

EVALUATION OF CRITICAL CARE NURSES UTILIZATION OF PAIN  
ASSESSMENT TOOLS IN CLINICAL PRACTICE

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Rebecca R. Griffin, titled Evaluation of Critical Care Nurses Utilization of Pain Assessment Tools in Clinical Practice and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.


  
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## ABSTRACT

**Background:** Unmanaged pain among critically ill patients is a primary stressor that leads to acute and long-term complications, increased mortality, and a decline in patient outcomes (Chookalayia et al., 2018; Gélinas, 2010). This project inquiry aims to evaluate TMC critical care nurses' utilization of BPS and NVPS pain assessment tools used and the amount of analgesics used in clinical practice.

**Methods:** A retrospective chart review on 16 ventilated patients requiring analgesic administration to (1) to evaluate nurses' utilization of the BPS and NVPS pain assessment tools to guide analgesic administration and (2) determine if the pain assessment scores correlate with the current pain scale used and analgesics given for pain control, and utilization of RASS to guide sedation administration used in clinical practice.

**Results:** Of the 16 patients evaluated approximately 25.8% of the time were critical care nurses compliant in documenting NVPS with analgesic titrations and 24.5% compliant in recording BPS with analgesic titrations. This data showed that critical care nurses used both pain scales successfully 30.5% of the time when titrating analgesia.

**Conclusion:** The literature supports the use of NVPS or BPS as a pain assessment tool to guide titration of analgesics in the general population admitted to the ICU requiring mechanical ventilation (Bouajram et al., 2018; Rijkenberg et al., 2017). However, this DNP project showed low compliance with using validated tools NVPS or BPS, indicating that the current practice utilized at Tucson Medical Center (TMC) does not correspond to the current literature. Future studies could explore a nurse's perspective on ease of use and effectiveness of the NVPS or BPS

for assessing pain to the general population admitted to the ICU requiring mechanical ventilation.



## INTRODUCTION

### Background Knowledge

Uncontrolled pain presents as one of the most common experiences reported by patients throughout their stay in an intensive care unit (ICU) (Georgiou et al., 2015). The reported complications related to uncontrolled pain in critically ill patients include significant physiological and psychological deterrents such as increased infection rate, prolonged time on a mechanical ventilator, hemodynamic instability, ICU delirium, compromised immunity, and increased mortality (Georgiou et al., 2015; Rijkenberg et al., 2017). Due to this epidemic of uncontrolled pain in ICU throughout the country, on January 1, 2018, The Joint Commission (TJC) revised additions to “the golden standard” to provide better assessment strategies and management of pain for all Joint Commission-accredited hospitals (TJC, 2019). In addition to The Joint Commission additions for pain control, The Society of Critical Care Medicine (SCCM) updated the Clinical Practice Guidelines (CPG) for management of pain, agitation, and delirium to provide a systematic approach to integrating evidence-based practice and patient-centered protocols for the treatment of pain and anxiety (SCCM, 2019).

The Society of Critical Care Medicine concluded that the contributing factors related to uncontrolled pain are primarily due to difficulty in assessing pain in the ICU (SCCM, 2019). The identified causes include (1) difficulty in assessing for pain in a nonverbal patient, (2) recognizing when to intervene for medication administration, and (3) critical care nurses’ attitudes and perceptions towards utilizing pain assessment tools to control pain (Georgiou et al., 2015; Rijkenberg et al., 2017). Bouajram et al. (2018) discussed that the neurological and physical status of critically ill patients could fluctuate; therefore, self-reported and behavioral

pain assessment scales used to assess for pain over time. One of the strategies proposed by the Society of Critical Care Medicine is to implement a pain assessment tool in ICUs such as the behavioral pain scale (BPS) or critical pain observational tool (CPOT) to (1) assess for pain levels and (2) determine if the current medication regimen for pain control is appropriate for each patient. In addition to the findings reported by Bouajram et al. (2018), Georgiou et al. (2015) discovered that the type of pain assessment tool chosen will need to provide a systematic and comprehensive assessment of pain to help guide clinicians in the decision-making process relating to use of “as-needed” analgesia for pain relief.

### **Problem Identification and Significance**

Unmanaged pain among critically ill patients is a primary stressor that leads to severe acute, long-term complications, increased mortality, and a decline in patient outcomes (Chookalayia et al., 2018; Gélinas, 2010). Every year over five million admissions into ICU reported an average length of stay of six to nine days, with over 53% of patients requiring mechanical ventilation (Johnson & Al-Dahr, 2016). In a survey of 80 patients treated for acute respiratory distress syndrome (ARDS) four years post ICU discharge; 38% reported a high incidence of pain in ICU, 27% reported post-traumatic stress disorder (PTSD) symptoms, and 20% lower health-related quality of life, with 10% reported deaths (Schelling, Richter, & Roozendaal, 2003). The pain experienced by patients is related to disease processes, endotracheal intubations, surgeries, routine examinations and medical procedures such as endotracheal suctioning and repositioning (Chen & Chen, 2015; Schelling et al., 2003).

Pain occurs in the presence of nociception, which transfers information from one location of tissue damage to the central nervous system (Reardon, Anger, & Szumita, 2015).

When the noxious stimulus is exposed, a nerve impulse is generated, transmitted to the spinal cord and brain that signifies pain (Reardon et al., 2015). Adequate pain management not addressed in a useful and timely manner; patients can experience both physiological and psychological discomfort that will persist with time (Bouajram et al., 2018; Chen & Chen, 2015). The adverse physiological impacts of uncontrolled pain, as described by Reardon et al. (2015), indicate that in the presence of stress response from pain, catecholamines, cortisol, and glucagon release. The release of this cascade of events will cause tachycardia, hypertension, an increase in myocardial oxygen demands, insulin resistance due to hyperglycemia, and changes in fat and protein metabolism (Reardon et al., 2015). Also, prolonged exposure to uncontrolled pain will lead to hyperalgesia and sensitization of the spinal cord, which will lead to a heightened response to noxious stimuli or transmission of pain without painful stimuli leading to chronic pain (Reardon et al., 2015). The Arizona Department of Health Services (AZDHS) (AZDHS, 2019) indicated that uncontrolled pain in the ICU leads to prolonged opiate use that can contribute to the opioid epidemic currently affecting the community in southern Arizona.

Uncontrolled pain with consequent increases in the length of stay in ICU concurrently increases the costs of care. The ICU is costly in the healthcare system accounting for close to 1% of the annual gross domestic product of the United States with an estimated average cost of \$20,000 to \$30,000 for each stay ranging from 10 - 12 days (Milbrandt et al., 2004). In addition to ICU stay costs, nearly one-third of the inpatient pharmacy's budget spent in the ICU alone (Awissi et al., 2012; Milbrandt et al., 2004). Therefore, a great deal of effort has been put forth within hospitals all over the health industry for developing standards for pain

control, maintaining routine pain monitoring, standardizing policies and procedures regarding pain management, and targeting analgesics based on patient's pain scores (Bouajram et al., 2018; Rijkenberg et al., 2017).

For patients in intensive care units requiring mechanical ventilation, the current recommendation is to reduce the length of time on the ventilator by minimizing excessive amounts of sedatives and analgesics (Chookalayia et al., 2018; Ito et al., 2017). Researchers have found that by clarifying the pain assessment method based on the patient's clinical presentation, proper administration of sedation and analgesics can decrease complications such as (1) developing ICU delirium, (2) promote early withdrawal from the mechanical ventilator, and (3) preventing development of chronic pain from occurring (Ito et al., 2017). Three pain assessment tools employed to help with controlling the opioid epidemic by assessing for pain in ICU are (1) BPS, (2) CPOT, and (3) nonverbal pain scale (NVPS) (Bouajram et al., 2018; Rijkenberg et al., 2017).

A frequent type of pain assessment tool used by clinicians and critical care nurses in ICU to assess for pain in patients requiring mechanical ventilator support is BPS. The components of the BPS pain scale incorporate (1) facial expression ranging from relaxed, partially tightened to fully tightened, (2) upper limb movement ranging from no movement to permanently retracted, and (3) compliance with the ventilator with a total range score of 3-12 (Rijkenberg et al., 2014). However, the BPS tool does not include assessment of body movements, emotions, facial, verbal cues, applies to intubated patients; therefore, the application of an additional pain assessment tool such as the nonverbal pain scale (NVPS) used in conjunction to BPS (Chen & Chen, 2015; Paulson-Conger et al., 2011). The NVPS

assessment includes (1) face (grimacing, tearing, frowning, wrinkled forehead), (2) activity movement, (3) guarding (rigidity and body tension), (4) increase in physiological vital signs, and (5) increase or change in respirations with a total range score of 0-10 (Chen & Chen, 2015; Paulson-Conger et al., 2011). The BPS and NVPS displayed in Tables 1 and 2.

TABLE 1. *Behavioral pain scale (BPS).*

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened (e.g., brow lowering)	2
	Fully tightened (e.g., eyelid closing)	3
	Grimacing	4
Upper limb	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing but tolerating ventilation most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4

(Rijkenberg et al, 2014)


TABLE 2. *Nonverbal pain scale (NVPS).*

Categories	0	1	2
Face	No particular expression or smile	Occasional grimace, tearing, frowning, wrinkled forehead	Frequent grimace, tearing, frowning, wrinkled forehead
Activity (movement)	Lying quietly, normal position	Seeking attention through movement or slow, cautious movement	Restless, excessive activity and/or withdrawal reflexes
Guarding	Lying quietly, no positioning of hands over areas of body	Splinting areas of the body, tense	Rigid, stiff
Physiologic I (vital signs)	Stable vital signs (no change in past 4 hours)	Change over past 4 hours in any of the following: SBP > 20 mm Hg, HR > 20/min, RR > 10/min	Change over past 4 hours in any of the following: SBP > 30 mm Hg, HR > 25/min, RR > 20/min
Physiologic II	Warm, dry skin	Dilated pupils, perspiring, flushing	Diaphoretic, pallor

(Bouajram et al., 2018)

The CPOT is another commonly used pain assessment tool in the ICU. The CPOT pain assessment tool comprises of four specific behavior domains to assess pain: facial expression, body movements, muscle tension, and vocalization for patients not intubated, or compliance with the ventilator with intubated patients (Joffe et al., 2016). Each domain of the CPOT pain assessment tool rated on a scale of '0' to '2,' with a total range score of '0' to '8' (Joffe et al., 2016). The CPOT pain assessment tool studied in over 500 adult ICU with various diagnoses including surgical, medical, and trauma patients who were not able to self-report their pain level (Bouajram et al., 2018; Joffe et al., 2016; Rijkenberg et al., 2017). Studies have shown that utilizing the CPOT pain assessment tool provides a reliable and validity tool for assessing pain among critically ill patients requiring mechanical ventilation (Bouajram et al., 2018; Joffe, McNulty, & Marsh, 2016; Rijkenberg et al., 2017). Clinicians and critical care nurses can utilize the CPOT pain assessment tool to evaluate pain in the nonverbal patient requiring mechanical ventilation and adequately coordinate each patient's medication regimen based on the clinical presentation of each patient. The CPOT is displayed in Table 3.

