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# Psychometric Evaluation of the Neonatal Pain, Agitation, and Sedation Scale (n-Pass) Tool in Infants and Children Age One to Thirty-Six Months in the Post-Anesthesia Care Unit

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# PSYCHOMETRIC EVALUATION OF THE NEONATAL PAIN, AGITATION, AND SEDATION SCALE (N-PASS) TOOL IN INFANTS AND CHILDREN AGE ONE TO THIRTY-SIX MONTHS IN THE POST-ANESTHESIA CARE UNIT

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To the infants and children who experience pain as a result of their disease or treatment:
May this research add to the body of knowledge necessary to alleviate their suffering.

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ABSTRACT

The purpose of this study was to investigate the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) tool for evidence of validity and reliability in infants and children aged one to thirty-six months in the Post-Anesthesia Care Unit (PACU). This study design was a prospective, non-experimental psychometric evaluation of the N-PASS tool.

The research was conducted at a Midwestern Medical Center. The sample analyzed comprised forty subjects aged one to thirty-six months.

Data collection involved the evaluation of participants every five minutes, utilizing the N-PASS sedation subscale along with the University of Michigan Sedation Scale (UMSS) and the N-PASS pain/agitation subscale along with the Face, Legs, Arms, Cry, Consolability (FLACC) tool. All subjects were observed for a minimum of ten observations.

The results showed that the Cronbach's alphas of the N-PASS sedation scale ranged from .853 to .923, and from .935 to .971 for the N-PASS pain/agitation scale. Correlations between the N-PASS sedation scale and the UMSS tool ranged from .847 to .967. Correlations between the N-PASS pain/agitation scale and the FLACC tool ranged from .980 to .996.

Repeated Measures ANOVA analysis revealed that the N-PASS sedation score decreased linearly over time. Repeated Measures ANOVA indicated that the N-PASS

pain/agitation scores changed over time, but not at a linear, quadratic, or cubic form. Regression analysis revealed a statistically non-significant linear trend for the prediction of amount of time spent in PACU as a function of change in sedation levels from time 1 to time 10.

Principal axis factor analysis found that two factors accounted for 80.46 to 87.77% of the variance. One factor represented pain/agitation, and one factor represented sedation, confirming the two subscales of the N-PASS tool. All items had high factor loadings (> .60). Factor structure remained similar over the three time periods.

The implications for this research indicate sufficient evidence for use of the N-PASS tool for sedation and pain/agitation assessment in infants and children one to thirty-six months of age.

# CHAPTER ONE

# STATEMENT OF THE PROBLEM

## Introduction

Management of pain and alleviating suffering are ethical mandates for nursing practice (American Nurses Association, 2001). Pain assessment is an essential nursing responsibility and the foundation of pain management. Sedation assessment is also an essential nursing responsibility—monitoring for inadvertent sedation following analgesic medications, or the level of sedation following sedative administration, or post-anesthesia in the perioperative setting. Nonverbal patients, including infants and preverbal toddlers, critically ill or unconscious patients, persons with intellectual disabilities, and patients at the end of life all challenge the nurse to detect and interpret behavioral indicators of pain and sedation.

Each of these populations may be unable to self-report pain due to cognitive, developmental, or physiologic issues, including medically induced conditions, creating a major barrier for adequate pain assessment and achieving optimal pain control. Inability to provide a reliable report about pain leaves the patient vulnerable to under-recognition, and under- or over-treatment. Nurses are integral to ensuring assessment and treatment of these vulnerable populations (Herr, Coyne, McCaffery, Manworren, & Merkel, 2011).

Behavioral assessment tools are widely used in nonverbal populations to provide an assessment and measurement of specific behaviors as objectively as possible in the

clinical setting, providing information necessary to deliver safe care and to evaluate clinical interventions. Psychometric evaluation of these behavioral assessment tools is essential, as the instruments are used to guide clinical care and as outcome measures in pain management research.

The Joint Commission pain management standards, implemented in 2001, stated that every patient has a right to have their pain assessed and treated (JCAHO, 2000). The standards mandate that tools with evidence of reliability and validity are used for pain assessment, and that the appropriate tool be used for the patients' age and situation. This standard spurred the implementation of pain assessment and management protocols in health care organizations. This, in turn, identified gaps in knowledge, leading to an increase in the development and implementation of pain assessment tools designed, researched, and used mainly by registered nurses to assess pain and guide interventions.

Behavioral pain assessment tools, developed empirically over the past thirty to forty years, are used in the clinical setting and in research. These tools were first designed for use in the pediatric population, and then expanded to the neonatal and the adult nonverbal population. The Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) tool was one of the earliest tools developed to assess and document pain behaviors in young children (McGrath et al., 1985). Within a few years, The Neonatal Facial Coding System (NFCS) was developed for use in newborn infants (Grunau & Craig, 1987). Dozens of pain assessment tools have been developed since that time for use in all nonverbal populations including the preterm neonate through the nonverbal adult.

Sedation assessment and measurement has not been formally mandated, other than in safety guidelines for discharge following procedural sedation in children

(American Academy of Pediatrics, 2006). Tools with evidence of validity and reliability that standardize assessment of the child's sedation level enhance systematic assessment and documentation, allow individual alterations in the therapeutic regimen, and help avoid insufficient or excessive sedative use (Marx et al., 1994). Sedation assessment tools are commonly used as an outcome measure in clinical research.

Sedation assessment tool development and testing in the adult and pediatric populations has emerged over the past decade, in response to clinical and research requirements for sedation level documentation. The University of Michigan Sedation Scale (UMSS) is an observational tool that scores the adult or pediatric patients' responsiveness to stimulation as a measure of sedation during procedures (Malviya et al., 2002). The Richmond Agitation-Sedation Scale (RASS) is a commonly used adult sedation scale, grading behavior on a scale of combativeness to deep sedation (Sessler et al., 2002).

Neonatal and pediatric pain research has been subjected to systematic review and analysis, identifying core outcomes and measures recommended for pain research (Anand et al., 2006; McGrath et al., 2008). The National Institute of Child Health and Human Development and the U.S. Food and Drug Administration (NICHD/FDA) task force on neonatal pain identified pain assessment knowledge gaps; current tools were delineated, and the need for further validity and reliability testing of the tools was identified (Anand et al., 2006). The N-PASS tool (Hummel, Puchalski, Creech, & Weiss, 2008) was recommended for use in the neonatal population. The Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMMPACT) consensus statement reviewed observational pain assessment tools and identified those appropriate

for use in acute pain trials (McGrath et al., 2008). Both reviews identify the need for the development of tools designed for pain and sedation measurement in infants and preverbal toddlers, particularly in the intensive care setting.

An assessment tool with evidence of validity and reliability that measures pain and sedation in critically ill or perioperative children has implications for all realms of nursing, including education, practice, and research. Nursing education includes pain and sedation assessment and management in the nonverbal population. Assessment tools quantify pain indicators, facilitate classroom learning, and reinforce the role of the nurse in pain assessment and evidence-based intervention. Pediatric nursing textbooks by Algren (2005) and by Hockenberry and Wilson (2009) devote several pages to pain assessment. Tools for verbal children and for behavioral pain assessment are listed, with basic explanations of behavioral pain assessment. Pediatric behavioral pain rating scales outlined in chapters focusing on family-centered care of the child during illness and hospitalization include the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) (McGrath et al., 1985) and the Face, Legs, Activity, Cry, Consolability tool (FLACC) (Merkel, Voepel-Lewis, Shayevitz, & Malviya, 1997), as well as other tools that are used clinically but lack psychometric evaluation. Infant assessment tools included are the Neonatal Infant Pain Score (NIPS) (Lawrence et al., 1993); the Crying, Requires oxygen, Increased vital signs, Expression, Sleepless (CRIES) (Krechel & Bildner, 1995); the Premature Infant Pain Profile (PIPP) (Stevens, Johnston, Petryshen, & Taddio, 1996); and the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) (Hummel et al., 2008); as well as other clinically used tools that lack psychometric evaluation. Sedation

assessment instruments are not included in the textbooks (Algren, 2005; Hockenberry & Wilson, 2009).

Nurse researchers interested in assessment of nonverbal patients have unprecedented opportunities at this time for conducting pain research in nonverbal populations including infants and preverbal children. Studies should focus on comparison of existing instruments to determine those with the strongest psychometric properties and to identify the weaknesses in instruments that may be widely used but have significant psychometric weaknesses that lead to incorrect inferences. Validated assessment tools can be used in nursing intervention pain and sedation research, contributing to evidence-based nursing practice guidelines.

Pain and sedation assessment and providing comfort are universal nursing functions that require measurement based on patient characteristics including age and stage of development. The nursing diagnosis of alteration in comfort is applicable for infants and children experiencing pain (North America Nursing Diagnosis Association International, 2009). Clinical practice is based on findings from research-based assessment tools, providing the means by which to make an accurate nursing diagnosis, leading to appropriate intervention.

There is a need for an empirically developed instrument with adequate psychometric evaluation to measure pain and sedation in the infant and pediatric populations. Such an instrument is essential to the implementation and evaluation of evidence-based interventions in the clinical and research settings.

## Problem Statement

There is a clinical need for an assessment tool that measures pain and sedation in infants and children. The N-PASS tool has been researched in preterm and term infants, twenty-three to forty weeks gestation at birth up to 100 days of age; the upper age limit for use of the N-PASS tool has not been researched (Hummel, Lawlor-Klean, & Weiss, 2010; Hummel et al., 2008). Users regularly contact the author of the N-PASS to inquire if the tool can be used in older infants and toddlers, indicating a need for testing of the tool in older age groups, particularly with infants up to thirty-six months of age. This age group is justified for research, as children over three years of age may be developmentally able to provide verbal self-report of pain. Children under three years of age are developmentally unable to clearly and reliably self-report pain, necessitating behavioral pain assessment (Wong & Baker, 1988). The N-PASS tool requires investigation to determine the age usage limits for validity and reliability evidence, guiding appropriate clinical and research use.

## Purpose of the Study

The purpose of this study was to investigate the N-PASS tool for evidence of validity and reliability in a sample of infants and children one to thirty-six months of age in the Post-Anesthesia Care Unit (PACU). Nurses and physicians in the PACU provide care for infants and children in the immediate postoperative condition. This setting allows for observation of infants and children emerging from general anesthesia, providing data for psychometric evaluation of the sedation assessment portion of the N-PASS tool. This setting also enables observation of infants and children in pain, providing data for psychometric testing of the pain assessment portion of the N-PASS tool.

The research questions for infants one to thirty-six months of age in the PACU setting are the following:

1. Do the N-PASS tool subscales of sedation and pain/agitation exhibit internal consistency as measured by Cronbach's alpha?
2. Does the N-PASS tool sedation subscale exhibit criterion validity when compared with the UMSS instrument?
3. Does the N-PASS tool pain/agitation subscale exhibit criterion validity when compared with the FLACC instrument?
4. Do the N-PASS tool sedation and pain/agitation subscales exhibit construct validity in the PACU setting by showing significant difference in scores over time through Repeated Measure ANOVA testing?
5. Does the N-PASS tool provide a predicted pathway of behaviors over time of recovery in the PACU setting?
6. What is the factor structure of the N-PASS tool?

The chapters that follow provide a review of the literature involving pain and sedation assessment and a research plan for the psychometric evaluation of the N-PASS tool in infants and toddlers, one to thirty-six months of age in the PACU setting. Research findings will be delineated and discussed.

# CHAPTER TWO

# LITERATURE REVIEW

This chapter reviews the conceptualization of pain and sedation in infants and children, with an emphasis on assessment. The state of theoretical knowledge and clinical practice is summarized, reviewing behavioral pain and sedation indicators and the current pain and sedation assessment tools used in the pediatric population. Gaps in knowledge are identified, justifying the need for this research.

## Conceptualization and Theory

Pain experience  physiology is a complex phenomenon (Marchand, 2008). Pain perception and response is dependent upon intact nerves, tracts, neurotransmitters, and cortical function, and can be interrupted in any or all of these areas by analgesic medications, or by physical or physiological variants.

### Conceptualization of Pain

A concise overview of pain is provided by Loeser and Melzack (1999). The pain experience begins with nociception. This is the detection of tissue damage in the periphery with pain receptors, the nociceptors, activating a stimulus that travels to the dorsal horn of the spinal cord, resulting in reflexive response along with transmission to the brain via ascending fibers. Descending inhibitory pain tracts are simultaneously activated and may diminish transmission to the brain. Multiple areas of the brain are involved in pain perception and response; there is no specific pain center. Cortical interpretation of the pain stimulus leads to a response which may be verbal, or nonverbal, or both. Suffering is a negative response induced by pain and also by fear,

anxiety, stress, loss of loved objects, and other psychological states (Cassel, 1982). Pain expression and behaviors result from pain and suffering. The verbal individual can communicate their pain to others using words describing the location, intensity, and character of the experience. The nonverbal individual communicates with a behavioral response if physiologically able to do so.

The International Association of Pain (IASP) describes pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain is always subjective" (IASP, 1994). This description was expanded in 2001, adding that the inability to communicate in no way negates the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment (IASP, 2001).

The absolute subjectivity of the pain experience leads to difficulty in the measurement of pain in the person who is unable to verbally express their level of pain. The American Society for Pain Management Nursing delineates a hierarchy of pain assessment and treatment techniques, providing guidelines for the clinician (Herr et al., 2006; Herr et al., 2011; McCaffery & Pasero, 1999). This guideline gives a sequence of five steps to achieve optimal pain assessment in the clinical setting:

1. The most optimal pain assessment technique is verbal self-report.
2. In the absence of self-report, the clinician should search for potential causes of pain and treat the patient accordingly, ensuring that patients are treated in painful situations regardless of behaviors.
3. The clinician should observe patient behaviors, cautioning that these behaviors may not always be accurate reflections of pain intensity and in some cases indicate another source of distress, such as physiologic or emotional distress.

4. The clinician should use surrogate reporting from parents and caregivers.
5. An analgesic trial should be employed if there are pathologic conditions or procedures likely to cause pain or if pain behaviors persist after attention to basic needs and comfort measures.

Pain and sedation are viewed as separate yet linked phenomena. Pain levels range from mild to severe, while sedation levels range from light sedation to general anesthesia. Analgesic medications may relieve pain and may also lead to sedation. Sedative medications cause sedation by altering neurotransmitters, receptors, or cortical processes. Sedatives may mask behavioral pain signals without providing analgesia. Pain and sedation may be present simultaneously or independently.

**Conceptualization of Sedation**

Sedation is defined as a calm tranquil state that allays anxiety and excitement (Curley, Harris, Fraser, Johnson, & Arnold, 2006). The American Society of Anesthesiologists delineates a continuum of sedation from minimal (anxiolysis) to general anesthesia (American Society of Anesthesiology House of Delegates, 2012). (See Table 1.) In this continuum, levels of sedation are evaluated by assessing responsiveness, airway maintenance, spontaneous ventilation, and cardiovascular function; these items are particularly important in the perioperative or procedural/diagnostic situations.

Sedative medications modulate receptors in the central nervous system as well as other organs in the body (American Society of Anesthesiology House of Delegates, 2012; Crain, Slonim, & Pollack, 2002). Sedatives are used to reduce anxiety, decrease agitation, and induce sleep. Vital functions such as respiration are depressed. General anesthetics cause a loss of awareness and a general insensitivity to pain.

Table 1. Continuum of Sedation

| | Minimal sedation anxiolysis | Moderate sedation/analgesia ("conscious sedation") | Deep sedation/ analgesia | General anesthesia |
|---|---|---|---|---|
| Responsiveness | Normal response to verbal stimulation | Purposeful[a] response to verbal or tactile stimulation | Purposeful[a] response following repeated or painful stimulation | Unarousable even with painful stimuli |
| Airway | Unaffected | No intervention required | Intervention may be required | Intervention often required |
| Spontaneous ventilation | Unaffected | Adequate | May be inadequate | Often inadequate |
| Cardiovascular function | Maintained | Maintained | Impaired | |

[a]Reflex withdrawal from painful stimulus is not considered a purposeful response (American Society of Anesthesiology House of Delegates, 2012).

Anesthesia professionals are concerned with defining awakening from anesthesia in the perioperative setting. To define awakening in infants, Bould and Sury (2011) used a modified Delphi technique with an iterative process of questionnaires and anonymous feedback by email. Thirty-one consultant pediatric anesthetists were surveyed. Consensus was defined a priori as 80% agreement. This consensus was reached on six criteria that define awakening in infants. Crying and attempting to cry were combined, leaving five criteria: 1) crying or attempting to cry; 2) vigorous limb movements; 3) gagging on a tracheal tube; 4) eyes open; and 5) looking around.

The authors propose that at least two of the five behaviors are present to consider a neonate awake after anesthesia. The authors did not psychometrically evaluate this tool.

They anticipate that future investigators may modify the criteria and develop a consciousness-level scale for infants.

**The Gate Theory of Pain**

The Gate Theory of Pain, introduced by Melzack and Wall (1965) over forty years ago, remains a widely accepted theory of pain perception for all populations. This theory includes a conceptualization of pain transmission and transduction of pain messages via neurological pathways from the body to the brain, with a complex array of ascending, as well as descending, mechanisms. Messages travel from the periphery through the spinal cord to the brain and pass back to the periphery. Some pain messages do not reach the brain due to the closed gate; the message is blocked by descending inhibitory pathways or modified by endorphin release. This protective mechanism allows the person to function in the presence of a painful stimulus by blunting pain perception. Cognitive thought processes and emotional responses to the pain are influential in modulating the pain response, as well as affecting the personal experience of pain. Pain is a physiological sensation that an individual quantifies objectively, according to their personal experience of pain events.

**Behaviorism**

Behaviorism is a psychological perspective introduced over one hundred years ago that seeks to explain animal and human behavior entirely in terms of observable and measurable responses to environmental stimuli (Watson, 1913). Behaviorism theory is an essential framework used in pain assessment research in the nonverbal population. Observable and measurable responses to pain are the basis of behavioral pain and sedation assessment methodologies.

**The Psychological Behaviorism Theory of Pain**

The Psychological Behaviorism Theory of Pain facilitates the development of a common vocabulary for pain research across disciplines (A. W. Staats, 1996; P. S. Staats, Hekmat, & Staats, 2004). In this theory, pain is proposed to consist of seven interacting dimensions: basic biology, conditioned learning, language cognition, personality differences, pain behavior, the social environment, and emotions. Because pain is a multidimensional response to a physiological stimulus, examining the bidirectional impact of emotion is pivotal to understanding pain. Emotion influences each of the other areas of interest and causes the impact of each factor to amplify or diminish in an additive fashion. This theory and its definitions of pain, however, are problematic when applied to the nonverbal subject, as emotions are difficult to quantify through behavioral observation.

**The Social Communication Model of Pain**

A theory that guides pediatric/infant research and practice is the Social Communication Model of Pain (Craig, 2009; Craig & Pillai Riddell, 2003; T. Hadjistavropoulos & Craig, 2002). In this theory, infant pain, pain assessment, and pain management are understood within the context of the caregiver. The infant experiences pain, and expresses the pain behaviorally. Pain behaviors are influenced by the caregiver's assessment and management of pain. The infant in pain is assessed within the context of a dynamic, interactive process involving both the child and caregiver, each of whom is uniquely influenced by the greater spheres of family, community, and culture. Infant pain is posited to be comprised of states within the child, within the caregiver, and

between the child and caregiver.

This theory posits that the infant or child's internal experience of pain is influenced by the biological composition of the infant (such as nervous system thresholds), the infant's past experiences with pain, and the different social contexts (such as in the hospital alone or at home with the parents) in which the pain occurs. A caregiver can never obtain a definitive understanding of the child's internal pain experience (Craig & Pillai Riddell, 2003). Healthy infants react to tissue damage with vigorous vocal and non-vocal activity, providing a means for inferring their subjective state. The infant is dependent on others for survival; these actions communicate distress. The aspects of the social context and the presence of parents will impact the infant's pain expression.

The theory conceptualizes pain assessment as a process that involves the caregivers becoming aware of and interpreting the infant's expression of pain. The caregiver may or may not gather information to classify the distress as pain; this process is influenced by the sensitivity of the caregiver. The caregiver's interpretation is influenced by their knowledge base—knowledge of the specific child and of children in general, and knowledge of common pain indicators. The caregiver considers possible alternatives for the distress. Interpretation of the infant's expressions is influenced by pre-existing attitudes and the environmental context. The caregiver processes the information and makes decisions as to whether the infant is in pain. Interventions may then be instituted to relieve the infant's pain. If the infant's distress is not relieved, the caregiver further assesses the infant and employs a new management strategy.

This theory led to the development of a theory of pain assessment as a transaction (Schiavenato & Craig, 2010). This theory proposes a more comprehensive

conceptualization of pain assessment as a transaction based on the interplay between the patient and the clinician. This theory was supported by a review of the literature that includes the complexity of pain assessment in children, the difficulties in interpreting their pain scores, and the difficulties in nurses' clinical pain management decisions (Voepel-Lewis, Piscotty, Annis, & Kalisch, 2012).

**The Fuller Infant Pain Assessment Model**

A similar infant pain assessment model describes a process whereby the nurse acknowledges the infant distress signal, most often crying, then postulates on possible sources of distress such as hunger or pain (Fuller, 1998). The nurse examines background data such as clinical setting, baseline behaviors, surgical and medication history, food and fluid status, and opinions or actions of colleagues, followed by a more complete assessment for pain behaviors. Comfort measures are provided and the consolability of the infant is judged. Response to these comfort measures and consolability facilitate the assessment of the infant's pain status.

**Prescriptive theory of acute pain management in infants and children.** This middle-range theory was developed heuristically from national pain guidelines, with the goal of providing guidance for research on children's pain and findings that have clinical application (Huth & Moore, 1998). The assumptions of this behavioral theory are: 1) healthcare professionals collaborate to manage acute pain in the infant and child; 2) nurses are responsible for pain assessment and intervention; 3) nurses have current knowledge of pediatric pain management, growth and development, and dosage calculation; 4) opioid analgesia and/or pharmacologic adjuvants are indicated for pain reduction; 5) medication for side effects is given if needed; 6) the patients are

between six months and twelve years old; and 7) past pain influences the pain experience.

Based on this theory, pediatric pain management is achieved by using assessment strategies, pharmacologic and non-pharmacologic pain relief techniques, and child/parent participation. The theory includes three sequential steps used in practice:

1. An initial assessment consisting of past pain history, current pain assessment, assessments of developmental level, coping strategies, plus cultural background leads to choice of appropriate therapeutic intervention.

2. Therapeutic interventions, consisting of child-parent teaching and/or opioid analgesics, pharmacologic or non-pharmacologic adjuvants, contribute to pain reduction that is satisfactory to child, parent, and nurse.

3. Reassessment consisting of regular assessment of pain by child or parent report, assessment of behavioral and physiological states, and side effects leads to identification of inadequate pain relief, behavioral distress, unacceptable physiological measures, and side effects, which contributes to a choice of appropriate therapeutic interventions.

Further research on this theory was not found in the literature.

