, 2020). NCCN (2020) provided a detailed guideline approach regarding comprehensive pain assessment. The goal of such comprehensive pain assessment is to ultimately find the cause of pain for the clinician to identify appropriate optimal therapies. An individualized pain assessment is based on the patient's pain etiology and pathophysiology that should be investigated through a thorough medical history assessment (NCCN, 2020). They also provided an algorithm on universal screening assessment management of pain for clinicians to use that can be also utilized at the project site (NCCN, 2020). Similarly, the European Society for Medical Oncology (ESMO) also showed a detailed

guideline for adequate assessment of the patient with pain at any stage of the cancer disease (Fallon et al., 2018). The SEOM clinical guideline validated ESMO's emphasis on the importance of pain assessment in cancer pain management. In the SEOM clinical guideline report, they found that regular and adequate self-report pain assessment intensity with the help of validated multidimensional assessment tools, are critical for an effective treatment. A pain assessment approach that can both diagnose and monitor a patient's specific pain and that is simple enough to apply in practice is necessary (Jara et al., 2017)**.**

Barriers

Hospice patients and families undergo a lot of stress and distressing factors. EOL prescribers and nurses need to thoroughly assess different aspects of possible barriers such as patient and family culture, religion, dynamics, and beliefs. Several barriers to optimal cancer pain management have been acknowledged (Jara et al., 2018). Coyne et al. (2018) divided the barriers into three major categories: (1) patient and family, (2) healthcare providers, and (3) healthcare system. Possible existing barriers come in many forms and visiting hospice providers should assess and recognize if any of the barriers exist. Some of the documented barriers include (1) patient/family's fear of pain medicine and addiction and abuse, (2) patient's cognitive and affective factors, (3) patient/family's belief that pain is a natural part of the illness and cannot be relieved, (4) denial by the patient and/or family member, (5) inadequate assessment of pain by the hospice HCP, (6) fear of doing harm and causing adverse effects, or tolerance to opioid effectiveness, (7) fear of legal issues by the HCP, (8) lack of recognition of the global nature of pain by prescribers and nurses, and (9) lack of support for adequate pain education and resources (Coyne et al., 2018). In addition, lack of healthcare professionals on cancer pain assessment and management is another huge barrier as mentioned in the SEOM clinical guideline for treatment

of cancer pain (Jara et al. 2018). It is ultimately the responsibility of the hospice prescribers and nurses to provide safe and effective pain care in a holistic manner, including assessment of any possible and existing barriers.

Opioids Therapy

Numerous articles have documented the effective and beneficial use of opioids especially in EOL care and cancer pain management. One of the popular guidelines is from WHO with their sequential three-step analgesic ladder starting from non-opioids to weak opioids and to strong opioids (WHO, 2018). The WHO (2018) ladder recommends to always starting at non-opioid analgesics as possible options at all steps; however, opioids are the mainstay of analgesic therapy. As healthcare science continues to evolve and new research emerges, some research experts have suggested eliminating the second step of the analgesic ladder, with weak opioids being replaced with low doses of oral morphine (Fallon et al., 2018). Experts and scholars are still under the works of exploration of the place of step 2 in the WHO three-step ladder. Uncontrolled studies have showed that the effectiveness of the second step of the WHO ladder has a time limit of 30–40 days for most patients and that the shift to the third step is mainly due to insufficient analgesia, and create a ceiling effect with weak opioids, rather than to adverse effects (Fallon et al., 2018). For moderate-severe cancer pain, accepted recommendations have suggested that opioid is the mainstay of analgesic therapy being oral morphine as the opioid of first choice (WHO, 2018). The NCCN (2020) also validated this statement in their adult cancer pain guideline. However, if oral morphine is not the best option, oxycodone or hydromorphone in both immediate-release and modified-release formulations for oral route, along with oral methadone are effective alternatives to oral morphine (Fallon et al., 2018).

NCCN's clinical practice guideline (CPG) is an excellent resource on opioid use with adult cancer pain. NCCN (2020) described the opioid principles, prescribing, titration, maintenance, and safety issues that can help hospice HCPs in their practice. In determining the appropriate dosage of opioid, the lowest dose that relieves the patient's pain and maximizes his or her function throughout the dosing interval without causing unmanageable side effects is the appropriate opioid dose to use (NCCN, 2020). An oral and parenteral equivalences and relative potency of drugs as compared with morphine based on single-dose studies is presented to help guide HCPs during medication titrations, adjustments, and/or rotations (NCCN, 2020).

Literature Theme Development

During the literature review process four themes emerged. These themes have repetitively occurred across the literature and highlights what is currently understood in the topic of cancer pain management and EOL care. Moreover, the overarching problem of ongoing challenges, struggles, and undertreatment of advanced or EOL cancer pain highlights the significance and need for hospice HCPs' to step up in honing their clinical and theoretical expertise in hospice pain symptom management. The problem is also that many local hospice organizations have no formal protocol or systematic approach to their cancer-related pain symptom management.

Suboptimal Treatment and Challenges on EOL Cancer Pain. The popularity of cancer pain in all stages is very well known. Although pain intensity (PI) and the types of pain are variable, the prevalence of cancer-related pain is high including breakthrough pain (BTP) (Margarit et al., 2012). Despite medical advances in the recent years on cancer pain clinical practice and the development and upgrades on highly effective opioids, and interventional techniques, cancer-related pain continues to be a primary challenge in the integral management of cancer patients (Margarit et al., 2012). In fact, such initial advances resulted from

development of the analgesic ladder by WQHO, which recommended for clinicians to base their analgesic drug choices on PI and which ultimately allow all patients to have access to optimum pain management. However, despite all these efforts, studies and literature including those by the WHO continue to emphasize that severe cancer pain is still a world healthcare problem (WHO, 2018). Most of the relevant articles in this project have at one point mentioned or discussed this issue of suboptimal treatment and continuous struggle on EOL cancer pain management such as by Coyne et al. (2018), Hunnicutt et al. (2016), Margarit et al. (2012), Jara et al. (2018), and WHO (2018) itself.

EOL HCPs' Obligation to Mitigate Patients' Suffering Including Pain. Hospice care stresses maintaining terminally-ill patient's QOL. Hospice HCPs' primary goal is to control pain and other distressing symptoms so patients can still live as comfortable as possible in the last phase of their lives (CHPCA, 2019). Emphasis on QOL as one the of main tenets of hospice care. Hospice nurses and prescribers play an integral role in providing holistic care to the hospice patients and families and many actually even live longer under hospice care due to their symptoms being managed and treated effectively based on their unique needs and preferences (CHPCA, 2019). The American Society for Pain Management Nursing (ASPMN) and Hospice and Palliative Nurses Association (HPNA) hold the joint position statement that HCPs must be an advocate for effective, efficient, and safe pain and symptom management to relieve suffering for every patient under EOL or hospice care regardless of their demographics and history in the past (Coyne et al., 2018). They have an ethical obligation to alleviate patients' suffering. The hospice healthcare team remains available for ongoing help and support to the patient and family. EOL HCPs' knowledge and expertise regarding cancer pain and hospice symptom management is important to the success of the treatment plan and compliance. The appropriate

management in a timely manner of both acute and chronic pain is a critical component that nurses and prescribers must be aware to optimally promoting patients' health and QOL (Sanders et al., 2018). Part of this ethical obligation is to actively involve the patient and the family by educating them on hospice philosophy and the importance of adherence and compliance of both pharmacological and non-pharmacological interventions (Sanders et al., 2018). However, despite the availability of EOL resources, it has been documented that adherence to the prescribed medication regimen remains a significant issue in the management of pain and is a barrier to optimum pain management (Sanders et al., 2018). Accordingly, the American Nurses Association (ANA) released a position statement that nurses have an ethical responsibility to provide clinically excellent care to address patient's pain, which includes excellent clinical indications, mutual identification of goals for pain management, interprofessional collaboration, and awareness of professional standards for the assessment and management of different types of pain (Coyne et al., 2018). Lastly, hospice nurses and prescribers should educate and put awareness to hospice patients and caregivers that the national response to opioid crisis does not negate the ethical responsibility to mitigate pain and suffering (Coyne et al., 2018).

A Multi-Modal or Integrated Approach in EOL Cancer Pain Management. EOL care such as hospice can be very complex and practitioners many times encounter complex cases. Clinicians are guided by the theoretical and clinical knowledge they have learned and acquired in school and over the years of clinical experience. Great advances over the past decades have been made in pain management, resulting in clinical practice guidelines (CPG) that guides evidence-based treatment approaches and consensus-based practices to provide practical recommendations to guide clinical care (Jara et al., 2018). Across the literature, hospice or EOL cancer pain management suggested that advanced cancer pain management should not be a sole

approach (Jara et al., 2018). A multi-modal or integrated approach is the recommended practice in EOL cancer pain management including pharmacological and non-pharmacological interventions, patient and family/caregiver involvement and education, and multidimensional pain assessment tools are all needed for an effective treatment (WHO, 2018). A combination approach of nonpharmacological therapies such as psychological approaches, physical measures, integrative therapies, and interventional techniques along with analgesic and adjuvant therapies and drugs should all be utilized by hospice HCPs (Coyne et al., 2018). Importance of assessment of all components of pain and suffering should be acknowledged such as psychosocial distress, as it may amplify pain and similarly, undertreatment of pain may cause psychological distress (Fallon et al., 2018). It is to be realized that EOL providers should pay attention to emphasis on an effective, efficient, yet safe pain management treatment plan and outcome that are derived from a comprehensive approach assessment.

Opioids as the Mainstay of Analgesic Therapy in Moderate-Severe Cancer Pain.

Drug analgesic use at the EOL is widely used in hospice care settings. However, practice guidelines and literature across the board have documented the excellent use and benefits of opioids in pain management, especially cancer-related pain (Koivu et al., 2014). As the cancer disease becomes more advanced or terminal, more pain management is geared towards more frequent use of opioids (Koivu et al., 2014). The WHO (2018) declared that opioid analgesic therapy is the mainstay of analgesic therapy in moderate-severe cancer pain symptoms, being oral morphine as the opioid of first choice. The same recommendations are being followed by other EOL or cancer guidelines by other healthcare organizations nationally and internationally. When acute or urgent relief is needed, oral morphine can be titrated with parenteral opioids, so as in patients for whom oral route are not suitable and analgesic requirements are unstable (WHO,

2018). A study in Finland in 2010 on EOL pain medication among cancer patients in hospice settings revealed that 96.4% of patients received strong opioids during hospice care and 63% were administered regularly dosed opioids. At transfer, 63% of hospice patients were receiving regularly scheduled opioids, 76.8% for second day admission, and 89.9% one day prior to expiration (Koivu et al., 2014). Strong opioid is the cornerstone of analgesic therapy in the hospice setting. Morphine, methadone, oxycodone, hydromorphone, fentanyl, and buprenorphine are most widely used in the U.S. and in Europe (Jara et al., 2018). Hospice prescribers should consider drug's efficacy, safety, and flexibility with level II evidence as the degree of recommendation (Jara et al., 2018). As this theme on opioids emerged, it is clear through evidence and literature that opioid use is the gold standard in cancer-related pain management.

Purpose Statement/Aims

The purpose of this DNP Quality Improvement (QI) project is to develop and implement a standardized evidence-based pain management guideline (based off of the NCCN approved national guideline) at the hospice project site, to assist hospice providers (prescribers and nurses) to optimally manage terminal cancer-related pain at the EOL. Currently, the project site has no existing protocol in place with regards to their symptom pain management for terminal cancer patients.

The aim of this project is for EOL or hospice providers to ultimately improve care practice and patient's outcome by optimally managing patients' pain levels and improve providers' compliance with the newly implemented pain management guidelines. By improving care practice, patient's outcome (controlled pain levels), and providers' compliance with the new pain management protocol, it can not only help bridge the gap of sub-optimal treatment with regards to pain control in the field of EOL or hospice care, but also the local hospice project site

through the initiation and implementation of the new evidence-based pain management guideline in addressing terminal cancer pain in hospice care**.**

Project Objectives

In the timeframe of this DNP project, these are the objectives that will be implemented at the project site:

1. Develop an evidence-based pain management guideline/protocol utilizing the NCCN national clinical practice guideline (CPG) for terminal cancer patients in hospice care as a standardized care approach by EOL HCPs'.
2. Implement the new EOL pain management guideline (based from the NCCN national clinical practice guideline) for cancer patients at the project site to be utilized by hospice nurses and prescribers, rather than their current practice.
3. Improve hospice cancer patients' pain levels and maintain hospice providers' compliance with utilization of the approved evidence-based pain management protocol intervention.

