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A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

Katherine Newnam
Virginia Commonwealth University

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

By

Katherine Marie Newnam
BSN, Old Dominion University, Norfolk, VA 1983
MS, Old Dominion University, Norfolk, VA 1990
Post Masters-Pediatric Nurse Practitioner, Old Dominion University, Norfolk, VA 1999
Post Masters-Neonatal Nurse Practitioner, East Carolina University, Greenville, NC 2004

Co-Directors: Jeanne Salyer, PhD, RN, Associate Professor, Adult Health and Nursing Systems, Virginia Commonwealth University School of Nursing
Jacqueline M. McGrath, PhD, RN, Professor, School of Nursing, University of Connecticut
Director, Nursing Research, Connecticut Children's Medical Center, Hartford, CT

Virginia Commonwealth University Richmond, Virginia
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Abstract

A COMPARATIVE EFFECTIVENESS STUDY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) RELATED SKIN BREAKDOWN WHEN USING DIFFERENT NASAL INTERFACES IN THE EXTREMELY LOW BIRTH WEIGHT (ELBW) NEONATE

By Katherine M. Newnam, MS, RN, NNP-BC, CPNP

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

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Major Directors: Jeanne Salyer, PhD, RN, FNAP, Associate Professor, Adult Health and Nursing Systems, Virginia Commonwealth University School of Nursing
Jacqueline M. McGrath, PhD, RN, FNAP, FAAN, Professor, School of Nursing, University of Connecticut, Director, Nursing Research, Connecticut Children's Medical Center

Nasal continuous positive airway pressure (CPAP) is reportedly superior to mechanical ventilation in the neonatal population by reducing bronchopulmonary dysplasia (BPD). The neonate is vulnerable to injury secondary to immature physiological systems and skin structures and the current CPAP devices place constant pressure on nares, nasal septum and forehead, increasing injury risk. Through the framework of comparative effectiveness research an examination of nasal interfaces currently used during neonatal CPAP was conducted in an effort to provide scientifically supported recommendations and improve clinical outcomes.

The primary aim of this study was to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask/rotation) used in the treatment of neonatal respiratory distress syndrome (RDS). A secondary aim of the study was to identify risk factors that may be associated with skin breakdown during nasal CPAP administration. A three group prospective randomized

experimental design was used to study78 neonates <1500 grams receiving nasal CPAP using the same delivery system. The subjects were randomized into three groups: 1) continuous nasal prong group, 2) continuous nasal mask group, or 3) alternating mask/prongs group. Serial data collection included: demographic, biophysical measures and the Neonatal Skin Condition Scale (NSCS).

This study demonstrated a significant difference in the frequency and severity of skin injury when utilizing a method of rotating mask and prong nasal interfaces during neonatal CPAP therapy; a useful clinical recommendation. Specific nursing care implications related to study findings include; choosing a device for best fit for infant (face shape and infant size); positioning of the CPAP device; developmental position of the infant; and focused skin assessment with rapid intervention. Standardized care including skin barriers, clinical expertise of nursing and respiratory therapy, and skin care management are strategies that warrant additional research.

Chapter 1

An Integrative Review of Skin Breakdown in the Preterm Infant Associated with Nasal Continuous Positive Airway Pressure

The following manuscript was prepared in partial fulfillment of the requirements for a manuscript-format dissertation.

Katherine Marie Newnam, MS, RN, CPNP, NNP-BC
Virginia Commonwealth University, Richmond, Virginia 23298
Newmankm2@vcu.edu

Jacqueline M. McGrath, PhD, RN, FNAP, FAAN
Professor, School of Nursing, University of Connecticut
Director, Nursing Research, Connecticut Children's Medical Center, Hartford, CT
Jacqueline.mcgrath@uconn.edu

Tracy Estes, PhD, DNP, RN, FNP-BC
South University Program Director, Graduate Nursing
College of Nursing and Public Health
Glen Allen, Virginia 23060
tsestes@southuniversity.edu

Nancy Jallo, PhD, FNP-BC, WHNP-BC, CNS
Assistant Professor, Adult Health and Nursing Systems, Virginia Commonwealth University
School of Nursing, Richmond, Virginia 23298
njallo@vcu.edu

Jeanne Salyer, PhD, RN, FNAP
Associate Professor, Adult Health and Nursing Systems, Virginia Commonwealth University
School of Nursing, Richmond, Virginia 23298
jsalyer@vcu.edu

W. Thomas Bass, MD
Professor of Pediatrics, Eastern Virginia Medical School
Attending Neonatologist, Children's Hospital of the Kings Daughters
Norfolk, Virginia 23507
Thomas.bass@chkd.org

Abstract

Objective: Identify factors associated with skin injury during nasal continuous positive airway pressure (NCPAP) and describe differences in frequency, severity, and type of skin injuries when comparing nasal interfaces used during NCPAP in the preterm infant.

Data Sources: Scientific databases were searched using provided key terms which yielded 113 articles.

Study Selection: Fourty-six articles were included in this integrative review: 6 case studies; 22 with identified aim examining skin and nasal injury during NCPAP; 18 included skin care considerations during NCPAP.

Data Extraction: Studies were categorized into four themes; 1) types of nasal injuries 2) associated risk factors that increase incidence of injury; 3) differences between NCPAP devices and/or nasal interface and corresponding rate and severity of nasal injury; 4) recommended prevention strategies to reduce iatrogenic cutaneous injury.

Data Synthesis: Skin injury was a common theme during neonatal NCPAP with skin breakdown rates 20-60%. Increased skin injury risk was associated with smaller infant size, gestational age, and duration of therapy. Nursing care strategies to improve skin integrity during NCPAP had little supportive evidence. Nursing practice is varied with reportedly little standardized care during NCPAP therapy. Limited studies were discovered comparing various types of nasal interfaces during NCPAP and the reported frequency and severity of skin injury.

Conclusions: Risk factors during NCPAP include nasal injury and trauma secondary to tight fitting nasal interfaces necessary to provide continuous distending pressure for respiratory stability. Identifying strategies to reduce skin breakdown will support non-invasive treatment success, reduce reintubation rates, reduce sepsis, reduce patient discomfort, and improve

developmental outcomes during NCPAP use. Specific care strategies described to reduce skin injury during NCPAP had limited experimental studies to support recommendations.

Key words: nasal CPAP of the neonate, CPAP, non-invasive respiratory management of the preterm, respiratory devices of the newborn, respiratory pressure sources of the preterm infant, nasal trauma, preterm infant nasal skin breakdown, nasal prongs, skin care and pressure ulcer, or skin breakdown during NCPAP use.

Call Outs:

1) Identifying evidence based strategies to reduce skin breakdown during neonatal nasal continuous positive airway pressure can support non-invasive treatment success.
2) Empirical evidence is needed to support nursing interventions to reduce iatrogenic skin injury during nasal continuous positive airway pressure administration.
3) Half of the reviewed articles included nursing and skin care considerations used to prevent skin injuries that developed during nasal continuous positive airway pressure.

Scientific evidence within the field of neonatal respiratory care demonstrates several advantages of early nasal continuous positive airway pressure (NCPAP) or early extubation to NCPAP. Reduction in the duration and/or exposure to mechanical ventilation in the preterm neonate has many advantages including decreased incidence of chronic lung disease, ventilator associated pneumonia, blood stream infections, periventricular leukomalacia (PVL), improved neurodevelopmental outcomes and shortened hospital length of stay (Davis, Morley, & Owen, 2009; DePaoli, Davis, Faber, & Morley, 2008; Squires & Hyndman, 2009; Verder, Bohlin, Kamper, Lindwall, & Jonsson, 2009). Preterm neonates require some degree of respiratory support to maintain functional residual capacity (FRC) and to decrease the symptoms of respiratory distress syndrome (RDS) (Buettiker, Hug, Baenziger, Meyer, & Frey, 2004; Verder, 2007). NCPAP is often used to meet this need.

NCPAP is a non-invasive method for providing a constant distending pressure during both the inhalation and exhalation phases of the respiratory cycle. Used in the spontaneously breathing preterm neonate, NCPAP provides stability of the neonate's FRC, improves oxygenation, conserves surfactant, aids in the prevention of atelectasis, improves gas exchange, and aids in the prevention of obstructive and central apnea (Davis, Jankov, Doyle, & Henscke, 1998; Diblasi, 2009; Squires & Hyndman, 2009). This non-invasive respiratory therapy was first described as "an overpressure apparatus" in a German textbook about the diseases of the newborn (von Reuss, 1914). Early CPAP, a system of hoses placed into water filled receptacle with a gas source and face mask was attached to an infant to provide treatment for respiratory distress of the newborn. This early CPAP was useful to provide continuous airway pressure (Diblasi, 2009). Ventilator delivered CPAP was used in the late 1970's (Gregory, Kitterman, Phibbs, Tooley, & Hamilton,

1971) and by the late 80's and 90's free standing nasal CPAP delivery systems were designed and widely accepted (Diblasi, 2009; Verder, 2007).

There are three major types of NCPAP, traditionally classified by the technique used to control the gas flow to the patient. These include the constant flow or bubble NCPAP, variable flow CPAP devices that have fluidic control to maintain set pressures, and ventilator delivered CPAP that is generally delivered through an endotracheal tube (ETT) or bi-nasal pharyngeal tubes. All devices share four components: 1) a heated and humidified blended gas source, 2) a nasal interface, 3) a patient circuit, and 4) a pressure-generating apparatus.

Risks attributed to NCPAP therapy in the preterm neonatal population include abdominal distension, inability to provide enteral nutrition secondary to gut disturbance, slightly increased incidence of necrotizing enterocolitis (NEC), pneumothorax, and nasal injury or nasal mucosal damage (Janta et al., 2010; Squires & Hyndman, 2009; Verder, 2007). The current CPAP devices are effective in maintaining needed positive end expiratory pressure (PEEP) but also place constant pressure on the nares, nasal septum, and forehead sometimes leading to decreased skin integrity and injury especially in the most immature of preterm neonates (DePaoli et al., 2008; Squires & Hyndman, 2009). As more preterm neonates are managed with NCPAP, the incidence and prevalence of nasal trauma and skin injury will likely increase.

The primary aim of this review was to determine differences in the frequency, severity, location and/or description of nasal injuries when comparing different nasal interfaces (prongs/mask) during NCPAP administration. A secondary aim was to describe reported risk factors associated with nasal injury and skin breakdown during NCPAP use. Lastly, strategies were identified to support the reduction of nasal injuries during NCPAP administration in preterm neonates.

Methods

Pub Med, Google Science, Web of Science, and CINAHL electronic databases were included in the search. The dates were restricted to the last 16 years (1996-2011) to correlate with the widespread adoption of surfactant administration which transformed respiratory care of the extremely low birth weight (ELBW) infant to include early extubation strategies and widespread NCPAP use. The search was also restricted to English language. Initially a broad search was conducted with search terms to include NCPAP of the neonate, continuous positive airway pressure, non-invasive respiratory management of the preterm, respiratory devices of the newborn, and respiratory pressure sources of the preterm neonate. This broad search was completed to obtain background information on NCPAP use in the neonate and identify specific skin concerns. This initial search yielded 88 pertinent articles. A more specific database search followed using selective key terms, including nasal trauma, preterm infant nasal skin breakdown, nasal prongs and skin care, and pressure ulcer or skin breakdown during CPAP use. This search provided an additional 14 articles for a total of 102 publications. Non-published abstracts or articles were not searched or reviewed.

A secondary review of individual article citations and recently published research revealed an additional eleven articles for a total of 113 total publications representing specialty areas from neonatology, otolaryngology, nursing, and pediatrics. Each article was fully examined by the lead author for applicable content and included when criteria for both subject matter and identified population of interest were met.

Each of the 113 studies were evaluated for content related to neonatal skin breakdown as an iatrogenic injury secondary to NCPAP use, regardless of the primary or secondary aim of the study. This method was utilized to ensure inclusion of all studies which described skin

breakdown and/or identified nursing care strategies to improve outcomes during NCPAP therapy. Preterm neonates were defined as < 37 weeks gestation and birth weight restriction was <3000 grams. Descriptive studies and global reports of recommended skin care strategies during NCPAP use were also included in the findings section of this review.

Studies were eliminated if there was no discussion of skin breakdown related to the administration of NCPAP (53). Studies also were eliminated if the sample was not comprised of preterm neonates (13). The methodology of each study was examined for the level of evidence, one through seven as described in Melnyk and Fineout-Overholt (2011) (see Table 1; on-line). A single interventional study was eliminated from this review based on sample size (n = 5) which was not adequately powered to detect significant differences raising questions regarding study recommendations.

