Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients

John Weldon
jweldon8@students.kennesaw.edu

Follow this and additional works at: http://digitalcommons.kennesaw.edu/nursmast_etd

Part of the Critical Care Nursing Commons

Recommended Citation
http://digitalcommons.kennesaw.edu/nursmast_etd/4

This Thesis is brought to you for free and open access by the Wellstar School of Nursing at DigitalCommons@Kennesaw State University. It has been accepted for inclusion in MSN in Leadership in Nursing Final Projects by an authorized administrator of DigitalCommons@Kennesaw State University. For more information, please contact digitalcommons@kennesaw.edu.
Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients

By

JOHN TYLER WELDON

A Thesis
Presented in Partial Fulfillment of Requirements for the Degree of Master’s in Nursing Science
In the Wellstar College of Health and Human Services Kennesaw State University

Kennesaw, GA
October 17, 2017
Acknowledgements

The thesis process is a complicated one that could not be completed without the assistance, guidance, and encouragement of many people. I am very grateful to the Lord and Savior, Jesus Christ, for the blessings and guidance that have enabled me to make it through this season and challenge in life.

I would also like to express thanks to my committee thesis chair, Dr. Patricia Hart, and Dr. Richard Sowell who assisted me in finalizing my thesis efforts. These two kept me focused and moving along through each step of the research process. They were always quick to answer questions and offer guidance anytime I needed it. In addition, I would also like to express thanks to Dr. Nancy Ballard, my thesis committee co-chair, for her assistance in editing my project and always being readily available when needed. All of the staff has been very supportive throughout the graduate school process, and for that, I’ll be forever grateful.

Next, I would like to thank my family, friends, and fiancée, Alisha Shirley, for always being supportive through this graduate school process. Many long nights of high stress and great effort has went in to this research project and the program as a whole, and each has always been there to encourage me to continue on and press forward through each obstacle faced. Their love, patience, and encouragement have been my rock over the past 15 months. I also must thank the Momentum Youth group in which I serve for being patient and always being an encouragement and source of laughter over the past 15 months. The potential and love demonstrated by this group is an encouragement for those of all ages.

Lastly, I would like to thank all of the nurses that are employed in the surgical intensive care unit where I conducted my project. Their compassion, commitment, and hard work are truly inspirational. The nurses’ commitment to improving and providing the most up-to-date
evidenced based practice is unmatched, and their daily efforts pushed me to further my education and strive to improve patient care processes myself. They, along with all the others mentioned, have made it possible for me to obtain my Masters of Science in Nursing.
# Table of Contents

Acknowledgements........................................................................................................... ii

Table of Contents.............................................................................................................. iv

Table of Tables.................................................................................................................. v

Abstract............................................................................................................................. vi

Chapter 1: Introduction....................................................................................................... 1

Chapter 2: Review of Literature......................................................................................... 7

Chapter 3: Methods.......................................................................................................... 19

Chapter 4: Results............................................................................................................. 30

Chapter 5: Discussion........................................................................................................ 36

References........................................................................................................................ 40

Appendix A: Nurse Informed Consent............................................................................. 44

Appendix B: Recruitment Flier......................................................................................... 47

Appendix C: Behavioral Pain Scale................................................................................... 49

Appendix D: Behavioral Pain Scale Consent................................................................. 51

Appendix E: Critical Care Pain Observation Tool.......................................................... 53

Appendix F: Critical Care Pain Observation Tool Consent.......................................... 56

Appendix G: Nurses’ Evaluations of the BPS and CPOT............................................. 58

Appendix H: Nurses’ Evaluations of the BPS and CPOT Consent.................................. 61

Appendix I: Demographic Survey................................................................................... 67

Appendix J: Hamilton Medical Center IRB Approval.................................................. 69

Appendix K: Kennesaw State University IRB Approval................................................ 71

iv
Table of Tables

Table 1 ........................................................................................................... 33
Table 2 ........................................................................................................... 34
Table 3 ........................................................................................................... 35
Abstract

Purpose: The study aimed to compare the Behavioral Pain Scale (BPS) and the Critical Care Pain Observation Tool (CPOT) in their effectiveness to identify the presence of pain in nonverbal mechanically ventilated critically ill patients. Nurses' evaluation with the feasibility, clinical relevance, and satisfaction of the tools were also gathered and compared.

Design: This study followed a non-experimental, correlational, comparative design.

Methods: Nurses were recruited from the surgical intensive care unit in a midsized community hospital in the Southeastern United States. After training, nurse participants obtained pain assessments on ventilated critically ill patients at rest, following a normal blood pressure measurement, and following endotracheal suctioning. Pain assessments were gathered and recorded using the Critical Care Pain Observation tool and the Behavioral Pain Scale. The researcher aimed to obtain 84 total assessments. Following collection of the pain assessments, nurses were provided evaluation tools with the two scales along with a demographic questionnaire.

Data Analysis: IBM SPSS 24.0 software was utilized to compute and report statistical data following data collection. Descriptive statistics such as frequencies, percentages, means, and standard deviations were utilized to describe demographic variables and scores for the CPOT, BPS, and the nurses' evaluation tool. Correlational statistics such as Pearson’s r analyzed the relationships between the CPOT and the BPS scores. Paired t tests examined the differences in nurses’ evaluation between the CPOT and BPS.

Results: Internal consistency reliability was assessed for the questionnaires assessing the Behavioral Pain Scale (BPS) for feasibility, clinical relevance, and satisfaction and for the questionnaires assessing the Critical Care Pain Observation Tool (CPOT) for feasibility,
Clinical relevance, and satisfaction by calculating Cronbach's alpha reliability coefficients. The results of these Cronbach's alpha reliability coefficients indicate that the two questionnaires demonstrate high levels of internal consistency reliability. Statistically significant relationships were also found between the BPS and CPOT scores at rest $r(85) = 0.821, p = .01$, after taking a noninvasive blood pressure $r(85) = 0.815, p = .01$, and after turning $r(85) = 0.906, p = .01$. BPS and CPOT scores had positive high correlations at each level of pain assessment. The correlation strengthened following turning indicating that both pain assessment tools do tend to increase and reflect sensitivity. Overall, 85 total pain assessments were collected by seven nurses, including the primary investigator. There was not a statistically significant difference between nurses' perceptions of the feasibility, clinical relevance, or satisfaction with the two tools.

**Discussion:** The findings show that observational pain scales, such as the Behavioral Pain Scale (BPS) and Critical Care Pain Observation tool (CPOT) are effective in measuring pain in the ventilated nonverbal patient. The correlation strength indicates that both pain assessment tools do tend to reflect sensitivity to pain. Though the difference was not statistically significant, mean scores were determined to be slightly higher for the CPOT in feasibility, clinical relevance, and satisfaction when compared to the mean evaluation scores of the BPS. The study also supported the decoding nature of the BPS and CPOT as described by The Social Communication Model of Pain. More comparative research is needed to establish a gold standard for observational pain scales, however, the comparative nature of this study can serve as a framework to reproduce and for research going forward.

**Keywords:** Observational Pain Scales, Critical Care Pain Observation Tool, CPOT, Behavioral Pain Scales, BPS, Nurses' Evaluations of the Feasibility, Clinical Relevance, Satisfaction, The Social Communication Model of Pain
Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients

Chapter 1: INTRODUCTION

Effective pain assessment is paramount in all patients, particularly critically ill patients. Critically ill patients are much more vulnerable to the side effects of untreated pain, and ineffective assessment of pain is associated with negative patient outcomes (Gélinas, 2016). Self-reporting pain remains the gold standard for pain measurement, and should be obtained whenever possible. However, assessing pain becomes difficult when patients are ventilated and unable to self-report pain due to altered level of consciousness and sedation (Batiha, 2014). Observational pain scales, such as the Behavioral Pain Scale (BPS) and Critical Care Pain Observation tool (CPOT) are tools used to measure pain in the ventilated nonverbal patient and are used to better assess pain.

This chapter identifies the study’s purpose, background and significance, statement of the problem, and theoretical framework. Research questions, definitions, assumptions, and limitations will also be discussed.

Purpose

The purpose of this study was to conduct a small-scale quantitative comparison study with ventilated patients in the surgical intensive care unit at a midsized community hospital located in the southeastern United States (US). The study aimed to compare the BPS and the CPOT in their effectiveness to identify the presence of pain in nonverbal mechanically ventilated critically ill patients. Nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the tools were also gathered and compared. This research further assists in identifying a superior observational pain scale to assess pain in nonverbal ventilated critically ill patients.
Background and Significance

Pain has been shown to be experienced by critically ill patients at rest in more than 30% of patients and increases to more than 50% when routine care procedures are being performed (Gélinas, 2016). Invasive tubes, diagnostic tests, and operative related pain are common for the critical care patient (Ayasrah, 2016). Critically ill patients are much more susceptible to the side effects of untreated pain and ineffective assessment of pain is associated with negative patient outcomes that can include: increased need for mechanical ventilation, increased length of stay, and increased mortality (Gélinas, 2016). Furthermore, pain in the critical care patient can cause increased sympathetic nervous system activity, noncompliance with ventilation, and place patients at higher risks for cardiovascular events (Ayasrah, 2016). Pain often goes unrecognized due to inadequate assessment, and as a result pain is often poorly managed (Craig, 2009). Pain assessment is further complicated in the absence of verbal communication, and such is the case in the mechanically ventilated critically ill patient. Observational pain scales such as the BPS and CPOT offer an assessment tool to assess pain in the nonverbal patient so pain can be treated more effectively (Gélinas, 2016).

Statement of the Problem

In a midsized community hospital in the southeastern US, nurses only use a standard 0 to 10 Numeric Rating Score (Gélinas, 2016) to assess patients’ pain. Assessing pain on this scale becomes difficult to do when patients are ventilated and unable to self-report pain. When self-reporting is not possible, observational tools including the BPS and the CPOT have been verified to evaluate pain in critical care settings (Gélinas, 2016). The BPS provides a pain scale that is based on facial expressions, upper limb movement, and compliance with ventilation (Payen et al., 2011). The CPOT is similar, but it uses four different categories to assess pain including:
facial expressions, body movements, muscle tension, and compliance with the ventilator (Gélinas, Fillion, Puntillo, Viens, & Fortier, 2006). Though observational pain scales have been established, there have not been repeated comparison studies between the BPS and the CPOT to evaluate if one scale is superior to the other or if both indicate comparable pain assessment simultaneously. Nurses’ evaluation of the feasibility, clinical relevance, and satisfaction of the tools is also an area for further evaluation.

Theoretical Framework

The Social Communication Model of Pain is a theoretical model that describes the psychological concept of individuals’ pain, the methods in which it is expressed and the link between individuals’ and the caretakers’ assessment, detection, and management of pain (Hadjistavropoulos et al., 2011). The Social Communication Model of Pain provides the theoretical framework for a quantitative pilot study in which the BPS and the CPOT, along with nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the tools, are compared. The Communication Model of Pain describes the steps of pain communication and assessment as a three-step process that includes: the internal pain experience, encoding of pain experience through expression, and decoding or assessment of the painful behavior (Hadjistavropoulos et al., 2011).