The QI project intervention regarding the new protocol on hospice cancer pain management will be evaluated through patient chart reviews or audits pre and post-implementation to determine if the aims and objectives are met.

Theoretical Framework

The framework selected for this project is a QI method known as the rapid-cycle improvement technique: Model for Improvement/Plan-Do-Study-Act (PDSA) Cycle (Institute for Healthcare Improvement, 2021). QI methods have been widely used in the healthcare arena. The QI method such as the PDSA cycle helps in delivering improvements in the quality and safety of healthcare (Taylor et al., 2014). The Model for Improvement framework was developed by the Associates in Process for Improvement (Langley et al., 2009, as cited in,

Moran et al., 2017) that is utilized by the Institute for Healthcare Improvement (IHI) to guide improvement work. This framework is a scientific-based model for driving quality improvement for developing, testing, and implementing changes leading to the actual improvement, with the wisdom of careful study (ACT Academy, n.d.). The PDSA cycle is an iterative and continuous four-stage cycle for improving a process or carrying out change (Minnesota Department of Health, 2020). PDSA cycle is shorthand for testing a change and the second step that allows for testing a change on a small scale prior to implementing it in a much larger scale. The Model for Improvement's first part includes three focus questions that will help guide this QI project or any QI implementation: What are we trying to accomplish (Setting aims), how will we know that a change is an improvement (Establishing measures), and what changes can we make that will result in improvement? (Selected change) (Moran et al., 2017). After these focus questions have been answered, the next step is to test a change in the real work setting or clinical practice via the PDSA cycle. This framework model is in perfect alignment for this QI DNP project with the requirements for implementation science research and with the end goal to ultimately improve quality in healthcare and practice.

Historical Development of Theory

The PDSA cycle method originated from Walter Shewhart and Edward Deming in 1986 out of the Crisis MIT Center for Advanced Engineering Study (Quality Improvement Methods, 2016). It was originally called PDCA (plan-do-check-act) following Deming's early teaching in Japan; however, the terms PDSA and PDCA are still often used interchangeably (Taylor et al., 2014). Walter Shewhart is Deming's mentor. Dr. Deming is a statistician, American engineer, and a management consultant. He championed the management principle of statistical process control, a precursor of Total Quality Management (Millard, 2015). Shewhart on the other hand is

an American physicist, engineer, and a statistician. Shewart introduced the concept of a straight-line, three-step scientific process of specification, production, and inspection. The PDSA cycle or also known as the Deming Wheel was built off of Shewhart's Cycle and Deming modified it. Deming emphasized the importance of constant interaction among the four steps of design, production, sales, and research and came to be known as the Deming Wheel or Deming's Circle (Millard, 2015). It was during 1993 when Deming introduced his new revision of the cycle to be called as the PDSA cycle. Currently, the PDSA cycle approach is used by businesses, healthcare arenas across the globe to solve problems, improve quality and enhance products brought to us by some of the world's greatest thinkers in the science of process control and continuous improvement (Millard, 2015).

Application of Major Tenets of Theory to the DNP Project

The major tenets are the three fundamental questions of the Model for Improvement: What are we trying to accomplish?, how will we know that a change is an improvement?, and what changes can we make that will result in improvement? The next major tenet to be discussed is the four stages of the PDSA cycle: plan, study, do, and act as it applies to the DNP project and the hospice site regarding terminal cancer pain management.

Model for Improvement. This first key question of the Model of Improvement framework (what are we trying to accomplish?) is for setting aims. The aim for this DNP project (*as mentioned above*) is to ultimately improve care practice and patient's outcome by optimally managing patients' pain levels and improve hospice HCPs' compliance with the newly implemented pain management protocol based on the NCCN national approved guideline (NCCN, 2020). By achieving this aim or goal, it can also help bridge the gap of under treatment in hospice or EOL cancer pain management, not only at the project site but in other hospice/EOL

organizations. How will we know that a change is an improvement? This portion of the Model of Improvement is for establishing measures (ACT Academy, n.d.). The measures of outcomes are to be done using chart reviews or audits and data collection pre and post- implementation to determine if the change leads to an improvement of pain levels report and providers' compliance with the cancer pain management protocol/guideline). Moreover, the intervention for selected change that met the DNP project's aims was the pain management guideline or protocol as the local hospice HCPs' new standardized care approach based from the NCCN 2020 national guideline. The outcomes and objectives of this project were also delineated above: (1) develop an evidence-based pain management protocol for terminal cancer patients in hospice care as a standard care approach by hospice HCPs', (2) implement the new EOL pain management guideline from the NCCN national CPG for hospice cancer patients at the project site, and (3) improve hospice cancer patients' pain levels/optimize analgesia and maintain hospice providers' compliance with the usage of the approved evidence-based pain management protocol/guideline intervention at the local hospice project site.

PDSA Stage 1: Plan. The first step of the PDSA cycle is the planning stage (Moran et al., 2017). Part of this planning stage includes drafting an aim statement, answering the three key questions from the Model for Improvement framework as mentioned above, stating the objectives, describing the problem, and developing a plan to test the change (IHI, 2021). Brainstorming with the project site's stakeholder and the DNP project mentor is also part of this stage one process. A strong buy-in from the hospice project site's organization and stakeholder has also already been determined early on during the DNP practice immersion experience. The project site has no current cancer pain management protocol for prescribers and nurses to utilize and justifies the need to implement the QI DNP project intervention. After extensive research,

and assessment of current issues/problems at the project site (hospice specialty population), and drafting the PICOT question, the plan to implement a standardized care approach for hospice HCPs' have been made clear to help improve care practice, patients' pain levels/optimize analgesia, and improve quality care by maintaining compliance of the newly implemented adult cancer pain protocol intervention. The projected timeframe for the QI DNP project intervention starting from the first stage (Plan) until the last stage (Act) is around four to eight weeks.

PDSA Stage 2: Do. This second stage is for the change test to be carried out at the local project site and for related data to be gathered on an ongoing basis to help understand the results of the change (Quality Improvement Methods, 2016). The "Do" phase of the PDSA cycle is the actual implementation of the terminal cancer pain management guideline/protocol intervention at the local hospice (home-based) organization with measurable outcomes in a smaller scale (IHI, 2021). It is advisable during this phase for the stakeholders and/or involved parties to conduct continuous observations and documenting any current or unexpected problems or effects and a general observation overall (Minnesota Department of Health, 2020). Part of the intervention is incorporating the themes that have emerged from the literature as discussed in earlier section. These themes are conducting an ongoing comprehensive assessment, utilizing a multi-modal/integrated approach in EOL cancer pain management, and proper usage of opioids therapy as the mainstay of analgesics for moderate-severe cancer pain and all were included as part of the new evidence-based adult cancer pain management protocol at the EOL as per the NCCN guideline (NCCN, 2020).

PDSA Stage 3: Study. The PDSA "Study" phase includes evaluation and study of the data and/or results. The initial collection of data and/or results and observation done in the stage 2 of the PDSA cycle should help in this stage of the cycle. Analysis of the data is conducted in

this phase and also reflection on what was learned and observed from the results (IHI, 2021). Asking questions such as did the plan and testing the intervention (newly implemented pain management protocol at the hospice project site) resulted in an improvement? A review of charts and audits and possibly a survey from patients and prescribers and nurses are some ways to help during the study or analyzation part.

PDSA Stage 4: Act. The last phase of the PDSA cycle reflects on the plan and the outcomes (Minnesota Department of Health, 2020). The PDSA "Act" stage was based on the results of the stated QI DNP project intervention, and determined further changes were necessary. The involved parties and stakeholders of this QI DNP project determined that the plan resulted in success or an improvement, standardizing the newly implemented care approach (adult cancer pain management protocol at the EOL/hospice population) for hospice prescribers and nurses to utilize at the hospice project site. The PDSA cycle is an ongoing and iterative process to help organizations such as the local hospice project site to become more efficient as they intuitively adopt the new QI intervention and the PDSA cycle into their future planning (Minnesota Department of Health, 2020).

Project Design

The DNP project is a QI project utilizing quantitative methods for data collection and analysis. Moran et al. (2017) mentioned that QI projects in the healthcare arena encompass those efforts that seek to improve services for the future. The QI method chosen for this project is the MFI/PDSA cycle (Appendix B) and is one of the most common tools used in QI projects in healthcare (Moran et al., 2017). MFI/PDSA cycle is a framework that is delineated in the earlier section to guide this DNP student with improvement work. The selected intervention was the pain management protocol based from the NCCN 2020 national guideline to be implemented at

the project hospice site in a specified timeframe. The outcomes of improved patient pain levels and providers' compliance in using the new cancer pain management protocol are to be analyzed and monitored using patient chart reviews and data collection pre and post implementation. It is important to note that the primary aim of this DNP QI project is for hospice providers to improve care practice and patient's outcome through optimally managing cancer pain levels and improve providers' compliance utilizing the newly implemented pain management protocol/guideline.

Setting

The setting for this DNP project is a community hospice care in Las Vegas, Nevada. The project site serves the communities of Las Vegas, Henderson, and Pahrump. The hospice practice size has an average patient census of about 50 per quarter. The project site hospice organization primarily receives funding from the federal, state, and the city government. Medicare is the primary payer of this specific hospice site and most hospice organizations. The hospice care organization sees a wide range of patients from adolescents all the way to geriatrics; however, most of their hospice patients are mid-age patients (from 40 years old and up) and elderlies. The hospice organization provides a variety of services including medical and nursing care, physical therapy, personal care, dietary, social work services, and bereavement services. In addition, there are different levels of hospice care being provided to patients which includes routine home care, continuous care, respite care, and general inpatient care. This DNP QI project is focusing on terminal cancer patients under their routine home care and continuous care level of care. The hospice site also utilizing an electronic medical record (EMR) system called Hospicesoft.

Population of Interest

The population of interests are the hospice HCPs' (prescribers and non-prescribers/RNs) at the practice site including the project mentor (PM). The direct population of interests are the

two owners (both an RN), one primary medical director, one sub medical directors, two NPs, seven RN case managers, one lead case manager, the DON, and the project mentor (PM). These are the staff that will be educated about the new protocol. However, only the prescribers (two physicians and two NPs) will be the direct participants for the convenience of this QI project during the implementation phase and the data collection process. These hospice healthcare professionals were chosen for the project because they all directly and indirectly provide patient care with regards to managing the terminally-ill cancer patient's pain level and QOL. The newly implemented pain management protocol will be administered by the project site's hospice HCPs' (participants) to their patients.

The hospice patients (adult terminally-ill cancer patients) will be the indirect population of interest that this DNP student hope to indirectly positively impact by improving their pain levels post the implementation period. The patients that will indirectly be part of the project are adult hospice patients that are 18 years old and above with primary hospice diagnosis of cancer. The project site is very limited in accepting hospice patients with a primary diagnosis of terminal cancer. With that being said, there will be only four to five indirect sample chart patients to be monitored and reviewed retrospectively for this DNP project. Exclusion criteria in this DNP project include hospice patients in the general inpatient unit, patients without cancer diagnosis as their primary hospice diagnosis, and hospice cancer patients less than 18 years of age.

Stakeholders

The stakeholders for the DNP QI project are key individuals who have a strong buy-in and interest in the DNP project and the project outcome to help improve patient outcome and care practice. Stakeholders can provide valuable expertise and support to the DNP project to help with various aspects of the study or the DNP project implementation so it can perform optimally.

The stakeholders for the DNP project include the owners who are nurses themselves, the medical directors, nurse practitioners, RN case managers, DON, office manager, PM, the patients and their family members or caregivers. The hospice office manager, although not a clinician, is also a stakeholder in this QI intervention as she wants to ensure for the hospice HCPs (prescribers and nurses) to provide the best quality of care, comfort, and maximize the patient's quality of life by optimally managing patient's pain level. Permission to complete the project at the project site has been granted and also no affiliation agreements is required from the hospice project site. The site authorization letter and the affiliation agreement are attached in the Appendix A of this paper.

Interventions

The selected intervention will be an introduction of a protocol for hospice HCPs' at the project site based from the NCCN CPG in Oncology: Adult Cancer Pain national guideline. The intervention's goal is to implement an evidence-based protocol for hospice providers (prescribers and nurses) in the selected hospice project setting as their standardized care approach. The goal is to ultimately improve care practice and patients' outcome by effectively managing hospice cancer patients' pain levels and improve providers' compliance with the newly implemented cancer pain management guidelines.