TABLE 3: *Critical care pain observation tool (CPOT).*

Indicator	Score	Description
<b>Facial expression</b> 	Relaxed, neutral	0 No muscle tension observed
	Tense	1 Presence of frowning, brow lowering, orbit tightening, and levator contraction or any other change (eg, opening eyes or tearing during nociceptive procedures)
	Grimacing	2 All previous facial movements plus eyelid tightly closed (the patient may have mouth open or may be biting the endotracheal tube)
<b>Body movements</b>	Absence of movements or normal position	0 Does not move at all (does not necessarily mean absence of pain) or normal position (movements not aimed toward the pain site or not made for the purpose of protection)
	Protection	1 Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements
	Restlessness	2 Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed
<b>Compliance with the ventilator (intubated patients)</b>	Tolerating ventilator or movement	0 Alarms not activated, easy ventilation
	Coughing but tolerating	1 Coughing, alarms may be activated but stop spontaneously
	Fighting ventilator	2 Asynchrony: blocking ventilation, alarms frequently activated
<i>or</i> <b>Vocalization (nonintubated patients)</b>	Talking in normal tone or no sound	0 Talking in normal tone or no sound
	Sighing, moaning	1 Sighing, moaning
	Crying out, sobbing	2 Crying out, sobbing
<b>Muscle tension</b> Evaluation by passive flexion and extension of upper limbs when patient is at rest or evaluation when patient is being turned	Relaxed	0 No resistance to passive movements
	Tense, rigid	1 Resistance to passive movements
	Very tense or rigid	2 Strong resistance to passive movements, inability to complete them
<b>Total</b>		___/8

(Gélinas, 2010)

### Local Problem

As a current registered nurse in the ICU of a community hospital in Tucson, Arizona, I have discovered that early pain recognition is challenging to identify and manage amongst patients requiring mechanical ventilation. During a patient's initial ICU admission, the chosen sedation medication ordered by providers often includes propofol or versed as first-line agents of treatment rather than performing an initial assessment of pain. The second choice for medications after sedation would be to include an analgesic such as fentanyl. As an attempt to identify the understanding between pain and agitation, the medical staff reported difficulty differentiating pain versus agitation. Tucson Medical Center (TMC) currently uses BPS and

NVPS for pain assessment and the Richmond agitation and sedation scale (RASS) for sedation assessment. The critical care nursing staff often question whether they should increase sedation versus analgesics as they are not sure whether the patient is in pain or agitated. Nursing staff discusses that utilizing BPS and NVPS allows them to assess for facial expression, limb movement, and ventilator compliance; however, they find that patients typically receive more sedation than analgesics due to the inability to distinguish between pain versus agitation from using multiple assessment tools. The current TMC order set for analgesic administration includes a fentanyl ventilator panel for analgesic administration while intubated. This order set includes a fentanyl loading dose of 50 mcg IV bolus from the bag for a BPS score greater than '6' when starting a continuous IV fentanyl infusion. The next component to the fentanyl ventilator panel for analgesic administration is a titratable continuous infusion, which ranges from 0-200 mcg/ hour. Orders are to start the continuous infusion at 25 mcg/hour, then may titrate by 25 mcg/hour if two or more breakthrough boluses given within an hour. Fentanyl bolus order administration is a 25-mcg bolus from the bag IV every 15 minutes as needed for BPS greater than '6.' The maximum bolus dose cannot exceed 100 mcg in one hour. The goal is for a BPS score of less than '6.'

The current TMC order set for sedation administration includes a propofol or versed ventilator panel. TMC employs the RASS to assess agitation for critically ill patients requiring mechanical ventilation and unable to self-report pain. Propofol continuous drip-rate ranges from 15 to 60 mcg/kg/min, titrating by 2.5 mcg/kg/min every 30 min for a RASS score higher or less than '0' to '-1.' Versed continuous drip-rate range from 0-10 mg/min, titrating by 0.5 mcg/kg/min every 30 min for a RASS score higher or less than '0' to '-1.' The current process



for RASS assessment includes (1) observe the patient to determine if they are alert, restless, or agitated- ranging from 0 to +4, (2) if not alert, ask the patient name and ask to open their eyes, score -1 if the patient awakens maintaining eye contact, -2 if eyes open but not sustained, -3 for no eye contact, (3) physical stimulation by rubbing sternum -4 any visible movement, -5 for no response to stimulation (Table 4).

TABLE 4. *Richmond agitation sedation scale (RASS).*

Score	Term	Description	
+4	Combative	Overtly combative, violent, immediate danger to staff	
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive	
+2	Agitated	Frequent non-purposeful movement, fights ventilator	
+1	Restless	Anxious but movements not aggressive vigorous	
0	Alert and calm		
-1	Drowsy	Not fully alert, but has sustained awakening (eye-opening/eye contact) to <i>voice</i> ( $\geq 10$ seconds)	} Verbal Stimulation
-2	Light sedation	Briefly awakens with eye contact to <i>voice</i> ( $< 10$ seconds)	
-3	Moderate sedation	Movement or eye opening to <i>voice</i> (but no eye contact)	
-4	Deep sedation	No response to voice, but movement or eye opening to <i>physical</i> stimulation	} Physical Stimulation
-5	Unarousable	No response to <i>voice</i> or <i>physical</i> stimulation	

(Gélinas, 2010)

The critical care staff at TMC recognized the occurrence of uncontrolled pain in the ICU amongst this patient population and the current problem related to higher usage of sedation versus inadequate administration of analgesics due to uncontrolled pain. The critical care staff recognizes the occurrence of uncontrolled pain in the ICU through dialogue and observations by nursing staff and leadership amongst this patient population. The current problem involves the higher usage of sedation versus inadequate administration of analgesics due to uncontrolled pain. Critical care nurses should first address pain, then agitation, which

may facilitate critical care nurse's perception and ability to minimize sedation and provide adequate analgesics. The current issue related to uncontrolled pain is determining whether the current pain scale is an appropriate scale to use to assess and manage pain in critical care patients. The current issues discussed to the clinical nursing leaders, clinical nurse specialist, unit manager, unit director, and medical director of the ICU. All members agreed that methods employed for the effectiveness of using BPS and NVPS for pain assessment in the ICU.

### **Purpose**

The purpose of this DNP project was to evaluate the effectiveness of the current pain assessment tools used: BPS and NVPS in the cardiac, neurological, and medical intensive care unit at TMC. Despite the use of the BPS and NVPS to assess for pain, the nursing staff reports an inability to control pain for their patient population, higher incidence of utilizing sedation, and development of ICU delirium. Current research shows that the application of both BPS and CPOT is useful to provide therapeutic pain assessment and management; however, usage of BPS vs. CPOT pain scale appropriateness is not yet determined.

Reardon et al. (2015) discussed the benefits of CPOT outweighs the benefits to BPS not only for assessment of pain, but for simplicity for critical care nurses. Critical care nurses would only need to use one pain assessment tool with CPOT, whereas two different assessment tools using BPS and NVPS. BPS assesses only three domains (facial, ventilator/vocalization, upper limb movements) whereas CPOT assesses four behavioral categories associated with pain: (1) facial expression, (2) body movements, (3) muscle

tension, and (4) ventilator compliance for intubated patients or vocalization for extubated patients (Reardon et al., 2015).

Research has been inconclusive regarding whether the use of BPS with NVPS or CPOT will provide a more appropriate pain assessment for nonverbal patients. This DNP project attempts, as an initial step, to employ methods to determine if the current pain assessment tools at TMC: BPS and NVPS are adequate or an alternative pain scale (CPOT) is needed to assess for pain amongst critical care patients adequately. Therefore, the aims for this DNP project included (1) conducting a retrospective chart review to evaluate nurses' utilization of pain assessment tools utilization of BPS and NVPS pain assessment tools to guide analgesic administration and (2) determining if the pain assessment scores correlate with the current pain scale used and analgesics given for pain control, and utilization of RASS to guide sedation administration used in clinical practice.

### **Project Question**

What are TMC critical care nurses' utilization of BPS and NVPS pain assessment tools in order to guide analgesic administration; what is the utilization of RASS to guide sedation administration used in clinical practice?

### **Theoretical Framework**

The theory of the knowledge to action (K2A) and the social cognitive theory (SCT) frameworks guided this DNP project. The incorporation of the K2A framework allows communication between knowledge producers and users throughout the discovery application cycle (Center for Disease Control and Prevention [CDC], 2014). The K2A Framework identifies three phases: (1) research, (2) translation, and (3) institutionalization to allow all the

necessary decision points, interactions, and supporting structures within each phase of the framework (CDC, 2014). The CDC discusses strategies to improve a quality improvement project that includes translating scientific knowledge into action (CDC, 2014).