Hadjistavropoulos et al. (2011) indicate that the first step of the process, the internal pain experience, involves neurological processes that can be exacerbated or diminished by mental, emotional, and behavioral components. Hadjistavropoulos et al. (2011) designate that the internal pain experience becomes more complicated in the face of cultural, social, and situational circumstances. The situational contexts in this study would include the stay in the intensive care unit and patients’ inability to communicate due to being mechanically ventilated.
Hadjistavropoulos et al. (2011) describe the second step of the process, encoding of the pain experience and expression, as a combination of two processes including the subjectivity or self-report of the pain experience and other nonverbal cues such as facial expressions or limb movement. The nonverbal response of pain expression tends to be more automatic and often times difficult for a patient to control by a psychological means (Craig, 2009). Due to the mechanically ventilated patient being unable to self-report pain, the encoding aspect being evaluated in this study will be the nonverbal and automatic responses to pain. Hadjistavropoulos et al. (2011) describe the third step, decoding or assessment of pain, as being based on the clearness of the pain message, as well as the sensitivity and cultural context of the individual interpreting the message. Hadjistavropoulos et al. (2011) also suggest that nonverbal cues are much more difficult to assess and that individuals are more likely to misinterpret these cues in the absence of self-reports.

Interpreting painful behaviors in the absence of verbal communication is an area that needs further attention. Scales such as the BPS and CPOT offer a tool that assists in decoding often times unrecognized pain responses (Gélinas, 2016). Gélinas (2016) suggests that the theoretical framework of The Communication Model of Pain assists nurses in considering different characteristics of patients’ expressions in regards to pain assessment and it also sets a scientific basis for the use of observational pain scales. Therefore, The Communication Model of Pain will be used as the theoretical framework in this pilot study which evaluates the Behavioral Pain scale and The Critical Care Pain Observation Tool, along with nurses’ evaluation of the feasibility, clinical relevance, and satisfaction of the tools.

**Research Questions**

The research questions that guided this study were:
1) What is the relationship between the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in assessing pain in ventilated critical care patients?

2) What is the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale compared to the Critical-Care Pain Observation Tool?

Conceptual Variable Definitions

**Critical care nurse.** A licensed professional nurse who has the responsibility to ensure and safeguard the assessment, care, and delivery of care to an acutely and critically ill patient.

**Critical care patient.** A patient that is acutely or critically ill and at high risk for the potential for or currently experiencing actual life threatening health conditions and requires more attentive and advance nursing care (Gélinas, 2016).

**Pain.** A neurological process brought on by discomfort, illness, injury or suffering that can be exacerbated or diminished by mental, emotional, and behavioral components and can become further complicated by cultural, social, and situational circumstances (Hadjistavropoulos et al., 2011).

Operational Variable Definitions

**Patients’ pain level.** Pain was measured utilizing the scores of the BPS and CPOT. The BPS measures pain and provides a numerical score of 1 to 4 for the area of facial expressions, upper limb movement, and compliance with ventilation for a total score of 3 to 12 (Payen et al., 2011). The CPOT measures the areas of facial expressions, body movements, muscle tension, and compliance with the ventilator with a possible score of 0 to 2 in each area for a possible total score ranging from 0 to 8 (Gélinas, Tousignant-Laflamme, Tanguay, & Bourgault, 2011).
Evaluation tool measuring critical care nurses’ evaluation with the feasibility, clinical relevance, and satisfaction of pain scale. This tool developed by Gélinas et al. (2014) contains a questionnaire that asks a series of questions and allows participants to rank answers on a numerical scale measuring 1 to 4, where 1 equates to “not at all” or worst possible response and 4 equates to “very” or the best possible response. Nurses’ evaluations of the feasibility, clinical relevance, and satisfaction of the tools were obtained utilizing this tool and then total scores between the two were compared.

Assumptions

Assumptions for this research study included: 1) nurses would assess pain on the scales honestly, without outside influence or bias; 2) nurses would assess pain on both scales at the same time before and after painful and non-painful procedures as instructed; and 3) nurses would respond to evaluation survey questions independently, honestly, and without influence or bias.

Limitations

A limitation of this study included the varied assessment skills and subjective nature of the nurses performing the assessment. Though all nurses attended the same training class and were supervised completing an assessment, the subjective nature of assessment cannot be eliminated. Generalizability was also limited by use of a single midsized community hospital in the southeastern US, and a relatively small convenience sample of critical care nurses within this individual facility.
Pain assessment in the critically ill is a complex process. In order to understand the complexity of pain assessment, one must evaluate the effects of pain in the ventilated critical care patient. This chapter provides a review of the literature to explore pain in the ventilated critical care patient, the use of the BPS to assess pain, and the use of the CPOT's to assess pain.

**Pain in the Ventilated Critical Care Patient**

In a cross-sectional study, Rose et al. (2011) used a self-report survey to examine all licensed registered nurses working in the intensive care units at a 600 bed university hospital in Toronto, Canada. Rose et al. used the survey to determine nurses' current practice and knowledge related to pain assessment and current management for critically ill adults able and unable to self-report pain. Rose et al. found that nurses often times were more likely to use formal pain scales when patients were able to self-report pain compared to using them when patients were unable to report pain \( (p < .0001) \). Though more experienced nurses reported feeling more comfortable than nurses with less experience, nurses as a whole reported that they felt less comfortable in their ability to assess pain for patients unable to self-report pain \( (p < .0001) \). Rose et al. concluded that there was a clear gap between pain assessment practices for critically ill patients able to self-report pain and those unable to communicate. Rose et al. determined that pain assessment and management were likely to be worse for patients with limited ability to communicate pain when compared to those that could communicate. Despite behavioral pain assessment tools being available for use in patients unable to self-report pain, nurses in the study did not use these tools often and lacked confidence in their ability to accurately assess pain (Rose et al., 2011).
Georgiou, Hadjibalassi, Lambrinou, Andreou, and Papanassoglou (2015) conducted a systematic review of ten scholarly research studies to review current evidence of the use of pain assessment tools and their effect on health-related outcomes. Georgiou et al. (2015) found that the use of validated pain assessment tools can have positive impacts on nurses’ practice. Eight of the reviewed studies correlated the effect of pain assessment on the duration of mechanical ventilation in patients, and two of the eight studies showed significant decreases in duration of mechanical ventilation. It was concluded that the latest guidelines and quality improvement initiatives indicate that pain assessment tools should be used in everyday nursing practice to assess pain in all patients (Georgiou et al., 2015).

In a quantitative descriptive study, Ayasrah (2016) assessed and described care-related pain associated with painful and non-painful procedures within the critical care setting. This study focused on 247 mechanically ventilated critically ill patients within a military hospital in Jordan. Ayasrah assessed pain using the behavioral pain scale and physiological indicators before and after procedures. The painful procedures of repositioning, endotracheal suctioning, and vascular punctures were evaluated as well as the non-painful procedures of mouth care, eye care, and dressing changes. Ayasrah found the highest mean procedural pain score was during repositioning ($M = 9.25, SD = 1.29$), while the lowest procedural pain score was during eye care ($M = 3.65, SD = 0.67$). The study results also showed that the overall mean procedural pain score of 6.34 ($SD = 2.36$) was significantly higher than the mean preprocedural pain score of 3.43 ($SD = 0.67, P < .001$). Ayasrah concluded that mechanically ventilated patients experience pain during everyday nursing procedures. Nurses need to consider pain associated with their everyday interventions when caring for critically ill patients, (Ayasrah, 2016).
Sutari, Abdalrahim, Hamdan-Mansour, and Ayasrah (2011) used a quantitative descriptive correlational design to examine 301 mechanically ventilated patients within three major hospitals in Jordan. The goal of this study was to evaluate pain levels and predictors among mechanically ventilated patients during rest and during routine nursing interventions. Pain was assessed before and after the following procedures: repositioning, endotracheal suctioning, intravenous access insertion, mouth care, eye care, and nasogastric tube insertion. Sutari et al. (2011) found the mean pain scores at rest \((M = 3.69, \text{SD} = 0.81)\) were lower than the mean pain scores during the nursing interventions \((M = 7.1, \text{SD} = 2.5)\). The paired \(t\)-test of the mean pain scores (mean difference = 3.41) was statistically significant \((t = -28.7, p < 0.001)\). Sutari et al. determined that mechanically ventilated patients experience pain during rest and during routine nursing procedures. Past surgical history and age should be considered as important predictive factors of how patients will respond to pain (Sutari, Abdalrahim, Hamdan-Mansour, & Ayasrah, 2011).

Engström, Nyström, Sundelin, and Ratray (2013) conducted a descriptive qualitative study using self-report surveys in an effort to have people describe their intensive care unit experiences six months after undergoing mechanical ventilation. The study conducted surveys on eight separate people that had previously been intubated in an intensive care unit in the northern part of Sweden. Diaries were kept by medical personnel throughout patients’ stay and provided to patients to read to assist in filling the memory gaps of the patients. Audio taped interviews were conducted with each of the participants. Engström et al. (2013) found that patients’ inability to communicate was considered the worst experience by those that were mechanically ventilated and that the pain caused by the endotracheal tube was significant. It was concluded that being mechanically ventilated meant patients had to rely on medical equipment for survival and this
created the feeling of being delivered into the hands of caretakers. This accompanied by the pain, inability to communicate, and being connected to machines was very stressful on patients (Engström, Nyström, Sundelin, & Ratray, 2013)

In a qualitative descriptive study, Samuelson (2011) surveyed 250 mechanically ventilated patients five days after being discharged from the intensive care unit. This study was performed within two general intensive care units in Sweden. The patients surveyed were provided a journal kept by staff and family that detailed each day of their stay. Each patient/participant was interviewed by the author face to face. The participants were given opportunity to respond to two open ended statements: "Please describe what you remember as unpleasant during your Intensive Care Unit stay" and "Please describe what you remember as pleasant during your ICU stay." Samuelson found that of the 250 patients included, 203 (81%) remembered being in the ICU, 178 (71%) had recall of unpleasant memories and 147 (59%) of pleasant memories. Patients also expressed the discomfort of suffering from pain, thirst, feeling sick, dizziness, or the feeling of heartburn and described the inability to communicate discomforts with the medical staff. Samuelson concluded that most mechanically ventilated survivors had both unpleasant and pleasant memories, though often times the unpleasant memories overshadowed the pleasant memories.

Use of the BPS to Assess Pain

Payen et al. (2001) performed a quantitative descriptive evaluation study in order to validate and identify the reliability of a new behavioral pain scale (BPS) for critically ill sedated adult patients. The subjects of their study were 30 mechanically ventilated patients who were receiving pain medication and sedation in a 10-bed trauma and surgical intensive care unit at a university teaching hospital. Payen et al. found that painful stimulations resulted in significantly
higher BPS values than non-painful procedures (4.9 vs. 3.5, \( p < .01 \)), and the two groups had comparable BPS values before the procedure was started (3.1 vs. 3.0). A trend was also identified between the dosage of sedation/pain medication and BPS: the higher the dosage, the lower the BPS values and BPS changes to painful stimulation. The results provided by Payen et al. indicate that the presence of pain can be assessed reliably and accurately by using the BPS in sedated, mechanically ventilated patients.

