

DNP PROJECT PROPOSAL

TREATING DEPRESSION AND SLEEP IMPAIRMENT TO IMPROVE PAIN LEVELS AND  
QUALITY OF LIFE FOR PATIENTS WITH SICKLE CELL DISEASE: A QUALITY  
IMPROVEMENT PROJECT

BY

SHERAN MAXWELL SIMO

DR. DEB SIELA – FACULTY ADVISOR

BALL STATE UNIVERSITY

MUNCIE, INDIANA

MAY 3, 2016

## TABLE OF CONTENTS

TABLE OF CONTENTS.....	2
ABSTRACT.....	4
INTRODUCTION AND BACKGROUND.....	5
Problem Statement.....	5
Summary of Current Knowledge.....	5
Literature Review.....	7
Local Problem.....	16
Intended Improvement.....	18
Project Outcome Objectives.....	19
THEORETICAL/CONCEPTUAL MODEL FRAMEWORK.....	20
Model Description.....	20
Conceptual Framework.....	20
Five Phases of Stetler Model.....	21
Assumptions.....	24
Literature to Support Use of the Model.....	24
Use of the Theory for Proposed Project.....	27
Strengths and Limitations of the Model.....	29
PROJECT DESIGN.....	29
Setting.....	29
Population.....	32
Intervention Plan.....	33

Ethical Issues.....	38
STUDY OF INTERVENTION.....	40
Project Questions.....	40
Project Outcome Objectives.....	41
Study Design.....	42
Methods of Evaluation – Outcome Objectives.....	45
Methods of Data Analysis.....	48
Methods of Evaluation – Process Objectives.....	49
REFERENCES.....	52
Appendix A: The Pittsburgh Sleep Quality Index (PSQI).....	59
Appendix B: Patient Health Questionnaire (PHQ-9).....	60
Appendix C: Quality of Life Scale (QOL).....	61
Appendix D: Outcomes Evaluation Tools Table.....	62
Appendix D: Informed Consent Table.....	67

In the world of sickle cell disease, vaso-occlusive crisis pain is both an acute and chronic factor. Many of the complications associated with sickle cell disease have some aspect of pain associated with them, beginning in infancy and continuing throughout the lifespan (Ballas, 2011; Ballas et al., 2012). Acute, recurrent, and unrelenting pain is often joined by other affective disorders that impact pain chronicity, and some patients with sickle cell disease have depression and/or sleep disturbances that may impact pain levels and quality of life. The purpose of this quality improvement project is to improve the process of assessment and treatment of depression and sleep disturbance in patients admitted to Bridgeport Hospital, Bridgeport, CT with vaso-occlusive crisis. The Stetler Model was used to guide the process of translating existing research regarding the impact of depression and sleep impairment on pain and quality of life, in patients presenting with sickle cell pain crisis, into evidence-based practice for this quality improvement project. Patients will be evaluated and treated based on the *Depression and Sleep Impairment Guideline and Treatment Protocol* developed by the interdisciplinary sickle cell team. The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.

## **Introduction and Background**

### **Problem Statement**

According to the Sickle Cell Disease Association of America (SCDAA, 2015) there are an estimated 70,000+ people with sickle cell disease (SCD) in the United States. Approximately 1000 babies are born each year in the US with the disease. Persons living with SCD are at risk for many complications associated with both the acute and chronic effects of sickling red blood cells. Close attention to the physiological and biochemical aspects of the disease, as well as, the psychological aspects associated with it is important in order to prevent increased morbidity and mortality.

In the world of SCD, vaso-occlusive crisis (VOC) pain is both an acute and chronic factor. Many of the complications associated with SCD have some aspect of pain associated with them, beginning in infancy and continuing throughout the lifespan (Ballas, 2011; Ballas et al., 2012). Acute, recurrent, and unrelenting pain is often joined by other affective disorders that impact pain chronicity, such as depression, insomnia, anxiety, aggression, despair, helplessness, and inappropriate pain coping strategies as well as other psychiatric disturbances (Anie, 2005; Ballas et al., 2012; Vichinsky, 2014).

### **Summary of Current Knowledge**

Studies have evaluated the negative effects of chronic pain, depression, and anxiety, and found higher levels of each of the affective disorders in several chronic pain conditions (Gerrits et al, 2014; Outcalt et al., 2015; Sherman, Turk & Okifuji, 2000). Nicolson, Caplan, Williams and Stern (2009) also found that comorbid pain and affective disorders could contribute to the intensity of experienced pain, increased disability associated with pain, increased sleep impairment and poorer pain outcomes despite treatment. It has been suggested that alleviating

depression, anxiety and sleep impairment may be the more effective treatment in the management of pain (Nicolson, Caplan, Williams & Stern, 2009).

Patients with SCD have a higher incidence of depression and anxiety compared to those in the general population (Treadwell, Barreda, Kaur & Gildengorin, 2015). These psychiatric conditions may develop as a result of unmanaged acute or chronic pain (Ballas et al., 2012; Edwards et al., 2005), and can have a significant impact on quality of life (QOL) (Mann-Jiles & Morris, 2009). According to the U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung and Blood Institute (USDHHS, 2014) guidelines, providing adequate pain relief will improve both function and QOL in these patients.

Porter, Gill, Carson, Anthony, and Ready (2000) found a role for physical and psychological stress, as a significant predictor of pain and onset of VOC. Addressing the psychosocial as well as the physical aspects of sickle cell pain can have a positive impact on QOL, functional ability and overall level of pain. The NHLBI (2014) recommends a referral to a mental health professional such as a psychiatrist or social worker if necessary.

In addition to the negative effects that psychological disorders can have on pain, several authors found a negative impact of disrupted sleep on pain, physical functioning and disability in both adolescents and adults in a variety of chronic pain conditions, including SCD (Emery, Wilson, & Kowal, 2014; Goral, Lipsitz, & Gross, 2010). Another study evaluated the effect that sleep deprivation has on depression and the combined effect on pain (Wallen et al., 2014). Sleep disorders and sleep deprivation, discussed by Mann-Jiles, Thompson, and Lester (2015) can have negative effects on both physical and psychological health. Edwards et al. (2005) found that these psychiatric factors could impact QOL, diminish ability to cope with pain, contribute to a cycle of intensified pain, as well as have a disabling effect on life and function.

Several studies have found a significant reduction of QOL in patients with SCD as compared to the general population. According to Anie (2005) there may not be a significant difference in QOL from those affected by other chronic illnesses, however, McClish et al. (2005) found the overall QOL impaired when compared to patients with many other chronic illness, including cystic fibrosis, asthma, and dialysis. Both McClish et al. and Anie et al. (2012) found considerable impairment in QOL during admission for VOC. According to Anie et al., while QOL improved slowly after discharge, steady-state QOL was likely to remain impaired.

Evaluation and treatment of depression and sleep deprivation in addition to aggressive pain interventions can improve overall chronic pain levels, QOL and potentially lessen the impact of both severity and incidence of VOC. Expanding the focus to all factors affecting pain in this patient population is important to help with identifying appropriate interventions in a multidisciplinary approach to managing sickle cell pain, improving QOL, and reducing morbidity and mortality.

### **Literature Review**

Goral, Lipsitz, and Gross (2010) reported the results of the Israel National Health Survey-World Mental Health survey, as part of a 27 country survey to determine the prevalence of psychiatric disorders in association with other correlates, including physical health conditions, disabilities, health care utilization and cost, as well as socioeconomic and demographic correlates. Of 4855 participants, 29.9% (n=1453) reported chronic pain, which was significantly associated with higher levels of depression, anxiety, and sleep disorders. The authors also determined a significant association between participants with pain alone ( $p < .001$ ) or in combination with depression or anxiety ( $p = .0002$ ) and higher numbers of health care visits. Goral et al. (2010) found a strong association with chronic pain and comorbid psychiatric

disorders. Those participants with comorbid depression and anxiety also reported more problems sleeping. The authors suggested a comprehensive approach to treating chronic pain by including treatment for depression, anxiety, and sleep disturbance.

Anie (2005) reviewed published works looking for common psychological complications associated with SCD across the lifespan, specifically psychological coping, QOL and neuropsychology. This review confirmed that the most frequent psychological problems included anxiety, depression, social withdrawal, aggression, poor relationships and poor school performance. QOL was found to be negatively impacted in patients with SCD, although not significantly different from patients with other chronic pain conditions. The review also revealed considerable evidence for neuropsychological complications associated with infarcts and cerebrovascular accidents. The authors indicated that these complications resulted in neuropsychological deterioration and cognitive impairment, including dementia in adults.

Recommendations from this review included psycho-education, cognitive behavioral therapy, and a recommendation for comprehensive neuropsychological assessments in complement to neurological examinations as a basis for treatment. Anie (2005) hoped the recommendations would help to improve patients' knowledge and understanding of their illness, thereby improving coping ability; as well as help patients lead more productive and satisfying lives by changing self-defeating thoughts and behaviors to more positive and productive ones.

Anie et al. (2012) completed a retrospective, longitudinal study, looking at 510 patients with SCD on admission, before discharge and one-week post-discharge. The purpose was to evaluate self-assessments of pain, mood and QOL with health utility. The authors found that while there was a statistically significant reduction of pain from standard treatment from admission to discharge ( $p < 0.001$ ), patients were neither pain free at discharge nor one week after



discharge ( $p < 0.001$ ). Mood and QOL each showed a statistically significant improvement from admission to discharge ( $p = 0.001$ ;  $p < 0.001$ ) and again from discharge to one week after discharge ( $p < 0.001$ ;  $p < 0.001$ ). However, the authors found that daily function may not return fully for some time after VOC, and overall QOL was likely to remain impaired.

The authors recommended a multidimensional approach to pain management, including psychological interventions with coping strategies based on knowledge that “adults with SCD have shown to have an impaired [QOL] compared to the general population with pain and psychological distress being contributors” (Anie et al., 2012, p. 4). The authors suggested that these psychological interventions should be provided to inpatients and post-hospitalization, to “enhance the use of appropriate pain coping techniques, alleviate any comorbid mental health difficulties and ultimately improve [QOL]” (p. 5).

Asnani, Fraser, Lewis, and Reid (2010) administered questionnaires to a cohort of 277 patients with SCD in Jamaica, identified during screening at birth and followed through their lifetime and to 65 controls with normal adult phenotype of the same sex born closest in time and matched at birth with the cohort patients. The purpose was to evaluate demographics, disease severity, depression and loneliness. The authors found that 21.6% ( $n = 60$ ) of the cohort patients, compared to 9.4% ( $n = 6$ ) of controls were depressed, and loneliness was significantly higher in cohort patients ( $16.9 \pm 5.1$ ) versus controls ( $14.95 \pm 4.69$ ). In addition, the authors found a significant association with depression and unemployment ( $p < 0.001$ ) and unemployment and lower educational level with loneliness ( $p = 0.002$ ), associated with more frequent pain crises, leg ulcers (a common occurrence in patients with SCD), and frequent hospitalization.

The authors concluded that there is a moderately high correlation between loneliness and depression, as well as a higher level of loneliness among those patients who are depressed. The

authors also expressed concern that socially isolated young adults have higher rates of mortality. As a result of the findings, Asnani et al. (2010) recommended to help ensure that education continued in younger patients with SCD, and to encourage employment. The authors also recommended providing treatment for, rather than minimizing, feelings of depression and anxiety while focusing on treatment of the crises.

Grant, Gil, Floyd, and Abrams (2000) completed a cross-sectional, within group study in which they interviewed 43 adults with SCD, 11 with and 32 without depression. The purpose of the study was to investigate depression and health care use and evaluate a range of cutoff scores on the Center for Epidemiologic Studies – Depression Scale (CES-D). According to the authors, previous studies showing higher than normal incidence of depression in persons with SCD, may have been reporting the prevalence of general distress and not depression. The authors believed that the actual rates might have been inflated by somatic symptoms. The authors found that 11 of the 43 patients (25.6%) interviewed met the criteria for depression. However, reported numbers of painful episodes, emergency room visits, and acute complications for those patients who were depressed were not statistically significant, although there were statistically significant between-group differences on severity of depression and functioning.

Grant et al. (2000) cautioned that use of this and similar tools may provide false positive depression results, reflecting symptoms of medical illness, and not psychological symptoms. The authors also suggested “that negative thinking and somatic awareness (i.e. bodily hypervigilance) may be components of the same construct, namely negative affectivity” (Grant, Gil, Floyd, & Abrams, 2000, p. 10). Based on these results, the authors suggested that both psychological and disease severity be targeted for therapy.

Hasan, Hashmi, Alhassen, Lawson, and Castro (2003) conducted a study to evaluate the prevalence and impact that demographics, disease severity and health care use variables have on depression in patients with SCD whose health had been stable for a one-month period. Using a convenience sample of 50 clinic patients, the authors assessed the incidence of depression using the Beck Depression Inventory (BDI) as well as a variety of health outcomes. The authors found that 22 (44%) of the patients studied had mild to severe depression, and 14 (24%) of those had severe depression. Those with severe depression were more likely to have a low family income, no high school diploma, be female, with a history of multiple transfusions, have poor pain control, limited social support, be undergoing hydroxyurea treatment, and have a history of frequent VOC.