The institutionalization phase of the K2A Framework uses conceptual methods to guide this project through the concerns for knowledge translation to deliver sustainable, evidence-based practice guidelines into clinical practice (CDC, 2014; Field, Booth, Ilott, & Gerrish, 2014). By utilizing this conceptual framework in this DNP project, it provides a reference for systematic thinking, action, and interpretation (Field et al., 2014). The last component to the institutionalization phase of the K2A Framework is the evaluation phase, which uses a systematic method to 1) improve actions, and 2) evaluate the effectiveness of the new intervention so improvement can occur (Field et al., 2014).

The social cognitive theory (SCT) framework uses concepts of behavior and cognition so that personalization and environmental factors can influence and interact continuously with each other (Burgess et al., 2007). This DNP project will utilize the SCT framework to analyze critical care nurse's understanding in the utilization of the appropriate scales to titrate analgesia and sedation in critically ill patients requiring mechanical ventilation. Burgess et al. (2007) discussed four components to the SCT framework that allows personnel to develop competencies via mastery modeling, enhancing their own beliefs, and increasing self-motivation. After adopting the components of the SCT framework, personnel can enhance internal motivation, increase understanding of the proposed innovation, and enhance confidence.

### **Concepts and Definitions**

Uncontrolled pain assessment and treatment in critically ill patients can lead to significant physiological and psychological complications leading to increased infection rate, prolonged time on a mechanical ventilator, hemodynamically instability, ICU delirium, and compromised immunity (Georgiou et al., 2015; Rijkenberg et al., 2017). The application of the K2A framework allows the organization to adopt a systematic process utilized by practitioners to gather evidence, develop, test interventions, and generate innovations required for translation of change (CDC, 2014).

The application of the K2A framework uses three phases: research, translation, and the final phase. The research phase of the K2A framework includes (1) developing and testing of advances in scientific data to determine if the research is appropriate for translation and (2) incorporates definitions such as efficacy, effectiveness, and implementing research into the framework (CDC, 2014). The translation phase of the K2A framework includes (1) incorporating framework processes to implement evidence-based programs, policies, and practices, (2) transform evidence-based research into formidable action plans (CDC, 2014). The process during the translation phase is as follows: (1) translation, (2) decision to translate, (3) knowledge of the product, (4) dissemination of information or material, (5) engagement of active participants or stakeholders, (6) decision to adopt decision into the organization, (6) perform practice objective to achieve goal, and (7) translation of supporting structures that enhance organizations capability to plan, implement, and evaluation of an innovation (Centers for Disease Control and Prevention (CDC), 2014). The final phase of the K2A framework is called the institutional phase involving (1) maintaining the innovation within the organization

and (2) evaluation of the systematic process into the organization (CDC, 2014). This quality improvement project emphasizes the final phase of the K2A framework by conducting an evaluation survey on the ICU staff from critical care nurse's understanding, attitudes, and perceptions regarding pain.

### **Synthesis of Evidence**

A literature search was performed limited to English studies using the BPS, NVPS, and CPOT tools for pain control in the ICU setting. CINAHL, PubMed, Google Scholar were used for original research studies on using BPS vs. CPOT for pain in ICU setting using keywords “pain-assessment-tool-in-ICU,” “BPS-and-NVPS,” “psychometric-components-CPOT,” “CPOT-application-clinical-practice,” “nursing-perception-pain-management-ICU,” and “research librarian assisted in search,” combined with the keyword “ICU.” Date delimitations were set to the year 2010 to present, so selected articles were within the last 10 years. The search resulted in 105 studies. An inclusion criterion was applied, which narrowed down the studies to 46.

The inclusion criteria included original research studies that examined BPS, NVPS or CPOT in adult men and women ages 18 years and older in the ICU setting in Western countries. Nonwestern countries not included due to the characteristics in sample size, setting, characteristics, and social norms that may not represent critical care nurses and pain in the ICU in the United States. The selected articles narrowed down related to the DNP project question and aims. An exclusion criterion, which was limited to the English language, human studies, published within the last 10 years, adults aged 18 years and above, studies performed in nonwestern countries. After applying the exclusion criteria, 15 articles remained. Of the 15

articles remaining articles, nine were quantitative regarding using BPS vs. CPOT for pain in ICU; one was qualitative regarding nurses' perceptions and attitudes for pain management in ICU. The last five articles remaining were mixed-method studies and, therefore, were excluded from the project. Ten articles were utilized for the synthesis of evidence and further explored for this project. (Appendix A).

### **Overall Summary from Research Articles**

From the 10 articles synthesized for further evaluation, the findings consistently demonstrated the importance of using a pain assessment tool in ICU to determine the level of pain in critical care patients. Further explorations of articles showed a relationship between using a pain assessment tool for the assessment of pain using BPS vs. CPOT. Multiple studies, including research conducted by Kapritsou et al. (2019), Van der Voort et al. (2017), and Chanques et al. (2014) discussed a correlation between using BPS and CPOT for adequate pain assessment as scores increased during painful procedures and decreased at rest. In addition to increased scores in both BPS and CPOT, researchers found that there was a substantially decreased amount of sedation and analgesics used throughout the study due to proper pain management and control (Rijkenberg et al., 2017; Bouajram et al., 2018; Severgnini et al., 2016). All of the reviewed literature relating to utilizing pain assessment tools support the validity of CPOT and BPS scales to detect pain nonverbal critically ill patients requiring mechanical ventilation.

### **Variations in Concepts of Interest and Outcomes**

The studies conducted by Paulson-Conger et al. (2011) and Chanques et al. (2014) focused on the evaluation between using CPOT, BPS, and using a nonverbal pain scale

(NVPS) for the evaluation of pain. These results indicated that using both BPS and CPOT has higher reliability and internal consistency than NVPS when a patient was intubated or unable to verbalize their pain level (Paulson- Conger et al., 2011; Changes et al., 2014). Also, these studies found that BPS and CPOT demonstrate the highest responsiveness to pain; however, BPS specificity is questionable for detection in noncommunication patients leading researchers to use BPS with an additional tool such as the NVPS (Paulson- Conger et al., 2011; Changes et al., 2014).

The studies conducted by Kapritsou et al. (2019), Bouajram et al. (2018) and Severgnini et al. (2016), Van der Voort et al. (2017), Rijkenberg et al. (2017) focused on the evaluation between using CPOT vs. BPS and its correlation relating to assessment of pain assessment and management in the ICU. The results indicated that utilizing BPS and CPOT shows low sensitivities, which indicates a relatively high prevalence of pain undetected (Kapritsou et al., 2019; Bouajram et al., 2018). Besides, Kapritsou et al. (2019) discussed a significant correlation between CPOT and BPS, indicating that nurses did not underestimate the pain levels portrayed by patients, showing overall practical pain assessment. Findings indicated that BPS (91.7%) has more specificity for determining patients not in pain over CPOT (70.8%); however, CPOT (76.5%) has a higher sensitivity than BPS (62.7%), overall showing favoritism of CPOT over BPS (Severgnini et al., 2016). Also, the findings concluded by Rijkenberg et al. (2017) showed an excellent overall interrater reliability of the BPS and CPOT of 0.74 with a Cronbach's alpha values for the BPS were 0.62 and 0.59 between nurse one and two compared with 0.65 and 0.58 for the CPOT. Findings for all studies using both



BPS and CPOT discussed excellent reliability and validity for these pain assessment tools in clinical practice.

The finding concluded by Joffe et al. (2016), and Tousignant-Laflamme et al. (2010) focused on the evaluation between using CPOT to assess for pain in the ICU. The findings discovered from these articles portrayed a specificity higher than 85% that supports a direct correlation between increased CPOT scores to pain and its application in clinical use (Tousignant-Laflamme et al., 2010). Also, the findings from Joffe et al. (2016) demonstrates that the intraclass correlation coefficient results are 0.73 (95% confidence interval, 0.57-0.83) during turning along with CPOT scores that were significantly higher during turning compared with a “gentle touch” method of assessment for pain ( $P < .001$ ).

The findings of a study by Gélinas (2010), which looked at ICU nurses’ evaluations of the feasibility and clinical utility of the CPOT and their ability to assess pain, showed more than 70% of nurses thought CPOT is helpful to apply in clinical practice to assess for pain. The feasibility and clinical application of CPOT utilized by nurses in this study concluded a positive evaluation of the purpose of this research (Gélinas, 2010). On the post-evaluation tool, nurses established that CPOT would benefit the nursing staff by adequately assessing patient pain to determine in the use of analgesics is appropriate (Gélinas, 2010).

### **Strengths Supported by More than One Study**

Overall the studies analyzed showed a correlation between patients being in pain and increased scores when using BPS and CPOT that demonstrates reliability and validity in both of these assessment tools. CPOT was identified to be more complicated; however, resulted in an a high interrater reliability and internal consistency (Paulson- Conger et al., 2011; Changes

et al., 2014). Overall, results have found that CPOT is more specific than BPS to evaluate pain in noncommunicative patients (Paulson- Conger et al., 2011; Changes et al., 2014). Also, Gélinas (2010) explained that critical care nurses acknowledged that the use of CPOT in ICU provides a common language and a way to standardize a way to assess for pain in nonverbal patients. Furthermore, Gélinas (2010) discussed that CPOT is a valid pain assessment tool currently researched for use in clinical practice in ICU in Western countries.

### **Inconsistent Findings among Studies**

The findings from Rijkenberg et al. (2017) discovered that the discriminant validation of both BPS and CPOT is inconclusive in sedated or agitated patients, which warrants additional research and further investigation. Also, Bouajram et al. (2018) reported that using a pain assessment tool does not correlate with self-reported pain measurement, and the accuracy in reporting the degree of pain needed further investigation. The findings between Kapritsou et al. (2019) and Severgnini et al. (2016) were inconsistent as BPS scored high reliability and validity in Kapritsou et al. (2019); however, CPOT scored higher in Severgnini et al. (2016).