Results

As described in the methodology section, each article underwent a full review by the author to explore findings which corresponded to primary and secondary study aims. The discussion section of many articles also included critical information related to aspects of skin care during NCPAP use in the preterm population. The 46 studies were classified into three groups to aid in clarity when discussing results. The first group was those studies with the primary or secondary aim related to skin breakdown. Twenty-two articles were included, some which reported specific descriptions of the most common types of nasal injuries. Anatomical descriptions including diagrams to aid in the explanation of injury risk for the preterm infant were included in some of these articles. The second group included case studies of trauma or injury associated with NCPAP use. Six individual cases were discussed with descriptions of facial, nasal, and/or nerve disruption during NCPAP use. Descriptions of injuries often included strategies for

prevention. Lastly, 18 articles described skin care concerns during NCPAP use in the discussion sections of each article. These findings supported nursing care strategies and/or observations during NCPAP care that were often exclusive of the primary and secondary aim of the studies.

The study sample sizes ranged from 3 to 989 infants. The largest sample represented 13,719 NCPAP days. Duration of NCPAP ranged from 1-32 days. Samples included preterm neonates whose birth weight ranged from >800 grams to <3000 grams and most were cared for within Level II or III neonatal intensive care units (NICU).

Summary of Findings

The purposes of the reviewed articles can best divided into four topical categories including: 1) types of nasal injuries that correlate with NCPAP use, 2) associated risk factors that increase incidence of injury, 3) the differences between types of NCPAP devices and/or nasal interface and the reported rate and severity of nasal trauma injury, and 4) the recommended prevention strategies to reduce iatrogenic cutaneous injury (See Figure 2). Several of the reviewed articles provided overlapping information applicable in two categories. These findings are explored under each heading as appropriate. A detailed summary of findings in these categories is described below.

Types of nasal injuries that correlate with NCPAP use

Multiple reports of nasal injury were identified including nasal snubbing or the upward pressure on the nose, nasal flaring described as the abnormal enlargement of the nare, columella nasi (nasal septum) necrosis (Buettiker et al., 2004; Robertson, McCarthy, Hamilton, & Moss, 1996) crusting or scab formation and/or excoriation of the septum typically at the base (Yong, Chen, & Boo, 2005), and nasal hyperemia described as redness or blanching (Rego & Martinez, 2002). Disfigurement of the size and shape of the nostrils was described in multiple studies,

most commonly associated with the Hudson prongs (Fischer et al., 2010; Owen, Morley, & Davis, 2010). Several examples include neonates that were reintubated for mechanical ventilation secondary to loss of nasal tissue (nasal erosion) and bleeding, although stable respiratory status on NCPAP therapy (Verder, 2007; Yong et al., 2005). Authors of descriptive studies included recommendations for frequent skin assessment intervals and strategies for positioning the neonate in an effort to reduce the rate of injury through early identification of skin breakdown and/or prevention (Diblasi, 2009; McCoskey, 2008; Squires & Hyndman, 2009). Many suggested interventions have not been empirically tested, including the described use of barrier protection with silicon between the infant's skin and NCPAP interface (Gunlemez, Isken, Gökalp, Türker, & Arisoy, 2010).

Interestingly, case studies of nasal vestibular stenosis were reported. Several preterm infants who required NCPAP for treatment of RDS suffered from stenosis or an obstruction of the nasal passage thought to be the result of pressure from the NCPAP device or constant CPAP flow against fragile nasal tissue. This injury was typically identified several months following NICU discharge when care was sought for feeding difficulty (DeRowe, Lansburg, Fishman, Halperin, & Fliss, 2004; Smith & Roy, 2006). Standard assessment and evaluation of the inner nares and septum without obvious bleeding/trauma was not mentioned or evaluated in the included articles. Given this finding, this area may need to be included in the frequent assessment of the neonate during treatment with NCPAP. Anticipatory guidance upon discharge from the NICU should also include parental awareness for symptoms of nasal obstruction.

Case Study Reports: One case study found in the literature described a neonate who had significant nasal septum erosion that would typically require reintubation to allow the area to heal; however, the authors describe a method of providing oral CPAP using an ETT fashioned

through a pacifier that allowed time required for nasal healing (Carlisle, Kamlin, Owen, Davis, & Morley, 2010). This was a single finding and although successful in this case, empirical trials would be required to encourage widespread adoption. A full thickness laceration of the alae nasi was documented following treatment with NCPAP for one week (Shanmugananda & Rawal, 2007). Facial nerve palsy secondary to the pressure against the seventh cranial nerve was reported in a case study presented by Maffei (2008) and colleagues secondary to the tight fitting Velcro® attachment to the nasal interface that is positioned across the facial nerve causing compression. Forehead pressure necrosis resulting in permanent scarring of both the central forehead and left eyebrow was reported as a consequence of tight fitting NCPAP hats creating sources of friction and uneven pressure points (Hogeling, Fardin, Frieden & Wargon, 2012). Lastly, an auricular seroma was noted in a single neonate secondary to tight fitting strap attachments which secure the nasal interface to the cap across the vulnerable ear of the preterm neonate (Eifinger, Lang-Roth, Woelfl, Kribs, & Roth, 2005).

Associated risk factors that increase incidence of injury

Universally the smaller birth weight and lower gestational age neonates were identified as most at risk for iatrogenic nasal injury while on NCPAP (Kopelman & Holbert, 2003; Rego & Martinez, 2002; Robertson et al., 1996; Yong et al., 2005). In a randomized controlled trial by Buettiker et al. (2004) larger neonates with birth weights >2500 grams had the fewest reported skin and nasal injuries. The reported duration of NCPAP ranged from 1 day to 32 days. Increased time on nasal CPAP was identified as a significant risk factor for skin injury although nasal trauma was reported in as little as 3 days of continuous use (Robertson et al., 1996; Yong et al., 2005). A cross-sectional study utilizing a convenience sample in Brazil described the incidence of nasal skin injury of nearly 100% of preterm and term infants who were provided NCPAP for

greater than 2 days (do Nascimento, Ferreira, Coutinho, & Santos Verissimo, 2009). A cross-sectional study by Jatana and colleagues (2010) reported smaller neonates with corresponding smaller nasal columella and inferior turbinate along with the complication of immature preterm skin and often longer CPAP duration, demonstrated the highest incidence of nasal complications. Also noted by these researchers was a correlation between skin injury and low APGAR scores that had not been reported by other researchers (Jatana et al, 2010) although the study was not powered to detect significant differences among groups for this measure.

A recent multi-site prospective cohort study was conducted to examine the incidence of pressure ulcers in neonatal patients cared for in the NICU. Eighty one patients were examined with a reported incidence of 16% (14); seven of which occurred on the nose. These researchers were the first to examine the incidence and risk factors for pressure ulcer development in the ELBW infant. Researchers identified NCPAP as an independent risk factor for nasal pressure ulcers in addition to previously described compression necrosis and/or nasal deformities (Fujii, Sugama, Okuwa, Sanada, & Mizokami, 2010).

Specialist within the field of otolaryngology reported specific injuries related to NCPAP use in the preterm neonate. These injuries include nasal vestibular stenosis, described earlier in this review, or columellar necrosis that develops in a stepwise fashion with delivered pressure from the nasal prongs or air trauma from constant flow against soft nasal mucosa (DeRowe et al., 2004). This process over time can lead to ulceration, bacterial colonization and then secondary healing with granulation tissue formation leading to disruption of nasal patency (DeRowe et al., 2004; Jatana et al, 2010; Smith & Roy, 2006). Vestibular stenosis occurred in as early as 8 days of continuous NCPAP according to these researchers. Overall increased incidence of nasal

suctioning needs, coupled with an increased rate of coagulase negative staphylococcus was also reported (Kopelman & Holbert, 2003; Ronnestad et al., 2005).

Researchers reported nasal prong size as a concern during NCPAP therapy. Prongs that are too large distend and distort the nares and cause pressure to the inner aspect of the nose leading to decreased perfusion and tissue necrosis. The prong size that is inappropriately small also leads to excessive damage with greater mobility in the nare causing friction and traumatic injury to the mucosal lining (do Nascimento et al., 2009; Squires & Hyndman, 2009).

Differences between device types, nasal interfaces and the rate and severity of nasal trauma

Hudson prongs were associated with more injuries than the mask or Argyle prongs because of failure to meet anatomic positioning against the neonate's skin. These prongs are not translucent, making it difficult to assess the fragile skin under them (Buettiker et al., 2004; Fischer et al., 2010; Robertson et al., 1996; Yong et al., 2005). The Argyle prong system was reportedly more difficult to maintain in the smaller (<1000 gram) neonates but had no greater incidence of trauma (Buettiker et al., 2004). The shorter binasal prongs reportedly have clear advantages over the single prong devices in the reduction of RDS (DePaoli, 2008). Little difference was detected when comparing aforementioned nasal CPAP devices and more evidence is needed to detect differences between the types of nasal interface and the rate and/or severity of nasal trauma and injury to the preterm neonate (DePaoli, 2008; Fischer et al., 2010; Owen et al., 2010).

Rego and colleagues (2002) conducted a randomized prospective study to compare the performance and patient tolerance of two difference nasal prongs that are typically used during NCPAP administration. The Hudson device that is the typical nasal interface used for bubble CPAP and the Argyle device were compared to determine tolerance (incidence and severity of nasal breakdown) and efficacy (measured by blood gases and vital signs) of the devices. This

was the first study reviewed which compared nasal interfaces during NCPAP administration with the preterm population. The researchers found a significant increase in the incidence of hyperemia with the use of the Argyle prongs in the smallest patients (≤ 1000g). There was no difference between groups in the other measures of skin breakdown including excoriation, bleeding or erythma (Rego & Martinez, 2002). No studies were found that specifically examined differences between nasal prongs, nasal mask and the systematic rotation of these nasal interfaces thought to relieve pressure points on the nares, nasal columella, forehead, or other facial surfaces of the preterm neonate.

The recommended prevention strategies to reduce iatrogenic cutaneous injury

The use of barriers demonstrates efficacy in this population by protecting the nasal columella. In a randomized control trial, Gunlemez et al. (2010) studied the application of a silicon gel sheeting at the nasal surfaces to protect from direct pressure from the CPAP prongs to the maxillary spine located behind the collumella. Researchers in two studies suggested wetting the prongs with sterile water or saline to prevent friction during placement and gently shaping prongs posterior to best align with the physiological angle of the neonates nares (do Nascimento et al., 2009; Robertson et al., 1996).

From the results of their descriptive studies researchers suggested nursing implications to both assess and prevent iatrogenic nasal injury during nasal CPAP administration (McCoskey, 2008; Squires & Hyndman, 2009). These included barriers under the device, frequent assessment, developmental positioning, and focused examinations to identify hyperemia early. Other researchers discuss suggestions for manufactures' to engineer prongs to coincide with the anatomical position of the neonatal nose (Verder et al., 2009; Yong et al., 2005). In addition, alternating the nasal mask and nasal prongs in an effort to alter pressure points on the nares and

nasal mucosa of the neonate has been suggested as a potential method to reduce tissue injury (McCoskey, 2008). Empiric testing of these measures is needed prior to widespread adoption.

Nursing care experience and expertise was a common theme throughout several included studies. Verder and colleagues (2009) reported that nasal complications of NCPAP are to a large extent avoidable with proper technique, nursing experience and the ongoing skilled care of the neonate. Nursing care during NCPAP was described as of "utter-most importance" in the treatment success of NCPAP with several key points for care delivery offered that included: providing open nasal passages, optimal body positioning, avoidance of unnecessary suctioning, adequate humidification, correct prong size and inspection of skin surfaces (Bohlin, Jonssan, Gustafsson, & Blennow, 2008). Nursing care was described as "exquisite" and paramount to the success of NCPAP for the extremely low birth weight (ELBW) neonate during studies at Columbia University (Ammari et al., 2005).

Of special interest is the development of alternative devices to provide CPAP to neonates without placing pressure on the nares, a stated negative consequence of the therapy. Alternative CPAP methods whose design correlates to an early plastic pressure chamber device developed by Gregory and others in the 1970's, made a recent comeback with helmet CPAP devices to provide PEEP to the neonate while sparing nasal surfaces (Chidini et al., 2010; Trevisanuto et al., 2005; Zaramella et al., 2006). These methods are currently experimental without widespread application.