Hasan et al. (2003) suggested that both demographics and disease severity appear to play a role in the increased incidence of depression in patients with SCD compared to the general population, even when the patients have been relatively healthy. The authors' recommendations included providing adequate social support, including a close physician-patient relationship. They also recommended rapid and adequate pain management, including the use of antidepressants that can serve the dual role of analgesic as well as antidepressant, and cognitive behavioral techniques to help improve QOL and disease course.

Levenson et al. (2008) participated in a prospective cohort study as part of a larger *The Pain in Sickle Cell Epidemiology Study (The PiSCES Project)*. For six months, 308 patients with SCD completed a daily pain diary for The PiSCES Project. In order to measure the prevalence of depression, anxiety and their effects on crisis and non-crisis pain, as well as QOL, opioid use and health care utilization, Levenson et al. evaluated the diaries of 232 of the patients who had completed pain diaries for one month. The authors found that 27.6% (n=64) were depressed and

6.5% (n=15) had anxiety. In addition, the authors found that those who were depressed had more pain days than those who were not depressed (71.1% versus 49.6%,  $p<.001$ ), as well as higher mean pain scores, and more interference and distress from pain. In patients with anxiety, the authors found more pain, distress and interference from pain as well as more opioid use on both crisis and non-crisis days. An interesting result of the study was that most of the days that pain and depression were reported, were not crisis days. Levenson et al. recommended that those who manage the pain of SCD routinely screen for depression and anxiety in the clinical setting as well as in the acute setting, during a crisis, and suggested their findings have implications for both clinical care and future research.

Naughton, Ashworth, and Skevington (2007) completed a study to determine if sleep quality (for example disrupted sleep), independently predicted disability. The authors evaluated the self-reported relationships between sleep and disability in 155 patients with chronic pain who were seen at a chronic pain clinic. The authors found a positive correlation when comparing disrupted sleep and rest patterns and poor sleep quality with depression and pain-related disability. The findings of the study showed a positive association between sleep disruption and pain related disability ( $r=0.45$ ,  $p<0.001$ ), sleep disruption and depression ( $r=0.42$ ,  $p<0.001$ ), and sleep disruption and pain severity ( $r=0.40$ ,  $p<0.001$ ). In addition, Naughton et al. found a positive correlation between sleep disruption and sleep quality ( $r=0.39$ ,  $p<0.001$ ), although pain severity and depression showed no significant correlation ( $r=0.12$ , n. s.). A surprising result, according to the authors was a negative correlation between age and depression ( $r=-0.29$ ,  $p<0.001$ ). The authors' recommendation to provide treatment to improve sleep, may have a positive impact on affect and disability, as well as reduce pain levels.

Emery, Wilson, and Kowal (2014) examined the effects of depression on sleep behaviors in 60 patients with chronic musculoskeletal pain, who did or did not meet the DSM-IV diagnostic criteria for major depressive disorder (MDD). The patients completed sleep diaries for four days, as well as completed questionnaires that assessed their pain severity, disability, as well as sleep quality, beliefs and attitudes about sleep and sleep hygiene. The authors found that 33 patients (55%) met the diagnostic criteria for major depressive disorder, and 32 of those patients (97%) met the criteria for insomnia disorder. However, insomnia was a common occurrence in all the chronic pain patients, exhibited in 21 of 27 patients (78%) without MDD. The authors explain that even though the 27 patients did not meet the criteria for MDD, greater than 25% fell into a category of MDD in partial remission; therefore, reinforcing the findings that sleep disturbance is a common problem in patients with chronic pain, whether with MDD, with MDD in partial remission, or not depressed.

Emery et al. (2014) concluded that depression does not seem to significantly impact the sleep disturbance associated with chronic pain. However, the presence of depression may relate more to the cognitive and behavioral aspects of insomnia such as dysfunctional attitudes about sleep, greater pre-sleep arousal and poorer sleep hygiene.

Wallen et al. (2014) studied the prevalence of sleep disturbance and its association with pain and depression in 328 patients with SCD. The authors found a 71.2% (n=234) prevalence of sleep disturbance, with 65 (20.6%) of the patient results scoring consistent with depression, and one-half of those (10%) having thoughts of suicide. Older patients ( $p=.002$ ), with a higher body mass index ( $p=.011$ ), those with more pain days ( $p=.033$ ) and those with more frequent hospitalizations in the previous 12 months ( $p<.001$ ), were more likely to suffer sleep disturbance. The authors also found that the scores for depression and sleep quality were correlated ( $p<.001$ ),

and most common among those patients with more frequent pain. Wallen et al. recommended that providers who care for patients with SCD screen for both depression and sleep disturbance.

Palermo and Kiska (2005) completed a study, using a convenience sample of adolescents with chronic pain (including juvenile arthritis [JA]), SCD, and recurrent migraine or tension headache) to evaluate the relationship between pain symptoms, daily functioning, health-related QOL, and sleep disturbance. Upon evaluation, patients with headaches reported more daytime sleepiness than those with SCD ( $p < .05$ ), as well as more pain, depression, and disability compared to those with JA or SCD. According to the authors, there were low correlations on bivariate analysis, between pain symptoms and sleep variables. However, the authors found moderate to high relationships when looking at depressive symptoms, functional disability, health-related QOL and sleep. In addition, the authors found that depressive symptoms were a significant predictor of how severe sleep disturbance was.

Palermo and Kiska (2005) suggested that the nature of the relationship between depression and sleep disturbance is unknown, and recognized that sleep disturbance may cause depressive symptoms or that pain may be contributing to both depression and sleep disturbances. The authors recommended routinely assessing adolescents with chronic pain for sleep habits and behaviors, and target therapies to help improve sleep and QOL.

Mann-Jiles et al. (2015) completed a retrospective chart review of 72 patients with SCD seen between January 2006 and October 2010 in comprehensive oncology outpatient clinics in a Midwest city. The purpose of the study was to examine clinical and psychological factors associated with sleeplessness and insomnia. Mann-Jiles et al. found that 47% ( $n=34$ ) of the patients suffered from insomnia, 15% ( $n=11$ ) from sleep impairment, and 20% ( $n=14$ ) of the patients suffered from depression, yet only 15% ( $n=3$ ) were actually taking an antidepressant.

The authors found a significant association between pain and sleep impairment ( $p=.00$ ), pain and insomnia ( $p=.00$ ), morning hours of sleep ( $p=.00$ ), and evening hours of sleep ( $p=.00$ ). The authors also found that there was less incidence of insomnia in those patients who took long-acting opioid pain relievers compared to those who only took short-acting opioids ( $p=.01$ ), suggesting that it is the recurrence of pain, when short-acting medications wear off, interrupting sleep. Recommendations by the authors included appropriate assessments and referrals or treatment for insomnia, as well as consideration for use of long-acting opioid pain relievers rather than relying solely on short-acting opioids in those patients with chronic pain.

Graves and Jacob (2014) completed a study with 66 children and adolescents with SCD to examine the relationships between pain, pain coping and sleep, and to determine the factors which impact these. The authors found that while most children cope with their pain in positive ways (seeking information, problem solving, seeking out social support and positive self-statements), there were significant negative correlations between worsening pain severity, behavioral distraction and internalizing or catastrophizing. In addition, the authors found that the majority (91.2%) had mild to severe sleep disturbances, and a small portion of those required sleep medication three or more times a week (18.2%). Results of the Pittsburgh Sleep Quality Index (PSQI) showed a significant correlation between pain and sleep disturbance ( $p<.0001$ ) and day dysfunction ( $p<.0001$ ) due to sleepiness. The authors recommended that providers address sleep when instituting a pain intervention, including creating environments conducive to sleep as well as pharmacological interventions.

McClish et al. (2005) completed a sub-study of the PiSCES Project in which 308 patients with SCD completed a Medical Outcomes Study 36-item Short-Form to evaluate health related QOL. The authors found significantly worse results ( $p<0.0001$ ) in patients with SCD compared

to patients with asthma, cystic fibrosis and renal failure on hemodialysis on scales for “physical function, physical and emotional role function, bodily pain, vitality, social function,... and general health” (p. 1). Their findings suggested that patients with SCD experience a poor health-related QOL except for mental health ( $p=0.0396$ ), when compared to patients with other chronic illnesses. The authors pointed out a concerning finding, where older age is a significant factor in worsening QOL results for the other medical conditions, the younger SCD cohort had worse QOL scores. The authors recommended that improvement in QOL should be a clinical endpoint in the SCD patient population.

### **Local Problem**

According to Bridgeport Hospital (BH), Bridgeport, CT, metrics for June 21, 2014 to November 22, 2014, approximately 84 patients (ages 18+) comprised the list of patients who had presented to the hospital with SCD as the principle or secondary diagnosis (ICD-10: D571, D5700, D5720, D57219, D5780, D57819, D5740, D57419, excluding Sickle Cell Trait: D573). Approximately 65% ( $n=55$ ) of these patients were admitted as inpatient, with an average length of stay (LOS) 10.3 days (June 21, 2014 to November 22, 2014). According to ChimeData (Connecticut Hospital Association, FY 2010 to FY 2014, for patients 17+ years), BH had the longest average LOS compared to other hospitals in the state.

Recognizing that we had an opportunity to implement best practices and standardize care for patients presenting in VOC, a quality improvement project was identified and a Sickle Cell Initiative was implemented by the Medicine Service Line and Medicine Clinical Program Team on June 22, 2015. The intent of the initiative was to provide rapid intervention and treatment to patients in VOC when presenting to the emergency department (ED) and when admitted for hospitalization.



In the effort to effectively treat acute sickle cell crisis pain, treatment plans were implemented to provide aggressive individualized pain interventions to rapidly lower pain levels in patients presenting to the ED or admitted with VOC. A single nursing unit was identified to admit these patients. A dedicated treatment team consisting of hospitalist physicians (MDs), the Palliative and Pain advanced practice registered nurse (APRN), the registered nurse (RN) assistant nurse manager of the target unit, the patient's primary RN, a dedicated social worker (SW) and RN case manager (CM) was formed. This *Sickle Cell Team*, rounds daily Monday through Friday, with a pharmacist rounding once weekly. The Palliative Care chaplain provides individual spiritual care visits to patients. The goal of this interprofessional team is to provide a consistent, holistic approach to treating these patients, and build a level of trust.

According to studies, even when patients reported less than complete relief of their pain, most patients reported being satisfied with their pain management when providers addressed pain control in partnership with the patient. These results imply that it is with the *effort* of the caregivers in trying to manage pain that patients were satisfied (Sherwood et al, 2000; Comley and DeMeyer, 2001).

During the initial months of the initiative, as trust developed, the team had opportunity to learn more about these patients than ever before. As a result of this work, walls that had built up previously due to mistrust and poor pain management have been crumbling, and the patients are beginning to open up to the team regarding various psychosocial stressors, including social isolation and withdrawal, feelings of abandonment, and poor relationships with friends and family members. Another significant finding, was the observation by the nursing staff, that many of our patients do not sleep, something which seen in single patients scattered throughout

the hospital might not be significant, but in five or six patients hospitalized at the same time with the same condition, on the same unit, bears exploration.

### **Intended Improvement**

#### **Description of Project Goals.**

The purpose of this quality improvement project is to improve the process of assessment and treatment of depression and sleep disturbance in patients admitted to BH with VOC. The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.

#### **Description of Those Involved in the Intervention.**

The project will take place on a medical unit specifically chosen to provide care to patients admitted with VOC. A team of healthcare providers, the Sickle Cell Team, including a hospitalist MD, APRN, RN assistant manager, RN CM and SW, as well as the patient's primary RN, round on the patients each day, Monday through Friday. A pharmacist and chaplain both round weekly with the team. The chaplain also visits with patients individually over the course of the admission. If necessary, a licensed clinical social worker (LCSW) is available through the BH Geriatric and Palliative Care Service to meet with patients over the course of their hospitalization, as well as on an outpatient basis.

All patients with SCD admitted to the designated medicine unit for care by the Sickle Cell Team, will be included in this project. In addition, the APRN will provide pain management to patients with SCD who are admitted to other units when beds are not available on the designated unit or to critical care areas if clinically stable. The full team assumes care once a bed is available or after they are stable enough to transfer to the designated medicine unit.

Participants in the project will complete assessments for depression (*Patient Health Questionnaire* [PHQ-9]), sleep impairment (*The Pittsburgh Sleep Quality Index* [PSQI]), pain (Numerical or Verbal Rating Scale), and QOL (*Quality of Life Scale* [QOL]), administered by the APRN each time they are admitted during the project period. These tools will help to determine existence of and information related to the effects of physical and psychological stress on these patients' pain, QOL, increased incidence of VOC, as well as response to treatment (Anie & Green, 2015; Howard, Thomas & Rawle, 2009; NHLBI, 2014; Nicholson, Caplan, Williams, & Stern, 2009). Patients identified as having depression and/or sleep impairment, will be offered both pharmacological and psychological therapies, and assessed for response to treatment and its impact on pain and QOL.

### **Project Outcome Objectives**

1. One hundred percent of patients with SCD admitted and readmitted during the three-month project period will be assessed for depression, sleep impairment, pain and quality of life.
2. The Sickle Cell Team will develop a treatment algorithm for the management of depression and sleep impairment in all patients admitted to the sickle cell unit during the first month of the project.
3. One hundred percent of patients who have been identified with depression and/or sleep impairment during the three-month project period will have been offered treatment for same based on an algorithm designed by the treatment team during the first month of the project.