### **Gaps in the Literature Evidence**

Weaknesses and limitations in the literature was noted when conducting this synthesis of evidence. These weaknesses and limitations include relatively small sample sizes, including mostly descriptive methods and cross-sectional data collection, leading to selection bias (Rijkenberg et al., 2017; Bouajram et al., 2018; Severgnini et al., 2016). Most of the literature used one to two assessors educated on BPS or CPOT before the study leading to bias from inconsistent pain assessment. Several authors failed to discuss the grounds for the exclusion of

participants in the study, which increases the potential selection bias of the investigators. Most of the literature reviewed did not incorporate the use of analgesics with a high BPS or CPOT score; therefore, additional research needed relating to using BPS or CPOT in conjunction with analgesic administration for pain management.

### **Further Questions that Need to be Answered**

There was limited research on the perceptions and attitudes of critical care nurses when it comes to utilizing pain assessment and management. Further research relating to this topic should determine whether implementing BPS versus CPOT will help critical care nurses grasp better assessment for pain.

## **METHODS**

### **Design**

The purpose of this DNP project was to evaluate nurses' utilization of pain assessment tools utilization of BPS and NVPS pain assessment tools in order to guide analgesic administration, as well as to evaluate the utilization of RASS to guide sedation administration used in clinical practice. Also, this project aimed to determine whether the pain scale utilized at TMC is an appropriate scale to use to assess and manage pain in critical care patients. Furthermore, this project aimed to evaluate the effectiveness of the current pain assessment tools used: BPS and NVPS in the neurological, medical, and cardiovascular intensive care unit at TMC.

In January 2013, TMC implemented a pain assessment tool by using BPS and NVPS so that critical care nurses can better manage pain for their patients. However, the critical care nurses at TMC continued to observe an increased occurrence of uncontrolled pain and a

current concern related to higher usage of sedation versus inadequate administration of analgesics due to uncontrolled pain. The purpose of this DNP project was to evaluate the utilization of the current pain assessment tools used: BPS and NVPS in the cardiac, neurological, and medical intensive care unit at TMC. Despite the use of the BPS and NVPS to assess for pain, the nursing staff reports an inability to control pain for their patient population, higher incidence of utilizing sedation, and development of ICU delirium. Therefore, the aims for this DNP project included (1) conducting a retrospective chart review to determine if the chosen analgesia medication administration given, such as bolus or rate change, included a documented pain scale, and if so, was the protocol followed by critical care nurses and (2) determine if the chosen sedation medication administration given, such as a rate change, was accompanied by a documented sedation scale used, and if so, was the protocol followed by critical care nurses.

Identifying stakeholders played a crucial role in implementing this DNP project in the hospital as they make the crucial decision to finalize, implement, provide financial and executive support for a project (Zaccagnini & White, 2017). The key stakeholders to this DNP project include ICU nurses, nurse practitioners, clinical nurse leaders, clinical nurse specialists, unit manager, ICU director, the director of nursing, the chief nursing officer, and the chief executive officer.

### **Ethical Considerations and Consent**

To obtain consent, first site permission was obtained from TMC by directing working with the research coordinator for IRB approval. Secondly, the IRB determination form was obtained from TMC and submitted to the College of Nursing at the University of Arizona

(Appendix B). The IRB application needed for submission is the application for a Retrospective Review of Data or Specimens (F203). Three basic principles will help guide research involving human subjects. These are (1) respect for persons, (2) respect for beneficence, and (3) respect for justice (Polit & Beck, 2017).

### **Respect for Persons**

Each person has an individual right, unique and free, with value and dignity, and the right for informed consent (Polit & Beck, 2017). Having respect for a person is considered one of the fundamental principles applied to research (Polit & Beck, 2017). Respect for persons identifies the autonomous, uniqueness, and freedom of each, the right for each person to make his or her own decisions, and to respect each person's dignity (Polit & Beck, 2017). To achieve respect for persons, submission of a consent requirement be waived as the research involves minimal risk to the subject, and the research will not adversely affect the rights and welfare of the subjects.

### **Beneficence**

The principle related to beneficence means "do no harm" in order to provide the optimal benefit and, at the same time, minimizing harm (Polit & Beck, 2017). This DNP project does not meet the definition of research on human subjects by the University of Arizona. So, no harm anticipated to any of the study participants. Approval from TMC hospital obtained before the implementation of this project. This project consisted of conducting a chart review and conducting an evaluation survey, no harm was expected to occur; therefore, beneficence achieved. To apply beneficence to this study, TMC and its patients might benefit from the findings of the project.

**Justice**

The principle of justice ensures that a fair distribution of risks and benefits displayed to the participants of the project (Polit & Beck, 2017). To be successful in ensuring that justice achieved, well-established fairness and equality with favoritism used. Since this project was a retrospective chart review, all information relating to the privacy and confidentiality was obtained through consent from TMC and University of Arizona IRB process.

**Setting**

Tucson Medical Center is a community hospital that provides a variety of healthcare services, including emergency care, neurological, cardiovascular, orthopedic, general surgery, and intensive care. This project took place in a combined neurosurgical, medical intensive care unit, and cardiovascular intensive care unit at TMC, a community hospital in Southern Arizona. The ICU is composed of a 28-bed unit that manages pain assessment and interventions, including protocols for nonverbal patients requiring mechanical ventilation.

Per TMC protocol #55.03.10, revised on 01/31/2018, pain assessment, and documentation serve to provide positive outcomes for patient comfort, standardize pain management practice, and aids clinicians in practice proper pain management techniques. The current protocol requires (1) a patient's pain level assessed based on the appropriate pain assessment scale and documented on each comprehensive assessment form and (2) a patients' pain level is determined and documented by nurses and providers every two hours or more on patients that are intubated requiring mechanical ventilation support or not able to communicate their pain-needs. Finally, the RN is expected to document location, characteristics of pain (severity, character, frequency, duration, exacerbating and relieving

factors) followed by documentation of progression of pain, associated symptoms, and effects of pain medication when applicable.

### **Data Collection**

The main strategy to achieve the aim of this project consisted of conducting a retrospective chart review. The retrospective chart review included a group of patients who were in the intensive care unit who were mechanical ventilated and unable to self-report pain. The chart review evaluates documentation of the selected patient's behavioral pain scale, nonverbal pain scores, and the pain interventions used. This component of the project evaluated the utilization of the behavioral pain scale and nonverbal pain scale relating to pain assessment and management in critically ill patients at TMC. Furthermore, this method helped to determine if the pain assessment scores correlated with the pain protocol and analgesics administered.

To evaluate the charts of the selected patients, the behavior pain scale, nonverbal pain scale scores, and the pain interventions were documented. Components of the project included: (1) charted scores of behavior pain scale for each patient ranging from 4-9 and NVPS for each patient that ranges from 5-10; (2) documented amount of fentanyl continuous intravenous infusion ranging from 0-200 mcg/hour; (3) documented frequency of as needed boluses; (4) documented Richmond Agitation Sedation Scale (RASS); (5) amount of sedation used; and, (6) days requiring mechanical ventilation. This author evaluated the scores of BPS and NVPS and its correlation to interventions used (fentanyl bolus and/or rate change); as well as correlation of RASS scores to analgesic administration. A score of '3' on a BPS indicates the patient is not in pain; therefore, chart review began with a BPS charted between

4 and 12. A score of '0' on a RASS scale indicates the patient is not agitated; therefore, chart review began with RASS of +1 and +4.

### **Sample and Participants**

The intensive care unit at TMC is a 28-bed unit. Patients selected for the retrospective chart review were admitted to the ICU between August 20, 2019 to August 27, 2019. The inclusion criteria for this project included patients who were between the 18 years and older, intubated requiring mechanical ventilation for four days or more, not delirious, and currently prescribed analgesia for pain control. The exclusion criteria included patients requiring neuromuscular blockade, severe sepsis requiring more than two vasopressors, delirious, neurological deficits, and post-cardiac open hearts. A total of 14 patients were eligible for chart review.

### **Data Analysis**

Descriptive statistics was used to analyze the data collected in this project. Data is presented using frequency distribution and percentage to describe the characteristics of the population sample and to describe documented BPS and NVPS scores, and the pain interventions used. Next, descriptive statistics was used to analyze the relationship between the utilization of sedation versus pain medications using BPS, NVPS, and RASS.

Abstracted data from the medical records included age, days on a mechanical ventilator, scores for NVPS, BPS, and RASS, and fentanyl and sedation rate/ changes. Data was imported directly into Microsoft Excel where the frequency, percentage, fentanyl boluses, and rate changes were analyzed. All the data was kept secure on a devoted USB drive protected with both a password and encryption. The USB drive was kept in a safe in the



principal investigator's home during the project. The data will be deleted off the USB drive after the project and safely USB discarded.

## RESULTS

This retrospective chart review occurred at TMC hospital from October 16, 2019 to October 30, 2019. Patients were in the ICU from August 20, 2019 to August 27, 2019. Patients intubated less than four days excluded involve patients become hemodynamically unstable for the first two to three days without consistent analgesia pain scales; therefore, starting the patient's timeframe at intubated for four days or more provided better information for this project. Secondly, patients initially intubated are also on the neuromuscular blockade, and open-heart surgery patients (42% of this ICU) intubated are being weaned from the ventilator and extubated within 8-10 hours.

The ICU at TMC collects a log of every patient that is admitted and discharged from the ICU, which resulted in 28 admissions in the timeframe of seven days chosen for data collection review. A total of 28 patients (n=28) reviewed for exclusion and inclusion criteria. A total of 12 charts dismissed secondary to data collection that does not meet inclusion criteria, mechanical ventilation less than four days, or no analgesia or sedation medications ordered. All data was collected using EPIC version 3.0. Of the 28 eligible ICU patients selected for the chart review, n=16 met the criteria included in this project. The data extracted from the 16 charts that met the criteria in this project which included each time analgesia and sedation given and the corresponding documented pain scale for each titration. The documented scores extracted from the charts include documented and undocumented scores for the following: NVPS, BPS, and RASS.

Data was imported directly into Microsoft Excel. From Microsoft Excel, the frequency, percentage, fentanyl boluses, and rate changes were determined. All the data that was collected was moved into Excel and kept secure on a devoted USB drive protected with both a password and encrypted. Data analysis was performed using SPSS. Frequency distribution and percentage to describe the characteristics of the population sample and to describe findings the charts of the selected patients BPS and NVPS scores and the pain intervenes used.