High flow nasal cannula (HFNC) and vapo-therm have been used in comparative effectiveness studies as a means to compare and contrast supportive strategies while providing nasal sparing, non-invasive respiratory support in the preterm neonate (Campbell, Shah, Shah, & Kelly, 2006; Sreenan, Lemke, Hudson-Mason, & Osiovich, 2001). These devices clearly have a

place in the non-invasive respiratory support of the preterm neonate, but they have not been shown as effective in maintaining the extubation status of the preterm neonate (Campbell et al., 2006; Courney & Barrington, 2007; Shoemaker, Pierce, Yoder, & DiGeronimo, 2007).

Limitations of described studies

There are several limitations to the included studies that must be considered with reported findings. Most of the sample sizes were small (less than 15 patients per group) making differences difficult to detect. Most were completed in single NICU settings and none of the US studies included multi-centered sites. Only three studies examined the incidence of nasal trauma and breakdown during NCPAP therapy as the primary aim of the study, all other studies either mentioned it as part of the discussion or secondary measure. Descriptive designs were often employed with lower assigned levels of evidence, identified as limitations with several studies (See evidence Table 1; on-line). Smaller infants who are most at risk for skin injury secondary to their extreme immaturity were often excluded.

Discussion

Early use of NCPAP at delivery or as respiratory support following early extubation has shown merit in improving neonatal outcomes and preventing chronic lung disease. Overall NCPAP use has increased dramatically throughout NICU's across both the United States and developed nations (Jatana et al., 2010; Pelligra, Abdellatif, & Lee, 2008). This therapy is considered by many health care providers who care for preterm neonates as the current standard for respiratory support (Ammari et al., 2005; Davis et al., 2009; de Winter, DeVries, & Zimmermann, 2010; Verder, 2007). The major focus of recent research in this area is to provide evidence on the best strategies to prevent reintubation, to determine when early intubation, surfactant administration and then extubation to non-mechanical ventilation therapy is an

appropriate component of resuscitation in extremely preterm patients, to provide guidelines for weaning neonates from CPAP and the best methods and equipment to provide NCPAP (Davis et al., 1998; Pelligra et al., 2008; Verder et al., 2009). Nursing care requirements and skin care considerations to prevent nasal skin injuries are a common thread overlapping nearly half of the reviewed articles, although few studies identified this concept as a primary or secondary aim of the research study.

Significant progress has been made over the last 50 years in the understanding of the neonatal pathophysiology and the underlying causes of respiratory distress syndrome but there is much work left to be done. Identified gaps in the literature include delivery room decision making with regard to choice of intubation for the purpose of surfactant delivery or the immediate application of NCPAP. Clinical decisions with regard to intubation when NCPAP is initiated remains ill defined. Empirical evidence is needed to support universal weaning guidelines for NCPAP, the prophylactic use of NCPAP in those preterm neonates less than a predetermined gestational age, and which types of NCPAP interfaces and/or devices are superior.

The overall clinical management of preterm neonates whose respiratory system is supported through the use of NCPAP is based on anecdotal experience and unit standards rather than on scientific evidence. Nursing skill level and experience with positioning, frequent assessment and intervention, all of which takes significant nursing time has been well described by nearly half of the included studies. Practices vary widely from unit to unit making standardization of nursing care to protect vulnerable preterm neonatal skin difficult during this therapy. Most of the injuries described can be prevented with careful application of the CPAP device and frequent assessment with early identification of skin breakdown or injury.

We clearly understand the advantages of using NCPAP in this population and they definitely outweigh the observed risks (DePaoli, Davis, Faber, & Morley, 2008; Squires & Hyndman, 2009; Verder, Bohlin, Kamper, Lindwall, & Jonsson, 2009). We must now examine different delivery methods and nasal interface devices while providing non-invasive NCPAP to preterm neonates to best manage the preterm neonate's respiratory distress syndrome using scientific evidence to make recommendations for care and test best clinical practices. In a meta analysis completed on the devices and pressure sources for the administration of NCPAP, implications for further research include determining which nasal interface device is the least traumatic to the neonatal nose, particularly the very low birth weight neonate (DePaoli et al., 2008). A review of current non-invasive ventilation of the preterm infant describe NCPAP interfaces as "too rigid, oversized or too heavy for smaller infants" recommending manufacture development of physiologic appropriate devices (Bancalari & Claure, 2008). Additionally, a systematic review is needed of those non-invasive ventilatory strategies describing both nasal prongs and nasal masks for use in the neonate. In a study by Courtney and Barrington (2007), nasal masks reportedly required less pressure to remain in place but "will need empiric testing to determine safety in this population".

Empiric evidence based on current scientific literature is needed to support nursing interventions to reduce iatrogenic skin injury of the nose, face and head during NCPAP administration to provide for improved long term outcomes. Specific attention to those details of nursing care for this vulnerable patient population is needed to address strategies for optimal outcomes. This integrated review of the current literature offers a springboard for future nursing research.

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Chapter 2

A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

Abstract

Purpose: Identify differences in frequency and severity of nasal injuries when comparing nasal CPAP interfaces (prongs/mask) used to treat neonatal respiratory distress syndrome. Describe risk factors associated with nasal injury and skin breakdown during nasal CPAP.

Design: A three group prospective randomized experimental design.

Methods: 78 neonates <1500 grams receiving nasal CPAP using the same delivery system were randomized into three groups: 1) continuous nasal prong group, 2) continuous nasal mask group, or 3) alternating mask/prongs group. Serial data collection was conducted by the Core Research Team to include: demographic, biophysical measures and the Neonatal Skin Condition Scale (NSCS).

Results: Significant differences between groups included infant weight at start of nasal CPAP ($p = <0.001$), and CPAP flow rate ($p = 0.037$). Repeated measures ANOVA with Bonferroni correction was used to measure group differences for frequency and severity of injury. Significantly less skin injury was detected in the rotation interface group using the NSCS variables of erythma and excoriation when compared to both mask and prong groups.

Stepwise regression was utilized to determine significant risk factors within and across groups in relation to skin breakdown. In the final model significant differences were found in two variables; number of days on NCPAP (beta = 0.031, $p<0.001$) and the current mean post menstrual age (beta =0.030, p 0. 006).

Conclusions: Nasal CPAP is reportedly superior to mechanical ventilation in reducing effects of bronchopulmonary dysplasia (BPD). Current CPAP devices place constant pressure on nares, nasal septum and forehead, increasing injury risk. This study demonstrated a significant difference in the frequency and severity of skin injury when utilizing a method of rotating mask and prong nasal interfaces during neonatal CPAP therapy; a useful clinical recommendation. Attention to infant size and CPAP duration is also recommended as these were identified as significant risk factors for skin injury. Specific nursing care implications related to findings include; choosing a device for best fit for infant (face shape and infant size); positioning of the CPAP device; developmental position of the infant; and focused skin assessment with rapid intervention. Standardized care including skin barriers, clinical expertise of nursing and respiratory therapy, and skin care management are strategies that warrant additional research.

Key Terms: Nasal CPAP of the neonate, CPAP, non-invasive respiratory management of the preterm, respiratory devices of the newborn, nasal trauma, preterm infant nasal skin breakdown, nasal prongs and skin care, and pressure ulcer or skin breakdown during NCPAP.

The use of nasal continuous positive airway pressure (CPAP) has become the gold standard in the care of preterm infants with respiratory distress syndrome (RDS) (Davis, Morley & Owen, 2009; Verder, 2007; Verder, Bohlin, Kamper, Lindwall, & Jonsson, 2009). Various nasal interfaces are currently available to provide neonatal CPAP yet few studies have compared the effectiveness of these devices to determine both performance as well as determine differences in incidence and/or the severity of nasal skin breakdown, a well described side effect of this useful treatment (Ramanathan, 2010; Rego & Martinez, 2002; Yong, Chen & Boo, 2005).

Following a systematic review of 113 articles related to the use of nasal CPAP on the preterm infant, only two randomized controlled trials (RCT's) included comparisons of nasal interfaces to determine the frequency of skin breakdown or nasal trauma (Rego & Martinez, 2002; Yong, Chen & Boo, 2005). Rego and Martinez (2002) conducted their RCT in Sao Paulo, Brazil. They evaluated the performance of two types of nasal prongs, Argyle™ and Hudson™, to deliver nasal CPAP to preterm infants (Rego & Martinez, 2002). Although both were found to be equally effective in the delivery of nasal CPAP, the Argyle™ prong was more difficult to maintain in the infant's nares and had a higher incidence of nasal hyperemia or erythma, the first sign of skin breakdown when compared to the Hudson™ prong. Yong, Chen and Boo (2005) conducted a RCT to compare the incidence of nasal trauma associated with continuous nasal prongs or continuous nasal mask during nasal CPAP in neonates < 1500 grams. Although no significant difference in rate of nasal injury was found between the two interfaces (mask and prongs) there was a significant correlation between nasal trauma and length of therapy. No comparisons between prongs, mask or a rotation of devices often used as a nursing care strategy to reduce pressure on nasal skin during the use of NCPAP were found in the literature (Robertson, McCarthy et al., 1996; McCoskey, 2008; Squires & Hyndman 2009). Additionally,

there was agreement that nasal injury is a potential risk factor when using nasal interfaces during CPAP delivery with clear directives for attention to skin assessment, increased nursing care, and clinical expertise which was cited as a concern in 46 of the 113 reviewed articles (Newnam et al, 2013).

Evidence based practice supports clinical decision making based on scientific evidence with the clear aim to improve patient outcomes and reduce health care waste (Melnyk &Fineout-Overholt, 2011). Comparative effectiveness research (CER) has emerged as a method to critically evaluate scientific evidence, identifying major gaps in current evidence typically identified by systematic reviews, clinical guidelines developed by consensus review and other methods to aggregate clinical research and then compare this information with current patient care practices (Tricoci, Allen, Kramer, Califf, & Smith, 2010). Clinicians are discovering the evidence that emerges from real world settings is a valuable part of evidence based practice. Consequently clinicians are placing less emphasis on the previous gold standard of randomized controlled trials (RCT) and as described in CER supporting clinical decisions based on results from alternative study designs. The conduct of RCT's is not always possible in every clinical venue and population thereby missing critical information required for the purpose of helping patients, clinicians and payers to make informed health-care decisions (Prosser, 2012).

Defined as "the generation and synthesis of evidence that compares the benefits and harm of best care methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care, the purpose of CER is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels" (Institute of Medicine of the National Academies, 2009). CER examines both efficacy and effectiveness of practice decisions through clinical research comparing current

methods to proposed strategies in order to develop superior "best practices" based on clinical evidence (Institute for Integrative Health, 2009). The described research utilized the principals of CER as a framework to examine current neonatal nasal CPAP care, specifically the nasal interfaces to determine differences in effectiveness and efficacy. Thus, an overall goal of this study was to utilize previous and current findings to support practice changes grounded in evidence trough increased understanding of the effects of nasal CPAP and nasal interfaces on neonatal skin integrity in a single NICU.

Background and Significance:

The dynamic approach to respiratory care of the preterm neonate has progressed following scientific evidence which clearly demonstrates advantages to early nasal continuous positive airway pressure (CPAP) or early extubation to nasal CPAP in this population. It is now well understood that reduced mechanical ventilation in high-risk preterm infants has many advantages which includes; decreased chronic lung disease, decreased incidence of ventilator associated pneumonia as well as overall reduction in blood stream infections, reduction in the incidence of periventricular leukomalacia (PVL) previously associated with long term ventilation, improved neurodevelopmental outcomes and shortened hospital length of stay (De Paoli, Davis et al., 2008; Squires & Hyndman 2009). These very low birth weight (VLBW) preterm infants however require some adjunct to maintain functional residual capacity (FRC) as well as improve the symptoms of respiratory distress syndrome (Buettiker, Hug et al., 2004). Nasal continuous positive airway pressure (CPAP) is often used to support this need.

Nasal CPAP is a non invasive method for providing a constant distending pressure during both the inhalation and exhalation phase of respiration. Used in the spontaneously breathing preterm infant it provides stability of the infant's FRC, improves oxygenation, conserves surfactant, aids

in the prevention of atelectasis, improves gas exchange and aids in the prevention of obstructive and central apnea (Davis, Jankov et al., 1998; Diblasi, 2009; Squires & Hyndman, 2009). First described in 1914 in a German textbook about the diseases of the newborn, a system of hoses placed into a water filled receptacle, a face mask with a gas source was used on a newborn who had symptoms of respiratory distress to provide continuous airway pressure (Diblasi, 2009). Ventilator delivered CPAP first was reported in the late 1970's and 1980's that were adapted from adult models (Gregory, Kitterman et al., 1971); then in the 90's free standing nasal CPAP delivery systems were designed and widely adapted into routine practice (Verder, 2007; Diblasi, 2009).

