A revised comfort care order set incorporating symptom assessment tools: A quality improvement project

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Abstract

Hospitalized patients in the last stages of their natural lives needed excellent symptom management to ensure comfort at the end of life. The use of Revised Comfort Care Order Set (RCCOS) that incorporated validated, evidence-based tools was paramount in guiding clinicians in recognizing, identifying and properly managing symptoms. It also served as a reminder to the clinicians to incorporate other non-pharmacological interventions such as holistic/alternative healing modalities and spiritual involvement to the standard of care of the patients at the end of life based on their discussions of patient's goals and wishes. This was a comparative descriptive, retrospective study. The primary goal was to determine whether the revision of the comfort care order set would have an effect on the documentation and management of pain and dyspnea and increase the utilization of non- pharmacological interventions such as integrative and spiritual care in patients at the end of life. The Theory of Unpleasant Symptoms (TOUS) was used as a framework for this study. TOUS stated that the symptoms were additive and multiplicative and affected one another. If symptoms were controlled, an individual would perform better (controlled symptoms). This study showed that the RCCOS had a positive effect on the nurses' documentation of the symptoms particularly dyspnea (x^2= 44.938; p= .000). Furthermore, the documentation of reasons for administering medications was nearing statistically significant result (x^2= 5.938; p= .051). The use of alternative therapies such as integrative care was improved with a statistical significant result (x^2= 81.777; p= .000). The final disposition had statistically significant result (x^2-20.165; p= .000). There were various limitations due to the length of time allowed with regards to the use of the RCCOS. The recommendation was to allow more time for the RCCOS use before collecting data.

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Chapter I Introduction

Background

The landmark report "Dying in America" from the Institute of Medicine (IOM) called for providing quality end of life care while taking into consideration the patient and family's wishes, values and culture (Institute of Medicine of the National Academies, 2014). One of the recommended components was the management of pain and other symptoms at the end of life. It stated that all clinicians should be able to provide and direct the initial and basic management of pain and other distressing symptoms (IOM, 2014). Additional recommended components from the IOM report included frequent assessment of the patient's emotional, social and spiritual well being; management of emotional distress, family and caregiver support and counseling for patient and family (IOM, 2014).

Defining "good death" was personal and unique to an individual. Some of the themes in what constituted good death included dying pain free, the death scene (dying in one's sleep), emotional well-being, life completion, dignity and family (Meier et al., 2016). However, patients at the end of life commonly suffered from pain, dyspnea, breathlessness, anxiety, restlessness and noisy respirations (death rattle) (Jansen, Haugen, Pont & Ruths, 2018). In alleviating the person's distressing symptoms at the end of life, clinicians should follow guiding principles when prescribing medications (Albert, 2017).

Identification of the Problem

To assure the comfort and well being of the patient, the implementation of a well-defined comfort care order set was necessary. More often than not, most patients die in the hospital without using a comfort care order set that could guide clinicians in managing distressing symptoms for end of life care (Walling, Ettner, Barry, Yamamoto & Wenger, 2011). Variations

in management in transitioning a person at the end of life from aggressive care to symptom management exist (Walling et al., 2011). The comfort care order set consisted of standardized medications for particular symptoms to be implemented by the healthcare providers to patients who have defined goals of care discussions with the expectation of imminent death.

The fourth edition of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care (Ferrell, Twaddle, Melnick & Meier, 2018) underscored the importance of delivering quality palliative care to all people with serious illnesses regardless of setting, diagnosis, prognosis or age (Ferrell et al., 2018). It also reinforced the importance of the involvement of all clinicians and all disciplines to assure that the seriously ill patients were getting treated with evidence-based care (Ferrell et al., 2018). For example, one of the guidelines was to provide a comprehensive palliative care assessment of the person, which focused on the domain of the physical aspect of care. The discussion of goals of care and determination of the patient's values and wishes (example was the context of their physical, emotional, spiritual and functional well being) was of utmost importance. The assessment and formulation of a care plan to relieve symptoms and improve their quality of life included pharmacological, non-pharmacological, holistic/complementary alternative treatments and possibly interventional treatments (Ferrell et al., 2018).

Purpose of the Study

The purpose of this study was to determine whether there would be an improvement in patient comfort level for pain and dyspnea by examining the nurses' documentation of pain and dyspnea at the end of life utilizing reliable and validated symptom assessment tools incorporated in the RCCOS. This study also explored the frequency of the titration of opioids based on the results of the utilization of the RCCOS with the incorporated tools. This order set for end of life

care contained evidence-based practices for pharmacological management of the most common symptoms at the end of life such as pain, dyspnea, upper airway secretions, agitation, restlessness and fever. It also contained an assessment of the patient every 30 minutes (three times), every hour (eight times) and every shift thereafter upon the initiation of the RCCOS. Once the patient became comfortable, assessment was done once every shift to assure the timely identification of the symptoms. This was reflected on the nurses' dashboard by the use of clocks to remind the nurses of their tasks at hand. Validated assessment tools for pain and dyspnea was used to objectively identify symptoms and the medications needed to increase comfort. The use of these validated tools could improve the identification of symptoms thereby increasing comfort and quality at the end of life (Kelley & Morrison, 2015). This research would also determine whether there would be an increase in the utilization of non-pharmacological interventions such as the involvement of holistic practitioners in alleviation of these distressing symptoms. The holistic practitioner's and integrative healing certified nurses' documentation of intervention would be included in the data collection. It also explored whether there would be an increase in involvement of the spiritual care support team such as the chaplains and priests. Documentation of the discussion of the goals of care between the clinician and the patient and/or the family/surrogate was recorded. These would be the difference between the old comfort care order set (OCCOS) and the RCCOS as the existing comfort care order set in the healthcare institution did not contain specific parameters and screening tools to accurately guide the nurses in initiation and/or titration of medications.

There was inadequate literature regarding the use of evidence-based and validated assessment tools to determine if a patient was suffering from distressing symptoms at the end of life (Blinderman & Billings, 2018). Additionally, there was a gap in research regarding patients

who cannot self- report, as validated assessment tools were not widely used such as in the case of dyspnea. Campbell, Kiernan, Strandmark and Yarandi (2018) conducted a study regarding respiratory distress on patients in the last month of life. The study concluded that respiratory distress escalated in the last days of life and the person's inability to self-report put them at risk for under recognition and under-treatment of respiratory distress (Campbell et al., 2018). Therefore, the use of these validated tools for symptom assessment on non self-reporting patients was vital in assuring that patients at the end of life remain comfortable and free of distressing symptoms (Campbell et al., 2018). The symptoms of patients who cannot self-report were captured by two of the incorporated validated assessment tools.

The challenge in self- report was that many of the patients who were critically ill and cognitively impaired were limited to provide self-report (Choi et al., 2017). The generally accepted definition of a symptom was the perception and the self-report of the individual of their experience of disease and physical disturbance (Choi et al., 2017). Symptoms such as pain, delirium, dyspnea, respiratory distress, weakness that was acquired from the Intensive Care Unit (ICU) stay and fatigue were some of the symptoms that were associated in patients in the Critical Care units who were unable to self-report (Choi et al., 2017). Interventions used in ICU such as endotracheal intubation, sedation, and mechanical ventilation often lead to patients becoming minimally responsive and sometimes unable to participate in self-report of unpleasant symptoms (Choi et al., 2017). Assessing the ability of the patient to communicate effectively was the first step in providing adequate symptom management.

The gold standard of pain assessment was self-reporting (American Pain Society, 2009). Herr, Coyne, McCaffery, ManWorren and Merkle (2011) established a position statement to address the five populations who may be unable to provide self-report on symptoms. These five

groups were: older adults with advanced dementia, infants and preverbal toddlers, critically ill/unconscious patients, persons with intellectual disabilities and patients at the end of life (Herr et al., 2011). For pain assessment, these individuals may not be able to self-report and may create a barrier to thorough assessment and adequate management of symptoms (Herr et al., 2011). This may be due to cognitive, developmental or physiological issues including medically induced condition (Herr et al., 2011). This inability to self-report increased the possibility of under or over treatment. The study recommended that nurses use the current best evidence based practice and the current tool for assessment of pain in patients who cannot self-report (Herr et al., 2011).

Statement of the Problem

In order to investigate whether there was an impact in symptom assessment and management using the revised comfort care order set which included validated, evidence-based assessment tools for symptom management, a PICOT question was generated. The (P) population were the nurses caring for patients at the end of life, the (I) intervention was the use of RCCOS that included the validated, evidence-based symptom assessment tools, the (C) was the comparison from the data from previous year that used the old comfort care order set, the (O) was that patient's symptoms were assessed, identified and relieved at a timely manner and (T) was time which was measured by the comparison of 2018 data with the OCCOS versus the 2019 data using the RCCOS. To heed the call of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care (Ferrell et al., 2018), all clinicians should recognize, identify, and manage the patient's distressing symptoms at a timely manner to assure comfort at the end of life. The purpose was to evaluate the effectiveness of the RCCOS in management of distressing symptoms particularly pain and dyspnea in patients at the end of life.

Research Question

What is the effect of the RCCOS in the documentation and management of pain and dyspnea of patients in end of life care?

H1: It is predicted that there will be a significant effect of the RCCOS in the documentation and management of pain in patients in end of life care.

H2: It is expected that there will be a significant effect of the RCCOS in the documentation and management of dyspnea in patients in end of life care.

Subquestion 1. Would there be an increase in the utilization of non-pharmacological interventions such as the involvement of holistic practitioners in alleviation of pain and dyspnea?

Sub H1: It is hypothesized that the RCCOS will result in an increase in the utilization of non -pharmacological interventions such as the involvement of holistic practitioners in alleviation of pain and dyspnea.

Subquestion 2. Would there be an increase in involvement of the chaplains and priests for spiritual care support?

Sub H2: It is hypothesized that the RCCOS will result in increase in spiritual assessment of the person that will lead to an increase in involvement of the chaplains and priests for spiritual care.

Subquestion 3. Would there be an increase in documentation of the discussion of the goals of care between the clinician and the patient and/or the family/surrogate as evidenced by documentation of conversation between the clinician and patient and/or family members/surrogate decision maker?

Sub H3: It is hypothesized that RCCOS will result in an increase in documentation of the discussion of the goals of care between the clinician and the patient and/or family/surrogate by the documentation of their conversation.

Definition of Key Terms

1. Revised Comfort Care Order Set (RCCOS)- a standardized framework for assessing patients' symptoms at the end of life (Lau et al., 2017). The RCCOS utilized validated tools, which were not present in the old comfort care order set. It also incorporated the use of non-pharmacological interventions, the involvement of holistic practitioners and spiritual care and discussion of goals of care with patients and families.

2. Validated symptom assessment tools – standardized tools that measured pain and dyspnea (Gray, Grove & Sutherland, 2017).

3. Patients in end of life care- individuals with irreversible life threatening illness without regard to diagnosis that will likely result in death (Center to Advance Palliative Care: Policies and Tools, 2018).

4. Distressing symptoms- the report of discomfort from a specific symptom that is being experienced by the individual specifically pain and dyspnea (McCorkle & Young, 1978).

5. Old Comfort Care Order Set (OCCOS)- the old comfort care order set that the institution used that contained orders for nurses to perform for patients at the end of life.

Significance to Nursing

Basic symptom management for patients at the end of life was an essential skill especially for nurses who were at the bedside and who were at the core of patient care on a daily basis. The RCCOS could be a useful tool in providing nurses with guidance in providing patients with compassionate, evidence-based care to assure patient's comfort at the end of life

(Lau et al., 2017). Nurses would be able to assess and choose the medications to be administered guided by the RCCOS. Nurses were essential in discussions of goals of care (GOC) and advocating for patients and family members at their most vulnerable moment. Barriers in nursing exist in advocacy for patients at the end of life (Lau et al., 2017). Some of these barriers were differing system wide policies and practices in health care, existing end of life nursing education and negative attitudes of nurses towards the end of life (Lau et al., 2017).

DNP Objectives

This study satisfied the following DNP competencies (American Association of Colleges of Nursing, 2006).

1. Essential I- Scientific Underpinnings for Practice (integrate nursing science with knowledge from ethics, biophysical, psychosocial, analytical, and organizational sciences as the basis for the highest level of nursing practice)- the incorporation of discussion of goals of care between the clinicians and the patient and/or family/surrogate/healthcare proxy, spiritual care and holistic practitioners in the revised comfort care order set satisfied this essential.

2. Essential II- Organizational and Systems Leadership for Quality Improvement and Systems Thinking (develop and evaluate care delivery approaches that meet current and future needs of patient populations)- the revised comfort care order set used the validated assessment tools to communicate a universal language in assessing patient's pain and dyspnea symptoms. Discussion of goals of care ensured that the values and wishes of the patient and the family were honored.

3. Essential III- Clinical Scholarship and Analytical Methods for Evidence-Based Practice (design, direct, and evaluate quality improvement methodologies to promote safe, timely, effective, efficient, equitable and patient-centered care against national

benchmarks)- the RCCOS was consistent with the call of the National Consensus Project Clinical Guidelines for Quality Palliative Care. Incorporating the evidence-based symptom assessment tools into the RCCOS guided clinicians in early recognition, identification and management of distressing symptoms to assure comfort at the end of life.

4. Essential IV- Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care- the RCCOS incorporated standard of care (SOC) using the evidence-based symptom assessment tools that were embedded in the order before the nurses can titrate medications for pain or dyspnea.

5. Essential V- Health Care Policy for Advocacy in Health Care (advocate for social justice, equity, and ethical policies within all health care arenas). The RCCOS provided patient and family centered care by incorporating physical, emotional and spiritual support by the interdisciplinary team. It also assured that the clinicians provide evidence-based care through the use of symptom assessment tools.

6. Essential VI- Interprofessional Collaboration for Improving Patient and Population Health Outcomes (lead interprofessional teams in the analysis of complex practice and organizational issues)- the RCCOS was presented to the Critical Care Committee, Medical Surgical Committee, Director's Committee, Quality Improvement, Nurse Practice Education Council, Research Shared Governance Council, Information Technology, Medical Board and Medical Records Committee for approval prior to implementation.

7. Essential VII- Clinical Prevention and Population Health for Improving the Nation's Health (synthesize concepts including psychosocial dimensions and cultural diversity, related to clinical prevention and population health in developing, implementing, and evaluating interventions to address health promotion/disease prevention efforts, improve health

status/access patterns, and/or address gaps in care of individuals, aggregates, or populations)- the RCCOS addressed the gap in the symptom management and care of patients at the end of life.

8. Essential VIII- Advanced Nursing Practice- the use of the RCCOS with the incorporation of the evidenced-based symptom assessment tools guided the clinicians through complex health and situational transition at the end of life. The set developed a therapeutic relationship between the clinicians and the patients/family/surrogates/health care proxy through the discussion and incorporation of patient's wishes at the end of life.