The median age of the sample was 60.5, with a mean of 57.6 and mode of 63. The age of the participants fell slightly below the national age average admitted to the ICU of age 65 and older (SCCM, 2019). The mean, median, and mode of mechanical ventilator days was 7.4, 6.5, and 5 respectively. The national average length of ventilator days is three to four (SCCM, 2019); however, this project excluded patients on mechanical ventilation less than four days. The mean, median, and mode of ICU length of stay was 8.6, 8, and 7, 6, 8, respectively. As expected, the sample LOS was higher than the national ICU LOS of 3.8 days, as patients who were intubated less than four days were excluded. (SCCM, 2019). There were 519 total sedation and analgesic changes made in this sample; 469 were analgesic changes, and 50 were sedation (Figure 1).

### **Aim 1**

The goal of aim 1 was to conduct a retrospective chart review to determine if the chosen analgesia medication administration given (such as bolus or rate change) included a documented pain scale, and if so, was the protocol followed by critical care nurses. All selected patients were reviewed for the following: titrated analgesia with either boluses or rate

changes for NVPS/ BPS with pain scale scores titrated analgesia with either boluses or rate changes with no pain scale scores. Also, this retrospective chart review reviewed the following information on the selected patients: the total amount of analgesia changes made, how many analgesia titration orders have both NVPS/BPS scores, how many had only one of each, how many analgesia/ sedation titrations have all three scales documented (NVPS, BPS, and RASS). Next, the selected patient's charts were reviewed for analgesia titration (either boluses or rate change) and pain scale scores (NVPS/BPS), comparing whether the critical care nurses followed the protocol adopted by TMC for analgesia titration.

After successful data extraction from the data collected from this project a total of 469 analgesic changes for the 16 selected patients. The total 469 analgesic changes separated into three different categories: titrated analgesia with NVPS pain scale score, titrated analgesia with BPS pain scale score, titrated analgesia with no pain scale scores. The results from NVPS with pain scale scores showed 121 in total boluses and rate change out of 469 total rate change concluding that 25.8% of the patient population chosen for this project had documented NVPS with each analgesic titration. The results from BPS with pain scale scores showed 115 in total boluses and rate change out of 469 total rate change concluding that 24.5% of the patient population chosen for this project had documented BPS with each analgesic titration. Next, the results from titrated analgesia with no pain scale scores showed 233 in total boluses and rate change out of 469 total change concluding that 49.6% of the patient population chosen for this project had no pain scale documentation with each analgesic titration.

Next, patients who had an analgesia titration in either boluses or rate change were examined to determine if the titration followed the protocol for the documented BPS and/or

NVPS score. Protocol adherence includes a fentanyl continuous infusion ranging from 0 to 200 mcg/hour, then may titrate by 25 mcg/hour if two or more breakthrough boluses given within an hour. Fentanyl bolus order administration is a 25-mcg bolus from the bag IV every 15 minutes as needed for BPS greater than '6' or NVPS greater than '3.' Protocol adherence for the NVPS with pain scale resulted in 113 analgesia titrations with a documented pain scale out of a total of 469 analgesic titrations followed the TMC protocol. The results concluded that 24.0% of critical care nurses adhered to the TMC analgesic titration protocol. Protocol adherence for the BPS with pain scale resulted in 106 analgesia titrations with a documented pain scale out of a total of 469 analgesic titrations followed the TMC protocol. The results concluded that 22.6% of critical care nurses adhered to the TMC analgesic titration protocol. During the times that critical care nurses did not adhere to TMC protocol, the patients were given analgesic titration inappropriately as either no pain scale was documented, or the documented NVPS or BPS did not reflect the patient being in pain (Figure 2).

Next, this project looked at titration orders that have both NVPS/ BPS scores as documented both pain scales are the current protocol required of critical care nurses at TMC. The analgesic titrations used both NVPS/ BPS scores; 115 analgesic changes administered out of 469 with documented both NVPS/BPS scores concluding that 24.5% of all analgesic titrations have both documented NVPS/BPS pain scale scores.

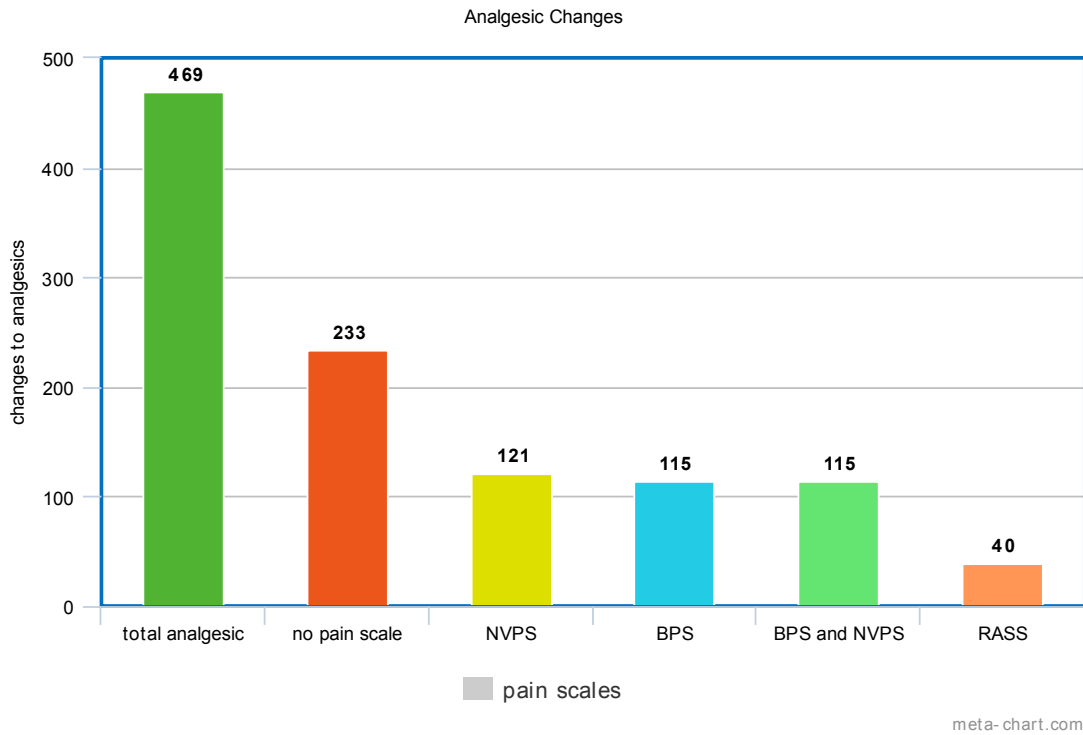


FIGURE 1. Analgesic changes.

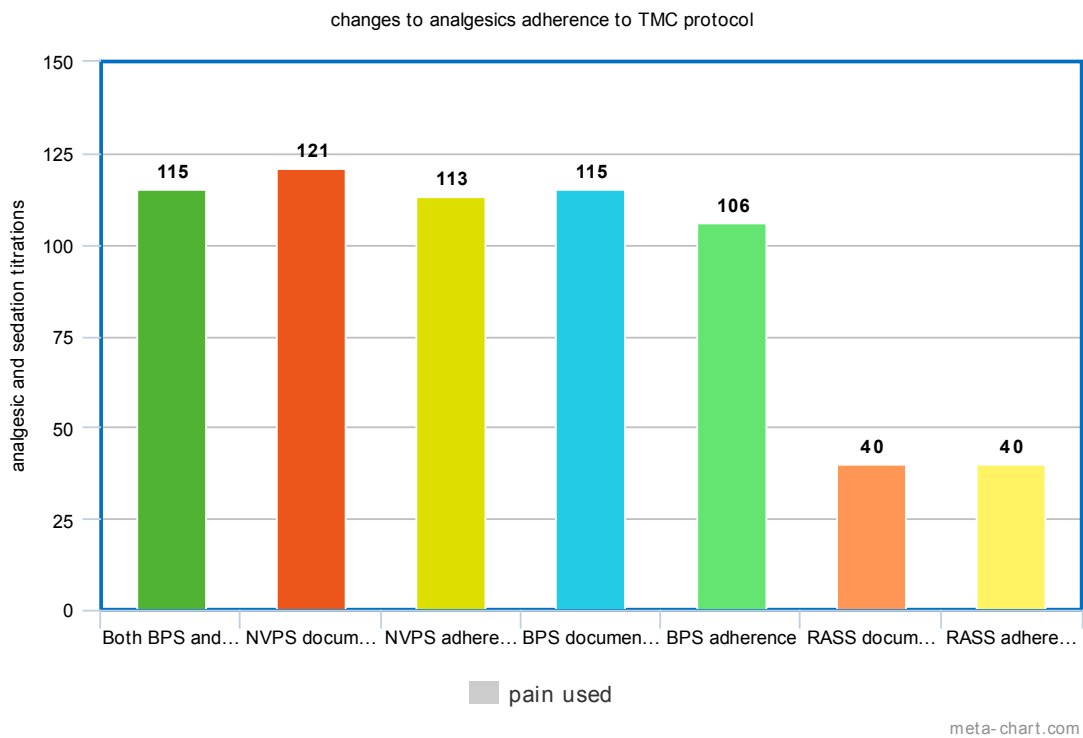
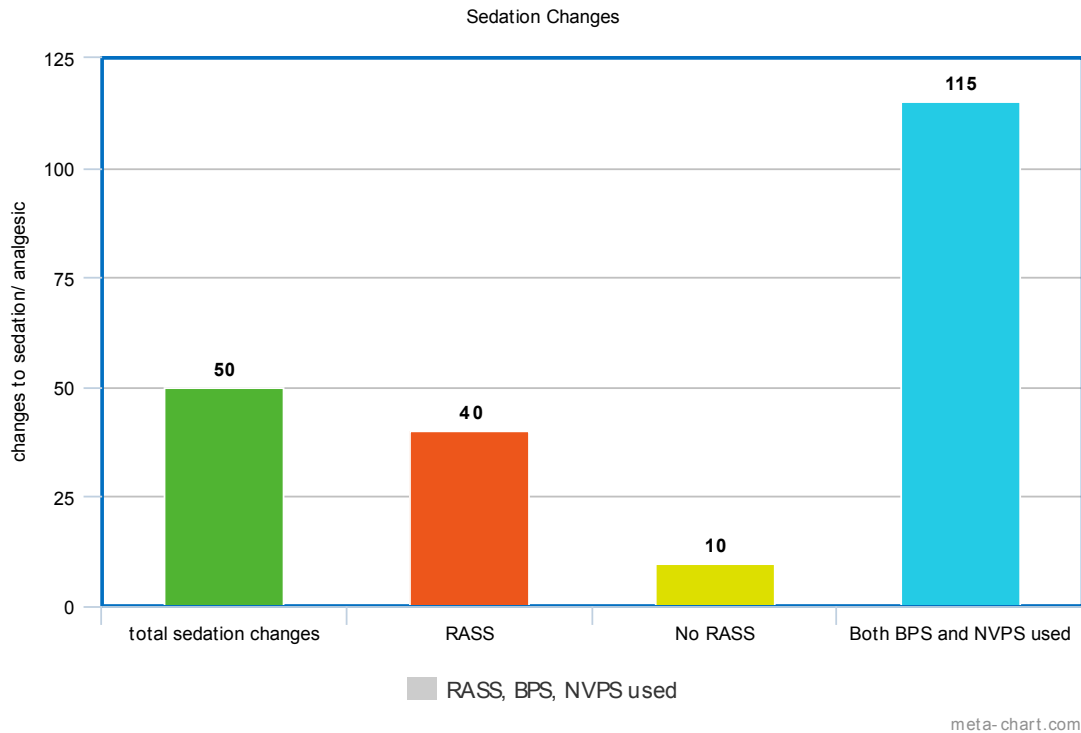