**The Onion Theory of Pain**

The Onion Theory of Pain developed by Loeser (1982) includes the concept of pain behavior, providing a theoretical basis for nonverbal pain assessment (Loeser & Melzack, 1999). Pain is described as a five-layer phenomenon, with layers similar to an onion. The first layer, the core of the onion, consists of nerve damage or stimulus, or the

physiology of pain, which involves nociception and transmission of the stimulus to the brain. The second layer is termed pain perception, described as the cognition of pain in the brain. Suffering is the third layer, a judgment of the meaning of the experience, or negative response induced by pain. Pain behavior is the fourth layer, resulting from pain and suffering. Pain behaviors include verbal expressions, grimacing, limping, lying down, seeking health care, or refusing to work. Nociception, pain, and suffering are inferred from pain behaviors, history, and physical examination. The outer layer, interaction with environment, entails the social context, such as the location of person, the response of other people, and cultural influences (see Figure 1).

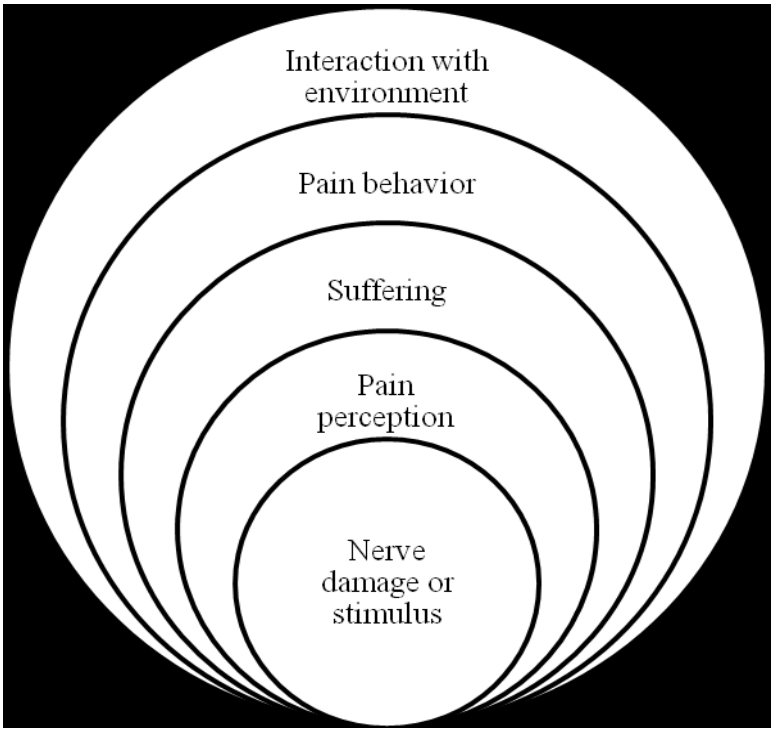


Figure 1. The Onion Theory of Pain (Loeser, 1982).

This model gives greater awareness of the multi-layered effects of pain, illustrating that pain is not a simplistic stimulus-response concept, and explains the concepts that form the basis for behavioral pain assessment. This also relates pain behavior to the suffering associated with pain. Suffering is not considered in most models of behavioral pain assessment; suffering is a subjective experience, which can lead to behavioral manifestations of pain. The person with verbal abilities can verbalize pain and the suffering caused by the pain.

**The modified Onion Theory of Pain and Sedation for the nonverbal infant or child.** The Onion Theory of Pain is useful in conceptualization of behavioral pain assessment in the nonverbal infant or child, but is expanded by this author to include modifiers unique to the nonverbal infant or child, based on research findings, and to include the concept of sedation assessment. An important consideration that is not explicit in the Onion Theory of Pain is that all layers of the process are modified internally, by physiological differences such as genetics, maturity, and biochemistry; and externally, by environmental and caregiver factors. In addition, suffering is inferred, but cannot be determined by behavioral observation.

The first layer, physiology of pain and sedation, is similar, as infants and children have mature nociception and transmission pathways, albeit modified by genetics, biochemistry, and the nature of the pain or stressor stimulus (Anand & Craig, 1996; Craig, McMahon, Morison, & Zaskow, 1984; Craig, Whitfield, Grunau, Linton, & Hadjistavropoulos, 1993). The first layer also includes the physiology of sedation, as pharmacologic agents are given orally or intravenously and then travel to the brain for the desired effect.

The second layer, pain perception, is better termed cortical perception of pain in the nonverbal infant or child. Cognition implies that the person can recognize and know pain; this may not be present in the infant or any nonverbal person with diminished cognitive abilities. Cortical perception involves the pain being transmitted to and perceived by the brain, producing a response that is more than simply reflexive (Bartocci, Bergqvist, Lagercrantz, & Anand, 2006; Fitzgerald & Anand, 1993; Holsti, Grunau, & Shany, 2011). Cortical perception is modified by endorphins, pain inhibitory and modulation tracts, spinal cord transmission, neurotransmitters, anatomic maturity, and the structure and function of the brain (Anand & McGrath, 1995; Fitzgerald & Anand, 1993). Cortical perception of pain can also be modified by medications. The second layer involves sedation, with the cortical slowing of the brain activity by sedative or opioid medications. Neurotransmitters are affected, to slow signal transmission, leading to the sedative effect.

The third layer in the modified Onion Theory of Pain and Sedation, suffering, is the emotion experienced as a result of pain. Suffering is modulated by personal interpretation of the event. Suffering is unable to be precisely measured in the nonverbal population, and is inferred from behavior (Ambuel, Hamlett, Marx, & Blumer, 1992; Anand et al., 2006; Garten, Deindl, Schmalisch, Metze, & Buhrer, 2010; McGrath et al., 2008). Suffering is assumed to be reduced by the administration of sedative or analgesic medications.

The fourth layer, pain and sedation behavior, is present and observable in the nonverbal infant or child. Pain behaviors are present due to the suffering caused by the cortical perception of pain. Pain behaviors including crying, consolability, facial

expression, body movements, and vital sign changes have been described and validated through observation of painful events. Behaviors indicative of sedation include a decreased response to verbal or tactile stimuli and slowing of physiologic functions such as breathing and airway maintenance. The verbal child is able to express the pain's intensity, location, and quality; in the nonverbal child, these are inferred through behavioral observation. Behavioral expression of pain is modified by many factors, including maturity and energy levels, neurological abilities, and neurotransmitter function (Johnston, Stevens, Craig, & Grunau, 1993; Lilley, Craig, & Grunau, 1997). Medications such as sedatives or analgesics, as well as non-pharmacological interventions or comfort measures, may modify pain behaviors. The verbal child may be able to express light levels of sedation, stating that they feel sleepy or dizzy. Deeper levels of sedation require behavioral observation as the child becomes unable to verbalize the sensations.

The fifth and outer layer, interaction with environment, explains the impact of the caregiver interacting with the nonverbal person. The caregiver must recognize the pain behaviors exhibited, and then take appropriate action to relieve the pain and distress, inferred by decreasing behavioral signs of pain (Craig, 2009; Fuller, 1998; Voepel-Lewis et al., 2012). The caregiver must also recognize the behaviors of sedation. The environment also impacts pain and sedation levels, as it is more difficult to achieve sedation or analgesia when the person is being stimulated, such as with painful procedures or if the environment is not quiet or calm. See Figure 2 for the modified Onion Theory of Pain and Sedation for the nonverbal infant or child.

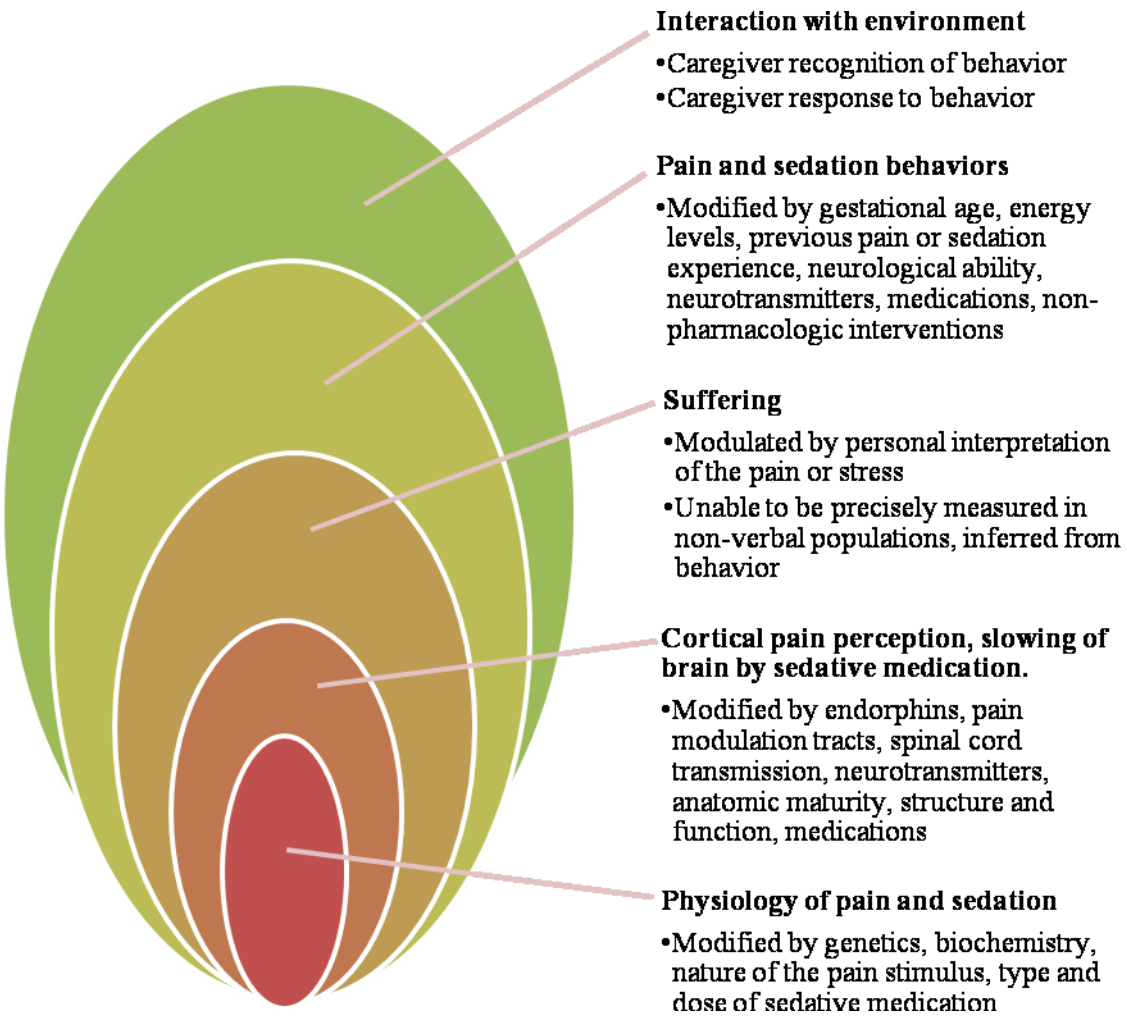


Figure 2. The modified Onion Theory of Pain and Sedation for the nonverbal infant or child.

Pain and sedation assessment theories and research guide the creation of tools to assess pain in the verbal and nonverbal populations. These tools require psychometric evaluation which is explained in the following section.

## Psychometrics

Psychometrics is the field of study concerned with the theory and techniques of measurement, primarily concerned with the construction and validation of measurement instruments (Nunnally & Bernstein, 1994a). Measurement consists of rules for assigning symbols to objects so as to represent quantities of attributes numerically (scaling) or to define whether the objects fall in the same or different categories with respect to a given attribute (classification) (Nunnally & Bernstein, 1994a). Standardized measures remove guesswork from scientific observation and permit the use of powerful methods of statistical analysis. Communication between clinical practitioners and researchers is facilitated when standardized measures are available, enhancing evidence-based care in the clinical setting and increasing validity in research.

Behavioral pain and sedation assessment tools have been developed through various methodologies. Most commonly, behaviors that are observed empirically with a known pain stimulus or after sedative administration have been incorporated into assessment tools. Expert caregivers, generally nurses with clinical experience caring for patients in pain, have provided input on the indicators in assessment tools.

Behavioral pain assessment tools score pain by assigning numeric values to the presence and/or intensity of selected pain behaviors. Generally, a higher number reflects increased incidence, duration, and/or intensity of specific pain behaviors. Some pain experts caution that pain intensity cannot be specifically measured behaviorally, recommending that a list of behaviors be used rather than a composite score (Pasero & McCaffery, 2005). The debate regarding an increased behavioral response as a sign of pain and, conversely, a decreased response as a sign of diminished pain is extensive and

involves beliefs and emotions. Consensus on this has not been achieved (Anand et al., 2006; Goldman & Koren, 2002; McGrath et al., 2008; A. R. Wolf, 1993).

The behavior (indicator) is rated by the observer based on frequency and/or intensity of the behavior. Simplicity and clinical utility are valued, keeping the number of indicators to a minimum; the ideal number is undetermined. Most behavioral pain tools include at least three behaviors, some include over ten behaviors. Clinicians clearly prefer fewer indicators. The scaling of a behavior can be simplified to present or not present, yielding nominal data, though this is not frequently done. Behaviors are often Likert-type scaled from 0 (not present) to a higher number. Again, there is no standard for scaling pain behaviors. Clinically, it is difficult to rate several behaviors on a large scale; behaviors are generally scaled from 0-2, possibly 0-5. Increasing the scaling number could increase precision, but decrease clinical utility. Each indicator is rated, and then the item scores are generally totaled.

Many measures, such as behavioral pain assessment measures, yield a score, a sum of item responses, of each scaled behavior. Data from each indicator are ordinal: the number is assigned based on the decision that the observer makes to assign a higher number because the behavior is observed more frequently or with more intensity than the low number indicates. The total score is usually treated as interval data, with computed means, assuming equality of intervals (Nunnally & Bernstein, 1994a).

Reliability, or stability, of the clinical pain assessment instrument is commonly assessed through inter-rater reliability with more than one person assessing and scoring the subject simultaneously and independently. Scores are then compared, individual items are analyzed by Cohen's kappa, and the total score is analyzed by the Intra-class

Correlation Coefficient. Intra-rater reliability is established by videotaping the event, then scoring the video repeatedly, comparing scores by correlation. Cronbach's alpha (Cronbach, 1951) is the statistic of choice for evaluating the internal consistency of a measurement tool using multidimensional scoring formats. This gives the average of all of the possible split-half reliabilities of a scale. Cronbach's alpha can be calculated multiple times, deleting one item each time with the goal of obtaining the shortest instrument that represents the phenomenon. Homogeneity of the scale is increased if the alpha increases significantly when a specific item is left out (Streiner & Norman, 2003). DeVellis (2003) provides guidelines for Coefficient alpha identifying that "…below .60 is unacceptable, between .60 and .65 undesirable, between .65 and .70 minimally acceptable, between .70 and .80 respectable, and between .80 and .90 very good". Further, he describes that "scales that are intended for individual diagnostic, employment, academic placement, or other important purposes should probably have considerably higher reliabilities, in the mid-.90's, for example". Cronbach's alpha is commonly employed in psychometric evaluations as it is useful with both dichotomous and continuous variables (Cortina, 1993).

Validity, the ability of the instrument to measure the attributes of the construct under study (Trochim, 2001), is usually a matter of gradation rather than an all-or-none property. Validation is a continuous process and requires empirical investigations (Nunnally & Bernstein, 1994b). Validity of a behavioral pain assessment tool can be difficult to establish in the nonverbal population. Ideally, self-report or a biologic pain marker would be used in construct validation; neither is readily available in the infant and toddler population. Empirical documentation of behaviors during procedures or events

known to be painful or during sedation is the foundation of extant measures. Criterion or convergent validity can be assessed by utilizing the tool along with a previously validated tool. Construct validity can be assessed by 1) comparing the score during a painful event to a score during a non-painful event; 2) comparing the scores before and after an analgesic or sedative intervention; 3) examining scores for differences over time; or 4) examining items through factor analysis or principal component analysis procedures. Both techniques are designed to explore the variation in a set of observed variables on the basis of a few underlying dimensions (Dunteman, 1989). Further refinement of construct validation requires a network of evidence that accumulates with repeated research.

DeVon et al. (2007) reviewed the concepts of instrument reliability and validity in published nursing research. Findings indicate that studies frequently reported content validity, often with fewer than five experts reviewing the tool, and rarely reported evidence of criterion validity, erroneously reported criterion validity, and under-reported construct validity. The majority of reports included Cronbach's alpha for study instruments. The authors concluded that lack of psychometric information is common in the literature.

## Nonverbal Pain Assessment

Behavioral and physiologic cues are the current accepted standard for assessment and evaluation of pain and sedation in the nonverbal patient. Nonverbal pain assessment has been studied widely in the infant population, and more recently in the adult population, including critically ill adults and those with dementia (Herr et al., 2006).

Pediatric pain behavioral research initially was conducted as observation of inflicted pain, such as a pinprick. Due to ethical guidelines, pain assessment research is

now accomplished through observing and monitoring the infant or child during and following a medically necessary procedure that causes tissue injury (Anand et al., 2005; Anand & McGrath, 1995). Behavioral and physiological changes with tissue injury have been documented, such as facial grimacing and vital sign changes. Researchers have validated that the infant is experiencing pain and that the behaviors and physiologic changes that occur are a result of the pain from the tissue injury. In the absence of verbal report and a biological marker for pain, these physiologic and behavioral correlates are accepted as indicators of pain (Anand et al., 2005; Herr et al., 2006).

Neonatal pain behavioral research began over sixty years ago, with a single study of infant reaction to pinprick (McGraw, 1941). The prevailing belief in this period viewed the cerebral cortex as non-functioning at birth, as indicated in histological studies of the brain. This led the researcher to assume that the sensorimotor experiences of the newborn infant did not extend beyond the subcortical or thalamic level, leading to reflexive, non-purposeful reactions. The infants' non-specific neonatal motor response—generalized body movements rather than isolated withdrawal to repeated pin pricks—strengthened the long-held belief that neonates were incapable of perceiving pain (Anand & McGrath, 1995; McGraw, 1941). This assumption curtailed further research on the topic for the next three decades (Stevens, Johnston, & Gibbins, 2000).

In the 1970s, infant pain research resumed, mainly using basic observational techniques in the context of medically necessary short-term pain experiences such as heelstick, circumcision, or intramuscular injection. Behavioral pain indicators were also validated in pain management research, as the effectiveness of an intervention was evaluated by observing changes in pain behaviors. Infant cry variations and response to

pinprick were documented (Fisichelli, Karelitz, Fisichelli, & Cooper, 1974; Rich, Marshall, & Volpe, 1974). Neonatal pain behavior research confirmed that infants feel and express pain, delineating and validating neonatal pain behaviors (Craig et al., 1984; Craig et al., 1993; Fitzgerald, Shaw, & MacIntosh, 1988).

Research published in the late 1980s by Anand and colleagues advanced the knowledge of infant pain and the consequences of pain in preterm neonates. Anand's research demonstrated a decreased mortality rate and a more rapid recovery in infants receiving adequate anesthesia and analgesia perioperatively. This body of research was instrumental in changing attitudes regarding neonatal pain (Anand & Hickey, 1987; Anand, Sippell, & Aynsley-Green, 1987). Another major factor in the attitudinal change was a mother's account, in 1986, of her preterm infant's thoracotomy for patent ductus arteriosus ligation without anesthesia, published in the *Washington Post* (Rovner, 1986). Public outcry demanded change in clinical management of infant pain, contributing to an increase in pain assessment and management research.

Research completed over the past thirty years has verified that neural pathways for afferent/ascending pain transmission and cortical interpretations are present in even the smallest preterm infant, dispelling the perception that neonates are unable to perceive pain (Andrews & Fitzgerald, 1994; Fitzgerald, 1999; Fitzgerald & Anand, 1993; Fitzgerald et al., 1988; Kostovic & Rakic, 1990; Okado, Kakimi, & Kojima, 1979).

Undertreatment of pediatric pain has been documented beyond the neonatal period. Multiple research studies documented that children in the postoperative period received opioid analgesics infrequently, far less than a comparable adult sample (Beyer,

DeGood, Ashley, & Russell, 1983; Eland & Anderson, 1977; Hamers, Abu-Saad, van den Hout, & Halfens, 1998; Mather & Mackie, 1983).

Nursing has been the primary discipline researching pain assessment. Medicine, pharmacy, psychology, and developmental pediatrics have also contributed to pain assessment and management research (Debillon, Zupan, Ravault, Magny, & Dehan, 2001; Grunau & Craig, 1987; Stevens et al., 1996; Taddio et al., 2009). The following section describes the identification of biologic pain markers. The clinical and research utility of these markers is outlined.

**Biologic Pain and Sedation Markers**

In the absence of verbal report, a specific biologic pain marker with clinical utility would be preferable to behavioral assessment. Such a biologic marker has yet to be discovered. Stress hormone measurement in infant's serum or saliva perioperatively, during heelstick, and during mechanical ventilation has been studied (Anand & Hickey, 1987; Guinsburg et al., 1998; Herrington, Olomu, & Geller, 2004; Simons et al., 2005). These researchers reported that the stress hormone levels of cortisol, epinephrine, and norepinephrine increase with a painful experience, and are modified by analgesic administration. Clinical utility is limited as these levels rise inconsistently due to the infant's physiological immaturity or disease process, and due to clinical administration of medications that alter these levels. Biochemical markers are unethical to use if this leads to additional pain due to an additional needlestick and also wasting blood volume to obtain the levels. The practitioner cannot wait for lab results before adjusting analgesia in the clinical setting.

Hormonal or endocrine response, as measured by blood or saliva analysis, palmar sweating, and electrical brain activity monitoring have been researched for utilization in pain assessment and for evaluation of pain management strategies. Emotional sweating in the palm and sole resulting from neurophysiologic arousal with increased activity in the sympathetic nervous system during a heel-lance procedure is measured as skin conductance or Galvanic Skin Response (GSR) (Eriksson, Fremming, Gradin, Schollin, & Storm, 2003). Researchers compared the behavioral response with the Neonatal Facial Coding System (NFCS) and GSR during three events: touching (deemed non-painful), placing a cloth soaked with alcohol on the skin (deemed stressful), and heel-lance (deemed painful). The GSR increased minimally with the alcohol cloth placement, and markedly with heel lance. The NFCS score showed a larger increase with touch than with stress and a significant increase with heel lance. GSR was found, in healthy term infants, to differentiate between stress and acute pain situations as well or better than the measurement by the NFCS. The GSR method needs to be evaluated with established/ongoing pain and with infants. This technique is not expected to be valid in the premature infant, as palmar sweating is not present until closer to term gestation (Anand et al., 2006). In addition, sensitivity and specificity are low with skin conductance (Van Dijk & Tibboel, 2012). Skin conductance is further discussed with physiologic pain assessment.

EEG recording is used extensively to evaluate neurological cerebral function. Reactivity to somatosensory stimuli is important clinically, and may be useful in pain assessment. Evaluation of pain in full-term infants with EEG found a significant increase in the higher frequency band components of the EEG in frontal regions, but not

somatosensory or other regions (Norman et al., 2008). Other research found an evoked response after a single painful stimulus using a time-locking technique (Slater, Fabrizi, et al., 2010; Slater, Worley, et al., 2010). More research is needed to explore pain assessment with EEG for clinical or research purposes (Holsti et al., 2011).