During week one of the pre-intervention phase, the project lead (DNP student) will have a formal onsite meeting session briefing the direct population of interest (two owners/RNs, four providers/prescribers, RN case managers, DON, office manager, and the PM, discussing about the project timeline, purpose, aims, and objectives of the QI project, and review of the goals of the project over the next five weeks. Dissemination of the NCCN CPG protocol intervention will be done via a presentation slideshow at the project site led by this project leader. Sometime in between week 1 to week 2 of the project timeline, an educational material presentation

(including the NCCN protocol teaching) will be provided to the project site via a slideshow presentation, which includes the established tools to be used as part of the QI project. The four providers (two physicians and two NPs) will be the direct participants for four weeks for the convenience of this QI project during the implementation and data collection process. Data collection process conducted by this project leader will start during week one (pre-intervention) until week four (post-intervention) via chart audit tools to monitor patients' pain scale rate and providers' compliance or adherence of the new cancer pain management protocol (selected intervention). The goal is to see whether the selected intervention (new hospice cancer pain management protocol) will help improve patients' pain rate and providers' compliance with the newly implemented protocol pre versus post intervention.

Tools/Instrumentation

According to Tidwell & Anaya (2017) researchers develop tools and instruments to assist in data collection process and analysis. The established tools/instruments that will be utilized for this QI project are the NCCN CPG cancer pain management protocol via an educational presentation slideshow (Appendix C), Numerical Pain Rating Scale (NPRS) and PAINAD Scale (Appendix D), chart audit tools to monitor providers' compliance of the NCCN protocol and monitoring of the patient pain scale rate (Appendix E), and the Hospicesoft EMR system. Permission request to reference and use NCCN CPG and their approval can be seen in Appendix F.

NCCN CPG Protocol Intervention

The NCCN national approved guideline developed the adult cancer pain management protocol as there is a mounting evidence in oncology literature that patient's QOL and survival are linked to an early and effective palliative care, which includes pain management (NCCN,

2021). More importantly, there is vast evidence in research studies that undertreatment of pain remains a significant struggle or issue in cancer patients, including hospice or terminally-ill patients (NCCN, 2021). It is the NCCN's intent to achieve the goals of pain management through optimizing the pain treatment outcomes in five dimensions or frequently known as the "5 A's" of pain management (analgesia, activities, adverse effects, aberrant drug taking, and affect) (NCCN, 2021). Through this newly implemented evidence-based hospice cancer pain protocol intervention, the intent is to improve terminally-ill cancer patients' outcome through a more controlled pain levels and improve providers' compliance in utilizing the new pain management protocol by the end of the QI project. The NCCN CPG in Oncology protocol (Comprehensive Pain Assessment and the Principles of Cancer Pain Management) will be explained and presented through a PowerPoint presentation by this project lead as an educational material for the project site's stakeholders and direct participants to see and follow (Appendix C). The NCCN cancer pain management protocol comprises of protocols, guidance, and an uncomplicated algorithm for the hospice HCPs' (nurses and prescribers) to follow that all participants can implement without any difficulties, directing the cancer care practice to the correct flowchart as with any other CPGs'.

Numerical Pain Rate Scale and PAINAD Scale

The NPRS (see Appendix D) is an established pain assessment tool widely implemented in clinical practice because of its reliability and validity. It is an 11-point scale from 0-10, zero being no pain and 10 being the most intensity pain (Ability Lab, 2021). NPRS is commonly used for verbal patients as he or she selects a value that is most in line with their pain intensity in the last 24 hours. Williamson & Hoggar (2005) reported that NPRS has a good sensitivity while producing data that can statistically be analyzed (Ability Lab, 2021). This pain scale tool is also

already being currently utilized in the hospice project site as one of their primary pain assessments tools for verbal hospice patients. More so, the NPRS is also widely suggested and presented in the NCCN CPG protocol.

The PAINAD scale (see Appendix D) is another established pain assessment tool and currently being widely utilized in hospice and/or palliative care settings due to its high reliability and validity for non-communicative patients. Currently, it is also being used by nurses and providers at the project site as their pain assessment tool for their non-verbal patients. The NPRS and PAINAD scale will be a necessary tool to gather data and monitor patients' pain scale rate pre and post intervention. The patients' pain rate will be collected on a weekly basis by this project lead directly from the patients' chart via the EMR system during week one through four with the goal to see an improvement in patients' pain rate pre and post intervention.

Chart Audit Tools

The chart audit tools will be comprised of two parts: Chart Audit Tool for Providers' Compliance Monitoring and for Pain Scale Rate Monitoring (see Appendix E). The project lead (with the help and guidance of the project team) has determined an efficient chart audit tool necessary for data collection process and analysis. Both chart audit tools are based from the NCCN CPG protocol.

Chart Audit Tool to Monitor Providers' Compliance of the Protocol. The project lead has determined two key elements within the NCCN CPG protocol to determine the prescriber's compliance. These two key elements are the utilization of the comprehensive pain assessment and the integrative/multi-modal approach of interventions through the recommended principles of cancer pain management and algorithm (NCCN, 2021). The project lead thoroughly reviewed the NCCN cancer pain management protocol alongside with the current literature and has

determined that compliance of usage of the comprehensive pain assessment and a multi-modal approach by hospice HCPs' are aligned with evidence-based best practices in the field of adult cancer pain management, including EOL care (NCCN, 2021). The chart audit tool questionnaire will be filled out by the project lead with the help of EMR charts once weekly on all terminal cancer sample patients for data collection. Data collection will start beginning on week one until week four and information and results will be transferred over to an Excel spreadsheet for data analysis on week 5 (See Appendix G). The spreadsheet shown (Appendix G) is just a snapshot sample of how the spreadsheet is going to look like for the reader's clarification.

Chart Audit Tool to Monitor Pain Scale Rate. The second part of the audit tools is to monitor patients' pain scale rate pre and post intervention from week one to week four. As mentioned previously, the hospice project site is limited in accepting patients with primary hospice diagnosis of cancer. There were only 12 patients in the year 2020 with primary diagnoses of terminal cancer. It is for this reason there is a limited sample included in this QI project to be monitored for their pain rate pre and post implementation. The sample patients may range between five or six during the time of implementation (depending on the hospice' census with primary diagnosis of terminal cancer). The project lead will monitor patients' pain scale rate via chart audits using the Hospicesoft EMR one to three times a week (depending on the nurse's frequency visit to the patients) starting on week one (pre-intervention) until week four (post-intervention). Excel spreadsheet (Appendix G) will also be utilized for data collection for this section and to determine whether the newly initiated protocol was effective in improving adult hospice cancer patient's pain level as seen during data analysis pre versus post implementation (See Appendix G).

EMR System

The EMR system utilized for this DNP project will be Hospicesoft. It is an EMR system widely used in the hospice/palliative care setting. Hospicesoft allows the project lead the ability to view and search within a patient's chart such as viewing their medication profile, treatment plan, any changes in the treatment plan, progress notes, prescribers and nurses documentations and SOAP notes including patient's updated pain scale rate on every patient's visit. The EMR allows for a thorough data review process and a necessary tool for data collection and analysis for the QI project**.**

Data Collection Procedures

For the data collection, all identifying information will remain confidential and redacted. The sample patients will be numbered one through five or six and will be coded as patient 1 through 5 or 6. The four providers/prescribers will be coded as provider 1 through 4. Demographic information has been determined as not necessary for this project. As mentioned above, the data collection process will start during week one (pre-intervention phase) until week four (post-intervention phase) using the chart audit tools to monitor patients' pain rate and providers' compliance of the new cancer pain management protocol. The data collection entries will be inputted into an Excel spreadsheet (Appendix G). The project lead will then utilize the hospice site's Hospicesoft EMR system to perform one to three times weekly chart audits for the pain scale (depending on the nurse's patients visits), reviewing for all sample hospice cancer patients' pain rate pre and post intervention.

For the providers' protocol compliance monitoring (Appendix E), this project leader will fill out the chart audit tool questionnaire (based on the NCCN guideline/protocol) on day one via the EMR system. The questionnaire will be filled out once weekly basis for all sample hospice

cancer patient during the duration of the implementation phase (four weeks). The providers' compliance tool questionnaire will have a total maximum number between zero to 18 (18 being the most compliant) and will be using this as a numeric basis to determine whether the provider(s) are being compliant none, some, or almost all the time.

The chart audit tools (Appendix E) for both the patients' pain scale rate and the providers' compliance monitoring will be transferred over to a spreadsheet (Appendix G) by the project leader for a more efficient and organized data collection process and extraction, along with the data analysis and evaluation on week five. Week five is the time for data analysis report, evaluation of the project results, final meeting and discussion with the project site's stakeholders and direct patient population through a presentation, and for any last-minute question and answer portion from the project site.

Ethics/Human Subjects Protection

As mentioned above, the data collection process will remain confidential and redacted. The sample patients' (five or six) and the four providers as participants will retain their anonymity by coding them as patients one through five and providers one through four. Only the project lead will have access to the data collection entries from Excel using a secured protected password. Throughout the duration of the QI project, the patients and the providers' personal and health information will remain confidential and protected by the project lead. There will be zero incentive or compensation nor risks to the participants and the project site's population of interests.

The participants partaking in the QI project and all involved in the project (as mentioned above) voluntarily agreed to collaborate and participate in the QI project. The hospice project site administrator has approved the use of their site to conduct the QI project, as it will be

impacting the overall care practice of providers and patients' outcomes when it comes to cancer pain management. The main aim of this QI project intervention is to evaluate the initiated changes in adult cancer pain management protocol through chart audits and data collection pre- and post-implementation to determine if the selected intervention (NCCN cancer pain protocol) will have an effect and improve patient's pain level and provider's compliance.

Measures/Plan for Analysis

With the help of TUN's statistician and the project team, it has been determined that a paired t-test will be utilized to ascertain if there was a difference between the pre-intervention (before the cancer pain protocol is introduced) compliance or pain scores compared to post-intervention compliance or pain scores at three separate time points. There will be three different time points of comparisons from week 1 (pre-intervention) versus week 2 (post-intervention); week 1 (pre-intervention) versus week 3 (post-intervention); and week 1 (pre-intervention) versus week 4 (post-intervention) comparing the pre-protocol providers' compliance and the patients' pain rate to each time point after the protocol intervention was introduced. The resulting p-value will be from the paired t-test comparing pre-protocol intervention data results to each time point post-intervention (weeks two through four). The results will be plotted on a line graph to better demonstrate and further interpret the results for this QI project.

For the providers' compliance data analysis, the chart audit tool questionnaire will be filled out by this project lead (once a week) with the help of the EMR system for the pre and post intervention phase all. The data will be transferred over to the Excel spreadsheet (Appendix G) by the project lead. There will be a maximum potential score of 18 points (18 "yes" answers) from the chart audit tool questionnaire. Change in the number of yes answer will be used to assess whether there is an improvement in the providers' compliance to the protocol from pre-

intervention (week 1) through week 4 (post-intervention). Each provider's compliance rate will be gathered on a weekly basis and input into the spreadsheet. The hypothesis is that providers will have a higher score (more compliance) starting from a low score during pre-intervention phase versus the post-intervention phase. The provider's compliance was not measured as yes or no variables because the goal is to determine improvements in their compliance due to introduction of the new NCCN cancer pain protocol. Week 5 will be used for data extraction via the Excel spreadsheet (Appendix G) and data analysis of results, including visualization and interpretation using a line graph.

The same method will be employed for the pain rate data. On a weekly basis from week one through four, the project lead will collect the maximum pain rate level of each patient for the week (maximum potential score of 10 from NPRS or PAINAD) and input the value for each patient into the spreadsheet. The hypothesis is for the patients to have a decreased maximum pain score (because of the new cancer pain protocol intervention) from pre-intervention versus post-intervention from three different time points as mentioned above. Week 5 will again be used for data analysis and explanation of results including an interpretation using a line graph.

Data Analysis/Results

The data collection of the four weeks was entered into an Excel spreadsheet by the project lead. During the implementation phase, the spreadsheet was organized into a more readable and organized manner every week for an easier interpretation of results and statistical analysis. A statistician's professional expertise was utilized in collaboration with data collection and data analysis to solidify the accuracy of the data collection and statistical analysis/evaluation process. A statistics software calculator R version 4.0.5 was also utilized to calculate statistical data analyses from the spreadsheet such as the standard error, mean compliance, mean pain

score, degrees of freedom, and p values. The primary objective of this QI project is to improve care practice and patients' outcome through effective management of hospice cancer patients' pain levels. Further, it is to improve providers' compliance through introduction and utilization of the new intervention cancer pain management guidelines or protocol at the project site. The hypothesis is that the new intervention (NCCN cancer pain protocol) will help improve the sample patients' pain level and providers' compliance with the new cancer pain protocol from pre to post intervention phase.