Summary

In summary, the provision of compassionate, competent, evidence-based and holistic end of life care practices to patients at the end of their life's journey was one of the essential roles of nursing (Meier et al., 2016). Guiding the patients and the families in goals of care discussion so that nurses can represent the patients during the times of vulnerability, helplessness, dependency, loss of control, inability to speak and powerlessness was vital in nurse-patient relationship (Meier et al., 2016). Assuring the patient's comfort by making sure that all the distressing symptoms such as pain and dyspnea at the end of life are controlled was vital to giving the patients a comfortable, peaceful and dignified death. Using evidence-based guided care was essential to assure a good, peaceful, dignified death. The use of holistic practitioners who offered non-pharmacological intervention for the management of patient's pain and dyspnea was paramount in end of life care. The involvement of the chaplains and priests who offered spiritual care contributed to the holistic care of the person. The institution's current comfort care order set did not contain validated symptom assessment tools that can guide the nurses in managing the patients' distressing symptoms such as pain and dyspnea. This was a compelling reason to revise

the current comfort care order set and incorporate validated symptom assessment tool to provide quality care outcomes for patients at the end of life.

Chapter II Literature Review

Theoretical Framework

The Theory of Unpleasant Symptom (TOUS) (Lenz, Pugh, Milligan, Gift & Suppe, 1997) (Appendix A) was utilized as a framework for this study. This theory focused on multiple symptoms and its additive and multiplicative value toward each other. Unlike other symptom theories that focus on one symptom, TOUS described the symptoms as affecting each other in an additive, multiplicative ways. It also posited that if one symptom was controlled, it would contribute to the management of other symptoms (Peterson & Bredow, 2017). It was developed in 1995 and was updated in 1997 to support the understanding of multiple symptoms that happen simultaneously (Lee, Vincent & Finnegan, 2017).

The theory further stated that symptoms have influencing factors. The three factors were physiologic, psychological and situational factors (Lee et al., 2017). Physiologic factors were age, gender, comorbidities and/or illness, events such as pregnancy, abnormal blood values and any other physiologic events like interventions needed for illnesses such as surgery, radiation, chemotherapy. Psychological factors included the person's mental state, mood, emotional state, and reaction to the illness, the meaning of the illness from the individual's perspective, the perceived idea of self-efficacy and the level of uncertainty about the illness. Situational factors were those factors that were external to the individual such as the actual surroundings (noise, peace and quiet, room temperature), the family support, social support, religious support, job, socioeconomic status, resources that were available, relationship with the providers, and all other physical aspect of the environment (Lee et al., 2017).

In the TOUS, all the cluster symptoms are connected to each other, which also affected the performance of the individual (comfort) (Lee et al., 2017). This was reciprocal influence between the antecedent factors, the symptoms and performance. The theory had concrete concepts and propositions and a goal of understanding multiple unpleasant symptoms, therefore it was categorized as a middle-range explanatory theory (Lee et al., 2017). The theory was also used to develop preventive interventions to adjust the influencing factors to the symptoms (Lee et al., 2017).

The three factors that guided TOUS were physiologic, psychological and situational. Patients at the end of life had physiologic needs due to their illness and co-morbid conditions that nurses need to alleviate. Most distressing symptoms that were associated with varied illnesses and co-morbid conditions could be alleviated by pharmacological and non-pharmacological interventions. Psychological state involved the meaning of the illness to the patient. Nurses and clinicians needed to determine the patient's GOC and what was most important to them at this point in their lives. Nurses and clinicians at each encounter with patient and families documented the GOC as these might change day by day.

Finally, situational factors were those factors that were external to the individual such as the actual surroundings (noise, peace and quiet, room temperature), the family support, social support, religious support and all other physical aspect of the environment. It was imperative that chaplains, holistic practitioners, spiritual support staff and nurses made sure that the optimal environment and support was provided to the patient at the end of life. According to TOUS, the individual would have a better performance (comfort) when these symptoms were controlled. These factors were reflected in the RCCOS.

Literature Review

Providing care to patients at the end of life was a privilege that most nurses treasure and most families remember. Comfort care was one of the most essential components of the clinicians' provision of medical care at the end of life (Meier et al., 2017). The meaning of peaceful death or a good death was different with each individual. Depending on their religious background, culture, ethnicity, education and values, the interpretation and meaning of good death may vary (Meier et al., 2016).

In general, when people were in the last stages of their natural life, the following four areas were of utmost importance: physical comfort, mental and emotional needs, spiritual issues and practical tasks (National Institute on Aging, 2017). Most of the dying patients identified core components of good death: preferences for a specific dying process, pain-free status, religiosity/spirituality, emotional well-being, life completion, treatment preferences, dignity, family, quality of life and relationship with healthcare providers (Meier et al., 2016). On the other hand, family's preferences included life completion, quality of life, dignity and presence of family (Meier et al., 2016).

In order for clinicians to aspire for good and peaceful deaths for their patients, there must be an understanding of the prevalence and management of distressing symptoms at the end of life. There were certain guiding principles in the management of distressing symptoms. The most common distressing symptoms for patients at the end of life were: pain, dyspnea, delirium and agitation, nausea and vomiting, constipation, oropharyngeal secretions, and fever (Albert, 2017). Medications were used to treat the primary etiology of the symptom (Albert, 2017). An example was a patient with severe dyspnea who as having anticipatory anxiety. The focus of the treatment was on managing the dyspnea to relieve the primary symptom (Albert, 2017).

A study by Hansen, Dieckmann, Kolbeck, Naugler and Chang (2017) regarding patient with hepatocellular carcinoma (HCC) toward the end of life revealed that pain and lack of energy were the most distressing symptoms. This was a prospective, longitudinal, descriptive design that used a purposive sampling of 18 patients (15 men and 3 women). Inclusion criteria were over 21 years of age and a diagnosis of HCC beyond criteria for transplantation. Exclusion criteria were if they had another type of cancer or previous liver transplantation. The study used the Memorial Symptom Assessment Scale (Hansen et al., 2017), a Likert-type scale, which measured global distress, psychological distress and physical distress. Data were collected for six months. Study found that there were areas of improvement in symptom management for patients with advanced HCC at the end of life (Hansen et al., 2017). The recommendation was for clinicians to assess all physical and psychological symptoms that must include the presence, frequency, severity and distress of each symptom and the provision of comprehensive symptom management for patients with HCC (Hansen et al., 2017). This study used a revised comfort care order set.

The problem of symptom management was global. For example, in Bangladesh, a study conducted by Doherty et al. (2017) regarding symptom prevalence in patients with advanced, incurable disease found that very few patients received strong opioids to control their severe pain. More often than not, the distressing symptoms that the patients were experiencing were not resolved (Doherty et al., 2017). This study used a standardized interview questionnaire. Participants were patients with diagnosis of HIV/AIDS and cancer from 221 patients in public hospitals in seven administrative divisions in Bangladesh. There were 181 patients with cancer and 40 with HIV. This study revealed that pain is the most common symptom (Doherty et al., 2017). A majority of the patients (70.3%) reported experiencing pain during their illness. About

half of the patients (51.3%) reported that they were in constant pain all the time. The study also found that even with treatment, 40.5% stated that they continued to have severe pain (Doherty et al., 2017).

In Brazil, Soares et al. (2018) studied the prevalence and intensity of dyspnea, pain and agitation among people dying with late stage dementia compared with people dying with cancer. This was a retrospective review of charts using the Edmonton Symptom Assessment Scale (ESAS) (Soares et al., 2018) scores. The sample size was 57 patients who died with dementia and 54 patients who died with cancer for a total of 111 patients. Dyspnea (dementia n=34 versus cancer n=39; p- 0.23) and agitation (dementia n=7; versus cancer n= 14; p-0.17) prevalence were similar between the two groups (Soares et al., 2018). However, pain was less common in dementia (p-0.02). The study found that pain was more intense in dying patients afflicted with cancer (odds ratio >1). The study found that dyspnea was most prevalent symptom at the end of life in both groups (Soares et al., 2018). Their study concluded that the need to manage the distressing symptoms at the end of life must be improved in terms of existing protocols (Soares et al., 2018).

There was inadequate literature regarding protocols and comfort care order sets that could provide guidance to clinicians when it comes to management of distressing symptoms at the end of life. Walling, Ettner, Barry, Yamamoto and Wenger (2011) conducted a study on the implementation of an end-of life symptom management order protocol (ESMO). The method used was chart review of complete medical record of patients who died from April 2005 to April 2006. Patients who had a length of stay of at least three days and expired were included. Patients who had a length of stay for less than three days were excluded. A medical abstraction tool was designed including the timing of initiation of protocol, whether opiate infusion was used

and titrated for symptoms, the highest dose attained prior to expiration, the adherence to the protocol and certain demographics data (Walling et al., 2011).

An experienced nurse abstractor was used to comb through the medical records. To determine inter- rater reliability, 10% of chart was abstracted. The final model indicated 0.86 inter- rater reliability. Risk ratios were calculated for the final model and used boot-strapping methods to calculate bias-corrected empirical 95% confidence intervals (Walling et al., 2011). The study used bivariate logistic regression and multivariate logistic regression. Sample was 496 expired patients who died expectedly. The ESMO protocol was used in 236 of these patients (56%).

Results of the study showed mean time of 1.1 days between initiation of ESMO and death (Walling et al., 2011). Mean age at the time of death was 62 years, 47% female, 60% married, 78% white, 62% non-Hispanic white with Medicare or private insurance, 55% had end stage disease on admission and 25% were considered for transplant (Walling et al., 2011). The study concluded that implementation of a standardized order set for end of life care can identify quality improvements and missed opportunities in the care of dying patients (Walling et al., 2011).

In a recent study, Lau et al., (2017) conducted a research using comfort care order sets and its impact on end of life care. This was a retrospective chart review of patients under oncology and general internal medicine who were referred to palliative care for end of life care. The comfort care order set (CMOS) was developed by the institution, which provided evidence-based guidance to the clinicians in comprehensive care of the dying (Lau et al., 2017). Bereaved families, and expert panel from the organization consisting of palliative care physicians, advance practice nurses, pharmacists, social workers and spiritual care providers validated the CMOS (Lau et al., 2017).

Total sample size was 83. Sixty seven percent (56 patients out of 83) used the CMOS. Study found that most patients who were referred to palliative care die within 72 hours (Lau et al., 2017). Average number of days from consult to death was 2.6 days for CMOS patients versus 3.1 days for non-CMOS patients (Lau et al., 2017). Most prevalent symptoms were pain, restlessness, dyspnea and upper airway secretions (Lau et al., 2017). The most distressing symptom around the time of death for both CMOS group and non-CMOS group was dyspnea (Lau et al., 2017). There was a significant increase in spiritual care involvement in CMOS versus non-CMOS patients (66%) $p<0.05$ (Lau et al., 2017).

In the CMOS group, the most responsible physician (MRP) initiated CMOS twenty one percent of the time versus seventy nine percent by palliative care consult team (PCCT). Ninety five percent had goals of care conversation (GOC) prior to referral to PCCT for both CMOS and non-CMOS group but when PCCT got involved, the GOC conversation continued with 90% being led by the PCCT (Lau et al., 2017). For adjustment of medications, there were an average of 1.7 adjustments per patient of symptom management on CMOS group as compared to 3.3 adjustments per patient on non-CMOS group after the PCCT got involved (Lau et al., 2017).

In summary, the CMOS provided guidance to symptom management and therefore resulted in fewer symptom adjustments (Lau et al., 2017). The study underscored the utility of a standard protocol for managing patient's symptoms at the end of life (Lau et al., 2017). The study also revealed a positive trend towards patients being more comfortable when CMOS was used (Lau et al., 2017).

At the end of life, there was little evidence on how the pharmacokinetic parameters (drug clearance and volume of distribution) affect the use of different medications to ease the patient's symptom burden (Franken et al., 2016). Medications such as opioids (pain and dyspnea),

Haloperidol and Risperidone (agitation), corticosteroids (inflammation), Hyoscyamine, Atropine drops, Scopolamine patch and Glycopyrrolate (excessive oral secretions), Reglan and Prochlorperazine (nausea and vomiting), Colace, Miralax and Lactulose (constipation), Relistor (opioid induced constipation) were the medications that were commonly used at the end of life for symptom management (Jansen et al., 2018). The value of the non-pharmacological interventions such as the involvement of holistic practitioners was explored.

Summary

In summary, the timely identification and documentation of the distressing symptoms such as pain and dyspnea and the use of appropriate medications were essential to assure the efficacy of the management of patients at the end of life. Studies have shown that pain and dyspnea were two of the most distressing symptoms during this time (Doherty et al., 2017; Soares et al., 2018). The use of comprehensive comfort care order sets that guided clinicians in assessing symptoms and providing appropriate medications and interventions can promote "good death" (Meier et al., 2017). Goals of care discussion to determine the patient's wishes and values were paramount. Depending on their religious background, culture, ethnicity, education and values, the interpretation and meaning of "good death" may vary (Meier et al., 2016). Determining the personal meaning of "good" and peaceful death for each individual was vital to assure that patient's personal wishes and goals are honored at the end of life. The collaboration of different disciplines such as spiritual care and holistic practitioners were most valuable.

Chapter III Methodology

Introduction

Hospitalized patients who were in the last stages of their natural life needed palliative care to assure that distressing symptoms were managed and controlled. The use of RCCOS that

incorporated validated, evidence-based tools was paramount in guiding clinicians to recognize, identify and properly manage symptoms. It also assisted in assuring that other non-pharmacological interventions such as holistic/alternative healing modalities and spiritual care were considered.

Research Design

This was a comparative descriptive, retrospective design. Demographics information such as discharge disposition, religion, race, age, gender, ethnicity, primary insurance, marital status, and goals of care including code status were collected. For symptoms abstraction, dyspnea and pain severity, protocol adherence and titration of opioids (as evidenced by documentation in the electronic medical records (EMR)) was recorded. The rate and number of opioid titration using the OCCOS was logged and was compared to the samples that used the RCCOS. Spiritual care and holistic nurses involvement was registered. The improvement of symptoms of dyspnea and pain after the implementation of the RCCOS was recorded. This was compared to the data from the OCCOS. To protect anonymity, the excel spreadsheet only used the visit number (V number) which was secured in a locked drawer. Only the primary investigator had access to the file. A report was generated of all the discharges from the palliative care service. A report from QLIK (a database collecting mechanism used by the hospital) was also used to generate report from the old EMR.

Procedure

The primary investigator collected data from patients who used the revised comfort care order set from December 17, 2019-February 6, 2020 as the exact same time period from the previous year that used the old comfort care order set on December 17, 2018-February 6, 2019. These were all conducted with retrospective chart review. The data collection tool was a

combination from Joint Commission National Quality Measure (JCNQM) and the Center for Palliative Care Advancement (CAPC) (Appendix B and C). The abstraction tool contained the combined data (Appendix D). The primary investigator had years of experience in Joint Commission's quality assessment and compliance through chart abstraction. Data was collected on an Excel spreadsheet and only the investigator had access to file. In this particular institution, the old comfort care order set did not contain any validated tools to give the nurses precise guidance and instructions on how to administer and titrate medications based on symptom management. Therefore, this comfort care order set was revised by incorporating validated symptom assessment tools.