Near infra-red spectroscopy (NIRS) is used in the neonate to measure cerebral auto-regulation, blood volume, flow, and oxygenation (M. Wolf & Greisen, 2009). This non-invasive method is useful in the assessment of brain activity through the intact skull. Pain increases oxygenation and thus indicates higher activity. Research in preterm infants found that standardized tactile stimuli and venipuncture elicit specific hemodynamic responses in the somatosensory cortex, implying conscious sensory perception (Bartocci et al., 2006). NIRS may be more sensitive than behavioral pain assessment; researchers found cortical pain responses with NIRS without a change in facial expression (Slater, Cantarella, Franck, Meek, & Fitzgerald, 2008). NIRS remains challenging for clinical bedside assessment because movement artifacts can interfere with the signal, and environmental factors such as sound, light, odors, and clinical conditions that affect blood flow and oxygenation can influence NIRS recordings (Holsti et al., 2011).

Other biologic markers of pain might include changes in intracranial pressure (measured through the anterior fontanel), thresholds for the dorsal cutaneous flexion reflex or abdominal skin reflex, event-related potential (ERP) measured by detailed electrical mapping, or neuroimaging techniques such as functional Magnetic Resonance Imaging (fMRI) (Anand et al., 2006). Again, clinical feasibility of these methods is limited.

Bispectral (BIS) index technology monitoring of sedation levels is used in surgery, and has also been described in adult critical care patients, and, more recently, in the Pediatric Intensive Care Unit (PICU) (Crain et al., 2002). BIS monitoring has been validated in children over one year of age.

**Developmental Changes in Pain Expression**

Developmental changes in pain expression in infants and children occur with maturation. The neonatal facial indicators of pain are involuntary and include brow bulge, eye squeeze, stretched mouth, and taut tongue. Fuller posits that these expressions are not as valid in the infant older than three months (Fuller & Conner, 1995). However, facial expression is used as a pain indicator in all nonverbal populations, infants to adults. Older infants and children are able to make facial expressions deliberately to elicit a response in their caretaker. Vocalizations of infants seven months and older are more intentional and more variable in pitch and intensity (Fuller & Conner, 1995). Researchers compared the cries and facial expression in the response of premature, term, and two- and four-month-old infants to painful procedures (Johnston et al., 1993). While two- and four-month-old infants were similar, preterm and term infants showed significant differences in their response. Preterm infants had higher pitched cries, inability to sustain facial distress, and a more horizontally stretched mouth. Therefore it is important for the clinician to take into consideration the age and developmental stage of the infant or child during pain assessment.

Many infant pain behaviors are also observed and validated in nonverbal children and adults. While crying is used as a pain indicator in infants and children, sounds of distress such as groaning and moaning are indicators of pain in older children and adults.

Children age three and above with verbal abilities may be capable of expressing pain more directly, although imprecisely. Behavioral pain assessment is abandoned when the child is able to verbalize pain and, more specifically, pain intensity (McGrath et al., 2008). Limited verbal skills place children at a disadvantage, unable to communicate their pain directly (McGrath et al., 2008). Several pain assessment tools have been developed that facilitate self-report of pain in children. The Wong and Baker FACES Pain-Rating Scale, with seven faces indicating degrees of pain, is commonly used in children around three years of age and older, in the absence of developmental disorders (Wong & Baker, 1988). This pain scale has been tested in multiple populations. The scale was researched and revised to include six faces (The Faces Pain Scale Revised, FPS-R), with scoring from zero to five. The FPS-R was found to be appropriate for use in assessment of the intensity of children's acute pain from age four or five onward (Hicks, von Baeyer, Spafford, van Korlaar, & Goodenough, 2001) . Other pediatric rating scales utilize objects or symbols, such as poker chips that represent pain (von Baeyer & Spagrud, 2007). Postoperatively, verbal pain expression is not possible until anesthetic effects are minimal or absent. Therefore, behavioral pain assessment is used until verbal self-report is possible.

**Behavioral Indicators of Pain**

Crying is a distress signal—a response by neonates, infants, and children—to both acute and established pain (Craig, Gilbert, & Lilley, 2000; H. D. Hadjistavropoulos, Craig, Grunau, & Johnston, 1994; Howard & Thurber, 1998; Krechel & Bildner, 1995; Owens & Todt, 1984; Partanen et al., 1967; Ramelet, 1999; Ramelet, Abu-Saad, Bulsara,

Rees, & McDonald, 2006; Rich et al., 1974; Stevens et al., 2000; Van Cleve, Johnson, Andrews, Hawkins, & Newbold, 1995). A "pain cry" is described as more persistent and higher-pitched (Craig et al., 2000). Crying is frequently used in behavioral pain assessment in the clinical setting as a sign of distress, while recognizing that crying has limited specificity as a pain indicator (since infants and children sometimes cry for many reasons other than pain). Older infants and children may verbalize pain by moaning or groaning.

General behavior and sleep/awake state is assessed by observing body movements, such as arching and kicking, and the ability to rest and sleep, indicative of general comfort level (Beacham, 2004; Craig et al., 1993; Gedaly-Duff & Huff-Slankard, 1998; Grunau, Holsti, Whitfield, & Ling, 2000; Ramelet et al., 2006). Many behavioral pain scales validated in various ages and populations include these signals of distress, including the CHEOPPS (McGrath et al., 1985), FLACC (Merkel et al., 1997), NIPS (Lawrence et al., 1993), CRIES (Krechel & Bildner, 1995), and the EDIN tool (Debillon et al., 2001).

Facial expression as a behavioral expression of pain has extensive validity and reliability testing (Craig et al., 2000). Facial changes indicative of pain include lowered brows drawn together, bulge between brows, eye squeeze, nasolabial furrow, nose broadened and bulging, cheeks raised, mouth open and squarish (Grunau & Craig, 1987; Grunau, Oberlander, Holsti, & Whitfield, 1998; H. D. Hadjistavropoulos et al., 1994; Johnston & Strada, 1986; Lilley et al., 1997). The cluster of facial activity associated with pain is similar across infancy and in adults (Craig, Prkachin, & Grunau, 1992). One neonatal pain assessment tool, the Neonatal Facial Coding System (NFCS), utilizes facial

expression only (Grunau & Craig, 1987). This tool has been widely used in the research setting, usually employing videotape analysis, but has not been widely accepted for clinical use, as it is difficult to score multiple pain expressions without the benefit of videotaped replay (Grunau et al., 1998). The NFCS has been used widely in acute pain intervention research. A computer program under development analyzes facial expression, the Classification of Pain Expressions (COPE), using facial recognition techniques to extract and examine the infant's facial expression, reported to have > 90% accuracy in initial testing (Brahnam, Chuang, Shih, & Slack, 2006). Further testing has not been reported in the literature.

Observing the position of the extremities, fisting/clenching, finger splay, and general tone of the body assists in evaluating comfort and relaxation, and is helpful in assessing both acute and established pain (Bozzette, 1993; Craig et al., 1993; Fuller, 1998; Grunau et al., 2000; Johnston & Strada, 1986). Extremity movement and posturing are used in nonverbal pain assessment tools used in various populations.

Infant behavioral pain indicators have also been validated in children and adults. Pediatric nonverbal pain measures commonly include facial expression, extremity movement, cry, consolability, behavioral state, muscle tone, and mechanical ventilation tolerance (Ambuel et al., 1992; McGrath et al., 1985; Merkel et al., 1997).

Pediatric nonverbal pain indicators are similar to those used in infants (von Baeyer & Spagrud, 2007). Facial expression, extremity movement, cry, compliance with mechanical ventilation, and consolability are common indicators found in pediatric pain assessment tools.

A child's specific reactions to pain at any stage in life are the optimal adaptations given the child's experience and competence (Anand & Craig, 1996). Reactions to aversive stimuli are essentially automatic in early life as infants are not able to process information and control response to pain (T. Hadjistavropoulos & Craig, 2002). Pain expression is increasingly shaped during the toddler and preschool years by the child's growing understanding of emotions and ability to anticipate outcomes and feelings. By preschool age, children are developing an ability to feign, exaggerate, or suppress outward signs of pain (von Baeyer & Spagrud, 2003). Children's expression of pain is influenced both by age and by social context. The child learns how others react to pain by parental and professional interactions during common painful experiences, such as bumps, bruises, scrapes, and immunization injections.

Pediatric pain assessment concerns infants over one month old, up to fourteen years of age. Adult pain assessment scales are commonly employed over fourteen years of age. Behavioral pain assessment in the adult population has achieved more recent attention. Adult nonverbal pain assessment includes variations of the infant and pediatric pain indicators. Indicators of pain used in adult nonverbal pain assessment commonly include facial expression, compliance with ventilation, activity, limb movement, and compliance with commands (Kabes, Graves, & Norris, 2009; Payen et al., 2001; Prkachin, 2009). Vocalizations such as moaning or groaning are validated indicators in the older children and adult populations (Bjoro & Herr, 2008). Facial expression, such as grimacing and tension are also validated adult pain indicators (Aissaoui, Zeggwagh, Zekraoui, Abidi, & Abouqal, 2005). Limb movement and compliance with ventilation are common indicators in adult nonverbal pain assessment (Aissaoui et al., 2005).

**Physiological Indicators of Pain**

Vital sign changes are related to the autonomic stress response associated with pain (Franck & Miaskowski, 1997). Heart rate increase is consistently documented as a pain indicator (Butler-O'Hara, LeMoine, & Guillet, 1998; Cote, Morse, & James, 1991; Craig et al., 1993; Dale, 1986; Gonsalves & Mercer, 1993; Johnston, Stevens, Yang, & Horton, 1995; Johnston & Strada, 1986; McIntosh, Van Veen, & Brameyer, 1993; Owens & Todt, 1984; Pereira et al., 1999; Stevens & Johnston, 1994; Taksande, Vilhekar, Jain, & Chitre, 2005). Heart rate variability may also be a physiological indicator of pain. Research with heel lance and with postoperative patients showed decreased variability (Faye et al., 2010; Padhye, Williams, Khattak, & Lasky, 2009). Blood pressure and respiratory rate increases above baseline in painful situations (Goldstein & Brazy, 1991; Hamon, Hascoet, Debbiche, & Vert, 1996; Quinn et al., 1992). Blood pressure variations may be less useful when obtained utilizing the blood pressure cuff rather than central arterial monitoring, as obtaining a cuff blood pressure increases distress (Hudson-Barr et al., 2002). Oxygen desaturation per pulse oximetry is observed in both acute and established pain situations (Pokela, 1994; Taddio, Ohlsson, Einarson, Stevens, & Koren, 1998).

Skin conductance measurement has more recently been evaluated as an objective approach to pain assessment (Harrison et al., 2006; Hullett et al., 2009; Munsters, Wallstrom, Agren, Norsted, & Sindelar, 2012; Valkenburg, Niehof, van Dijk, Verhaar, & Tibboel, 2012). This is measured by a device and is based on stress-induced sweating of the palms of the hand or soles of the foot, as sweat glands are stimulated by sympathetic activity with pain. Skin conductance measurement is not accepted for clinical practice

due to the wide range of reported sensitivity and specificity (Van Dijk & Tibboel, 2012). Physiologic indicators of pain can be problematic with pain assessment, as variations in these parameters occur with many disease states. Therefore, these indicators should not be used alone, but as an adjunct to behavioral pain assessment (Herr et al., 2006; von Baeyer & Spagrud, 2007).

**Infant Nonverbal Pain Assessment Tools**

Several behavioral pain measurement tools, developed over the past twenty years, are currently used in research and the clinical setting. Pain assessment reviews concur that pain assessment tools should be multidimensional as well as having evidence of validity and reliability (Byers & Thornley, 2004; Duhn & Medves, 2004; Hummel & van Dijk, 2006; von Baeyer & Spagrud, 2007). Most infant behavioral pain assessment tools are designed for use in acute pain, while few are useful for ongoing or chronic pain assessment.

Behavioral pain indicators are distress signals used in scoring the infant based on the frequency and/or intensity of the behavior. Absence of pain behaviors does not ensure that pain is not present, as some infants, such as those that are neurologically impaired, are unable to mount a behavioral response (Bozzette, 1993; Johnston et al., 1999). Premature infants have a limited ability to display and maintain behavioral or physiological manifestations of pain (Craig et al., 1993; Johnston, Stevens, Yang, & Horton, 1996; Stevens, Johnston, & Horton, 1994).

The Neonatal Facial Coding System (NFCS) was developed to monitor pain in newborn infants, using only facial movements (Grunau & Craig, 1987). The NFCS was developed and researched using videotaping which allowed for intensive slow motion

stop frame video coding and playback. Interrater reliability was acceptable (r = 0.82). Construct validity has been supported in several studies, as the tool discriminates tissue insult and non-tissue insult procedures, and differentiates infants receiving pharmacologic treatment (Benini, Johnston, Faucher, & Aranda, 1993; Craig et al., 1993; Grunau et al., 1998; Johnston et al., 1993; Johnston et al., 1995; Taddio, Katz, Ilersich, & Koren, 1997). The NFCS has been widely employed in research but not in the clinical setting due to the extensive training and scoring time needed to use this tool.

The Premature Infant Pain Profile (PIPP) tool (Stevens et al., 1996) was developed and tested methodically, utilizing seven steps:

1. identification of the indicators through literature review and clinical observation
2. pilot testing of the indicators on a sample of 124 premature neonates 24-32 weeks gestation undergoing a heelstick procedure
3. evaluation of the specificity and sensitivity of the indicators whereby an indicator had to be present at least 50% of the time during the painful procedure but less than 20% of the time during a nonpainful situation
4. determination of the factor structure of the indicators through factor analysis where the three-factor solution with six-indicators yielded acceptable limits of error
5. developing indicator scales based on the distributional characteristics of each factor
6. providing evidence for internal consistency of the indicators through Cronbach's alpha calculation

7. establishing construct validity of the measure by scoring infants in painful versus non-painful situations

The seven indicators in the PIPP tool include heart rate elevation and oxygen desaturation, three components of facial activity, and two modifiers, gestational age and pre-procedural behavioral state. PIPP scores range from 0-21. Factor structure was explored on a data set of 124 infants of 32 to 36 weeks gestation. Six of these indicators (gestational age was not included as it was a modifier that did not vary in the study) were analyzed by principal component analysis to determine the underlying structure of the data or indicator groupings. Indicators were retained if the commonality was at least 0.30 and a loading of 0.40 on any factor. Orthogonal rotations were examined for all factor solutions. Factors with eigenvalues greater than one were retained, accounting for 78.3% of the variance. Three factors—facial activity, physiological activity, and behavioral state—were identified. Upper facial activity accounted for the majority (42.4%) of the variance in the total score, while physiological activity explained 19.1% of the total variance. Behavioral state accounted for 16.7% of the total variance. The six indicator, three factor solution had a root-mean squared residual correlation of 0.040, within acceptable limits of error.

Cronbach's alpha for the PIPP was .71 for the total set of indicators. Initial construct validity was assessed, finding that scores were different between heelstick ($M$ = 12.9, $SD$ = 3.4) and handling ($M$ = 6.0, $SD$ = 2.7), a significant difference by paired t test ($t$ = 12.24, $p < .01$). Construct validity was also tested by comparing a real heelstick to a sham heelstick procedure; the mean PIPP score for the actual heelstick was higher than for the sham procedure, ($M$ = 10.3, $SD$ = 4.5) and ($M$ = 6.3, $SD$ = 3.2), respectively.

These scores were significantly different ($t = 2.4$, $p < .02$). In addition, the PIPP was tested with full-term infants during circumcision, comparing topical anesthetic and placebo treatment. The mean PIPP score with the topical anesthetic was lower than in the placebo group, ($M = 11.8$, $SD = 2.7$) and ($M = 14.1$, $SD = 1.4$), respectively. The difference between the two groups was significant ($t = 2.6$, $p < .02$).

An additional study demonstrated construct validity and inter- and intra-rater reliability for the PIPP tool in the clinical assessment of procedural pain of preterm and term infants (Ballantyne, Stevens, McAllister, Dionne, & Jack, 1999). Interrater reliability coefficients (.93-.96) were high. The PIPP tool has been widely employed in pain management research but has not been widely adopted for use in the NICU, possibly because the tool is designed for acute pain, while prolonged pain measurement is more relevant in clinical care of the ill neonate (Hummel & van Dijk, 2006).

The Neonatal Infant Pain Score (NIPS) was also developed to assess acute/procedural pain (Lawrence et al., 1993). The tool was developed through data from a survey of forty-six experienced neonatal nurses at one Canadian hospital, and adapted from a pediatric pain assessment tool. The initial scale of eight indicators was used by the researchers to document responses to twenty needle-intrusive procedures. Two indicators, facial color and torso movement, were deleted due to assessment difficulties. Six behavioral indicators of pain—facial expression, cry, breathing patterns, arm movement, leg movement, and state of arousal—are scored on either a two-point or three-point scale; higher points are scored with an increase in intensity or quantity of the indicators. Ninety procedures in thirty-eight infants were videotaped for analysis. A research assistant scored the procedures, documenting scores before, during, and after the event. A random

sample of twenty videotaped procedures was also scored by one of the investigators. Twenty-seven preterm and seventeen term infants were included, with an average gestational age at birth of 33.5 ($SD$ = 4.8) weeks at birth, and an average corrected age of 35.4 ($SD$ = 4.1) weeks at the time of the first procedure. Interrater reliability was high, with a Pearson's correlation of two raters of twenty videotapes ranging from .92-.97 ($p <$ .05). A Repeated Measures ANOVA utilizing the total NIPS scores for twenty-two infants undergoing a heelstick procedure revealed that the NIPS scores were significantly different before ($M$ = 1.1, $SD$ = 2.2), during ($M$ = 4.8, $SD$ = 2.58), and after ($M$ = 2.0, $SD$ = 2.09) the painful procedure ($F(2.42) = 18.97$, $p <.01$), providing evidence for construct validity. Non-parametric Friedman test was also used to confirm the Repeated Measure ANOVA evaluating the NIPS scores before, during, and after the painful procedure; results were also significant ($\chi^2$ (2, $N$ = 66) = 18.89, p <.01), suggesting construct validity. Concurrent validity was explored by using Pearson's correlations to compare the Visual Analog Scale (VAS) with the NIPS during the procedure. The observer rated the baby with the VAS by assigning a number from 0-10 to the infant's behavior. The correlations between the NIPS and VAS at each observation ranged from .53 to .84. Internal consistency was calculated on the scores before, during, and after the procedure, with Cronbach's alphas of .95, .87, and .88. The NIPS tool has had scattered utilization, again due to the low clinical need for routine procedural assessment in the neonatal setting. Utilizing the VAS for concurrent validity is not currently acceptable, as the raters' assignment of one number on a 0-10 scale does not validate the more objective itemized scoring in an acceptable manner. However, at the time of tool development, few other objective tools were available for concurrent validity assessment.

The Crying, Requires oxygen, Increased vital signs, Expression, Sleepless (CRIES) tool was developed through literature review and a survey of neonatal care givers for ongoing postoperative pain assessment in infants (Krechel & Bildner, 1995). The five indicators are scored 0-2 for a total maximum score of 10. Twenty-four infants between thirty-two and sixty weeks post-conceptual age (mean age of forty-four weeks) were enrolled. The infants were assessed hourly by two nurses, between twenty-four and seventy-two hours postoperatively. The infant was judged subjectively by the nurse to be in pain or not in pain. Secondly, each nurse evaluated the infant with the Objective Pain Scale (OPS), a scale used with older children, and with the CRIES scale. Concurrent validity was assessed by comparing the CRIES and OPS scores, with a Spearman Rank Correlation Coefficient of 0.73 ($p < .01$). Discriminant validity was implied, as pain scores were significantly lower following analgesic administration, with a decline in CRIES score of 3.0 units, assessed by the Wilcoxon Sign Rank Test, ($p<0.01$). Interrater reliability was acceptable, per Spearman correlation ($r = 0.72$, $p < .01$). The CRIES does not appear to be valid for small premature infants. It was not tested in infants less than thirty-two weeks, and the oxygen/pulse oximetry parameter of requiring oxygen to maintain oxygen saturation > 95% is not inclusive of care standards for preterm infants. Thus, clinical use in the NICU is limited.

The Echelle Douleur Inconfort Nouveau-Né neonatal pain and discomfort scale (EDIN) was developed to assess ongoing pain in the premature infant (Debillon et al., 2001). The tool was developed by videotaping infants with short- and long-term assisted ventilation, necrotizing enterocolitis, and postoperatively following patent ductus arteriosus surgical closure. Potential indicators were evaluated by a panel of physicians,

nurses, psychologists, and physiotherapists, who selected the indicators found to be highly relevant and eliminating those difficult to observe clinically. The EDIN tool utilizes five behavioral indicators of prolonged pain: facial activity, body movements, quality of sleep, quality of contact with nurses, and consolability. The EDIN tool does not contain any physiological criteria for evaluation. The indicator "quality of contact with nurses" has poor content validity when applying the tool to extremely preterm infants (Aranda et al., 2005). This indicator asks the rater to judge if the infant is smiling or responding; preterm neonates do not socially interact routinely, particularly when their eyes are fused or they are critically ill, causing researchers and clinicians to question the validity of this indicator. Initial research was conducted in seventy-six preterm infants, 26-36 weeks ($M$ = 31.5 weeks, range 26-36 weeks) gestational age. Inter-rater reliability, calculated for each indicator, revealed moderate agreement—kappa coefficients ranging from .59-.74. Internal consistency was high, with Cronbach's alpha coefficients calculated after deletion of each item ranging from .86-.94, and was .92 for the full scale. Construct validity was supported by paired t-test when the scores before ($M$ = 9.2 ($SD$ = 1.7) and after ($M$ = 4.7 ($SD$ = 2.1) analgesic administration vs. were compared in forty ventilated preterm infants. The standard error of the mean (SEM) difference was significant ($SEM$ = 4.4(0.4), $CI$ (3.6, 5.2), $p < .01$). In thirty-six less critically ill infants EDIN scores on admission day and the day before discharge were compared. The mean score was significantly lower by paired t-test at discharge ($M$ = 1.5, $SD$ = 1.5) than at admission ($M$ = 4.5, $SD$ = 3.7). The SEM difference was significant ($SEM$ = 3.0 (0.5), $CI$ *(2.0, 3.9),* $p < .01$). This was interpreted by the authors as evidence of construct validity, assuming that infants are in more pain on admission to the NICU than at discharge.

Parametric statistics were applied despite the fact that normalcy of the distribution is questionable in this area of research. Non-parametric statistics should be used. The EDIN tool has not been widely adopted, possibly due to poor content validity and limited testing.

**Pediatric Nonverbal Pain Assessment Tools**

The Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) quantifies six behaviors: cry, facial expression, verbal expression, torso position, touch, and leg position, each on a scale of 0-3 (McGrath et al., 1985). This tool has been validated with procedural and postoperative pain in children one to twelve years of age. Interrater reliability was high, ranging from .90-.95. Concurrent validity for postoperative pain assessment was moderate to high; correlations ranging from .56 to .90. The CHEOPS tool has been judged to have sufficient psychometric testing to be used as an outcome measure in pain research in various situations, including general surgery, closed fracture reduction, bladder nerve stimulation, intravenous cannulation, sickle cell episodes, circumcision, and immunizations (von Baeyer & Spagrud, 2007).