Morete, Mofatto, Pereira, Silva, and Odierna (2014) performed a quantitative prospective evaluation on mechanically ventilated adults admitted to an intensive care unit in a large private hospital located in São Paulo. Morete et al. (2014) intended to adapt the BPS developed by Payen et al. (2001) to Brazilian Portuguese and to evaluate the psychometric properties of the scale. In regards to reliability and clinical utility, Morete et al. found that the observed agreement between the assessments was 92.08% for compliance with mechanical ventilation, 88.1% for upper limb movement, and 90.1% for facial expression evaluation. The kappa coefficient of agreement for “adaptation to mechanical ventilation” was found to be .740. Good agreement was observed between the assessments with an intra-class correlation coefficient of .807 (95% CI: 0.727-0.866). Therefore, Morete et al. concluded that the BPS was easy to manage, reproduce and that the scale had adequate internal consistency.

Dehghani, Tavangar, and Ghandehari (2014) performed a quantitative descriptive prospective study to evaluate the validity and reliability of the BPS in patients with low level of consciousness due to head trauma hospitalized in the intensive care unit. The study was performed in Yazd and included the assessments of 50 adult intensive care patients. The researchers collected information on patients including age, sex, and the Glasgow coma scale score as well as a checklist of behavioral pain scale criteria. Dehghani et al. (2014) found that
there was no significant difference in average score of BPS scores recorded by two separate day and night evaluators ($P > .05$). They found the average score during painful procedures was 7.79 in the morning and 7.71 at night ($P = .135$). The average score during non-painful procedures was 3.30 in the morning and 3.26 at night ($P = .569$). These results confirmed that the BPS during procedures in the morning and at night were not significantly different, further confirming the reliability aspect of the scale. It was concluded that the BPS has strong reliability and validity in patients with low levels of consciousness related to head trauma, indicating that the scale could be successfully implemented for use in the intensive care unit (Dehghani, Tavangar, & Ghandehari, 2014).

Liu, Li, and Herr (2015) conducted a quantitative prospective observational study that focused on 117 adult critically ill patients in a general intensive care unit within a university hospital in China. The study aimed to examine and compare the reliability and validity of two observational pain assessment tools, including the BPS and CPOT. In an effort to assess the scales, Liu et al. (2015) assessed patients’ pain on both scales before and after routine painful procedures and routine procedures including suctioning and non-invasive blood pressure checks. Liu et al. found that scores of the CPOT and the BPS during painful procedures (P1) were both significantly higher than those during non-painful procedures (NP1) ($Z = -14.352, P < .001; Z = -14.440, P < .001$) and scores during the painful procedures (P1) were higher than those at rest before the painful procedures. A Spearman correlation analysis also showed scores of the CPOT and the BPS was strongly correlated ($r = 50.951, P < .001$). Therefore, it was concluded that the CPOT and the BPS were reliable and valid tools to assess pain in Chinese intubated and non-intubated patients within a general intensive care unit (Liu, Li, & Herr, 2015).
Chanques et al. (2014) performed a quantitative statistical comparison study to evaluate the inter-rater agreement, validity, responsiveness, and feasibility of three observational pain scales, including the BPS, CPOT, and the Non-verbal Pain Scale (NVPS). This study was based on 20 bedside nurses’ assessment of pain in critically ill patients within a 16-bed medical intensive care unit. Chanques et al. measured data obtained by separate nurses assessing pain simultaneously using all the scales before, during and 10 minutes after routine care procedures. Following assessment of pain, the nurses rated the three tools on a scale (0 = the worst, 10 = the best) for accuracy, usefulness and ease of learning. Chanques et al. found that nurses scored all three at a median of 7 to 8 for accuracy, usefulness, and ease of learning. The BPS was rated higher with regard to ease of learning than the CPOT ($P = .02$), but the BPS was the same as the NVPS ($P = .07$): BPS, 8 (7–10); CPOT 8 (5–8), NVPS 8 (6–8). There was no significant difference (all $p$ values >.49) between the three tools with regard to accuracy (Chanques et al., 2014). It was concluded that all three tools demonstrate good inter-rater reliability in both intubated and non-intubated intensive care patients unable to self-report their pain. However, the researchers did determine that the BPS and CPOT have significantly higher inter-rater reliability, internal consistency and responsiveness than NVPS (Chanques et al., 2014).

Pudas-Tähkä, Axelin, Aantaa, Lund, and Salanterä (2009) performed a systematic review of 1586 abstracts, 58 full-text articles from 7 databases in an effort to review instruments developed for pain assessment in unconscious or sedated intensive care patients. Five separate pain assessment tools were identified, including the BPS, which had been used with unconscious or sedated intensive care patients. All five instruments reviewed by Pudas-Tähkä et al. (2009) included behavioral indicators and three of the instruments included physiological indicators. However, the psychometric properties of the instruments included in this review varied and
evidence of the dependability of the scales were non-conclusive. It was also not possible to determine the tools’ clinical usefulness (Pudas-Tähkä et al., 2009). Pudas-Tähkä et al. stated “that before any of these instruments can be regarded as the gold standard, it is essential to further research their validity, reliability and feasibility (p. 954).”

**Use of the CPOT to Assess Pain**

Topolovec-Vranic et al. (2013) performed a quantitative prospective repeated-measures study to validate the clinical utility of two pain assessment tools, the revised Adult Non-Verbal Pain Scale (NVPS-R) and the CPOT. This study was conducted in a trauma and neurosurgical patient population and included 66 patients within a 19-bed intensive care unit at an urban teaching hospital. In an effort to validate the two scales, a study was designed where assessments were completed using the NVPS-R and the CPOT during two procedures: a painful procedure of turning of the patient and a non-painful procedure of checking a noninvasive blood pressure. Assessments were completed at several different intervals including 5 minutes before the procedure, during the procedure, and 20 minutes following the procedure, for both painful and non-painful events (Topolovec-Vranic et al., 2013). Findings by Topolovec-Vranic et al., supported that both the CPOT and the NVPS-R scores increased when participants were exposed to turning but not during blood pressure cuff inflation. Also, mean scores with turning (before, during and after) were higher for non-communicative patients compared with communicative patients using both tools. Generally acceptable intraclass correlation coefficients (ICC) were observed for the CPOT (.60 to .97) and generally lower ICC were observed for the NVPS-R (.34 to .92). With these results, Topolovec-Vranic et al. concluded that the CPOT and NVPS-R were validated for use in assessing pain in communicative and non-communicative patients in the
trauma and neurosurgical intensive care unit. However, Topolovec-Vranic et al. also concluded that the inter-rater and concurrent validity were weaker for the NVPS-R than the CPOT.

Echegaray-Benites, Kapoustina, and Gélinas (2014) conducted a quantitative repeated-measure within subject prospective study that aimed to validate the CPOT in neurosurgery patients. The study focused on 43 elective neurosurgery patients within a Canadian university hospital. Patients were assessed using the CPOT during two separate nursing procedures, a painful procedure of turning and non-painful procedure of non-invasive blood pressure checks. For each procedure, the CPOT was used to assess pain at rest, during the procedure and 15 minutes after the procedure. Echegaray-Benites et al. (2014) found that the median CPOT score increased significantly from 0 during non-invasive blood pressure checks to 2 during turning (Z = 4.40, p < 0.001). ICC was also calculated and obtained for the CPOT scores obtained at each assessment. All ICC scores showed high agreement (all ICC > 0.75). Echegaray-Benites et al. concluded that the CPOT appeared to be valid for the detection of pain in elective brain surgery patients in the neurosurgical intensive care unit.

Rijkenberg, Stilma, Endeman, Bosman, and Oudemans-van Straaten (2015) studied 68 mechanically ventilated critically ill patients unable to report pain in an effort to compare the validation and reliability of the CPOT and the BPS at the same time. They focused their study on mechanically ventilated patients within a mixed adult ICU in Amsterdam, the Netherlands. All patients were assessed at bedside after admission to the unit. Rijkenberg et al. (2015) found that median BPS and CPOT scores of all 68 patients increased by 2 points from rest when conducting a painful procedure. The median BPS scores between rest and the non-painful procedure showed an increase of 1 point, but the median CPOT score remained unchanged. Cronbach’s alpha values were determined and showed that the BPS and CPOT had acceptable internal consistency.
reliability during the painful procedure of turning (0.70 and 0.71). With these results, Rijkenberg et al. concluded that both the CPOT and the BPS had a fair to good interrater reliability, but after determining discriminant validation, the CPOT was found to be more effective than the BPS in assessing pain.

Gélinas et al. (2014) performed a descriptive quantitative study that aimed to describe nurses’ evaluations of the feasibility, clinical relevance and satisfaction with the CPOT 12 months after being implemented. This study focused on nurses within a medical-surgical intensive care unit in Quebec Canada. Gélinas et al. offered all nurses using the tool after one year a questionnaire to rate it, in which 38 nurses responded. Gélinas et al. found that in regards to feasibility, a majority of the nurses rated the CPOT as quick to use, simple to understand and easy to complete (92–100%). In regards to clinical relevance, it was found that close to 70% of the nurses reported that the CPOT had influenced their practice, but reported lower results (<50%) for effectiveness of pain assessment. Gélinas et al. concluded that the CPOT use was found to be feasible and relevant in nurses’ daily practice, and it also provided an effective handoff from nurse to nurse in regards to patients’ pain. However, the tool was found to be limited in its ability to provide effective handoff with other ICU care team members due to lack of use and familiarity with the tool (Gélinas et al., 2014).

Gélinas, Tousignant-Laflamme, Tanguay and Bourgault (2011) conducted a study that explored the validity of the bispectral (BIS) index (mean arterial pressure and heart rate), activity (EMG) of the corrugator superciliii muscle, the CPOT score, and vital signs during rest and painful procedures in sedated and mechanically ventilated critically ill adults. This quantitative pilot study was conducted on nine participants from the surgical and medical ICUs of a 642 bed tertiary healthcare center in a suburban region of the province of Quebec in Canada. Gélinas et
al. (2011) found that both BIS parameters and CPOT increased during painful procedures of turning and endotracheal suctioning (median increase of CPOT from 0 to 3) when compared to rest. Gélinas et al. concluded that the BIS index, EMG and the CPOT score were found to be higher during known painful procedures. The BIS index and the CPOT were found to be much more sensitive indicators than vital signs, which remained unchanged through painful events (Gélinas, Tousignant-Laflamme, Tanguay & Bourgault, 2011).

Arbour, Gélinas, and Michaud (2011) conducted a quantitative before-and-after pilot study to explore the impact of the implementation of the CPOT on pain management and clinical outcomes in critically ill mechanically ventilated trauma patients. This pilot study evaluated 30 medical files including 15 pre- and 15 post evaluations of the implementation of the CPOT. All patients included in the study were admitted to the unit following a trauma and had been intubated and mechanically ventilated for at least 24 hours. Arbour et al. (2011) found that length of stay in the ICU was reduced in half after the implementation of the CPOT. Also, the post-implementation CPOT group showed a lower number of complications than those of the pre-implementation group ($P < .05$). Given the results, Arbour et al. concluded that the post-CPOT implementation group showed a lower number of complications and a tendency toward a shorter ICU length of stay than those in the pre-implementation group. The researchers also concluded that there was an increased frequency of pain assessments and identification of pain episodes following CPOT implementation (Arbour, Gélinas, & Michaud, 2011).