The two main distressing symptoms at the end of life that were incorporated into the RCCOS were pain and dyspnea. Tools for self-reporting and for people unable to verbalize symptoms were included. The tool that was used for patients unable to verbalize pain was the Face, Legs, Activity, Cry, Consolability (FLACC) tool (Appendix E). For self-reporting patients who can verbalize the intensity of their pain, the Numerical Rating Scale (NRS) (Appendix F) was used.

The Respiratory Distress Observation Scale (RDOS) was used for patients who cannot self-report their dyspnea and breathlessness (Appendix G). The tool was an 8-item ordinal scale that was used to assess the patients who cannot self-report for dyspnea (Campbell, 2018). The Modified BORG Scale (MBS) was used for self-reporting patients (Appendix H). According to the study conducted by Johnson, Close, Gillon, Molassiotis, Lee and Farquhar (2016), the modified BORG scale was preferred for patients with severe daily breathlessness.

The initial assessment of pain and dyspnea were recorded from palliative care provider's consult and nursing assessment notes. All four tools were previously incorporated in the

palliative care provider notes and were present for both OCCOS and RCCOS. Nursing notes already contained the FLACC and NRS for both OCCOS and RCCOS. The main difference was the incorporation of the RDOS and mBORG as the OCCOS did not contain these tools in nursing documentation. The data from the pain and dyspnea improved within 48 hours were collected as per guidelines from Joint Commission and CAPC. The data were abstracted within day two (48-hour) of the initial assessment and the results were recorded and compared with the initial assessment. Any reduction from the initial assessment versus the 48-hour assessment was considered an improvement. The data from the pain and dyspnea improved prior to discharge or death were collected using the documentation of pain and dyspnea results closest to the discharge time or death. Any documentation from the nurse or the clinicians was included. Any reduction in number as compared to the assessment by the advance practice clinician at the time the comfort care decision was made was considered improvement in symptoms.

Spiritual and integrative care, goals of care discussion and order were all yes or no answer if present in documentation. Nurses' documentation was also a yes or no answer if the assessment tools were used in either the medication administration record or the nurses' dashboard (the assessments were added as clock timers to remind the nurses to assess the patients). Titration of the medication were counted as to how many times the nurses increased the rate of the opioids.

Sample

Chart records of patients who used the OCCOS and were discharged from the Palliative Care Service from December 17, 2018 to February 6, 2019 were reviewed. For comparison data, patients in Palliative Care service who used the RCCOS and were discharged from December 17, 2019 to February 6, 2020 were reviewed. Data from both were compared.

According to Gray, Grove and Sutherland (2017), a sample should contain at least 30 subjects for every variable measured. Thirty (30) subjects were the minimum amount to reach normal distribution (Gray et al., 2017). It was also suggested to consider adding attrition rate at 10-15%. For distressing symptoms, pain and dyspnea variables were measured. For two variables, a sample of 60 was needed to ensure that final sample reached normal distribution (Gray et al., 2017). There was no attrition to this study as this was a retrospective chart review of all patients on palliative care service who were discharged and used the old comfort care order set and RCCOS.

Inclusion criteria were discharged patients from the Palliative Care Service who were 18 and above year olds and used the OCCOS from December 17, 2018 to February 6, 2019 and used the RCCOS from December 17, 2019 to February 6, 2020. All diagnoses were included. Exclusion criteria were deaths that did not use comfort care order set and age below 18.

Methods

The current Comfort Care Order Set (Appendix I) was revised incorporating the symptom assessment tools. Different committees in the hospital involved in utilization of the RCCOS such as Critical Care, Heart and Vascular Institute and Medical Surgical Committee approved the RCCOS. In addition, the Quality and Safety Committee, Medical Executive Committee (Medical Board), Research Shared Governance, General In Patient Hospice and Nurse Practice Shared Governance reviewed and approved the RCCOS. The current protocol for physician order set revision was followed. The above validated symptom assessment tools were incorporated into the RCCOS. The RCCOS (Appendix J) with the titration parameter (Appendix K) and its algorithm (Appendix L) was submitted and approved by the Medical Records Committee. It was submitted to the Information Systems Clinical Team and the order set was

built into Physician Order Management (POM). Education was provided by the Palliative Care Department regarding the use of RCCOS.

The investigator and the members of the palliative care team provided education to the nurses and the physicians regarding the incorporation of the validated symptom tools. Education regarding the use of the RCCOS was performed through attending staff meeting, circle ups and sending flyers and emails. A one- time education using My Path was instituted. A tile in the Intranet (the general website for all information for the staff) was completed. An article in the Vital Capacity Newsletter (the hospital newsletter) was submitted and published. The champions identified in the units (Advance Practice Nurses and Clinical Shift Supervisors) were educated in the use of RCCOS.

Discharged patients from the Palliative Care Service who were 18 and above year olds and used the OCCOS from December 17, 2018 to February 6, 2019 and used the RCCOS from December 17, 2019 to February 6, 2020 were included. Exclusion criteria were deaths that did not use comfort care order set and age below 18. Data were collected from these discharges from the combination of abstraction tool from the JCNQM and CAPC. Statistical analysis was conducted after collecting all the data.

Instruments

The two main symptoms at the end of life that were incorporated in the RCCOS were pain and dyspnea. Tools for self-reporting and people unable to verbalize symptoms were included. Some of the patients who were started on comfort care were still able to report the level of their pain and dyspnea at the initiation of the process.

The tool that was used for patients unable to verbalize the intensity of pain was the Face, Legs, Activity, Cry, Consolability (FLACC) tool. The tool was found to be valid and reliable in

assessing pain of critically ill adults and children (Voepel-Lewis, Zanotti, Dammeyer & Merkel, 2010). In this study, three nurses simultaneously rated three pain scales (FLACC, checklist of non-verbal pain indicators for adults and COMFORT scale for children). The study found that FLACC scores correlated highly with the other 2 scores ($p= 0.963$ and $p= 0.849$) indicating criterion validity (Voepel-Lewis et al., 2010). After analgesia or at rest, the significant decrease in FLACC scores supported construct validity (mean, 5.27; SD 2.3 vs. mean 0.52; SD-1.1; $p<.001$) (Voepel-Lewis et al., 2010). Cronbach alpha was 0.882 indicating internal consistency (Voepel-Lewis et al., 2010). Correlation coefficients (0.67-0.95) indicate excellent interater reliability (Voepel-Lewis et al., 2010).

For self-reporting patients (some patients may still be able to self-report prior to their discharge), the Numerical Rating Scale (NRS) was used. This was a self-reporting pain assessment scale with points ranging from 0 to 10. Number 0 represents no pain and number 10 represents the worst possible pain (Fadayevatan et al., 2019). Mild pain was considered 1-3 scores, moderate was 4-6 and severe was considered 7-10 (Fadayevatan et al., 2019). The study by Fadayevatan et al. (2019) showed strong correlation between the 11-face Faces Pain Scale and the NRS. It concluded that since NRS was the gold standard of pain detection, then the criterion validity of FPS-11 was approved (Fadayevatan et al., 2019).

Alghadir, Anwer, Iqbal & Iqbal (2018) conducted a test-retest reliability, validity and minimum detectable change of visual analog, numerical rating, and verbal rating scales for measurement of osteoarthritic knee pain. The study found that NRS had excellent test-retest reliability. Reliability for NRS showed 95% Confidence Interval (CI) at 0.95, standard error of measurement at 0.48 and the minimal detectable change at 1.33 (Alghadir et al., 2018).

For patients who cannot self-report dyspnea, the Respiratory Distress Observation Scale (RDOS) was used. The tool was an 8-item ordinal scale that was used to assess the patients who cannot self-report for dyspnea. Psychometric testing for inter- rater, scale reliability, construct, convergent and discrimination was performed (Campbell, 2018). The internal consistency was 0.64 to 0.86 and the inter- rater reliability was perfect between nurse and data collectors (r=1.0) (Campbell, 2018). Construct validity was established through correlation with hypoxemia, and use of oxygen (Campbell, 2018). Convergent validity was established through comparison with dyspnea self-report (Campbell, 2018). Discriminant validity was established with comparisons of RDOS for COPD patients with dyspnea to patients with acute pain and health volunteer (Campbell, 2018). The RDOS was the only scale available for patients who cannot self-report dyspnea. Receiver Operating Curve Analysis determined RDOS the following: 0-2 no respiratory distress; 3-mild respiratory distress; 4-6 moderate respiratory distress; ≥7 severe distress.

The Modified BORG Scale was used for self-reporting patients. According to the study conducted by Johnson, Close, Gillon, Molassiotis, Lee and Farquhar (2016), the modified BORG scale was preferred for patients with severe daily breathlessness (n-368; mean ±SD 2.36 ± 1.79; 95% CI -0.05-0.33). Eakin, Sassi-Dambron, Ries and Kaplan (1995) performed a study on the reliability and validity of dyspnea measures in patients (n-143) with obstructive lung disease. The study found that the MBS was reliable. The test and re-test correlation was 0.45 and p=.001. Kendrick, Baxi and Smith (2000) assessed the usefulness of the MBS in assessing the dyspnea severity in asthma and chronic obstructive pulmonary disease (COPD) patients in the emergency department. This study found that MBS (n-102) was a valid and reliable tool. There was a negative correlation between peak expiratory flow rate and the MBS (r= -.31 p= <.05) for asthma and (r= -.42, p= <.0001) for COPD patients.

The data collection tools were a combination of Joint Commission National Quality Measure (JCNQM) and the Center for Palliative Care Advancement (CAPC). Some data collected were also reported to the CAPC. The primary investigator had years of experience in Joint Commission's quality assessment and compliance through chart abstraction.

Protection of Human Subjects

Permission was obtained and granted by the Research Shared Governance from the Institution and the Western Institutional Review Board (WIRB) that oversees all the research in the healthcare institution. Permission from a medium–sized public institution of higher learning in the northeastern United States Review Board (IRB) was granted (Appendix N). Data collected was kept in the computer with the Principal Investigator as the only person who had access to the data. There were no risks associated with this study since the data collected were from patients who died or were discharged to hospice.

Data Analysis

Descriptive statistics were used to describe the categorical variables. Crosstabs/Chi-square test were used to test measures of association among the variables such as the use of integrative healing, spiritual care, disposition, goals of care discussions and orders to reflect comfort care status. It was also used to measure the association between the documentation of symptom management between the old and revised comfort care order sets Data analysis was done using SPSS version 26.

Chapter IV Results

Descriptive Statistics

A comparison was performed using the data from the OCCOS versus the RCCOS. A total of 74 discharges were collected from December 17, 2018 to February 6, 2019 using the

OCCOS. In contrast, 67 discharges were logged from December 17, 2019 to February 6, 2020 using the RCCOS. The total samples collected were 141 combined (See Table I).

There were no major differences from the data regarding religion, race, gender, marital status and insurance. Majority of sample from both cohorts were white with Medicare as the primary payor source. Catholic was the predominant religion. The count of women was slightly higher than the men. There was a difference in age between cohorts.

Discharges when it comes to age showed that predominantly, the samples came from the 71-90 years of age accounting for 55.3%. (n=78). The second highest were samples from the 91 and above segment at 29.8% (n=42). Samples from 51-70 years of age came in third with 12.1% (n=17). For samples age 31-50, n-3, which accounted for 2.1% and for the age bracket of 16-30, there was n=1 for .7%. The ages between 71-90 and 91 and above were the main difference in the two comfort care order sets. In the OCCOS, there was 59.5% (n=44) sample from the age bracket of 71-90 years old as opposed to 50.7% (n=34) in the RCCOS. In the age bracket of 91 and above, there were 20% (n=20) in the OCCOS as compared to 32.8% (n=22) in the RCCOS. It was unclear at this point if the curve will flatten if the number of samples was higher or if this was a sign that the population of hospitalized patients was getting older (See Table II).

Catholic religion was predominant on both cohorts. Combined samples accounted for 57.4% (n=81). Others were second at 22% (n=31). These include Christians, Pentecostal, Jehovah's Witness and other religion not captured individually. Jewish were third at 9.2% (n=13). Protestant was fourth at 7.1% (n=10). Baptist came fifth at 2.8% (n=4) and Muslim at 0.7% (n=1).

Whites comprised the majority of the demographics at 87.2% (n=123). Latinos were second at 5.7% (n=8); African American Blacks at 3.5% (n=5) third; Others came in fourth at 2.8% (n=4); and Asian were last at 0.7% (n=1).

With respect to gender, female came in the highest at 53.9% (n=76) as compared to male at 46.1% (n=65). Majority were married at 46.1% (n=65), second is widowed at 37.6% (n=53). Single came third at 9.9% (n=14) and divorced fourth at 5% (n=7). Others came in at 1.4% (n=2).

Majority of the sample used Medicare as their payor source at 66% (n=93). Private insurance came in second at 21.3% (n=30); other came in third at 9.2% (n=13). Fourth is Medicaid at 2.8% (n=4) and no insurance at 0.7% (n=1).

Measures of Association between Variables

For the provision of spiritual care, there was no statistical significance (x^2= 1.616; p= .204) when OCCOS and RCCOS were compared (See Table III). However, 22% (n=16) was not seen under OCCOS and 13% (n=9) were not seen under RCCOS. With respect to the utilization of Integrative Healing, there was a statistically significant result with (x^2= 81.777; p= .000). In OCCOS, 1.4% (=-1) was documented as having been provided integrative care as compared to 74.6% (=-50) in RCCOS (See Table IV). According to TOUS, the three factors that affect the person's performance were physiologic, psychological and situational (Lee et al., 2017). The utilizations of integrative and spiritual care for non-pharmacological, complementary interventions were paramount in achieving the goal. In RCCOS, there were more patients who were given holistic and integrative interventions than those in OCCOS.

There were three target points recorded in this study for dyspnea. Assessment of dyspnea within 24 hours of initial encounter, improvement of dyspnea within 48 hours after initial

encounter, and improvement of dyspnea prior to discharge or death. The first two markers were reportable data to Center for Advancement of Palliative Care (CAPC).

First was the assessment of dyspnea within 24 hours of initial encounter (See Table V). Although there was no statistically significant result (x^2= 2.392; p=.122), there was a significant improvement in the assessment of dyspnea within 24 hours of initial assessment, 98.5% (n=66) after the initiation of RCCOS versus 93.2% (n=69) with OCCOS. The second marker collected in this study was the improvement of dyspnea within 48 hours of initial assessment (See Table VI). This data were also reported to Center for Advancement of Palliative Care (CAPC). In this data, there were no statistically significance between the two cohorts (x^2= 1.291; p= .256). It was interesting to note that result showed that symptoms of dyspnea were not improved after 48 hours of initial assessment (RCCOS 41.8% OCCOS 51.4%). The last data in dyspnea assessment were the improvement of the symptom prior to discharge or death (See Table VII). There was no statistically significant from this result (x^2=3.284; p=.070). However, only 45.9% of the patients who used the OCCOS had improvement in their dyspnea while 61.2% had improvement using the RCCOS prior to discharge or death.