The FLACC (Face, Legs, Activity, Cry, Consolability) tool is a five-item scale designed to assess postoperative pain in young children (Merkel et al., 1997). The tool was developed with input from clinicians to provide a simple method for pain assessment, as previous tools were found to be too lengthy and cumbersome for routine clinical use. Eighty-nine children aged two months to seven years were observed postoperatively in the Post-Anesthesia Care Unit. Initial psychometric evaluation of the tool revealed high interrater reliability (.94, $p < .01$). Construct validity was suggested, as preanalgesic scores ($M = 7.0$, $SD = 2.9$) were significantly higher than the postanalgesia

scores at ten minutes ($M$ = 1.7, $SD$ = 2.2), thirty minutes ($M$ = 1.0, $SD$ = 1.9), and sixty minutes ($M$ = 0.2, $SD$= 0.5) per ANOVA analysis ($p$ <.01). Criterion validity was supported; the FLACC showed a significant correlation with the Objective Pain Scale ($r$ = .80, $p$ <.01). The FLACC tool has wide clinical use and has been used as an outcome measure in multiple research studies of postoperative pain and minor noninvasive procedures (McGrath et al., 2008).

Many instruments have been created to assess pain in nonverbal infants and children. Some tools purport to assess acute pain, and some ongoing or prolonged pain. Most are multidimensional, including five to seven indicators. All tools reviewed have one published psychometric evaluation; few have been researched more than once.

## Sedation Assessment Tools

Sedation is a concept less studied in the neonatal and pediatric population. A literature search found that no neonatal sedation assessment tool was available for infants prior to the N-PASS. The Cochrane review of sedative use in neonates recognized the need for a validated neonatal sedation tool (Ng, Taddio, & Ohlsson, 2000). The N-PASS is the sole sedation assessment tool available for use in preterm and term neonates.

Sedation assessment tools are a more recent addition to pediatric practice, corresponding to the increased use of analgesics and sedatives over the past 20 years. Items in pediatric sedation scales include level of consciousness, agitation, ventilation, pain, psychological variables, muscle tone, and reaction to tracheal suction (Ista, van Dijk, Tibboel, & de Hoog, 2005).

The Modified Glasgow Scale (MGS) evaluates level of consciousness, scoring the best eye, verbal, and motor responses in the pediatric population (Reilly, Simpson, Sprod,

& Thomas, 1988). The MGS is used regularly in the emergency room setting, but is not widely used clinically for sedation assessment, as it was not designed to evaluate the level of consciousness associated with medication administration.

The State Behavioral Scale (SBS) was developed to provide systematic description of the sedation-agitation continuum in pediatric patients ages six weeks to six years old supported on mechanical ventilation (Curley et al., 2006). Indicators of sedation and agitation included in this scale are respiratory drive, response to ventilation, coughing, best response to stimulation, attentiveness to care provider, tolerance to care, consolability, and movement after being consoled. A total of ninety-one intubated and mechanically ventilated patients six weeks to six years of age provided a median of two observations for a total of 198 sets of observations. Patients were observed for one minute, and then incremental levels of stimulation were applied until patient response. After two minutes of consoling, the SBS assessment and a numeric rating system (NRS) were completed. Weighted kappa scores for all 198 dimension ratings ranged from .44 to .76, indicating moderate to good interrater reliability. The intra-class coefficient of .79 was acceptable. Cluster analysis revealed five distinct state profiles which grouped behaviors into score clusters, indicating five states ranging from deep sedation through agitation, with mean ratings of 1.1, 2.5, 4.0, 5.3, and 7.6, all of which differed significantly from each other ($F = 75.8$, $p < .001$), supporting the profile's construct validity.

The University of Michigan Sedation Scale (UMSS) is a one item observational tool that scores the patient's responsiveness to stimulation as a measure of sedation during procedures (Malviya et al., 2002). Thirty-two children four months to five years of

age were scored, following sedative administration, every ten minutes with the UMSS and two other sedation assessment tools, the Visual Analog Scale (VAS), and the Observer's Assessment of Alertness/Sedation Scale (OASS), which had not been tested in the pediatric population. The assessments were also videotaped for further analysis. Change in scores from baseline to discharge supported construct validity ($p < .01$). Criterion validity was supported as correlation with the VAS and OASS were .96 ($p < .01$) and .93 ($p < .01$). Inter-rater reliability ranged from .47 to .97 at the various levels of sedation and among four blinded observers. Test-retest reliability showed .67 agreement between repeated observations. Furthermore, UMSS scores have been shown to be sensitive and specific in determining return to baseline level of alertness and discharge readiness after sedation (Malviya, Voepel-Lewis, Ludomirsky, Marshall, & Tait, 2004). Data regarding the tool's reliability in differentiating moderate to deep sedation are limited.

An example of a commonly used adult sedation assessment tool is the Richmond Agitation-Sedation Scale (RASS); it has not been studied in the pediatric population. Similar to pediatric sedation tools, behavior is graded on a scale of combativeness to deep sedation (Sessler et al., 2002). Interrater reliability was high, ranging from .92-.98. The RASS also correlated significantly with other sedation measures, .75 to .93. In other research, the RASS correlated significantly with Bispectral Index Scoring, ($r = .90$, $p < .01$), supporting its validity (Turkmen, Altan, Turgut, Vatansever, & Gokkaya, 2006).

**Tools that Assess Pain and Sedation**

The COMFORT tool was developed as a measure of behavioral and physiologic factors, assessing distress in the Pediatric Intensive Care Unit (PICU) (Ambuel et al.,

1992). Indicators were selected based upon literature review and a survey of PICU nurses. The COMFORT scale assesses distress; the indicators assess pain or sedation/agitation. Indicators include level of consciousness which is an indicator of sedation. Other indicators included are facial grimacing, muscle tone, physiological values, and level of agitation; these are more indicative of pain but could also indicate sedation. Principal components analysis revealed two correlated factors, behavioral and physiologic, accounting for 84% of the variance. Criterion validity was assessed by correlation of the COMFORT score to a global rating given by the bedside nurse (.75). Internal consistency was acceptable, with Cronbach's alpha at .84.

The COMFORT scale was more recently evaluated for evidence of reliability and validity as a postoperative pain instrument in newborn to three-year-old children (van Dijk et al., 2000). The COMFORT scale was evaluated in 158 neonates and toddlers (newborn to three years old) postoperatively in a PICU. Interrater reliability ranged from .63 to .93 in this study. Criterion validity of the COMFORT scale was supported by a high correlation (.92) between the observed Visual Analog Scale and the COMFORT scores. The COMFORT tool has been widely adopted in the PICU setting and has been used in studies of heart surgery pain, positioning and oxygenation interventions, and mechanical ventilation interventions.

An observational study examined the behaviors of twenty sedated, mechanically ventilated children, ages one month to fourteen years, using the COMFORT scale, and observing for body and facial movements, behavior state, and environmental activity (Grap, Pickler, & Munro, 2006). Children were observed to be at minimal levels of sedation on the COMFORT scale but the subjects still displayed body and facial

movement. The authors concluded that further investigation of existing sedation measures as well as the development of more sensitive measures of sedation in children is warranted.

The Neonatal Pain, Agitation, and Sedation Scale (N-PASS) was developed by this author with two subscales, pain/agitation assessment and sedation level assessment, for infants born at twenty-three weeks gestation to term, and studied up to 100 days age (Hummel et al., 2008). The N-PASS was designed in the year 2000 as a clinical tool for all infants in the NICU. The literature review revealed many validated pain and sedation behaviors, as well as many validated pain assessment tools. A tool to assess prolonged pain in the neonate, and a valid neonatal sedation assessment tool were not found in the literature.

The N-PASS was developed based upon the Onion Theory of Pain. Observable pain behaviors are due to the suffering that occurs with a painful stimulus. Observable sedation behaviors are due to the changes in the central nervous system following medication administration.

The author observed infants in the clinical setting for over twenty years, yielding a list of empirically derived pain and sedation behaviors. Based on these behaviors, and the literature review that showed that there were no tools to measure prolonged pain in neonates, the N-PASS tool was developed. Expert opinion from experienced NICU nurses was obtained, and the tool was modified based on clinical applicability and ease of assessment. The N-PASS items that these experts believed best represented neonate pain and sedation behaviors were retained.

The scale was developed with a range of 0 to 10, as this is consistent with the tools used for children and adults in the institution (VAS and FLACC). Five criteria are graded 0, 1, or 2 for pain/agitation and 0, -1, or -2 for sedation; pain scores are indicated by a positive number, sedation scores by a negative number. A high pain/agitation score indicates more frequent or intense behaviors, and a low sedation score indicates a decreased response to stimulation, or a deeper level of sedation. See Appendix A and Figure 4 for the N-PASS tool.

One to three points were added to the preterm infant's pain score due to their limited ability to display and maintain behavioral or physiological manifestations of pain, approximating the normal response of a full-term infant (Craig et al., 1993; Johnston et al., 1996; Stevens & Johnston, 1994). Gestational age categories and points assigned were initially based on the PIPP tool categories (Stevens et al., 1996). Corrected gestational age determines the number of points added to the score, with less mature infants receiving a higher baseline score than more mature infants. These points for prematurity were modified after the two research studies, as the preterm infant was found in both studies to respond less than the full term infant, but only by about one point. The sedation score does not require this adjustment as gestational age is not known to affect the premature infant's ability to exhibit signs of sedation.

Five indicators are included in the N-PASS, chosen for evidence of validity, clinical applicability, and ease of assessment: 1) crying/irritability, 2) behavior/state, 3) facial expression, 4) extremities/tone, and 5) vital signs (heart rate, respiratory rate, blood pressure, and/or oxygen saturation). Within each category, examples of criteria are provided to assist in the assignment of a numerical value.

The pain assessment portion of the N-PASS is labeled "pain/agitation" due to clinical difficulties in differentiating these two entities behaviorally, particularly in prolonged or chronic pain situations. Although researchers have attempted to categorize behaviors into "typical of pain" and "typical of agitation," many commonalities exist, such as crying, facial expression, and ability to console (Ramelet, 1999). An infant who appears to be in pain or agitated should be evaluated within the context of the situation in an attempt to determine causality for the behavior, guiding treatment. This is consistent with the modified Onion Theory of Pain and Sedation.

Formatting the N-PASS using the same criteria to assess both pain/agitation and sedation allows evaluation of the infant on a theoretical continuum, ranging from deeply sedated, to lightly sedated, to normal, to mild pain/agitation, to severe pain/agitation. Despite this theoretical continuum, pain and sedation must be evaluated and scored as separate entities since both can occur simultaneously, although it is recognized that increasing levels of sedation may mask the infant's response to pain (Alexander & Todres, 1998). Clinically, infants that become sedated due to analgesics are not likely to be in pain, but pain may be masked by sedative administration. Sedation behaviors and neurological depression behaviors are similar, and neurological irritability and pain behaviors are similar, highlighting the difficulties with pain and sedation assessment in an infant with an abnormal neurologic status.

Initial investigation of the N-PASS with prolonged pain was accomplished in the clinical setting. Ventilated and/or postoperative infants with prolonged pain (not acute/procedural pain) were evaluated before and after pharmacologic intervention. Infants received an opioid and/or a sedative, based upon standard unit practices.

Morphine was administered by bolus in the majority of infants to achieve analgesia and/or sedation. Lorazepam was administered when the clinical goal was sedation. The N-PASS tool was independently and concurrently administered on an infant with a pain score over three, when two data collection nurses were present. The infant was observed for 5-10 minutes before and one hour after analgesic and/or sedative administration. One nurse also administered the PIPP tool concurrently with the N-PASS.

Inter-rater reliability was high, measured by intra-class coefficients (ICC) of .85-.95 ($p$ <.01). Criterion validity was demonstrated by correlation with the PIPP scores (Spearman rank correlation coefficient of .83 at high pain scores, .61 at low pain scores). The lower correlation of the lower pain scores is due to the fact that the PIPP tool is designed to measure acute/procedural pain where infants react less when the procedure is started when they are sleeping, and therefore adds points for the sleeping infant. The N-PASS assigns lower scores for the sleeping infant.

Internal consistency, measured by Cronbach's alpha, was evident at high pain scores (.82), and with high and low sedation scores (.87, .89). At low pain scores, internal consistency was lower (.31). This is due to the fact that the majority of the post-intervention pain scores were zero, resulting in limited variability of scores for internal consistency evaluation. Construct validity was assessed via the Wilcoxon Signed-Ranks Test, comparing the distribution of N-PASS scores before and after pharmacologic intervention showing pain scores of ($M$ = 4.86, $SD$ = 3.38) and ($M$ = 1.81, $SD$ = 1.53), ($p$ < .01), and sedation scores of ($M$ = -0.85, $SD$ = 1.66) and ($M$ = -2.78, $SD$ = 2.81), ($p$ < .01), for pre- and post-intervention assessments, respectively.

The pain/agitation subscale of the N-PASS was also researched with acute/procedural pain (Hummel et al., 2010). The N-PASS was studied with routine heelstick procedures in the NICU, compared to a sham heelstick procedure in a prospective psychometric evaluation with a randomized crossover design. The bedside nurse randomly determined the order of events through coin toss. A researcher and a trained staff nurse scored the infant with both the sham and real heelstick procedures utilizing the N-PASS tool. One observer also scored the infant using the PIPP tool. Each infant was assessed prior to and during each procedure. The observers were trained in the use of both tools. When scoring the both tools, the raters were instructed to watch the entire procedure, then score utilizing the N-PASS and PIPP.

An infant blanket or screen was placed over the incubator or crib, obstructing the view of the lower half of the baby's body, in order to blind the observers to the procedure, while still allowing the bedside nurse to perform the procedure without additional stress to the infant. Videotaping included the upper half of the infant's body only, to maintain blinding of the observer with scoring of the actual versus sham heelstick.

The sham heelstick consisted of the nurse holding the foot as if doing a heelstick, wiping the heel gently with a dry 2x2 gauze, and holding the heel in place for at least 30 seconds. No lancing, squeezing of the heel, or alcohol/other prep was allowed with the sham procedure. The blood collection supplies were used as if in an actual heelstick, but no blood was obtained. The actual heelstick consisted of the standard NICU procedure of holding the foot in the usual position, prepping and collecting blood.

The second procedure, whether real or sham, occurred after the infant was quieted following the first procedure. The interval between procedures was between five and ten minutes. The observers watched the infant's behavior and monitored vital signs to enable scoring with the N-PASS and the PIPP tools. The assessment occurred before any intervention (baseline) and was repeated with each of the real and sham heelsticks. The order of the procedure was randomized by coin toss. Thirteen heelstick and sham procedures were videotaped with parental consent to enable intra-rater reliability (test-retest) analysis.

Discriminant (construct) validity was evaluated via the Wilcoxon Signed-Ranks Test, comparing the distribution of the heelstick and sham N-PASS scores, hypothesizing that the score would be higher with the actual heelstick than with the sham heelstick. Pain scores differed significantly for the heelstick and sham procedures ($M = 3.93$, $SD = 2.30$) and ($M = 0.81$, $SD = 1.21$), respectively, ($z = -6.429$, $p < .01$). Convergent validity was demonstrated by correlation with the PIPP scores (Spearman rank correlation coefficient of .75 and .72 for raters 1 and 2, respectively). Inter-rater reliability was high, measured by intra-class coefficients; the ICC estimates (95% *C.I.*) of the pain scale were .86 (.78, .92) and .93 (.88, .96) for a single rating and average of two independent ratings, respectively ($p < .01$). Internal consistency, measured by Cronbach's alpha, was evident (.84-.89). Test-retest reliability was demonstrated by repeat scoring of videotaped heelsticks, measured by Spearman's rho correlation (.87, $p < .01$). The N-PASS scores were compared between the group of infants receiving the heelstick first ($n = 28$) as compared with those receiving the sham procedure first ($n = 31$) using the Mann-Whitney

U-test. The mean ranks were not significantly different, (28.74 and 29.43), respectively ($z$ = -0.114, $p$ = .91).

European researchers evaluated the association between an empathy-based Faces Pain Scale Revised (FPS-R) and the item-based N-PASS tool when used to assess prolonged distress in term and preterm infants (Garten et al., 2010). Sequential evaluations of distress were done at four-hour intervals during a forty-eight hour time period. The two scales were used in parallel in forty-four term and preterm infants. When infants were categorized as being in distress or not, the rate of agreement between the two tools showed little variation (79.6 to 89.4%).

The N-PASS tool has been widely adopted for use in the NICU, with over 350 units currently utilizing this tool in the United States and internationally. The N-PASS has been translated into several languages, and is beginning to be used in research. See Appendix A for the N-PASS tool.

## Analysis of Research

Nonverbal pain assessment has focused on behavioral indicators due to the lack of a valid and specific biologic marker for pain. Initially, research was accomplished by the developmental psychology discipline. Nurses have become leading researchers in pain assessment, creating nearly all of the current neonatal/infant pain assessment tools. Pharmacy and medical disciplines have also contributed to neonatal pain assessment research.

Neonatal pain assessment research has evolved over the past fifty years due to changes in underlying assumptions. Initially, researchers believed that neonates do not use their cerebral cortex. Thus, when the researcher observed the neonate with a pinprick

and saw a non-specific and generalized response, the interpretation was that the infant did not feel pain. The paradigm has shifted: the current view is that neonates have an active cortex and are capable of cortical input and output. With the revised paradigm, based on improved neuroscience data, researchers observe the neonate during a painful situation and view the behaviors as signals of pain. Researchers also now understand that repeated painful experiences may contribute to abnormal cortical development and to an altered response to pain. Pain assessment and management research ultimately should contribute to improved patient outcomes.

Neonatal and pediatric behavioral pain assessment has progressed rapidly in the past twenty years. Assessment tools have been developed by nurses, mainly using empiric observations of behaviors during a painful procedure or postoperatively, by surveying experienced nurses, and by literature review. Multiple tools were designed for acute/procedural pain; few were designed for use in ongoing pain, such as postoperative pain and mechanical ventilation. Clinically, tools that are less cumbersome have become more widely used. Pain management research has increased, incorporating pain assessment tools as outcome measures.

Psychometric evaluation of these tools is an evolving process. Historically, tools were created and used without validity and reliability evidence, not acceptable by current standards of evidence-based practice. Pain assessment tools have been validated with acute procedural pain by comparing scores during the procedure to scores before the procedure or during a sham procedure. Validation of tools with ongoing pain has been accomplished through comparing scores before and after an analgesic intervention. Validity evidence is also assessed by comparing scores of a newer tool to a tool with

evidence of validity measuring the same inferred variable, which assumes that the criterion tool shows evidence of validity. Reliability is assessed by having two nurses score the subject simultaneously, giving inter-rater reliability, and through repeated scoring of a videotape, giving intra-rater reliability. Internal consistency is reported with all psychometric evaluations.

Precise evaluation of validity could be accomplished if valid and reliable biologic pain and sedation markers were available. In the absence of a biologic marker, validity testing will continue unchanged. Repeated psychometric evaluation of pain assessment tools in various populations and settings adds to the ongoing process of evaluating validity and reliability evidence of any tool. There is no gold standard of behavioral pain and sedation assessment methodology, or of the rigor of the psychometric evaluation of the assessment tools.

Sedation assessment is less developed in the neonatal and pediatric populations, despite the accepted use of analgesics and sedatives in these populations. Development and psychometric evaluation of sedation assessment tools has followed the methodologies of pain assessment tools. There is a potential to study validity for sedation assessment tools in the pediatric population through the use of BIS monitoring, a biologic marker of sedation levels used in the clinical setting.

## Gaps in Knowledge

The search for a biologic marker for pain should continue. In the absence of a biologic marker, objective validation of behavioral pain indicators is lacking. Pain assessment in neurologically abnormal infants and during neuromuscular blockade remains difficult in the clinical setting. Pain assessment has been widely studied in acute

pain; chronic pain assessment research is necessary for clinical use, as well as when researching chronic pain management strategies. Pain assessment tools currently used should be researched more extensively, in various situations and populations.

There is currently no tool available to assess both pain and sedation in nonverbal children. The N-PASS requires testing in older populations, to determine appropriate use of the tool. Following this, the N-PASS tool could be modified for use in pediatrics and subjected to psychometric evaluation utilizing the same methodology as was used in the neonatal population.

This research, testing the N-PASS tool in populations of older infants and toddlers, is necessary for expanded clinical use of the tool. The NICU population occasionally includes infants with long stays, up to twelve months of age in some units. Testing the upper limits of age use for the N-PASS tool is necessary before modifying the tool for use in the pediatric population. Testing the instrument in children up to thirty-six months of age is warranted, as behavioral pain assessment is utilized on all children of this age span, while children over thirty-six months of age may be able to provide self-report of pain verbally or through other measures.

# CHAPTER THREE

# RESEARCH METHODS

This chapter describes the research design, setting, target population, sample, sample size, ethical considerations, data collection procedures, measures, and method of data analysis.

## Research Design

This study was a prospective, non-experimental psychometric evaluation of the Neonatal Pain, Agitation, and Sedation Scale (N-PASS). The primary goal of this study was to evaluate the internal consistency and validity evidence of the N-PASS tool in infants and preverbal toddlers aged one to thirty-six months in the Post-Anesthesia Care Unit (PACU). This setting allows for multiple sequential observations of subjects that are experiencing sedation and pain.

### Setting

This study was conducted at a university-affiliated medical center located in Illinois. This facility is a private, not-for-profit comprehensive academic medical center with 592 licensed beds, including a Level 1 trauma center and a Children's Hospital. The Post-Anesthesia Care Unit (PACU) is a 40-bed unit that cares for adult and pediatric patients directly from the operating room until discharge to the inpatient unit or outpatient surgery center.

**Population**

The target population for this study was infants and toddlers aged one month to thirty-six months of age who have received general anesthesia, who are recovering in the PACU. Over 300 pediatric surgeries are completed yearly in this institution. The surgical sub-specialties include general pediatric, cardiac, otolaryngology, orthopedic, or urologic surgeries. Subjects that were transferred from the operating suite immediately to an inpatient unit for recovery are not included.

**Sample**

The target population was described in the previous section. A non-probability convenience sample was obtained. The study sample inclusion criteria were as follows: 1) postoperative admission to the PACU and 2) age at one month to thirty-six months old. Exclusion criteria were as follows: 1) brain injury, suspected or confirmed; 2) neuromuscular disease with abnormal baseline neurologic status; or 3) neurosurgical intervention.

Participants meeting the criteria were identified weekly via the surgical schedule by the PACU nursing manager. This participant list was given to the researcher, who collected data based on the availability of the researcher. The PACU nursing manager estimated that two to eight subjects would meet the criteria for inclusion each week. The manager retrieved the information from the surgical schedule which is available in the electronic medical record. The potential subject information included the name, age, gender, diagnosis, surgical procedure, and the surgical procedure schedule. The information was transmitted electronically to the investigator via a password protected electronic mailbox. The name of the subject was used only to assure that the investigator

was collecting data on the planned participant, and was kept in a locked data collection file.

**Sample Size**

Power analysis was based on the ANOVA analysis as the primary analysis. The sample size calculation was based on the possibility of obtaining a medium correlation effect size (r = .38) with at least 80% power with a two-tailed p of <0.05. This requires a sample size of forty participants. A sample size of eighty-four participants provided the possibility of detecting a smaller effect size (r = .30). A sample size of 100 provided the possibility of detecting a slightly smaller effect size (r = 0.28) with at least 80% power (Osborne & Costello, 2004).