Summary

Accurate pain assessment is paramount in the critically ill patient. Observational pain scales such as the BPS and CPOT have been found to be valid and effective in their individual assessment of pain in critically ill patients. The implementation of observational pain scales have
also been shown to improve patient outcomes as shown in the study conducted by Arbour et al. (2011). However, in comparison studies between the BPS and CPOT scales, as noted by Chanques et al. (2014) and Rijkenberg et al. (2015), there is conflicting evidence on which scale is superior in regards to ease of learning and effectiveness in detecting pain. Furthermore, there have been limited studies such as Chanques et al. (2014) and Gélinas et al. (2014) that have addressed nurses’ evaluations of the tools. Therefore, more research is needed in the areas of comparison studies to confirm the validity and reliability of the observational pain scales. Further research is also needed in the area of nurses’ evaluations to evaluate the feasibility of the tools. As suggested by Pudas-Täähkä et al. (2009), further research is a necessity before one of these tools can be considered a “gold standard” for pain assessment in the mechanically ventilated critically ill patient. Pain in the critical care patient is essential to assess and treat because pain can cause a host of issues including increased sympathetic nervous system activity, noncompliance with ventilation, and higher risks for cardiovascular events (Ayasrah, 2016). Given the impact and effects of pain, it is imperative that these observational tools be further evaluated so pain in the critically ill nonverbal patient pain can adequately be assessed.
Chapter 3: METHODS

This study focused on the comparison of the Behavioral Pain Scale and Critical Care Pain Observation Tool in assessing pain in critically ill ventilated patients. The study evaluated the relationship between the BPS and the CPOT in assessing pain in ventilated critical care patients and aim to identify the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the BPS compared to the CPOT. This chapter will discuss the research designs, population and setting, data collection procedures, instruments, threats to validity, procedures for the protection of human subjects, and data analysis plan.

Study Design

The research questions that were addressed in this study are:

1.) What is the relationship between the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in assessing pain in ventilated critical care patients?

2.) What is the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale compared to the Critical-Care Pain Observation Tool?

This study followed a non-experimental, correlational, comparative design. The correlational research design allows for the relationship of multiple variables to be examined (Polit & Beck, 2017). The correlational structure for this study evaluated the variables of pain score at rest and following a normal routine nursing intervention that is generally thought to be painful such as turning or routine endotracheal suctioning. Through the use of the correlational design, the strength of the tools in identifying the presence of pain was evaluated. The effectiveness of the tools in identifying the presence of pain as well as nurses’ evaluations of the tools was utilized to compare the CPOT and BPS. The correlational and comparative methods were utilized and
served as the best approach to explore nonexperimental relationships since experimental manipulation of variables is not ethically feasible in human subjects (Polit & Beck, 2017).

**Population and Setting**

This nonexperimental, correlational, comparative research was conducted in a midsized community hospital in the southeastern U.S. Pain assessments were evaluated on mechanically ventilated critically ill patients in an eight-bed surgical intensive care unit within the medical facility. This eight-bed unit received a variety of patients including post-surgical, trauma, psychiatric, and medical over flow patients. Only patients that were mechanically ventilated were evaluated. Professional registered nurses employed within the surgical intensive care unit were the ones evaluating patients utilizing the CPOT and BPS. On a normal operating day, four registered nurses staff the surgical intensive care unit each shift. These professional registered nurses must hold a current nursing license within their state of practice in order to be employed by the facility. Nurses were trained and had to perform a dual assessment alongside the researcher prior to being able to conduct pain assessments independently.

**Data Collection Procedures**

The data collection plan for this study included collecting data via observation utilizing the BPS and CPOT scales as well as utilizing a questionnaire to compare the feasibility, clinical relevance and satisfaction evaluation of the two pain scales, along with a demographic survey. The CPOT (Gélinas et al., 2006) and BPS (Payen et al., 2001) were researched and found to have validity and reliability. Data collection occurred between June and July of 2017.

**Research Question 1**

The nurse researcher was responsible for collecting the data. The nurse researcher composed a packet consisting of envelopes, a consent form (Appendix A), copies of each scale, a
written step-by-step reference sheet, and scale scoring sheets. Each participating nurse received a packet. Additional scoring sheets were stored by the collection bin in the nurses’ lounge when needed. Nurses were recruited within the surgical intensive care unit within a midsized community hospital in the Southeastern U.S. on each shift including weekdays, weeknights, and weekend days and nights. The nurse researcher posted fliers (Appendix B) in the break room that offered education times for each shift of nurses and offer the opportunity to participate in the study. The flier also stated that nurses that participated had the chance to win a twenty-five dollar gift card to Walmart. Nurses that responded attended a brief training session in which they were trained on how to conduct the CPOT and BPS assessment and complete competency checkoff with the nurse researcher. During this training class, each question of each scale was covered and explained. Each participating nurse had to complete a dual assessment with the nurse researcher to ensure competency. Once the project began, these nurses filled out the BPS and CPOT assessments on the provided scoring sheets, and nurses placed the assessments each shift in a sealed envelope and placed in a labeled collection bin inside the nurses’ lounge. Pain on the two scales were measured at rest, following a routine non-painful nursing intervention, noninvasive blood pressure check, and following a routine nursing intervention known to be painful, turning. The painful procedure assessment needed to be conducted at least five minutes apart from the nonpainful nursing procedure assessment. The scales were used for routine scheduled nursing care procedures that would be done despite the research project. The CPOT and BPS assessments were used for data collection purposes, and were not used to treat patients. Only the approved hospital pain assessment procedure was used to treat pain. The nurse conducting pain assessments were asked to repeat the pain assessments three times throughout their shift. The nurse researcher collected these assessments weekly and place in storage bin inside a locked
office. A power analysis was conducted using G Power software (Faul, Erdfelder, Lang, & Buchner, 2007) to estimate sample size to ensure adequate statistical power for data analysis. With a power of .80, an α value of .05, and an effect size of 0.30, 84 BPS completed questionnaires and 85 CPOT completed questionnaires were needed for the sample.

**Research Question 2**

Following collection of the behavioral pain scale data, a set time was arranged to distribute the designed evaluation and demographic questionnaires for each scale to nurses that participated. Participants were asked to complete the questionnaire before leaving the designated completion area. Participants answered each of the questions concerning the feasibility, clinical relevance, and satisfaction surveys on the BPS and CPOT, as well as the provided demographic questions. These questionnaires were placed in sealed envelopes and collected by the nurse researcher. This process was carried out to prevent bias or influence from others. This step promoted accuracy and reflected the true opinion of the responder. Upon receipt of the participant’s completed packet, a raffle ticket was provided to the participants. Participants dropped the ticket in a designated bin. The drawing was completed after all data was collected and the drawn ticket holder won the twenty-five dollar Walmart gift card.

**Instruments**

The data collection in this thesis project was obtained utilizing the BPS and CPOT scales as well as utilizing a questionnaire to compare the feasibility, clinical relevance and satisfaction evaluation of the two pain scales. The CPOT (Gélinas et al., 2006), BPS (Payen et al., 2001), and referenced tool evaluation questionnaire (Gélinas et al., 2014) have been researched and found to have validity and reliability. A demographics questionnaire was also created and utilized. The following paragraphs will discuss each of the tools individually.
Behavioral Pain Scale (BPS)

The Behavioral Pain Scale (Appendix C) was developed by Payen et al. in 2001 and a corresponding quantitative study was conducted to validate and identify the reliability of the behavioral pain scale for critically ill sedated adult patients. The subjects of their study were 30 mechanically ventilated patients who were receiving pain medication and sedation in a 10-bed trauma and surgical intensive care unit at a university teaching hospital. The tool developed by Payen et al. (2001) includes a scale from 1-4 in the areas of “facial expression”, “upper limb movement”, and “compliance with ventilation”. In each area, the numbers have corresponding measurements where a score of “1” would most likely be associated with the absence of pain and a “4” being the presence of intense pain. The study was conducted by assessing pain at three separate times within the day. Nurses were asked to obtain a scaled measurement at rest initially. Nurses were then asked to collect a measurement following a routine nursing intervention not known to cause pain such as sequential compression device application or a central venous catheter dressing change. Next, nurses were asked to collect another measurement following a routine nursing intervention that is known to cause discomfort such as endotracheal suctioning or turning, however they were asked to collect them at least thirty minutes apart from the other measurements.

Statistical analysis was completed on 269 total assessments and showed that painful stimulations resulted in significantly higher BPS values than non-painful procedures (4.9 vs. 3.5, \( p < .01 \)), and the two groups had comparable BPS values before the procedure was started (3.1 vs. 3.0). A trend was also identified between the dosage of sedation/pain medication and BPS: the higher the dosage, the lower the BPS values and BPS changes to painful stimulation (Payen
et al., 2001). The magnitude of difference between evaluators and chance agreement were also calculated with a weighted kappa test of 0.74 and shown to be statistically significant ($p < .01$).

Validity is generally assessed by comparing results with standard criterion, however on creation of the BPS, no scale that measured pain in ICU patients had been tested for validity previously, and as a result, Payen et al. (2001) assessed validity by gathering indirect arguments assessing whether the BPS really measured the level of pain. The researchers submitted each BPS evaluation to the care procedures that were known to be either non-painful or painful. In knowing that each of these procedures was either painful or non-painful, if BPS scores between non-painful and painful procedures could be obtained and showed significant differences, provided support for the discriminating value of the BPS in evaluating painful aspects of a procedure. Another indirect support for the validity of the BPS in measuring pain included the correlation found between sedation and analgesia in relation to the BPS score. The analysis of the data indicated that lower BPS scores were assessed on patients with higher doses of analgesia/sedation. Based on the paired patient assessments completed in the study, the BPS was found to be a reliable assessment of pain (Payen et al., 2001). Payen et al. also suggest that the correlated and rated kappa scores are very similar to those studies validating other pain and sedation scales. Permission to use the BPS tool in this thesis study was obtained from Jean-Francois Payen, one of the researchers and contacts listed in the study (Appendix D).

**Critical Care Pain Observation Tool (CPOT)**

The CPOT (Appendix E) was developed by Gélinas, Fillion, Puntillo, Viens, and Fortier in 2006 to be tested and validated for use in assessing pain for the critically ill patient who was unable to verbally communicate. The CPOT was originally developed in the French language, and consists of four sections, which include: facial expression, body movements, muscle tension,
and compliance with the ventilator for intubated patients or vocalization for extubated patients. Each of the areas are scored from 0 to 2, with a possible total score ranging from 0 to 8 overall with a lower scale indicating less pain than a higher one (Gélinas et al., 2006). Gélinas et al. (2006) conducted a quantitative research study on 105 cardiac surgery patients in the intensive care unit. Pain scales were collected throughout 3 different periods of the patients stay, including when the patient was intubated and unconscious, intubated and conscious, and when the patient was extubated and conscious. Gélinas et al. (2006) established content validity of the CPOT by having four physicians and 13 critical care nurses complete a questionnaire on the relevance of the inclusion of these indicators within the CPOT. Content validity indices were calculated to be 0.88 to 1.00, and were determined to be sufficiently satisfactory to add all four sections to the final CPOT product (Gélinas et al., 2006).