This particular facility did not have a uniform dyspnea assessment. Respiratory therapists used a different tool for their assessment, mainly for patient who were verbal and able to express their complaints. This was also true with nursing. Their assessments focused mainly on the verbal patients using a numeric scale. The incorporation of the RDOS gave nursing the ability to quantify the non-verbal patients' severity of the dyspnea. The initial assessment was mainly retrieved from the nurse practitioner's initial consult. The nurse practitioners used the RDOS from both OCCOS and RCCOS. The comparison between OCCOS and RCCOS results was not statistically significant but the percentage of patients assessed was higher in RCCOS

(RCCOS- 98.5% OCCOS- 93.2%). The second marker was obtained from the assessment either by nurses or nurse practitioners of the dyspnea closest to the end of second day from the initial assessment (dyspnea-24). The third marker was obtained from the RDOS and/or mBORG results immediately prior to discharge or death. The three markers for the dyspnea did not reveal any significant improvement but the percentage were trending upwards with respect to improvement.

Assessment within 24 hours of initial encounter (See Table VIII), after 48 hours of initial assessment (See Table IX) and if pain was improved prior to discharge or death (See Table X). For initial assessment of pain within 24 hours of initial encounter, there was no statistically significant data found (x^2= .247; p=.619). However, data showed that the percentage of samples assessed within 24 hours of initial encounter were higher in RCCOS 98.5% (n=67) versus OCCOS 97.3% (n=74). The second data collected were pain improved within 48 hours of assessment. There was no statistically significant result (x^2= .002; p=.967). Data almost mirrored each other for both RCCOS at 74.6% (n=50) versus OCCOS at 74.3% (n=55). Finally, the third marker was pain improved prior to discharge or death. Again, there was no statistically significant finding (x^2= 1.665; p=.197). Data showed that the percentage of pain improved prior to death or discharge were higher in RCCOS 91% (n=61) versus OCCOS 83.8% (n=74). The retrieval of the data from the pain was exactly the same format as dyspnea explained previously.

This study showed a statistically significant result in nurses' documentation of symptoms prior to administering medications ($x^{2=}$ 44.936; p= .000). The OCCOS showed 32.4% (n=24) documentation of explicit reason for medication administration versus 88.1% (n=59) for RCCOS (See Table XI). Reasons for administering medications for pain and dyspnea recorded from the OCCOS varied from sedation, comfort care protocol, work of breathing and respiration. Reasons

documented for RCCOS were explicit and contained the four incorporated tools of FLACC or NRS and/or mBORG or RDOS.

As previously found in literature review, there were minimal studies that included the use of comfort care order set at the end of life. One study showed that the incorporation of comfort care order set provided guidance to symptom management and therefore resulted in fewer symptom adjustments at 1.1(Lau et al., 2017). However, when the palliative care team got involved, the median adjustment went up to 3.3. Our results were consistent with this study with 13.4% no titration (n=9) for RCCOS versus 29.7 titration (n=22) with OCCOS. However, our results further revealed that once titration was needed (as in the case of uncontrolled symptoms), 59.7% (n=40) needed 4 and more titration for RCCOS as opposed to 52.7% (n=39) for OCCOS. This result was approaching statistical significance (x^2= 5.938; p=.051).

One of the core components of good death according to the dying patients was the discussion of treatment preferences (Meier et al., 2017). In this study, there was no statistically significant result (x^2= .912; p=.340) when it comes to goals of care discussion. However, the samples with RCCOS had 100% discussion of goals of care (n=67) versus 98.6% (n=73) for OCCOS.

Making sure that goals of care were ordered prior to initiating comfort care was very crucial as this was the determination of what patient would allow with respect to their medical preference. This was the basis of the clinicians' plan of care for the patient. In this study, there was no statistically significant result (x^2= 2.775; p=.096). Similar to goals of care discussion, the samples with RCCOS had 100% result (n=67) versus 95.9% (n=71) with OCCOS.

Finally, this study showed that there were fewer samples that died under Palliative Care service at 61.2% (n=41) using the RCCOS versus 81.1% (n=60) using OCCOS. Routine hospice

discharge went down to 10.4% (n=7) using RCCOS versus 14.9% (n=11) using OCCOS. This was a statistically significant result at (x^2= 20.165; p=.000). The summary of all the measures of association between the variables can be found in Table XVI.

Chapter V Conclusions

Discussion

Depending on different background such as religion, culture, ethnicity, education, values and how the person lived his life, the interpretation of "good death" may vary (Meier et al., 2017). The purpose of this study was to examine whether revising the existing comfort care order set would affect the documentation and management of pain and dyspnea in end of life care, increase the use of spiritual care and integrative care and finally, increase the documentation of discussions and actual written orders of goals of care.

The first hypothesis was that RCCOS would have a significant effect in the documentation and management of pain in end of life care. The results of all three data points were not significant. There was no difference in the assessment within 24 hours of encounter (x^2= .247; p=.619) although the percentage of patients assessed was higher in the RCCOS. The second data point was the improvement of pain within 48 hours of initial assessment. Again, there was no statistically significant result at (x^2= .002; p=.967). The two data almost mirrored each other at RCCOS at 74.6% (n=50) versus OCCOS at 74.3% (n=55). Finally, the third marker was pain improved prior to discharge or death. Again, there was no statistically significant finding (x^2= 1.665; p=.197). However, the improvement of pain percentage is higher with RCCOS (91%) as opposed to OCCOS (83.8%).

This study was consistent with the study by Doherty et al. (2017), which revealed that a majority of the patients (70.3%) reported experiencing pain during their illness. About half of

the patients (51.3%) reported that they were in constant pain all the time. The study also found that even with treatment, 40.5% stated that they continued to have severe pain (Doherty et al., 2017). Even though there were no statistically significant findings on the area of pain management, improvement of pain percentage is higher with RCCOS (91%) as opposed to OCCOS (83.8%). One explanation was that pain had always been clearly documented and managed by nurses. Pain was also a clear mandate by Joint Commission and had always been at the forefront of nurses' goals of care. There were no changes that were made in RCCOS when it comes to pain assessment and tools. However, the overall percentage of assessment and improvement of pain prior to death and discharge were higher with RCCOS.

The second hypothesis was that RCCOS would have a significant effect in the documentation and management of dyspnea in end of life care. The first data point was the assessment of dyspnea within 24 hours of initial encounter. There was no statistically significant result (x^2= 2.392; p=122). However, like pain, there was an improvement in the percentage of dyspnea assessed (RCCOS= 98.5% and OCCOS= 93.2%). The second data point was dyspnea improved within 48 hours of initial assessment. There was no statistically significant result (x^2= 1.291; p=.256) and unfortunately, the result showed that more symptoms of dyspnea were not improved after 48 hours of initial assessment with the RCCOS (RCCOS=41.8% OCCOS=51.4%).

The third and final marker was the improvement of dyspnea prior to discharge or death. The data collected was very close to statistical significance (x^2= 3.284; p=.070). The data showed that RCCOS had a higher percentage of dyspnea improved prior to death or discharge 61.2% (n=41) as compared to OCCOS at 45.9% (n=34). This finding was consistent with the study by Soares et al. (2018), which concluded that dyspnea was most prevalent symptom at the

end of life. The study further recommended the incorporation of protocols to effectively manage the symptoms at the end of life (Soares et al., 2018).

An explanation was the fact that nurses did not have any valid, reliable, evidence based dyspnea assessment tool that can be used objectively to measure dyspnea. The tools incorporated were new to the nurses and would probably require more time to get them acclimated with the new way of assessment. Further education and practice would be needed to assure that nurses are using and documenting the tools correctly. There was also a change in the documentation of the results and this would also take practice and getting used to.

As stated earlier in the review of existing literature, the report "Dying in America" from the IOM and the recommendations from the fourth edition of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care (Ferrell et al., 2018) both underscored the importance of the assessment and provision of patient and family's spirituality. Both reports also emphasized the use of non-pharmacological interventions to assist patients in the alleviation of their unpleasant symptoms such as the utilization of integrative healing. The assessment of spirituality was also emphasized. To make sure that the care plan of the patients at the end of life includes all pharmacological and non-pharmacological, holistic/complementary treatments, the RCCOS incorporated the spiritual and integrative care into the set. Hansen, Dieckmann, Kolbeck, Naugler and Chang (2017) recommended that clinicians assess all physical and psychological symptoms. The incorporation of automatic referral to Spiritual and Integrative Care was congruent to the recommendation from this study.

There was no statistically significant result with the incorporation of spiritual care (x^2= 1.616; p=.204). There was a statistically significant result with the inclusion of integrative care (x^2= .81.777; p=.000). The facility was one of the topmost hospitals with employed registered

nurses who were integrative healing certified. There were two holistic practitioners who saw patients on a daily basis. The integrative healing was incorporated into the nurses' documentation at least once a shift in November 2019. This might have contributed to the amount of the patients seen and the statistical significance of integrative care.

Conversation regarding patient and families treatment preferences is of utmost importance when it comes to patients at the end of life. This discussion is fluid and can change depending on patients' clinical progression. Documenting the patient's preference and making sure that it was ordered so that the medical team can follow the patient's wishes were recorded. There were no statistically significant results for goals of care discussion (x^2= .912; p=.340) but data were at 100% on RCCOS. This can be attributed to the order that was incorporated into the order set that automatically defaulted to Do not Resuscitate/Do not Intubate comfort care only when the order set was chosen. Same was true with goals of care ordered (x^2= 2.775; p=.096). Similar to goals of care discussion, the samples with RCCOS had 100% result (n=67) versus 95.9% (n=71) with OCCOS.

Previous studies showed that nurses needed guidance in providing patients with compassionate, evidence-based care to assure comfort at the end of life (Lau et al., 2017). The RCCOS incorporated symptom assessment tools that the nurses used for documentation prior to administering medications to the patients. These tools served as guide for the nurses for timely and adequate medication administration. The documentation of reason for administering medication was collected and showed statistical significance at (x^2= 44.938; p=.000). This can be attributed to the fact that the nurses now have a "hard stop" in the documentation in EMR of reason prior to medication administration.

As previously found in literature review, there were minimal studies that included the use of comfort care order set at the end of life. One study showed that the incorporation of comfort care order set provided guidance to symptom management and therefore resulted in fewer symptom adjustments (Lau et al., 2017). Our results were consistent with this study with 13.4% no titration (n=9) for RCCOS versus 29.7 titration (n=22) with OCCOS. However, our results further revealed that once titration was needed (as in the case of uncontrolled symptoms), 59.7% (n=40) needed 4 and more titration for RCCOS as opposed to 52.7% (n=39) for OCCOS. This result was approaching statistical significance (x^2= 5.938; p=.051). This can be attributed to the fact that in RCCOS, the nurses had evidence based care tools to guide them in symptom management.

One of the data that was collected was the disposition on discharge. This was a statistically significant result (x^2= 20.165; p=.000). However, caution must be exercised because the general in patient in house hospice was not offered during the OCCOS time period.

DNP Essential

1. Essential I- Scientific Underpinnings for Practice (integrate nursing science with knowledge from ethics, biophysical, psychosocial, analytical, and organizational sciences as the basis for the highest level of nursing practice)- RCCOS incorporated the spiritual and integrative care, discussion of goals of care to make sure that patients or family members' values and wishes were incorporate into the care plan, the medications needed to take care of the biophysical need and the use of the organizational resources to ensure that the order set is utilized.

2. Essential II- Organizational and Systems Leadership for Quality Improvement and Systems Thinking (develop and evaluate care delivery approaches that meet current and future needs of patient populations)- RCCOS was approved by the Quality Improvement and

Safety Department of the organization to make sure that it was compliant to all the measures from the accrediting bodies. It outlined all the intervention of the nurses so that they do not practice beyond their scope.

3. Essential III- Clinical Scholarship and Analytical Methods for Evidence-Based Practice (design, direct, and evaluate quality improvement methodologies to promote safe, timely, effective, efficient, equitable and patient-centered care against national benchmarks)- the RCCOS is consistent with the call of the National Consensus Project Clinical Guidelines for Quality Palliative Care. Tools incorporated into the RCCOS provided clinicians with evidence-based symptom assessment tools that would guide them in early recognition, identification and management of distressing symptoms to assure comfort at the end of life. The data on pain and dyspnea assessment and improvement are currently being submitted to CAPC but they do not have the aggregate data for all their participating hospitals at this time and therefore, no comparisons can be given at this time.

4. Essential IV- Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care- with the help of the Clinical Informatics Team which consisted of pharmacist and nurses, the RCCOS was embedded into the physician ordering management (POM) system. Clinicians could choose orders for continuous or intermittent opioids for naïve and tolerant opioid patients. It also included the titration parameters for the three opioid medications (Morphine, Hydromorphone and Fentanyl).

5. Essential V- Health Care Policy for Advocacy in Health Care (advocate for social justice, equity, and ethical policies within all health care arenas). The RCCOS provided patient and family centered care by incorporating physical, emotional and spiritual support by the interdisciplinary team. It also assured that the clinicians provide evidence based care through the

use of symptom assessment tools. This set is used for all patients regardless of diagnosis to assist with symptom management after the documentation of patient and families values and medical treatment preferences that reflect wishes for comfort care only and foregoing disease directed and life sustaining treatments.

6. Essential VI- Interprofessional Collaboration for Improving Patient and Population Health Outcomes (lead interprofessional teams in the analysis of complex practice and organizational issues)- the RCCOS was presented and approved by the Critical Care Committee, Medical Surgical Committee, Director's Committee, Quality Improvement and Safety Department, Nurse Practice Education Council, Research Shared Governance Council, Medical Board and Medical Records Committee for approval prior to implementation.

7. Essential VII- Clinical Prevention and Population Health for Improving the Nation's Health (synthesize concepts including psychosocial dimensions and cultural diversity, related to clinical prevention and population health in developing, implementing, and evaluating interventions to address health promotion/disease prevention efforts, improve health status/access patterns, and/or address gaps in care of individuals, aggregates, or populations)- the RCCOS addressed the gap in the symptom management and care of patients at the end of life.

8. Essential VIII- Advanced Nursing Practice- the use of the RCCOS with the incorporation of the evidenced-based symptom assessment tools provided guidance to the clinicians through complex health and situational transition at the end of life, thereby developing a therapeutic relationship between the clinicians and the patients/family/surrogates/health care proxy through the discussion and incorporation of patient's wishes at the end of life.