Three major types of nasal CPAP are used in the neonatal population, traditionally classified by the technique used to control the gas flow to the patient (Gupta, Sinha et al., 2009). These include constant flow or bubble CPAP, variable flow which are devices that have fluidic control to maintain the CPAP pressure and finally ventilator delivered CPAP generally delivered through an endotracheal tube (ETT) or a long single nasal pharyngeal tube. All devices share in four components, 1) a heated/humidified blended gas source, 2) a nasal interface, 3) a patient circuit and 4) a pressure-generating apparatus (Diblasi, 2009).

Risks attributed to the use of nasal CPAP in this population have also been described. These include abdominal distension, inability to provide enteral nutrition secondary to gut disturbance, slightly increased incidence of necrotizing enterocolitis (NEC), pneumothorax and nasal injury or nasal mucosal damage (Verder, 2007; Squires & Hyndman, 2009). The current CPAP devices are effective in maintaining needed positive end expiratory pressure (PEEP) but also place constant pressure on the nares, nasal septum and forehead leading to decreased skin integrity and injury (De Paoli, Davis et al., 2008). Research is needed to 1) compare nasal CPAP interfaces

commonly used to determine differences in frequency and severity of skin break down, and 2) identify strategies to reduce skin breakdown during nasal CPAP use in extremely low birth weight (ELBW) infants.

The overall clinical management of preterm infants whose respiratory status is supported through the use of nasal CPAP is based on reported anecdotal experience and unit standards rather than on scientific evidence. Nursing level of expertise and experience with positioning, frequent assessment and intervention, all of which takes significant nursing time has been well described by nearly half of the reviewed articles. Routine nursing care practices vary widely from unit to unit making standardization of nursing care to protect vulnerable preterm infant skin during this therapy difficult.

The advantages of using nasal CPAP in this population outweigh the observed risk related to this therapy. Best practices for choosing and implementing neonatal CPAP delivery methods and nasal interface devices to best manage RDS must be guided by scientific evidence. A meta analysis was completed to examine different devices and pressure sources for the delivery of nasal CPAP which provided implications for further research. These included determining which nasal interface device is the least traumatic to the infant nose, particularly in the VLBW infant (De Paoli, Davis et al., 2008). Additionally, a systematic review of non-invasive ventilation strategies described care-giving implications related to both nasal prongs and newer nasal masks for use in the neonate. The masks were described to require less pressure to remain in place but "will need empiric testing to determine safety in this population" (Courtney & Barrington, 2007).

Standards of care based on previous findings and clinical evidence are needed to support recommended nursing interventions to reduce iatrogenic skin injury of the nose, face and head during nasal CPAP administration, ultimately improving long term outcomes. Thus, the primary

aim of this study was to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask/rotation) used in the treatment of neonatal RDS. A secondary aim of the study was to identify risk factors that may be associated with skin breakdown during nasal CPAP administration.

The hypotheses included:

1) There is no difference in the incidence and/or severity of skin breakdown in the extremely low birth weight (ELBW) preterm neonate (less than 1500 grams) when nasal CPAP is administered using three types of nasal interfaces: 1) continuous nasal prongs, 2) continuous nasal mask or 3) alternating the nasal mask and prongs every 4 hours.
2) There are no differences in the incidence and/or severity of skin breakdown related to other predisposing risk factors such as gestational age, birth weight, length of therapy, environmental humidity level, amount of CPAP flow administered and/or nursing interventions that include positioning techniques, nasal suctioning devices and the use of nasal saline during suctioning.

Methods:

Design, sample and setting

A three group prospective randomized experimental study design was conducted in a 70 bed level III Neonatal Intensive Care Unit (NICU) in the southeastern United States. The study was approved by the Institutional Review Board (IRB), and parents provided informed consent for their infant's participation in the study. A flow diagram describes the process of screening through completion of data collection following Consolidated Standards of Reporting Trials (CONSORT) guidelines (Moher, Schulz & Altman, 2001) (see Figure 1).

Each infant admitted to the NICU was screened for inclusion criteria from mid-April, 2012 through mid-January, 2013. Preterm infants with birth weight 500 to 1500 grams were eligible for the study. Exclusion criteria included infants born with airway or other physical anomalies that influenced their ability to extubate to nasal CPAP. Infants who were not consented within 8 hours of nasal CPAP initiation or who had nasal skin breakdown at enrollment were also excluded. A sample size estimation was calculated to use 80% power, alpha = 0.05, prior to study initiation and was used to direct the enrollment for each group. The group size of 72 total subjects, 24 subjects in each of the three groups (continuous nasal prongs, continuous nasal mask or alternating nasal mask and prongs every 4 hours) was deemed adequate to determine significant differences between groups.

Procedures

After informed consent was obtained and the patients were extubated to nasal CPAP they were randomized into one of the three groups, 1) continuous nasal prong group, 2) continuous nasal mask group, or 3) alternating mask/prongs every 4 hours group. The specific timing of extubation was based on demonstrated clinical readiness (respiratory stability) or self-extubation with appropriate clinical indications for nasal CPAP trial. Infants recruited for the study were block stratified according to weight into four categories according to birth weight: < 750 grams, 750-1000 grams, 1001-1250 grams and > 1251-1500 grams. Known differences in the skin integrity have been demonstrated with the lowest birth weights proven the most vulnerable; thus, stratification according to birth weight was utilized to keep the groups more homogeneous since it was expected that the < 750 gram group would contain the fewest patients. All infants were managed with the same type of nasal CPAP delivery system, the Cardinal™ variable flow driver with Air Life™ prongs/mask. Infants transported from the delivery room or outlying hospitals

initially treated with nasal CPAP were also eligible for enrollment. Infants that were extubated to other respiratory support devices (high flow nasal cannula, vapor-therm or nasal cannula) based on medical decision were excluded from enrollment unless nasal CPAP was medically indicated at a later time-frame.

The randomization process was conducted by the respiratory therapist assigned to that patient during the time of extubation. Randomization into assigned groups was accomplished using serially numbered opaque sealed and color coded envelopes developed by the researcher located close to the storage area which housed CPAP equipment within the NICU. The respiratory therapist was responsible for drawing the next sequentially numbered envelop based on birth weight groups as described during departmental education. Once group assignment occurred the equipment was collected and placed on the patient to provide nasal CPAP therapy.

Variables and measures

Demographic data, which included gestational age, birth weight and current weight, was retrieved from the medical record. Clinical information related to therapy included oxygen liter flow, day number of CPAP, humidification of environment as measured on the incubator humidity gauge using the Giraffe™ , and temperature of the humidifier device connected to the nasal CPAP was extrapolated from direct observation or from the medical record. Information regarding suctioning practices and the use of normal saline during suctioning was also collected.

The Neonatal Skin Condition Scale (NSCS) is a skin condition scoring system developed by Lane and Drost (1993) which was later modified by Lund et al. (2001) for the development of neonatal skin care guidelines. The tool uses three clinical outcome categories which includes dryness, erythma and breakdown or excoriation of the skin. Each category is graded one through three. The score of one in each category indicates a healthy skin assessment and the score of two

or three indicates an increasing level of skin breakdown with a total score of nine (three in each category) being the worse skin evaluation score possible. The tool was tested for both validity and reliability and for interrater reliability (r = 0.6 to 0.7). Kappa values were also significant at the < p=0.001 (Lund, Kuller et al. 2001; Lund and Osborne 2004). In the current project neonatal skin assessments using the NSCS were performed by the Core Research Team every 10 to 12 hours in coordination with the participant's routine nursing care. A brief educational session for the Core Research Team was required prior to study initiation and interrater reliability was measured between team members.

In the current study interrater reliability using the kappa statistic was performed to determine consistency among NSCS scores. It was established a priori that 10% of the data collection points would be conducted by 2 members of the Core Research Team for purposes of reliability measure. The interrater reliability for the NSCS was found to be kappa = 0.74 ($p < 0.001$), 95% CI (0.432, 0.914). The internal consistency of the NSCS tool was measured using the Cronbach's α (0.416) which was lower than reported in the literature. Analysis of which variable was significant for reduced internal consistency was completed and through the elimination of the dryness variable of the tool in the study population changed the Cronbach's α to 0.721 which is above the acceptable value of 0.7 (Devillis, 2003).

Data collection procedures

A team of skin experts, described as the Core Research Team was made up of the principal investigator and three advanced practice nurses. This research team was responsible for obtaining parental consent and conducting serial skin care evaluations on enrolled subjects during routine nursing care in an effort to protect the infant's quiet environment. The initial skin

assessment was completed within 8 hours of extubation and at intervals of every 10-12 hours while receiving nasal CPAP therapy.

Tool and interrater reliability of the NSCS (reported as Cohen's Kappa and chronbach's alpha) was conducted through the use of two experts assessing 10% of the study subjects. This information was collected in conjunction with scheduled skin care assessments.

Statistical analysis

Demographic information was collected for descriptive analysis. Variables included gestational age, birth weight, post menstrual age at time of CPAP, current weight, number of days on nasal CPAP, liter flow of CPAP, and environmental humidity. Counts and percentages were reported for categorical variables and range, median, mean and standard deviation for continuous/ordinal data. The means of both demographics and clinical characteristics were computed and reported for the total sample and by group. Group means were compared using a one way analysis of variance (ANOVA) to identify group differences in an effort to demonstrate homogeneity among randomized interface groups. Significant differences among group means were analyzed using the Tukey multiple comparison test.

Statistical analysis for the primary aim of the study, to determine differences in the incidence and severity of skin breakdown when comparing three types of nasal CPAP interfaces included repeated measures ANOVA. The NSCS means for each category (erythma, dryness and excoriation) and NSCS sum score was calculated by using three time points universal to all subjects in an effort to mitigate the variance of data collection points among the subjects. Within group means were compared through repeated measures ANOVA. The assumption of sphericity was evaluated using Mauchly's test and the Bonferroni method was used to perform the pairwise comparisons.

Statistical analysis to determine those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration, the secondary aim of the study was completed using stepwise multiple regression. The stepwise approach was supported through use of scientific evidence and literature review. Bivariate correlations between number of CPAP days and NSCS sum scores and the post menstrual age of subjects and NSCS sum scores using Spearman rho was conducted following modeling.

Results

A total of 377 admissions to the NICU were screened for eligibility criteria during the study period. Of these, 140 patients met birth weight criteria of 500-1500 grams. Two patients were diagnosed with airway deformities that compromised their ability to successfully extubate to nasal CPAP and were eliminated. Parental consent was obtained on 90 patients (65%). Two parents refused study participation for their infant (1%). Fourteen patients (10%) expired prior to obtaining study consent and 32 patients (23%) were missed. The missed patients were typically patients who were admitted on nasal CPAP or quickly extubated with limited ability to obtain consent within the 8 hour time limitation (see Figure 1). The final sample of 78 patients was randomized into three groups (nasal prongs, n = 21; nasal mask, n = 35; and alternating mask/prongs, n = 22). Each of the three groups was block stratified according to the patient's birth weight. These four categories included: < 750 grams, 750-1000 grams, 1001-1250 grams, and > 1251-1500 grams. There were no significant differences between nasal interface grouping and birth weight stratified during randomization (see Table 1). Infants whose size prevented correct fit with nasal prongs according to manufacture guidelines were defaulted to the mask group, regardless of group assignment. This safety maneuver although necessary accounted for the unequal group distribution.

Demographics for both total sample and per group are presented in Table 2 and 3. The number of days on nasal CPAP ranged from 1 to 16 days with 730 data collection time points representing 365 CPAP days with a mean of 4.68 days (± 3.45). The frequency of skin injury reported for the group was 24.2% and the area of the face most frequently assessed and reported with skin breakdown was the nasal septum (85.3%). The nasal bridge (29.9%) and forehead (26.6%) were locations with the second and third highest frequency. There were no significant differences between the groups and location of skin injury reported.

The demographic variables of each group were evaluated to determine homogeneity using a one-way analysis of variance (ANOVA) to determine significant differences between groups. Significant differences were reported between the mean current weight at the time of nasal CPAP ($p = <0.001$) and the mean CPAP liter flow delivered during therapy ($p = 0.037$). The variable current weight at time of CPAP, a Tukey multiple comparisons test performed at the 0.05 significance level found significant differences between the mask and other two groups (prong and rotation group). This finding was most likely related to the necessary default to mask group when prongs could not fit safely into small nares. For the variable CPAP liter flow the Tukey multiple comparisons performed at the 0.05 significance level found significant differences between the prong and rotation groups (see Table 3).