The CPOT was also shown to have interrater reliability and criterion and discriminant validity (Gélinas et al., 2006). Both the primary researcher and critical care nurse performed assessments at nine separate times, and were unaware of the other’s score. Weighted kappa coefficients were moderate to high at all assessments. Gélinas et al. (2006) obtained mean CPOT scores and compared them to patients' self-reports of the presence or absence of pain during the second testing period and the results showed that CPOT scores were significantly higher for intubated patients reporting pain than for those who had no pain. Mean pain intensity scores were also found to be significantly higher during the positioning procedure when compared to those at rest in all three testing periods. Spearman correlations were also determined to be 0.49, 0.59, and 0.40 ($P \leq 0.001$) indicating that patients' self-reported pain intensity scores were moderately correlated with the CPOT scores (Gélinas et al., 2006). Gélinas et al. concluded that their findings validated the CPOT tool to assess pain in critically ill patients. Permission to
reproduce and use this CPOT tool in my study was obtained from Michael Muscat, who is the publishing manager for the American Association of Critical Care Nurses (Appendix F).

Nurses’ Evaluation with the Feasibility, Clinical Relevance and Satisfaction of the Tools

Gélinas et al. (2014) performed a study that aimed to describe nurses’ evaluations with the feasibility, clinical relevance and satisfaction with the CPOT 12 months after being implemented. This study focused on nurses within a medical-surgical intensive care unit in Quebec Canada. Gélinas et al. (2014) offered all nurses using the CPOT tool (Appendix G) after one year a questionnaire to rate it, in which 38 nurses responded. The self-administered evaluation tool consisted of closed-ended questions on a Likert scale of 1 to 4 that measured the feasibility, clinical relevance and satisfaction with the CPOT. Through use of the developed evaluation tool, Gélinas et al. (2014) was able to assess nurse’s opinions on the CPOT. For this study, permission to utilize the tool and to use the same questions to assess the BPS was obtained from John Wiley and Sons. John Wiley and Sons are the producers of the Nursing of Critical Care Journal where the research was initially published (Appendix H).

Demographic Survey

A demographic survey (Appendix I) was attached to each evaluation questionnaire that assessed the variables of sex, race, age, highest college degree that was achieved, national certification and years of nursing experience. Each of the variable measurements were classified on the nominal, ordinal, interval, or ratio level of measurement. By measuring each of these demographic variables, data was presented with the results so the study can be replicated to test for generalizability. In the study, data on age and years of nursing experience were measured on the ratio level. When asked on the survey, options or categories were not be provided, but rather participants just entered a number. Both of these questions are important to discuss the
experience of nurses involved in the study. Ratio measurements such as these can be presented as a mean or averages along with a standard deviation since all arithmetic measurements were possible (Polit & Beck, 2017).

Ordinal data was collected for the highest college degree and presence of a national certification. Options such as diploma, associates, bachelor's, etc. were placed on the survey for participants to choose from. Limited mathematic operations are appropriate for this level, and data is generally presented as frequency counts or percentages (Polit & Beck, 2017). The variables of sex and race were measured on the nominal level because these areas are solely categorical. Like ordinal data, mathematical operations are limited and data can only be presented in frequency tables or percentages (Polit & Beck, 2017).

Data Security

Participant confidentiality was assured through restriction of data access and no use of identifying information. Only the student nurse researcher and school faculty have access to the data. All data was locked and secured in a file cabinet. All data will be destroyed once the study is completed.

Threats to Validity

Given the limitations of the study there are several threats to validity out of the control of the researcher. Internal threats to validity included the research design as it relates to varied assessment skills of the nurses and nurses’ discussion of the study amongst themselves. Though all nurses attended the same training class and was supervised completing an assessment, the subjective nature of assessment cannot be eliminated. Nurses were also encouraged to complete assessments independently and free of outside influence, however given the close proximity of
work conducted within the ICU environment, the nurse researcher had no way to prevent project
discussion amongst the nursing staff.

External threats to validity included the generalizability of the study to other populations.
The study is being conducted within one midsized community hospital in the southeastern US. A
convenience sample of critical care nurses were only selected from this one hospital within the
southeastern US. Both could limit the generalizability of the findings.

Data Analysis

IBM SPSS 24.0 software will be utilized to compute and report statistical data following
data collection. Descriptive and inferential statistics were both used in this study. Descriptive
statistics such as frequencies, percentages, means, and standard deviations were utilized to
describe demographic variables and scores for the CPOT, BPS, and the nurses’ evaluation tool.
Correlational statistics such as Pearson’s r were used to analyze the relationships between the
CPOT and the BPS scores. Paired t tests examined the differences in nurses’ evaluation between
the CPOT and BPS.

Protection of Human Subjects

Prior to implementation of the research or data collection procedures, Institution Review
Board (IRB) approval was obtained from the IRB of the hospital in which the research study is
being conducted and from the Kennesaw State University IRB. This process involved a
presentation of the proposed research study in front of the hospital board that reviewed and asked
questions concerning the study. This presentation took place in late April, 2017. Following
hospital approval (Appendix J), the nurse researcher sought approval from the Kennesaw State
IRB in a similar format with a written request for approval (Appendix K). All revisions
recommended by each IRB were made and resubmitted as necessary prior to starting the data
collection. After recruitment of nurses for the data collection process, each nurse was provided a consent form (Appendix A) which explained their role and participation in the research process. Each nurse was provided a copy, which explained that their participation in the study is strictly voluntary and their intent to proceed and complete the provided questionnaires denotes their consent.
Chapter 4: Results

This chapter presents a summary of the analyzed data from the study. The analysis of the data will include a discussion on instrument reliability, the results of the BPS and CPOT pain assessments, description of the demographics of those who participated in the study, and data concerning nurse’s evaluations of the feasibility, clinical relevance, and satisfaction with the use of the two pain scales. The findings of each of the research questions will be presented. The research questions for this study included: 1) What is the relationship between the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in assessing pain in ventilated critical care patients? 2) What is the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale compared to the Critical-Care Pain Observation Tool?

Instrument Reliability

Internal consistency reliability was assessed for the questionnaires assessing the Behavioral Pain Scale (BPS) for feasibility, clinical relevance, and satisfaction and for the questionnaires assessing the Critical Care Pain Observation Tool (CPOT) for feasibility, clinical relevance, and satisfaction by calculating Cronbach’s alpha reliability coefficients. The Cronbach’s alpha reliability coefficient assessing reliability of the nurses’ questionnaires concerning feasibility, clinical relevance, and satisfaction with the CPOT was found to be 0.921. The Cronbach’s alpha reliability coefficient with the questionnaire assessing reliability of the nurses’ questionnaires concerning feasibility, clinical relevance, and satisfaction with the BPS was found to be 0.950. The results of these Cronbach’s alpha reliability coefficients indicate that the two questionnaires demonstrate high levels of internal consistency reliability.
Results of Research Question 1

Research question one examined the relationship between the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in assessing pain in ventilated critical care patients.

Behavioral Pain Scale (BPS)

The potential range of pain scores on the BPS was 4 to 12 (Table 1). Eighty-five total assessments were conducted and the BPS was measured when patients were at rest, following a normal noninvasive blood pressure check, and after turning. BPS scores ranged at rest from 3 to 9 with a mean of 3.600 ($SD = 1.125$). BPS scores ranged after a normal blood pressure check from 3 to 9 with a mean of 3.906 ($SD = 1.171$). BPS scores ranged after turning from 3 to 10 with a mean of 6.377 ($SD = 2.664$). The results suggest that the average BPS scores did increase from initial resting scores following turning, which is known to be a painful procedure.

Critical Care Pain Observation Tools (CPOT)

The potential range of pain scores on the CPOT was 0 to 8 (Table 1). Eighty-five total assessments were conducted and the CPOT was also measured when patients were at rest, following a normal noninvasive blood pressure check, and after turning. CPOT scores ranged at rest from 0 to 6 with a mean of 0.894 ($SD = 1.512$). CPOT scores ranged after a normal blood pressure check from 0 to 6 with a mean of 1.212 ($SD = 1.604$). CPOT scores ranged after turning from 0 to 9 with a mean of 4.012 ($SD = 3.080$). The results suggest that the average CPOT scores did increase from initial resting scores following turning, which is known to be a painful procedure.
Table 1

**Score Ranges, Means, and Standard Deviations for the BPS and CPOT (N = 85).**

<table>
<thead>
<tr>
<th></th>
<th>CPOT at Rest Total</th>
<th>BPS at Rest Total</th>
<th>CPOT BP Total</th>
<th>BPS BP Total</th>
<th>CPOT Turning Total</th>
<th>BPS Turning Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potential Range Scores</strong></td>
<td>0-8</td>
<td>3-12</td>
<td>0-8</td>
<td>3-12</td>
<td>0-8</td>
<td>3-12</td>
</tr>
<tr>
<td><strong>Participant's Range Scores</strong></td>
<td>0-6</td>
<td>3-9</td>
<td>0-6</td>
<td>3-9</td>
<td>0-8</td>
<td>3-10</td>
</tr>
<tr>
<td><strong>M</strong></td>
<td>0.894</td>
<td>3.600</td>
<td>1.212</td>
<td>3.906</td>
<td>4.012</td>
<td>6.377</td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td>1.512</td>
<td>1.126</td>
<td>1.604</td>
<td>1.171</td>
<td>3.080</td>
<td>2.664</td>
</tr>
</tbody>
</table>

**Correlations between BPS and CPOT**

Statistically significant relationships were found between the BPS and CPOT scores at rest \( r(85) = 0.821, p = .01 \), after taking a noninvasive blood pressure \( r(85) = 0.815, p = .01 \), and after turning \( r(85) = 0.906, p = .01 \). BPS and CPOT scores had positive high correlations at each level of pain assessment. The correlation strengthened following turning indicating that both pain assessment tools do tend to increase and reflect sensitivity.

**Sample Characteristics**

Overall, 85 total pain assessments were collected by seven nurses, including the primary investigator. As participation was strictly voluntary, 7 out of 14 (50%) of the full time surgical intensive care staff members chose to participate and fill out the follow up questionnaires. Of the participants, a majority were female \( (n = 5, 71.4\%) \) with a small representation of males \( (n = 2, 28.6\%) \) and all participants were Caucasian \( (n = 7, 100\%) \). Participants ranged in age from 26 to 54 \( (M = 47.2857, SD = 15.40254) \) and years of experience ranged from 4 to 38 years \( (M = 21.1429, SD = 13.34702) \). All nursing participants had degrees, which were either associate's degrees \( (n = 5, 71.4\%) \) or bachelor's degrees \( (n = 2, 28.6\%) \). A majority of the nurses that participated also
had national certifications \((n = 5, 71.4\%)\). Table 2 displays all the demographic data from nurses that participated.

Table 2  

Demographic Characteristics \((N = 7)\).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>47.29</td>
<td>15.40254</td>
</tr>
<tr>
<td>Years of Experience</td>
<td>21.14</td>
<td>13.34702</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>28.6</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>71.4</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associate's</td>
<td>5</td>
<td>71.4</td>
</tr>
<tr>
<td>Bachelor's</td>
<td>2</td>
<td>28.6</td>
</tr>
<tr>
<td>National Certification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>71.4</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>28.6</td>
</tr>
</tbody>
</table>

Research Question 2

Research question two examined the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale compared to the Critical-Care Pain Observation Tool.