Implications for Practice

The RCCOS was an innovative approach in ensuring that patients' at the end of life receive timely identification and documentation of distressing symptoms such as pain and dyspnea with the use of appropriate medications that were efficacious in relieving the distressing symptoms that the patients were suffering from. Nurses, advance practice providers and all disciplines involved in the patients' care had the obligation to relieve and improve patients' sufferings at any point in the disease process. This was consistent with the recommendation from the IOM and the fourth edition of the National Consensus Project Clinical Practice Guidelines for Quality Palliative Care, which underscored the importance of the involvement of all clinicians and all disciplines in making sure that patients at the end of life receive evidence care (Ferrell et al., 2018). The incorporation of naïve versus tolerant dosing including instructions on how to determine whether the patient is tolerant to opioid served as guidance to the clinicians to avoid variations in starting doses of opioids for the patients. For nursing, the incorporation of the evidence based symptom assessment tools and the clear and concise instructions on titration of opioids eliminated the risk of subjective decisions as to when to medicate the patients. It also eliminated the insertion of bias based on the nurses' and clinicians' background and values in life. This was consistent with the study of palliative care at the end of life, which stated that incorporation of validated tools increase comfort and quality at the end of life (Kelley & Morrison, 2015).

Limitations

Since this project was generated to fulfill the requirements of the practice dissertation project, there were time constraints in collecting data. RCCOS was rolled out for live use starting December 17, 2019. As with any new live introductions, there were errors that were discovered which needed to be fixed particularly with the clinical informatics component of the set. The

facility also was scheduled to enhance the current EMR system, which took a couple of months to complete, thereby delaying the start of the implementation of the RCCOS. After the roll out, the collection of data took place in less than 2 months as the desired sampling number was achieved.

The future recommendation was to make sure that all the problems with the order set were fixed prior to the data collection and allow possibly a minimum of six months for data collection. Also make sure that there were no competing agenda prior to setting a date for the implementation. It took a whole year for RCCOS to be approved by different stakeholders in the facility. Since this order set affected both the clinicians who were responsible for ordering the medications and the nurses responsible for making sure that the orders were completed, there were multiple departments, committees and shared governance councils that needed to approve the set prior to implementation. Most of these councils and departments met once a month, thereby delaying the approval on a monthly basis. Another recommendation was to make sure that all the aspect of the order set was thoroughly reviewed prior to presentation to the different departments and councils. It was also imperative to know the dates of the monthly meetings of all the councils and departments to adequately prepare the presentation.

Future research

The implementation of RCCOS was welcomed by both nursing and medical staffing alike. The incorporation of the symptom assessment tools and titration table that give the nurses objective guidance in administering and titrating opioids gave them peace of mind that they are providing evidence care and not just relying on subjective judgments. These measures that were incorporated to the RCCOS were consistent with the recommendations from IOM and the fourth edition of the National Consensus Project Clinical Practice Guidelines for Quality Palliative

Care, which underscored the importance of the involvement of all clinicians and all disciplines in making sure that patients at the end of life receive evidence care (Institute of Medicine of the National Academies, 2014; Ferrell et al., 2018).

Future research should concentrate on adding different tools for other unpleasant symptoms such as agitation and anxiety. A parameter for weaning high flow oxygen, BIPAP and ventilator settings should also be incorporated to give clear instructions and guidance to nurses and respiratory therapist to avoid practicing beyond their scopes. These recommendations were consistent with a study from Blinderman and Billings (2018), which recommended the incorporation of evidence based and validated tools to determine if patient is suffering from distressing symptoms at the end of life. Lastly, a qualitative research would be beneficial to determine whether the use of all these tools would result in a "good death" of the patient from the family's perspectives.

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Appendix A Theory of Unpleasant Symptoms

Theory of Unpleasant Symptoms Hierarchy of Performance and Comfort

From: Lenz, Elizabeth <lenz.23@osu.edu>
Sent: Tuesday, November 20, 2018 3:19:45 PM
To: Garrido, Meliza
Subject: Re: Theory of Unpleasant Symptoms

Dear Ms. Garrido,
Thank you for your interest in the Theory of Unpleasant Symptoms. You certainly may use the theory to guide your research. If you wish to use a reproduction of the figure in a publication, you must secure permission from the publisher of ANS where it was originally published. The authors do not hold the copyright; the journal does. If your use of the figure is for an assignment or a report that will not be published nationally, you can go ahead and use the figure.
Best wishes in your research.
Sincerely,
Elizabeth R. Lenz, PhD, RN
Professor Emeritus
The Ohio State University

Sent from my iPhone

On Nov 20, 2018, at 1:18 AM, Garrido, Meliza <garridom@wpunj.edu> wrote:

Good morning Dr Lenz,

My name is Meliza Garrido and I am a student at William Paterson University in Wayne, New Jersey in their Doctorate in Nursing Program. I am a Palliative Care Nurse Practitioner and would like to revise our comfort care order set for end of life care. I am wondering if I can use the Theory of Unpleasant Symptoms as a guiding theory for my research. I am using this as my project to complete my program at William Paterson University. Thank you in advance.

Meliza Garrido

Appendix B Joint Commission Specification Manual for Quality Measures

Specifications Manual for Joint Commission National Quality Measures (v2018A1)

Print this page

Release Notes:
Measure Information Form
Version 2018A1

Palliative Care (PAL)

On this page:

Set Measures

Set Measure ID	Measure Short Name
PAL-01	Pain Screening
PAL-02	Pain Assessment
PAL-03	Dyspnea Screening
PAL-04	Treatment Preferences and Goals of Care
PAL-05	Treatment Preferences Discharge Document

General Data Elements

Element Name	Collected For
Admission Date	All Records,
Birthdate	All Records,
Discharge Date	All Records, Not collected for HBIPS-2 and HBIPS-3
Sex	All Records,

Measure Set Specific Data Elements

Element Name	Collected For
Discharge Disposition	PAL-05,
Dyspnea Severity	PAL-03,
Goals of Care	PAL-04,
Initial Encounter	PAL,
Initial Encounter Date	PAL,
Pain Character	PAL-02,
Pain Duration	PAL-02,
Pain Effect	PAL-02,
Pain Factors	PAL-02,
Pain Frequency	PAL-02,
Pain Location	PAL-02,
Pain Severity	PAL-01, PAL-02,
Treatment Preferences	PAL-04,
Treatment Preferences Document	PAL-05,

Palliative Care (PAL) Initial Patient Population

The PAL Measure Set Population (common to all PAL measures) is defined as all patients who have received a consultation with any member of the palliative care service team. "Consultation" indicates that the patient received a face to face encounter visit with any member of the palliative care core interdisciplinary team. The core interdisciplinary team is comprised of the following: Physician(s); Registered nurse(s) or advanced practice nurse(s); Chaplain(s) or, spiritual care professional(s); Social worker(s).

The population of the PAL measure set can be identified by using data elements that are common to all of the performance measures in the set:

- Discharge Date
- Initial Encounter

While not required for the identification of the initial patient population or the calculation of the measures, the following data elements are collected for purposes of case identification:

- Admission Date
- Birthdate
- Sex

Note – General Data Elements:

Appendix C Center for Advancement of Palliative Care Rounding Tool

capc Center to Advance Palliative Care

The CAPC Clinical Rounding Tool - *Initial & Final* Assessment Only

Patient Name:_____ _____
Last *First*

Sex: Female Male **DOB:**___/____/____

Ethnicity: White/Caucasian Asian or Pacific Islander Don't Know
Black or African-American American Indian or Aleute/Eskimo
Hispanic or Latino Other (specify:_____)

MRN #:_____ **Admission/Serial #:** _____

Primary Diagnosis:_____

Hospital Admit Date:___/___/___ **Hospital D/C Date:** ___/___/___

Date of Initial PC Consult: ___/___/___ **Referring STAFF MD Specialty:** _____

Type of PC Involvement:

Transfer/Admit to Inpatient PC Unit:	*Consult then Transfer*	*Consult Only*
Direct Transfer		
Direct Admit from ER		
Direct Admit from Physician/Home		
Direct Admit from Hospice		

Date of Direct Admit/Transfer to PC Unit (if applicable): ___/___/___

Unit in the Hospital Prior to PC Transfer (if applicable):

Med/Surg	Rehab
Telemetry	Select/Chronic Ventilator Unit
ICU	Other:_____
ER	

Reason for Initial PC Consult (if applicable):

Pain	Hospice Referral/Discussion
Other symptoms	Withdrawal of Life Prolonging Interventions
Advance Care Planning	Transfer to Inpatient Unit
Goals of Care Discussion	Other:_____

Disposition:

Expired	Home with no services	Transfer to inpatient hospice unit
Expired before seen	Home with homecare	ECF skilled
Expired before transfer	Home with hospice	Acute rehab
Signed off service	ECF with hospice	Ventilator facility
		Other:_____

Transfer to Medicare Hospice Benefit: No Yes (Date: ___/___/___)

Outpatient PC Clinic Follow-up: No Yes (Date: ___/___/___)

capc Center to Advance Palliative Care

The CAPC Clinical Rounding Tool - *Initial & Final* Assessment Only

Patient Name:_____ _____
Last *First*

Sex: Female Male **DOB:**___/____/____

Ethnicity: White/Caucasian Asian or Pacific Islander Don't Know
Black or African-American American Indian or Aleute/Eskimo
Hispanic or Latino Other (specify:_____)

MRN #:_____ **Admission/Serial #:** _____

Primary Diagnosis:_____

Hospital Admit Date:___/___/___ **Hospital D/C Date:** ___/___/___

Date of Initial PC Consult: ___/___/___ **Referring STAFF MD Specialty:** _____

Type of PC Involvement:

Transfer/Admit to Inpatient PC Unit:	*Consult then Transfer*	*Consult Only*
Direct Transfer		
Direct Admit from ER		
Direct Admit from Physician/Home		
Direct Admit from Hospice		

Date of Direct Admit/Transfer to PC Unit (if applicable): ___/___/___

Unit in the Hospital Prior to PC Transfer (if applicable):

Med/Surg Rehab
Telemetry Select/Chronic Ventilator Unit
ICU Other:_____
ER

Reason for Initial PC Consult (if applicable):

Pain Hospice Referral/Discussion
Other symptoms Withdrawal of Life Prolonging Interventions
Advance Care Planning Transfer to Inpatient Unit
Goals of Care Discussion Other:_____

Disposition:

Expired Home with no services Transfer to inpatient hospice unit
Expired before seen Home with homecare ECF skilled
Expired before transfer Home with hospice Acute rehab
Signed off service ECF with hospice Ventilator facility
Other:_____

Transfer to Medicare Hospice Benefit: No Yes (Date: ___/___/___)

Outpatient PC Clinic Follow-up: No Yes (Date: ___/___/___)

Appendix D Abstraction Tool

Pain and Dyspnea Abstraction Tool 1st part

Account #	MR#	Discharge Date	Date of Initial Encounter	Pain assessed during initial encounter using a validated tool	Initial Pain Level	Pain assessed within 24 hours	Pain improved within 48 hours	Pain level at 48 hours	Dyspnea assessed on initial encounter Y/N	Dyspnea level	Patient received tx within 24 hours Y/N	Dyspnea Improved within 48 hours Y/N/NA	Dysnea level at 48 hours

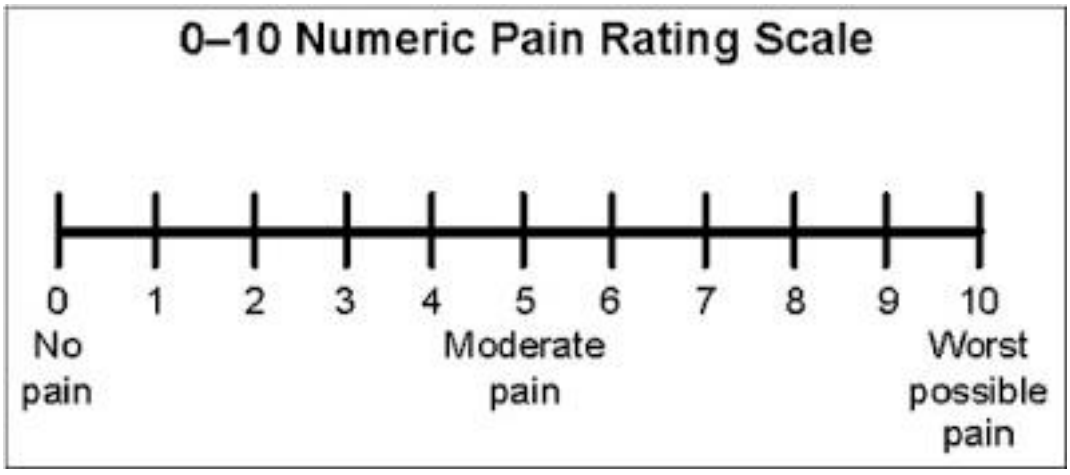
Pain and Dyspnea (2nd part)

Admission date	DOB	Age	Sex	Marital Stat	Disposition	GOC Disc	Ethnicity	Primary Dx	Religion	Race	Code Status	POLST	Symptom Documentation	Titration	Holistic Notes	SC notes

Appendix E FLACC Scale

Categories	0	1	2
Face	**No particular expression or smile**	**Occasional grimace or frown, withdrawn, disinterested**	**Frequent to constant quivering chin, clenched jaw**
Legs	**Normal position or relaxed**	**Uneasy, restless, tense**	**Kicking or legs drawn up**
Activity	**Lying quietly, normal position, moves easily**	**Squirming, shifting back and forth, tense**	**Arched, rigid or jerking**
Cry	**No cry (awake or asleep)**	**Moans or whimpers; occasional complaint**	**Crying steadily, screams or sobs, frequent complaints**
Consolability	**Content, relaxed**	**Reassured by occasional touching, hugging, or being talked to, distractable**	**Difficult to console or comfort**

Appendix F Numeric rating Scale (NRS)



Appendix G Respiratory Distress Observation Scale

Respiratory Distress Observation Scale © (Margaret L. Campbell, PhD, RN 2/19/09)

Variable	0 points	1 point	2 points	Total
Heart rate per minute	<90 beats	90-109 beats	≥110 beats	
Respiratory rate per minute	≤18 breaths	19-30 breaths	>30 breaths	
Restlessness: non-purposeful movements	None	Occasional, slight movements	Frequent movements	
Paradoxical breathing pattern: abdomen moves in on inspiration	None		Present	
Accessory muscle use: rise in clavicle during inspiration	None	Slight rise	Pronounced rise	
Grunting at end-expiration: guttural sound	None		Present	
Nasal flaring: involuntary movement of nares	None		Present	
Look of fear	None		Eyes wide open, facial muscles tense, brow furrowed, mouth open, teeth together	
Total				

Instruction for use:

1. RDOS is not a substitute for patient self-report if able.
2. RDOS is an adult assessment tool.
3. RDOS cannot be used when the patient is paralyzed with a neuromuscular blocking agent.
4. RDOS is not valid in bulbar ALS or quadriplegia.
5. Count respiratory and heart rates for one-minute; auscultate if necessary.
6. Grunting may be audible with intubated patients on auscultation.
7. Fearful facial expressions:

The Respiratory Distress Observation Scale (RDOS©) is an eight-item ordinal scale to measure the presence and intensity of respiratory distress in adults. It is intended for assessing the presence and intensity of respiratory distress when a patient is unable to report about dyspnea. Each parameter is scored from 0 to 2 points and the points are summed. Scale scores range from 0 signifying no distress to 16 signifying the most severe distress.