FIGURE 2. Adherence to TMC titration protocol.

## **Aim 2**

The goal of aim 2 was to determine if the chosen sedation medication administration given was a documented sedation scale used, and if so, was the protocol followed by critical care nurses. Selected patients chosen based on the inclusion criteria reviewed for the following: titrated sedation with rate changes for RASS sedation scale scores and titrated sedation with rate changes with no sedation scale scores. In addition, this retrospective chart reviewed the following questions on the selected patients: how many sedation changes administered and how many had a RASS score documented.

There were a total of 50 sedation changes made for the 16 selected patients, of which 40 rate changes out had a documented RASS score. The results showed that all 40 rate changes adhered to TMC sedation titration protocol. The results concluded that 80% of the patients chosen for this project had documented RASS scores with each sedation rate change. The results concluded that 20% of the patients chosen for this project did not have documented RASS scores with each sedation rate change (Figure 3).



*FIGURE 3.* Sedation changes.

## DISCUSSION

Inappropriate administration of analgesics continues to present with increased morbidity and mortality for patients admitted to ICU requiring mechanical ventilation (Johnson & Al-Dahr, 2016). Uncontrolled pain can lead to an increased potential for self-extubation, unintended catheter removal, ventilator desynchrony, vital sign instability, and post-traumatic stress disorder (Johnson & Al-Dahr, 2016). Controversially, overutilization of analgesics exposes patients to hospitalization, muscle weakness, prolonged cognitive dysfunction, prolonged ventilation, with an increased need for tracheostomy along with many other complications (Jacobi et al., 2002).

Pain assessment scales such as the NVPS and BPS are formulated to prevent complications of excessive or insufficient analgesic administration (Johnson & Al-Dahr,

2016). The use of pain scales has refined the ability to precisely document a patient's condition relating to pain, improve communication among providers, titrate analgesic therapy to an established goal, optimize analgesic administration, maximize patient safety and comfort, and has demonstrated a potential for minimizing ICU length of stay and days of mechanical ventilation (Jacobi et al., 2002).

The NVPS and BPS are examples of pain assessment scales that tested amongst critical care populations with reports of excellent reliability and validity; therefore, recommended for use published by the Society of Critical Care Medicine (SCCM, 2019). Despite efforts in the current literature regarding the use of NVPS and BPS for pain assessment and analgesic administration, the original thought was that there was a higher usage of sedation versus inadequate administration of analgesics due to uncontrolled pain. However, results from this DNP project observed a higher utilization of analgesia and improper documentation of pain scales (NVPS & BPS) and RASS at TMC.

Georgiou et al. (2015) reported that to successfully titrate analgesic in patients who are nonverbal requiring mechanical ventilation, critical care nurses must perform a pain and sedation scale to titrate analgesia and sedation. In this chart review, there were 519 analgesic and sedation changes; 469 were analgesic and 50 were sedation. The current clinical practice guidelines suggest that for every analgesic administration, whether a bolus, rate change for continuous infusion, or intravenous push, a pain score should be documented to support the analgesic administration given to the patient (Georgiou et al., 2015; Rijkenberg et al., 2017). Results for Aim 1 showed 25.8% documented NVPS with analgesic titrations but only 24.0% followed adherence to TMC analgesia titration protocol using NVPS. Results showed 24.5%



documented BPS with analgesic titrations but only 22.6% adhered to TMC analgesia titration protocol using BPS. When looking at the data reflecting when both NVPS and BPS were documented followed by analgesia titrations, only 24.5% were documented but not all titrations adherence to TMC analgesic titration protocol.

The results from Aim 2 concluded that 50 sedation changes made for the 16 selected patients chosen. From the 50 sedation changes, 40 rate changes had documented the RASS score. The results concluded that 80% of the patients had documented RASS scores with each sedation rate change. The current literature supports documenting a change in sedation titration, corresponding to a specific sedation scale (Rijkenberg et al., 2017). A total of 10 sedation changes did not have a documented RASS score resulting in 20% of patients received change in sedation without a documented RASS score.

The results obtained from this DNP project supports that there is a lack of adherence to the TMC policy concerning documentation in pain and sedation scale with every analgesia and sedation administration. It is evident when the results showed from aim 1 showed that even though critical care nurses only 25.8% documented NVPS and 24.5%. There was a lower percentage of documented pain scales that followed adherence to TMC analgesia titration protocol resulting in 21.9% documenting NVPS, and 22.6% documenting BPS. Findings discovered that even though patients were documented a pain score either NVPS and/ or BPS, the scores did not reflect a patient in pain but were given analgesia titration. In addition, there is a correlation between the same percentage of patient that were documented with a BPS and patients that received both NVPS and BPS scores, resulting in 24.5%. This data reflects that

critical care nurses documented NVPS more frequently than BPS as the total NVPS documented resulted in 25.8%.

Originally, this DNP project attempts to employ methods to determine if the current pain assessment tools: BPS and NVPS are adequate or an alternative pain scale (CPOT) is needed to assess for pain amongst critical care patients adequately. Another contributing factor is the use of the both NVPS and BPS corresponds with the original thought that the critical care nurses at TMC find a difficult time assessing for pain as multiple pain scale used to assess for pain. The current literature, as discussed by Bouajram et al. (2018) and Severgnini et al. (2016), utilized one pain scale throughout the project. Further research is needed to evaluate using both pain scales NVPS and BPS in a clinical setting.

Another thought is to identify the thought process of critical care nurses' understanding of the medications used to relieve pain versus sedation. The SCCM discussed that the main factors to uncontrolled pain includes (1) difficulty in assessing for pain in a nonverbal patient, (2) recognizing when to intervene for medication administration, and (3) critical care nurses' attitudes and perceptions towards utilizing pain assessment tools to control pain (SCCM, 2019).

### **Limitations**

Although this retrospective chart review provides initial insight, the short time frame, small sample size, and exclusion criteria, limits its generalizability to all patients in the TMC ICU. Additionally, factors affecting nurse utilization and documentation of pain and sedation scores were not examined. The literature suggests that evaluation of the nursing perspective of analgesic titration using the NVPS or BPS to measure the perception of accuracy to pain

assessment (Bouajram et al., 2018; Rijkenberg et al., 2017), as well as examining nurse's attitude of instituting the NVPS or BPS to evaluate pain is essential in evaluating any barriers to guide sedation titration (Bouajram et al., 2018; Rijkenberg et al., 2017).

### **Conclusion**

Several aspects from the literature support the use of NVPS or BPS as a pain assessment tool to guide titration of analgesics to the general population admitted to the ICU requiring mechanical ventilation (Bouajram et al., 2018; Rijkenberg et al., 2017); however, in this sample, there was low compliance to documenting pain and analgesic scores. Future projects could explore a nurse's perspective on ease of use and effectiveness of the NVPS or BPS for assessing pain, barriers to use, and time spent. A practice inquiry in a nurse's perspective could help disseminate any barrier(s) to assessing pain within the nursing profession. Another practice inquiry could investigate the reasons behind any lack of documentation before analgesic administration. Lastly, additional research conducted on nurses' perception of the understanding of the medications used to relieve pain versus sedation. By conducting additional research on critical care nurses' attitudes and perceptions, this could provide more information on whether TMC should implement an alternative pain assessment tool in clinical practice, or interventions to improve compliance with the current protocol.

### **OTHER INFORMATION**

#### **Resources and Budget**

The resources included in this project were the University of Arizona student email and Microsoft Excel. The projected budget for this project was minimal as the only cost was

that of driving to TMC to conduct the retrospective chart review on campus. The computers used to conduct the retrospective chart review were on the computers of the TMC campus. The projected cost was \$20.00 for driving to the clinical site; actual cost was \$40.00.