Nurses’ Evaluation with the Feasibility, Clinical Relevance, and Satisfaction of the Tools

There was not a statistically significant difference between nurses’ perceptions of the feasibility with the use of the Behavioral Pain Scale \((M = 3.3214, SD = .57217)\) compared to the
Critical-Care Pain Observation Tool (M = 3.7143, SD = .46611), t(7) = 4.260, p = .005. There was also not a statistically significant difference between nurses’ perceptions of the clinical relevance with the use of the Behavioral Pain Scale (M= 2.9592, SD= .59313) compared to the Critical-Care Pain Observation Tool (M= 3.6939, SD= .39922) t(7)= 3.753, p= .009. Likewise, there was not a statistically significant difference between nurses’ perceptions of satisfaction with the use of the Behavioral Pain Scale (M = 2.8571, SD = .69007) compared to the Critical-Care Pain Observation Tool (M = 3.7143, SD = .48795), t(7) = 3.286, p = .017. Results, along with questions included in each category are listed in Table 3.

Table 3

*Nurse Participants’ Responses to the BPS/CPOT Questionnaires about the Feasibility, Clinical Relevance and Satisfaction with the BPS/CPOT use in the ICU (n=7)*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>BPS</th>
<th>CPOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M=3.3214</td>
<td>M=3.7143</td>
</tr>
<tr>
<td></td>
<td>SD=.57217</td>
<td>SD=.46611</td>
</tr>
<tr>
<td>1) Is the BPS/CPOT quick to use?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Were the directives about the use of the BPS/CPOT clear?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Is the BPS/CPOT simple to understand?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Is the BPS/CPOT easy to complete?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Relevance Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>M=2.9592</td>
<td>M=3.6939</td>
</tr>
<tr>
<td></td>
<td>SD=.59313</td>
<td>SD=.39922</td>
</tr>
<tr>
<td>1) Is the BPS/CPOT helpful for nursing practice?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Has the BPS/CPOT influenced your practice in assessing the patient’s pain?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Has the BPS/CPOT allowed you to adequately evaluate pain in patients who are unable to communicate?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4) Has the BPS/CPOT allowed you to improve your practice in terms of pain management?

5) Has the BPS/CPOT helped you communicate effectively the results of the pain assessment to other members of the team:
   - Nurses
   - Doctors and residents
   - Other members of the team (physiotherapists, occupational therapists)

Satisfaction Score

1) How satisfied are you with the use of the BPS/CPOT Tool in ICU?
Chapter 5: Discussion

This chapter will focus on an interpretation of data, limitations of the study, and implications of the findings for future research.

Interpretation of Data for Research Question 1

The first research question addressed the relationships between the Behavioral Pain Scale (BPS) and the Critical-Care Pain Observation Tool (CPOT) in assessing pain in ventilated critical care patients. Eighty-five total assessments were conducted and the BPS and CPOT were both measured when patients were at rest, following a normal noninvasive blood pressure check, and after turning. BPS mean scores ranged from 3.600 at rest, to 3.906 with a noninvasive blood pressure check, to 6.377 following turning, and CPOT mean scores ranged from 0.894 at rest, to 1.212 following a noninvasive blood pressure check, to 4.012 following turning. Only a slight increase in mean scores was found between assessments conducted at rest and following a noninvasive blood pressure check. This was an expected finding, given that noninvasive blood pressure checks are classified as a non-painful procedure according to Payen et al. (2001). However, a greater increase was found between resting and turning, which supports the findings of Rijkenberg et al. (2015), whom found BPS and CPOT scores of studied patients increased by two points from rest when conducting a painful procedure. An increase in mean pain scores totals between rest and turning suggest that the tools do detect and reflect the presence of pain, as also concluded by Rijkenberg et al. (2015).

Statistically significant relationships were also found between the BPS and CPOT scores at rest $r(85) = 0.821$, $p = .01$, after taking a noninvasive blood pressure $r(85) = 0.815$, $p = .01$, and after turning $r(85) = 0.906$, $p = .01$, indicating that total scores on both assessment tools are sensitive and similar in the way they reflect pain. Sensitivity and correlational scores between the
two tools represent an expected finding concurrent with research conducted by Liu et al. (2015), Payen et al. (2001), and Gélinas, Fillion, Puntillo, Viens and Fortier (2006). These correlations also indicate that both the BPS and CPOT are similar in their ability to reflect pain consistently which also supports the findings of Chanques et al. (2014).

**Interpretation of Data for Research Question 2**

The second research question addressed the difference in nurses' evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale (BPS) compared to the Critical-Care Pain Observation Tool (CPOT). Seven nurses evaluated the scales, and their evaluations showed that the overall mean values between the BPS and CPOT did not show a significant statistical difference between the two scales in their feasibility, clinical relevance, or satisfaction. Though the difference was not statistically significant, mean scores were determined to be slightly higher for the CPOT in feasibility, clinical relevance, and satisfaction when compared to the mean evaluation scores of the BPS. These results do seem to slightly reflect the findings of Rijkenberg et al. (2015) which found that the CPOT was generally found to be more useful than the BPS in assessing pain.

The study also supported the decoding nature of the BPS and CPOT as described by The Social Communication Model of Pain (Hadjistavropoulos et al., 2011). The mean scores of nurses' evaluations on the BPS (M= 2.9592) and CPOT (M= 3.6939) in regards to clinical relevance does reflect that the scales did have an impact on increasing the likelihood that pain was decoded or detected by the nurses or care providers. The mean clinical relevance scores reflect that the two tools did moderately influence the nurses' practice of assessing pain and communicating it with the healthcare team. These results support findings from Dehghani et al. (2014) and Gélinas et al. (2014), which found that the BPS and CPOT were feasible and relevant
in nurses’ daily practice. Overall, these findings concerning the decoding nature of the two scales, as well as nurses’ evaluations of the scales support the argument of Georgiou et al. (2015), which recommends that pain assessment tools like the BPS and CPOT be used in every day nursing practice to assist nurses in accurately assessing pain in all patients.

**Limitations of the Study**

The study had a few limitations. One limitation of the study involved use of the behavioral pain scales in patients with actual or near brain death scenarios. In these scenarios, pain measurements provided minimal scores and could serve as a means of potentially skewing data results. However, in efforts to protect the privacy of patients, no identifiable information or diagnosis information was collected, making it impossible to distinguish the amount of significantly brain injured patients included in the study. Another limitation of this study included the varied assessment skills and subjective nature of the nurses performing the assessment. Though all nurses attended the same training class and were supervised completing an assessment, the subjective nature of assessment cannot be eliminated. Generalizability was also limited by use of a single midsized community hospital in the southeastern US, and a relatively small convenience sample of critical care nurses within this individual facility.

**Implications**

This study supports the utility of observational pain scales, such as the BPS and CPOT, to evaluate pain in mechanically ventilated critically ill patients. Pudas-Tähkä et al. (2009) found that further research was a necessity before one of these observational pain scales could be considered a “gold standard” for pain assessment in the mechanically ventilated critically ill patient. This study serves as further research to establish the gold standard for pain assessment so pain in the critically ill mechanically ventilated patient can be more appropriately managed.
Further comparative studies, such as this one, that evaluates the effectiveness and clinicians’ evaluations of observational pain scales are paramount to promote their usage and acceptance in the medical profession.

**Conclusion**

Effective pain assessment is paramount in critically ill patients. Critically ill patients are much more vulnerable to the side effects of untreated pain, and ineffective assessment of pain is associated with negative patient outcomes (Gélinas, 2016). Self-reporting pain remains the gold standard for pain measurement, and should be obtained whenever possible. This study has shown that observational pain scales, such as the Behavioral Pain Scale (BPS) and Critical Care Pain Observation tool (CPOT) are effective in measuring pain in the ventilated nonverbal patient. Though more comparative research is needed to establish a gold standard for observational pain scales, the comparative nature of this study can serve as a framework to reproduce and repeat going forward with hope of establishing a critical care nationally accepted observational pain scale.
References


Dehghani, H., Tavangar, H., & Ghandehari, A. (2014). Validity and reliability of behavioral Pain scale in patients with low level of consciousness due to head trauma hospitalized in
intensive care unit. *Archives of Trauma Research, 3*(1), e18608.

http://doi.org/10.5812/atr.18608


Appendix A

Nurse Informed Consent
Title: Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients

Principal Investigator: Tyler Weldon RN BSN
Faculty Advisor: Patricia Hart Ph.D.

I am seeking nurses in critical care units to participate in this research study. The purpose of the study is to:

1. Examine the relationship between the Behavioral Pain Scale (BPS) and the Critical-Care Pain Observation Tool (CPOT) in assessing ventilated critical care patients.
2. Examine the difference in nurses’ evaluation of the feasibility, clinical relevance, and satisfaction with the use of the Behavioral Pain Scale compared to the Critical-Care Pain Observation Tool?

Procedures: If you decide to participate, you will need to attend a mandatory training seminar in which you will be taught how to assess pain using both the CPOT and BPS. Following your collection of data, you will be asked to complete an evaluation of both tools which consists of 10 questions each and a demographic questionnaire which consists of 6 questions. The CPOT and BPS evaluation tool will ask questions concerning the feasibility, clinical relevance, and satisfaction of the two tools. The demographic survey will be attached to each evaluation questionnaire and filled out after participation in the study. The demographic questionnaire will assess the variables of sex, race, age, highest college degree that was achieved, national certification and years of nursing experience. Your completion of the training course and the questionnaires denotes your consent to participate.

Risks: There are no physical risks in participating in the study outside of typical exposure risks that come with any nursing care. You may experience the urge to discuss results or feel uneasy after completing some of the questions on the questionnaires due to reflecting on the outcomes of some of the evaluated patients.

Benefits: There may be no direct benefit to you for participating in this study. However, it is possible that through participating in this study that a new behavioral pain scale can be adopted for ventilated patients that would better benefit patient care in the future.

Incentives: The researcher will provide a drawing for a $25 Walmart gift card. Upon receipt of your completed packet a raffle ticket will be provided in which you can drop in a designated bin. The drawing will be completed after all data has been collected and the drawn ticket holder will win the prize.
**Confidentiality:** No personal identifying information will be collected or reported in the results of the study. The results will be presented in a group format without identifying information. Demographic questionnaires are only obtained to promote the generalizability of the study. You maintain all of your rights during the study.

**Voluntary Participation/Withdrawal:** Participation in this study is strictly voluntary. Participants have the right to drop out or to stop participating at any point in the study without any repercussions. You also have the right to refuse to answer any question on the provided questionnaires.

**Data Security:** Participant confidentiality will be assured through restriction of data access and no use of identifying information. Only the student nurse researcher, school faculty, and statistician will have access to the data. Data will be entered electronically and stored on a secured drive. All data will be kept secured, locked, and destroyed after the research study is completed.

**Contact Person:** If you have any questions or concerns about this study, you may contact the investigator: Tyler Weldon RN BSN @ jweldon@students.kennesaw.edu

**Institutional Review Board:** Research at Kennesaw State University involving human participants is conducted under the oversight of the Institutional Review Board. You may contact the Institutional Review Board with any questions or concerns regarding the protection of your rights. The address is as follows: Institutional Review Board, Kennesaw State University, 1000 Chastain Road, Kennesaw, GA, 30144, (678) 797-2268.
Appendix B

Nurse Recruitment Flier
**We Need You!!!**

**SICU NURSING PARTICIPANTS NEEDED**

I am conducting a research study to evaluate behavioral pain scales in mechanically ventilated patients and need your help in obtaining data.