RE: RDOS

Margaret Campbell <m.campbell@wayne.edu>

Mon 11/19/2018 7:48 AM

To:Garrido, Meliza <garridom@wpunj.edu>;

3 attachments (458 KB)

RDOS - copyright with instructions for use.pdf; The Respiratory Distress Observation Scale -development and psychometric summary.docx; 1-s2.0-S0147956316301418-main.pdf;

Dear Meliza:

This email gives you permission to implement the RDOS as you requested. I've attached some materials you find useful during your implementation.

Best wishes,

Meg

Margaret L. Campbell, PhD, RN, FPCN
Professor, Research
Wayne State University, College of Nursing
5557 Cass Ave.
Detroit, MI, 48201
313-577-5726
m.campbell@wayne.edu

From: Garrido, Meliza <garridom@wpunj.edu>
Sent: Wednesday, November 14, 2018 7:54 AM

Appendix H Modified BORG Scale (mBORG)

0	None
0,5	Very, very light
1	Very light
2	Light
3	Moderate
4	A little intense
5	Intense
6	
7	Very intense
8	
9	Very, very intense
10	Maximum

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Karla Kendrick <karlak49@cox.net>
Sun 10/6/2019 6:10 AM

Dear Ms Garrido
Thank you for your interest in using the modified Borg Scale to assess dyspnea in your population . Permission granted.

I would like to have a copy of your comfort care order set for my records.

Here is my address
5017 Avenida De La Plata
Oceanside CA. 92057

Again thank you for the honor of being apart of you protocol in assessing dyspnea.
If I can be further assistance don't hesitate to write.

Karla Kendrick RN BSN MSN

Appendix I Old Comfort Care Order Set (OCCOS)

COMFORT CARE AND DNR A

1) **DNR A:**
   a) Do Not Resuscitate: Comfort Care Treatment Plan. Medical treatment aimed at providing relief of pain and suffering. No Intubation. Comfort Care only.
2) **Consultations:**
   a) ☐ Palliative Care
   b) ☐ Integrative Healing
   c) ☐ Case Manager from Nursing Units (Select to order hospice)
   d) ☐ Social Services
   e) ☐ Pastoral Care
3) **Comfort Care:** *Reminder: Discontinue IV fluids, TPN, tube feedings, routine labs, Accu-Cheks, SCDs, and diagnostic tests that are active on patient' review order screen. Turn off – ICD, BI-PAP, High flow oxygen.
   a) Monitor vital signs: Heart rate and respirations only every shift
   b) ☐ Convert IV to saline lock
   c) ☐ Turn off ICD. Contact ICD device representative to de-activate.
   d) ☐ Discontinue A line
   e) ☐ Discontinue telemetry
   f) ☐ Extubate patient after comfort measures are implemented. Post extubation: Low flow oxygen _____
   g) ☐ Dr requests/notification: If a patient is not responding to these suggestions, contact ordering physician and/or the palliative care services at beeper: Linda Gurick, RN,APN-C: 50-2334, Meliza Garrido, RN, APN-C; 50-0283; Yusimi Sobrino-Bonilla, RN, APN-C: 50-2009, Dr Amit Tibb 50-2628.
4) **Continuous Opioid Drip and Titration for Pain/Dyspnea:**
   Titration Parameters:
   Pain- titrate up 25% to the nearest whole number for pain scale 1-5
   -titrate up 50% to the nearest whole number for pain scale 6-10
   Dyspnea- titrate 25% to the nearest whole number for mild to mod
   - titrate 50% to the nearest whole number for severe
   a) ☐ Morphine Sulfate 2 mg IV bolus one time prior to initiation of continuous drip
   b) ☐ Morphine Sulfate 5 mg IV bolus one time prior to initiation of continuous drip
   c) ☐ Morphine Sulfate 120 mg in 0.9% Sodium Chloride 120 ml at 2 mg/HR: Titrate after bolus per parameters to maintain comfort
   d) ☐ Morphine Sulfate 120 mg in 0.9% Sodium Chloride 120 ml at 5 mg/HR: Titrate after bolus per parameters to maintain comfort
   e) ☐ Fentanyl (Sublimaze) 25 mcg IV bolus one time prior to initiation of continuous drip
   f) ☐ Fentanyl (Sublimaze) 2,000 mcg in 60 ml in 0.9% Sodium Chloride at 50 mcg/hour; Increase by 25 mcg/hour every 15 minutes for moderate (4-6) to severe (7-10) pain or moderate to severe

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dyspnea
g) ☐ Hydromorphone (Dilaudid) 1 mg IV bolus one time prior to initiation of continuous drip
h) ☐ Hydromorphone (Dilaudid) 20 mg in 90 ml of 0.9% Sodium Chloride at 1mg/hour. Titrate after bolus per parameters to maintain comfort

5) **Intermittent opioid medication for pain/dyspnea:**
a) ☐ Morphine Sulfate 1 mg IV every 15 minutes PRN for pain rating 1-3 or moderate to severe dyspnea
b) ☐ Morphine Sulfate 2 mg IV every 15 minutes PRN for pain rating 4-6 or moderate to severe dyspnea
c) ☐ Morphine Sulfate 5 mg IV every 15 minutes PRN for pain rating 7-10 or moderate to severe dyspnea
d) ☐ Morphine Sulfate 5 mg PO every 2 hour PRN for pain rating 1-5 or moderate to severe dyspnea
e) ☐ Morphine Sulfate 10 MG PO every 2 hours PRN for pain rating 6-10 or moderate to severe dyspnea
f) ☐ Fentanyl (Sublimaze) 25 mcg IV every 15 minutes PRN for pain rating 1-5 or moderate to severe dyspnea
g) ☐ Fentanyl (Sublimaze) 50 mcg IV every 15 minutes PRN for pain rating 6-10 or moderate to severe dyspnea
h) ☐ Hydromorphone (Dilaudid) 1 mg IV every 15 minutes PRN for pain rating 1-5 or moderate to severe dyspnea
i) ☐ Hydromorphone (Dilaudid) 2 mg IV every 15 minutes PRN for pain rating 6-10 or moderate to severe dyspnea

6) **Medications for Anxiety/Confusion/Delirium**
a) ☐ Haloperidol (Haldol) 2 mg PO every 4 hours PRN Delirium/Confusion
b) ☐ Haloperidol (Haldol) 5 mg PO every 4 hours PRN Delirium/Confusion
c) ☐ Haloperidol (Haldol) 2 mg PO every4 hours PRN Delirium/Confusion
d) ☐ Haloperidol (Haldol) 1 mg IV every 6 hours PRN Delirium/Confusion
e) ☐ Lorazepam (Ativan) 1 MG IV every 1 hour PRN Anxiety
f) ☐ Lorazepam (Ativan) 1 MG IV every 2 hours PRN Anxiety
g) ☐ Lorazepam (Ativan) 1 MG IV every 4 hours PRN Anxiety
j) ☐ Lorazepam (Ativan) 1 MG SL every 1hour PRN Anxiety
i) ☐ Lorazepam (Ativan) 1 MG SL every 2 hours PRN Anxiety
j) ☐ Olanzapine Zydis Tab (Zyprexa Zydis Tab) 5 mg PO every 12 hours PRN Anxiety/Confusion
k) ☐ Risperidone Solution (Risperdal Solution) 0.5 mg PO every 12 hours PRN Confusion

7) **Medication for Noisy Respirations:**
a) ☐ Scopolamine 1.5 mg Patch (Transderm-Scop 1.5 mg Patch) 1 transdermal patch every 3 days at 1000
b) ☐ Glycopyrrolate (Robinul) 0.2 mg IV x 1 30 minutes prior to extubation
c) ☐ Glycopyrrolate (Robinul) I 0.2 mg IV every 4 hours as needed for noisy respirations

d) ☐ Glycopyrrolate (Robinul) 0.4 mg IV every 4 hours as needed for noisy respirations

8) **Medications for Nausea/Vomiting:**
   a) ☐ Ondansetron (Zofran) 4 mg IV every 4 hours PRN Nausea/Vomiting
   b) ☐ Ondansetron (Zofran) 4 mg PO every 4 hours PRN Nausea/Vomiting
   c) ☐ Prochlorperazine (Compazine) 10 mg IV every 6 hours PRN Nausea/Vomiting
   d) ☐ Prochlorperazine (Compazine) 25 mg PR every 12 hours PRN Nausea/Vomiting
   e) ☐ Metoclopramide (Reglan) 10 mg IV every 8 hours

9) **Anti-inflammatory Medication**
   a) Hydrocortisone 100 mg IV x one dose prior to extubation

Appendix J Revised Comfort Care Order Set

COMFORT CARE AND END OF LIFE CARE

1) **DNR/DNI comfort care only- must document goals of care conversation to reflect comfort care status. Document who was present in the conversation and the agreed goals and plan.**

a) ☐ Do not Resuscitate and Do not Intubate: Comfort Care Treatment Plan. Medical treatment aimed at providing relief of pain and suffering. Comfort Care only.

2) **Consultations:**

a) ☐ Palliative Care
b) ☒ Integrative Healing
c) ☐ Case Manager from Nursing Units
d) ☒ Social Services (To order hospice)
e) ☒ Spiritual Care

3) **Comfort Care:** *Reminder

a ☐ Discontinue IV fluids, antibiotics, TPN, tube feedings, routine labs, Accu-Cheks, SCDs, and diagnostic tests that are active on patient's review order screen, BI-PAP, High flow oxygen; discontinue non-comfort medications

b) ☒Monitor Respiratory Distress Observation Scale (RDOS)/modified BORG every 30 minutes x 3, then every one hour for the next 8 hours or until RDOS/MBORG ≤ 2 or the self-reported function goal is attained, and then every shift

c) ☒ Monitor Numerical Rating Scale (NRS)/FLACC every 30 minutes x 3, then every one hour for the next 8 hours or until FLACC/NRS ≤ 3 or the self-reported function goal is attained, and then every shift

d) ☒ Convert IV to saline lock
e) ☐ Turn off ICD. Contact ICD device representative to de-activate.
f) ☐ Order Terminal AICD turn off
g) ☒Discontinue A line prior to transfer to regular floor
h) ☒ Discontinue telemetry
i) ☐ Extubate patient when goal of NRS/FLACC and/or mBORG/RDOS achieved
Post extubation: Low flow oxygen
☐ Face tent
☐ O2 2L via NC
☐ O2 3L via NC

j) ☒ LIP communication to Respiratory Therapist- do not take O2 saturation- comfort care only ; wean BIPAP and High Flow O2 when goal of NRS/FLACC and/or mBORG/RDOS achieved

k) ☒ Dr requests/notification: If a patient is not responding to these suggestions, contact ordering MD/Advance Practice Clinicians and/or the Palliative Care Services 201-447-8413 (after hours, please contact the attending MD/Advance Practice Clinicians)

Use these tools for the administration of intermittent doses and titration of opioids for both pain and/or dyspnea (choose medications for whichever is the highest score from

Respiratory Distress Observation Scale/modified BORG or FLACC/Numerical Rating Scale)

***Goal is NRS or FLACC ≤ 3 or mBORG or RDOS ≤ 2 or self-reported comfort function goal is attained**

Initiation of opioid for pain and/or dyspnea- recommendation is trial of intermittent opioid dosing prior to initiation of opioid continuous infusion

If initial NRS or FLACC ≤ 3 or mBORG or RDOS ≤ 2 or self-reported comfort function goal is attained, use as needed Intermittent Opioid Doses:
For opioid naïve patients:

a) ☐ Morphine Sulfate 1 mg IV every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

b) ☐ Morphine Sulfate 2 mg IV every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

c) ☐ Morphine conc. liquid 5 mg SL every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

d) ☐ Morphine conc. liquid 10 mg SL every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

e) ☐ Fentanyl 12.5 mcg IVP every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

f) ☐ Fentanyl 25 mcg IVP every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

g) ☐ Hydromorphone (Dilaudid) 0.5mg IV every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

h) ☐ Hydromorphone (Dilaudid) 1 mg IV every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

i) ☐ Hydromorphone (Dilaudid) 1 mg PO every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

j) ☐ Hydromorphone (Dilaudid) 2 mg PO every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

For opioid tolerant patients:
Opioid Tolerant is taking the following for 1 week or longer: 60mg of oral Morphine/day; 25 mcg transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; 25 mg oral oxymorphone/day; an equianalgesic dose of another opioid.
**To convert opioid:
1. Determine the total daily usage of the current opioid. This should include all long- acting, rapid-acting/short-acting and breakthrough doses (for patients who can still use oral opioids, do not discontinue current regimen including patches).
2. Divide the total by 24 hours to get the hourly dosing.
3. Adjust the starting dose based on #2. If using another opioid, adjust the starting dose 10-15% lower.

Opioid Conversion

Morphine:Hydromorphone	5:1
Morphine Oral: Morphine IV	3:1
Hydromorphone Oral: Hydromorphone IV	3:1
Morphine:Oxycodone	2:1
Morphine: Fentanyl Patch	75 mg:25 mcg
Morphine: Hydromorphone: Fentanyl	1 mg/ml:0.2 mg/ml:20 mcg/ml

a) ☐ Morphine Sulfate 2 mg IV every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

b) ☐ Morphine Sulfate 4 mg IV every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

c) ☐ Morphine conc. liquid 10 mg SL every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

d) ☐ Morphine conc. liquid 20 mg SL every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

e) ☐ Fentanyl 25 mcg IVP every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

f) ☐ Fentanyl 50 mcg IVP every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

g) ☐ Hydromorphone (Dilaudid) 1 mg IV every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

h) ☐ Hydromorphone (Dilaudid) 2 mg IV every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

i) ☐ Hydromorphone (Dilaudid) 2 mg PO every 1 hour PRN for NRS or FLACC 4-6 or mBORG or RDOS 3-6

j) ☐ Hydromorphone (Dilaudid) 4 mg PO every 1 hour PRN for NRS or FLACC ≥ 7; mBORG or RDOS ≥ 7

If initial NRS or FLACC ≥ 4 or mBORG or RDOS ≥3 or self-reported comfort function goal is not attained, use the following:

For opioid naïve patient:

- ☐ Morphine 1 mg IVP x 1 (1st dose), Morphine 2 mg IVP x 1 (2nd dose), Morphine 3 mg IVP x1 (3rd dose) in 30 minute intervals. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

- ☐ Fentanyl 12.5 mcg IVP x 1 dose (1st dose), Fentanyl 25 mcg IVP x 1 dose (2nd dose), Fentanyl 37.5 mcg IVP x 1 dose (3rd dose) in 30 minute intervals. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

- □ Hydromorphone (Dilaudid) 0.5 mg IVP x 1 (1st dose), Hydromorphone (Dilaudid) 1 mg IVP x 1 dose (2nd dose), Hydromorphone (Dilaudid) 2 mg IVP x 1 (3rd dose) in 30 minutes interval. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

☐ If after 3 doses of intermittent pushes and NRS or FLACC is ≥ 4 and MBORG or RDOS is ≥3 or self-reported comfort function goal is not achieved, **CALL MD/Advance Practice Clinicians** and initiate opioid infusion.