The providers' compliance to the new cancer pain management protocol intervention and the patients' pain rate were analyzed using the paired t-test. The paired t-test was chosen based on the following assumptions: (1) The observations are dependent matched pairs; (2) The variables of weeks are categorically labeled as "before and after". The analysis was adjusted using a student t-test for a sample size less than 30. This specific test was chosen because it is appropriate for matched proportions. They are all hospice patients admitted with terminal cancer and pain management.

Providers' Compliance

Hypothesis for Week 1 and Week 2: Null Hypothesis (H_o: $u_1 = u_{2)}$: The mean providers' compliance of week 1 and week 2 are equal. **Alternative Hypothesis** (H_a: $u_1 \neq u_{2)}$: The mean providers' compliance of week 1 and week 2 are not equal.

Mean compliance for week 1 = 11.05

Mean compliance for week 2 = 12.0

Test *(t)* statistic is -5.6 (degrees of freedom=19), with an associated p-value = 0.001, which is less than the significance level, alpha level of significance = 0.05. We reject the null hypothesis that the mean providers' compliance of each group is equal. There is evidence that the mean

compliance of week 1 and week 2 are not equal. Therefore, we can say that there is a significance increase of mean providers' compliance from week 1 to week 2 by 8.6%.

Hypothesis for Week 1 and Week 3. Null Hypothesis (H_o: $u_1 = u_{2)}$: The mean providers' compliance of week 1 and week 3 are equal. **Alternative Hypothesis** (H_a: $u_1 \neq u_{2)}$: The mean providers' compliance of week 1 and week 3 are not equal.

Mean compliance for week 1 = 11.05

Mean compliance for week 3 = 12.95

The *t statistic* is -8.8 (degrees of freedom =19), with an associated p-value = 0.001, which is less than the significance level, alpha level of significance =0.05. We reject the null hypothesis that the mean compliance of each group is equal. There is evidence that the mean compliance of week 1 and week 3 are not equal. Therefore, we can say that there is a significant increase in mean providers' compliance from week 1 to week 3 by 17.2%

Hypothesis for Week 1 and Week 4. Null Hypothesis (H_o: $u_1 = u_{2)}$: The mean providers' compliance of week 1 and week 4 are equal. **Alternative Hypothesis** (H_a: $u_1 \neq u_{2)}$: The mean providers' compliance of week 1 and week 4 are not equal.

Mean compliance for week 1 = 11.05

Mean compliance for week 4 = 15.45

The *t* statistic is -14.1 (degrees of freedom=19), with an associated p-value = 0.001, which is less than the significance level, alpha level of significance =0.05. We reject the null hypothesis that the mean providers' compliance of each group is equal. There is evidence that the mean providers' compliance of week 1 and week 4 are not equal. Therefore, we can say that there is a significant increase in mean providers' compliance from week 1 to week 4 by 39.8%.

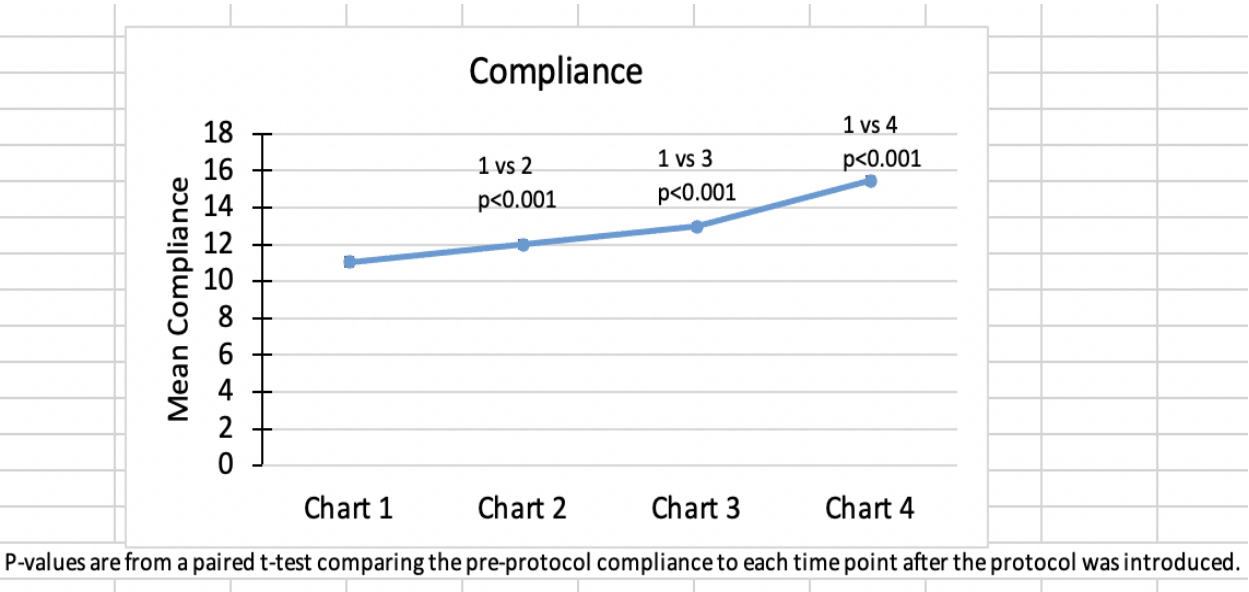

Figure 1. Providers' compliance line graph from three different time points (Weeks 1-4).

Pain Rate

Hypothesis for Week 1 and Week 2: Null Hypothesis (H_o: $u_1 = u_2$): The pain rate of week 1 and week 2 are equal. **Alternative Hypothesis** (H_a: $u_1 \neq u_2$): The pain rate of week 1 and week 2 are not equal.

Mean pain rate for week 1 = 7.5

Mean pain rate for week 2 = 7.2

The *t* statistic is 0.6 (degrees of freedom=4), with an associated p-value = 0.573, which is greater than the significance level, alpha level of significance =0.05. We cannot reject the null hypothesis that the mean pain rate of each group is equal. Therefore, we can say that the decrease in pain rate from week 1 to week 2 is not significant.

Hypothesis for Week 1 and Week 3. Null Hypothesis (H_o: $u_1 = u_2$): The pain rate of week 1 and week 3 are equal. **Alternative Hypothesis** (H_a: $u_1 \neq u_2$): The pain rate of week 1 and week 3 are not equal.

Mean pain rate for week 1 = 7.5

Mean pain rate for week 4 = 6.1

The *t* statistic is 2.7 (degrees of freedom=4), with an associated p-value = 0.052, which is greater than the significance level, alpha level of significance =0.05. We cannot reject the null hypothesis that the mean pain rate of each group is equal. Therefore, we can say that the decrease in pain rate from week 1 to week 3 is not significant.

Hypothesis for Week 1 and Week 4. Null Hypothesis (H_o: $u_1 = u_2$): The pain rate mean of week 1 and week 4 are equal. Alternative Hypothesis (H_a: $u_1 \neq u_2$): The pain rate mean of week 1 and week 4 are not equal.

Mean pain rate for week 1 = 7.5

Mean pain rate for week 4 = 4.3

The *t* statistic is 6.2 (degrees of freedom=4), with an associated p-value = 0.003, which is less than the significance level, alpha of significance=0.05. We can reject the null hypothesis that the mean pain rate of each group is equal. We can reject the null hypothesis that the mean pain rate of week 1 and week 4 are equal. There is a significant decrease in pain rate from week 1 to week 4 by 42.7%.

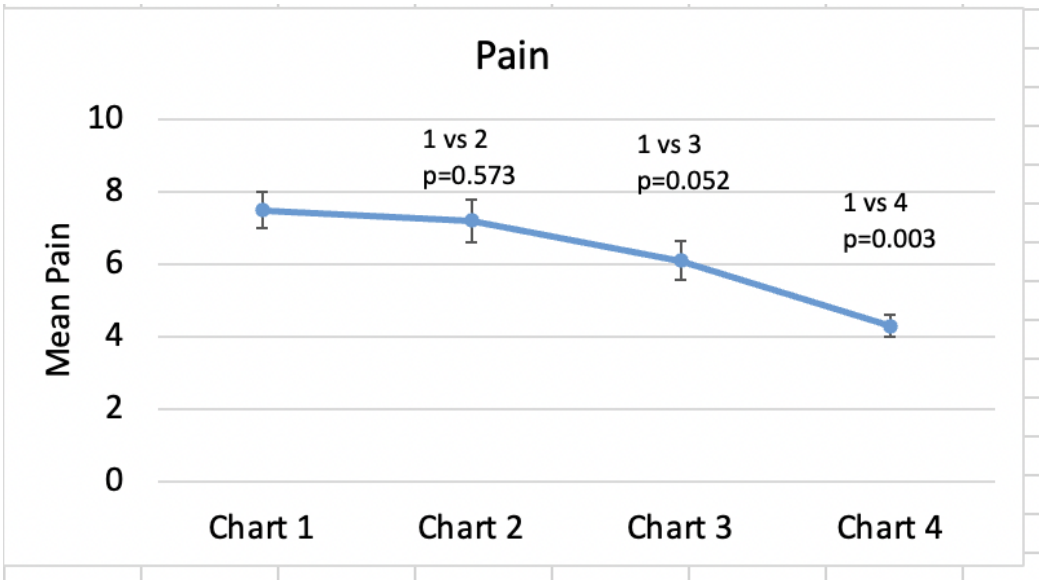

Figure 2. Pain rate line graph from three different time points (Weeks 1-4).

The project lead is acknowledging that the failure of significant decrease in pain scores may be due to a very limited small sample size. However, the project lead is also aware that there could also be other significant factors that can affect patients pain scores surrounding terminal cancer pain management.

Discussion

It is important for the readers to know that the project site has no formal and uniformed terminal cancer pain protocol for the EOL clinicians/providers prior to the implementation of this QI project. The need for a clear and uniformed evidence-based cancer pain protocol during hospice care has been heightened after seeing the positive results of the QI project during the data analysis phase of this QI project. Because of the new intervention cancer pain protocol by the NCCN, the providers at the project site were able to better manage and optimize hospice cancer pain which also led them to be more compliant with the new EOL pain protocol as seen in the data analysis and results section of the implementation phase.

The findings from the providers' compliance analysis indicated that there is a steady increase of protocol compliance from pre-intervention phase to post-intervention phase from weeks 2 to 4. There was a significance increase of mean providers' compliance form week 1 to week 2 by 8.6%; 17.2% increase from week 1 to 3; and a big jump of compliance on the last week of implementation on week 4 by 39.8% (see figure 1). The results from the data analysis justified the hypothesis that the new intervention of the NCCN cancer pain protocol helped improve the providers' compliance from pre to post intervention phase.

The findings from the sample patients' pain rate indicated that there is a decrease of pain rate from week 1 (pre-intervention) to week 4 (post-intervention). As seen in the line graph, there

is not much of a decrease of pain rate from the pre-intervention phase (week 1) to weeks 2 and 3 (post-intervention); however, by the last fourth week of the implementation phase, a significant decrease of 42.7% of pain rate was seen (see figure 2). This is probably due to some factor such as the patients' terminally-ill and complex cases that have significantly became more complex and declined overtime. In hospice or EOL care, sudden and drastic change or decline to the individual's prognosis is not uncommon. An example is with sample patient 4 who overtime has declined significantly and became non-verbal by the third week. The results from the data analysis justified the hypothesis that the new intervention of the NCCN cancer pain protocol helped improve patients' pain rate from pre to post intervention phase. For the readers' convenience, this DNP project objectives are listed below with the aim to overall improve care practice and patient's outcome by optimally managing patients' pain levels and improve providers' compliance with the newly implemented pain management guidelines.

1. Develop an evidence-based pain management guideline/protocol utilizing the NCCN national clinical practice guideline (CPG) for terminal cancer patients in hospice care as a standardized care approach by EOL HCPs'.
2. Implement the new EOL pain management guideline (based from the NCCN national clinical practice guideline) for cancer patients at the project site to be utilized by hospice nurses and prescribers, rather than their current practice.
3. Improve hospice cancer patients' pain levels and maintain hospice providers' compliance with utilization of the approved evidence-based pain management protocol intervention.

Therefore, the QI project designed to improve patient outcomes and care practice reached its objective to overall improve hospice cancer patients' pain levels and maintain hospice

providers' compliance with the utilization of the approved evidence-based management protocol intervention (NCCN CPG for adult cancer pain) (NCCN, 2020).