A brief mandatory training class will be conducted to educate and to complete competency. Classes will be conducted at your convenience. All participants may enter into a drawing to win a

**$25 Walmart gift card.**

Your participation would be greatly appreciated. Please

Contact Tyler Weldon, RN BSN for further details.

Cell: 423-987-1387

Email: jweldon8@students.kennesaw.edu
Appendix C

Behavioral Pain Scale
**Behavioral Pain Scale Data Collection Sheet**

Directions: Assess your patient using the Behavioral Pain Scale. Patients should be assessed at rest, following a normal blood pressure check, and immediately after turning. Data can be collected up to 3 times per shift. Record the scores in the appropriate boxes. Allow at least five minutes between each measurement. **Remember, this tool is to be used for the research study only, and should NOT be used to guide treatment.**

<table>
<thead>
<tr>
<th>Date:</th>
<th>Facial Expression</th>
<th>Upper Limbs</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date:</th>
<th>Facial Expression</th>
<th>Upper Limbs</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date:</th>
<th>Facial Expression</th>
<th>Upper Limbs</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Behavioral Pain Scale (BPS)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial expression</td>
<td>Relaxed</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Partially tightened (e.g., brow lowering)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Fully tightened (e.g., eyelid closing)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Grimacing</td>
<td>4</td>
</tr>
<tr>
<td>Upper limbs</td>
<td>No movement</td>
<td>1</td>
</tr>
<tr>
<td>movements</td>
<td>Partially bent</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Fully bent with finger flexion</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Permanently retracted</td>
<td>4</td>
</tr>
<tr>
<td>Compliance with</td>
<td>Tolerating movement</td>
<td>1</td>
</tr>
<tr>
<td>mechanical</td>
<td>Coughing but tolerating</td>
<td>2</td>
</tr>
<tr>
<td>ventilation</td>
<td>Fighting ventilator</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Unable to control ventilation</td>
<td>4</td>
</tr>
</tbody>
</table>

BPS score ranges from 3 (no pain) to 12 (maximum pain).
Appendix D

Behavioral Pain Scale Consent
From: John Weldon <jweldon8@students.kennesaw.edu>
Date: Wed, Aug 24, 2016 at 3:27 PM
To: jfpayen@ujf-grenoble.fr

Dear Dr. Payen,

I am a graduate student at Kennesaw State University in the United States. I read your article titled, “Assessing pain in critically ill sedated patients by using a behavioral pain scale.” I am asking for permission to use the tool in my thesis research study. If you approve, could you send me a copy of the tool?

Thank you for your time and consideration with this request.

Sincerely,
Tyler Weldon

----------

From: Jean-Francois Payen <Jean-Francois.Payen@ujf-grenoble.fr>
Date: Wed, Aug 24, 2016 at 3:30 PM
To: John Weldon <jweldon8@students.kennesaw.edu>

Of course you can use the BPS. Attached is the requested item.

JF Payen
Pr Jean-François PAYEN
Pôle Anesthésie-Réanimation
CHU Grenoble
CS 10217
F-38043 Grenoble Cedex 9
Tel : 04 76 76 92 88 ou 04 76 76 72 53
Fax : 04 76 76 51 83
Appendix E

Critical Care Pain Observation Tool
Critical Care Pain Observation Tool Data Collection Sheet

Directions: Assess your patient using the critical care pain observation tool. Patients should be assessed at rest, following a normal blood pressure check, and immediately after turning. Data can be collected up to 3 times per shift. Record the scores in the appropriate boxes. Allow at least five minutes between each measurement. **Remember, this tool is to be used for the research study only, and should NOT be used to guide treatment.**

<table>
<thead>
<tr>
<th>Date: Time:</th>
<th>Facial Expression</th>
<th>Body Movements</th>
<th>Muscle Tension</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date: Time:</th>
<th>Facial Expression</th>
<th>Body Movements</th>
<th>Muscle Tension</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date: Time:</th>
<th>Facial Expression</th>
<th>Body Movements</th>
<th>Muscle Tension</th>
<th>Compliance with Ventilator</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Rest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Following B/P Check</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately After Turning</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Critical care Pain Observation Tool (CPOT)

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial expressions</td>
<td>No muscular tension observed</td>
<td>Relaxed, neutral 0</td>
</tr>
<tr>
<td></td>
<td>Presence of freckling, brow lowering, orbit tightening and facial contracture</td>
<td>Tense 1</td>
</tr>
<tr>
<td></td>
<td>All of the above facial movements plus eyes and tightly closed</td>
<td>Grimacing 2</td>
</tr>
<tr>
<td>Body movements</td>
<td>Does not move at all</td>
<td>Absence of movements 0</td>
</tr>
<tr>
<td></td>
<td>Movements, rubbing or rubbing the pain site, seeking attention through movements or pulling tube, attempting to sit up, moving limbs, breathing, not following commands, striking at staff, trying to climb out of bed</td>
<td>Restlessness 2</td>
</tr>
<tr>
<td>Muscle tension</td>
<td>No resistance to passive movements</td>
<td>Relaxed 0</td>
</tr>
<tr>
<td></td>
<td>Resistance to passive movements</td>
<td>Tense, rigid 2</td>
</tr>
<tr>
<td>Compliance with the ventilator</td>
<td>Alarms not activated, easy ventilation</td>
<td>Tolerating ventilator or movement 0</td>
</tr>
<tr>
<td>In mechanical ventilated patients</td>
<td>Alarms do not spontaneously activate</td>
<td>Coughing but tolerating 1</td>
</tr>
<tr>
<td></td>
<td>Airways block ventilation, alarms frequently activated</td>
<td>Fighting ventilator 2</td>
</tr>
<tr>
<td>Vital signs (in mechanically ventilated patients)</td>
<td>Talking in normal tone or no sound</td>
<td>Talking in normal tone or no sound 0</td>
</tr>
<tr>
<td></td>
<td>Sighing, moaning</td>
<td>Sighing, moaning 1</td>
</tr>
<tr>
<td></td>
<td>Crying out, sobbing</td>
<td>Crying out, sobbing 2</td>
</tr>
</tbody>
</table>

*Am J Crit Care 2006; 15:420-7*
Appendix F

Critical Care Observation Tool Consent
September 26, 2016

John Tyler Weldon
24 Elm Drive
Ringgold, GA 30736

Dear Mr. Weldon:

Thank you for your reuse permission request. We hereby grant permission for your reuse of the Critical-Care Pain Observation Tool, or CPOT, at no charge subject to the following conditions:


2. Reuse of this material is limited as follows: for use for five (5) years (until September 26, 2021) in a research study titled “Nurses’ Evaluations of the Feasibility and the Clinical Utility of the CPOT and Behavioral Pain Scale.” The tool will be distributed to critical care nurses within a single medical center to evaluate patients’ pain.

3. Additional details of this use case: print distribution, academic institution, United States, no translation, 4,999 or fewer circulation, no ancillary uses or other modifications. For other uses please reapply.

Thank you for your interest in the American Association of Critical-Care Nurses. To learn more about our association and its mission, visit our website: www.aacn.org.

Sincerely,

Michael Muscat
Publishing Manager
American Association of Critical-Care Nurses

Accepted:

[Signature]  [Title]  [Date]
Appendix G

Nurses’ Evaluations of the BPS and CPOT
### Feasibility, Clinical Relevance and Satisfaction Evaluation of Pain Scales

**Behavioral Pain Scale Tool**

Please circle the number that best represents your opinion about the Behavioral Pain Scale Tool.

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at All (1)</th>
<th>A Little (2)</th>
<th>Sufficiently (3)</th>
<th>Very (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the Behavioral Pain Scale Tool quick to use?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Were the directives about the use of the Behavioral Pain Scale Tool clear?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Is the Behavioral Pain Scale Tool simple to understand?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Is the Behavioral Pain Scale Tool easy to complete?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Is the Behavioral Pain Scale Tool helpful for nursing practice?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Has the Behavioral Pain Scale Tool influenced your practice in assessing the patient’s pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Has the Behavioral Pain Scale Tool allowed you to adequately evaluate pain in patients who are unable to communicate?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Has the Behavioral Pain Scale Tool demonstrated potential to improve your practice in terms of pain management?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Has the Behavioral Pain Scale Tool helped you communicate effectively the results of the pain assessment to other members of the team: Nurses</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Doctors/Residents</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Other members of the team (physiotherapists, occupational therapists)</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. How satisfied are you with the use of the Behavioral Pain Scale Tool in ICU?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Question</td>
<td>All (1)</td>
<td>A Little (2)</td>
<td>Sufficiently (3)</td>
<td>Very (4)</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------</td>
<td>--------------</td>
<td>-----------------</td>
<td>----------</td>
</tr>
<tr>
<td>1. Is the Critical Care Pain Observation Tool quick to use?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Were the directives about the use of the Critical Care Pain Observation Tool clear?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Is the Critical Care Pain Observation Tool simple to understand?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Is the Critical Care Pain Observation Tool easy to complete?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Is the Critical Care Pain Observation Tool helpful for nursing practice?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6. Has the Critical Care Pain Observation Tool influenced your practice in assessing the patient's pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>7. Has the Critical Care Pain Observation Tool allowed you to adequately evaluate pain in patients who are unable to communicate?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Has the Critical Care Pain Observation Tool demonstrated potential to improve your practice in terms of pain management?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Has the Critical Care Pain Observation Tool helped you communicate effectively the results of the pain assessment to other members of the team:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Doctors/Residents</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other members of the team (physiotherapists, occupational therapists)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. How satisfied are you with the use of the Critical Care Pain Observation Tool in ICU?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix H

Nurses’ Evaluations of the BPS and CPOT Consent
This Agreement between Patricia L. Hart ("You") and John Wiley and Sons ("John Wiley and Sons") consists of your license details and the terms and conditions provided by John Wiley and Sons and Copyright Clearance Center.

License Number 3975401232771
License date Oct 24, 2016
Licensed Content Publisher John Wiley and Sons
Licensed Content Publication Nursing In Critical Care
Licensed Content Title Nurses' evaluations of the CPOT use at 12-month post-implementation in the intensive care unit
Licensed Content Author Céline Gélinas, Melody Ross, Madalina Boitor, Sylvie Desjardins, Francine Vaillant, Cécile Michaud
Licensed Content Date May 9, 2014
Licensed Content Pages 9
Type of use Dissertation/Thesis
Requestor type University/Academic
Format Print and electronic
Portion Figure/table
Number of figures/tables 2
Original Wiley figure/table number(s) Table 2 Page 276 I am requesting permission to use the questions in Table 2 for a thesis research study for my graduate student, John Tyler Weldon. We also are seeking permission to revise the questions using the CPOT and the Behavioral Pain Scale names of the instrument for nurses comparison of the two instruments.
Will you be translating? No
Title of your thesis / dissertation Nurses' Evaluations of the Feasibility and the Clinical Utility of the Critical-Care Pain Observation Tool and Behavioral Pain Scale
Expected completion date Dec 2017
Expected size (number of pages) 100
Requestor Location Patricia L Hart
520 Parliament Garden Way
Prillaman Hall, MS 4102
POWDER SPRINGS, GA 30127
United States
Attn: Patricia L Hart
Publisher Tax ID EU826007151
Billing Type Invoice
Billing Address Patricia L Hart
TERMS AND CONDITIONS

This copyrighted material is owned by or exclusively licensed to John Wiley & Sons, Inc. or one of its group companies (each a "Wiley Company") or handled on behalf of a society with which a Wiley Company has exclusive publishing rights in relation to a particular work (collectively "WILEY"). By clicking "accept" in connection with completing this licensing transaction, you agree that the following terms and conditions apply to this transaction (along with the billing and payment terms and conditions established by the Copyright Clearance Center Inc., ("CCC's Billing and Payment terms and conditions"), at the time that you opened your RightsLink account (these are available at any time at http://myaccount.copyright.com).