4. Patients who have accepted treatment for depression and/or sleep impairment will show a 50% improvement from baseline in their depression and/or sleep impairment, as well as in their pain and QOL by the end of the three-month project period.

### **Theoretical/Conceptual Model Framework**

According to the American Association of Colleges of Nursing (2006) Essential III, doctor of nursing practice (DNP) graduates “engage in advanced nursing practice and provide leadership for evidence-based practice [EBP]” (p. 11). In order to meet these expectations, DNP-graduates must be able to translate research in to practice, evaluate practice, improve the reliability of health care practice and outcomes and participate in collaborative research.

EBP integrates “the best available research evidence with information about patient preferences, clinical skill level and available resources to make decisions about care” (as cited in Schaffer, Sandau & Diedrick, 2012, p. 1198).

### **Model Description**

The Stetler Model is one of several commonly used EBP models for nursing, and will be used to guide implementation of EBP for this quality improvement project. While initially meant to be used as part of individual practitioner practice with an emphasis on the critical thinking process, it can also be used by groups of practitioners to implement formal organizational changes.

### **Conceptual Framework**

The Stetler Model, originally developed by Stetler and Marram (1976) as a prescriptive approach to assist in research utilization, was designed to help nurses to “complete three essential phases of critical-thinking” (p. 559) in relation to research findings. These phases included: validation, comparative evaluation and decision-making. According to Stetler (1994),

it was not based on any specific conceptual framework nor did it have any basis in research, but focused on studies that tested causal hypotheses rather than on a broader range of research. The model was refined in 1994 to include conceptual underpinnings and a set of assumptions.

The refined model (Figure 1), was grounded in a conceptual framework based on research *on the process of research and knowledge*, and explores the application of available knowledge or knowledge utilization (Stetler, 1994). Further refinements were made to the model in 2001, to allow it to fit better into the EBP paradigm, to emphasize evaluation of the evidence and use of research findings, as well as affirm a critical-thinking process core (Schaffer et al., 2012; Stetler, 2001). According to Stetler (2001), the critical-thinking and decision-making steps of the Stetler Model are designed to facilitate the safe and effective use of research findings.

Additional 2001 refinements to the model included differentiating between internal and external evidence that influence the implementation of evidence (Stetler, 2001). Internal factors include the characteristics of individual EBP users and organizational practices and refer to “other sources of credible data” (Stetler, 2001, p. 272), including data from quality improvement processes, operational and evaluation projects. External factors work together with internal factors and include formal research, organizational standards and practices as well as consensus of national experts.

### **Five Phases of Stetler Model**

The Stetler Model assists individual clinician or organization to apply research findings at the individual practice or organizational level (Stetler, 2001). The model has five phases: (I) preparation, (II) validation, (III) comparative evaluation and decision-making, (IV) translation and application, and (V) evaluation. Critical thinking and decision-making are emphasized.

Phase I, the preparation phase, requires the clinician or organization to determine a purpose or problem of significance (or priority), as well as the potential significance and influence of both internal and external factors. During this phase, the clinician searches, sorts and selects sources of research evidence as well as defines the purpose and measurable outcomes of the project. In the preparatory phase, a project team may assemble to participate in each phase of decision-making as well as in dissemination and implementation of the new knowledge into the practice setting.

Phase II, the validation phase, is necessary to assess strengths and weaknesses of the findings of existing research and its focus on utilization, and whether to accept or reject the study in guiding practice. The clinician/team performs utilization-focused critiques and completes a synopsis to determine whether the research evidence applies to the problem identified. It is during this phase that the clinician/team eliminates non-credible sources, but may determine that a methodologically weak study may still provide useful evidence.

Phase III, comparative evaluation and decision-making, includes synthesizing findings and evaluating criteria for fit of setting, feasibility, substantiating evidence and determining how the evidence fits with current practice. Once this is completed, a decision is made: use, do not use or consider to use the findings.

Phase IV, the translation/application phase, is completed by confirming the type, level and method of application, determining how the information will be used in practice, and identifying evidence-based documentation for dissemination. Completing this phase helps to guide the transition of new knowledge into practice, and plans are developed to either informally or formally implement the change from an individual clinician level or at an organizational level.

Phase V, the evaluation phase, involves the evaluation and identification of the goal for use of the information and includes both formative and summative data to assess achievement of the outcome or goal. Once the evaluation phase is complete, a decision is made whether to implement the change formally, informally, individually or institutionally.

As described by Stetler (2001) refinements to the 1994 Stetler Model, included clarifying information and options within the phases to facilitate the use of the model, and apply to both individual and organizational users. Content changes specific to phase IV, provided alternatives applicable to planned organizational use.

**Figure 1. The Stetler Model**

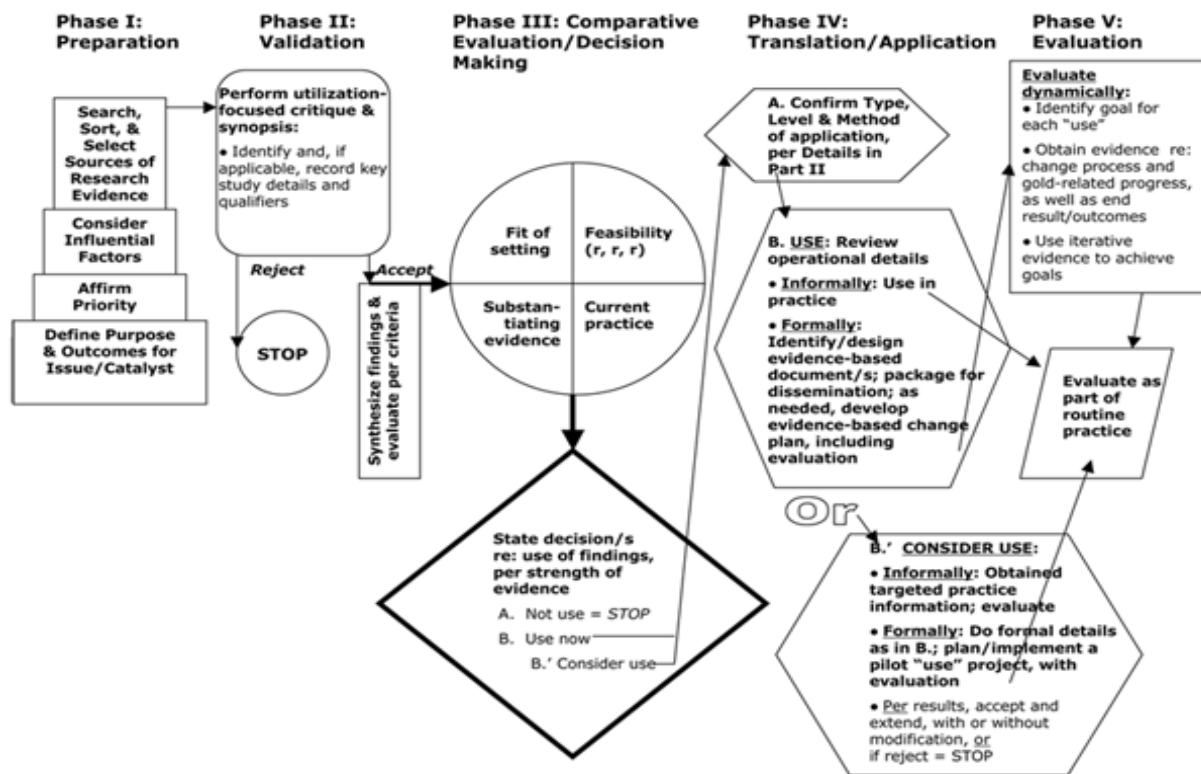


Diagram retrieved from [http://ktdrr.org/ktlibrary/articles\\_pubs/ktmodels/](http://ktdrr.org/ktlibrary/articles_pubs/ktmodels/)

## **Assumptions**

The Stetler Model makes six practitioner-based assumptions. These assumptions include: (1) formal organizations may or may not be involved in the individual's utilization of research; (2) utilization may be instrumental, conceptual and/or symbolic; (3) to facilitate decision-making or problem-solving, other types of evidence and/or non-research-related information are likely to be combined with research findings; (4) an individual or groups' view and use of the evidence can be influenced by internal and external factors; (5) research and evaluation provide probabilistic information, not absolutes; and (6) appropriate and effective use of research utilization and EBP can be impacted by lack of knowledge and skills (Stetler, 2001).

## **Literature to Support Use of the Model**

Cole, Waldrop, D'Auria, and Garner (2006) used the model in their integrative research review. The authors intended to evaluate the current research of school-based interventions that used healthy lifestyle education, dietary habits and/or physical activity using the theoretical underpinning of the Social Cognitive Theory. Using the five phases of the Stetler Model to guide the review, the authors prepared (Phase I) their sampling frame. They included effective school-based interventions studies for children aged four to 14, which manipulated at least one of the variables of lifestyle education, dietary habits and/or physical activity interventions and studies which showed a significant decrease in BMI or weight. Studies were validated (Phase II) based on the above criteria and those that did not meet the criteria were excluded. Comparative evaluation/decision-making (Phase III) was performed of all studies by the use of research synthesis tables. The authors used translation/application (Phase IV), and found that eight of the ten acceptable studies successfully used the theoretical underpinnings of the Social Cognitive Theory. Because the authors did not evaluate (Phase V) the quality of the



studies nor the effectiveness of the interventions, they could not determine an appropriate time-frame to implement the interventions in their own facility. However, they did draw the conclusion that the Social Cognitive Theory should be considered when planning interventions for overweight children.

Bishop (2007) utilized the Stetler Model to critique evidence relating to the development of postpartum depression in previously depressed pregnant women compared to those who were not previously depressed. The author hoped to identify risk factors that would help to guide treatment in this patient population. The author effectively completed Phase I, by formulating the research question, completing the literature search, and appraising the literature. During Phase II, the author critiqued the six articles that pertained to postpartum depression and history of depression as a risk factor. The author further examined the literature in Phase III to determine if a conclusion could be reached concerning the study question. The author was able to determine that previous depression is a strong risk factor for developing postpartum depression. Once the author synthesized the findings, she compared them to current guidelines and found that they did not recommend screening pregnant women for depression during prenatal care. Bishop then determined that there was evidence to support a change in practice. During Phase IV, the author determined that the most appropriate place to implement the change was at the primary care level, with initial screening of patients, flagging of charts of those patients identified as depressed, and following the patients through the pregnancy if they became pregnant. Bishop then evaluated whether the new system was effective in Phase V.

Snyder, Facchiano, and Brewer (2011) utilized the Stetler Model to improve recognition of anxiety in patients with Parkinson's Disease (PD). During Phase I, Snyder et al. utilized the PICOT framework: *population of interest, intervention of interest, comparison of interest, and*

outcome of interest over time to develop the research question, “In patients with PD, what is the most effective tool to screen for anxiety compared to present standard of care (non-assessment) to improve the recognition of anxiety at the time of the office visit?” The authors completed several literature searches related to their research question, utilizing several databases, finally narrowing the results to ten citations for further review. During Phase II, the authors used appraisal rating scales to critique the strength of the evidence. In Phase III, Snyder et al. constructed a comparative table to help determine whether to use the findings in practice. During Phase IV, the process yielded a recommendation that the authors then presented to their group practice. The recommendation was then integrated into practice at the organizational level. During Phase V, the authors evaluated and refined the application of the findings, reviewed and changed policies, developed guidelines and offered educational opportunities.

Velez, Becker, Davidson and Sloand (2014) applied the five phases of the Stetler Model to guide the development of an intervention aimed to improve care provided during an eight-week evidence-based educational intervention on appropriate antibiotic prescribing associated with community acquired methicillin resistant *Staphylococcus aureus* (CA-MRSA) infections. In Phase I, the authors prepared by identifying the problem of increasing CA-MRSA infections and the priority of using education to influence the way prescribers treat CA-MRSA infection. In Phase II, the authors used validation to critique and complete a synopsis of qualitative and quantitative research and clinical guidelines. During Phase III, the authors identified that clinicians’ treatment of CA-MRSA was inconsistent with the guidelines, and so applied Phase IV to determine the steps required to guide project inquiry, operationalize the details to both educate prescribers and measure the influence of the education. During Phase IV, the authors determined that they would proceed with implementation of the project. In Phase V, the authors were able to

measure the outcome of the education with test scores (pre-test versus post-test), complete chart audits to evaluate adherence to the clinical guidelines and report and disseminate the findings.

Bauer (2014) used the Stetler Model, the PICOT format and the Newman Systems Model to determine if a stress relief guided imagery intervention helped to improve nursing students' perceived stress. The Stetler model was used to guide the step-by-step process of the project. During Phase I, Bauer identified the purpose of consulting the evidence, after previously identifying the need to address the problem of stress for nursing students. During Phase II, Bauer validated the sources of information, assessing each source of evidence for credibility, applicability and operational details. During Phase III, the author determined whether it was appropriate to use the evidence and apply it to her project. Phase IV involved addressing and identifying the type of research utilized, by identifying the method and level of use, determining whether translation went beyond actual findings, considering the need for a variation of the information, and finally planning for dissemination and change. During Phase V, Bauer was able to clarify outcomes, differentiate between formal and informal application of the findings into practice, and determined whether it was appropriate to implement the stress intervention.