Significance

The QI project clearly reflected its significance to nursing and EOL care arena. By achieving the objectives and aims of this QI project, it opens the opportunity to help bridge the gap of under treatment in hospice or EOL cancer pain management at the project site. As part of the planned intervention, incorporating the themes (discussed in earlier section) that have emerged from the literature helped pave the way for hospice providers and the project site to point out the importance of ongoing comprehensive assessment, utilize a multi-modal approach in EOL cancer pain care, and appropriate usage of opioids therapy as their mainstay of analgesics for moderate-severe cancer pain as part of the new intervention NCCN cancer pain protocol (NCCN, 2020). In fact, EOL care literature widely suggests that advanced cancer pain control should not be a sole approach (Jara et al., 2018). A multi-modal or integrated approach is the current recommended practice including both pharmacological/non-pharmacological interventions, involving both the family and the patient in hospice care education, and comprehensive pain assessment tools are all necessary for an optimum cancer pain treatment (WHO, 2018). More so, these combination approaches of pharmacological/non-pharmacological interventions, physical measures, integrative therapies, and interventional techniques with analgesics and adjuvants are all suggested approaches for hospice HCPs to use (Coyne et al., 2018). These aforementioned approaches are part of the providers' compliance to the new protocol as seen in the providers' compliance chart audit tool section. The new EOL adult cancer pain protocol (intervention) provided the project site clinicians a systematic way of approaching cancer pain management with hospice patients through the algorithm provided by the NCCN CPG guideline.

Limitations

The QI project design presented three significant limitations to the project. One primary limitation is the small sample size of five participants. Despite the significant statistical result, the limited small sample size does not fully represent the target population. Moreover, a sample size that is too small may increase the potential for a Type II error such as when the null hypothesis is incorrectly valid and no difference between the study groups is reported; hence potentially skewing the results. The small sample size limitation can potentially decrease the power of the study (Deziel, 2018). Further QI projects related to this topic may be feasible to implement the introduced new protocol or guideline in other hospice centers. A multiple hospice care study related to cancer pain management may be necessary to obtain a larger sample size and increase the strength and power of the study.

The second limitation for this QI project is the short time period at only four weeks of implementation. The QI project demonstrated a significant improvement in pain management at later weeks. This may be due to the increased skill of the clinicians/providers. The statistical results could show a more accurate statistically significant increase in improved EOL cancer pain management through compliance of the protocol, if the time period is increased from even possibly eight to 12 weeks. Increasing the time period of the QI project implementation can help minimize biased interpretation of the results.

The third limitation is the COVID-19 pandemic that is unfortunately still going on. Although luckily, the innovation of virtual meetings and many video call conference platforms helped this project lead overcome the barriers to a successful professional collaboration and communication with the project site and stakeholders. There were few instances where the project site had to be closed for a few days and/or up to two weeks due to possible exposures of some staff to COVID-

19 and proper quarantine protocol had to be followed for everyone's safety. Fortunately, the possible exposures of staff happened prior to the actual four weeks project implementation phase which led little to no disruption during the implementation period (e.g. data collection method, data analysis, & chart audits process).

Dissemination

Areas for and further dissemination of the QI project will be geared towards the actual project site, TUN faculty and students, and the DNP online repository site. Internally, the DNP project will be disseminated through a PowerPoint presentation at the project site where the project was implemented to ensure the stakeholder and population of interest are well-informed the including benefits of implementing such cancer pain protocol. The QI project will also be disseminated internally as a deliverable by the project lead via a PowerPoint presentation to the TUN faculty and students on October 21, 2021 (a DNP program deliverable requirement). External dissemination plan will include the DNP repository to further promote the online dissemination of the QI project (Moran et al., 2017) making it more accessible to a wider range of target population such as nurses, undergraduate and graduate nursing students, healthcare professors, clinicians, and other stakeholders. Moreover, the project lead is currently exploring to disseminate and publish the DNP scholarly paper at the Journal of Hospice & Palliative Nursing (JHPN) by the Hospice and Palliative Nurses Association that is being indexed in Medline. It is an excellent way to recognize the importance of the scholarly nursing and the profession in the field of EOL care. JHPN has a writing mentorship program for new authors wanting to publish scholarly work (JHPN, 2021). DNP repository is an excellent platform to showcase and see other DNP nurse leaders' project contribution in the nursing/healthcare field arena. Lasty, the

standardization and the low cost of the pain assessment tools utilized in this project is also a practical method of disseminating this protocol to larger targeted population of cancer patients.

Sustainability

The protocol has also great sustainability at the project site because of its simple and straightforward nature. The chosen NCCN guideline or protocol intervention can be appropriately applied to the project site to improve patient outcomes as the protocol was independently validated outside of the project. More importantly, the theoretical framework/QI method design (MFI/PDSA cycle) for the QI project was carefully chosen to help improve and strengthen the project's long-term sustainability at the project site. Due to its iterative and continuous four-stage cycle nature for improving a process or executing a change, the PDSA cycle QI method allows the project site to standardize the improvement but also gives an opportunity to continuously reflect on the plan and outcome (Stage 4: Act) (Minnesota Department of Health, 2020). Re-examination and re-visitation of the whole four-stage plan/process whilst standardizing the improvement is a suggested exercise by the project site to keep and sustain the original planned intervention or change and/or develop a new plan that might result in better clinical results or patient outcomes (Minnesota Department of Health, 2020).

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Appendix A

Site Authorization Letter

ALTA CARE Hospice & Palliative Care

info@altacare-hospice.com
PH:702.522.8803
FAX:702.522.9483
6280 S Valley View Blvd. Suite 122
Las Vegas, NV 89118

To whom it may concern:

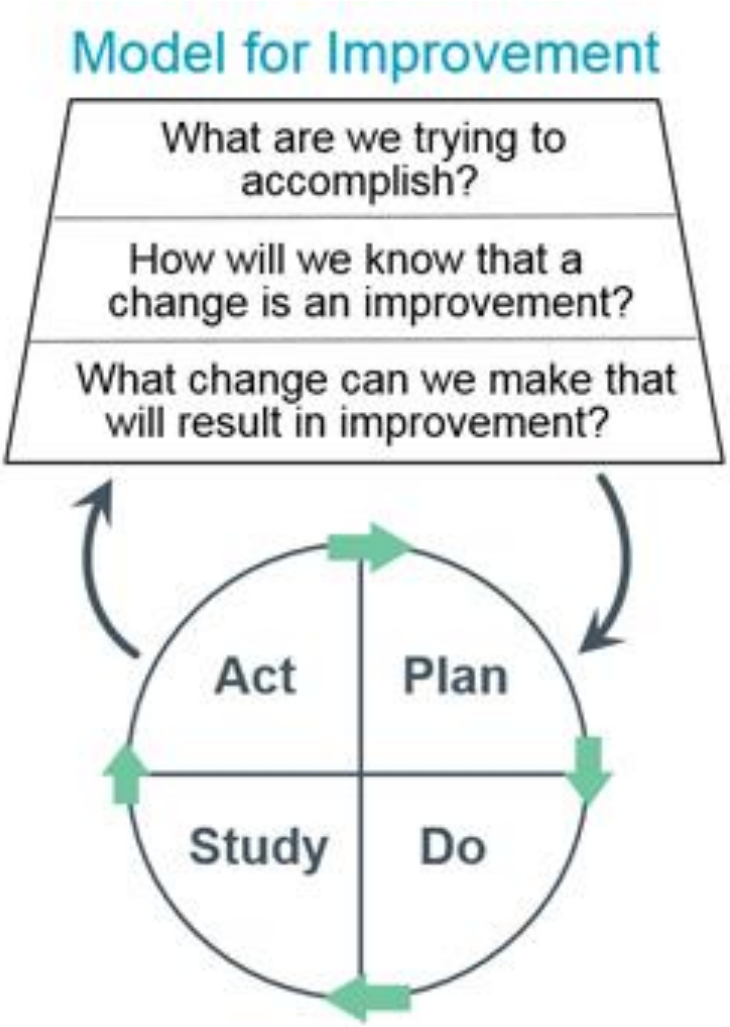
Rodelyn Arceo has permission to complete her Doctoral project at Alta Care Hospice and Palliative Care, Inc. No Clinical affiliation and or agreement is needed.

Sincerely,

Gerlie Comahig, RN
Administrator

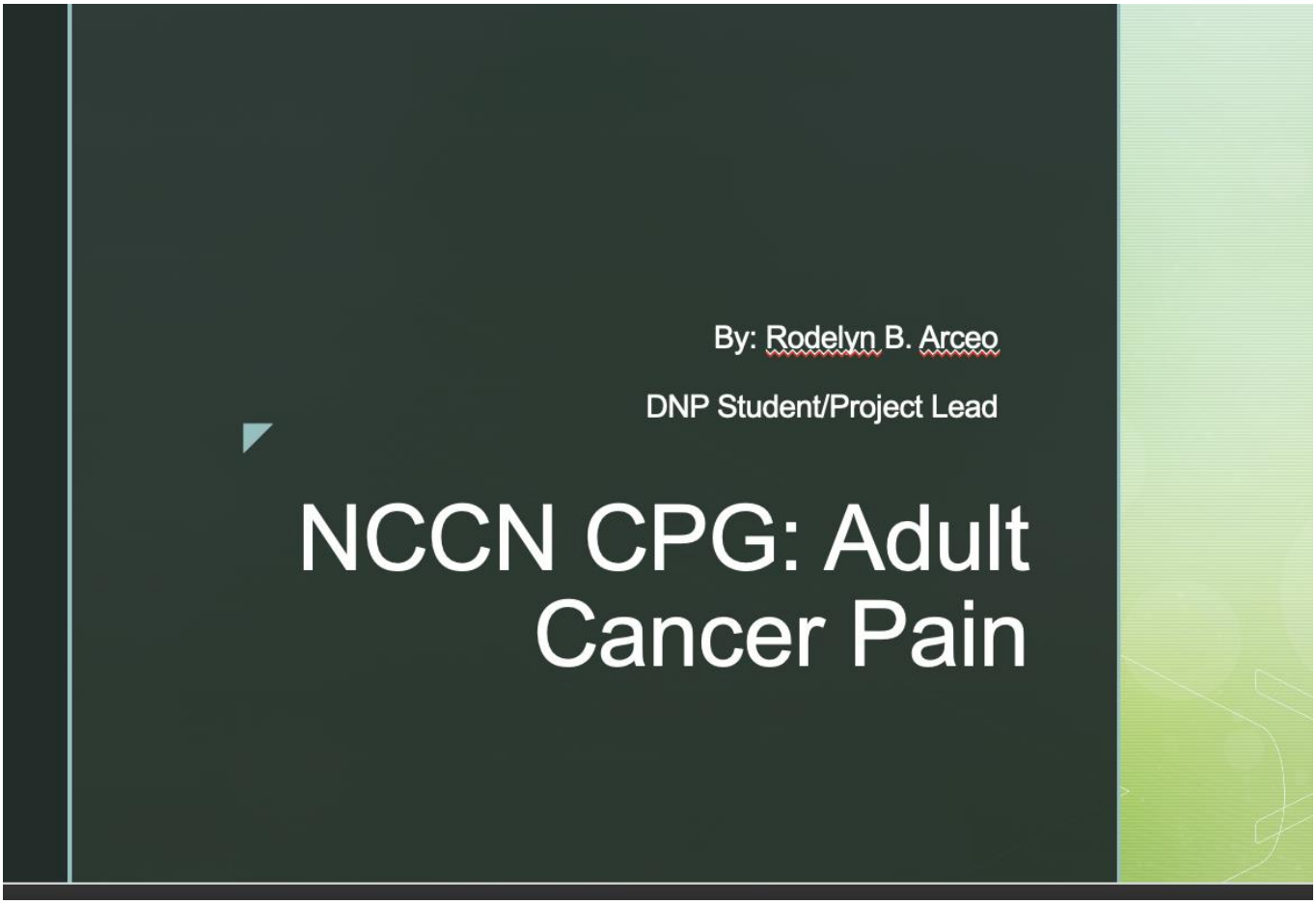
Appendix B

MFI/PDSA Cycle



Source: Institute for Healthcare Improvement. (2021)

Appendix C


By: Rodelyn B. Arceo
DNP Student/Project Lead
NCCN CPG: Adult Cancer Pain

COMPREHENSIVE CANCER PAIN ASSESSMENT

National Comprehensive Cancer Network®

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COMPREHENSIVE PAIN ASSESSMENT

- Patient's self report of pain is the standard of care. If the patient is unable to verbally report pain, an alternative method to obtain pain rating and response should be utilized. (See PAIN-A, 2 of 2).
- The goal of comprehensive pain assessment is to find the cause of the pain and identify optimal therapies. Individualized pain treatment is based on the etiology and characteristics of pain, the patient's clinical condition, and patient-centered goals of care.
- The etiology and pathophysiology of the pain should be investigated, including medical history (including psychosocial factors), physical exam, laboratory tests, and imaging studies.
  - Etiology factors may include direct involvement of cancer itself, cancer therapy (chemotherapy, RT, surgery) or procedures, and coincidental or acute or chronic noncancer pain (eg, arthritis).
  - Pathophysiology factors may include nociceptive, neuropathic, visceral, affective, behavioral, and cognitive components.