A sample size of forty subjects was planned for this research, based on a minimum of ten observations for each subject. Initial psychometric evaluation of the N-PASS tool with prolonged pain revealed an effect size of r = .42. Psychometric evaluation of the N-PASS tool with acute pain revealed an effect size of r = .65. Since this research included subjects experiencing both acute and prolonged pain, a sample size of forty subjects was adequate.

Data from several earlier studies of pain and sedation assessment tools indicate that sample sizes of thirty to forty-five are used, sometimes collecting several data sets for each subject (Curley et al., 2006; Debillon et al., 2001; Lawrence et al., 1993; Merkel et al., 1997; Stevens et al., 1996).

## Ethical Considerations

This study was guided by both ethical and legal considerations. Consideration for the protection of the interests of subjects, the supporting facility, and the principal

investigator were incorporated. Confidentiality of identity and information, and protection of the research subjects against physical, mental, or emotional injury were maintained. Approval from the Medical Center Institutional Review Board was obtained. Consultation with the director of the Human Research Protections Program confirmed that informed parental consent was not required due to the observational nature of the research. Nursing and medical student observation of care is a frequent phenomenon in the academic medical center. The research was explained to the parent by the nursing staff during the admission procedure. The nurse explained that the investigator would be observing the subject continually during the PACU stay, and would be recording observations regarding the infant's pain and sedation behaviors, and that the investigator's observations would not influence the care of the subject. Observation and data collection were planned to not occur if the parents expressed objections to the process.

The unit nursing and medical management teams were informed, and their suggestions were incorporated into the design and data collection plan. Suggestions included feasibility of subject recruitment and education of the nursing staff. The nursing staff was in-serviced in person during staff meetings, and the researcher contacted the nurse prior to the admission procedure, with a reminder to discuss the research with the subjects' parents.

The researcher observed the participant without interfering in the usual care and monitoring. The researcher did not interfere with the care, or give suggestions about the monitoring or care. The researcher answered parental questions regarding the research as

these arose. Data collection was planned to be terminated if the parent expressed any reluctance or objections to the process.

Data entry was confidential, and completed solely by the investigator. Data files were maintained in a password-protected directory of a personal computer located at the investigator's private residence. The participants' name and medical record number were not in the data file. Demographic data collected included date of birth, age in months, gender, diagnosis, and surgical procedure. Accuracy of data entry was assured as data were cleaned of errors by the investigator and also by statistical support staff by visual inspection and by running descriptive statistics.

**Risks and Benefits**

The parent(s) could experience additional stress due to the investigator's presence and documentation. However, it was not anticipated that this would be experienced by a significant number of parents. Data collection was planned to not be initiated or to be terminated if the parent expressed distress or discomfort due to the investigation. There was no risk to the participants, as the investigator was collecting observational data only.

The potential risks of this study were outweighed by the anticipated benefits. Pain and sedation assessment tools with evidence of reliability and validity are essential to the safe care of the patient in the PACU.

## Data Collection

Data collection began on 06/04/2013 upon Institutional Review Board approval. The researcher administered the N-PASS and the gold standard instruments, the FLACC and the UMSS, every five minutes following admission to the PACU, for a minimum of ten observations or until discharge from the PACU. The assessments were documented

on data collection sheets (Appendix B). See Appendix A for the FLACC tool and the UMSS tool. Participant recruitment and data collection continued until the sample size was achieved. Data collection was completed on 12/16/2013.

**Measures**

In addition to the N-PASS tool, the FLACC (Merkel et al., 1997) and the UMSS (Malviya et al., 2002) were used in this study. The psychometric evaluation of these measures was discussed in Chapter Two. See Appendix A for the FLACC and UMSS tools. In addition, the subjects' heart rate as displayed on the cardiac or pulse oximetry monitor was recorded with every observational scoring.

## Data Analysis

The primary objective of this research involved testing of the internal consistency and validity of the N-PASS tool. Data analyses included descriptive statistics of the sample data, evaluations of reliability through internal consistency, and construct and criterion validity assessments. Validity evidence was also examined through an analysis of how the N-PASS scores change over time. The analysis also permitted a test of the value of the tool in the evaluation of readiness for discharge from the PACU. The factor structure of the N-PASS tool was examined. SPSS version 20.0 was used as the statistical software for analysis.

**Descriptive Statistics**

Descriptive statistics provide an overall picture of the sample. Demographics included age in months, gender, and surgical procedure. This information was summarized through means and standard deviations for interval level data. Frequencies were used to summarize nominal level data.

**Reliability**

The first research question, "Do the N-PASS tool subscales of sedation and pain/agitation exhibit internal consistency as measured by Cronbach's alpha?" was answered by using Cronbach's alpha analysis (Cronbach, 1951). The N-PASS pain/agitation and the N-PASS sedation subscales were analyzed separately for internal consistency.

Inter-rater and test-retest reliability of the N-PASS tool was not researched as this has been estimated in two previous studies. This information was discussed in Chapter Two. Data collection for this research was accomplished with one observer, the researcher.

**Criterion Validity**

The second and third research questions, "Does the N-PASS tool exhibit criterion validity when the sedation subscale is compared to the UMSS instrument?" and "Does the N-PASS tool exhibit criterion validity when the pain/agitation subscale is compared to the FLACC instrument?" were answered by using correlation statistics. Criterion related validity describes the empirical association of an instrument in relation to some criterion or gold standard. It assesses the practical nature rather than the theoretical nature of an instrument (DeVellis, 2003). The most widely used pediatric pain assessment tool is the FLACC tool (Merkel et al., 1997), considered the gold standard tool (McGrath et al., 2008). No gold standard tool has emerged for pediatric sedation assessment; the UMSS has the most extensive testing and appears to be the most widely used in the pediatric population (Malviya et al., 2002).

Pearson correlations were calculated, assessing the correlation between the FLACC and the N-PASS pain score, and between the UMSS and the N-PASS sedation score. It was hypothesized that these scores would correlate significantly, supporting criterion validity.

The heart rate, as depicted on the cardiac or pulse oximetry monitor, was documented with every observation, as heart rate is known to rise in painful situations, and fall when pain is alleviated. Pearson correlations were calculated to assess the correlation between the heart rate and the N-PASS subscales.

**Construct Validity**

The fourth research question, "Does the N-PASS exhibit construct validity in the PACU setting by showing significant difference in scores over time through Repeated Measures ANOVA testing?" was answered by analyzing the change in scores. Sedation scores were hypothesized to change over time in the PACU setting, as the subject emerges from general anesthesia through the sedation continuum. Pain scores should also change over time as the effects of anesthesia diminish, as post-surgical pain is inevitable due to tissue damage. The omnibus test of Repeated Measures ANOVA was used to test if there is significant change over time, either in sedation or in pain constructs, demonstrating that the instrument measures changes in pain and sedation levels. This test determines if the instrument is sensitive to detect change across the multiple observations/time points, testing for significant differences over time.

The fifth research question "Does the N-PASS tool provide a predicted pathway of behaviors over time of recovery in the PACU setting?" was answered by regression analysis. Simultaneous regression was performed to use the rate of change in sedation to

predict time of discharge. Regression is used to predict a continuous dependent variable by a continuous independent variable. The hypothesis was that the faster a child's sedation decreases, the sooner they will be discharged. Assuming a linear trend to the data, slopes were created by calculating change scores by subtracting difference score = V1-V2. These calculated slopes may predict time in the PACU and assist in determining the optimal time of discharge from the PACU.

**Factor analysis.** The sixth research question, "what is the factor structure of the N-PASS tool?" was examined through Principal Axis Factoring (PAF). PAF separates the variance in items into common variance, which is predicted by the latent variables. PAF also separates the variance in items into unique error variance, which is unrelated to the latent variable. It was hypothesized that the N-PASS has two latent factors, one that represents the underlying spectrum of pain and one that represents sedation. PAF analysis was conducted at three different time points to determine if the same factor structure is found repeatedly over time.

## Methods Summary

Reliability and validity evidence of the N-PASS tool were obtained using a sample of infants and children aged one to thirty-six months in a PACU setting. One observer, the researcher, scored the subjects every five minutes using the N-PASS tool along with the FLACC and UMSS tools. The heart rate was also recorded at each observation point.

Reliability was tested through internal consistency evaluation. Validity was tested using criterion validity and Repeated Measure ANOVA. Regression analysis was used to determine if discharge could be predicted by the change in sedation scores over time.

Factor structure of the N-PASS was explored through PAF. The results of these analyses are presented in the next chapter.

# CHAPTER FOUR

# RESULTS

The purpose of this study was to test an assessment tool designed to evaluate pain and sedation in infants and children one to thirty-six months age. This chapter includes the results of the psychometric evaluation of the N-PASS tool in this population.

## Sample

A convenience sample was obtained. Forty subjects, ranging in age from three to thirty-five ($M$ = 19.25, $SD$ = 10.84) months of age, were enrolled during their stay in the Post-Anesthesia Care Unit (PACU) at a large Midwestern medical center. The subjects were observed postoperatively during recovery following general anesthesia. Fourteen subjects (35%) were female, twenty-six (65%) were male. Otolaryngology surgical procedures were the most common at nineteen (48%). These procedures included adenoidectomy, pressure equalization (PE) tube insertion, neck mass resection, and tonsillectomy. Urologic procedures such as circumcision or circumcision revision and ureteral re-implant procedure accounted for nine (22%). Other surgical procedures were the remainder, eleven (28%), e.g., inguinal hernia repair and umbilical hernia repair. One subject underwent an orthopedic procedure (open reduction of a fractured arm).

All subjects were recovering from general anesthesia, and 50% of the urologic and general surgical subjects received local or regional anesthesia. Operating room time ranged from 35-245 minutes ($M$ = 88, $SD$ = 36). Time in the PACU setting ranged from

50-110 minutes (*M* = 63, *SD* = 18). Most (90%) of the subjects were discharged home from the PACU, 10% were admitted to the hospital as inpatients for ongoing care.

## Descriptive Analysis

This section contains the descriptives and frequencies of the N-PASS (pain/agitation and sedation subscales), FLACC, and UMSS. The N-PASS sedation numbers in clinical use are negative numbers, with 0 being not sedated and a -10 being most sedated. This allows for clinical clarity when the scores are being documented or discussed; positive numbers indicate the pain score, negative numbers indicate the sedation score. For this analysis, the sedation numbers and scores were changed to positive, with 0 being not sedated and 10 being most sedated. This was done to provide clarity when comparing the N-PASS sedation scale to the UMSS scale, which has positive numbers with higher numbers indicating deeper sedation. See Appendix A for the N-PASS tool.

The N-PASS sedation tool has a possible score of 0 to 10, with 10 being most sedated, and 0 being not sedated. The mean N-PASS sedation scores ranged from 0 to 10, beginning at the first observation with a mean of 5.925 (*SD* = 2.63), and falling to a mean of 1.725 (*SD* = 2.75). The UMSS tool has a possible score of 0 to 4, with 4 being most sedated, and 0 being not sedated. The mean UMSS scores ranged from 0 to 4, beginning at the first observation with a mean of 2.3 (*SD* = .992) and falling to a mean of .75 (*SD* = 1.056). The N-PASS pain tool has a possible score of 0 to 10, with 10 indicating the most pain and 0 indicating no pain. The mean N-PASS pain scores fluctuate at varying intervals, ranging from 0 to10, beginning with a mean of 1.225 (*SD* = 2.25) and fluctuating between means of 1.15 (*SD* = 2.23) and 2.4 (*SD* = 3.10). The FLACC tool has a possible score of 0-10, with 10 as the most pain and 0 as no pain. The mean FLACC

scores also fluctuated at varying intervals, ranging from 0 to10, beginning with a mean of 1.18 (*SD* = 2.26), and fluctuating between means of 1.18 (*SD* = 2.23) and 2.4 (*SD* = 3.02).

The descriptives of the sum score of the N-PASS sedation score and the UMSS score for the first ten observations are presented in Table 2. The descriptives of the sum score of the N-PASS pain score and the FLACC score for the first ten observations are presented in Table 3.

Table 2. Descriptive Statistics (N-PASS sedation/ UMSS)

| Sum Score | N | Minimum | Maximum | Mean | S.D. |
|---|---|---|---|---|---|
| 1 N-PASS sedation | 40 | .00 | 10.00 | 5.9250 | 2.68316 |
| 1 UMSS | 40 | 0 | 4 | 2.30 | .992 |
| 2 N-PASS sedation | 40 | .00 | 10.00 | 5.0000 | 3.18651 |
| 2 UMSS | 40 | 0 | 4 | 2.03 | 1.209 |
| 3 N-PASS sedation | 40 | .00 | 10.00 | 4.9000 | 3.41790 |
| 3 UMSS | 40 | 0 | 4 | 1.92 | 1.289 |
| 4 N-PASS sedation | 40 | .00 | 10.00 | 4.5500 | 3.07971 |
| 4 UMSS | 39 | 0 | 4 | 1.85 | 1.182 |
| 5 N-PASS sedation | 40 | .00 | 10.00 | 4.0250 | 3.16623 |
| 5 UMSS | 40 | 0 | 4 | 1.70 | 1.285 |
| 6 N-PASS sedation | 40 | .00 | 10.00 | 3.7000 | 3.26756 |
| 6 UMSS | 39 | 0 | 4 | 1.62 | 1.248 |
| 7 N-PASS sedation | 40 | .00 | 10.00 | 3.1250 | 3.09000 |
| 7 UMSS | 40 | 0 | 4 | 1.32 | 1.207 |
| 8 N-PASS sedation | 40 | .00 | 10.00 | 2.8500 | 3.00896 |
| 8 UMSS | 39 | 0 | 4 | 1.26 | 1.251 |
| 9 N-PASS sedation | 40 | .00 | 10.00 | 2.2750 | 2.73615 |
| 9 UMSS | 40 | 0 | 4 | 1.02 | 1.187 |
| 10 N-PASS sedation | 40 | .00 | 9.00 | 1.7250 | 2.74551 |
| 10 UMSS | 40 | 0 | 4 | .75 | 1.056 |

Table 3. Descriptive Statistics (N-PASS pain/FLACC)

| Sum Score | N | Minimum | Maximum | Mean | S.D |
|---|---|---|---|---|---|
| 1 N-PASS pain | 40 | .00 | 8.00 | 1.2250 | 2.24736 |
| 1 FLACC | 40 | .00 | 8.00 | 1.1750 | 2.26328 |
| 2 N-PASS pain | 40 | .00 | 10.00 | 2.4000 | 3.01959 |
| 2 FLACC | 40 | .00 | 10.00 | 2.3250 | 2.99048 |
| 3 N-PASS pain | 40 | .00 | 10.00 | 2.2500 | 3.34932 |
| 3 FLACC | 40 | .00 | 10.00 | 2.2000 | 3.32974 |
| 4 N-PASS pain | 40 | .00 | 10.00 | 1.1750 | 2.22903 |
| 4 FLACC | 40 | .00 | 10.00 | 1.1500 | 2.25945 |
| 5 N-PASS pain | 40 | .00 | 7.00 | 1.5750 | 2.39537 |
| 5 FLACC | 40 | .00 | 7.00 | 1.5000 | 2.37508 |
| 6 N-PASS pain | 40 | .00 | 10.00 | 1.5000 | 2.63117 |
| 6 FLACC | 40 | .00 | 10.00 | 1.4000 | 2.47863 |
| 7 N-PASS pain | 40 | .00 | 10.00 | 1.7750 | 2.96551 |
| 7 FLACC | 40 | .00 | 10.00 | 1.8000 | 2.99743 |
| 8 N-PASS pain | 40 | .00 | 10.00 | 2.0000 | 3.21056 |
| 8 FLACC | 40 | .00 | 10.00 | 1.9500 | 3.16997 |
| 9 N-PASS pain | 39 | .00 | 10.00 | 1.4615 | 2.78951 |
| 9 FLACC | 40 | .00 | 10.00 | 1.4250 | 2.66879 |
| 10 N-PASS pain | 40 | .00 | 10.00 | 1.7500 | 3.04454 |
| 10 FLACC | 40 | .00 | 10.00 | 1.7500 | 3.01917 |

## Reliability Analysis

This section answers the first research question, “Does the N-PASS tool exhibit internal consistency as measured by Cronbach’s alpha?” Alphas were calculated for the N-PASS Sedation scale, the N-PASS Pain/agitation scale, and the FLACC scale. Alpha could not be calculated for the UMSS as it is a single item scale.

**N-PASS Sedation Scale**

Cronbach's alphas were computed for each of the first ten observations. Alphas ranged from .853-.938. This indicates an acceptable internal consistency. Also, the alphas fell slightly over the time period as the sedation scores fell. See Table 4 for these results.

Table 4. N-PASS Sedation Score/Cronbach's alpha

| | | | |
|---|---|---|---|
| Time 1 | .923 | Time 6 | .908 |
| Time 2 | .931 | Time 7 | .878 |
| Time 3 | .938 | Time 8 | .881 |
| Time 4 | .916 | Time 9 | .872 |
| Time 5 | .917 | Time 10 | .853 |

All Cronbach's alphas for the sedation scale if each item was deleted were > .77. The alphas were highest if the sedation vitals item was deleted. This indicates that the N-PASS sedation subscale has slightly improved internal consistency without the vital sign items, but is acceptable with the vitals indicator.

**N-PASS Pain/Agitation Scale**

Cronbach's alphas were computed for each of the first ten observations. Alphas ranged from .935-.971, indicating acceptable internal consistency. The scores remained fairly constant over the ten observations. Cronbach's alphas if each item was deleted were > .8. See Table 5 for Cronbach's alpha for the N-PASS pain scale.

Table 5. N-PASS Pain Score/Cronbach's alpha

| | | | |
|---|---|---|---|
| Time 1 | .944 | Time 6 | .966 |
| Time 2 | .967 | Time 7 | .963 |
| Time 3 | .974 | Time 8 | .966 |
| Time 4 | .945 | Time 9 | .964 |
| Time 5 | .935 | Time 10 | .971 |

**FLACC Tool**

Cronbach's alphas were computed for each of the first ten observations. Alphas ranged from .935-.971, remaining constant, and indicating an acceptable internal consistency. See Table 6 for FLACC Cronbach's alphas.

Table 6. FLACC/Cronbach's alpha

| | | | |
|---|---|---|---|
| Time 1 | .966 | Time 6 | .970 |
| Time 2 | .974 | Time 7 | .967 |
| Time 3 | .982 | Time 8 | .978 |
| Time 4 | .967 | Time 9 | .969 |
| Time 5 | .936 | Time 10 | .974 |

## Correlation Analysis

This section answers the second and third research questions, "Does the N-PASS tool exhibit criterion validity when the sedation subscale is compared to the UMSS instrument?" and "Does the N-PASS tool exhibit criterion validity when the pain/agitation subscale is compared to the FLACC instrument?"

**Correlations between N-PASS Sedation Scale and UMSS**

The sum scores of the N-PASS sedation scale and the UMSS were analyzed for criterion validity at ten observation times. The correlations ranged from .847 to .967, all were significant at $p < .001$. See Table 7 for correlations between the N-PASS sedation scale and the UMSS instrument.

Table 7. Correlations of N-PASS Sedation Scale and UMSS

| Observation time | N-PASS sedation and UMSS Pearson correlation | Significance |
|---|---|---|
| Time 1 | .847 | <.001 |
| Time 2 | .932 | <.001 |
| Time 3 | .930 | <.001 |
| Time 4 | .928 | <.001 |
| Time 5 | .941 | <.001 |
| Time 6 | .958 | <.001 |
| Time 7 | .945 | <.001 |
| Time 8 | .967 | <.001 |
| Time 9 | .961 | <.001 |
| Time 10 | .931 | <.001 |

**Correlations between N-PASS Pain Scale and FLACC**

The sum scores of the N-PASS pain scale and the FLACC were analyzed for criterion validity. The correlations ranged from .977 to .996, all were significant at $p < .001$. See Table 8 for correlations between the N-PASS pain scale and the FLACC instrument.

Table 8. Correlations of N-PASS Pain Scale and FLACC

| Observation time | N-PASS pain and FLACC Pearson correlation | Significance |
|---|---|---|
| Time 1 | .985 | <.001 |
| Time 2 | .990 | <.001 |
| Time 3 | .996 | <.001 |
| Time 4 | .977 | <.001 |
| Time 5 | .980 | <.001 |
| Time 6 | .987 | <.001 |
| Time 7 | .990 | <.001 |
| Time 8 | .983 | <.001 |
| Time 9 | .994 | <.001 |
| Time 10 | .994 | <.001 |

**Correlations between the N-PASS Scale and Heart Rate**

Correlations were calculated between the N-PASS subscales and the documented heart rate as heart rate is known to rise with pain and to fall with decreased pain and also with sedation. Correlations were computed between the N-PASS sedation scale and the recorded heart rate at each observation. The sample size was adequate for observations at times 1, 5, and 10, (at admission, at 25 minutes, and at 50 minutes). Correlations were high: -.708 at time 1, -.526 at time 5, and -.516 at time 10, and all were significant. At all three times the correlation between the heart rate and the N-PASS sedation scores indicated a negative relationship such that as the sedation score increases, heart rate decreases; heart rate was lower with increased sedation. Sample size decreased after the tenth observation and was inadequate for correlation calculations. Sample size decreased over time as subjects had varying lengths of stay/observation. See Table 11 for the N-PASS sedation score and heart rate correlations.

Correlations were computed between the N-PASS pain scale and the recorded heart rate at each observation time point. The sample size was adequate for observations at times 1, 5, and 10. Correlations were high—.623 at time 1, .651 at time 2, and .687 at time 10—and all were significant. At all three times the correlation between the heart rate and the N-PASS pain scores indicated a positive relationship such that as the pain score increases, heart rate increases; heart rate is higher with increased pain. Sample size decreased after the tenth observation and was inadequate for correlation calculations. See Table 9 for the N-PASS pain score and heart rate correlations.

Table 9. Correlations of Heart Rate and N-PASS Sedation and Pain Scales

| | | df | N | Heart rate and N-PASS sedation | Heart rate and N-PASS pain/agitation |
|---|---|---|---|---|---|
| Time 1 | Pearson correlation | 1 | | -.708 | .623 |
| | Sig. (2-tailed) | | | .000 | .000 |
| | N | | 39 | 39 | 39 |
| Time 5 | Pearson correlation | 1 | | -.526 | .651 |
| | Sig. (2-tailed) | | . | .001 | .000 |
| | N | | 39 | 39 | 39 |
| Time 10 | Pearson correlation | 1 | | -.516 | .687 |
| | Sig. (2-tailed) | | | .001 | .000 |
| | N | | 38 | 38 | 38 |

## Analysis of Variance

The fourth research question—"Does the N-PASS exhibit construct validity in the PACU setting by showing significant difference in scores over time?"—was answered by Repeated Measures Analysis of Variance (ANOVA) testing.

Repeated Measures ANOVA was performed to obtain an analysis of change over time for both sedation and pain N-PASS scores. These changes can be evaluated in terms of linear change, quadratic, or cubic functions. The analyses for sedation and pain/agitation were done independently.

### N-PASS Sedation Scale

Sedation levels were predicted to change at a constant linear rate over the course of the first ten observations. A Repeated Measure ANOVA was executed with the first ten observations of N-PASS sedation scale as the dependent variable. This is a "fixed effects" model as there is an assumption of a mean intercept (starting point) and mean rate of change for the sample.