APPENDIX A:  
SYNTHESIS OF EVIDENCE

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
<p>Bouajram, R. H., Sebat, C. M., Love, D., Louie, E. L., Wilson, M. D., &amp; Duby, J. J. (2018). Comparison of self-reported and behavioral pain assessment tools in critically ill patients. <i>Journal of Intensive Care Medicine</i>.  <a href="https://doi.org/10.1177/0885066618757450">https://doi.org/10.1177/0885066618757450</a></p>	<p>The purpose of this study was to describe the correlation between self-reported and behavioral pain scores used in critically ill patients such as CPOT and BPS.</p>	<p>Prospective, observational study</p>	<p><b>Sample</b>  N= 115  Sixty-seven patients were not delirious, and 48 patients were delirious.  <b>Inclusion criteria:</b>  18 years of age or older, hospitalized in the ICU, and able to communicate verbally or able to squeeze hand when asked.</p> <p><b>Setting</b>  Large academic medical center  Washington</p>	<p><b>Data Collection</b>  The evaluator assessed pain by asking participants whether they were experiencing any pain  CPOT and BPS pain scales were performed first to eliminate bias.  Next, numeric rating scale and Wong Baker faces pain scale were used.  Lastly, patients were surveyed regarding pain assessment scale preference.</p> <p><b>Data Analysis</b>  The association between self-reported and behavioral scores was assessed using Spearman correlation.</p>	<p>The sensitivity for using CPOT for moderate to severe pain was 58.2% in the combined cohort which shows a large portion of patients with uncontrolled pain.  Patients with delirium resulted to have higher sensitivity and lower specificity confirms an enhanced display of the components of CPOT.  Results showed low sensitivities (BPS: 62.7%, CPOT: 76.5%) were observed in both delirious and non-delirious patients, confirming a</p>	<p><b>External Validity/ Limitations</b>  Single center study  Small portion of patients reported pain.  Only one assessor was used.</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				Sensitivity and specificity were calculated for using CPOT and NPS.	relatively high prevalence of undetected pain.	
<p>Chanques, G., Pohlman, A., Kress, J. P., Molinari, N., de Jong, A., Jaber, S., &amp; Hall, J. B. (2014). Psychometric comparison of three behavioral scales for the assessment of pain in critically ill patients unable to self-report. <i>Critical Care</i>, 18(5). <a href="https://doi.org/10.1186/cc14000">https://doi.org/10.1186/cc14000</a></p>	<p>The aim of this study is to evaluate the psychometric data and component of three different behavioral pain scales utilized in ICU: BPS, CPOT, and non-verbal pain scale</p>	<p>Cross-sectional Study</p>	<p><b>Sample:</b> N = 30 Inclusion: greater than 18 yrs old, Richmond Agitation Sedation Scale (RASS) above -4, and unable to self-rate pain</p> <p><b>Setting:</b> 16-bed medical ICU of the University of Chicago Hospital</p>	<p><b>Data Collection:</b> Pain assessment using BPS, CPOT, and NVPS used pre and post procedure. First, repositioning of the patient in the bed to evaluate pain Second, a complete turn to wash back and change linens was used to stimulate pain Third, endotracheal suctioning if possible A total of 258 paired assessments of pain was performed</p>	<p>Kappa coefficients showed a high significance for BPS (<math>0.81 \pm 0.03</math>) and CPOT (<math>0.81 \pm 0.03</math>) in comparison to NVPS (<math>0.71 \pm 0.04</math>, <math>P &lt; 0.05</math>). Cronbach-<math>\alpha</math> showed greater significance for BPS (<math>P &lt; 0.01</math>) and CPOT (<math>P &lt; 0.001</math>) in comparison to NVPS BPS and CPOT showed higher reactivity than NVPS</p>	<p><b>External Validity/ Limitations</b> Smaller sample size Additional research needed to assess reliability</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				<p><b>Data Analysis:</b> Kappa coefficient was used to determine inter-rater reliability The Cronbach-<math>\alpha</math> method was used to measure internal consistency. The Mann-Whitney-Wilcoxon test used to measure discriminant validation of different scores</p>		
<p>Gélinas, C. R. (2010). Nurses evaluations of the feasibility and the clinical utility of the critical-care pain observation tool. <i>American Society for Pain Management Nursing, 11</i>(2), 115–125. <a href="https://doi.org/10.1016/j.pmn.2009.05.002">https://doi.org/10.1016/j.pmn.2009.05.002</a></p>	<p>The purpose of this study was to determine ICU nurses' evaluations of the feasibility and clinical utility of the CPOT and their ability to assess pain in critically ill ventilated adults</p>	<p>Descriptive design</p>	<p><b>Sample:</b> N = 55 (cared for by nurse participants) Inclusion: greater than 18 years old, underwent abdominal, thoracic surgery and were mechanically ventilated.</p>	<p><b>Data Collection:</b> 62 ICU nurses underwent one-hour training on using CPOT Nurses were asked to score CPOT pre and post turning, taking noninvasive blood pressure and 20 min after The CPOT</p>	<p>Results showed more than 70% of the nurses thought CPOT is helpful in its application to clinical practice CPOT common assessment and application to assess patients' pain. More than half of the nurses that participated</p>	<p><b>External Validity/ Limitation</b> Small sample size Only moderate participation from nurses</p>



Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
			<p><b>Setting:</b> ICU of a university health medical center in the Montreal area</p>	<p>assessments a total of six assessments per patient After CPOT, nurses were asked to participate in evaluation tool on feasibility of CPOT</p> <p><b>Data Analysis:</b> Descriptive statistics were calculated to determine nurse sample and response in evaluation tool Qualitative data were also compiled from nurses for comments and suggestions.</p>	<p>supports using CPOT in practice</p>	
<p>Joffe, A. M., McNulty, B., &amp; Marsh, R. (2016). Validation of the Critical-Care Pain Observation Tool in brain-injured critically ill adults. <i>Journal of Critical Care</i>, 36(2016), 76-80. <a href="https://doi.org/10.1016/j.jcrc.2016.05.011">https://doi.org/10.1016/j.jcrc.2016.05.011</a></p>	<p>This study aimed to test the reliability and validity of the CPOT application for adult patients that have undergone brain-injured in ICU.</p>	<p>Prospective cohort study</p>	<p><b>Sample</b> N=79 Sustained brain injury requiring mechanical ventilator support</p>	<p><b>Data Collection</b> Selected personnel such as nurse and medical student who received training on pain</p>	<p>The intraclass correlation coefficient results are 0.73 (95% confidence interval, 0.57-</p>	<p><b>External Validity/ Limitations</b> Modest sample size Future research on larger sample</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
			<p>Inclusion:            (1) adults greater than 18 years old            (2) sustained brain injury including surgery from 2 days to 4 weeks in duration; and            (c) had a Glasgow Coma Score greater than 4.</p> <p><b>Setting</b>            Neuroscience Intensive Care Unit of the Harborview Medical Center in Seattle, WA.</p>	<p>assessment and CPOT selected patient presenting clinically with pain and performed a CPOT pain assessment.            Assessors observed the patient's face, body movements, and compliance with the ventilator or vocalization, and then assessed muscle tension by performing passive flexion and extension of the patient's arm            Next, patients were asked to nod head if pain is present for confirmation.  <b>Data Analysis</b>            Descriptive statistics was utilized by</p>	<p>0.83) during turning.            CPOT scores were significantly higher during turning compared with gentle touch (<math>P &lt; .001</math>)            Sensitivity of 0.90 and Specificity of 0.67.            CPOT results include high sensitivity which results in a valid assessment tool for pain.</p>	<p>size for conclusive results</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				<p>imputing demographics, behavioral changed, and CPOT data. The Shapiro-Wilk test was used to assess the normality of the distribution of self-report and CPOT scores. Intra-class correlation coefficients (ICC) was used for before and after procedure results to assess for interrater reliability. Friedman 2-way analysis of variance and the related-sample Wilcoxon signed rank test to determine discriminant validation. Mann-Whitney tests, and Spearman correlation</p>		

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				coefficient for self-reports of pain intensity used for criterion validation.		
<p>Kapritsou, M., Kalafati, M., Giannakopoulou, M., Korkolis, D. P., Kaklamanos, I., Siskou, T., &amp; Konstantinou, E. A. (2019). Cross-correlation among visual analog, observational, and behavioral pain scales of oncological patients undergoing major abdominal surgery. <i>Journal of Perianesthesia Nursing</i>, 1–5. <a href="https://doi.org/10.1016/j.jopan.2018.11.008">https://doi.org/10.1016/j.jopan.2018.11.008</a></p>	<p>To determine the perception of postoperative pain intensity between nurses and oncology patients undergoing major abdominal surgery.</p>	<p>A prospective cross-correlation study</p>	<p><b>Sample:</b> 203 screened. N =173 met criteria that underwent pancreatectomy or hepatectomy. 96 males and 77 females.</p> <p><b>Setting:</b> Oncological Hospital in Athens, Greece. Dates between May 2012 and March 2015.</p>	<p><b>Data Collection:</b> Verbal Assessment Scale (VAS) 0 to 10 was used to evaluate pain on day and 6 hours after surgery. Second method, on the day of operation, pain levels were evaluated by the CPOT. Third method, the day of operation, pain levels were evaluated by the BPS.</p> <p><b>Data Analysis:</b> Both the CPOT and BPS scales which are</p>	<p>There was a significant correlation between CPOT and BPS (<math>p = 0.796</math>, <math>P &lt; .001</math>). VAS correlated with CPOT and BPS (<math>p = 0.351</math>, <math>P &lt; 0.001</math> and <math>p = 0.352</math>, <math>P &lt; 0.001</math>, respectively). Age impacted the pain scales negatively. Young patients particularly experienced higher pain levels than the elderly. BMI-patients' BMI was not correlated with the pain levels</p>	<p><b>External Validity:</b> Limitations of study limits data to only oncological patients undergoing pancreatectomy and hepatectomy surgery.</p> <p>Performed in a one single tertiary hospital</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				observational, were completed by the researcher, based on patient's clinical appearance and vital signs. The VAS was completed by the patients.	experienced by patients (P>.05).	
Paulson-Conger, M., Leske, J., Mairl, C., Hanson, A., & Dziadulewicz, L. (2011). Comparison of two pain assessment tools in nonverbal critical care patients. <i>Pain Management Nursing</i> , 12(4), 218-224. <a href="https://doi.org/10.1016/j.pmn.2010.05.008">https://doi.org/10.1016/j.pmn.2010.05.008</a>	The purpose of this study is to compare the scores of CPOT to a nonverbal pain scale.	A descriptive, comparative, prospective design was used in this study	<b>Sample:</b> N = 100 in neuro, surgical, and medical ICUs Inclusion: (1) adults greater than 18 years old (2) mechanically vented for more than 24 hours; and <b>Setting:</b> All patients who were admitted to ICUs in level 1 trauma medical center in Chicago.	<b>Data Collection:</b> Two assessors were used that received training prior to start of study During 0800 to 1000 shifts, the two assessors stood on the two sides of the beds and observed the patients. Changing positions was the first method used as painful procedure Washing eyes with cotton soaked in saline	Correlation coefficients were $r = 0.86$ The results of confirmed the analysis and internal consistency prove efficiency of increased pain with high CPOT scores.	<b>External Validity/ Limitations</b> Sample size from four different units