- Pain experience
  - Location, referral pattern, radiation of pain(s)
  - Intensity See Pain Intensity Rating (PAIN-A)
    - Last 24 hours worst and least pain and pain now
    - At rest and with movement
  - Interference with activities
    See Impact of Pain Measurement (PAIN-B, 3 of 3)
    - General activity, mood, walking ability, work ability, relationship with others, sleep, appetite, and enjoyment of life
  - Timing: onset, duration, course, persistent, or intermittent
  - Description or quality
    - Aching, stabbing, throbbing, or pressure often associated with somatic pain in skin, muscle, and bone
    - Gnawing, cramping, aching, or sharp pain often associated with visceral pain in organs or viscera
    - Burning, tingling, shooting, or electric/shocking pain often associated with neuropathic pain caused by nerve damage
  - Aggravating and alleviating factors
  - Other current symptoms; symptom clusters
  - Current pain management plan, both pharmacologic and non-pharmacologic. If medications are used, determine:
    - What medication(s), prescription and/or over the counter (OTC)?
    - Dose, route of administration, frequency?
    - Current prescriber?

- Pain experience continued
  - Response to current therapy
    - Pain relief
    - Patient adherence to medication plan
    - Medication adverse effects such as constipation, sedation, cognitive slowing, nausea, and others
  - Breakthrough pain is episodic pain not controlled with existing pain regimen; see breakthrough pain on PAIN-G, 2 of 13.
  - Prior pain therapies
    - Reason for use, length of use, response, reasons for discontinuing, and adverse effects encountered
  - Special issues relating to pain
    - Meaning and consequences of pain for patient and family/caregiver
    - Patient and family/caregiver knowledge and beliefs surrounding pain and pain medications
    - Cultural beliefs toward pain, pain expression, and treatment
    - Spiritual, religious considerations, and existential suffering
    - Patient goals and expectations regarding pain management
    - Assess for use of integrative therapies (See PAIN-D)
    - Screen for potential adverse interactions or effects
    - Assess risk of opioid abuse/misuse/diversion
- List of potential risk factors for misuse/abuse (See PAIN-G, 4 of 13)

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COMPREHENSIVE PAIN ASSESSMENT

- **Psychosocial Support** (See PAIN-H) (See NCCN Guidelines for Palliative Care)
  - **Patient distress** (See NCCN Guidelines for Distress Management)
  - **Family and other support; assess impact and burden on caregiver and recommend resources as appropriate**
  - **Psychiatric history including current or prior patient, family/caregiver, or household history of substance abuse**
  - **Risk factors for aberrant use or diversion of pain medication** (See PAIN-G, 4 of 13)
    - ◊ **Patient, environmental, and social factors as identified by a detailed patient evaluation[1] and/or screening tools at initiation of care (eg, SOAPP®-R[2], ORT[3]) and monitoring of ongoing analgesic use (eg, COMM).[4] (Specific screening tools have not been validated in the setting of cancer care).[5]** (See PAIN-G, 6 of 13)
  - **Risk factors for undertreatment of pain**
    - ◊ **Geriatric, minority, or female patients; communication barriers; history of substance abuse; neuropathic pain; cultural factors**
- **Medical history**
  - **Oncologic treatment including current and prior chemotherapy, hormonal therapy, RT, and surgery**
  - **Other significant illnesses, conditions**
  - **Pre-existing chronic pain**
- **Clinical assessment, physical examination, and laboratory and imaging studies to evaluate for disease progression**

COMPREHENSIVE CANCER PAIN ASSESSMENT

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IMPACT OF PAIN MEASUREMENT[6,7]

Mark the number that describes how much, in the past [week/24 hours], pain has interfered with your:

1. General Activity	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
2. Mood	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
3. Walking Ability	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
4. Normal Work (includes both work outside the home and housework)	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
5. Relations with other people	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
6. Sleep	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes
7. Enjoyment of life	0 Does not Interfere	1	2	3	4	5	6	7	8	9	10 Completely Interferes

[6] Used with permission from Cleeland CS, Nakamura Y, Mendoza TR, et al. Dimensions of the impact of cancer pain in a four country sample: New information from multidimensional scaling. Pain 1996;67:267-273

PRINCIPLES OF CANCER PAIN MANAGEMENT

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PRINCIPLES OF CANCER PAIN MANAGEMENT

Pain Definition

Pain is defined by the International Association for the Study of Pain (IASP) as an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.[a]

General Principles

- Optimal use of disease-specific therapies is essential to managing tumor-related pain.
- Survival is linked to symptom control and pain management, which contribute to broad quality-of-life improvement. Pain management is an essential part of oncologic management.
- Analgesic therapy is done in conjunction with management of multiple symptoms or symptom clusters. Consider the interaction of complex pharmacologic therapies and the risk for analgesic misuse.
- An interdisciplinary team is optimal; consider early referral to a palliative care provider. (See NCCN Guidelines for Palliative Care)
- Provide/refer for psychosocial support, including emotional and informational support and coping skills training. (See PAIN-C)
- Provide accessible educational material to improve pain assessment, pain management, and the safe use of opioid medications based on the patient's identified needs.[b] (See PAIN-I)
  - Involve patients in developing treatment plans and setting meaningful, realistic expectations and measurable goals.
- Address the multidimensional impact of "suffering" on patients and caregivers in a culturally respectful manner.

Assessment

- Screen all patients for pain at each contact. (See PAIN-2)
- Routinely quantify and document pain intensity and quality as characterized by the patient (whenever possible). Include patient reporting of breakthrough pain, treatments used and their impact on pain, satisfaction with pain relief, pain interference, provider assessment of impact on function, and any special issues for the patient relevant to pain treatment. If necessary, get additional information from caregiver regarding pain and impact on function.
- Perform comprehensive pain assessment if new or worsening pain is present and regularly for persisting pain. (See PAIN-B)
- Evaluate for risk factors for opioid abuse/misuse/diversion.

Management/Intervention

- Goals of pain management are highlighted by the "5 A's" of outcomes:[b]

1. Analgesia (optimize analgesia)
2. Activities (optimize activities of daily living [ADLs])
3. Adverse effects (minimize adverse effects) (See PAIN-G)
4. Aberrant drug taking (avoid aberrant drug taking) (See PAIN-H)
5. Affect (relationship between pain and mood)

- Prevention of analgesic side effects, especially constipation, is of paramount importance.
- For acute, severe pain or pain crisis, consider hospital or inpatient hospice admission.
- Treat persistent cancer pain with regularly scheduled analgesics or long-acting analgesics, and breakthrough pain with supplemental doses of short-acting analgesics.
- For chronic pain in cancer survivors, See NCCN Guidelines for Survivorship.

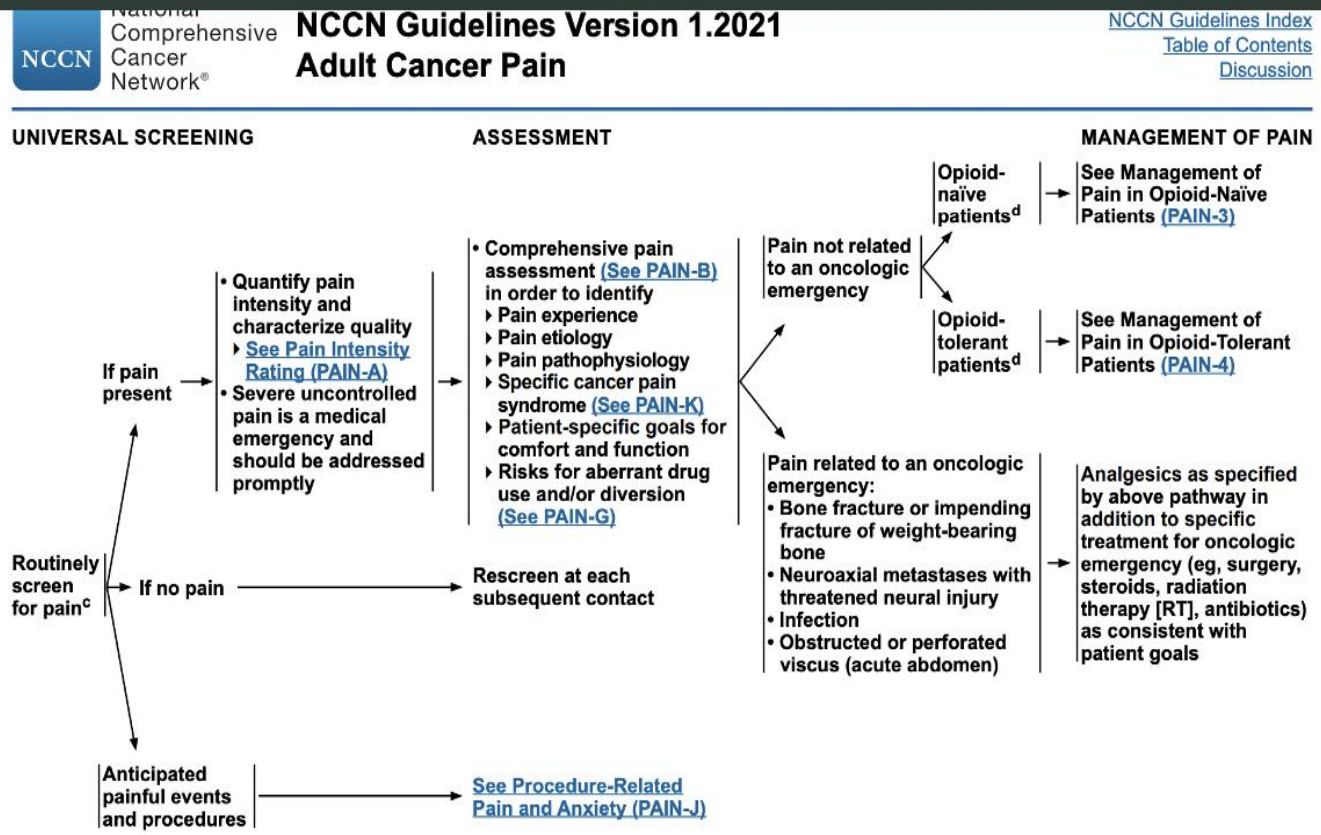
Reassessment

- Perform pain reassessment at specified intervals to ensure that analgesic therapy is providing maximum benefit with minimal adverse effects, and that the treatment plan is followed.
- Encourage patients to report ongoing pain assessments in between visits, as needed.

[a] Raja SN, Carr DB, Cohen M, et al. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises Pain 2020;161:1976-1982.

[b] The Joint Commission. New and Revised Pain Assessment and Management Standards. 2018. https://www.jointcommission.org/assets/1/18/APPROVED_New_and_Revised_Pain_Assessment_and_Management_Standards.pdf.

PRINCIPLES OF CANCER PAIN MANAGEMENT



[c] For chronic pain in cancer survivors, see the NCCN Guidelines for Survivorship.

[d] Opioid-naïve patients are those not chronically receiving opioid analgesic on a daily basis and therefore have not developed significant tolerance. Opioid tolerant includes patients who are chronically receiving opioid analgesic on a daily basis.The FDA identifies tolerance as receiving at least 25 mcg/h fentanyl patch, at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer.