The N-PASS sedation level was found to change linearly over the first ten observations. ANOVA Tests of Within-Subjects Effects, sphericity assumed: SS = 631.102 (df = 9); MS = 70.122; $F = 19.187$; $p<.001$. The linear trend across the ten observations was the best fit to the data: SS = 623.573; df = 1; MS = 623.573; F = 44.075; $p<.001$. See Table 10 and Figure 3 displaying the estimated marginal means of the N-PASS Sedation Scale.

Table 10. N-PASS Sedation ANOVA Marginal Means, First Ten Observations

| N-PASS sedation observation times | Mean | Std. error | 95% Confidence interval | |
|---|---|---|---|---|
| | | | Lower bound | Upper bound |
| 1 | 5.925 | .424 | 5.067 | 6.783 |
| 2 | 5.000 | .504 | 3.981 | 6.019 |
| 3 | 4.900 | .540 | 3.807 | 5.993 |
| 4 | 4.550 | .487 | 3.565 | 5.535 |
| 5 | 4.025 | .501 | 3.012 | 5.038 |
| 6 | 3.700 | .517 | 2.655 | 4.745 |
| 7 | 3.125 | .489 | 2.137 | 4.113 |
| 8 | 2.850 | .476 | 1.888 | 3.812 |
| 9 | 2.275 | .433 | 1.400 | 3.150 |
| 10 | 1.725 | .434 | .847 | 2.603 |

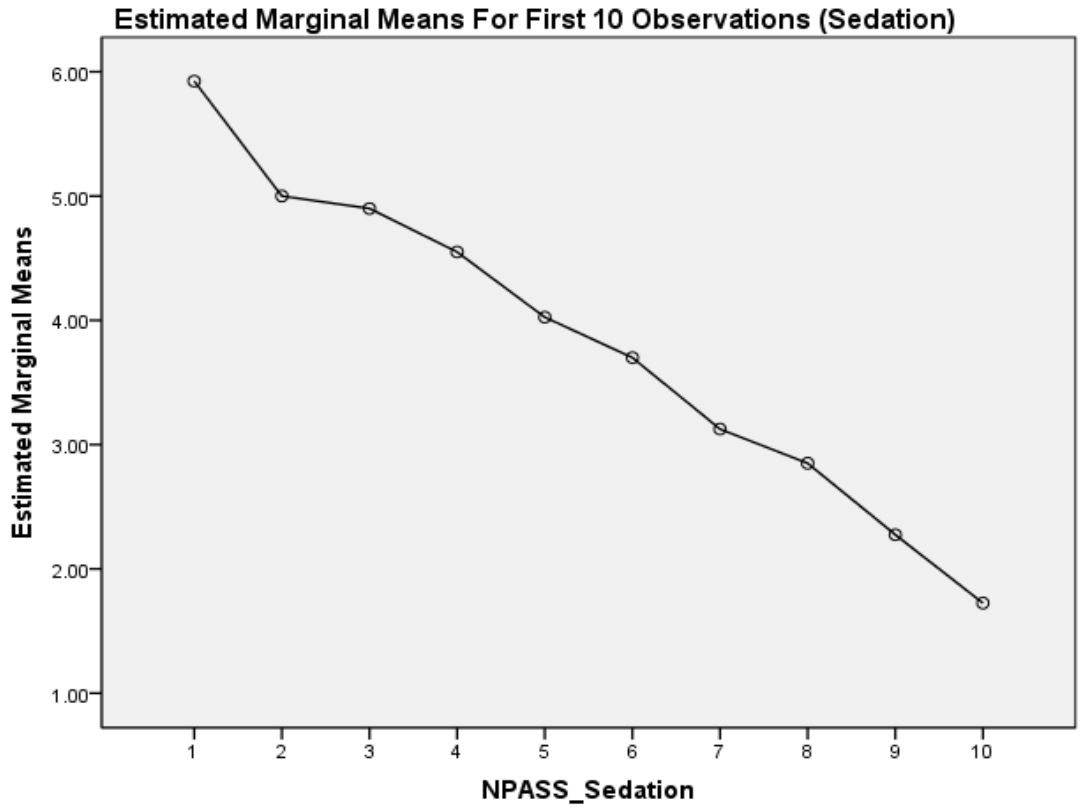


Figure 3. Estimated marginal means N-PASS sedation scale, first ten observations.

The intercept was statistically significant: SS = 5798.823; df = 1, MS = 5798.823; F = 96.71; $p<.001$. This indicates that the intercept is statistically significant from zero; the level of sedation at the start is greater than zero.

**N-PASS Pain Scale**

It was predicted that pain levels would change at a constant linear rate over the course of the first ten observations. Repeated Measure ANOVA was executed with the first ten observations of N-PASS pain scale as the dependent variable. This is a "fixed effects" model as there is an assumption of a mean intercept (starting point) and mean rate of change for the sample. The N-PASS pain scale scores did change over time, but not in a linear, quadratic, or cubic form. This indicates that the pain levels are not dependent on time postoperatively; pain levels fluctuate independently of time, due to many intervening factors such as analgesic administration, nursing and parental comfort interventions, individual differences, and other unknown factors. The effects of analgesic medications on the pain score could not be analyzed as only three subjects received analgesic medications during the observation period. ANOVA Test of Within-Subjects Effects was not significant, SS = 53.221 (df = 9); MS = 5.913; F = .903; $p = .523$. See Table 11 and Figure 4 displaying the estimated marginal means of the N-PASS pain scale.

Table 11. N-PASS Pain ANOVA Marginal Means, First Ten Observations

| N-PASS pain observation times | Mean | Std. error | 95% Confidence interval | |
|---|---|---|---|---|
| | | | Lower bound | Upper bound |
| 1 | 1.256 | .363 | .521 | 1.992 |
| 2 | 2.359 | .488 | 1.371 | 3.347 |
| 3 | 2.231 | .543 | 1.132 | 3.330 |
| 4 | 1.205 | .360 | .476 | 1.934 |
| 5 | 1.590 | .388 | .804 | 2.376 |
| 6 | 1.410 | .417 | .567 | 2.254 |
| 7 | 1.769 | .481 | .795 | 2.743 |
| 8 | 1.923 | .515 | .881 | 2.965 |
| 9 | 1.462 | .447 | .557 | 2.366 |
| 10 | 1.667 | .486 | .682 | 2.651 |

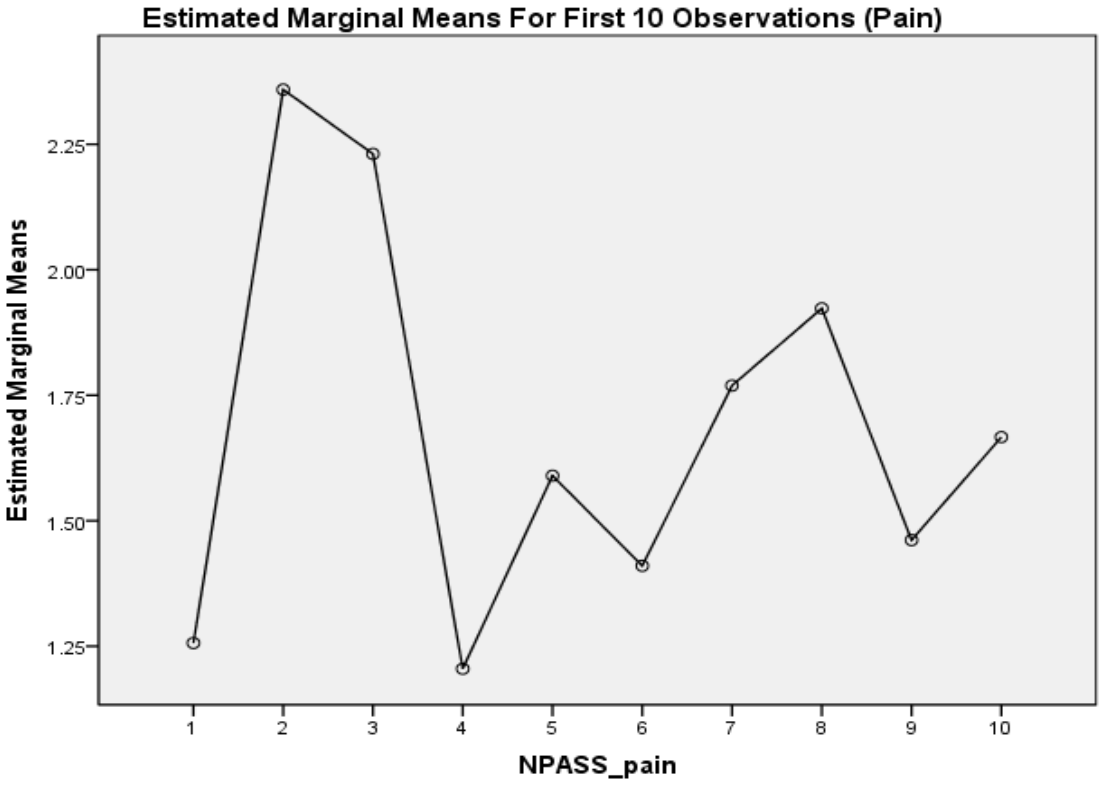


Figure 4. Estimated marginal means of the N-PASS pain score, first ten observations.

## Regression Analysis

The fifth research question—"Does the N-PASS tool provide a predicted pathway of behaviors over time of recovery in the PACU setting?"—was answered by regression analysis. Since a significant change over time for sedation was found by Repeated Measures ANOVA, post hoc tests were used to determine the rates or slopes of change. Simultaneous regression was performed to use the rate of change in sedation to predict time of discharge. Regression is used to predict a continuous dependent variable by a continuous independent variable. The hypothesis was that the faster a child's sedation decreases, the sooner they will be discharged. Regression was not performed for the pain/agitation subscale since the Repeated Measures ANOVA did not show a linear change in the scores.

### Test of Change in Sedation Predicting Time to Discharge

Change scores in sedation were calculated by subtracting Time 1 from Time 10 (T10-T1 = Change in Sedation). As the relationship is linear, the two scores can be subtracted. Time to Discharge or total time spent in PACU was calculated by subtracting time of admission from time of discharge. (Time of Discharge minus Time of Admission = Time to Discharge). Using the change in sedation variable, the subject's length of stay (Time to Discharge) was predicted. The independent variable was Change in Sedation from time 1 to time 10. The dependent variable was the amount of time spent in PACU.

The amount of time spent in the PACU was not predicted by the change in sedation scores from time 1 to time 10. A non-significant linear trend was found for the prediction of amount of time spent in PACU as a function of change in sedation levels from time 1 to time 10 ($\beta = .284$; $p = .075$; $R^2 = 0.081$).These findings indicate that every

standard deviation decrease in sedation is associated with a .284 standard deviations decrease in time to discharge. I.e., a greater decrease in sedation over time predicts shorter length of stays in the unit. Unstandardized coefficients: Constant /Intercept: 4178,674 (SE = 266.623); t = 15.673; $p$<.001. Slope/beta: 90.637 (SE = 49.553); t = 1.829; $p$ = .075. Standardized coefficients: rate of change in standardized units = .284.

**Principal Axis Factoring**

The sixth research question, "What is the factor structure of the N-PASS tool?" was examined through Principal Axis Factoring (PAF). PAF is a factor analysis method of data reduction. PAF separates the variance in items into common variance (which is predicted by the latent variables) and unique error variance (which is unrelated to the latent variables). It was predicted that the N-PASS would have two underlying factors—one representing pain/agitation and one representing sedation. Clinically, pain and sedation do not rise and fall together. Therefore it was predicted that sedation scores would be lower when pain scores were high, and conversely, sedation scores would be higher with lower pain scores. This would result in negative loadings for pain and positive loadings for sedation, or vice versa. Since two factors were found with factor extraction, with remaining factors contributing very little to the variance, analysis was run with rotation. Varimax (orthogonal) rotation was used as the two factors are assumed to be uncorrelated. Varimax rotation maximizes the variance of each of the factors, so the variance accounted for is distributed over the two extracted factors.

PAF was computed on the N-PASS scale at three separate observation times—Time 1 (the first observation upon admission to the PACU), Time 5 (the fifth observation, done at 25 minutes after admission), and Time 10 (the tenth observation,

done at 50 minutes after admission) since these were the time points used in the other analyses. These observational time points reflect changes over time with the largest sample size.

Two tests, the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) and Bartlett's Test of Sphericity, were run to determine the appropriateness of including factor analysis in this research. The KMO statistic varies between 0 and 1, and values closer to 1 are desired. A value of .6 is a suggested minimum (Kaiser, 1974). The KMO statistics were all well above .6: Time 1 = .826, Time 5 = .813, and Time 10 = .819.

Bartlett's Test of Sphericity tests the null hypothesis that the correlation matrix is an identity matrix (a matrix in which all the diagonal elements are 1 and all off-diagonal elements are 0). This null hypothesis was rejected. All three PAF analyses demonstrated significant Bartlett's tests. Time 1 Bartlett's test was 442.203, df = 45 ($p$ = .000). Time 5 Bartlett's test was 418.761, df = 45 ($p$ = .000). Time 10 Bartlett's test was 497.793, df = 45 ($p$ = .000). Together, the KMO and Bartlett's tests provide a minimum standard which should be passed before a factor analysis is conducted. These standards were met in these three analyses (see Table 12).

Table 12. KMO and Bartlett's Tests

| | | Time 1 | Time 5 | Time 10 |
|---|---|---|---|---|
| Kaiser-Meyer-Olkin measure of sampling adequacy | | .826 | .813 | .819 |
| Bartlett's test of sphericity | Approx. chi-square | 442.203 | 418.761 | 497.793 |
| | Df | 45 | 45 | 45 |
| | Significance | .000 | .000 | .000 |

**PAF Results Unrotated**

Extraction method of PAF analysis without rotation was run on all three time periods. Time 1 communalities for each item are high, over .5, indicating that a high proportion of each item's variance can be explained by the factors. The communalities for the vital sign item are slightly lower. See Table 13 for communalities for Time 1.

Table 13. Time 1 Communalities

| | Initial | Extraction |
|---|---|---|
| N-PASS sedation crying/irritability | .794 | .768 |
| N-PASS sedation behavior | .776 | .772 |
| N-PASS sedation facial expression | .861 | .816 |
| N-PASS sedation extremities/tone | .772 | .735 |
| N-PASS sedation vital signs | .609 | .518 |
| N-PASS pain crying/irritability | .941 | .911 |
| N-PASS pain behavior/state | .946 | .870 |
| N-PASS pain facial expression | .973 | .988 |
| N-PASS pain extremities/tone | .777 | .664 |
| N-PASS pain vital signs | .712 | .562 |

Two factors were extracted. By convention, the cutoff for accepting factors is an eigenvalue greater than one. The first factor explained 65.47% of the variance, and the second factor 14.99%. See Table 14 for total variance explained, unrotated. The scree plot depicts the variance explained, showing two factors with eigenvalues greater than one. See the Time 1 scree plot in Figure 5.

Table 14. Time 1 Total Variance Explained, Unrotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | |
|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 6.547 | 65.470 | 65.470 | 6.330 | 63.303 | 63.303 |
| 2 | 1.499 | 14.989 | 80.460 | 1.273 | 12.734 | 76.037 |
| 3 | .650 | 6.497 | 86.957 | -- | -- | -- |
| 4 | .404 | 4.037 | 90.994 | -- | -- | -- |
| 5 | .317 | 3.168 | 94.161 | -- | -- | -- |
| 6 | .245 | 2.454 | 96.616 | -- | -- | -- |
| 7 | .162 | 1.616 | 98.231 | -- | -- | -- |
| 8 | .112 | 1.119 | 99.350 | -- | -- | -- |
| 9 | .047 | .469 | 99.819 | -- | -- | -- |
| 10 | .018 | .181 | 100.000 | -- | -- | -- |

*Note.* Extraction sums of squared loadings are included only for factors with eigenvalues greater than 1.

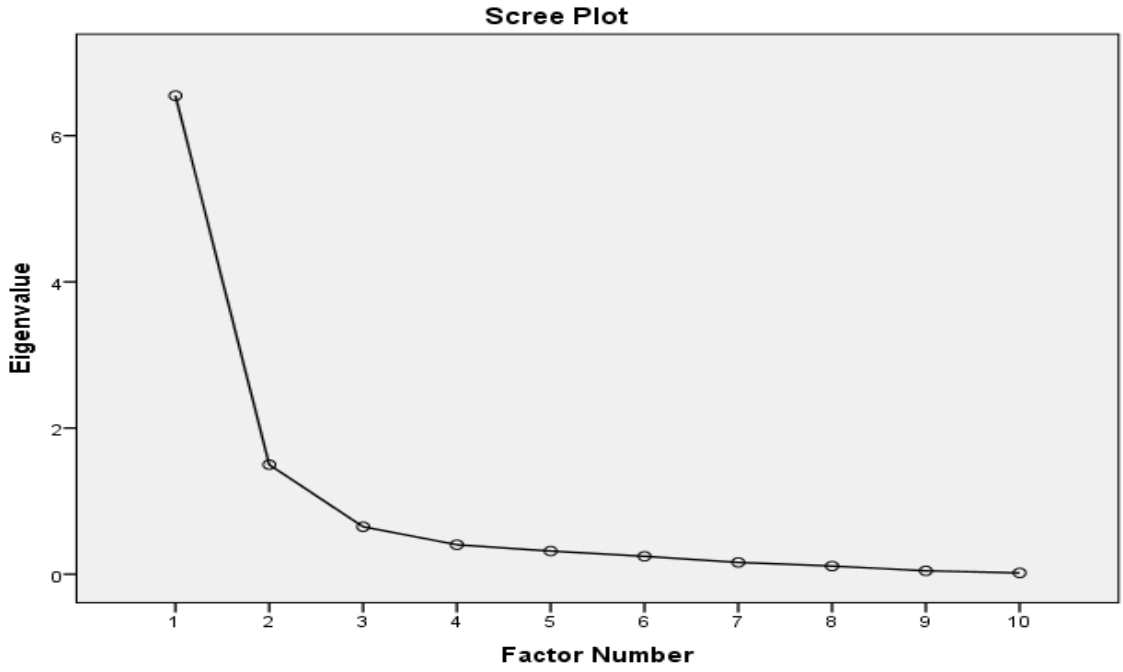


Figure 5. Time 1 scree plot.

Extraction method of PAF analysis without rotation was run on Time 5. The communalities for each item are also high, greater than .5. The vital sign item values are slightly lower. See Table 15 for communalities for Time 5.

Table 15. Time 5 Communalities

| | Initial | Extraction |
|---|---|---|
| N-PASS sedation crying/irritability | .907 | .856 |
| N-PASS sedation behavior | .954 | .954 |
| N-PASS sedation facial expression | .810 | .855 |
| N-PASS sedation extremities/tone | .855 | .756 |
| N-PASS sedation vital signs | .616 | .505 |
| N-PASS pain crying/irritability | .833 | .762 |
| N-PASS pain behavior/state | .868 | .894 |
| N-PASS pain facial expression | .853 | .815 |
| N-PASS pain extremities/tone | .798 | .746 |
| N-PASS pain vital signs | .711 | .619 |

Two factors were extracted. By convention, the cutoff for accepting factors is an eigenvalue greater than one. The first factor explained 61.33% of the variance, and the second factor 20.46%. See Table 16 for Time 5 total variance explained, unrotated. The scree plot depicts the variance explained, showing two factors with eigenvalues greater than one. See the Time 5 scree plot in Figure 6.

Table 16. Time 5 Total Variance Explained, Unrotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | |
|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 6.133 | 61.331 | 61.331 | 5.928 | 59.278 | 59.278 |
| 2 | 2.046 | 20.459 | 81.789 | 1.835 | 18.347 | 77.625 |
| 3 | .571 | 5.713 | 87.502 | -- | -- | -- |
| 4 | .451 | 4.505 | 92.007 | -- | -- | -- |
| 5 | .230 | 2.304 | 94.312 | -- | -- | -- |
| 6 | .182 | 1.815 | 96.127 | -- | -- | -- |
| 7 | .154 | 1.541 | 97.667 | -- | -- | -- |
| 8 | .121 | 1.211 | 98.879 | -- | -- | -- |
| 9 | .084 | .836 | 99.715 | -- | -- | -- |
| 10 | .029 | .285 | 100.000 | -- | -- | -- |

*Note.* Extraction sums of squared loadings are included only for factors with eigenvalues greater than 1.

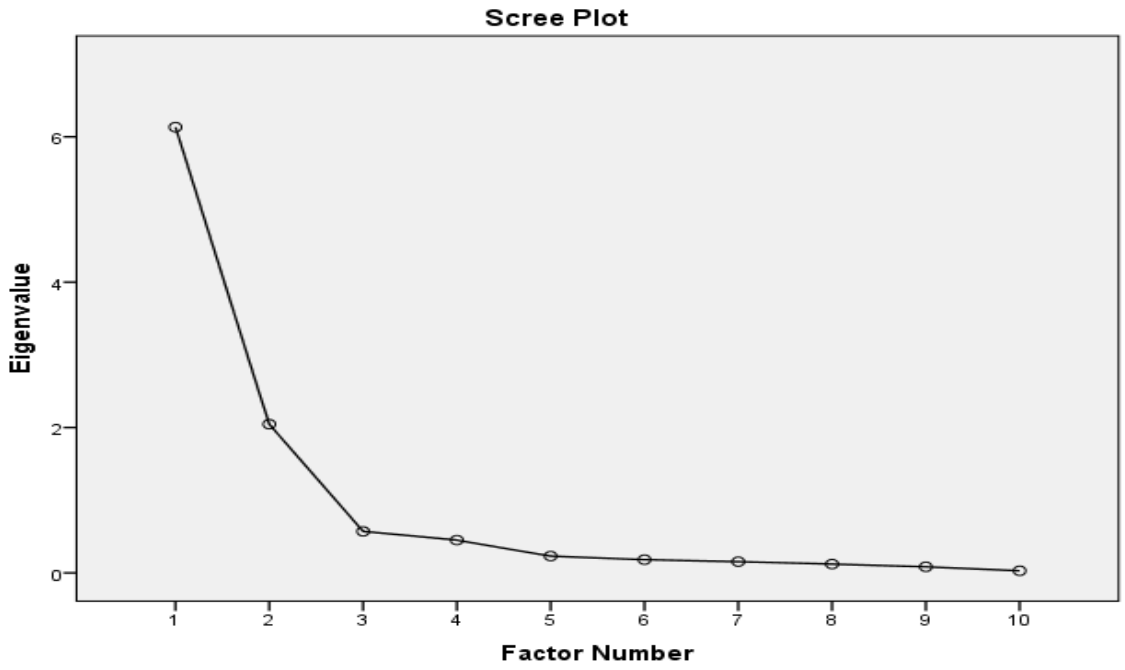


Figure 6. Time 5 scree plot.

Extraction method of PAF analysis without rotation was run on Time 10. The communalities for each item were also high, ranging from .734 to .919. The vital signs item was not as notably lower as in the first two time period analyses. See Table 17 for communalities for Time 10.