Correlations were performed to explore relationships among the study variables. These variables included; gestational age, birth weight, weight at start of CPAP, post menstrual age during CPAP, oxygen delivered, time between birth and CPAP introduction, number of days on CPAP, temperature and flow amount of CPAP, environmental temperature and humidity, developmental positioning of the infant, nasal suctioning, use of nasal saline during suctioning, and the individual and sum NSCS scores (see Table 4). Expected significant relationships were

found between birth weight and gestational age; gestational age and the number of CPAP days, the amount of oxygen required and amount of environmental humidity provided. There was also a significant correlation between time to nasal CPAP and number of CPAP days.

A repeated measures design was necessary to determine the mean NSCS scores (erythma, dryness, excoriation, and sum score) since many subjects had multiple timed data collection points, and were therefore not independent samples. To best control for the repeated measures, three specific time points were selected that were common to each participant, time 1 at initiation of nasal CPAP, time 2 mid-point during therapy and time 3 the last data collection prior to the completion of nasal CPAP. Means were calculated on these values and the repeated measures analysis of variance (RMANOVA) was conducted using pairwise comparisons with Bonferonni correction to determine differences within and between groups for the NSCS (see Table 3). Tests for homogeneity of variance and Mauchly spericity for RMANOVA were preformed. Spericity was assumed χ^2 (2) = 2.94, p = 0.23.

To determine differences in the severity of nasal injuries, part of the primary aim, we compared nasal CPAP interface groups with mean NSCS sum scores using RMANOVA. The results of this analysis were not statistically significant (see table 3). However, when examining the mean NSCS score for each of the three categories within the scale, specifically erythma ($p < 0.001$) and excoriation ($p = 0.007$), significant differences were found. Erythma and excoriation as well as hyperemia was noted in the literature to be specifically linked to skin breakdown and thereby examined for differences among groups.

To best evaluate the effect of additional risk factors and their influence on the incidence and frequency of skin breakdown, a regression model was developed. This model was guided by factors identified in the literature. Factors included in the model were birth weight, length of

therapy, post menstrual age at the time of CPAP, environmental temperature, amount of CPAP flow administered and/or nursing interventions that include positioning techniques, nasal suctioning type (oral/nasal), suctioning interval and the use of nasal saline during suctioning (see Table 5a). Post menstrual age at the time nasal CPAP explained 16% of the variance in the incidence of skin breakdown using the mean NSCS sum score as the dependent variable. Additionally the number of CPAP days placed in the model explained 25% of the variance. The mean post menstrual age made the largest unique contribution (beta = 0.46) although the number of CPAP days also made a statistically significant contribution (beta = 0.31) (see Table 5b).

Discussion

This study was conducted to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask/rotation) used to treat RDS in the preterm neonate < 1500 grams. The secondary aim of the study was to identify additional risk factors that may be associated with skin breakdown during nasal CPAP administration. The incidence of skin breakdown reported in the literature associated with nasal CPAP in the neonate was 20 to 60% (Fischer, Bertelle, Hohlfeld, Forcada-Guex, Stadelmann-Diaw, & Tolsa, 2010). This study demonstrated an overall skin breakdown rate of 24.2% which provides clear opportunity for clinicians to improve skin care outcomes.

Using the NSCS to determine differences in severity of nasal injury between nasal interface groups, significant differences in both excoriation and erythma were found. A reduction in skin injury was detected between the rotation mask/prong group and the other two nasal interface groups. Previous literature reported nasal interfaces (prongs/mask) are effective in the treatment of RDS (DePaoli, Davis, Faber, & Morley, 2008). In the RCT's conducted by Rego and Martinez

(2002) and Yong, Chen and Boo (2005), no significant differences in the frequency of skin injury (excoriation, bleeding or erythma) was found when comparing various nasal interface groups. Although no studies were discovered that specifically examined differences between nasal prongs, nasal mask, and the systematic rotation of these nasal interfaces thought to relieve pressure points on the nares, nasal columella, forehead or other facial surfaces of the preterm neonate. Providing knowledge that each interface is effective during CPAP treatment and the systematic rotation of interfaces was shown to reduce the risk of skin injury offers clinician's the ability to best manage neonatal CPAP. It is still clear that the clinician must choose the interface that best seals, comforts, and fits the neonate and one interface is best for all infants.

The significant correlation reported between the incidence of skin breakdown and number of days on nasal CPAP was not surprising and mirrors findings from previous research ((Robertson et al., 1996; do Nascimento, Ferreira, Coutinho, & Santos Verissimo, 2009; Yong et al., 2005). It is well understood that long term therapy (> 3 days) places infants at greater risk for skin breakdown resulting in significant clinical implications. Close observation at more frequent intervals is needed to identify/treat early signs of hyperemia or breakdown for those patients that require nasal CPAP for longer periods of time (> 3 days). Clinicians may consider the rotation from nasal CPAP to other therapy (Nasal Cannula/vapo-therm) during intervals when clinically appropriate to reduce skin breakdown from nasal CPAP pressure. These devices clearly have a place in the non-invasive respiratory support of the preterm neonate, but have not been as effective in maintaining the extubation status of the preterm neonate (Campbell et al., 2006; Courney & Barrington, 2007; Shoemaker, Pierce, Yoder, & DiGeronimo, 2007). Additional empiric testing is required prior to recommendation of this rotation strategy. What is clear from

the literature is the negative effects of mechanical ventilation should be avoided whenever possible (Verder, 2007; Ramanathan, 2010).

A second significant correlation reported between the incidence and severity of skin breakdown as the current weight of the infant during nasal CPAP administration, specifically smaller infants are at the greatest risk. Although the current study did not specifically identify that weight where the infant's risk is greatest, previous literature reported that infants <1250 grams were most at risk (Kopelman & Holbert, 2003; Rego & Martinez, 2002; Jatana et al, 2010; Yong et al., 2005). As we strive to extubate or not intubate smaller infants in our delivery rooms and NICUs, the use of nasal CPAP will continue to be a significant risk factor for skin injury.

Following a systematic review of literature multiple clinical factors were linked to nasal injury and breakdown during nasal CPAP in the preterm neonate (Newnam et al., 2013). Specific independent risk factors included nasal CPAP use, length of therapy, infant age and size, environmental humidity and temperature. These factors were significant indicators for the development of nasal pressure ulcers, compression necrosis, and/or nasal deformities (Fujii, Sugama, Okuwa, Sanada, & Mizokami, 2010).

In descriptive studies by McCoskey (2008) and Squires and Hyndman (2009) multiple care recommendations were described to reduce nasal skin injury during neonatal CPAP. These strategies included frequent skin assessment intervals and developmental positioning of the neonate in an effort to reduce the rate of injury through early identification of skin breakdown and/or prevention. Increased frequency of nasal suctioning needs was noted during nasal CPAP. Suctioning known to cause nasal trauma was coupled with an increased rate of coagulase negative staphylococcus (Kopelman & Holbert, 2003; Ronnestad et al., 2005). These identified factors were used to develop a stepwise regression model to explore the relationship between

these various independent variables and the dependent variable mean NSCS sum score. As noted previously, the mean post menstrual age made the largest unique contribution (beta = 0.46) and number of CPAP days also made a statistically significant contribution (beta = 0.31) to the model (see Table 5b).

Implications

The significant findings in both the frequency and severity of skin breakdown among different randomized groups, representing current nasal CPAP care in a single NICU setting has significant clinical implications. These findings aid the clinician with selecting the interface that best fits the size and shape of the infants face and nose without bias that one device is superior to others. Newly designed masks and nasal prongs which are small enough to fit infants to 500 grams have provided greater options for clinicians to select and/or rotate interfaces to reduce pressure points during therapy. Adequate supplies from manufactures continue to be a concern as appropriate sized masks and prongs to fit the ELBW are needed to be readily available to support non-ventilatory respiratory strategies in the neonate.

The use of the NSCS to measure specific skin injury or ulceration should be examined. As reported earlier, the internal consistency of the NSCS tool was measured in the study population using the Cronbach's α (0.416). This result was significantly lower than reported in the literature during the AWHONN/NANN skin care research based project. Our analysis revealed the specific variable responsible for the reduced internal consistency was dryness. As this variable is an expected physiological change that occurs as part of normal neonatal skin development during the first few weeks of life, it may have influenced the overall findings. Through the elimination of the dryness variable of the tool in the study population changed the Cronbach's α to 0.721, an acceptable result. The clinical observation of pressure or indentation of the tissue without

erythma or excoriation, a well described effect of nasal CPAP and one that was often observed during the current study may be a more valuable variable to consider during skin assessments.

Previously literature has described specific examples of neonates who were reintubated for mechanical ventilation secondary to loss of nasal tissue (nasal erosion) and bleeding, although the infants had a stable respiratory status on NCPAP therapy (Verder, 2007; Yong et al., 2005). Although this specific measure was not examined during this study, reintubation for skin breakdown while respiratory status remains stable is clinically significant and should be avoided.

A specific area of concern related to nasal CPAP is injury to the forehead, an area of pressure when mid face variable flow drivers are utilized. The report of forehead pressure necrosis resulting in permanent scarring of both the central forehead and left eyebrow was reported as a consequence of tight fitting nasal CPAP hats (Hogeling, Fardin, Frieden & Wargon, 2012) is beginning to appear in the literature. Forehead necrosis and injury has clinical significance related to nasal CPAP design, focused skin assessments and nursing care.

Limitations

The study utilized a convenience sampling method, which may generate a non-representative sample. The study was conducted at a single NICU site which may not be representative of all neonatal patients in the NICU that are 500-1500 grams and require nasal CPAP. Control for extraneous variables was challenging and often impossible during the care of these acutely ill neonates, cared for in the NICU. During the data collection phase, originally estimated to be between 4 and 6 months was extended to 9 months (April, 2012-January, 2013), we encountered multiple changes in the NICU including the implementation of an electronic medical record (EMR) and staffing pattern changes to accommodate the national reduction in resident and intern working hours. Any of these universal changes could have influenced results.

Power analysis conducted a priori demonstrated group size requirement of 24 each and total of 72 subjects necessary to demonstrate significant differences between groups. The prong group had 21 subjects enrolled; the rotation group had 22 subjects both of which were less than optimal. Care providers could override the randomized assignment if the CPAP interface did not fit the infant; we had a large number of smaller infants participate in this study and as such the number assigned to the mask group was larger. Single type of CPAP was used on all subjects in this study to reduce variability; further testing on other types of nasal CPAP (fluidic and variable flow) is needed.

Using the NSCS as a tool to assess neonatal skin injury was useful, however as the keritinazation of the neonatal skin occurs as a normal physiological process this category demonstrated poor correlation to skin breakdown or pressure injury, the goal of the project. Dryness as variable of the NSCS was independently responsible for lower than previously reported (Cronbach's $\alpha = 0.416$ vs. 0.6 to 0.7) showing the lack of reliability of this variable with the tested sample.

Summary & Conclusions

Early use of NCPAP at delivery or as respiratory support following early extubation has shown merit in improving neonatal outcomes and preventing chronic lung disease. Overall, nasal CPAP use has increased dramatically throughout NICUs across both the United States and developed nations (Jatana et al., 2010; Pelligra, Abdellatif, & Lee, 2008). This study examined differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask/rotation) used to treat RDS through a three group prospective randomized experimental study design. Significant differences between groups included current weight at start of nasal CPAP ($p = <0.001$), CPAP flow rate ($p = 0.037$).

Repeated measures ANOVA with Bonferroni correction was utilized to measure group differences for frequency and severity of injury. Significant differences between groups were found with individual NSCS scales (erythma & excoriation) two important aspects of skin breakdown in the neonate. Consideration of adding the variable of indentation or skin depression without redness/edema or excoriation may be valuable in future studies to measure skin injury related to various pressure devices.

An examination of additional risk factors that may be associated with skin breakdown during nasal CPAP administration was conducted. Stepwise regression was utilized to determine significant risk factors within and across groups in relation to skin breakdown. In the final model significant differences were found in two variables; number of days on NCPAP (beta = 0.031, $p<0.001$) and the current mean post menstrual age (beta =0.030, p 0. 006). Both variables were supported by scientific evidence, mirroring previous findings. This clinically significant finding supports guideline development to standardize neonatal CPAP care with raised awareness that smaller infant treated with nasal CPAP and longer duration of therapy increases risk for skin injury. Additional nursing care implications such as choosing a device for best fit for infant (face shape and infant size); positioning of the CPAP device; developmental position of the infant; and focused skin assessment are recommended. Standardized care including skin barriers, clinical expertise of nursing and respiratory therapy and skin care management are strategies that warrant additional research.