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				<p>0.9% was used as non-painful procedure.</p> <p><b>Data Analysis:</b> Internal reliability was used via the Cronbach alpha score. Bland Altman analysis was used to determine level of agreement between NVPS and CPOT</p>		
<p>Rijkenberg, S., Stilma, W., Bosman, R. J., van der Meer, N. J., &amp; van der Voort, P. H. J. (2017). Pain measurement in mechanically ventilated patients after cardiac surgery: Comparison of the behavioral pain scale (BPS) and the critical-care pain observation tool (CPOT). <i>Journal of Cardiothoracic and Vascular Anesthesia</i>, 31(4), 1227-1234. <a href="https://doi.org/10.1053/j.jvca.2017.03.013">https://doi.org/10.1053/j.jvca.2017.03.013</a></p>	<p>The aim to this study is to analyze the reliability and validation between using BPS vs CPOT in ICU.</p>	<p>prospective, observational cohort study</p>	<p><b>Sample:</b> N= 72 both men and women meeting criteria. Inclusion criteria: (1) &gt;18 years old, (2) unable to self-report pain, (3) expected to stay in the ICU more than 12 hours.</p>	<p><b>Data Collection:</b> Tested both CPOT and BPS with 4 different type of movements: (1) at rest, (2) during the nonpainful procedure, (3) at rest just prior to a painful procedure, and (4) during the painful</p>	<p>Cronbach's alpha for both scores were &lt;0.70. CPOT scores were between 0.31 and 0.81 BPS scores ranges from 0.63 to 0.77.</p>	<p><b>External Validity/ Limitations</b> Small sample size Induced selection bias</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
			<p><b>Setting:</b> 20-bed medical, surgical, and cardiac ICU in Amsterdam, The Netherlands.</p>	<p>procedure.</p> <p><b>Data Analysis:</b> Validation tested via Friedman test Wilcoxon signed test for ranking between the two tools</p>		
<p>Severgnini, P., Pelosi, P., Contino, E., Serafinelli, E., Novario, R., &amp; Chiaranda, M. (2016). Accuracy of critical care pain observation tool and behavioral pain scale to assess pain in critically ill conscious and unconscious patients: Prospective, observational study. <i>Journal of Intensive Care</i>, 4(1), 1-8. <a href="https://doi.org/10.1186/s40560-016-0192-x">https://doi.org/10.1186/s40560-016-0192-x</a></p>	<p>The main aim of this study was to compare two commonly used scales for pain evaluation: CPOT and BPS in both conscious and unconscious patients. Secondary aims: (1) identify the most relevant parameters to determine pain scales changes during nursing procedures (2) compare CPOT and BPS to pain scales with VAS (3) to identify the best combination of scales for evaluation of pain in patients unable to communicate.</p>	<p>Observational study</p>	<p><b>Sample:</b> N= 101 total N = 41 conscious patients N= 60 unconscious patients Inclusion criteria were (1) need of invasive mechanical ventilation and (2) admission in ICU longer than 24 h.</p> <p><b>Setting:</b> ICU at Italy</p>	<p><b>Data Collection</b> Pain was evaluated in both conscious and unconscious patients before, during, and 20 min after nursing care Pain assessment was performed by the CPOT and BPS scales in conscious and unconscious patients, while VAS in conscious patients The conscious patients were identified by using a GCS</p>	<p>Results for criterion and discriminant validity regarding CPOT and BPS are good (p &lt; 0.0001). BPS has more specificity (91.7 %) than CPOT (70.8 %), but less sensitivity (BPS 62.7 %, CPOT 76.5 %). The use of both BPS and CPOT resulted in higher sensitivity (80.4 %). Both BPS and CPOT can be</p>	<p><b>External Validity/ Limitations</b> Small sample size Pain scale subjective to assessor.</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				greater than 10  <u>Data Analysis</u> Discriminant validity was measures before, during after any procedures via Wilcoxon coefficient. Criterion validity was measured by observing CPOT and BPS scores with VAS using Spearman rank correlation coefficient.	utilized to for adequate pain assessment	
Tousignant-Laflamme, Y., Bourgault, P., Gélinas, C., & Marchand, S. (2010). Assessing pain behaviors in healthy subjects using the critical-care pain observation tool (CPOT): A pilot study. <i>Journal of Pain, 11</i> (10), 983-987. <a href="https://doi.org/10.1016/j.jpain.2010.01.266">https://doi.org/10.1016/j.jpain.2010.01.266</a>	The main objective to this study is to determine the relationship between self-reports of pain intensity and the CPOT score by utilizing the CPOT to different levels of pain intensity in healthy subjects.	Experimental/ Pilot Study	<u>Sample:</u> N=18, 9 women, 9 males. All participants signed a written consent and received a \$20 compensation.  <u>Setting:</u> Clinical Research	<u>Data Collection:</u> The experimental pain procedure used a cold pressor test (CPT) on participants. The right arm was emerged in cold water maintained at 7 C for 2 minutes.	Interrater reliability results of 0.963 (95% CI [0.904-0.986]). A positive correlation ( $r = 0.52$ , $p = 0.028$ ) between the CPOT and self-reports pain scale. Scores resulted in specificity of	<u>External Validity/ Limitations</u> Small sample size Participants are healthy individuals; results might be different in unstable ill patients.



Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
			Centre of the Centre Hospital University in Sherbrooke, Quebec, Canada.	To assess for pain, researchers used criteria of CPOT such as facial expressions, body movements (taping of foot), and muscle tension to assess for pain.  <b>Data Analysis:</b> Descriptive statistics For pain intensity and pain behaviors (CPOT). Interrater reliability used by 2 evaluators. Interclass correlation coefficient (ICC) examine self-reports of pain intensity and CPOT scores.	86%. Results supports an increase of CPOT score with direct correlation with increased pain and its application to clinical use.	
Van der Voort, P. H. J., Rijkenberg, S., Stilma, W., Bosman, R. J., & van der	The purpose of this study was to compare	A prospective,	<b>Sample:</b> 207 screening.	<b>Data Collection</b> The bedside	Scores using both CPOT and	<b>External Validity/</b>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
<p>Meer, N. J. (2017). Pain measurement in mechanically ventilated patients after cardiac surgery: Comparison of the behavioral pain scale (BPS) and the critical-care pain observation tool (CPOT). <i>Journal of Cardiothoracic and Vascular Anesthesia</i>, 31(4), 1227-1234. <a href="https://doi.org/10.1053/j.jvca.2017.03.013">https://doi.org/10.1053/j.jvca.2017.03.013</a></p>	<p>the reliability, internal consistency, and validation of the BPS and the CPOT in patients requiring mechanically ventilation after cardiac surgery.</p>	<p>observational cohort study</p>	<p>N=72 met criteria requiring analgesic and sedation while on mechanical ventilation</p> <p><b>Setting:</b> 20-bed, closed-format ICU with mixed medical, surgical, and cardiac surgery patients in a teaching hospital in Amsterdam, The Netherlands.</p>	<p>nurse and assessed both the BPS and CPOT during the following (1) at rest just before a nonpainful procedure (2) during the nonpainful procedure (3) at rest just before a painful procedure (4) during the painful procedure The times of between 4 PM and 10 PM were selected. Inclusion criteria includes able to respond to pain and unable to verbally communicate.</p> <p><b>Data Analysis</b> Data analyzed by SPSS. Interrater reliability of</p>	<p>BPS showed a significant increase of 2 points between rest and turning. The median BPS showed an increase of 1 point between rest and the nonpainful procedure. The interrater reliability of the BPS and CPOT showed an average score of 0.74. Cronbach's alpha values for the BPS were 0.62 and 0.59. CPOT showed scores of 0.65 and 0.58. Both CPOT and BPS adequately provides assessment tool for pain in nonverbal patients.</p>	<p><b>Limitations</b> Assessors were trained ICU nurses knowing which procedures will cause which might have increased inflation of the discriminant validation. Number of analyzed patients were small in comparison to sample size leading to selection bias.</p>

Author/Title	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings	Challenges to Scientific Rigor
				CPOT and BPS determined by intraclass correlation coefficients (ICC). Internal consistency determined by Cronbach's coefficient during peak of patient's pain		

APPENDIX B:  
THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL  
LETTER



Human Subjects  
Protection Program

1618 E. Helen St.  
P.O. Box 245137  
Tucson, AZ 85724-5137  
Tel: (520) 626-6721  
<http://hgw.arizona.edu/compliance/home>

**Date:** October 14, 2019  
**Principal Investigator:** Rebecca Ru Griffin  


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**Protocol Number:** 1910024667  
**Protocol Title:** EVALUATION OF CRITICAL CARE NURSES' UTILIZATION OF PAIN ASSESSMENT TOOLS IN CLINICAL PRACTICE  


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**Determination:** Human Subjects Review not Required

**Documents Reviewed Concurrently:**

**HSPF Forms/Correspondence:** *irb application 5.pdf*

**Other Approvals and Authorizations:** *COI Certification Complete for 1910024667.msg*

**Regulatory Determinations/Comments:**

- Not Research as defined by 45 CFR 46.102(1): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPF) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPF to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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