PRINCIPLES OF CANCER PAIN MANAGEMENT

PAIN INTENSITY — See Pain Intensity Rating (PAIN-A)

MANAGEMENT OF PAIN IN OPIOID-TOLERANT PATIENTS[d]

General Principles

- Select the most appropriate medication based on the pain diagnosis (See PAIN-K), comorbid conditions, and potential drug interactions
- Analgesic regimen may include an opioid (See PAIN-G), acetaminophen, NSAIDs (See PAIN-E), and/or adjuvant analgesics (See PAIN-F)
  - If pain is continuous, consider regularly scheduled analgesics
- Anticipate and treat analgesic adverse effects, including opioid-induced constipation (See PAIN-H)
- Provide psychosocial support (See PAIN-C)
- Provide patient and family/caregiver education (See PAIN-I)
- Optimize integrative interventions (See PAIN-D)

→ Reevaluate pain at each contact and as needed to meet patient-specific goals for comfort, function, and safety → See Ongoing Care (PAIN-6)

Mild Pain

- See General Principles above
  AND
- Non-opioids and adjuvant therapies, unless these are contraindicated due to adverse effects or potential drug interactions (See PAIN-G)
- Re-evaluate need for opioids and reduce if appropriate (See PAIN-G, 3 of 13)

Moderate/ Severe Pain

- See General Principles above
  AND
- Non-opioids and adjuvant therapies as appropriate with short-acting opioids as needed (See PAIN-G)
- Titrate short-acting opioid (may require dose increase of 30%–50% or more) (See PAIN-5)
- If 4 or more doses of short-acting opioid are consistently needed per day, consider addition or increase in dose of a long-acting opioid based on the total daily dose

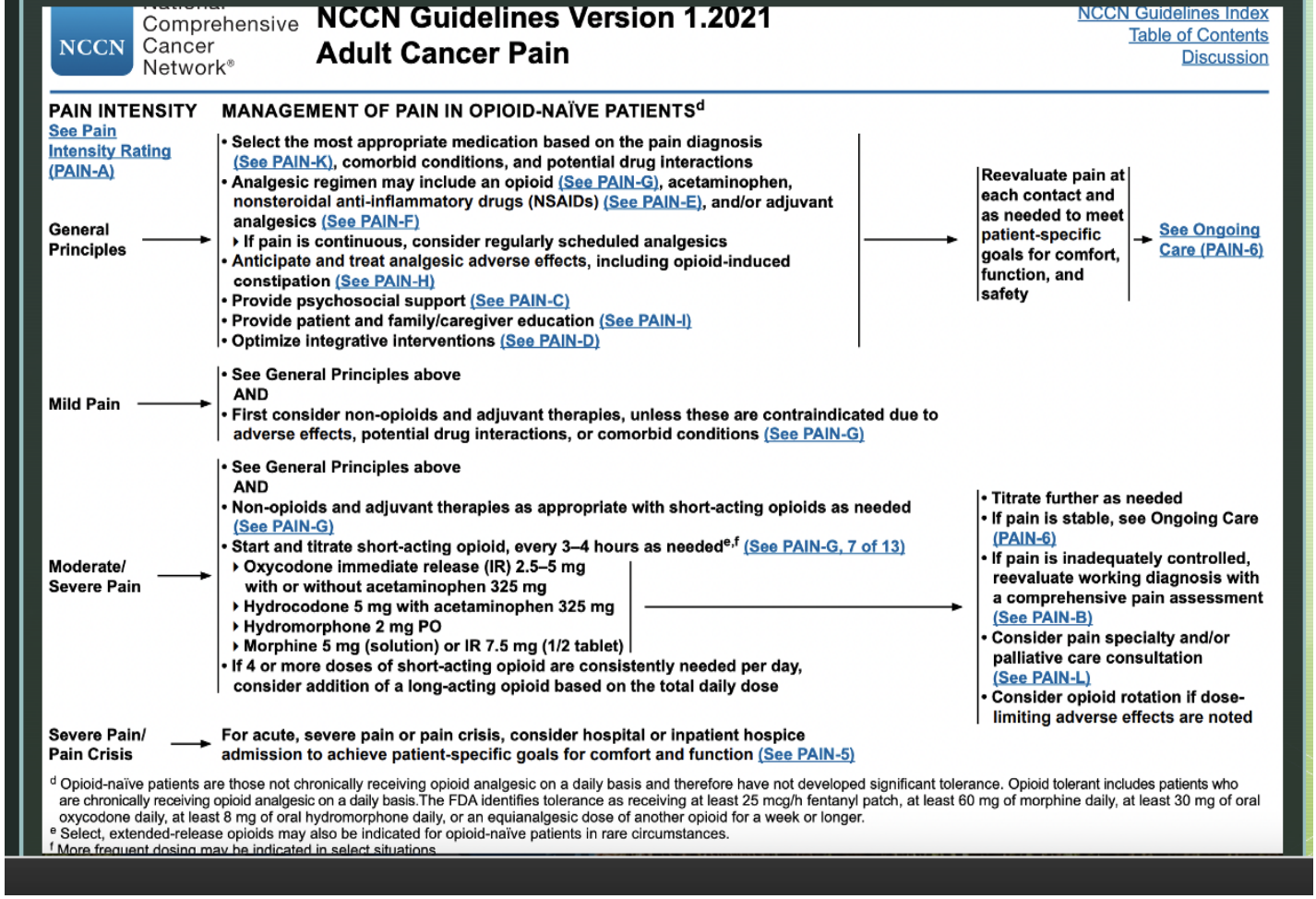
→
- Titrate further as needed
- If pain is stable, see Ongoing Care (PAIN-6)
- If pain is inadequately controlled, reevaluate working diagnosis with a comprehensive pain assessment (See PAIN-B)
- Consider pain specialty and/or palliative care consultation (See PAIN-L)
- Consider opioid rotation if dose-limiting adverse effects are noted

Severe Pain/ Pain Crisis → For acute, severe pain or pain crisis, consider hospital or inpatient hospice admission to achieve patient-specific goals for comfort and function (See PAIN-5)

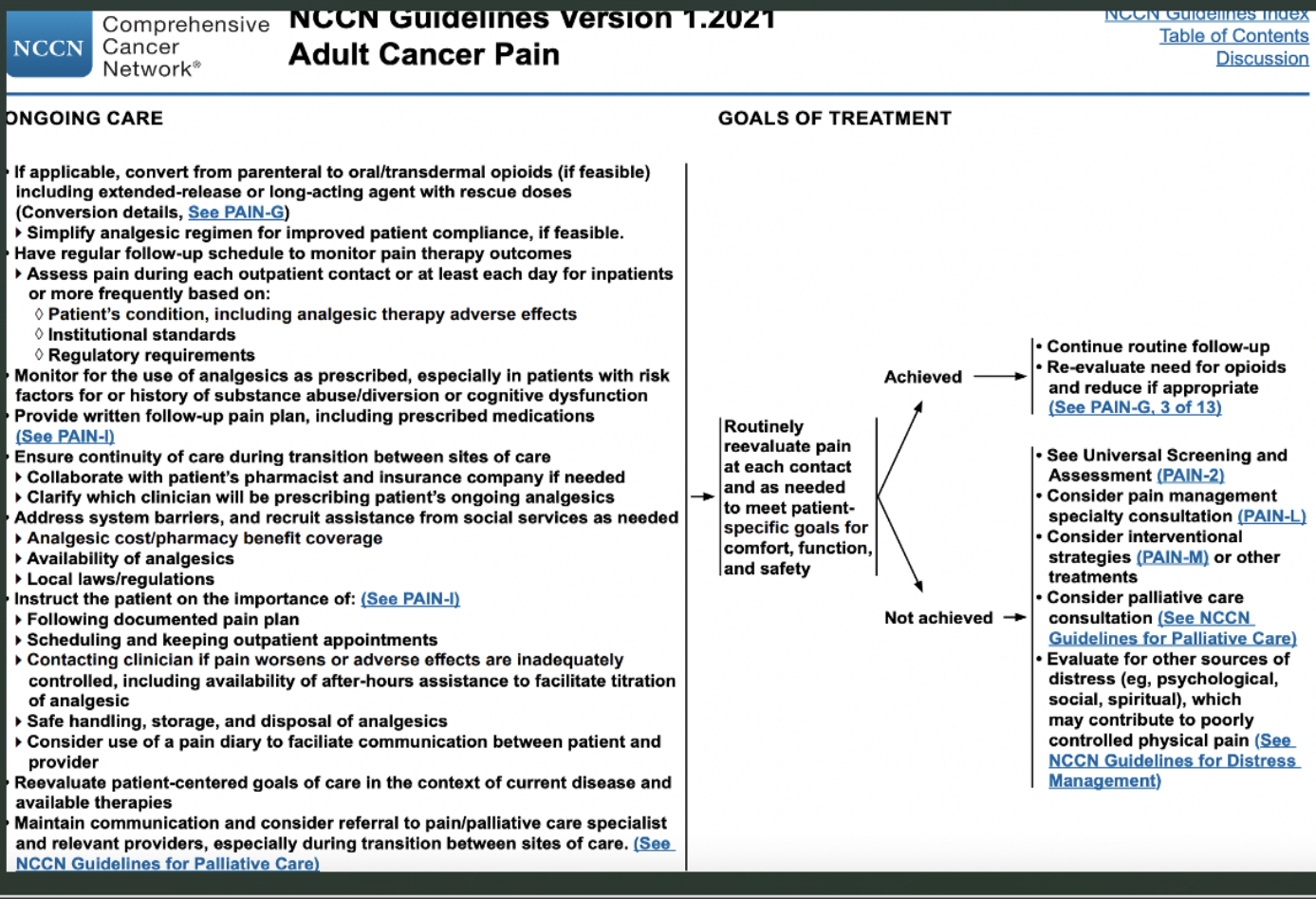
[d] Opioid-naïve patients are those not chronically receiving opioid analgesic on a daily basis and therefore have not developed significant tolerance. Opioid tolerant includes patients who are chronically receiving opioid analgesic on a daily basis.The FDA identifies tolerance as receiving at least 25 mcg/h fentanyl patch, at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

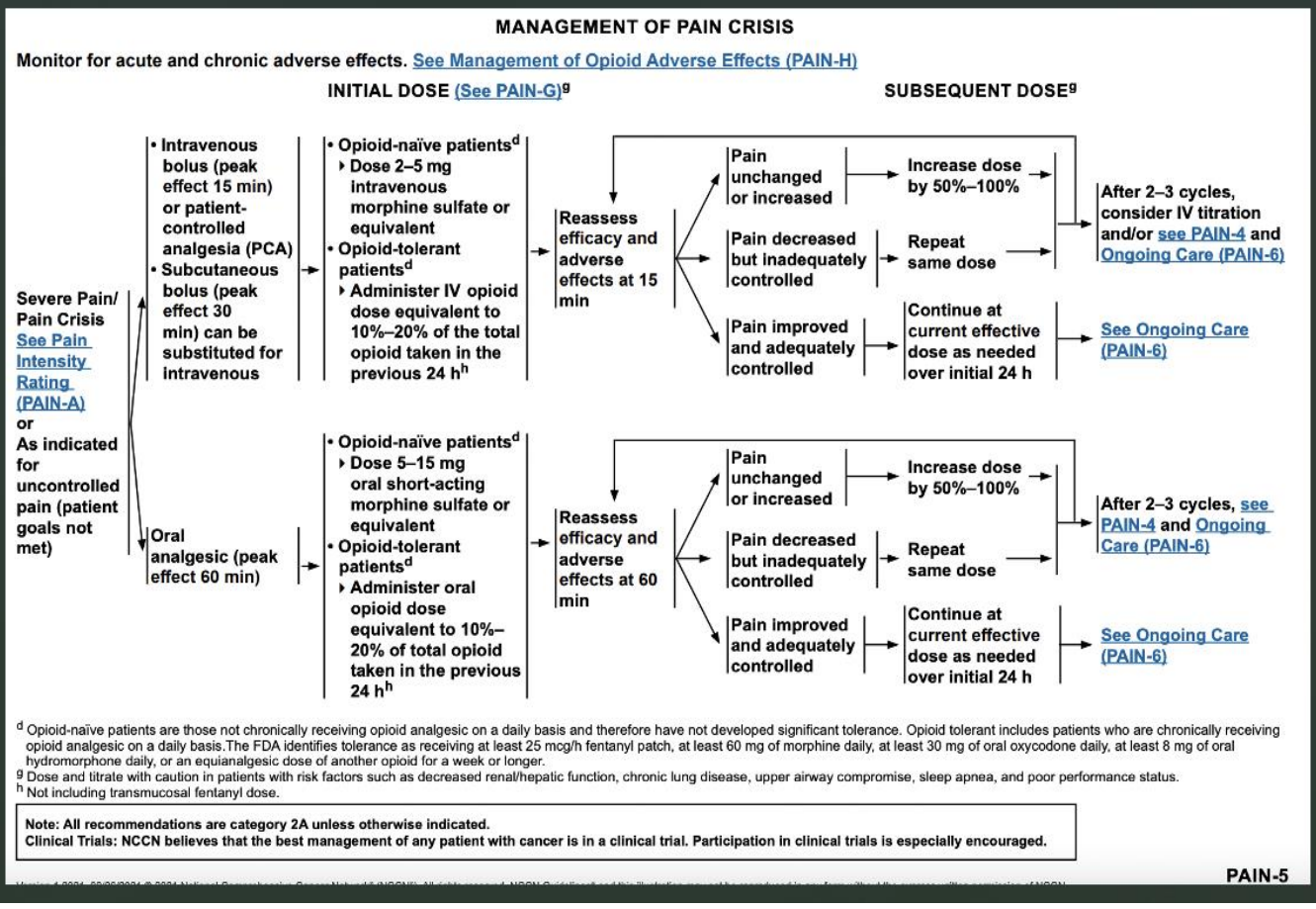
PRINCIPLES OF CANCER PAIN MANAGEMENT



PRINCIPLES OF CANCER PAIN MANAGEMENT



PRINCIPLES OF CANCER PAIN MANAGEMENT



[d] Opioid-naïve patients are those not chronically receiving opioid analgesic on a daily basis and therefore have not developed significant tolerance. Opioid tolerant includes patients who are chronically receiving opioid analgesic on a daily basis.The FDA identifies tolerance as receiving at least 25 mcg/h fentanyl patch, at least 60 mg of morphine daily, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer.