Table 17. Time 10 Communalities

| | Initial | Extraction |
|---|---|---|
| N-PASS sedation crying/irritability | .864 | .880 |
| N-PASS sedation behavior | .844 | .734 |
| N-PASS sedation facial expression | .897 | .893 |
| N-PASS sedation extremities/tone | .869 | .842 |
| N-PASS sedation vital signs | .815 | .753 |
| N-PASS pain crying/irritability | .938 | .919 |
| N-PASS pain behavior/state | .924 | .878 |
| N-PASS pain facial expression | .907 | .919 |
| N-PASS pain extremities/tone | .849 | .812 |
| N-PASS pain vital signs | .865 | .850 |

Two factors were extracted. By convention, the cutoff for accepting factors is an eigenvalue greater than one. The first factor explained 57.06% of the variance, and the second factor 30.71%. See Table 18 for total variance explained, unrotated. The scree plot depicts the variance explained, showing two factors with eigenvalues greater than one. See the Time 10 scree plot in Figure 7.

Table 18. Time 10 Total Variance Explained, Unrotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | |
|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 5.706 | 57.062 | 57.062 | 5.559 | 55.593 | 55.593 |
| 2 | 3.071 | 30.713 | 87.775 | 2.920 | 29.201 | 84.793 |
| 3 | .395 | 3.955 | 91.730 | -- | -- | -- |
| 4 | .237 | 2.375 | 94.105 | -- | -- | -- |
| 5 | .165 | 1.645 | 95.750 | -- | -- | -- |
| 6 | .143 | 1.428 | 97.178 | -- | -- | -- |
| 7 | .119 | 1.187 | 98.364 | -- | -- | -- |
| 8 | .079 | .787 | 99.152 | -- | -- | -- |
| 9 | .051 | .513 | 99.664 | -- | -- | -- |
| 10 | .034 | .336 | 100.000 | -- | -- | -- |

*Note.* Extraction sums of squared loadings are included only for factors with eigenvalues greater than 1.

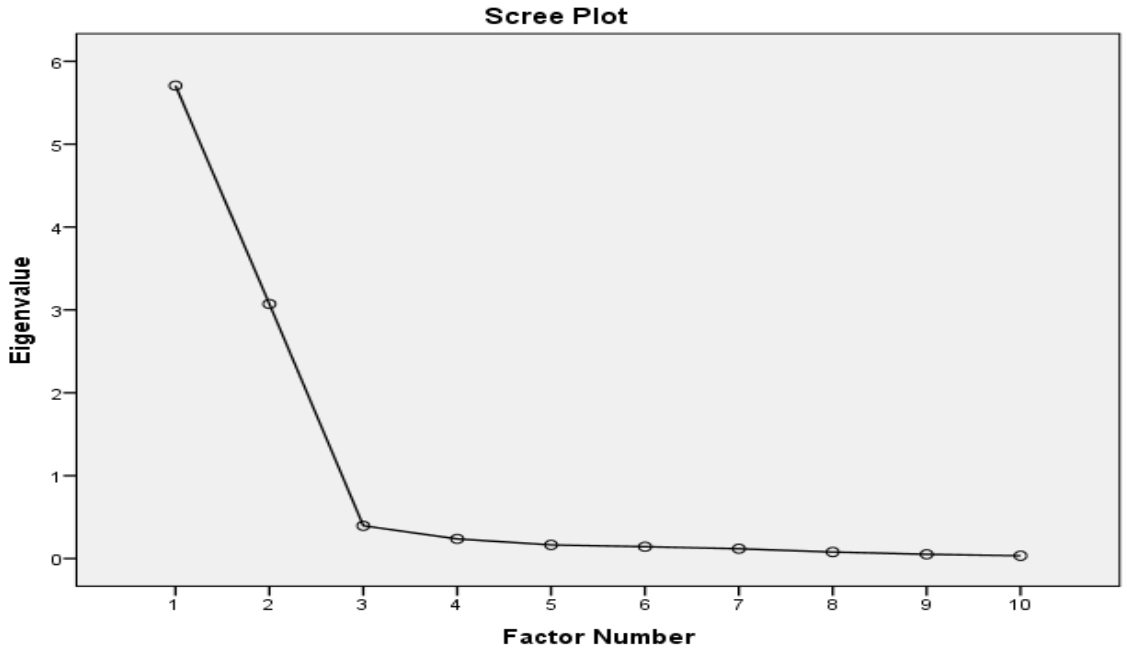


Figure 7. Time 10 scree plot.

**PAF Results Rotated**

Since two factors were found with extraction, with the remaining factors contributing very little to the variance, analysis was run with rotation. Varimax (orthogonal) rotation was used. Analysis was run at the same three observational time points: the first, fifth, and tenth observation after admission to the PACU. Factors with eigenvalues greater than one were considered significant variance.

PAF with Varimax rotation was completed for Time 1. One factor accounted for 40.09% of the variance. A second factor accounted for 35.94% of the variance. See Table 19 for the total variance explained, rotated.

Table 19. Time 1 Total Variance Explained, Rotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | | Rotation sums of squared loadings | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 6.547 | 65.470 | 65.470 | 6.330 | 63.303 | 63.303 | 4.009 | 40.094 | 40.094 |
| 2 | 1.499 | 14.989 | 80.460 | 1.273 | 12.734 | 76.037 | 3.594 | 35.943 | 76.037 |
| 3 | .650 | 6.497 | 86.957 | -- | -- | -- | -- | -- | -- |
| 4 | .404 | 4.037 | 90.994 | -- | -- | -- | -- | -- | -- |
| 5 | .317 | 3.168 | 94.161 | -- | -- | -- | -- | -- | -- |
| 6 | .245 | 2.454 | 96.616 | -- | -- | -- | -- | -- | -- |
| 7 | .162 | 1.616 | 98.231 | -- | -- | -- | -- | -- | -- |
| 8 | .112 | 1.119 | 99.350 | -- | -- | -- | -- | -- | -- |
| 9 | .047 | .469 | 99.819 | -- | -- | -- | -- | -- | -- |
| 10 | .018 | .181 | 100.000 | -- | -- | -- | -- | -- | -- |

*Note.* Extraction and rotation sums of squared loadings are included only for factors with eigenvalues greater than 1.
Extraction method: Principal Axis Factoring.

The rotated factor matrix shows the pain/agitation items loading on Factor 1 and the sedation items on Factor 2. Loadings less than .3 are not reported. Table 20 shows the rotated factor matrix.

Table 20. Time 1 Factor Matrix, Rotated [a]

| | Factor | |
|---|---|---|
| | 1 | 2 |
| N-PASS sedation crying/irritability | -.346 | .805 |
| N-PASS sedation behavior | -- | .836 |
| N-PASS sedation facial expression | -.432 | .793 |
| N-PASS sedation extremities/tone | -- | .826 |
| N-PASS sedation vital signs | -- | .667 |
| N-PASS pain crying/irritability | .903 | -.308 |
| N-PASS pain behavior/state | .861 | -.357 |
| N-PASS pain facial expression | .947 | -.304 |
| N-PASS pain extremities/tone | .764 | -- |
| N-PASS pain vital signs | .683 | -.310 |

*Note*. Factor loadings less than .3 are not displayed.
Extraction Method: Principal Axis Factoring.
Rotation Method: Varimax with Kaiser Normalization.
[a]Rotation converged in 3 iterations.

The rotated factor plot shows the two factors loading separately. See Figure 8 for the time 1 rotated factor plot.

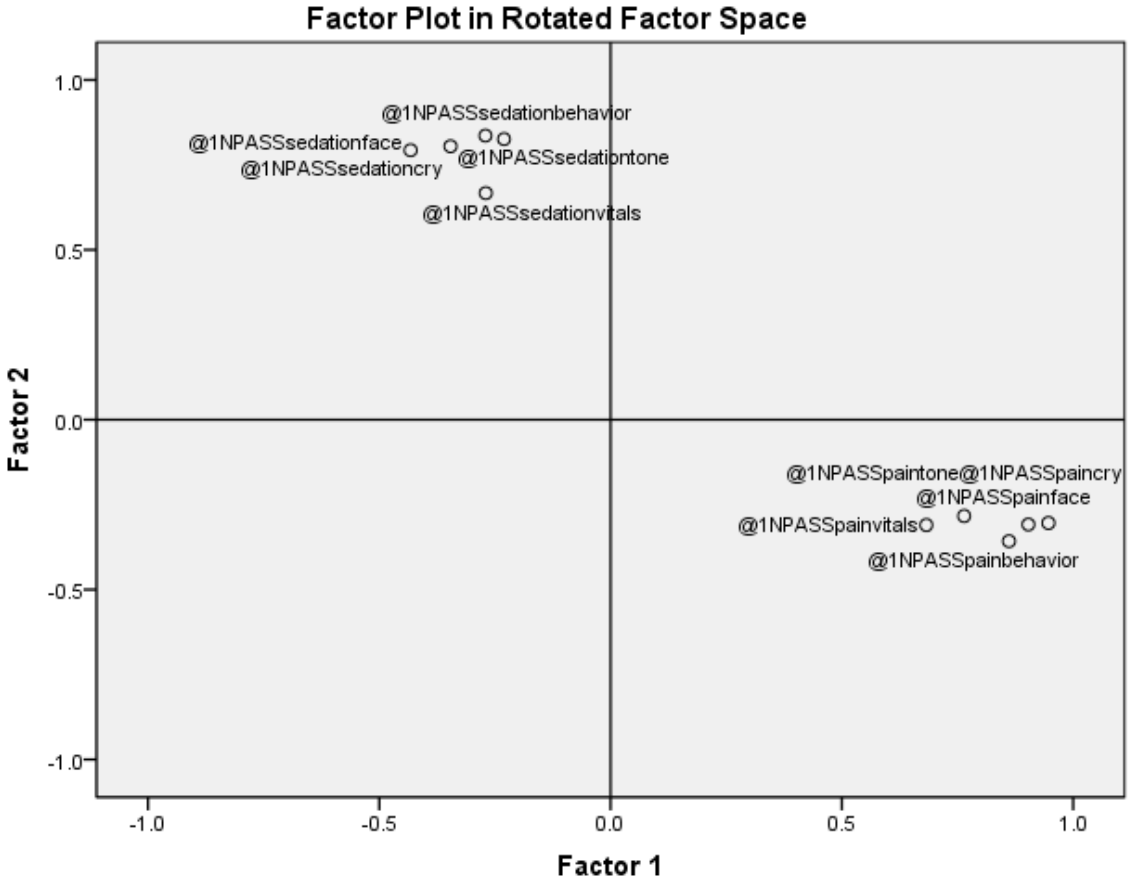


Figure 8. Time 1 rotated factor plot.

PAF with Varimax rotation was completed for Time 5. The first factor accounted for 39.09% of the variance. A second factor accounted for 38.56% of the variance. See Table 21 for the total variance explained, rotated.

Table 21. Time 5 Total Variance Explained, Rotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | | Rotation sums of squared loadings | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 6.133 | 61.331 | 61.331 | 5.928 | 59.278 | 59.278 | 3.909 | 39.090 | 39.090 |
| 2 | 2.046 | 20.459 | 81.789 | 1.835 | 18.347 | 77.625 | 3.854 | 38.535 | 77.625 |
| 3 | .571 | 5.713 | 87.502 | -- | -- | -- | -- | -- | -- |
| 4 | .451 | 4.505 | 92.007 | -- | -- | -- | -- | -- | -- |
| 5 | .230 | 2.304 | 94.312 | -- | -- | -- | -- | -- | -- |
| 6 | .182 | 1.815 | 96.127 | -- | -- | -- | -- | -- | -- |
| 7 | .154 | 1.541 | 97.667 | -- | -- | -- | -- | -- | -- |
| 8 | .121 | 1.211 | 98.879 | -- | -- | -- | -- | -- | -- |
| 9 | .084 | .836 | 99.715 | -- | -- | -- | -- | -- | -- |
| 10 | .029 | .285 | 100.000 | -- | -- | -- | -- | -- | -- |

*Note.* Extraction and rotation sums of squared loadings are included only for factors with eigenvalues greater than 1.
Extraction method: Principal Axis Factoring.

The factor matrix shows sedation items loading on Factor 1 and pain/agitation items loading on Factor 1. Loadings less than .3 are not reported. See Table 22 for Time 5 factor matrix, rotated.

Table 22. Time 5 Factor Matrix, Rotated [a]

| | Factor | |
|---|---|---|
| | 1 | 2 |
| N-PASS sedation crying/irritability | .878 | -- |
| N-PASS sedation behavior | .919 | -.331 |
| N-PASS sedation facial expression | .916 | -- |
| N-PASS sedation extremities/tone | .843 | -- |
| N-PASS sedation vital signs | .661 | -- |
| N-PASS pain crying/irritability | -- | .824 |
| N-PASS pain behavior/state | -- | .910 |
| N-PASS pain facial expression | -- | .861 |
| N-PASS pain extremities/tone | -- | .826 |
| N-PASS pain vital signs | -- | .776 |

*Note*. Factor loadings less than .3 are not displayed.
Extraction method: Principal Axis Factoring.
Rotation method: Varimax with Kaiser Normalization.
[a]Rotation converged in 3 iterations.

The rotated factor plot shows the sedation and pain/agitation items loading separately. See Figure 9 for Time 5 rotated factor plot.

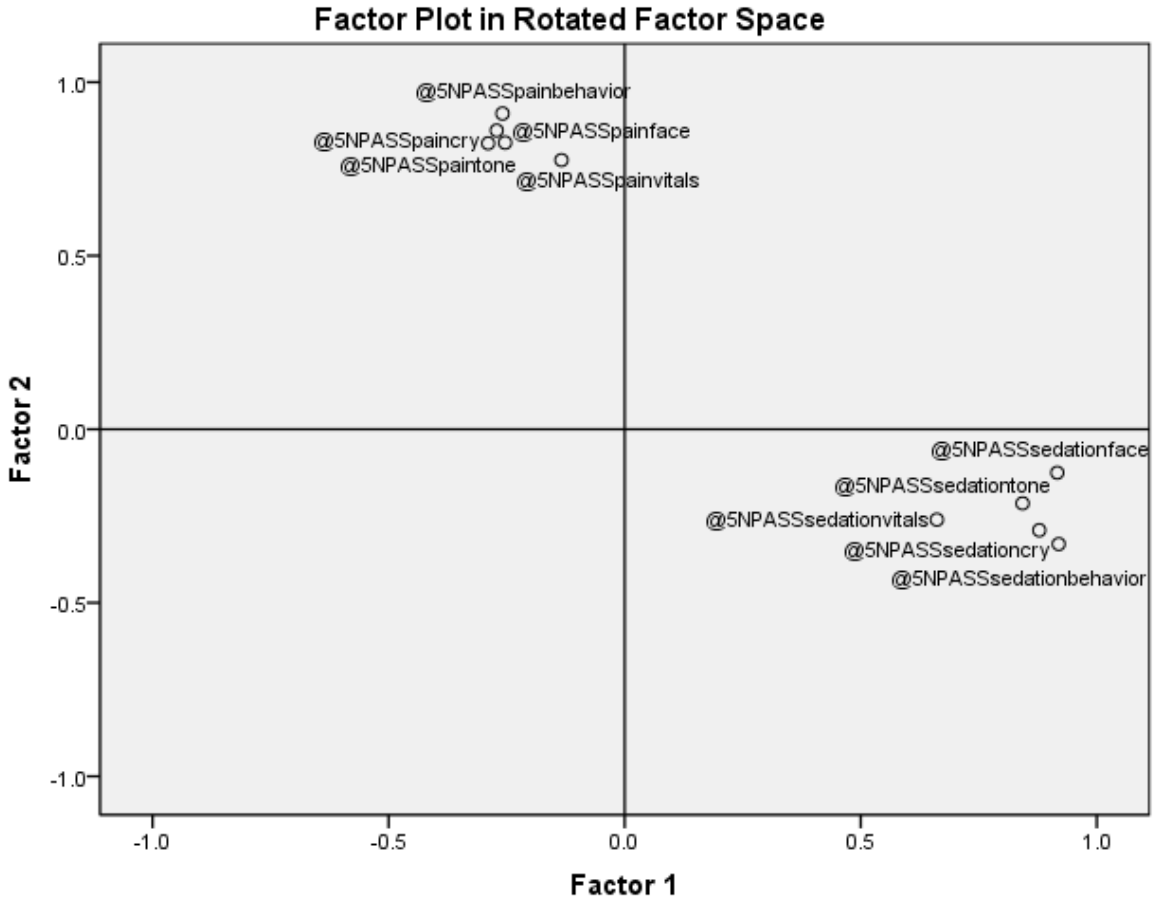


Figure 9. Time 5 rotated factor plot.

PAF with Varimax rotation was completed for Time 10. The first factor accounted for 43.9% of the variance. A second factor accounted for 40.9% of the variance. See Table 23 for the total variance explained, rotated.

Table 23. Time 10 Total Variance Explained, Rotated

| Factor | Initial Eigenvalues | | | Extraction sums of squared loadings | | | Rotation sums of squared loadings | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 5.706 | 57.062 | 57.062 | 5.559 | 55.593 | 55.593 | 4.390 | 43.897 | 43.897 |
| 2 | 3.071 | 30.713 | 87.775 | 2.920 | 29.201 | 84.793 | 4.090 | 40.896 | 84.793 |
| 3 | .395 | 3.955 | 91.730 | -- | -- | -- | -- | -- | -- |
| 4 | .237 | 2.375 | 94.105 | -- | -- | -- | -- | -- | -- |
| 5 | .165 | 1.645 | 95.750 | -- | -- | -- | -- | -- | -- |
| 6 | .143 | 1.428 | 97.178 | -- | -- | -- | -- | -- | -- |
| 7 | .119 | 1.187 | 98.364 | -- | -- | -- | -- | -- | -- |
| 8 | .079 | .787 | 99.152 | -- | -- | -- | -- | -- | -- |
| 9 | .051 | .513 | 99.664 | -- | -- | -- | -- | -- | -- |
| 10 | .034 | .336 | 100.000 | -- | -- | -- | -- | -- | -- |

*Note.* Extraction and rotation sums of squared loadings are included only for factors with eigenvalues greater than 1.
Extraction method: Principal Axis Factoring.

The rotated factor matrix for Time 10 shows the pain/agitation items loading on Factor 1 and the sedation items loading on Factor 2. Loadings less than .3 are not reported. See Table 24 for the Time 10 factor matrix, rotated.

Table 24. Time 10 Factor Matrix, Rotated [a]

| | Factor | |
|---|---|---|
| | 1 | 2 |
| N-PASS sedation crying/irritability | -- | .932 |
| N-PASS sedation behavior | -- | .834 |
| N-PASS sedation facial expression | -- | .941 |
| N-PASS sedation extremities/tone | -- | .884 |
| N-PASS sedation vital signs | -- | .863 |
| N-PASS pain crying/irritability | .940 | -- |
| N-PASS pain behavior/state | .919 | -- |
| N-PASS pain facial expression | .951 | -- |
| N-PASS pain extremities/tone | .896 | -- |
| N-PASS pain vital signs | .910 | -- |

*Note*. Factor loadings less than .3 are not displayed.
Extraction method: Principal Axis Factoring.
Rotation method: Varimax with Kaiser Normalization.
[a]Rotation converged in 3 iterations.

The rotated factor plot for Time 10 shows the sedation and pain/agitation items loading separately. See Figure 10 for the Time 10 rotated factor plot.

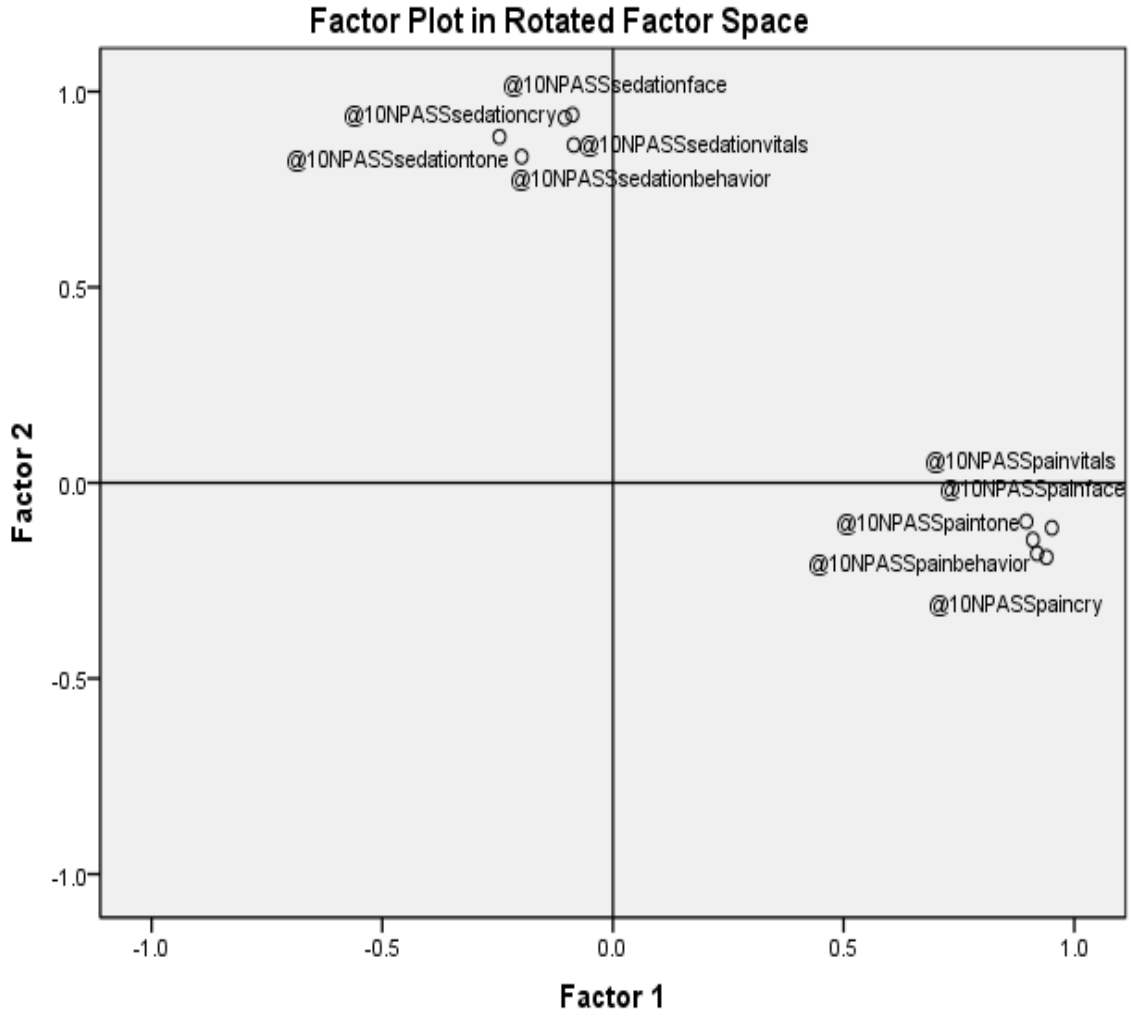


Figure 10. Time 10 rotated factor plot.