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Chapter 3

Supportive Tables and Figures for Chapter 1

An Integrative Review of Skin Breakdown in the Preterm Infant
Associated with Nasal Continuous Positive Airway Pressure

STUDY **Citation** **Location (Country)** **Level of Evidence**	**PURPOSE** **Research questions or stated hypotheses** **Design**	**SAMPLE/METHODS** **Subjects/Sample Size** **Selection criteria** **Measures (Primary/secondary outcome)**	**RESULTS** **Statistical Tests** **Key findings** **Feasibility of implementation**	**COMMENTS** **Clinical implications** **Study Limitations**
Robertson, N. J., McCarthy, L. S., et al. (1996). Nasal deformities resulting from flow driver continuous positive airway pressure. *Archives of Disease in Children, Fetal and Neonatal Edition, 75*(3), F209-212. United Kingdom (London) Level of evidence: IV	**Purpose:** describe incidence of nasal trauma following the use of flow driver (type) of continuous positive airway pressure in preterm infants ≤ 1500 grams **Design**: Descriptive	**Subjects/Sample Size**: 74 infants ≤ 1500gms born during enrollment period 35 infants required NCPAP 7 infants had nasal trauma (20% injury rate) **Selection criteria**: All infants were included that had reported incidence of nasal trauma or breakdown (n = 7). **Measures:** Little description regarding specific measures, only global descriptions of injury classified into three primary types, but how many infants fell into which type was not identified.	**Findings**: Three primary types of injury were reported • *Nasal snubbing* occurring after more than 60 days of NCPAP • *Flaring of the nostrils* with nasal rim becoming circular with progressive duration of NCPAP • *Columella Nasi necrosis* that may have progressed to septal necrosis was reported to occur in as little as 3 days on NCPAP. **Feasibility**: Descriptive design could be replicated in most NICU settings.	**Clinical implications**: • NCPAP interface not anatomically correct increasing risk for injury. • Clinical recommendations included: o appropriate fit (prongs to nares) o avoid tight fit o tie hats horizontally preventing the upward pull on the nose o support the weight of the tubing; rest the nose for half hour every 4-6 hours o use barriers under device o refresher training for staff; emphasis on fixation of device and assessment.
Rego, M.A., & Martinez, F.E. (2002). Comparison of two nasal prongs for application of continuous positive airway pressure in neonates. *Pediatric Critical Care Medicine, 3*(3) 239-243. Brazil, Sao Paulo Level of Evidence: II	**Purpose:** determine differences in tolerance and efficacy between two types of nasal prongs commonly used in a single NICU setting. **Design:** Prospective, randomized trial	**Subjects/Sample size:** n = 99 randomized to two groups (Argyle vs. Hudson Prongs) and then stratified into three weight categories Argyle prongs (≤ 1000 g) n= 19, Hudson prongs (1000 g) n = 14, Argyle prongs (1000-1500 g) n = 18, Hudson prongs (1000-1500 g) n = 18 Argyle prongs (1500-2500g) n = 11 Hudson prongs (1500-2500 g) n = 19 **Selection criteria:** Patients admitted to the NICU who required NCPAP **Measures:** *Tolerance* was assessed by time (hours) receiving NCPAP, number of times the catheters were out of the nostrils, feeding during therapy, abdominal distention, nasal hyperemia, nasal bleeding, and septum necrosis. *Efficacy* was measured by examining RR and HR, Silverman-Andersen retraction score and blood gas analysis.	**Findings**: Hyperemia was significantly increased in the Argyle prong (≤ 1000g) group. There was no difference between groups in the other measures of skin breakdown. Efficacy of nasal CPAP: Little changes in measured vital signs between groups and all groups showed an improvement in the Silverman-Andersen retraction score. The frequency of success did not differ between groups except for those babies who weighted >1500-2500 using the Hudson prong.	**Clinical implications**: This was clearly one of the first research designs to incorporate the differences between nasal interface, examining tolerance and efficacy to include skin breakdown. Nasal hyperemia was identified as the first sign of tissue aggression. No discussion of nursing care for the nasal interfaces

Kopelman, A.E. & Holbert, D. (2003). Use of oxygen cannula's in extremely low birth weight infants is associated with mucosal trauma and bleeding, and possibly with coagulase-negative staphylococcal sepsis. *Journal of Perinatology, 23*(2), 94-97. United States Level of Evidence: IV	**Study purpose:** #1: describe association between oxygen cannula (OC) and incidence of nasal trauma in the extremely low birth weight (ELBW) infant; #2: describe association between the use of OCs in the ELBW infant and incidence of coagulase-negative staphylococcal sepsis (CNSS). **Design:** Retrospective	**Subjects/Sample size:** #1: n = 24 #2: n = 57 **Selection criteria:** #1: First 2 ELBW infants who were extubated each month during the year of 1997 in a single site (East Carolina University Hospital, Greenville, NC) #2: All ELBW infants extubated within 28 days of birth during 1999 in a single site **Exclusion criteria**: None declared **Measures:** #1: Nasal trauma measured by nasal suctioning with and without blood in the nasal secretions. #2: Incidence of CNSS measured by lab confirmation. Comparison between OC/nasal CPAP and oxyhood also conducted.	**Findings:** #1: Infants who were treated with OCs had statically significant increased suctioning times daily (2.6 vs. 1.3 times daily) with significantly higher incidence of bloody nasal secretions (34.6% vs. 4.6%). Incidence in both suctioning and nasal trauma increased with > number of days of OC use. #2: Incidence of CNSS • occurred less frequently in infants with oxyhood treatment compared to CPAP or OC (1/13 or 8% vs. 10/44 or 23%); not significantly different. • most CNSS occurred at day #3 or day #7—may be of clinical significance. **Feasibility:** Easily replicated; retrospective chart review without intervention.	**Clinical Implications:** Secondary nasal mucosa damage possible with CPAP or OC highlights need for improved care practice strategies. Highlight possible use of the oxyhood as treatment modality. **Limitations:** • No conceptual definition of ELBW. • Retrospective review; assumption charting was accurate. • Two studies evaluated at different time frames reported in the same article; although linked were different studies and the discussion was confusing. • The purpose for #2 was association between OC and CNSS; discussion explored the time to extubation and rates of nosocomial infection with CNSS. Hypothesis and discussion should agree.
Buettiker, V., Hug, M. I., Baenziger, O., Meyer, C., & Frey, B. (2004). Advantages and disadvantages of different nasal CPAP systems in newborns. *Intensive Care Medicine, 30*, 929-930. Switzerland, Zurich Level of Evidence: II	**Purpose:** compare three different systems of nasal CPAP; the naso-pharyngeal tube and two pronged systems on newborns. **Design:** Randomized clinical study.	**Subjects/Sample size:** N = 40; stratified into 2 weight groups (1250-2500 and >2500 grams). Randomized into three groups (types of CPAP) Naso-pharyngeal tube n = 8, Hudson prongs n = 6, Infant Flow system, n = 6. **Selection criteria:** Newborn infants (<28 days) born between July 2000 and Sept 2001 in a single NICU, University Children's Hospital, Steinwiesstrasse, Zurich, Switzerland treated with CPAP. **Exclusion criteria**: CHD, NEC, or upper airway abnormalities. **Measures:** Treatment length, appropriateness for different weight classes, side effects and cost of individual therapy.	**Findings**: • Weight group > 2500 grams o median duration of CPAP 1.1 days o median time on NP 1 day o Hudson prongs 1.6 days o Infant Flow system 0.7 days • Weight group of 1250-2500 o median duration of CPAP 1.1 days o median time on NP 0.9 days o Hudson prongs 1.1 days o Infant Flow system 1.3 days Nasal injury analysis: • Weight group > 2500 grams o NP CPAP, 2 infants with moderate nasal injuries. o Hudson prong system, 2 developed moderate and 3 mild nasal injuries o Infant Flow system showed one mild and one moderate injury.	**Clinical implications**: Hudson system showed more injuries to the nose than the other systems. The NP prongs were noted to have blockage of secretions and had to be replaced q 24 hrs. **Limitations**: • 80% of infants required CPAP for < 2 days. • Small groups not powered to provide statistically significant differences. • Meta analysis did not well support the use of the naso-pharyngeal tube despite these study findings (see Cochrane review- 2008). • Cost seemed to drive the need to provide "equal" care (bias). • Weight stratifications too broad (1250-2500 and >2500).

			• Group 1250-2500 grams • NP CPAP, one mild and one moderate nasal injury • Hudson prong system, 2 patients developed moderate nasal injuries • Infant Flow system showed one severe and 2 mild injuries. Groups did not significantly differ.	
Yong, S.C., Chen, S.J., & Boo, N. Y. (2005). Incidence of nasal trauma associated with nasal prong versus nasal mask during continuous positive airway pressure treatment in very low birth weight infants: A randomized control study. *Archives of Disease in Children, Fetal and Neonatal Edition*, *90*(6), F480-483. Kuala Lumpur, Malaysia Level of Evidence: II	**Purpose: c**ompare the incidence of nasal trauma; nasal mask vs. nasal prongs during NCPAP treatment. **Design:** Randomized controlled clinical trial.	**Subjects/Sample size:** N = 137 (randomly assigned into two groups) * nasal mask group; n = 89 * nasal prong group; n = 48 Additional stratification between infants who had and who had not been intubated prior to NCPAP. **Selection criteria:** Very low birth weight (VLBW) infants; <1500 grams admitted to a single NICU in Malaysia. All diagnosed with respiratory distress treated with NCPAP via the Infant flow driver. **Exclusion criteria**: Other NCPAP methods (classical via ETT or bubble) or identified major congenital malformations. **Measures:** Presence of nasal trauma, interval between application of NCPAP and onset of trauma (days), age at onset of trauma (days), duration of CPAP (days), duration of conventional ventilation (days) prior to NCPAP, duration of NICU stay (days), oxygen requirement at 28 days and 36 weeks gestation and infant mortality. Demographic measures also included for analysis as additional risk factors.	**Findings**: • No significant demographic differences were discovered between groups. • No reported differences between duration of conventional and HF ventilation, duration of oxygen requirement or hospital stay. • No significant difference in measure of nasal trauma between groups. • Nasal prong group demonstrated a longer duration of CPAP. • Nasal prong group had nasal trauma reported earlier than the nasal mask group. • Correlation between nasal injury and additional risk factors; lower birth weight and longer mean duration of NCPAP. Overall, 12 infants in the mask group and 17 infants in the nasal prong group sustained nasal trauma.	**Clinical implications**: This study was described as the first randomized controlled study comparing nasal prong with nasal mask in VLBW infants who received treatment with nasal CPAP. Clearly designed result tables: #1 comparison of demographics, #2 clinical outcomes, and #3 associated risk factors. **Limitations**: • Single site in Malaysia may not be easily replicated. • Discussed other characteristics of preterm infant care that were contemporary and evidence based, which may have influenced study results. • Small sample sizes and not powered for less than 20% nasal breakdown rate. • Few nursing implications or strategies to reduce observed nasal trauma.
Rønnestad, A., Abrahamsen, T. G., Medbø, S., Reigstad, H., Lossius, K., Kaaresen, P. I., Engelund, I. E., Irgens, L. M., & Markestad, T. (2005). Septicemia in the first week of life in a Norwegian national cohort of extremely premature infants. *Pediatrics*,	**Purpose:** investigate causes, predictors, incidence, and the outcomes of septicemia of extremely premature infants during the first week of life. **Design:** Prospective descriptive	**Subjects/Sample size:** N = 462 **Selection criteria:** Gestational age <28 weeks or birth weight of < 1000 grams born in Norway in 1999-2000. **Measures:** Infant survival Septicemia (early onset) indicated by positive blood culture on day 2-7; (very early onset) with initial blood culture positive. .	**Findings**: • VEOS occurred in 15/462 patients. • Escherichia coli were identified as most prevalent bacteria reported. • EOS in 15/462 patients with staphylococcus aureus and coagulase-negative staphylocci being the most prevalent bacteria. • No patients were diagnosed with both VEOS and EOS. • Case fatality rates were 40% in the VEOS group and 13% in the EOS group.	**Clinical implications**: • The discussion states that n-CPAP treatment at 24 hours was a strong predictor of EOS, which suggests that the healthiest infants were at the greatest risk. • The link was discussed between the introductions of EOS through nasal route with nosocomial bacterial isolates found in the lower airway. • Additional suctioning requirements and irritation to the nasal mucosa may lead to systemic introduction of