- □ Morphine drip 1 mg/ml (Morphine Sulfate 120 mg in 0.9% Sodium Chloride 120 ml) at 2 mg/hour
- □ Fentanyl 20 mcg/ml 2,000 mcg in 100 ml in 0.9% Sodium Chloride at 25 mcg/hour
- □ Hydromorphone 0.2 mg/ml (Dilaudid) 20 mg in 100 ml of 0.9% Sodium Chloride at 1 mg/hour
    - ➢ Re- assess in one hour: if NRS or FLACC is 4 and above and MBORG or RDOS is 3 and above, bolus with Morphine IVP or Fentanyl IVP or Hydromorphone IVP (see titration parameter table and titrate the drip) (do not bolus and titrate if patient achieved self-reported comfort function goal)
    - ➢ See titration table for parameters
    - ➢ Rate of titration- every one hour
    - ➢ Titration goal- NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal

For opioid tolerant patient

Opioid Tolerant is taking the following for 1 week or longer: 60mg of oral Morphine/day; 25 mcg transdermal fentanyl/hour; 30 mg oral oxycodone/day; 8 mg oral hydromorphone/day; 25 mg oral oxymorphone/day; an equianalgesic dose of another opioid

**To convert opioid:

1. Determine the total daily usage of the current opioid. This should include all long- acting, rapid-acting/short-acting and breakthrough doses (for patients who can still use oral opioids, do not discontinue current regimen including patches).
2. Divide the total by 24 hours to get the hourly dosing.
3. Adjust the starting dose based on #2. If using another opioid, adjust the starting dose 10-15% lower.

- □ Morphine 4 mg IVP x 1 (1st dose), Morphine 6 mg IVP x 1 (2nd dose), Morphine 9 mg IVP x 1 dose (3rd dose) in 30 minutes interval. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

- □ Fentanyl 25 mcg IVP x 1 dose (1st dose), Fentanyl 37.5 mcg IVP x 1 (2nd dose), Fentanyl 50 mcg IVP x 1 (3rd dose) in 30 minutes interval. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

- □ Hydromorphone (Dilaudid) 1 mg IVP x 1 (1st dose), Hydromorphone (Dilaudid) 2 mg IVP x1 (2nd dose), Hydromorphone (Dilaudid) 3 mg IVP x 1 (3rd dose) in 30 minute interval. Re-assess the patient after each dose for the goal of NRS/FLACC ≤ 3 or mBORG/RDOS ≤ 2 or self-reported comfort function goal (do not give the succeeding doses if *goal is achieved after the first dose)

☐ If after 3 doses of intermittent pushes and NRS or FLACC is ≥ 4 and MBORG or RDOS is ≥3, or self-reported comfort function goal is not achieved, **CALL MD/Advance Practice Clinicians** prior to initiation of opioid infusion:

- □ Morphine drip 1 mg/ml (Morphine Sulfate 120 mg in 0.9% Sodium Chloride 120 ml) at 10 mg/hour

- □ Fentanyl 20 mcg/ml 2,000 mcg in 100 ml in 0.9% Sodium Chloride at 50 mcg/hour

- □ Hydromorphone 0.2 mg/ml (Dilaudid) 20 mg in 100 ml of 0.9% Sodium Chloride at 1mg/hour

    - Re- assess in one hour: if NRS or FLACC is 4 and above and MBORG or RDOS is 3 and above, bolus with Morphine IVP or Fentanyl IVP or Hydromorphone IVP (see titration parameter table and titrate the drip) (do not bolus and titrate if patient achieved self-reported comfort function goal)

    - See titration table for parameters

    - Rate of titration- every one hour

    - Titration goal- NRS or FLACC ≤ 3 or mBORG or RDOS ≤ 2 or self-reported comfort function goal

Medications for Anxiety/Confusion/Delirium

a) ☐ Haloperidol (Haldol) 2 mg PO every 4 hours PRN Delirium/Confusion
b) ☐ Haloperidol (Haldol) 5 mg PO every 4 hours PRN Delirium/Confusion
c) ☐ Haloperidol (Haldol) 2 mg IV every 4 hours PRN Delirium/Confusion
d) ☐ Haloperidol (Haldol) 5 mg IV every 4 hours PRN Delirium/Confusion
e) ☐ Lorazepam (Ativan) 1 MG IV every 1 hour PRN Anxiety
f) ☐ Lorazepam (Ativan) 1 MG IV every 2 hours PRN Anxiety
g) ☐ Lorazepam (Ativan) 1 MG IV every 4 hours PRN Anxiety
h) ☐ Lorazepam concentrated liquid (Ativan) 1 MG SL every 1hour PRN Anxiety
i) ☐ Lorazepam concentrated liquid (Ativan) 1 MG SL every 2 hours PRN Anxiety
j) ☐ Olanzapine Zydis Tab (Zyprexa Zydis Tab) 5 mg PO every 12 hours PRN

Anxiety/Confusion

k) ☐ Risperidone Solution (Risperdal Solution) 0.5 mg PO every 12 hours PRN Confusion

Medication for oral secretions:

a) ☐ Scopolamine 1.5 mg Patch (Transderm-Scop 1.5 mg Patch) 1 transdermal patch every 72 hours at 1000; may also be used for vestibular origin nausea
b) ☐ Glycopyrrolate (Robinul) 0.2 mg IV x 1 (30 minutes prior to extubation)
c) ☐ Glycopyrrolate (Robinul) 0.2 mg IV every 4 hours as needed for oral secretions
d) ☐ Glycopyrrolate (Robinul) 0.4 mg IV every 4 hours as needed for oral secretions
e) ☐ Atropine ophthalmic solution 1% 1 drop sublingual every one hour as needed for oral secretions

Medications for Nausea/Vomiting (see suggested indications): (indications in text for clinicians)

a) ☐ Ondansetron (Zofran) 4 mg IV every 4 hours PRN Nausea/Vomiting- chemotherapy related
b) ☐ Ondansetron (Zofran ODT) 4 mg PO every 4 hours PRN Nausea/Vomiting
c) ☐ Prochlorperazine (Compazine) 10 mg IV every 6 hours PRN Nausea/Vomiting
d) ☐ Prochlorperazine (Compazine) 25 mg PR every 12 hours PRN Nausea/Vomiting
e) ☐ Metoclopramide (Reglan) 10 mg IV every 8 hours PRN- gastroparesis origin
f) ☐ Scopolamine 1.5 mg Patch (Transderm-Scop 1.5 mg Patch) 1 transdermal patch every 72 hours at 1000 for vestibular origin nausea

May also consider the following medications (this is informational for MD/Advance Practice Clinicians)

Octreotide – 100 mcg IV daily for nausea/vomiting due to malignant bowel obstruction

Olanzapine Zydis Tab (Zyprexa Zydis Tab) 5 mg PO every 12 hours PRN for nausea/vomiting

Dexamethasone 4 mg IV every 6 hours PRN for nausea/vomiting due to increased intracranial pressure

Dexamethasone 4 mg PO every 6 hours PRN for nausea/vomiting due to increased intracranial pressure

Anti-inflammatory Medication

a) ☐ Hydrocortisone 100 mg IV x one dose PRN prior to extubation

Anti Pyretic

a) ☐ Acetaminophen 650 mg by mouth every 4 hours PRN for fever Temp F> 101.0
b) ☐ Acetaminophen 650 mg per rectum every 4 hours PRN for fever Temp F> 101.0
c) ☐ Cooling blanket

Neuropathic pain

a) ☐ Dexamethasone 4 mg IV daily PRN
b) ☐ Dexamethasone 4 mg PO daily PRN
c) ☐ Gabapentin 300 mg PO TID daily

Constipation

a) ☐ Senna 2 tablets PO twice daily PRN
b) ☐ Bisacodyl suppository 10 mg rectally daily PRN

☒Mouth care every shift
☒Carboxymethylcellulose 1% 1 drop to both eyes every shift

Appendix K Titration Parameter Table

Revised Comfort Care Order Set Opioid Titration Parameters
(See titration table)

**** Call APC if NRS or FLACC ≥ 3 or mBORG or RDOS ≥ 2 or self-reported comfort function goal is not attained after 3 boluses****

Starting Dose	See Starting dose field	Range:
Titration Increment	See Comfort care titration table	
Rate of Titration	Every 30 minutes	Notify physician/Advance Practice Clinician: after 3 increment changes
Titration Goal	RDOS/MBORG ≤ 2 or FLACC/NRS ≤ 3 or the self-reported comfort function goal is attained	
Reason to Start	Comfort Care Protocol	

Equianalgesic Rates		
Morphine	Dilaudid	Fentanyl
1 mg = 1ml	0.2mg	20mcg/ml = 1
2 mg	0.4 mg	40mcg/ml= 2
3 mg	0.6 mg	60mcg/ml =3
4 mg	0.8 mg	80 mcg/ml = 4
5 mg	1 mg	100 mcg/cl = 5
6 mg	1.2 mg	120mcg/ml = 6
7 mg	1.4 mg	140mcg/ml = 7
8 mg	1.6 mg	160mcg/ml = 8
9 mg	1.8 mg	180mcg/ml = 9
10 mg	2 mg	200mcg/ml = 10
11 mg	2.2 mg	220mcg/ml = 11
12 mg	2.4 mg	240mcg/ml = 12
13 mg	2.6 mg	260mcg/ml = 13
14 mg	2.8 mg	280mcg/ml = 14
15 mg	3 mg	300mcg/ml = 15
16 mg	3.2 mg	320mcg/ml = 16
17 mg	3.4 mg	340mcg/ml = 17
18 mg	3.6 mg	360 mcg/ml = 18
19 mg	3.8 mg	380 mcg/ml = 19
20 mg	4 mg	400 mcg/ml = 20

Morphine Titration Policy

Starting Dose	See Starting dose field	Range:
Titration Increment	See Comfort care titration table	1mg - 25mg/hr
Rate of Titration	Every 30 minutes	Notify physician/Advance practice Clinician: after 3 increment changes
Titration Goal	RDOS/MBORG ≤ 2 or FLACC/NRS ≤ 3 or the self-reported comfort function goal is attained	
Reason to Start	Comfort Care Protocol	

Current infusion mg/hour	Bolus	Titrate to mg/hour
1 mg	1 mg	2 mg
2 mg	2 mg	3 mg
3 mg	2 mg	4 mg
4 mg	2 mg	5 mg
5 mg	2 mg	6 mg
6 mg	2 mg	8 mg
7 mg	2 mg	9 mg
8 mg	2 mg	10 mg
9 mg	4 mg	11 mg
10 mg	4 mg	13 mg
11 mg	4 mg	14 mg
12 mg	4 mg	15 mg
13 mg	4 mg	16 mg
14 mg	4 mg	18 mg
15 mg	4 mg	19 mg
16 mg	4 mg	20 mg
17 mg	4 mg	21 mg
18 mg	4 mg	22 mg
19 mg	4 mg	24 mg
20 mg	4 mg	25 mg

Fentanyl Titration Parameters

Starting Dose	See Starting dose field	Range:
Titration Increment	See Comfort care titration table	20mcg – 500mcg/hr

Rate of Titration	Every 30 minutes	Notify physician/Advance Practice Clinicians: after 3 increments changes
Titration Goal	RDOS/MBORG ≤ 2 or FLACC/NRS ≤ 3 or the self-reported comfort function goal is attained	
Reason to Start	Comfort Care Protocol	

Current infusion mg/hour	Bolus	Titrate to mcg/hour
20mcg	20 mcg	40 mcg
40mcg	40 mcg	60 mcg
60mcg	40 mcg	80 mcg
80 mcg	40 mcg	100 mcg
100 mcg	40 mcg	120mcg
120mcg	40 mcg	160 mcg
140mcg	40 mcg	180 mcg
160mcg	40 mcg	200 mcg
180mcg	80 mcg	220 mcg
200mcg	80 mcg	260 mcg
220mcg	80 mcg	280 mcg
240mcg	80 mcg	300 mcg
260mcg	80 mcg	320 mcg
280mcg	80 mcg	360 mcg
300mcg	80 mcg	380 mcg
320mcg	80 mcg	400 mcg
340mcg	80 mcg	420 mcg
360 mcg	80 mcg	440 mcg
380 mcg	80 mcg	480 mcg
400 mcg	80 mcg	500 mcg