### **Use of the Theory for Proposed Project**

The Stetler Model works well to guide the process of translating existing research on the effect of depression and sleep impairment on pain and QOL in patients presenting with sickle cell pain crisis, into EBP. In Phase I, the purpose of consulting the evidence was determined. Based on information provided by patients cared for by the Sickle Cell Team, many suffer from a variety of psychosocial stressors, including depression, social isolation, withdrawal, feelings of abandonment, and poor relationships with friends and family members.

In addition, the nurses who provide care for these patients have noted that many of them do not sleep, and in fact have poor sleep hygiene.

During Phase I, the project director (PD) reviewed clinical guidelines specific for SCD, current research related to depression and sleep impairment as they relate to pain and quality of life, and current practice regarding the evaluation and treatment of depression and sleep impairment. The purpose of the project, improving the process of assessment and treatment of depression and sleep disturbance in patients admitted to the sickle cell unit with VOC was determined. The PD confirmed that the most suited project team would consist of existing sickle cell team members.

In Phase II, the PD completed several literature searches using the following search criteria: SCD, chronic pain, depression, sleep impairment, and quality of life. Relevant data which would contribute to the project were accepted while the data that did not apply, were rejected.

During Phase III, relevant research findings from Phase II will be presented by the PD to the sickle cell team. The team will evaluate the findings to determine whether they are feasible for use in the inpatient hospital setting, and whether they could be applied to and make an impact on current practice. If the team determines that the findings are applicable to the inpatient setting and current practice, a decision will be made to use the findings.

Determining how the information will be used in practice will be completed during Phase IV. The PD, working in conjunction with other members of the sickle cell team, will create a guideline and treatment protocol for the evaluation and treatment of depression and sleep impairment in this phase. During this phase, the guideline and treatment protocol will be implemented.

The final evaluation phase, Phase V, will include both a formative and summative evaluation of the data to assess whether the project's desired outcomes have been achieved. It is during this phase that the PD will determine how to use the project outcomes data.

The purpose of this project is to improve the process of assessment and treatment of depression and sleep disturbance in patients hospitalized with sickle cell pain crisis. If the project is successful, the team led by the PD will consider if it is feasible to expand the use of the guideline and treatment protocol to the outpatient setting, for use in the Sickle Cell Medical Home.

### **Strengths and Limitations of the Model**

The Stetler Model provides an easy to follow process based on critical thinking and decision-making to support the transition of research into EBP. By following each phase of the model, a plan can be developed using the most appropriate data, to help implement a project regarding the issue of depression and sleep impairment on pain and QOL in patients with SCD. A benefit of this model is that it can be used from both an individualized and organizational perspective. The model can be used in both inpatient and outpatient settings, and can assist in the transition of care from inpatient to the outpatient setting if successful in the inpatient setting.

No limitations were identified for the use of the model as it applies to this project.

## **Project Design**

### **Setting**

This quality improvement project will be implemented at Bridgeport Hospital (BH), part of the Yale-New Haven Health System (YNHHS), located in Bridgeport CT, the largest city in the state. BH is a private, not-for-profit general medical and surgical teaching hospital, with 385 licensed beds and 42 additional pediatric beds licensed under the Yale-New Haven Children's

Hospital. The YNHHS also includes Yale-New Haven Hospital (YNHH) and Yale-New Haven Hospital St. Raphael Campus, in New Haven; and Greenwich Hospital, in Greenwich.

According to fiscal year (FY) 2014 BH hospital metrics, approximately one in every 1500 patients serviced at BH had SCD, with the incidence of SCD in the US being about one in every 3,300 (Fiumidinisi, email communication May 13, 2015). In FY 2014, BH treated and released 115 patients with SCD in the Emergency Department (ED), and discharged approximately 75 patients, for a total of 719 patient days, and an average LOS of 9.7 days. During FY 2010 to 2014, BH had a total average length of stay (LOS) of 10.3 days, the highest LOS in the state (CHIME Data, October 2014).

Some of the BH Sickle Cell Clinical Redesign Project was based on a similar redesign project conducted at Yale-New Haven Hospital in 2012. According to the YNHHS Finance Officer, staffing for the sickle cell redesign project implemented at YNHH in 2011 required a physician (MD), advanced practice registered nurse (APRN) and SW to provide a focused care team. Funding from that project was supported as more than 75% of the patients' admissions were case-based reimbursed, and a length of stay reduction to 7.5 days covered the cost required (Loftus, YNHH Sickle Cell Business Plan, submitted February 2, 2011). Loftus indicated the same would be true during the planning sessions for the BH redesign project and implied that, "the targeted reduction to a Length of Stay of 7.5, will generate a reduction of \$753k in direct cost, an improvement of \$353 k in contribution margin, and \$1277 k improvement in overall gain/(loss)" (Financial report provided April 21, 2015).

As part of the BH Sickle Cell Clinical Redesign Project, an interdisciplinary group was formed representing BH administration; ED, Medicine, Outpatient and Hospitalist Services; Nursing; Admissions/Bed Control; Finance; Case Management; Social Work; Psychiatry;

Spiritual Care; Education; community representation from the SCDA, Southern CT; and the Palliative and Pain Service APRN (Clinical Lead/PD). The group met and began to develop a business plan and project charter that outlined the steps to be taken to improve the clinical care for adults with SCD. This plan relied on (1) the creation of individualized pain treatment plans created by the Clinical Lead imbedded into patients' EMRs; (2) updating the ED tracking board for rapid identification of sickle cell patients; (3) designation of a single nursing unit for patient admission; (4) "blocking off" two beds for sickle cell crisis admissions; (5) adjusting nurse/patient ratios from the current one to seven, down to one to four to enable more focused care of these patients during hospitalization; and (6) providing education to ED physicians and staff, the hospitalist service and nurses on the designated unit as well as agency and float nurses assigned to the targeted unit regarding the disease process, management and treatment of SCD and VOC.

An interdisciplinary "Sickle Cell Team" was created consisting of MDs from the hospitalist service, the Palliative and Pain Service APRN, RN assistant nurse manager of target unit, RN CM, SW, and Chaplain. Pharmacy participates weekly, and an LCSW through the BH Geriatric and Palliative Care Service and/or Psychiatry is available when needed. The core team rounds on the patients daily, Monday through Friday, and the larger interdisciplinary team meets monthly to address issues and opportunities to improve care delivery. The BH joint data and analytics team (JDAT) has been charged with collecting weekly, monthly and quarterly data regarding ED visits including "Door to Doc" and "Time to Med", admissions and LOS, as compared to the FY 2014 data. Since the initial project pilot (June 22, 2015) and subsequent transition to an ongoing program (October 20, 2015) the average LOS has dropped to 5.53 and the Sickle Cell Clinical Design Project has been deemed a success by administration.

BH Hospital administration continues to support the work being done by the team, and the project has expanded to the BH outpatient primary care setting to provide hours dedicated each week to the “Sickle Cell Medical Home”. Staffed by two Hospitalists and primary care Residents, the establishment of the Sickle Cell Medical Home is a way to provide comprehensive medical care and pain management to those patients who do not have access to these services. As of this writing, a grant through the BH Foundation has been approved to fund the hire of an APRN to see and manage the Sickle Cell Medical Home patients as outpatients, though the interview process has not started.

### **Population**

Participants of the project team include the sickle cell team members (PD, MDs, the RN assistant nurse manager, and Chaplain) as well as the LCSW and representatives from Pharmacy, and Psychiatry. The project team will be responsible for creating, implementing and evaluating the guideline and treatment protocol.

All patients with SCD who are admitted to the designated medicine unit for care by the sickle cell team, or seen by the PD (or one of her Palliative and Pain Service colleagues) for pain management on other units when beds are not available on the designated unit, or in critical care areas if clinically stable, will be included in the project.

The patient population for this project will be comprised of those patients ages 18 and above, admitted to the hospital with SCD as the principle or secondary diagnosis (ICD-10: D571, D5700, D5720, D57219, D5780, D57819, D5740, D57419). Patients will be excluded from the project if they are diagnosed with Sickle Cell Trait, (ICD-10: D573), if they are admitted to the Pediatric unit even though they are 18-years or older. Only patients who have proficiency in the



English language will be included. The pain consult, ordered by the MD, will provide the access to the patient for the purpose of the project.

Per the guideline and treatment protocol developed by the project team, patients will be assessed during the course of the pain consult for depression, sleep impairment, pain and quality of life, on each admission during the project period. Also, per the guideline and treatment protocol all patients who were previously admitted for VOC will have the same assessments repeated at follow-up visits or hospital admission.

At follow-up visits or re-admissions during the study period, the PD will inform the patient about the study outcomes aspect of the project. Upon informed consent, the patient will be considered a participant in the study of outcomes of the project. This participation will be limited to providing permission for the PD to collect data through review of the patient's health record regarding the assessments conducted while in the hospital and the current visit, results of the assessments, and treatments offered and provided. No identifying data will be recorded so confidentiality will be maintained and data will only be reported in aggregate form.

## **Intervention Plan**

### **Description of Project Goals.**

The USDHHS (2014) acknowledges that psychosocial factors such as depression, insomnia, anxiety, feelings of despair, loneliness, helplessness, post-traumatic stress disorder and dependence on pain medications are often associated with and can worsen chronic pain associated with SCD (p. 56). The USDHHS makes a strong recommendation with high-level evidence from the U.S. Preventive Services Task Force for depression screening for adolescents and adults when systems for diagnosis, treatment and follow-up are in place (2014, p. 27 & 28).

The purpose of this quality improvement project is to improve the process of assessment and treatment of depression and sleep disturbance in patients admitted to BH with VOC. The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.

Project outcome objectives include:

1. The sickle cell team will develop an interprofessional, evidence-based guideline during the first month of the project, to use to evaluate the existence of depression and sleep disturbance in all patients admitted for VOC.
2. The sickle cell team will develop a treatment protocol/algorithm during the first month of the project, for the management of depression and sleep impairment in all patients admitted for VOC.
3. One hundred percent of patients with SCD admitted and readmitted during the three-month project period will be assessed for depression, sleep impairment, pain and quality of life.
4. One hundred percent of patients who have been identified with depression and/or sleep impairment during the three-month project period will have been offered treatment for same based on an algorithm designed by the treatment team during the first month of the project.
5. Patients who have accepted treatment for depression and/or sleep impairment will show a 50% improvement from baseline in their depression and/or sleep impairment, as well as in their pain and QOL by the end of the three-month project period.

**Components of the Intervention.**

Based on the sickle cell guideline created by the sickle cell team, each patient admitted to BH for VOC will be assessed for depression, sleep impairment, pain and QOL during the initial pain consult. The PD or the Palliative and Pain Service clinician will conduct the evaluation using tools identified in the guideline. If depression and sleep impairment are identified, treatment options will be offered based on a treatment protocol designed by the sickle cell team. Pain will be reassessed, at each follow-up visit during hospitalization. Each patient will be reevaluated for depression, sleep impairment, pain and QOL on each readmission during the project period.

### **Contribution of Conceptual Model Toward Planning Intervention Strategies.**

The Stetler Model (described fully in the previous section) will be used to guide implementation of evidence-based practice (EBP) for this quality improvement project. The five phases: (I) preparation, (II) validation, (III) comparative evaluation and decision-making, (IV) translation and application, and (V) evaluation, will be used to guide the process of translating existing research, on the effect of depression and sleep impairment on pain and QOL in patients presenting with VOC, into EBP.

Once Phases I through III are completed and a decision is made that the findings are applicable to the inpatient setting and current practice, the team will use the findings for this project. During Phase IV, the PD, working in conjunction with the sickle cell team, Psychiatry, Pharmacy and the LCSW will develop a guideline and treatment protocol. The guideline will outline tools used for the assessment of all SC patients with VOC in regard to depression, sleep impairment, pain and quality of life. The treatment protocol will guide depression and sleep impairment treatment decisions.

During the project period, the PD will use the designated tools during the initial pain consult to determine the existence of depression and sleep impairment and their impact on pain and quality of life. These tools include the Patient Health Questionnaire (depression), the Pittsburgh Sleep Quality Index (sleep impairment), the Numerical or Verbal Rating Scale (pain) and Quality of Life Scale (QOL). Patients identified as having depression and/or sleep impairment, will be offered both pharmacological and psychological therapies based on the treatment protocol. The patients will then be assessed for response to treatment and its impact on pain and QOL by the PD during follow-up visits and subsequent admissions.

Phase V will include both a formative and summative evaluation of the process and the data to assess whether the project's desired outcomes have been achieved. During this phase, the PD will determine how to use the project outcomes data. The data will be reviewed with the sickle cell team to determine if the guideline and treatment protocol need any changes. If the project is successful at improving the assessment and treatment of depression and sleep disturbance in patients who are hospitalized with VOC, the PD and sickle cell team will determine if it is feasible to expand the use of the guideline and treatment protocol to the outpatient setting, for use in the Sickle Cell Medical Home.

**Project Timeline.**

- Spring 2016 – PD will obtain a letter of support from BH administration for inclusion with the IRB application (this will likely be Dr. Ryan O'Connell, Vice President of Performance and Risk Management and sponsor of the Sickle Cell Redesign Project).
- Summer 2016 – PD will clarify with her direct supervisor how clinical hours will be integrated into work hours.