115(3), e262-8. Norway Level of evidence: III			• Independent predictors for VEOS were clinical chorioamnionitis and increased maternal age. • In the EOS group independent predictors were not receiving systemic antibiotic therapy within 2 days of age and receiving nasal CPAP support at 24 hours of age.	these nasally colonized bacteria. **Limitations:** Association between NCPAP and EOS was based on author opinion, not specific outcome measure.
Peake, M., Dillon, P., & Shaw, N.J. (2005). Randomized trial of continuous positive airways pressure to prevent re-ventilation in preterm infants. *Pediatric Pulmonology, 39* (3), 247-250. United Kingdom Level of evidence: III	**Purpose:** compare the use of a short period (24 hours) of postextubation nasal CPAP vs. direct extubation into head box (oxygen hood) oxygen. **Design:** Prospective randomized controlled trial	**Sample size:** Total: N = 96 n = 47 randomized to receive nasal CPAP n = 49 randomized to head box oxygen. **Selection criteria:** Infants less than 32 weeks; gestation infants (October 1998-July 2001) with mechanical ventilation in the first 28 days of life, now extubated for the first time. **Measures:** *Tolerance* was successful extubation for up to one week with secondary measure at 2 weeks. *Incidence/severity* was nasal damage assessed during the study for each study group.	**Findings**: • Theoretical risk of nasal damage was minimized by frequent skin assessment and nasal prong position hourly and every 6-8 hours thereafter was an hour off nasal CPAP. • The nursing staff was trained in the use of the nasal CPAP device. • No statistical differences were found between the two group regarding reintubation rates. • The infants in the nasal CPAP group had a trend toward longer timeframe prior to reintubation.	**Clinical implications**: The importance of nasal CPAP nursing expertise noted as well as listing the possibility of nasal trauma with this therapy. **Limitations:** The practice of nasal CPAP with scheduled "time out" to some other device has been clearly shown in the literature to increase atelectasis in the preterm infant.
Campbell, D. M., Shah, P. S., & Kelly, E. N. (2006). Nasal continuous positive airway pressure from high flow cannula versus Infant Flow for Preterm infants. *Journal of Perinatology, 26*(9), 546-549. Canada Level of Evidence: II	**Purpose:** compare the feasibility of continuous positive airway pressure (CPAP) support generated by high flow nasal cannula with conventional CPAP for prevention of reintubation among preterm infants with a birth weight of <1250 g. **Design:** RCT (pilot study)	**Subjects/Sample size:** 2 group of 20 infants each group; N = 40 **Selection criteria:** <1250 grams who were extubated from mechanical ventilation were randomized into either group (HF-CPAP) or Infant Flow system using nasal prongs (brand not identified). **Measures:** *Tolerance* was the number of patients who required reintubation within 7 days. *Efficacy* was the change in oxygen use and frequency of apnea and bradycardia after extubation. *Incidence/severity* was nasal damage assessed during the study.	**Findings**: • Twelve infants in the HF- CPAP were reintubated compared to three Infant Flow (P = 0.003). • The high flow cannula group had increased oxygen use and more frequent apnea/bradycardia. • CPAP delivered by high flow nasal cannula failed to maintain extubation status among preterm infants <1250 grams as effectively as Infant Flow CPAP. *No infants had evidence of nasal injury according to the findings although the authors report that this may have been influenced by the "study effect." *Digital photography utilized as record.	**Clinical implications**: • Rapid flow from a simple NC can cause drying and bleeding of the nasal mucosa. • Head to head studies with nasal CPAP and HFNC or simple NC showed increased reintubation rates and increased oxygen requirements. • HF-CPAP not equal to efficacy of classic CPAP. **Limitations:** Study premise based on previous study which measured infants over a 6 hour period of time. Pilot study with limited sample size
Smith, L. P., & Roy, S. (2006). Treatment strategy for iatrogenic nasal vestibular stenosis in young children. *Pediatric*	**Purpose:** describe the diagnosis and treatment of infants who suffered from iatrogenic nasal vestibular stenosis as a result of treatment with	**Selection criteria:** All patients presented to the pediatric otolaryngology service of a large academic tertiary care center between 2003 and 2004. Infants who were treated with this type of iatrogenic nasal vestibular stenosis at the University of Miami (Miller School of Medicine)	**Findings**: Three former preterm infants at 25-34 weeks gestation that developed vestibular stenosis after extended use of nasal prongs for NCPAP. Common chief complaint was nasal airway obstruction with nasal blockage and	**Clinical implications**: Three examples of iatrogenic nasal vestibular stenosis; this tends to be an uncommon occurrence (according to other literature). Internal damage not obvious to external examination unless bleeding/other symptoms.

Oto – rhinolaryngology, 70, 1369-1373. USA **Level of Evidence:** VI	NCPAP as a preterm infant. **Design:** Case Report	secondary to nasal CPAP or feeding tube use as part of NICU care. **Sample size:** N = 4 (one not described here as vestibular stenosis determined as a result from nasal-gastric feeding tube use) N = 3 secondary to NCPAP. **Measures:** Physical examination/OR reports/CT in one case prior to surgical exploration/correction.	significant cosmetic deformity. • #1 a 4 month old ex-26 week preterm infant; 80% obstructed with adhesions within the nasal turbinate, vestibular retraction. • #2 a 5 year old ex-34 week preterm infant; 70% obstruction, adhesions within right nasal vestibule and collapse of the right nasal alar cartilage. • #3 a 5 month old ex-25 week preterm infant; 95% obstruction and adhesions within her nasal vestibule. Additional risk factors identified included very low birth weight (<1000), prolonged CPAP or nasal prong use.	May display symptoms later such as breathing difficulties/noisy breathing/difficulty feeding/FTT. Much less incidence in nasal trauma from CPAP has been reported per the authors as compared to previous literature on nasopharyngeal intubations. **Limitations**: Descriptive of case cluster, little to link to additional findings nationally or internationally.
Askin, D.F. (2007) Noninvasive ventilation in the neonate. *Journal of Perinatal & Neonatal Nursing, 21*(4), 349-60. Canada Level of Evidence : V	**Study purpose:** Systematic review of the topic of noninvasive ventilation (NIV) including history of therapy and nursing considerations. **Design:** Limited systematic review	**Subjects/Sample size:** 78 references cited; number of articles included in limited review not listed. **Selection criteria:** not listed **Exclusion criteria**: not listed	**Findings**: Nursing care considerations: • Prongs need frequent repositioning, mouth closed to prevent leak. • Careful patient assessment required; determine effectiveness of therapy, readiness for weaning, change in clinical assessment. • Positioning infant with proper developmental/bundling techniques decreased excessive movement of prongs against the nasal septum. • Required assessment every 2-3 hours and maintain patency of the nasal prongs. *Nasal injuries reported 20% with flow driver. *Injuries included necrosis of the columella nasi, flaring of nostrils and nasal "snubbing." *Injuries usually the result of friction, pressure and/or excessive moisture.	**Clinical implications**: Key statement: "The literature has clearly demonstrated that the success of NIV therapy increases with the increasing experience of the clinicians administering the therapy." • Time intensive requirement for nursing staff. **Limitations:** Limited review without clear methodology regarding selection/exclusion criteria.
McCoskey, L. (2008). Nursing care guidelines for prevention of nasal breakdown in neonates receiving nasal CPAP. *Advances in Neonatal Care, 8*(2), 116-124. USA	**Purpose:** describe the background and clinical indications of NCPAP use. To review the embryology/ pathophysiology of the nares and respiratory system of the neonate. Describe needed nursing assessment and care of the neonate with	**Methodology**: Descriptive article that examined the global issue of NCPAP use in the preterm infant population. Included was the issue of skin breakdown of the preterm infant during NCPAP use, pathway to injury and nursing care strategies to assess and correct problems.	**Findings:** • Pathophysiology review; including brief embryology on nasal development. • Description of CPAP mechanics with comparisons of types including clinical implications for use in the preterm population (excellent photos to illustrate description). • Example of a focused physical examination (systematic approach	**Clinical implications**: • Prevention stressed as the best strategy for decreased skin breakdown. • Focused exam utilized to identify areas that are at risk for excoriation/necrosis. • Positioning stressed as a strategy with suggestions to use body parts, hands and blanket rolls to assist with developmental positioning.

Level of Evidence: VI	NCPAP in use. **Design:** Descriptive		encouraged) to assess infant with CPAP in place. • Description of nasal breakdown with strategies for intervention/ prevention.	• Barriers are useful as preventative. • Importance of the bedside RN's ro in NCPAP care highlighted. **Limitations:** Descriptive with little scientific evidence cited to support recommended strategies.
DePaoli, A. G., Morley, C. J., Davis, P. G., Faber, B. B., & Morley, C. J. (2008). Devices and pressure sources for administration of nasal continuous positive airway pressure (NCPAP) in preterm neonates. *Cochrane Database of Systematic Reviews, 1*, CD002977. USA Level of evidence: I	**Purpose:** determine which technique of pressure generation and which type of nasal interface for NCPAP delivery most effectively reduces the need for additional respiratory support in preterm infants. **Design:** Meta-analysis of randomized or quasi-randomized trials	**Subjects/Sample size: N = 7** **Selection criteria:** A total of seven studies met inclusion criteria; randomized and quasi-randomized studies were included with the following types of participants: Preterm infants (<37 weeks) extubated to nasal CPAP after IPPV for RDS. Preterm infants (<37 weeks) initially treated with nasal CPAP within 24 hours. **Measures:** *Efficacy:* patients who required additional respiratory support by ETT and IPPV or NIPPV within a 7 day period. *Tolerance:* measured by demonstrated symptoms of respiratory failure, rescue by alternate nasal CPAP device or mode of pressure generation, CLD as measured by supplemental O2 at 28 days of life or supplemental O2 at 36 weeks gestation, effectiveness of gas exchange (RR/blood gas/saturations), NEC, weight gain, rate of sepsis, incidence of PVL and IVH, mortality, incidence of air leak (pneumothorax), apnea and bradycardia.	**Findings**: Four major categories • preterm infants extubated to nasal CPAP following a period of IPPV • preterm infants initially treated with nasal CPAP • randomized preterm infants to different nasal CPAP systems • awaiting further assessment to identify theme. *VLBW infants were included and most used methylxanthine (caffeine) to aid in treatment of RDS/apnea of prematurity. *Most studies used NCPAP settings of 4-6 cm H2O with outcome measure of reduction in the RDS symptoms; extubated >7 days. *Single study with older neonates (<36 weeks) was included. *NCPAP devices compared included measures of length and success of treatment. *Comparison between NCPAP types and treatment success (only Hudson prongs used). * Both devices provided adequate reduction in RDS symptoms.	**Clinical implications**: • Short binasal prongs seem to be more effective than the single prong devices in the reduction of RDS. • Argyle prong has a relatively high resistance to flow compared to the other form. • Argyle prongs caused the most nasal hyperemia when compared to Hudson prongs with significant differences in the rate of nasal trauma in most weight classes and gestational age neonate. • Larger babies showed fewer injury rates. • The most effective and least traumatic device REMAINS to be determined. **Limitations**: No conclusive evidence as to the best type of nasal CPAP device or nasal interface in this population. Defining the optimal short binasal prong device that proves to be less traumatic to the infant's nasal structures is needed.
Squires, A. J., & Hyndman, M. (2009). Prevention of nasal injuries secondary to NCPAP application in the ELBW infant. *Neonatal Network, 28* (1) 13-27. USA **Level of Evidence**: VI	**Purpose:** integrated review (limited) of studies that reported nasal injury secondary to NCPAP use in neonates since 1980. 2) description of nursing strategies to prevent nasal injury from CPAP in the extremely low birth weight (ELBW) infant. **Design**: Descriptive	**Sample**: The integrated review included 8 studies which described nasal injuries, type of CPAP used, additional patient risk factors and recommendations from each study. Included studies were a mixture of descriptive, retrospective, randomized controlled, and prospective randomized clinical studies.	**Findings**: • Integrated review (significant findings from each study) used to support the problem. • Description of the most common types of nasal injuries reported with anatomical descriptions/diagrams to aid in explanation. • Potentially better practices (PBPs were reported from the Vermont Oxford) which included frequent assessment (q4hrs), using the correct nasal interface for the patient, alternate between mask and prongs, application of protective barrier and	**Clinical implications**: • Review of the affected anatomy with diagrams including risk factors for breakdown in this population. • Strategies offered for bedside practice without strong clinical evidence to support practice change. • Limited list of current manufactures of NCPAP interfaces/equipment and barriers. **Limitations**: Integrated review limited to 8 studies which described mixed research methodologies without clearly defined methodology for inclusion.