[g] Dose and titrate with caution in patients with risk factors such as decreased renal/hepatic function, chronic lung disease, upper airway compromise, sleep apnea, and poor performance status.

[h] Not including transmucosal fentanyl dose.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Appendix D

NCCN Cancer Network®

Adult Cancer Pain

Table of Cont
Discus

PAIN INTENSITY RATING

- **Pain intensity rating scales can be used as part of universal screening and comprehensive pain assessment. At minimum, patients should asked about "current" pain, as well as "worst" pain, "average" pain, and "least" pain in the past 24 hours. For each pain intensity rating, u one of the scales below.**
- **For comprehensive assessment, also include "worst pain in past week," "pain at rest," and "pain with movement." See Comprehensive Pa Assessment (PAIN-B) for more details.**

Table 1: Numerical Rating Scale

- **Verbal: "What number describes your pain from 0 (no pain) to 10 (worst pain you can imagine)?"**
- **Written: "Circle the number that describes your pain."**

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain you can imagine**

Categorical scale: "What word best describes your pain?"

None (0) Mild (1–3) Moderate (4–6) Severe (7–10)

Pain Assessment Tool Guidelines for use: PAINAD

Indicator	Score = 0	Score = 1	Score = 2	Total Score
Breathing:	Normal breathing	Occasional labored breathing Short period of hyperventilation	Noisy labored breathing. Long period of hyperventilation. Cheyne-Stokes respiration	
Negative vocalizations:	None	Occasional moan/groan. Low level, speech with a negative or disapproving quality	Repeated troubled calling out. Loud moaning or groaning. Crying.	
Facial Expression	Smiling or inexpressive	Sad, frightened, frown	Facial grimace	
Body Language	Relaxed	Tense, distressed, pacing, fidgeting.	Rigid, fists clenched. Knees pulled up. Striking out. Pulling or pushing away.	
Consolability:	No need to console	Distracted by voice or touch.	Unable to console, distract or reassure.	
			TOTAL:	

Description:

The Pain Assessment in Advanced Dementia (PAINAD) was developed to assess pain in patients who are cognitively impaired, non-communicative, or suffering from dementia and unable to use self report methods to describe pain. Observation of patients during activity records behavioral indicators of pain: breathing, negative vocalization, facial expression, body language, and consolability.

How to use:

PAINAD is a five item observational tool with numerical equivalents for each of the five behavior items listed, with total scores ranging from 0 to 10. Each of the five assessments contains a range from 0 to 2 and the summation of each of the five categories results in the total numerical score. Please refer to the attached item descriptions. To use:

- Assess patient during periods of activity, such as turning, ambulating, transferring
- Assess patient for each of the 5 indicators: breathing, negative vocalization, facial expression, body language, and consolability
- Assign a numerical point value based on each of the 5 assessments observed
- Obtain a total score, by adding scores from the 5 indicators. Total score ranges from a minimum of 0 to a maximum of 10. Populations for use: The primary population for use of the PAINAD is the adult patient with dementia who is unable to self report pain level.

Appendix E

Chart Audit Tool to Monitor Providers' Compliance of the Protocol

(From NCCN CPG)

A. Monitoring for Comprehensive Pain Assessment:

In the past week, please check yes or no if the following criteria have been assessed or evaluated for every new, worsening, or persisting pain observed or indicated. Also recommended by the NCCN CPG to use as part of new patient evaluation.

1. **Pain experience**
    a. Location, referral pattern, radiation of pain(s), timing, quality, aggravating or alleviating factors, pain rate/intensity: Yes_____ No_____

    b. Intensity (last 24 hours worst and least pain now, at rest and movement): utilization of proper pain assessment tool for verbal and non-verbal patients

    Yes_____ No_____

    c. Interference with activities/utilization of Impact of Pain Measurement: (see Appendix?) Yes_____ No_____

    d. Current pain management plan (pharmacological and non-pharmacological). If medications are used, determine exactly: Yes_____ No_____

    e. Response to current therapy (pain relief, patient adherence to medication plan, medication adverse effect): Yes_____ No_____

    f. Prior pain therapies (reason or use, length, response, reasons for discontinuing, and adverse effects encountered): Yes_____ No_____

    g. Special issues relating to pain: Yes_____ No_____

(If yes, please check which one below)

i. Meaning and consequence of pain for patient and family/caregiver _____
ii. Patient and family/caregiver knowledge and beliefs surrounding pain and pain medications _____
iii. Cultural beliefs toward pain, pain expression, and treatment _____
iv. Spiritual, religious considerations, existential suffering _____
v. Patient goals and expectations regarding pain management. _____
vi. Use of integrative therapies _____
vii. Screen for potential adverse effects/interactions _____
viii. Assess risk for opioid abuse/misuse/diversion _____

2. List of potential risk factors for misuse/abuse (see Pain-G/ page 4 of 13 of NCCN guidelines): Yes_____ No_____

3. Psychosocial Support: Yes_____ No_____
(If yes, please check which one below)

i. Patient distress _____
ii. Family and other support; assess impact and burden on caregiver and recommend resources as appropriate _____
iii. Psychiatric history including current or prior patient, family/caregiver, or household history of substance abuse _____
iv. Risk of aberrant use or diversion of pain medication (patient, environmental, and social factors as identified by a detailed patient evaluation and/or screening tools at initiation of care such as SOAP and monitoring of ongoing analgesic use. _____
v. Risk factors for undertreatment of pain _____

4. Medical History (e.g. oncologic treatment past or current or most recent; other significant illnesses, conditions, pre-existing chronic pain) _____

5. Clinical assessment, physical examination, and laboratory and imaging studies to evaluate for disease progression **_____**

B. Monitoring for Integrative/Multi-modal Approach of Interventions by following the recommended principles of cancer pain management & algorithm:

Across the literature including the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (CPGs), although pharmacologic analgesics such as non-opioids, opioids, and adjuvants are the cornerstone of cancer pain management, they are not always adequate and are associated with adverse effects. Optimal use of nonpharmacologic integrative interventions (e.g. physical, cognitive modalities, and spiritual) may serve as valuable additions to pharmacologic interventions (NCCN, 2021). This approach applies to all new and existing patients.
In the past week, please check yes or no if the following have been utilized as recommended by the NCCN CPGs in Adult Cancer Pain.

1. **Management of Pain in Opioid-Naïve Patients Algorithm** (Opioid-naïve patients are those not chronically receiving opioid analgesic on a daily basis and so have not developed significant tolerance per NCCN, 2021).

    i. General Principles + Mild or Moderate or Severe Pain/Pain Crisis algorithm:
    Yes_____ No_____

    ii. Pharmacological & non pharmacological interventions:

    Yes_____ No_____

2. **Management of Pain in Opioid-Tolerant Patients Algorithm** (Opioid-tolerant patients are those who are chronically receiving opioid analgesics on a daily basis. The FDA identifies tolerance as receiving at least 25mcg/h fentanyl patch, at least 60mg of morphine daily, at least 30mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, or an equianalgesic dose of another opioid for a week or longer, per NCCN, 2021).

    i. General Principles + Mild or Moderate or Severe Pain/Pain Crisis algorithm:
    Yes_____ No_____

ii. Pharmacological & non pharmacological interventions: Yes_____ No_____

3. **Management of Pain Crisis Algorithm** (if applicable in case of pain crisis situation)
   Yes_____ No_____

4. **Goals of pain management that are highlighted by the "5 A's" of outcomes:**
   Yes_____ No_____

   (If yes, please check which one below):

   i. Analgesia (optimize analgesia) _____
   ii. Activities (optimize activities of daily living ADLs) _____

   iii. Adverse effects (minimize adverse effects) _____

   iv. Aberrant drug taking (avoid aberrant drug taking) _____

   v. Affect (relationship between pain and mood) _____

5. Ongoing Care Guidelines/recommendations (once pain control is achieved) (see PAIN-6)

Yes_____ No_____

Chart Audit Tool for Pain Scale Rate Monitoring

(From NCCN CPG)

Using the Numerical Rating Scale (verbal patients) or the pain assessment tool for non-verbal patients (e.g. PAINAD) please indicate the patient's pain rate/level:

Patient 1:

Week 1 (Pre-Intervention/Implementation):

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Week 2 Pain scale rate

Date:

Pain rate: NRS_____ or PAINDAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Week 3 Pain scale rate

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

<u>Week 4 Pain scale rate (Post-intervention/implementation)</u>

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Date:

Pain rate: NRS_____ or PAINAD _____

Week 5 (Data analysis evaluation/discussion)

***Process of data collection to be repeated for the remaining patients.**

Appendix F

Permission Request from NCCN

Dear Rodelyn:

On behalf of the National Comprehensive Cancer Network® (NCCN®), I am writing to grant you permission to reference from the **NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Adult Cancer Pain V.1.2021** for use within up to 15 copies of a project paper titled *Addressing Terminal Cancer Pain in Hospice: A Quality Improvement Project* authored by Rodelyn B. Arceo. Permission is granted solely for the purposes described herein, which you represent and warrant being for non-commercial, educational use only. The following qualifications also apply to the permission granted by this letter:

Appendix G

Data Collection Spreadsheet

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
Date	Chart Review (1-4)	Patient	Provider	COMPLIANCE score (0-18)	Chart Review (1-4)	Patient	Date of Max Pain	VERBAL: NPRS (1-10)	NON VERBAL: PAINAD (1-10)		Chart/Week	Mean Compliance sc	Std Error	Mean Pain score	Std Error
7/12/21	1	1	1	11	1	1	7/7 and 7/8/21	8			Chart/Week 1	11.05	0.2760149	7.5	0.5
7/12/21	1	2	1	10	1	2	7/7/21	7			Chart /Week 2	12	0.2051957	7.2	0.604152
7/12/21	1	3	1	12	1	3	7/7/21	7.5			Chart/Week 3	12.95	0.1697521	6.1	0.533854
7/12/21	1	4	1	12	1	4	7/11/21	9			Chart/Week 4	15.45	0.2233124	4.3	0.3
7/12/21	1	5	1	10	1	5	7/7/21	6							
7/12/21	1	1	2	9	2	1	7/17/21	7			paired t-test	t	degrees of freedom	p-value	
7/12/21	1	2	2	13	2	2	7/16/21	8.5		Compliance	1 vs 2	-5.6	19	<0.001	
7/12/21	1	3	2	10	2	3	7/16/21	7.5			1 vs 3	-8.8	19	<0.001	
7/12/21	1	4	2	10	2	4	7/16/21	8			1 vs 4	-14.1	19	<0.001	
7/12/21	1	5	2	11	2	5	7/16/21	5							
7/12/21	1	1	3	11	3	1	7/26/21	5.5			paired t-test	t	degrees of freedom	p-value	
7/12/21	1	2	3	11	3	2	7/22/21	7.5		Pain	1 vs 2	0.6	4	0.573	
7/12/21	1	3	3	9	3	3	7/22/21	6			1 vs 3	2.7	4	0.052	
7/12/21	1	4	3	10	3	4	7/23/21		7		1 vs 4	6.2	4	0.003	
7/12/21	1	5	3	11	3	5	7/23/21	4.5							
7/12/21	1	1	4	13	4	1	7/30/21	5							
7/12/21	1	2	4	12	4	2	7/30/21	5							
7/12/21	1	3	4	12	4	3	7/30/21	4							
7/12/21	1	4	4	11	4	4	7/30/21		4						
7/12/21	1	5	4	13	4	5	7/30/21	3.5							
7/19/21	2	1	1	11											
7/19/21	2	2	1	12											
7/19/21	2	3	1	12			**Date of Maximum Pain rate in between time pointst are gathered between 4-10 days								
7/19/21	2	4	1	13											