**Summary**

The psychometric evaluation shows adequate reliability determined by Cronbach's alpha analysis. Criterion validity is supported by the correlations between the N-PASS tool pain/agitation subscale and the FLACC tool and also between the N-PASS sedation subscale and the UMSS tool. Construct validity is supported by Repeated Measures ANOVA, as the scores exhibited variance; the sedation score fell in a linear

fashion, the pain/agitation score changed erratically over time. Regression analysis found a non-significant linear trend for the prediction of amount of time spent in the PACU as a function of change in the sedation levels. PAF analysis found two factors accounting for 80.77 to 87.77% of the variance. One factor was pain/agitation, and one was sedation. The factor structure remained stable over time.

# CHAPTER FIVE

# DISCUSSION

This research was conducted as a psychometric evaluation of the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) (Hummel et al., 2008) in an older population than previously studied, in a different setting, and with different methodology. Previous research had focused on preterm and term neonates up to 100 days of age, in an ongoing painful situation, or in an acute painful situation. This study was designed to obtain information regarding reliability and validity when using the N-PASS tool up to three years of age.

Studying the N-PASS sedation tool in the PACU allowed for improved evaluation of the tool, with repeated observations of subjects emerging from general anesthesia through the continuum of sedation. The N-PASS sedation tool had previously been evaluated in just one study of sedation in the NICU, with observations before and after sedative administration.

The PACU setting also allowed for evaluation of the N-PASS pain scale in a time-limited setting with repeated observations. Previous research of the N-PASS pain scale did not include repeated observations.

## Reliability

Cronbach's alpha for the N-PASS sedation and the N-PASS pain scales at each time period were found to be greater than .80. This answers the first research question,

"Does the N-PASS tool exhibit internal consistency as measured by Cronbach's alpha?" An alpha of over .80 is desirable for a clinical assessment tool. Thus, summing up the items from each scale to form a composite score is acceptable.

Repeated Measures ANOVA found that the sedation scores fell linearly over time. Cronbach's alpha values for the N-PASS sedation scale also fell slightly over the ten observation periods. The fall in the alphas could be due to the fact that as the sedation score fell over time, fewer items were scored leading to decreased variance and lower correlations as more items were scored zero.

If the vital sign indicator on the sedation scale was eliminated, the alpha rose to > .90. Elimination of the other sedation items did not raise the alpha to this degree. This was not found in previous research of the N-PASS tool. Perhaps the vital signs indicator is less valuable in the postoperative setting, as these physiologic parameters might be affected by the administration of anesthesia, slightly decreasing internal consistency of the tool. Modification of the tool for this situation is not indicated, as the alphas including the vital sign indicator were all over .80.

**Correlations**

Correlations between the N-PASS pain scale and the FLACC and between the N-PASS sedation scale and the UMSS were positive, of a large magnitude and great significance. This answers the second and third research questions, "Does the N-PASS tool exhibit criterion validity when the sedation subscale is compared to the UMSS instrument?" and "Does the N-PASS tool exhibit criterion validity when the pain/agitation subscale is compared to the FLACC instrument?"

Correlation coefficients between the corresponding N-PASS sedation ratings and UMSS ratings at each time point were positive and all were significant ranging from .847 to .967. Based on these results, it appears that the two scales are measuring a similar concept, sedation.

All correlations between the N-PASS pain/agitation ratings and FLACC ratings at each time point ranging from .977 to .996 were positive and significant. The strong positive, significant relationships between the N-PASS pain/agitation and FLACC suggest that the two scales are measuring the same phenomenon, pain.

Correlations between the heart rate and the N-PASS sedation scale were negative, indicating that the heart rate rose as sedation scores fell, consistent with research indicating that the heart rate is decreased with sedation. Correlations between the heart rate and the N-PASS pain scale were positive and significant, indicating that the heart rate rose as pain scores rose, consistent with research indicating that an elevated heart rate is an indicator of pain.

**Repeated Measure Analysis of Variance (ANOVA)**

The N-PASS ratings of sedation and pain changed significantly over time, answering the fourth research question, "Does the N-PASS tool sedation and pain/agitation subscales exhibit construct validity in the PACU setting by showing significant difference in scores over time?" Repeated Measures ANOVA was performed to obtain an analysis of change over time for both pain/agitation and sedation N-PASS scores. These changes can be evaluated in terms of linear change, quadratic, or cubic functions.

The N-PASS ratings of sedation decreased in a linear fashion over time, as expected. Subjects move through the sedation continuum, from general anesthesia

through deep sedation, moderate sedation, and light sedation before full recovery from pharmacologic anesthesia. N-PASS pain ratings increased and decreased in a non-linear fashion. The unpredictable variations in pain scores are probably due to many factors, including the varying effects of anesthesia and duration of action. Only three participants received analgesics in the PACU setting. Parental or nursing comfort interventions may also account for the non-linear pain ratings. Behavioral pain assessment scores are influenced by non-pain factors such as anxiety and fear, and situational factors such as hunger, nausea, and parental deprivation or presence.

These findings support the modified Onion Theory of Pain and Sedation for the nonverbal infant or child. The tissue damage from surgery is the stimulus, which is transmitted to the cortex. This causes suffering or distress, leading to pain and distress behaviors, scored by the N-PASS pain/agitation subscale. These behaviors are modified by interaction with the environment, nursing, and parental response and interventions. The anesthetic affected the cerebral cortex, slowing the brain and responses, as scored by the N-PASS sedation subscale.

## Regression

Since a significant change over time was found, post hoc tests were used to determine the rates or slopes of change, answering the fifth research question "Does the N-PASS tool provide a predicted pathway of behaviors over time of recovery in the PACU setting?" Post-hoc regression analysis was performed. A meaningful, yet statistically non-significant linear trend was found for the prediction of amount of time spent in PACU as a function of change in sedation levels from time 1 to time 10. The findings indicate that every standardized unit of decrease in sedation is associated with a

.284 standardized units decrease in time to discharge. In other words, a greater decrease in sedation over time predicts shorter length of stays in the unit. This finding may have been attenuated due to decreased sample size, but the observed findings suggest a meaningful trend in the association between sedation and time to discharge, which may hold promise in the utility in the N-PASS sedation scale.

**Principal Axis Factoring (PAF)**

PAF was performed to answer the sixth research question "What is the factor structure of the N-PASS tool?" The goal of PAF is to describe variability among correlated items to identify unobserved variables or factors.

Factor analysis is a technique that requires a large sample size. Suggested minimums for sample size include from three to twenty times the number of variables. Ideally, there are five to ten participants per item (Nunnally & Bernstein, 1994b). Sample size is sometimes recommended as an absolute size from 100 to over 1000. There is little empirical evidence to support these recommendations.

Research on this topic found that minimum sample sizes are smaller when the variables to factors ratio exceeds six (Mundfrom, Shaw, & Ke, 2005). Sapnas and Zeller (2002) evaluated research examples and concluded that a sample size of 50 to 100 subjects is adequate for evaluating the psychometric properties of social construct measures through factor analysis.

The sample size in this study is low for PAF analysis with forty participants; however, these analyses give some preliminary results for what to expect with a larger sample size. Two factors were found, giving a variable to factor ratio of ten to two; ten variables to two factors. There were forty cases for observation time points 1 through 10.

After Time 10, many patients were discharged from the PACU, ending observations, leading to the drop in sample size. Thus, data were primarily examined at three observation times: Time 1, Time 5, and Time 10.

It was assumed that there were two factors that represent the underlying spectrum of pain and sedation, one pain, and the other sedation. Negative loadings for sedation and positive loadings for pain, or positive loadings for pain and negative loadings for sedation were expected. PAF was conducted at three different time points to determine if the same factor structure is found repeatedly over time. Varimax rotation clearly demonstrated the two factors, one pain, and the other sedation.

Most of the assessment tools described in Chapter Two assess either pain or sedation. The COMFORT tool appears to have some items assessing pain and some assessing sedation. No evidence of factor analysis statistics is found in the literature. The N-PASS score was created to assess both pain and sedation; these two factors are supported by this research.

Two factors were found at each time period, pain, and sedation. Slight variations were found in the variance of the factors over time, but the factors remained quite constant. At Time 1, admission to the PACU, the pain factor accounted for 40% of the variance, while sedation accounted for 35.9% of the variance. At Time 5, twenty-five minutes after admission, sedation accounted for slightly more variance than pain; 39% and 38% respectively. At Time 10, fifty minutes after admission, pain accounted slightly more variance; 43.9% and 40.9% respectively. Overall, the factor structure is similar, with the pain and sedation subscales accounting for nearly equal variance.

## Limitations

Data were collected at one institution, in one setting. This can limit generalizability to other settings. Data were collected by one researcher, increasing the chance for bias. The study could be replicated with two observers to test inter-rater reliability. The tool should be tested with ongoing or chronic pain such as cancer pain, or in ventilated children with an endotracheal tube.

The sample size is low, particularly for PAF analysis. This increases the chance for error in analysis. This study should be replicated in different settings such as Pediatric Intensive Care or general pediatrics with a larger sample size.

## Implications for Nursing Practice

The N-PASS tool is widely used in Neonatal Intensive Care Units around the world. As the creator of the N-PASS tool, this author has given written consent for use of the N-PASS in over 350 settings and in many countries such as Canada, Mexico, Australia, South Africa, Great Britain, France, Taiwan, and China. Reliability and validity of the N-PASS tool has been researched up to 100 days of age. Some infants are hospitalized in the NICU for more than 100 days, leading to clinical use of the N-PASS beyond the age range of available psychometrics, or to nursing staff using another tool, such as the FLACC, for pain assessment in older infants in the NICU. The FLACC tool has been researched in subjects one month of age and older; this necessitates that nurses in the pediatric settings that use the FLACC tool employ an alternate tool such as the N-PASS, NIPS, or CRIES before one month of age.

Findings from this research provide preliminary support for the use of the N-PASS in a wider age range, from preterm birth to three years of age. This is helpful to

nurses practicing in the NICU, the PICU, and the PACU, where sedation and pain assessment are important nursing functions. Differences across age groups were not addressed as this would require a much larger sample size.

Sedating an infant or child is a potentially dangerous but necessary intervention. The potential for over-sedation or under-sedation are safety concerns in any setting. This research provides preliminary support for the use of the N-PASS tool to assess sedation levels in a wider population, potentially decreasing suffering by avoiding under-sedation, and increasing safety by avoiding or recognizing over-sedation.

## Implications for Nursing Research

Infants and young children continue to experience many painful situations and procedures in the inpatient and outpatient settings (American Academy of Pediatrics, 2006). Nurse researchers study nursing interventions to maximize comfort in these situations. Multi-modal pain assessment, including behavioral pain assessment, is often the primary outcome of research designed to study the effects of nursing interventions in painful situations. Findings from this study support the utilization of the N-PASS tool in clinical research studies.

Infants and young children also continue to receive medications to achieve a sedated state. Nurse researchers are concerned with the care of infants and children who are sedated. The N-PASS tool was recently used as the primary outcome in research designed to investigate the safety, efficacy, and pharmacokinetic profile of Dexmedetomidine in preterm and full-term neonates ≥28 to ≤44 weeks gestational age (Chrysostomou et al., 2014). This research supports the use of the N-PASS tool in researching interventions and medications in infants and children up to three years of age.

The N-PASS tool, studied in preterm and term infants, includes both pain and sedation assessment. This tool has been modified to assess the adult population, and is being tested in the adult intensive care unit, replicating the methodology of the initial neonatal N-PASS research.

## Implications for Nursing Theory

The Onion Theory of pain (Loeser, 1982) explains that the pain experience involves the physiology of the pain stimulus which is transmitted to the brain, where it is interpreted as a noxious individual experience. Suffering results; this is expressed in behaviors and may be modified by the environment. This theory was modified by expanding the process to better understand the experience of pain in nonverbal infants and children, and to include the process of sedation assessment.

The Modified Onion Theory of Pain and Sedation in infants and children explains that the core of these experiences is the physiology of the pain stimulus, or the sedative medication. The physiology is modified by genetics, biochemistry, nature of the pain stimulus, and the type and dose of the sedative medication. This is followed by changes in the cortical pain perception or by slowing the brain by sedative medications. Cortical perception is modified by endorphins, pain modulation tracts, spinal cord transmission, neurotransmitters, anatomic maturity, structure and function, and medications. Pain perception results in suffering, which is modulated by personal interpretation of the pain or stress. Pain cannot be reported in nonverbal populations, it can only be inferred from pain behaviors that are an outcome of the suffering. The degree of suffering is modified by gestational age, energy levels, previous pain or sedation experience, neurological ability, neurotransmitters, medications, and non-pharmacologic interventions.

Changes in sedation behaviors result from the brain slowing as a result of sedation medications. Pain and sedation behaviors are modified by interaction with the environment, such as in the recognition of the suffering by caregivers or healthcare professionals and their response through attempting to provide comfort to the infant.

Findings from this study show that the N-PASS instrument operationalizes the pain and sedation assessment process, as conceptualized in the modified Onion Theory of Pain and Sedation for nonverbal infants and children in this population up to thirty-six months of age recovering from surgical procedures. The infants and toddlers in this research had a surgical pain stimulus and also were sedated as a consequence of medications given to achieve general anesthesia during their surgical procedure. The painful stimuli and medications led to cortical perception and changes in brain function. According to the Onion Theory the suffering from the surgical pain was exhibited as pain behaviors. Sedation behaviors were exhibited as a result of the medications slowing cortical function. The environment included the caregivers in the PACU setting, nurses, and parents caring for the infants and children. The environment influenced the N-PASS scores, as caregivers recognized the behaviors and intervened to comfort the children. Only three subjects received analgesic medications during their stay. Comforting interventions included actions such as talking to the child, giving verbal reassurance, stroking, holding, and giving a pacifier or liquid by bottle or cup. The sedation behaviors decreased over time as the medication effect waned.

Unique findings include the evidence that comprehensive measurement of behavior and physiological attributes of pain and sedation should be included in practice and research. The modified Onion Theory is applicable to nursing practice and research.

This research provides additional evidence for use of the N-PASS tool in clinical practice and research, thus advancing nursing practice, including nonverbal pain assessment, sedation assessment, and nursing practice in the assessment and management of pain and sedation in young children. As nursing research continues to evaluate nursing care of infants and children who are in pain and/or sedated, middle-range theories can be formulated and evaluated. Practice theory could be formulated and evaluated by interviewing nurses to determine how decisions are made regarding pain and sedation assessment and management by nurses.

This research could be used in theory building regarding nursing care and the nurses' experiences, including the process of caring for patients through this continuum from deep sedation, as they become less sedated, weaned from medications, or as effects wane, and also when in painful situations. In addition, a need exists for development of a substantive theory of how nurses experience caring for infants and toddlers who experience chronic pain, such as when they are intubated over an extended time. Theory that conceptually describes the nursing process for caring for extremely preterm infants through thirty-six months of age who are sedated and/or in pain has not been generated.

## Implications for Nursing Administration

Nursing administration is concerned with the safety of patients, with patient satisfaction, and with meeting regulatory requirements and standards of care regarding pain and sedation management in children. The Joint Commission pain management standards, implemented in 2001, stated that every patient has a right to have their pain assessed and treated (JCAHO, 2000). The standards mandate that tools with evidence of reliability and validity be used for pain assessment, and require that the appropriate tool

be used for the patients' age and situation. In addition, sedation assessment and measurement is mandated in safety guidelines for discharge following procedural sedation in children (American Academy of Pediatrics, 2006).

Tools with evidence of validity and reliability that standardize assessment of the child's sedation level enhance systematic assessment and documentation, allow individual alterations in the therapeutic regimen, decrease suffering, and increase safety by avoiding insufficient or excessive sedative use (Marx et al., 1994). This research enables utilization of the N-PASS tool in a broader range of patients, which may lead to improved pain and sedation management. Regulatory requirements for pain and sedation assessment practices are met when assessment tools with sufficient psychometric evidence are used in the correct setting and with appropriate age groups.

Parents are vigilant in protecting their children from harm and undue suffering. Patient satisfaction may be enhanced as parents and families observe nursing efforts to assess and manage their child's pain and sedation safely and effectively.

Patient satisfaction surveys provide information to administrators and caregivers about the perceptions of patients in the setting, including nursing care. This information is valuable internally, as caregivers strive to provide excellent care for their patients. In addition, these surveys are available for public viewing, affecting public perception of the institution, which in turn has either positive or negative financial effects as patients choose hospitals based on these results. The surveys are also used by payers to determine preferred providers for reimbursement.

## Implications for Nursing Education

Nurse educators are responsible for preparing students to continue and advance the profession of nursing. Pain and sedation assessment are essential nursing functions. Alleviation of suffering is included in the nursing Code of Ethics (American Nurses Association, 2001). Pain assessment and management have been studied in children, adolescents, and adults but there has been scarce reference to infant sedation or pain assessment or management. Students need education regarding the nursing responsibility for the practice of nonverbal pain and sedation assessment adults as well as in infants and young children. Students are educated according to evidence-based practice guidelines. This research increases the evidence for pain and sedation assessment in infants and young children, and could be included in pediatric and maternal-child nursing textbooks.

## Future Research

Infant pain research began over sixty years ago with a study on infant's reaction to a pinprick. Research then ceased for about twenty years due to the prevailing paradigm that infants do not feel pain. Research began again in the 1970s as the inequities in pain management for children were noted (Eland & Anderson, 1977). Researchers confirmed that infants and children are able to feel pain. Pain research and interventions to treat pain became more prevalent.

This research extends the science of assessment of pain and sedation in children, a foundation for clinical management. Future research should include additional psychometric evaluation of the N-PASS in various settings and age groups. As multi-modal pain assessment research advances, the validity of the N-PASS tool could be researched using biochemical, electrographic, or brain imaging methods. The N-PASS

sedation scale could be researched with BIS monitoring to add to validity testing. The N-PASS could be modified and tested in the adult population. The N-PASS can be used more extensively in the research of clinical pain and sedation.

## Conclusion

Alleviation of suffering is recognized in the ANA Code of Ethics as part of the moral responsibility of nurses. Evidence-based position statements and practice guidelines address the recognition and treatment of pain and suffering, as well as the administration of analgesics and sedative agents, all essential to safety and to high quality nursing practice.

Infants and young children are a vulnerable population in any health care setting. Diseases and treatments, surgeries, and the health-care environment pose a high potential of pain and suffering if not treated appropriately. Analgesics and sedatives are given to decrease pain and suffering, with known and unknown benefits and risk. This requires close monitoring and accurate assessments to ensure safe and effective nursing care.

Many pain assessment tools have been created for use in infants and children. However, only the N-PASS instrument includes both pain and sedation assessment, including both behavioral and physiologic criteria. This research, in addition to previous studies, gives adequate psychometric evidence for use of the N-PASS tool in infants and children, born as early as twenty-three weeks of gestation, up to thirty-six months of age. Findings from this study provide evidence for evidence-based methodology to assess and relieve pain and suffering from the point of infant viability to three years of age when verbal means of pain assessment become possible.

# APPENDIX A:

# DATA ANALYSIS TOOLS:

# N-PASS, UMSS, FLACC

| Assessment Criteria | Sedation | | Sedation/Pain | Pain / Agitation | |
|---|---|---|---|---|---|
| | -2 | -1 | 0/0 | 1 | 2 |
| Crying Irritability | No cry with painful stimuli | Moans or cries minimally with painful stimuli | No sedation/<br>No pain signs | Irritable or crying at intervals<br>Consolable | High-pitched or silent-continuous cry<br>Inconsolable |
| Behavior State | No arousal to any stimuli<br>No spontaneous movement | Arouses minimally to stimuli<br>Little spontaneous movement | No sedation/<br>No pain signs | Restless, squirming<br>Awakens frequently | Arching, kicking<br>Constantly awake or<br>Arouses minimally / no movement (not sedated) |
| Facial Expression | Mouth is lax<br>No expression | Minimal expression with stimuli | No sedation/<br>No pain signs | Any pain expression intermittent | Any pain expression continual |
| Extremities Tone | No grasp reflex<br>Flaccid tone | Weak grasp reflex<br>↓ muscle tone | No sedation/<br>No pain signs | Intermittent clenched toes, fists or finger splay<br>Body is not tense | Continual clenched toes, fists, or finger splay<br>Body is tense |
| Vital Signs HR, RR, BP, $SaO_2$ | No variability with stimuli<br>Hypoventilation or apnea | < 10% variability from baseline with stimuli | No sedation/<br>No pain signs | ↑ 10-20% from baseline<br>$SaO_2$ 76-85% with stimulation – quick ↑ | ↑ > 20% from baseline<br>$SaO_2 \leq 75\%$ with stimulation – slow ↑<br>Out of sync/fighting vent |

N-PASS: Neonatal Pain, Agitation, and Sedation Scale

| UMSS Tool: The University of Michigan Sedation Scale | |
|---|---|
| 0 | **Awake/Alert** |
| 1 | **Minimally Sedated: Tired/sleepy, appropriate response to verbal conversation and/or sounds** |
| 2 | **Moderately Sedated: Somnolent/sleeping, easily aroused with light tactile stimulation** |
| 3 | **Deeply Sedated: Deep sleep, arousable only with significant physical stimulation** |
| 4 | **Unarousable** |

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

# APPENDIX B:

# DATA COLLECTION FORMS

**Demographic Variables Case #_____**

Date: __/__/__

Sex: ☐ Male ☐ Female Age: _____ Months

Primary Diagnosis: _____

Surgery type _____

**Time entering OR: _____**

**Time entering PACU:_____**

**Time leaving PACU:_____**

**Other pertinent information:**

**Data collection**

Case number:_____

| Time | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sedation cry/irritability | | | | | | | | | |
| Sedation Behavior/state | | | | | | | | | |
| Sedation Face | | | | | | | | | |
| Sedation ext/tone | | | | | | | | | |
| Sedation vitals | | | | | | | | | |
| | | | | | | | | | |
| Pain cry/irritability | | | | | | | | | |
| Pain Behavior/state | | | | | | | | | |
| Pain face | | | | | | | | | |
| Pain ext/tone | | | | | | | | | |
| Pain vitals | | | | | | | | | |
| | | | | | | | | | |
| FLACC face | | | | | | | | | |
| FLACC legs | | | | | | | | | |
| FLACC Activity | | | | | | | | | |
| FLACC Cry | | | | | | | | | |
| FLACC Consolability | | | | | | | | | |
| | | | | | | | | | |
| UMSS score | | | | | | | | | |
| | | | | | | | | | |
| Heart rate | | | | | | | | | |
| | | | | | | | | | |
| Event | | | | | | | | | |

A = analgesia administration specify _____

S = sedative administration specify _____

P = parent intervention

N= nurse intervention

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# VITA

Patricia Hummel received her Associate Degree in Nursing from Iowa Central Community College in 1975, Bachelor of Science Degree in Nursing from the University of Kansas in 1982, and Master of Arts in Nursing from the University of Iowa in 1989. She has practiced as a bedside nurse, transport nurse, charge nurse, Clinical Nurse Specialist, and Advanced Practice Registered Nurse throughout the Midwest. Ms. Hummel developed the Neonatal Pain, Agitation, and Sedation Scale (N-PASS) in 2000, in response to a clinical need for a tool to measure ongoing pain and sedation in the Neonatal Intensive Care Unit.

She completed two research studies to evaluate the N-PASS tool; one with ongoing pain and sedation, and another with acute pain. She has been an invited speaker nationally and internationally, educating nurses and physicians about the N-PASS tool and pain in neonates. The N-PASS tool is used in over 350 institutions around the world, and has been translated into several languages.