- Summer 2016– PD will lead the sickle cell team, Psychiatry, Pharmacy and the LCSW in development of a guideline and treatment protocol to use to evaluate the existence of and define treatment options for depression, sleep impairment and the impact on pain and quality of life.
- Summer 2016 – PD will develop an evaluation tool to be used during chart reviews.
- Summer 2016 – PD will develop informed consent for patient participation.
- Summer 2016 – PD will consult with the BH HIPAA compliance officer to determine any additional requirements.
- Summer 2016 – PD will submit the IRB approval application to Ball State University IRB
- Summer 2016 – PD will submit IRB approval application to BH
- Fall 2016 – PD, along with the treatment team, will begin assessing patients for depression, sleep impairment, pain and QOL using the evaluation tools designated on the guideline.
- Fall 2016 – PD and sickle cell team will offer treatments based on the treatment protocol to those patients who have been determined to have depression and sleep impairment.
- Fall 2016 through Spring 2017 – PD will meet with sickle cell team monthly to discuss any concerns with implementation of the guideline and treatment protocol.
- Fall 2016 through Spring 2017 – PD will collect data regarding assessment, incidence of depression and sleep impairment, response to treatment and impact on pain and quality of life.
- Spring 2017 – PD will present data to sickle cell team and review guideline and treatment protocol for any needed revisions.

- Spring 2017 – PD will complete the process to implement the Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol as standard of care at BH.
- Spring 2017 – if project is successful, PD will approach the Sickle Cell Medical Home with the results of the project, and make the Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol available for use in the outpatient setting.

### **Ethical Issues**

The purpose of this quality improvement project is to improve the process of assessment and treatment of depression and sleep disturbance in patients admitted to BH with VOC. The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.

Outcome evaluations will assess the use of the guideline and established assessment tools, treatments offered using treatment protocol, and improvement from baseline in depression and/or sleep impairment, as well as pain and QOL after treatment is initiated.

Completion of the assessments and initiation of treatment using the established guideline and treatment protocol will be considered part of the routine pain consult on admission, and will be standard of care for all patients admitted with VOC. As such, patients are not considered participants in a study in regard to implementation of the guideline and treatment protocol. The guideline will establish that any patient may accept or refuse to participate in the assessment as well as accept or refuse any treatments offered as a result of the assessments. No experimental treatments or interventions will be used in the course of the project. Patients will be notified that a decision to participate or not in the assessments, will not affect their ability to receive care.

Results of the assessments will be included in the documentation of the pain management consult completed on admission and entered into each patient's electronic medical record. Any treatment options offered and either accepted or refused, will also be entered into the patient's consult or follow-up notes, just as results of current evaluations and treatments for other conditions are.

Completion of the assessments again at follow-up visits after hospital discharge or any re-admissions using the established guideline and treatment protocol will be considered part of the routine care for patients after an admission for VOC, and will be standard of care. The PD will inform patients who are reassessed that as part of her DNP student project as well as to improve care for all patients admitted to BH with VOC she would like to be able to collect data through review of the patient's health record regarding the assessments conducted while in the hospital, including the current and subsequent hospitalizations during the project period, results of the assessments, and treatments offered and provided. Patients will be informed that no identifying data will be recorded so confidentiality will be maintained and data will only be reported in aggregate form. Written informed consent will be obtained. All data collection will be in accordance with HIPAA regulations.

Any raw data will be stored either in a locked file in the PD's workplace office or in a password protected personal network drive on the hospital computer system, with access only available to the PD. Should paper data need to be transported, it will either be carried in a locked briefcase, or scanned to a secured email, saved on the password protected network drive and accessed from the PD's home through password secured access to the network drive. All data will be destroyed within three years of the conclusion of the project by shredding all paper forms and wiping the electronic data clean.

A potential conflict of interest exists because the project will take place at the PD's employment site. The PD is a salaried employee, and functions as a clinical consultant for both the palliative care and pain management service. The project will require the PD to access patients with whom the PD currently consults on and follows for pain management, but work on this project will not be allowed to impact the daily expected relative value units (RVUs) of seven to nine patients the PD is expected to see during the course of this project.

Because the intent of the project is to expand the current level of evaluation and intervention in other aspects of pain associated with SCD, and patients currently being admitted to BH will benefit from the process, the conflict should be minimal. Any time spent in data collection will not be paid. Details of how to differentiate time spent on the project during hours of employment will be clarified with the PD's direct supervisor and hospital administration.

A letter of administrative support will be obtained from Dr. Ryan O'Connell, Vice President of Performance and Risk Management and sponsor of the Sickle Cell Redesign Project at BH. IRB approval will be obtained through Ball State University and BH before starting any aspect of the intervention.

### **Study of the Intervention**

The intended purpose of this quality improvement project is to improve the process of assessment and treatment of depression and sleep disturbance in patients admitted to BH with VOC. The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.

### **Project Questions**



1. Is the use of the Stetler Model for implementation of an evidence-based guideline and treatment protocol effective in implementing the proposed quality improvement project in this clinical setting?
2. Does implementation of an evidence-based guideline facilitate the assessment of depression and sleep disturbance on every patient admitted for VOC?
3. Does implementation of an evidence-based treatment protocol facilitate the treatment of depression and sleep impairment for all patients admitted for VOC?
4. Does identification and treatment of depression and sleep impairment result in a 50% improvement from baseline in depression, sleep impairment, pain and quality of life?

### **Project Outcome Objectives**

1. The sickle cell team will develop an interprofessional, evidence-based guideline during the first month of the project, to use to evaluate the existence of depression and sleep disturbance in all patients admitted for VOC.
2. The sickle cell team will develop a treatment protocol/algorithm during the first month of the project, for the management of depression and sleep impairment in all patients admitted for VOC.
3. One hundred percent of patients with SCD admitted and readmitted during the three-month project period will be assessed for depression, sleep impairment, pain and quality of life.
4. One hundred percent of patients who have been identified with depression and/or sleep impairment during the three-month project period will have been offered treatment for same based on an algorithm designed by the treatment team during the first month of the project.

5. Patients who have accepted treatment for depression and/or sleep impairment will show a 50% improvement from baseline in their depression and/or sleep impairment, as well as in their pain and QOL by the end of the three-month project period.

### **Study Design**

The study design for this quality improvement project will have descriptive and quasi-experimental components. The PD will examine data from a retrospective audit review to determine (1) the existence of depression and sleep disturbance in patients admitted with VOC, (2) patient perceived level of pain and QOL at the time of the assessment for depression and sleep disturbance, and (3) changes in patient perceived levels of pain and QOL after beginning treatment for diagnosis of depression and/or sleep disturbance. In this outcomes study, sampling will be both non-random (only those patients with the sickle cell diagnosis ICD-10 codes described above) and convenience (each patient admitted to BH for VOC during the study period).

A descriptive study design is appropriate in this project to evaluate the desired outcomes and effectiveness of the Stetler Model for use in the design and implementation of the guideline and treatment protocol for this project intervention. The descriptive study design is not intended to describe causal relationships, nor will this project be measuring causal relationships.

A quasi-experimental study design is appropriate for this project as it is used to identify causal relationships between depression, sleep impairment, pain and QOL, and provide a means to test the effectiveness of an intervention to improve patient outcomes (Grove, Burns, and Gray, 2013).

Based on the guideline and treatment protocol developed by the multidisciplinary team, each time a patient with SCD is admitted to the hospital, they will be asked to complete

assessments using the Pittsburgh Sleep Quality Index (PSQI), the Patient Health Questionnaire (PHQ-9) and the Quality of Life Scale (QOLS) as part of their pain consult (Smyth, 2012; Pfizer, 1999; Maurer, 2012). If it is determined that either depression or sleep disturbance exists, appropriate pharmacological treatment will be provided, either by the APRN or MD, as well as referral to appropriate specialists if needed per guideline and treatment protocol recommendations. The same assessments will occur at subsequent admissions, during the initial pain consult to evaluate improvement.

Pain level, as well as acceptable level of pain will be assessed on admission, using the Numerical Rating Scale (rated on a scale from 0 to 10, with 0 being no pain and 10 being the worst pain) and during hospitalization using a subjective pain rating (“better”, “same” or “worse”). Results of pain evaluations will be included in the APRN’s consult and follow-up notes. Demographic data will be retrieved from the patient’s electronic medical record (EMR).

#### **Threats to internal and external validity.**

Internal validity determines whether the effects detected in the study are a reflection of reality rather than the impact of extraneous variables (Grove et al., 2013). One threat to internal validity for this project could be a testing effect related to the number of times a subject is assessed with the assessment tools if hospitalized frequently. Familiarization with the questions may influence the responses on subsequent assessments. The selection process may also affect internal validity, as only those patients with VOC are included (non-randomized, convenience sample). Subject attrition could also impact internal validity. Since patients may or may not be readmitted during the project timeframe, and are not currently seen as outpatients, it may not be possible to assess the effects of treatment recommended by the protocol.

External validity is the extent that the project findings can be generalized beyond the hospital sample to the outpatient setting (Grove et al., 2013). Selection and treatment interaction may be impacted if patients decline to participate in the assessments and/or accept treatment if depression or sleep impairment are identified. Patients may decline to participate in the assessments and reassessments if the assessment questionnaires are too burdensome.

### **Strengths and weaknesses of the project design.**

A controlled environment is a strength of this project, as only hospitalized patients will be assessed. Extraneous variables will be controlled for in that the population is a homogenous sample of patients with VOC. The project does not include an experimental treatment since the assessments for and treatment of depression, sleep impairment, pain and QOL use the guideline and treatment protocol established by the interdisciplinary team. Assessments will be considered part of the routine pain consult on admission, and will be standard of care for all patients admitted with VOC. Patients are not considered participants in the project with regard to implementation of the guideline and treatment protocol. The guideline and treatment protocol developed by the multidisciplinary team will help ensure standardization of both assessment and treatment.

Extraneous variables can have a negative impact on the project. One possible weakness of the project design includes the phenomenon of a carryover effect. As a variety of treatments and dosages may be offered in the protocol, one treatment may influence the response to later treatments. Grove, Burns and Gray (2013) recommend a precautionary counterbalancing, in which treatments are randomized rather than being provided in the same sequence. Blocking is another means of controlling extraneous variables. Patients will be blocked from the study if they are younger than 18 years of age, or if between the ages of 18 and 21 and are admitted to the

Pediatric unit. Ethnicity would not be an extraneous factor because all patients with VOC crisis will be assessed, no matter the ethnicity.

### **Methods of Evaluation – Outcome Objectives**

The Stetler Model will guide the process in determining the appropriateness of each of the assessment tools for the project during Phases I through III. Phase IV will bring together the interdisciplinary members of the sickle cell team, psychiatry, LCSW and pharmacy in the creation of the guideline and treatment protocol. The assessment tools intended to be included in the guideline and treatment protocol include The Pittsburgh Sleep Quality Index, the Patient Health Questionnaire, the Quality of Life Scale, a verbal Numerical Rating Pain Scale, and Subjective Pain Scale.

*The Pittsburgh Sleep Quality Index (PSQI) – Appendix A.* The PSQI is a 19-question self-report tool, developed by researchers in Pittsburgh in 1988, used to measure the quality and patterns of sleep in the adult. The tool measures seven domains, including, “subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction” over the previous month (Smyth, 2012, para. 2). It has both an internal consistency and reliability coefficient (Cronbach’s alpha) of 0.83 for the seven components of the tool. The tool has been used previously in studies of chronic pain, including sickle cell pain, and has been shown to have good validity and test-retest reliability (Naughton, Ashworth, and Skevington, 2007). According to Wallen et al. (2014), “a global PSQI score >5 had a sensitivity of 89.6% and specificity of 86.5% (kappa=0.75, p<.001) in distinguishing subjects with good sleep quality from those with poor sleep” (p. 3).

*The Patient Health Questionnaire (PHQ-9) – Appendix B.* Created by researchers at Columbia University in the 1990s, the PHQ-9 is one of the most common instruments used by

primary care clinicians to screen for depression in adults and adolescents. The PHQ-9 is a nine-question self-assessment tool that can be used to both screen for and monitor treatment for depression (Maurer, 2012). In addition, the tool assesses symptoms of sleep disturbance and difficulty concentrating. Scores range from “0” (not at all) to “3” (nearly every day). Scores <10 reflect no symptoms of depression; 10-14, indicate mild depression; 15-19, moderate depression; and  $\geq 20$ , severe depression. A final question (#10) asks how difficult their symptoms make it for them to engage in daily activities. According to Maurer (2012), the tool has demonstrated sensitivity of 61% and specificity of 94% for mood disorders in adults, and has been used successfully in assessing depression in patients with SCD (Treadwell, Barreda, Kaur, & Gildengorin, 2015).

***The Quality of Life Scale (QOLS) – Appendix C.*** The QOLS was originally created in the 1970s by John Flanagan, an American psychologist. A 16-item self-assessment tool, it has been adapted for use in patients with chronic illnesses, to include a question regarding independence and ability to care for oneself (Burckhardt, 2003; Burckhardt & Anderson, 2003). The tool has been evaluated for reliability, content and construct validity, showing low to moderate correlations with physical health status and disease measures, yet yielding valid measurements for domains related to QOL in diverse patient groups with chronic illness. According to Burckhardt and Anderson (2003), there was an internal consistency ( $\alpha = .82$  to  $.92$ ) with a high test-test reliability in stable chronic illness groups over a three-week period ( $r = 0.78$  to  $0.84$ ), similar to reliability estimates for other researchers.