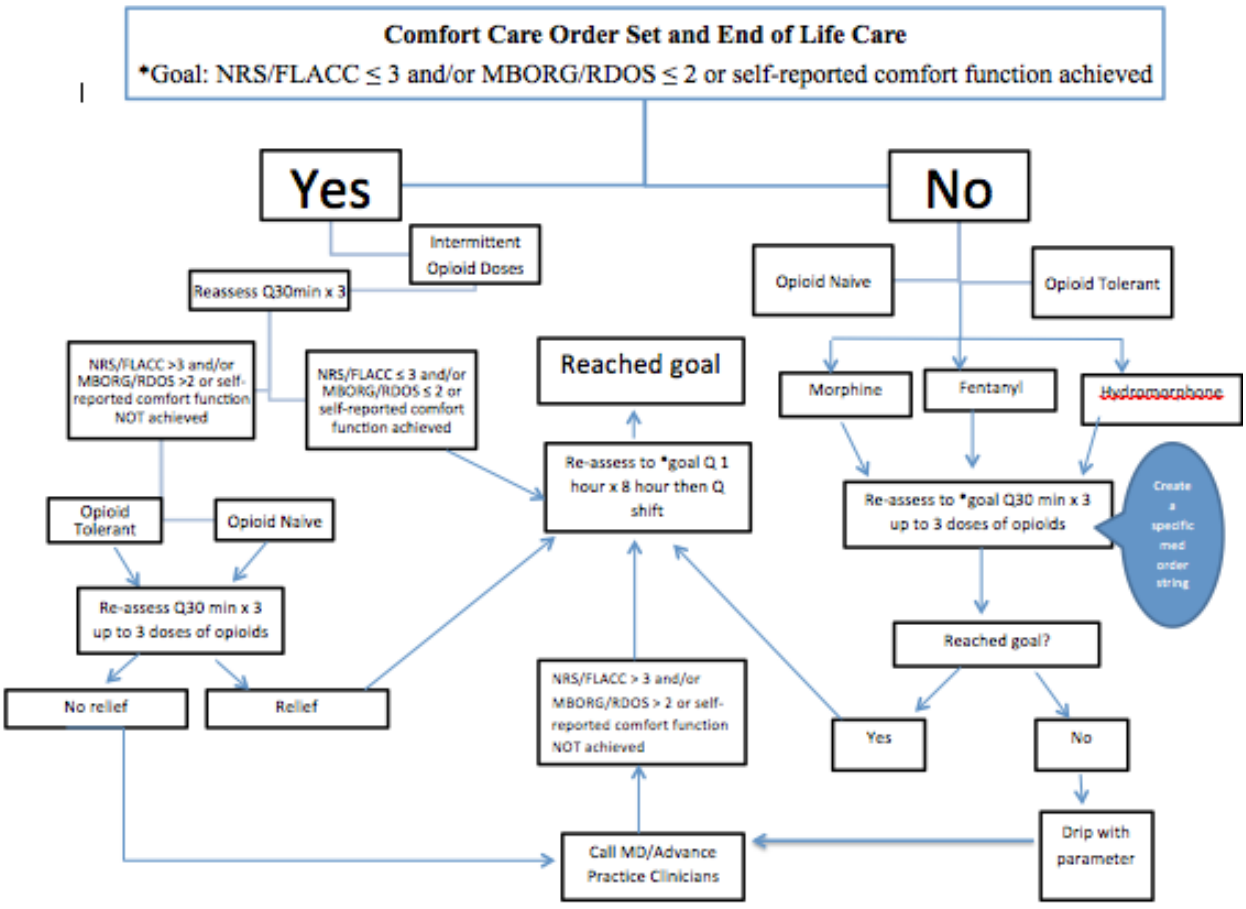
Hydromorphone Titration Parameters

Starting Dose	See Starting dose field	Range:
Titration Increment	25% of current rate- See Comfort care titration table	0.4mg - 5mg/hr
Rate of Titration	Every One Hour	Notify physician/Advance Practice Clinician: after 3 increment changes
Titration Goal	RDOS/MBORG ≤ 2 or FLACC/NRS ≤ 3 or the self-reported comfort function goal is attained	
Reason to Start	Comfort Care Protocol	

Current infusion mg/hour	Bolus	Titrate to mg/hour
0.2mg	0.2 mg	0.4 mg

0.4 mg	0.4 mg	0.5 mg
0.6 mg	0.4 mg	0.8 mg
0.8 mg	0.4 mg	1 mg
1 mg	0.4 mg	1.2 mg
1.2 mg	0.4 mg	1.6 mg
1.4 mg	0.4 mg	1.8 mg
1.6 mg	0.4 mg	2 mg
1.8 mg	0.8 mg	2 mg
2 mg	0.8 mg	2.2 mg
2.2 mg	0.8 mg	2.6 mg
2.4 mg	0.8 mg	2.8 mg
2.6 mg	0.8 mg	3 mg
2.8 mg	0.8 mg	3.2 mg
3 mg	0.8 mg	3.6 mg
3.2 mg	0.8 mg	3.8 mg
3.4 mg	0.8 mg	4 mg
3.6 mg	0.8 mg	4.2 mg
3.8 mg	0.8 mg	4.4 mg
4 mg	0.8 mg	5 mg

Appendix L RCCOS Algorithm



Appendix M Valley Hospital Western Institutional Review Board

July 3, 2019

Meliza Garrido, MSN, RN, ANP-BC, NP-C, FNP-BC
The Valley Hospital
223 N Van Dien Ave
Ridgewood, New Jersey 07450

Dear Ms. Garrido:

SUBJECT: REGULATORY OPINION: IRB EXEMPTION
Investigator: Meliza Garrido, MSN, RN, ANP-BC, NP-C, FNP-BC
Protocol Title: A revised comfort care order set incorporating symptom assessment tools: a quality improvement project

This letter is in response to your request for an opinion as to whether the above mentioned project would constitute human subject research requiring IRB review.

This opinion is based on federal regulation 45 CFR 46 and associated guidance.

Under 45 CFR 46.102(l), the definition of research includes "…a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. ."

The Office of Human Research Protection has issued guidance indicating that quality improvement projects do not meet the definition of research. This guidance states:

Question 2: Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

Answer: No. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research

> development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

This project does not involve research. This project aims to see whether the revised comfort care order set (RCCOS) will have an effect on the documentation and management of pain and dyspnea in patients in end of life care, and to see if it will increase the utilization of non- pharmacological interventions and spiritual care in patients at the end of life. Therefore, WIRB has determined this project is not research and does not require IRB review.

This determination that this project is not research subject to 45 CFR 46 can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make such determinations. WIRB cannot provide a determination that overrides the jurisdiction of a local IRB or other institutional mechanism for making such determinations. You are responsible for ensuring that each site to which this determination applies can and will accept WIRB's determination.

Please note that any future changes to the project may affect its status as research, and you may want to contact WIRB about the effect these changes may have on the status before implementing them. WIRB does not impose an expiration date on its determinations of research.

If you have questions, please contact WIRB Regulatory Affairs at 360-252-2500, or e-mail RegulatoryAffairs@wirb.com.

AI:tb
Not Research-Quality Improvement-Exemption-Garrido (07-03-2019)
cc: Sequoia Young, The Valley Hospital
WIRB Accounting
WIRB Work Order # 1-1198684-1

Appendix N William Paterson University Institutional Review Board

WILLIAM PATERSON UNIVERSITY

Protocol No.: _____

Date Received: _____
For IRB Use Only

Institutional Review Board for Human Subject Research

Page 1

Appendix A: Protocol Face Sheet for WPU Faculty, Staff and Doctoral Students

Instructions: Submit one original protocol prior to the initiation of any work involving human subjects or human material to the IRB Administrator c/o the Office of Sponsored Programs, Raubinger Hall, Room 309.

A complete protocol includes one copy of each of the following: completed and signed Appendix A: Protocol Face Sheet, description of the research plan, all test instruments, all draft informed consent statements and draft recruitment letters/emails/posters. Attach IRB Training Certification if not on file with the IRB. Attach WPUNJ Conflict of Interest and Commitment Disclosure Forms for each senior investigator if required.

Principal Investigator	Meliza Garrido, MSN, RN, ANP-BC, NP-C, FNP-BC
	☐ Faculty ☐ Staff ■ Doctoral Student
Department or Program	DNP
Other Investigators	
Faculty Advisor (for Doctoral Students Only)	Dr Nadine Aktan, PhD, FNP-BC
Project Title	A revised comfort care order set incorporating symptom assessment tools: a quality improvement project
Research Dates	Beginning: 4/5/2019 Ending: 4/5/2020
If Applicable: Funding Agency or Sponsor	The Valley Hospital
OSP Proposal Number	

PLEASE ANSWER THE FOLLOWING QUESTIONS:

	Yes	No	
1.	☐	☑	Is this application for a fellowship/stipend only?
2.	☐	☑	Is this application for an internal WPU funding program? Program: _____
3.	☐	☑	Is this project to be undertaken as part of a previously approved research, training, program development or program implementation grant? Funding agency, project title and project director's name and institution if not WPUNJ: _____
4.	☐	☐	Human subjects to be involved in the proposed activity are or have (mark all that apply):
			☐ Children or minors ☐ Cognitively Impaired ☐ Limited English Proficiency
			☐ Fetuses ☐ Developmentally Impaired
			☐ Abortuses ☐ Physical disorder or disability ☑ Other: Deceased patie
			☐ Pregnant women ☐ WPUNJ students
			☐ Prisoners ☐ WPUNJ employees ☐ Adults
5.	☐	☑	Will subjects be video recorded or audio recorded?
6.	☐	☑	Does the project involve in-person interviews with open-ended questions?
7.	☑	☐	Does this study include online surveys or other forms of electronic communication or data collection?

Tables

Table I
Total Sample of RCCOS versus OCCOS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Pre 2019	74	52.5	52.5	52.5
	Post 2019	67	47.5	47.5	100.0
	Total	141	100.0	100.0	

Table II
Age Comparisons

COHORT			Frequency	Percent	Valid Percent	Cumulative Percent
Pre 2019	Valid	31-50	1	1.4	1.4	1.4
		51-70	9	12.2	12.2	13.5
		71-90	44	59.5	59.5	73.0
		91 & above	20	27.0	27.0	100.0
		Total	74	100.0	100.0	
Post 2019	Valid	16-30	1	1.5	1.5	1.5
		31-50	2	3.0	3.0	4.5
		51-70	8	11.9	11.9	16.4
		71-90	34	50.7	50.7	67.2
		91 & above	22	32.8	32.8	100.0
		Total	67	100.0	100.0	

Table III
Spiritual Care

		COHORT		
		Pre 2019	Post 2019	Total
SPIRCARE	NO	16	9	25
	YES	58	58	116
Total		74	67	141

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.616[a]	1	.204		
Continuity Correction[b]	1.104	1	.293		
Likelihood Ratio	1.639	1	.200		
Fisher's Exact Test				.270	.147
Linear-by-Linear Association	1.605	1	.205		
N of Valid Cases	141				

Table IV

Integrative Healing

		COHORT	
		Pre 2019	Post 2019
INTEGCARE	NO	73	17
		98.6%	25.4%
	YES	1	50
		1.4%	74.6%
Total		74	67
		100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	81.777[a]	1	.000
Continuity Correction[b]	78.634	1	.000
Likelihood Ratio	98.047	1	.000
Linear-by-Linear Association	81.197	1	.000
N of Valid Cases	141		

Table V

Dyspnea assessment within 24 hours

		COHORT		
		Pre 2019	Post 2019	Total
DYS24	NO	5	1	6
		6.8%	1.5%	4.3%

	YES	69	66	135
		93.2%	98.5%	95.7%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.392[a]	1	.122
Continuity Correction[b]	1.274	1	.259
Likelihood Ratio	2.630	1	.105
Linear-by-Linear Association	2.375	1	.123
N of Valid Cases	141		

Table VI
Dyspnea improvement within 48 hours from initial assessment

		COHORT		
		Pre 2019	Post 2019	Total
DYS48	NO	36	39	75
		48.6%	58.2%	53.2%
	YES	38	28	66
		51.4%	41.8%	46.8%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1.291[a]	1	.256
Continuity Correction[b]	.935	1	.333
Likelihood Ratio	1.293	1	.255
Linear-by-Linear Association	1.282	1	.258
N of Valid Cases	141		

Table VII
Dyspnea improved prior to discharge or death

COHORT	
Pre 2019	Post 2019

DYS_GOAL_RED	NO		40	26
			54.1%	38.8%
	YES		34	41
			45.9%	61.2%
Total			74	67
			100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	3.284[a]	1	.070
Continuity Correction[b]	2.700	1	.100
Likelihood Ratio	3.299	1	.069
Linear-by-Linear Association	3.260	1	.071
N of Valid Cases	141		

Table VIII

Pain Assessment within 24 hours

		COHORT		
		Pre 2019	Post 2019	Total
PAIN24	NO	2	1	3
		2.7%	1.5%	2.1%
	YES	72	66	138
		97.3%	98.5%	97.9%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	.247[a]	1	.619
Continuity Correction[b]	.000	1	1.000
Likelihood Ratio	.253	1	.615
Linear-by-Linear Association	.246	1	.620
N of Valid Cases	141		

Table IX

Pain improved within 48 hours

		COHORT		
		Pre 2019	Post 2019	Total
PAIN48	NO	19	17	36

		25.7%	25.4%	25.5%
	YES	55	50	105
		74.3%	74.6%	74.5%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	.002[a]	1	.967
Continuity Correction[b]	.000	1	1.000
Likelihood Ratio	.002	1	.967
N of Valid Cases	141		

Table X

Pain improved prior to discharge or death

			Cohort Pre 2019	Post 2019
PAIN_GOAL_RED	NO		12	6
			16.2%	9.0%
	YES		62	61
			83.8%	91.0%
Total			74	67
			100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1.665[a]	1	.197
Continuity Correction[b]	1.077	1	.299
Likelihood Ratio	1.699	1	.192
Linear-by-Linear Association	1.653	1	.199
N of Valid Cases	141		

Table XI

Nurse Documentation of Explicit Reason for administering medications

			COHORT		
			Pre 2019	Post 2019	Total
NURSDoc	NO		50	8	58

		67.6%	11.9%	41.1%
	YES	24	59	83
		32.4%	88.1%	58.9%
Total		74	67	141
		100.0%	100.0%	100.0%

Table XII
Titration of Medications

		COHORT		
		Pre 2019	Post 2019	Total
TITRATE	NO TITRATION	22	9	31
		29.7%	13.4%	22.0%
	1-3	13	18	31
		17.6%	26.9%	22.0%
	4 & UP	39	40	79
		52.7%	59.7%	56.0%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5.938[a]	2	.051
Likelihood Ratio	6.099	2	.047
Linear-by-Linear Association	2.852	1	.091
N of Valid Cases	141		

Table XIII
Goals of Care Discussion

		COHORT		
		Pre 2019	Post 2019	Total
GOCDis	NO	1	0	1
		1.4%	0.0%	0.7%
	YES	73	67	140
		98.6%	100.0%	99.3%
Total		74	67	141
		100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)

Pearson Chi-Square	.912[a]	1	.340
Continuity Correction[b]	.000	1	1.000
Likelihood Ratio	1.296	1	.255
Linear-by-Linear Association	.905	1	.341
N of Valid Cases	141		

Table XIV
Goals of Care Ordered

			COHORT	
			Pre 2019	Post 2019
GOAL CARE	OTHER		3	0
			4.1%	0.0%
	COMFORT CARE		71	67
			95.9%	100.0%
Total			74	67
			100.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	2.775[a]	1	.096
Continuity Correction[b]	1.170	1	.279
Likelihood Ratio	3.927	1	.048
Linear-by-Linear Association	2.756	1	.097
N of Valid Cases	141		

Table XV
Disposition

			COHORT	
			Pre 2019	Post 2019
DISPO	GIP OUTSIDE		3	3
			4.1%	4.5%
	ROUTINE HOSPICE		11	7
			14.9%	10.4%
	GIP INSIDE		0	14
			0.0%	20.9%

	EXPIRE	60	41
		81.1%	61.2%
	OTHER	0	2
		0.0%	3.0%
Total		74	67
		100.0%	100.0%

Table XVI
Summary of Crosstabs/Chi Square

		X^2	P value
Table III	Spiritual Care	1.616	.204
Table IV	Integrative Care	81.777	.000
Table V	Dyspnea- 24	2.392	.122
Table VI	Dyspnea-48	1.291	.256
Table VII	Dyspnea-goal	3.284	.070
Table VIII	Pain- 24	.247	.619
Table IX	Pain- 48	.002	.967
Table X	Pain- goal	1.665	.197
Table XI	Nurse documentation	44.938	.000
Table XII	Titration of medications	5.938	.051
Table XIII	Goals of care discussion	.912	.340
Table XIV	Goals of care ordered	2.775	.096
Table XV	Disposition	20.165	.000