Terms and Conditions

- The materials you have requested permission to reproduce or reuse (the "Wiley Materials") are protected by copyright.

- You are hereby granted a personal, non-exclusive, non-sub licensable (on a stand-alone basis), non-transferable, worldwide, limited license to reproduce the Wiley Materials for the purpose specified in the licensing process. This license, and any CONTENT (PDF or image file) purchased as part of your order, is for a one-time use only and limited to any maximum distribution number specified in the license. The first instance of republication or reuse granted by this license must be completed within two years of the date of the grant of this license (although copies prepared before the end date may be distributed thereafter). The Wiley Materials shall not be used in any other manner or for any other purpose, beyond what is granted in the license. Permission is granted subject to an appropriate acknowledgement given to the author, title of the material/book/journal and the publisher. You shall also duplicate the copyright notice that appears in the Wiley publication in your use of the Wiley Material. Permission is also granted on the understanding that nowhere in the text is a previously published source acknowledged for all or part of this Wiley Material. Any third party content is expressly excluded from this permission.

- With respect to the Wiley Materials, all rights are reserved. Except as expressly granted by the terms of the license, no part of the Wiley Materials may be copied, modified, adapted (except for minor reformatting required by the new Publication), translated, reproduced, transferred or distributed, in any form or by any means, and no derivative works may be made based on the Wiley Materials without the prior permission of the respective copyright owner. For STM Signatory Publishers clearing permission under the terms of the STM Permissions Guidelines only, the terms of the license are extended to include subsequent editions and for editions in other languages, provided such editions are for the work as a whole in situ and does not involve the separate exploitation of the permitted figures or extracts,
COMPARISON OF THE BPS AND CPOT

You may not alter, remove or suppress in any manner any copyright, trademark or other notices displayed by the Wiley Materials. You may not license, rent, sell, loan, lease, pledge, offer as security, transfer or assign the Wiley Materials on a stand-alone basis, or any of the rights granted to you hereunder to any other person.

- The Wiley Materials and all of the intellectual property rights therein shall at all times remain the exclusive property of John Wiley & Sons Inc, the Wiley Companies, or their respective licensors, and your interest therein is only that of having possession of and the right to reproduce the Wiley Materials pursuant to Section 2 herein during the continuance of this Agreement. You agree that you own no right, title or interest in or to the Wiley Materials or any of the intellectual property rights therein. You shall have no rights hereunder other than the license as provided for above in Section 2. No right, license or interest to any trademark, trade name, service mark or other branding ("Marks") of WILEY or its licensors is granted hereunder, and you agree that you shall not assert any such right, license or interest with respect thereto.

- NEITHER WILEY NOR ITS LICENSIORS MAKES ANY WARRANTY OR REPRESENTATION OF ANY KIND TO YOU OR ANY THIRD PARTY, EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO THE MATERIALS OR THE ACCURACY OF ANY INFORMATION CONTAINED IN THE MATERIALS, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, ACCURACY, SATISFACTORY QUALITY, FITNESS FOR A PARTICULAR PURPOSE, USABILITY, INTEGRATION OR NON-INFRINGEMENT AND ALL SUCH WARRANTIES ARE HEREBY EXCLUDED BY WILEY AND ITS LICENSORS AND WAIVED BY YOU.

- WILEY shall have the right to terminate this Agreement immediately upon breach of this Agreement by you.

- You shall indemnify, defend and hold harmless WILEY, its Licensors and their respective directors, officers, agents and employees, from and against any actual or threatened claims, demands, causes of action or proceedings arising from any breach of this Agreement by you.

- IN NO EVENT SHALL WILEY OR ITS LICENSIORS BE LIABLE TO YOU OR ANY OTHER PARTY OR ANY OTHER PERSON OR ENTITY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY OR PUNITIVE DAMAGES, HOWEVER CAUSED, ARISING OUT OF OR IN CONNECTION WITH THE DOWNLOADING, PROVISIONING, VIEWING OR USE OF THE MATERIALS REGARDLESS OF THE FORM OF ACTION, WHETHER FOR BREACH OF CONTRACT, BREACH OF WARRANTY, TORT, NEGLIGENCE, INFRINGEMENT OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, DAMAGES BASED ON LOSS OF PROFITS, DATA, FILES, USE, BUSINESS OPPORTUNITY OR CLAIMS OF THIRD PARTIES), AND WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THIS LIMITATION SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.
• Should any provision of this Agreement be held by a court of competent jurisdiction to be illegal, invalid, or unenforceable, that provision shall be deemed amended to achieve as nearly as possible the same economic effect as the original provision, and the legality, validity and enforceability of the remaining provisions of this Agreement shall not be affected or impaired thereby.

• The failure of either party to enforce any term or condition of this Agreement shall not constitute a waiver of either party's right to enforce each and every term and condition of this Agreement. No breach under this agreement shall be deemed waived or excused by either party unless such waiver or consent is in writing signed by the party granting such waiver or consent. The waiver by or consent of a party to a breach of any provision of this Agreement shall not operate or be construed as a waiver of or consent to any other or subsequent breach by such other party.

• This Agreement may not be assigned (including by operation of law or otherwise) by you without WILEY’s prior written consent.

• Any fee required for this permission shall be non-refundable after thirty (30) days from receipt by the CCC.

• These terms and conditions together with CCC’s Billing and Payment terms and conditions (which are incorporated herein) form the entire agreement between you and WILEY concerning this licensing transaction and (in the absence of fraud) supersedes all prior agreements and representations of the parties, oral or written. This Agreement may not be amended except in writing signed by both parties. This Agreement shall be binding upon and inure to the benefit of the parties' successors, legal representatives, and authorized assigns.

• In the event of any conflict between your obligations established by these terms and conditions and those established by CCC’s Billing and Payment terms and conditions, these terms and conditions shall prevail.

• WILEY expressly reserves all rights not specifically granted in the combination of (i) the license details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC’s Billing and Payment terms and conditions.

• This Agreement will be void if the Type of Use, Format, Circulation, or Requestor Type was misrepresented during the licensing process.

• This Agreement shall be governed by and construed in accordance with the laws of the State of New York, USA, without regards to such state's conflict of law rules. Any legal action, suit or proceeding arising out of or relating to these Terms and Conditions or the breach thereof shall be instituted in a court of competent jurisdiction in New York County in the State of New York in the United States of America and each party hereby consents and submits to the personal jurisdiction of such court, waives any objection to venue in such court and consents to service of process by registered or certified mail, return receipt requested, at the last known address of such party.
Wiley Publishes Open Access Articles in fully Open Access Journals and in Subscription journals offering Online Open. Although most of the fully Open Access journals publish open access articles under the terms of the Creative Commons Attribution (CC BY) License only, the subscription journals and a few of the Open Access Journals offer a choice of Creative Commons Licenses. The license type is clearly identified on the article.

**The Creative Commons Attribution License**
The Creative Commons Attribution License (CC-BY) allows users to copy, distribute and transmit an article, adapt the article and make commercial use of the article. The CC-BY license permits commercial and non-commercial use.

**Creative Commons Attribution Non-Commercial License**
The Creative Commons Attribution Non-Commercial (CC-BY-NC) License permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.(see below)

**Creative Commons Attribution-Non-Commercial-NoDerivs License**
The Creative Commons Attribution Non-Commercial-NoDerivs License (CC-BY-NC-ND) permits use, distribution and reproduction in any medium, provided the original work is properly cited, is not used for commercial purposes and no modifications or adaptations are made. (see below)

**Use by commercial "for-profit" organizations**
Use of Wiley Open Access articles for commercial, promotional, or marketing purposes requires further explicit permission from Wiley and will be subject to a fee. Further details can be found on Wiley Online Library http://olabout.wiley.com/WileyCDA/Section/id-410895.html

**Other Terms and Conditions:**

v1.10 Last updated September 2015

Questions? customerscare@copyright.com or +1-855-239-3415 (toll free in the US) or +1-978-646-2777.
Appendix I

Demographic Survey
Demographic Survey

Directions: Please place a check mark [□] in the appropriate box or fill in the blank.

1. What is your gender? □ Male □ Female
2. What is your age? ________________
3. What is your race/ethnicity?
   □ White/Caucasian □ Black/African American □ Hispanic/Latino
   □ Native American □ Asian or Pacific Islander □ Arabic
   Other (specify):
4. What is your highest college degree achieved?
   □ Diploma □ Associate’s □ Bachelor’s □ Master’s □ Doctorate’s
5. How many years have you been working as a registered nurse? ________________
6. Are you nationally certified? □ No □ Yes, if so in what area is your certification?
Appendix J:

Hamilton Medical Center IRB approval
May 3, 2017

Tyler Weldon
Principal Investigator-Kennesaw State University
Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients

Dear Mr. Weldon:

This letter is to inform you that the Hamilton Medical Center IRB has reviewed and approved the study entitled, "Comparison of the Behavioral Pain Scale and the Critical-Care Pain Observation Tool in Assessing Pain in Ventilated Critical Care Patients", beginning June 2017.

The Hamilton IRB reviewed as well as approved use of the informed consent submitted as written. However if further modifications are made to the informed consent, it will be the responsibility of the PI to inform the local IRB.

Please share your results with us once the study is complete. An annual update and review are necessary should you need to continue the study.

Sincerely,

Steven Paynter, M.D.
Chairman, IRB Committee
Hamilton Medical Center
Appendix K

Kennesaw State University IRB Approval
John Tyler Weldon

RE: Your application dated 5/8/2017, Study #17-561: Comparison of the Behavioral Pain Scale (BPS) and the Critical-Care Pain Observation Tool (CPOT) in Assessing Pain in Ventilated Critical Care Patients

Dear Mr. Weldon:

Your application for the new study listed above has been administratively reviewed. This study qualifies as exempt from continuing review under DHHS (OHRP) Title 45 CFR Part 46.101(b)(2) - educational tests, surveys, interviews, public observations. The consent procedures described in your application are in effect. You are free to conduct your study.

NOTE: All surveys, recruitment flyers/emails, and consent forms must include the IRB study number noted above, prominently displayed on the first page of all materials.

Please note that all proposed revisions to an exempt study require IRB review prior to implementation to ensure that the study continues to fall within an exempt category of research. A copy of revised documents with a description of planned changes should be submitted to irb@kennesaw.edu for review and approval by the IRB.

Thank you for keeping the board informed of your activities. Contact the IRB at irb@kennesaw.edu or at (470) 578-2268 if you have any questions or require further information.

Sincerely,

Christine Ziegler, Ph.D.
KSU Institutional Review Board Chair and Director

cc: phart@kennesaw.edu