***Numerical Rating Pain Scale (NRS) and Subjective Pain Scale (SPS).*** Pain level will be assessed during the initial pain consult using a verbal 0-10 NRS, with “0” being no pain, and “10” being worst possible pain. During the course of the admission and prior to discharge,

patients will be asked to describe whether their pain is “better”, the “same” or “worse” as the previous evaluation using the SPS. Obtaining a numerical pain level on admission, provides a basis from which to gauge whether treatment has been successful or not and the subjective scale allows patients to verbalize whether pain is better, the same or worse than the initial pain level without having to “come up with a number” (personal conversation).

Bijur, Latimer, and Gallagher (2003) tested the validity of the verbally administered NRS compared to the visual analog scale on acute pain patients in the ED, and found the NRS can be substituted for the VAS for acute pain management ( $r = 0.94$ , 95% CI = 0.93 to 0.95). Validity and reliability for the 0-10 NRS has been well established and the tool has been promoted for many years (Pasero & McCaffery, 2011).

**Methods to assure data quality and adequacy.** According to Grove et al. (2013), higher quality and richness of data can help to limit the number of participants needed to saturate data in the project. During Phases I through III of the Stetler Model, evidence-based assessment tools will be chosen based on feasibility for use in the hospital setting, and whether they can be applied to and make an impact on current practice. Patients who are assessed will be encouraged to answer each question of the assessment tools.

**Description of plan for data collection.** Once the guideline and treatment protocol have been developed by the interdisciplinary team, initial assessments will begin on each patient hospitalized with VOC during the study period. During Phase V of the Stetler Model, the team will perform both formative and summative evaluations of the data to assess whether the project’s desired outcomes are being achieved. It is during this phase that the PD will determine how to use the project outcomes data.

On the second assessment for each patient, the PD will inform patients that as part of her DNP student project, as well as to improve care for all patients admitted to BH with VOC, she would like to be able to collect data through review of the patient's health record regarding the assessments conducted while in the hospital, including the current and subsequent hospitalizations during the project period, the results of the assessments as well as treatments offered and provided. Patients will be informed that no identifying data will be recorded so confidentiality will be maintained and data will only be reported in aggregate form. Written informed consent will be obtained at that time. Rates for refusal to participate, sample size, and attrition rates will be documented upon completion of the project in order to assure data quality and adequacy.

All data collection will be in accordance with HIPAA regulations. Any raw data will be stored either in a locked file in the PD's workplace office or in a password protected personal network drive on the hospital computer system, with access only available to the PD. Should paper data need to be transported, it will either be carried in a locked briefcase, or scanned to a secured email, saved on the password protected network drive and accessed from the PD's home through password secured access to the network drive. All data will be destroyed within three years of the conclusion of the project by shredding all paper forms and wiping the electronic data clean.

### **Methods of Data Analysis**

All of the assessment tools use scaled responses to determine the results. The PSQI, PHQ-9, QOLS and SPS use a Likert Scale, while the NRS uses a rating scale. Results of testing throughout the project period (patient readmission assessments) will be compared to initial testing at the start of the project to determine improvement in overall responses due to treatment.



Demographic data will include age, gender, ethnicity and race. Age will be rank ordered in the following categories for years, and measured at the ordinal level: (a) 18 – 20, (b) 21 – 30, (c) 31 – 40, (d) 41 – 50, (e) 51 – 60, and (f) 61+. Both gender and ethnicity will be measured at the nominal level of measurement. Gender will be classified as (1) female, (2) male, or (3) other. Ethnicity and Race will be classified as (1) Black or African American – Non-Hispanic, (2) Black or African American – Hispanic, (3) Hispanic or Latino, (4) White – Non-Hispanic, (5) White – Hispanic, or (6) Asian or Indian. Other nominal level demographic data may include sickle cell genotypes: (a) homozygous hemoglobin SS (HbSS), (b) hemoglobin S $\beta^0$ -thalassemia (Hb S $\beta^0$ -thalassemia), (c) hemoglobin S $\beta^+$ -thalassemia (Hb S $\beta^+$ -thalassemia), (d) hemoglobin SC disease (HbSC), as these genotypes are associated with the most severe clinical manifestations of VOC (U.S. Department of Health and Human Services, 2014), or (e) other.

The PD will work with the Ball State University (BSU) statistician for data analysis and interpretation. Data will be analyzed with the Statistical Package for Social Sciences (SPSS).

Descriptive statistics will be computed to include mean, standard deviation and frequency of depression, sleep impairment, pain and QOL. Pearson correlations and *t*-tests will be used to examine the linear relationships between pain, depression, sleep and QOL scores. A random-effects time series regression model using a numbered patient identifier as a panel variable will be used to account for within-person correlation. A *p* value of less than 0.05 will be considered statistically significant.

A limitation of this quality improvement project is the small convenience sample, with only those patients who are hospitalized being assessed. The small sample size impacts the ability to generalize the results, however the results may provide sufficient information to

determine if it is feasible to expand the use of the guideline and treatment protocol to the outpatient setting for use in the Sickle Cell Medical Home.

### Methods of Evaluation – Process Objectives

The timeline for completing the process objectives is shown below in Table 1. The PD will maintain a log detailing the process and progress, dates applicable and time spent on the process, revisions necessary during the process, and participants involved over the course of the project. Any changes to the project plans will be determined during the monthly meetings with the Sickle Cell Team to discuss concerns with implementation and continued use of the guideline and treatment protocol.

<b>Major Process Objectives</b>	<b>Responsible Party</b>	<b>Process Participants</b>	<b>Expected Completion</b>
1. Development of Guideline & Treatment Protocol for evaluation and treatment of depression and sleep impairment and the impact on pain and quality of life	Project Director	<ul style="list-style-type: none"> <li>• Sickle Cell Team Members (MD, PD, RN Assistant Manager)</li> <li>• LCSW and/or Psychiatry</li> <li>• Pharmacy</li> <li>• Chaplain</li> </ul>	End of Summer Semester 2016
2. Development of an evaluation tool to be used during chart reviews	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Ball State University Statistician</li> </ul>	End of Summer Semester 2016
3. Development of an informed consent	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Project Advisor – Deb Siela</li> <li>• Course Instructor – Beth Kelsey</li> </ul>	End of Summer Semester 2016
4. Ball State University IRB application submission	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Project Advisor</li> </ul>	End of Summer Semester 2016
5. Bridgeport Hospital IRB application submission	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> </ul>	End of Summer Semester 2016
6. Assessment of patients for depression, sleep impairment, pain and quality of life using	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Palliative &amp; Pain associates</li> </ul>	Mid-Spring Semester 2017

designated tools from guideline			
7. Treatment offered for depression and sleep impairment per protocol	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Palliative &amp; Pain associates</li> <li>• MD</li> </ul>	Mid-Spring Semester 2017
8. Monthly meeting to discuss concerns with implementation and continued use of the guideline and treatment protocol	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Sickle Cell Team</li> </ul>	Mid-Spring Semester 2017
9. Data collection regarding assessment, incidence of depression and sleep impairment, response to treatment and impact on pain and quality of life	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> </ul>	Mid-Spring Semester 2017
10. Completion of process to implement guideline and treatment protocol as standard of care at Bridgeport Hospital	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Bridgeport Hospital Policy and Procedures Committee</li> <li>• Yale-New Haven Health Services Policy and Procedures Committee</li> </ul>	Mid-Spring Semester 2017
11. Proposal to Sickle Cell Medical Home to adopt the guideline and treatment protocol for use in the outpatient setting	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Sickle Cell Medical Home attending physicians</li> </ul>	Mid-Spring Semester 2017
12. Completion of DNP Project paper	Project Director	<ul style="list-style-type: none"> <li>• Project Director</li> <li>• Project Advisor</li> </ul>	End of Spring Semester 2017

## References

- American Association of Colleges of Nursing. (2006). The essentials of doctoral education for advanced nursing practice. Retrieved from <http://www.aacn.nche.edu/publications/position/DNPpositionstatement.pdf>
- Anie, K. A. (2005). Psychological complications in sickle cell disease. *British Journal of Haematology*, *129*, 723-729. doi:10.1111/j.1365-2141.2005.05500.x
- Anie, K. A., & Green, J. (2015). Psychological therapies for sickle cell disease and pain (Review). *The Cochrane Library*, *5*, 1-33. Retrieved from <http://www.thecochranelibrary.com/>
- Anie, K. A., Grocott, H., White, L., Dzingina, M., Rogers, G., & Cho, G. (2012). Patient self-assessment of hospital pain, mood and health-related quality of life in adults with sickle cell disease. *British Medical Journal Open*, *2*, 1-6. doi:10.1136/bmjopen-2012-001274
- Asnani, M. R., Fraser, R., Lewis, N. A., & Reid, M. E. (2010). Depression and loneliness in Jamaicans with sickle cell disease. *BioMed Central Psychiatry*, *10*(40), 1-7.
- Ballas, S. (2011). Update on pain management in sickle cell disease. *Hemoglobin*, *35*(5-6), 520-529.
- Ballas, S. K., Kesen, M. R., Goldberg, M. F., Luty, G. A., Dampier, C., Osunkwo, I., Wang, W. C., . . . Malik, P. (2012). Beyond the definitions of the phenotypic complications of sickle cell disease: An update on management. *The Scientific World Journal*, *2012*(949535), 1-55. doi: 10.1100/2012/949535.
- Bauer, J. S. (2014). The use of stress reduction techniques in nursing education. Retrieved from [www.scholar.valp.edu/cgi/viewcontent.cgi?article=1053&context=ebpr](http://www.scholar.valp.edu/cgi/viewcontent.cgi?article=1053&context=ebpr)

- Bijur, P. E., Latimer, C. T., & Gallagher, E. J. (2003). Validation of a verbally administered numerical rating scale of acute pain for use in the emergency department. *Academy of Emergency Medicine, 10*(4), 390-392.
- Bishop, K. K. (2007). Utilization of the Stetler model: Evaluating the scientific evidence on screening for postpartum depression risk factors in a primary care setting. *Kentucky Nurse, 55*(1), 7.
- Burckhardt, C. S. (2003). Instructions for scoring the quality of life scale. Retrieved from <http://www.tellusnaturals.com/documentos/qol.pdf>
- Burckhardt, C. S., & Anderson, K. L. (2003). The quality of life scale (QOLS): Reliability, validity, and utilization. *Health and Quality of Life Outcomes, 1*(60), 1-7.
- Connecticut Hospital Association. (2015) ChimeData. Retrieved from <http://www.chime.org/member-services/data-services/chimedata/>
- Cole, K., Waldrop, J., D'Auria, J., & Garner, H. (2006). An integrative research review: Effective school-based childhood overweight interventions. *Journal for Specialists in Pediatric Nursing, 11*(3), 166-177.
- Comley, A. L., & DeMeyer, E. (2001). Assessing patient satisfaction with pain management through a continuous quality improvement effort. *Journal of Pain and Symptom Management, 21*(1), 27-40.
- Edwards, C. L., Scales, M. T., Loughlin, C., Bennett, G. G., Harris-Peterson, S., De Castro, L. M., . . . Killough, A. (2005). A brief review of the pathophysiology, associated pain, and psychosocial issues in sickle cell disease. *International Journal of Behavioral Medicine, 12*(3), 171-179.

- Emery, P., Wilson, K. G., & Kowal, J. (2014). Major depressive disorder and sleep disturbance in patients with chronic pain. *Pain Research and Management, 19*(1), 35-41.
- Gerrits, M. M., Van Oppen, P., Leone, S. S., Van Marwijk, H. W., Van der Horst, H. E., Penninx, B. W. (2014). Pain, not chronic disease, is associated with the recurrence of depressive and anxiety disorders. *BMC Psychiatry, 14*(187), 1-9.
- Goral, A., Lipsitz, J. D., & Gross, R. (2010). The relationship of chronic pain with and without comorbid psychiatric disorder to sleep disturbance and health care utilization: Results from the Israel National Health Survey. *Journal of Psychosomatic Research, 69*, 449-457.
- Grant, M. M., Gil, K. M., Floyd, M. Y., & Abrams, M. (2000). Depression and functioning in relation to health care use in sickle cell disease. *Annals of Behavioral Medicine, 22*(2), 149-157.
- Graves, J. K., & Jacob, E. (2014). Pain, coping and sleep in children and adolescents with sickle cell disease. *Journal of Child and Adolescent Psychiatric Nursing, 27*, 109-120.
- Grove, S., Burns, N., & Gray, J. (2013). *The practice of nursing research: Appraisal, synthesis, and generation of evidence*. St. Louis, MO: Elsevier Sanders.
- Hasan, S. P., Hashmi, S., Alhassen, M., Lawson, W. & Castro, O. (2003). Depression in sickle cell disease. *Journal of the American Medical Association, 95*(7), 533-537.
- Howard, J., Thomas, V. J., & Rawle, H. M. (2009). Pain management and quality of life in sickle cell disease. *Expert Reviews Pharmacoeconomics Outcomes Research., 9*(4), 347-352.
- Levenson, J. L., McClish, D. K., Dahman, B. A., Bovbjerg, V. E., de A. Citero, V., Penberthy, L. T., . . . Smith, W. R. (2008). Depression and anxiety in adults with sickle cell disease:

- The PiSCES project. *Psychosomatic Medicine*, 70, 192-196. doi:  
10.1097/PSY.0b013e31815ff5c5
- Mann-Jiles, V., & Morris, D. L. (2009). Quality of life in adult patients with sickle cell disease. *Journal of the American Association of Nurse Practitioners*, 21(6), 340-349.  
doi:1111/j.1745-7599.2009.00416.x
- Mann-Jiles, V., Thompson, K., & Lester, J. (2015). Sleep impairment and insomnia in sickle cell disease: A retrospective chart review of clinical and psychological indicators. *Journal of the American Association of Nurse Practitioners*, 27(8), 441-449.
- McClish, D. K., Penberthy, L. T., Bovbjerg, V. E., Roberts, J. D., Aisiku, I. P., Levenson, J. L., . . . Smith, W. R. (2005). Health related quality of life in sickle cell patients: The PiSCES project. *Health and Quality of Life Outcomes*, 3(50), 1-7. doi:10.1186/477-7525-3-50
- Maurer, D. M. (2012). Screening for depression. *American Family Physician*, 85(2), 139-144.  
Retrieved from <http://www.aafp.org/afp/2012/0115/p139.html>
- Naughton, F., Ashworth, P. & Skevington, S. M. (2007). Does sleep quality predict pain-related disability in chronic pain patients? The mediating roles of depression and pain severity. *Pain*, 127, 243-252.
- Nicholson, S. E., Caplan, J. P., Williams, D. E., & Stern, T. A. (2009). Comorbid pain, depression, and anxiety: Multifaceted pathology allows for multifaceted treatment. *Harvard Review Psychiatry*, 407-420. doi: 10.3109/10673220903463226
- Outcalt, S. D., Kroenke, K., Krebs, E. E., Chumbler, N. R., Wu, J., Yu, Z., & Bair, M. J. (2015). Chronic pain and comorbid mental health conditions: independent associations of posttraumatic stress disorder and depression with pain, disability, and quality of life. *Journal of Behavioral Medicine*, 38, 535-543. Doi: 10.1007/s10865-015-9628-3

- Palermo, T. M., & Kiska, R. (2005). Subjective sleep disturbances in adolescents with chronic pain: relationship to daily functioning and quality of life. *The Journal of Pain, 6*(3), 201-207.
- Pasero, C., & McCaffery, M. (2011). *Pain assessment and pharmacological management*. St. Louis, MO: Mosby Elsevier.
- Pfizer Inc. (1999). Patient health questionnaire (PHQ-9). Retrieved from <http://www.integration.samhsa.gov/images/res/PHQ%20-%20Questions.pdf>
- Porter, L. S., Gil, K. M., Carson, J. W., Anthony, K. K. & Ready, J. (2000). The role of stress and mood in sickle cell disease pain: An analysis of daily diary data. *Journal of Health Psychology, 5*(1), 53-63. doi: 10.1177/135910530000500109
- Schaffer, M. A., Sandau, K. E., & Diedrick, L. (2012). Evidence-based practice models for organizational change: Overview and practical applications. *Journal of Advanced Nursing, 69*(5), 1197-1209. doi: 10.000/j.1365-2648.2012.06122x
- Sherman, J. J., Turk, D. C., & Okifuji, A. (2000). Prevalence and impact of posttraumatic stress disorder-like symptoms on patients with fibromyalgia syndrome. *The Clinical Journal of Pain, 16*(2), 127-134.
- Sherwood, G., Adams-McNeill, J., Starck, P. L., Nieto, B., & Thompson, C. J. (2000). Qualitative assessment of hospitalized patients' satisfaction with pain management. *Research in Nursing and Health, 23*, 486-495.
- Sickle Cell Disease Association of America. (2015). About SCD & SCT. Found at <http://www.sicklecelldisease.org/index.cfm?page=faq>
- Smyth, C. (2012). The Pittsburgh sleep quality index (PSQI). *Try This: Best Practices in Nursing Care to Older Adults, 6.1*. The Hartford Institute for Geriatric Nursing, New York



University, College of Nursing. Retrieved from

[www.consultgerirn.org/uploads/File/trythis/try\\_this\\_6\\_1.pdf](http://www.consultgerirn.org/uploads/File/trythis/try_this_6_1.pdf)

Snyder, C. H., Facchiano, L., & Brewer, M. (2011). Using evidence-based practice to improve the recognition of anxiety in Parkinson's disease. *The Journal for Nurse Practitioners*, 7(2), 136-141.

Stetler, C. B. (1994). Refinement of the Stetler/Marram model for application of research findings to practice. *Nursing Outlook*, January/February, 15-25.

Stetler, C. B. (2001). Updating the Stetler model of research utilization to facilitate evidence-based practice. *Nursing Outlook*, 49(6), 272-279.

Stetler, C. B., & Marram, G. (1976). Evaluating research findings for applicability in practice.

*Nursing Outlook*, 24(9), 559-563. Treadwell, M. J., Barreda, F., Kaur, K., & Gildengorin,

G. (2015). Emotional distress, barriers to care, and health-related quality of life in sickle cell disease. *Journal of Clinical Outcomes Management*, 22(1), 10-20.

U.S. Department of Health and Human Services, National Institutes of Health, National Heart,

Lung and Blood Institute. (2014). *Evidence-based management of sickle cell disease:*

*Expert panel report, 2014*. Retrieved from <http://www.nhlbi.nih.gov/guidelines>

Velez, R. P. Becker, K. L., Davidson, P., & Sloand, E. (2014). A quality improvement intervention to address provider behavior as it relates to utilization of CA-MRSA guidelines. *Journal of Clinical Nursing*, 24, 556-562. doi: 10.1111/jocn.12684

Vichinsky, E. P. (2014). Overview of the clinical manifestations of sickle cell disease. Retrieved

from <http://www.uptodate.com/contents/overview-of-the-clinical-manifestations-of-sickle-cell-disease>

Wallen, G. R., Minniti, C. P., Krumlauf, M., Eckes, E., Allen, D., Oguhebe, A., . . . Taylor, J. G.

(2014). Sleep disturbance, depression and pain in adults with sickle cell disease. *BMC*

*Psychiatry, 14*, 1-8.

## Appendix A

## The Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions. During the past month,

1. When have you usually gone to bed? \_\_\_\_\_
2. How long (in minutes) has it taken you to fall asleep each night? \_\_\_\_\_
3. When have you usually gotten up in the morning? \_\_\_\_\_
4. How many hours of actual sleep do you get at night? (This may be different than the number of hours you spend in bed) \_\_\_\_\_

5. During the past month, how often have you had trouble sleeping because you...	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times week (3)
a. Cannot get to sleep within 30 minutes				
b. Wake up in the middle of the night or early morning				
c. Have to get up to use the bathroom				
d. Cannot breathe comfortably				
e. Cough or snore loudly				
f. Feel too cold				
g. Feel too hot				
h. Have bad dreams				
i. Have pain				
j. Other reason(s), please describe, including how often you have had trouble sleeping because of this reason(s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)
9. During the past month, how would you rate your sleep quality overall?				

Component 1 #9 Score..... C1 \_\_\_\_\_  
 Component 2 #2 Score ( $\leq 15$  min=0; 16-30 min=1; 31-60 min=2, >60 min=3) + #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3)..... C2 \_\_\_\_\_  
 Component 3 #4 Score (>7=0; 6-7=1; 5-6=2; <5=3)..... C3 \_\_\_\_\_  
 Component 4 (total # of hours asleep)/(total # of hours in bed) x 100 >85%=0, 75%-84%=1, 65%-74%=2, <65%=3 ..... C4 \_\_\_\_\_  
 Component 5 Sum of Scores #5b to #5j (0=0; 1-9=1; 10-18=2; 19-27=3)..... C5 \_\_\_\_\_  
 Component 6 #6 Score ..... C6 \_\_\_\_\_  
 Component 7 #7 Score + #8 Score (0=0; 1-2=1; 3-4=2; 5-6=3)..... C7 \_\_\_\_\_  
 Add the seven component scores together \_\_\_\_\_ **Global PSQI Score** \_\_\_\_\_

Buysse, D.J., Reynolds III, C.F., Monk, T.H., Berman, S.R., & Kupfer, D.J. (1989). The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Journal of Psychiatric Research*, 28(2), 193-213

Reprinted with permission from copyright holder for educational purposes per the University of Pittsburgh, Sleep Medicine Institute, Pittsburgh Sleep Quality Index (PSQI) website at <http://www.sleep.pitt.edu/content.asp?id=1484&subid=2316>.

## Appendix B

## PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: \_\_\_\_\_ DATE: \_\_\_\_\_

Over the last 2 weeks, how often have you been bothered by any of the following problems? (use "x" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things				
2. Feeling down, depressed, or hopeless				
3. Trouble falling or staying asleep, or sleeping too much				
4. Feeling tired or having little energy				
5. Poor appetite or overeating				
6. Feeling bad about yourself or that you are a failure or have let yourself or your family down				
7. Trouble concentrating on things, such as reading the newspaper or watching television				
8. Moving or speaking so slowly that other people could have noticed. Or the opposite being so fidgety or restless that you have been moving around a lot more than usual				
9. Thoughts that you would be better off dead, or of hurting yourself				

Add columns  +  + 

(Healthcare professional: For interpretation of TOTAL, please refer to TOTAL \_\_\_\_\_ accompanying scoring card).

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all _____
	Somewhat difficult _____
	Very difficult _____
	Extremely difficult _____

## Appendix C

## QUALITY OF LIFE SCALE (QOL)

Please read each item and circle the number that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.

		Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1	Material comforts home, food, conveniences, financial security	7	6	5	4	3	2	1
2	Health - being physically fit and vigorous	7	6	5	4	3	2	1
3	Relationships with parents, siblings & other relatives- communicating, visiting, helping	7	6	5	4	3	2	1
4	Having and rearing children	7	6	5	4	3	2	1
5	Close relationships with spouse or significant other	7	6	5	4	3	2	1
6	Close friends	7	6	5	4	3	2	1
7	Helping and encouraging others, volunteering, giving advice	7	6	5	4	3	2	1
8	Participating in organizations and public affairs	7	6	5	4	3	2	1
9	Learning- attending school, improving understanding, getting additional knowledge	7	6	5	4	3	2	1
10	Understanding yourself - knowing your assets and limitations - knowing what life is about	7	6	5	4	3	2	1
11	Work - job or in home	7	6	5	4	3	2	1
12	Expressing yourself creatively	7	6	5	4	3	2	1
13	Socializing - meeting other people, doing things, parties, etc	7	6	5	4	3	2	1
14	Reading, listening to music, or observing entertainment	7	6	5	4	3	2	1
15	Participating in active recreation	7	6	5	4	3	2	1
16	Independence, doing for yourself	7	6	5	4	3	2	1

Burkhardt, C. S. (2003). Instructions for scoring the quality of life scale. Retrieved from <http://www.tellusnaturals.com/documentos/qol.pdf>

## Appendix D

## Project Outcome Evaluation Tools

<b>List your Project Outcome Objectives</b>	<b>List the Types of Evaluation Tools You Plan to Use for Each Outcome</b>	<b>Rationale for Using Each Type of Tool</b>
1. The sickle cell team will develop an interprofessional, evidence-based guideline during the first month of the project, to use to evaluate the existence of depression and sleep disturbance in all patients admitted for VOC	N/A	1. The Stetler Model's is being used to determine the most appropriate research evidence to guide the process of creating the guideline and treatment protocol to be used in the project.
2. The sickle cell team will develop a treatment protocol/algorithm during the first month of the project, for the management of depression and sleep impairment in all patients admitted for VOC.	N/A	2. Meeting minutes will be kept for each meeting of the Sickle Cell Interdisciplinary Team over the course of the project.
3. One hundred percent of patients with sickle cell disease admitted and readmitted during the three-month project period will be assessed for depression, sleep impairment, pain and quality of life.	The Pittsburgh Sleep Quality Index (PSQI), the Patient Health Questionnaire (PHQ-9), the Quality of Life Scale (QOLS), a verbal Numerical Rating Pain Scale (NRS), and Subjective Pain Scale (SPS).	1. The PSQI is a 19-question self-report tool used to measure quality and patterns of sleep in the adult. It has been used previously to evaluate sleep in patients with sickle cell disease.
4. One hundred percent of patients who have been identified with depression and/or sleep impairment during the three-month project period will have been offered treatment for same based on an algorithm designed by the treatment team during the first month of the project.		2. The PHQ-9 is a 9-question self-assessment tool commonly used to both screen for and monitor treatment for depression. It also assesses for symptoms of sleep disturbance and difficulty concentrating.
4. Patients who have accepted treatment for depression and/or sleep impairment will show a 50% improvement from baseline in their depression and/or sleep impairment, as well as in their pain and quality of		3. The QOLS is a 16-item self-assessment tool that has been adapted for use in patients with chronic illnesses to include a question regarding independence and ability to care for oneself. 4. The NRS is a verbal 1-10 scale used to evaluate a patient's current level of pain.

life by the end of the three-month project period.		5. The SPS is a verbal scale using the terms “better”, the “same” or “worse” to describe pain compared to the previous evaluation.
--	--	--

### Chart Audits – Pre and Post Intervention

What You are Planning to Assess	Yes or No	If yes, list the specific content that should be addressed in the chart audit.
Do you want to assess changes in healthcare provider behaviors?	No	
Do you want to assess changes in patient outcomes?	Yes	<p>Each patient admitted to the hospital during the project period with SCD, assessed at first admission at the start of the DNP project and each subsequent admission.</p> <ul style="list-style-type: none"> <li>• Depression – accepts treatment – follow-up assessment at each hospitalization</li> <li>• Depression – refuses treatment – follow-up assessment at each hospitalization</li> <li>• Sleep disturbance – accepts treatment – follow-up assessment at each hospitalization</li> <li>• Sleep disturbance – refuses treatment – follow-up assessment at each hospitalization</li> <li>• Depression + Sleep disturbance – accepts treatment – follow-up assessment at each hospitalization</li> <li>• Depression + Sleep disturbance – refuses treatment – follow-up assessment at each hospitalization</li> <li>• No depression + no sleep disturbance – follow-up assessment at each hospitalization</li> <li>• Pain levels on all patients – assessment at each hospitalization and over the course of the admission</li> <li>• Quality of life on all patients – follow-up</li> </ul>
Do you want to assess something else? Explain	No	

Do you need to include demographic information on patients as part of your assessment?	<b>Yes</b>	Race, Ethnicity, Age, Gender, Sickle Cell Genotype Maybe number of admissions and length of hospitalization for each admission
////////////////////////////////////	////	////////////////////////////////////
<b>Chart Audit Process</b>	----- -	<b>Provide Answer and Rationale</b>
How will you choose which charts to audit?	----- -	The project entails assessing all patients admitted to the hospital with SCD (even if not admitted for VOC)
How will you choose the number of charts and time span of when patients were seen for pre and post intervention audit?	----- -	All patients admitted to the hospital with SCD (even if not admitted for VOC) from the beginning of DNP Project until the end of the project. May not see full benefit from antidepressants during that time frame, but should see improvement in pain, sleep and quality of life.
Who in the clinical setting is responsible for monitoring HIPAA compliance?	----- -	Julie Hamilton, MBA, CHC, Vice President, Chief Compliance and Privacy Officer Project Director
How will you access the charts for your audit?	----- -	Electronic Medical Record

### Other Evaluation Tools /Instruments /Methods

<b>What You Are Planning to Assess</b>	<b>Provide Answer and Rationale</b>
What tool/instrument/method are you planning to use?	1. Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol
What information do you want to obtain and from whom? List specific content.	<ul style="list-style-type: none"> <li>• Determine if the guideline developed by the Sickle Cell Interdisciplinary Team is effective in evaluating for depression and sleep impairment and the impact on pain and quality of life in patients with SCD.</li> <li>• Determine if the treatment protocol developed by the Sickle Cell Interdisciplinary Team to treat patients identified with depression and sleep impairment is effective in improving depression, sleep impairment, pain and quality of life.</li> <li>• Meeting minutes will be kept for each Sickle Cell Interdisciplinary Team meeting during the course of the DNP Project. <ul style="list-style-type: none"> <li>○ During development of the guideline and treatment protocol</li> </ul> </li> </ul>



	<ul style="list-style-type: none"> <li>○ At monthly (or more frequent) meetings to review the guideline and treatment protocol for revisions after implementation</li> <li>○ At the end of the DNP Project to determine the success of the guideline and treatment protocol.</li> </ul>
How will this information apply to the evaluation of your project outcomes?	Based on the successful implementation of the guideline and treatment protocol, the guideline and treatment protocol will be disseminated to the Bridgeport Hospital Primary Care Clinic Sickle Cell Medical Home for implementation during the outpatient visits.
How will this information fit with your project theoretical /conceptual model framework?	The Stetler Model will guide the process in helping to define the purpose and outcomes for the project (Phase I); guide the search for appropriate research evidence and the acceptance or rejection of the evidence (Phase II); evidence will be evaluated for fit of setting, feasibility, substantiating evidence and current practice (Phase III); will help to guide the decision to either formally or informally use the evidence or consider to use the evidence (Phase IV); and finally guide the evaluation process based on the decision made in Phase IV, likely making a decision to use the evidence formally and evaluating a goal for use, the change process and outcomes and results. The final evaluation step will be to evaluate the research as part of routine practice (Phase V).
How do you plan to disseminate or implement this tool/instrument/method?	<ul style="list-style-type: none"> <li>● Initially, the guideline and treatment protocol will be used to evaluate and treat for depression and sleep impairment and the effect on pain and quality of life in patients with SCD admitted as inpatients to the hospital.</li> <li>● Once it is determined that the guideline and treatment protocol are successful, the Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol will be proposed to the Bridgeport Hospital Primary Care Clinic Sickle Cell Medical Home for implementation during the outpatient visits.</li> </ul>

### Other Evaluation Tools /Instruments /Methods

What You Are Planning to Assess	Provide Answer and Rationale
What tool/instrument/method are you planning to use?	1. The Pittsburgh Sleep Quality Index (PSQI) is a 19-question self-report tool used to measure quality and patterns of sleep in the adult. It has been used previously to evaluate sleep in patients with sickle cell disease.

	<ol style="list-style-type: none"> <li>2. The Patient Health Questionnaire (PHQ-9) is a 9-question self-assessment tool commonly used to both screen for and monitor treatment for depression. It also assesses for symptoms of sleep disturbance and difficulty concentrating.</li> <li>3. The Quality of Life Scale (QOLS) is a 16-item self-assessment tool that has been adapted for use in patients with chronic illnesses to include a question regarding independence and ability to care for oneself.</li> <li>4. Numerical Rating Pain Scale (NRS) is a verbal 1-10 scale used to evaluate a patient's current level of pain.</li> <li>5. The Subjective Pain Scale (SPS) is a verbal scale using the terms "better", the "same" or "worse"</li> </ol>
<p>What information do you want to obtain and from whom? List specific content.</p>	<ul style="list-style-type: none"> <li>• Evaluate the incidence of depression and sleep impairment and the impact on pain and quality of life in patients with SCD.</li> <li>• Evaluate the improvement or no-improvement of treatment for depression and sleep impairment over the course of the DNP Project time frame.</li> <li>• Each patient admitted to the hospital for SCD (even if not admitted for VOC) will be assessed during pain consult by PD or her Palliative &amp; Pain colleagues during the course of the DNP Project.</li> <li>• Each patient who is readmitted to the hospital with SCD (even if not admitted for VOC) during the course of the DNP Project will be reassessed using the assessment tools specified by the guideline.</li> </ul>
<p>How will this information apply to the evaluation of your project outcomes?</p>	<p>It is believed that patients will begin to show improvement in their depression and sleep impairment and the impact these have on pain and quality of life.</p>
<p>How will this information fit with your project theoretical /conceptual model framework?</p>	<p>The Stetler Model will guide the process in helping to define the purpose and outcomes for the project (Phase I); guide the search for appropriate research evidence and the acceptance or rejection of the evidence (Phase II); evidence will be evaluated for fit of setting, feasibility, substantiating evidence and current practice (Phase III); will help to guide the decision to either formally or informally use the evidence or consider to use the evidence (Phase IV); and finally guide the evaluation process based on the decision made in Phase IV, likely making a decision to use the evidence formally and evaluating a goal for use, the change process and outcomes and results. The final evaluation step will be to evaluate the research as part of routine practice (Phase V).</p>
<p>How do you plan to disseminate or implement this tool/instrument/method?</p>	<ul style="list-style-type: none"> <li>• Initially, the guideline and treatment protocol will be used to evaluate and treat for depression and sleep impairment and the effect on pain and quality of life</li> </ul>

	<p>in patients with SCD admitted as inpatients to the hospital.</p> <ul style="list-style-type: none"> <li>• Once it is determined that the guideline and treatment protocol are successful, the Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol will be proposed to the Bridgeport Hospital Primary Care Clinic Sickle Cell Medical Home for implementation during the outpatient visits.</li> </ul>
--	--

## Appendix E

### Informed Consent Document

<b>Heading</b>	<b>Content</b>	<b>Notes</b>
Project Title	Treating Depression and Sleep Impairment to Improve Pain Levels and Quality of Life for Patients with Sickle Cell Disease: A Quality Improvement Project	
Project Purpose and Rationale	<p>Patients with sickle cell disease and vaso-occlusive pain crises experience significant pain that impacts their quality of life. Some patients with sickle cell disease have depression and/or sleep disturbances that may impact pain levels and quality of life.</p> <p>As part of a quality improvement project, the sickle cell team at Bridgeport Hospital has developed the Sickle Cell Depression and Sleep Impairment Guideline and Treatment Protocol to ensure that all patients who are admitted to the hospital for sickle cell disease or vaso-occlusive crisis are assessed during a pain consult for depression, sleep impairment, pain and quality of life. As part of the guideline and treatment protocol, a member of the sickle cell team will discuss a treatment plan with any patient who has depression or sleep impairment and start the treatment if the patient desires.</p> <p>All patients who are seen by the pain consultant for follow-up or a hospital re-</p>	

	<p>admission receive the same assessment as well as evaluating the effectiveness of any treatment.</p> <p>The goal of this quality improvement project is to improve overall pain levels and quality of life for patients with sickle cell disease through efficient and effective evaluation and treatment for depression and sleep disturbance.</p>	
Inclusion/Exclusion Criteria	<p>Because you are a patient who had these assessments during your hospital stay and again at this follow-up or readmission visit, you are being asked to participate in a study of the outcomes of these assessments and any treatment.</p> <p>You are eligible to participate in the study of outcomes if:</p> <ol style="list-style-type: none"> <li>1. You are age 18 or older</li> <li>2. You are able to speak and read English</li> <li>2. You were recently discharged from Bridgeport Hospital for vaso-occlusive pain crisis or other sickle cell disease related diagnosis</li> <li>3. You had an assessment for depression, sleep impairment, pain and quality of life during your hospitalization</li> <li>4. You have had an assessment for depression, sleep impairment, pain and quality of life today at your follow-up visit or hospital re-admission.</li> </ol> <p>You do not have to have depression or sleep impairment nor do you need to be under treatment if you do have depression or sleep impairment to participate.</p>	
Participation Procedures and Duration	<p>Please read this informed consent and then decide if you want to participate in the study of outcomes of this project. If you consent to participate you are giving permission to the Project Director (PD) to review your health records and collect data regarding the assessments and any treatment for depression, sleep impairment, pain and quality of life, as</p>	

	<p>well as your demographic data (race and ethnicity, gender, age, sickle cell genotype, number of admissions and length of stays during the project period).</p> <p>The PD will be the only individual who knows you have consented and the only individual collecting the data. The PD will not collect any data that would identify you and will only report data in an aggregate form.</p> <p>You will not be asked to participate in any other way in the study of outcomes.</p>	
Audio or Video Recordings (if applicable)	N/A	
Disclosure of Alternative Procedures (procedure for those who do not participate)	N/A	
Data Confidentiality or Anonymity	<p>The PI will be the only individual who has access to your informed consent and the only individual collecting data from your health record.</p> <p>No identifying data will be recorded. Confidentiality will be maintained and data will only be reported in aggregate form.</p>	
Storage of Data (include data retention)	<p>Any raw data will be stored either in a locked file in the project director's workplace office or in a password protected personal network drive on the hospital computer system, with access only available to the project director. Should paper data need to be transported, it will either be carried in a locked briefcase, or scanned to a secured email, saved on the password protected network drive and accessed from the project director's home through password secured access to the network drive. All data will be destroyed within three years of the conclusion of the project by shredding all paper forms and wiping the electronic data clean.</p>	

Risks or Discomforts	There are no known risks to participants in this project. Participation, and information obtained during data collection will be confidential.	
Who to Contact if Experience any Negative Effects from Participation	N/A	
Benefits (only direct benefits to participant)	There are no direct benefits to you for participating in this project.	
Voluntary Participation Statement	Your consent is entirely voluntary. Your care will not change if you decide not to consent to allow access to your health record for the purpose of this project.	
IRB Contact Information	<p>Bridgeport Hospital, Institutional Review Board, 267 Grant Street, Bridgeport, CT 06610, has granted approval to conduct this project. For questions regarding the rights as a participant in this project, please contact Karen Hutchinson, MD (Chair) or Evelyn Colon, CIP (Administrator), 203-384-4549</p> <p>Ball State University, Office of Research Integrity, has granted Institutional Review Board approval to conduct this project. For questions about the rights as a research subject, please contact the Director, Office of Research Integrity, Ball State University, Muncie, IN 47306, 765-285-5070 or <a href="mailto:irb@bsu.edu">irb@bsu.edu</a>.</p>	
Consenting Statement /Signatory Area	By signing the consent, you agree to allow Sheran Simo, APRN, project director, to access your health information and collect data regarding the assessments and any treatment for depression, sleep impairment, pain and quality of life, as well as your demographic data (race and ethnicity, gender, age, sickle cell genotype, number of admissions and length of stays during the project period).	
Project Director and Faculty Advisor Contact Information	For any questions or concerns, please feel free to call the project director, Sheran Simo, APRN, ACHPN, FNP-BC at 203-520-8575 or email <a href="mailto:smsimo@bsu.edu">smsimo@bsu.edu</a> .	

	Faculty Advisor is Deb Siela, PhD, RN, CCNS, ACNS-BC, CCRN, CNE, RRT at Ball State University, Muncie, IN, at 765-285-4650 or email <a href="mailto:dsiela@bsu.edu">dsiela@bsu.edu</a> .	
--	--	--