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			use a minimal 2mm separation between the nasal septum and interface. • Excellent photos demonstrated nasal trauma/breakdown.	Several key strategic clinical recommendations were not cited or supported with evidence.
Diblasi, R. M. et al. (2009). Nasal continuous positive airway pressure (CPAP) for the respiratory care of the newborn infant. *Respiratory Care, 54*(9), 1209-1235. USA Level of Evidence: VII	**Purpose:** "Provide clinicians with a comprehensive updated summary of the literature to better determine the clinical responses in infants supported by CPAP, describe the operational principles and physiologic effects related to CPAP systems and define the role of CPAP for improving outcomes in premature infants with RDS." **Design:** Systematic Review	**Subjects/Sample size:** Not specifically identified; review tables included 15, 16 &12 (N = 43) articles under separate headings. **Selection criteria:** not well defined	**Findings**: • Excellent review of the history and effects of CPAP. • Various types of CPAP and interfaces described. • Recommendations for clinical management including NCPAP in preterm infants with RDS are given. • Recommendations for clinical management of secondary complications of NCPAP including a description on nasal injury.	**Clinical implications**: Sound clinical management section including implications and guidelines useful during routine nursing care: • 5cm H20 or > to maintain FRC than lower levels of NCPAP • Proper airway positioning of the infant • Close monitoring for changes in respiratory assessment critical. • Strong recommendation for standard NCPAP bedside practice based on scientific evidence. **Limitations:** No description of methodology or selection for articles included in review. Clinical management of these infants supported by CPAP was based primarily on anecdotal experience and opinion than on scientific evidence. Practices vary widely among individual NICU's with little consensus regarding aspects of care, weaning, and equipment.
Davis, P. G., Morley, C. J., & Owen, L. S. (2009). Non-invasive respiratory support of preterm neonates with respiratory distress: Continuous positive airway pressure and nasal intermittent positive pressure ventilation. *Seminars in Fetal &Neonatal Medicine, 14*(1), 14-20. Australia Level of Evidence: V	**Purpose:** review of literature on the topic of non-invasive respiratory support of the preterm neonate with respiratory distress (RDS). **Design:** Limited systematic review	**Subjects/ Sample size**: N = 75 cited articles with n = 8 indicated by the authors as key works. The total number of reviewed studies was not indicated. **Selection criteria:** RCTs or metal analysis of these trials. **Measures:** Major headings included; how does CPAP work, CPAP delivery, practical problems of NCPAP (to include nasal trauma), clinical indications for NCPAP, nasal intermittent positive pressure ventilation (NIPPV), clinical indications for NIPPV, what do we still need to learn about NIPPV and conclusions. Subheadings for each sections included highlighted findings and lapses discovered in the literature.	**Findings**: • Nasal prongs and nasal mask have advantages over other CPAP interfaces; infant's nose and mouth can be more easily observed and cared for during the therapy. • Nasal trauma most often caused by incorrect positioning of the prongs. • Correct space allowance between the prongs and nasal columella has been demonstrated helpful. • Injury also reported inside the nose. • Proper prong size, constant nursing vigilance and attention to the correct prong position are required for therapy success.	**Clinical implications**: • Short bi-nasal prongs were more effective than NP prongs and single nasal prongs. • NCPAP provided as initial therapy in the delivery room provides an alternative to mechanical ventilation. • NCPAP administration provides improved success rates when transitioning patients from mechanical ventilation to NIPPV. **Limitations:** Only used RCTs in review may have been useful studies to include that were not randomized.

do Nascimento, R. M., Ferreira, A. L., Coutinho, A. C., & Santos Veríssimo, R. C. (2009). The frequency of nasal injury in newborns due to the use of continuous positive airway pressure with prongs. *Revista Latino-Americana de Enfermagem*, *17*(4), 489-494. Brazil Level of Evidence: V	**Purpose:** determine the frequency of nasal injuries in newborns through the use of continuous positive airway pressure with prongs. **Design:** Descriptive cross-sectional	**Subjects/ Sample size:** N = 147; convenience sample housed in single Brazil NICU from 10/2007 to 2/2008. **Selection criteria:** Newborns (term and preterm) located in a single NICU in Brazil who required nasal CPAP with prongs for ≥ 2 days. **Measures:** *Incidence* described as the number of occurrences. *Severity* classified as mild (hyperemia), moderate (hyperemia and erosion) and severe (bleeding and erosion).	**Findings**: Lesions were observed in all newborns who received treatment for ≥ 2 days. • Severity was classified as: mild (hyperemia) (79.6%), moderate (19.7%) (hyperemia and erosion) and severe (0.7%) (bleeding and erosion). • The use of prongs for more than two days represents a risk factor for the lesions to develop. • The infants who had CPAP in place for > 2 days had a higher incidence of moderate or severe nasal lesion. *Barriers were used in 97% of the infants observed. *Greater than 50% of the infants had smaller prongs in place than manufacture recommendation.	**Clinical implications**: • Appropriate size of nasal prong should be reinforced. • Appropriate cap size for the infant critical as too much movement can lead to increased incidence of nasal trauma. • Training and educational programs should be administered to improve newborn care with CPAP. **Limitations:** Study population included preterm and term infants not stratified to gestational age or birth weight.
Owen, L. S., Morley, C. J., & Davis, P. G. (2010). Pressure variation during ventilator generated nasal intermittent positive pressure ventilation in preterm infants. *Archives of Disease in Children, Fetal and Neonatal Edition*, *95*(5), F359-364. Australia, Melborne **Level of Evidence**: IV	**Purpose:** quantify the delivered peak pressures during the administration of non-synchronized ventilator-generated NIPPV using nasal prongs. **Design:** Observational cohort study	**Subjects/ Sample size:** N = 11 convenience sample, (a total of 9456 mechanical inflations). **Selection criteria:** Infants born < 30 weeks gestation and more than 48 hours old that were receiving ventilator-generated NIPPV delivered via Hudson prongs. **Measures:** *Descriptive* data were collected to describe groups. *Efficacy* was measured using a calibrated respiratory function monitor at the inspiratory limb of the Hudson prong. *Tolerance* was measured by RR, oxygen sats, spontaneous breathing and tidal volume which were recorded using various tools.	**Findings**: • Wide variability in the inflation rates and peep measurements (usually 5 cm below set parameters). • Delivered pressure varied considerably even when the infant was quiet/sleeping (stable resp pattern) based on video information. • Highest pressures were recorded with infant movement and noted desaturations occurred most commonly after these episodes. • Loss of pressure was noted with mouth leak, laryngeal resistance and glottis size. • NO documented correlations between the prong size and either delivered pressure, duration of nasal prong support or infant weight. • The only significant mention of nasal trauma/skin issue was "size and shape of the infant's nostril changes making it difficult to fit prongs consistently to infants who received CPAP or NIPPV."	**Clinical implications**: • No differences were found between the delivered pressures whether the PIP was set at 20 or 25 cm as the leak was noted to be greater with increasing pressure; utilizing the lower end of the spectrum is encouraged with titration to infant effect/need. • Loss of pressure with mouth leak and other factors should be considered during positioning and care of the neonate on NCPAP or NIPPV. **Limitations**: No correlation with either the length of time the infant had prongs in place or size of prongs.

Fischer, C., Bertelle, V., Hohlfeld, J., Forcada-Guex, M., Stadelmann-Diaw, C., & Tolsa, J. (2010). Nasal trauma due to continuous positive airway pressure in neonates. *Archives of Disease in Children; Neonatal-Fetal Edition, 95*, F447-F451. Lausanne, Switzerland **Level of Evidence**: III	**Purpose:** describe the incidence and the severity of nasal trauma secondary to NCPAP in neonates. **Design:** Prospective observational study .	**Subjects/Sample size:** N = 1133 (eligible- treated with NCPAP). n = 144 patients (lost to follow up) Final sample n= 989 infants for a total of 13,719 CPAP days. **Selection criteria:** Infants admitted to the neonatal intensive care unit (NICU) at the University Hospital of Lausanne, Switzerland between January 2002 and December 2007 who were treated with NCPAP. **Measures:** Incidence and severity of nasal trauma as measured by the US National Pressure Ulcer Advisory Panel (NPUAP) as stage I/II or III. Stage I was persistent erythma, II was superficial ulceration, and stage III was necrosis. Demographic neonatal variables were also recorded for analysis.	**Findings:** • Nasal trauma was reported in 420 (42.5%) of the patients. Most of the incidence was stage I (88.3%), stage II (11%), and stage III (0.7%). • The severity of nasal trauma was inversely correlated with the gestational age and birth weight. • Significant correlation was also noted with those infants staying in the NICU >14 days or having NCPAP for > 5 days in duration. Of note: The incidence of nasal trauma was usually noted by day 2 of use and rarely after the 9th day of CPAP use. **Feasibility:** The length of time (>5 yrs) that data collection continued made this study difficult to conduct/replicate.	**Clinical implications**: Nasal trauma secondary to NCPAP identified as a significant adverse complication with confirmed incidence ~ 40%. **Limitations:** Single site although large sample size. Single CPAP device (Infant Flow driver system). Difficult to compare studies with varied classification used to measure severity of nasal breakdown
Tagare, A., Kadam, S., Vaidya, U., Pandit, A., & Patole, S. (2010). A pilot study of comparison of BCPAP vs. VCPAP in preterm infants with early onset respiratory distress. *Journal of Tropical Pediatrics, 56*(3), 191-194. India Level of evidence: III	**Study purpose:** compare efficacy and safety of bubble CPAP (BCPAP) and ventilator CPAP (VCPAP) in preterm neonates with moderate respiratory distress syndrome (RDS). **Design:** Prospective RCT (Pilot)	**Subjects/Sample size:** N =30; randomization into two groups (BCPAP or VCPAP). **Selection criteria:** Preterm neonates (gestation <37 weeks) with a diagnosis of RDS and oxygen requirement >30% within the first 6 hrs of life. Study timeframe August 2007-April 2008 in a tertiary NICU in Pune, India. **Study Variables**: *Efficacy* was measured by the improvement in either oxygen requirement and/or Silverman-Anderson score (RDS measure).	**Findings**: • The success rate between the two types of CPAP (bubble vs. ventilator) was comparable in those preterm infants with moderate RDS. • Most common problem with NCPAP was the dislodgement of the short binasal prongs (Fischer Paykel in the bubble device and Argyle for the VCPAP). • The mean duration of CPAP was comparable between groups. • Nasal septal injury was seen in 27% of the BCPAP group (4/15) without incidence with the VCPAP group.	**Clinical implications**: Bubble CPAP is less costly to deliver than vent CPAP so would be important to ensure efficacy and safety of this method for potential use in NICUs with limited resources. **Limitations:** Small sample size; small number in each group, statistically difficult to determine differences. Specifically tested on patients with moderate RDS. Results may be not be generalized to all preterm infants. Need for cost containment may create bias.

Günlemez, A., Isken, T., Gökalp, A. S., Türker, G., & Arisoy, E. A. (2010). Effect of silicon gel sheeting in nasal injury associated with nasal CPAP in preterm infants. *Indian Pediatrics*, *47*(3), 265-267. India Level of Evidence: II	**Purpose:** describe whether the use of silicon gel sheeting on nares during NCPAP could reduce the incidence and severity of nasal injury in premature infants. **Design:** Randomized Control Trial	**Subjects/ Sample size:** N = 179; randomized into two groups Group 1 (n = 87) with no silicon gel application Group 2 (n = 92) with silicon gel sheeting on the surface of nares during NCPAP. **Selection criteria:** Preterm infants admitted to the NICU 11/2005 to 7/2007 who were receiving NCPAP. **Measures**: *Incidence* described as the number of occurrences. *Severity* described as bleeding, crusting, excoriation or columella necrosis).	**Findings**: • Nasal injury developed in 13 (14.9%) neonates in Group 1 and 4 (4.3%) newborns in Group 2 (OR: 3.43; 95% CI: 1.1-10.1; P<0.05). • The incidence of columella necrosis was also significantly higher in the Group 1 (no silicon sheeting) (OR: 6.34; 95% CI: 0.78-51.6; P<0.05). • It was concluded that the silicon gel application may reduce the incidence and the severity of nasal injury in preterm infants on nasal CPAP.	**Clinical implications**: • Major underlying mechanism of nasal injury is pressure generated on the columella by prongs. • The maxillary spine behind the columella and its surface is very small; CPAP places direct pressure on this area. • Infants should be closely monitored during CPAP administration. • Adequate nursing care and vigilance (not well defined) described as important to improved outcomes. **Limitations:** Single site/single flow driver CPAP device.

Table 1: Skin breakdown of the neonate during nasal continuous positive airway pressure (CPAP) use
Level of evidence taken from:
Melnyk, B. M., & Fineout-Overholt, E. (2005). Evidence-based practice in nursing and healthcare: A guide for best practice. Philadelphia: Lippincott, p. 10.

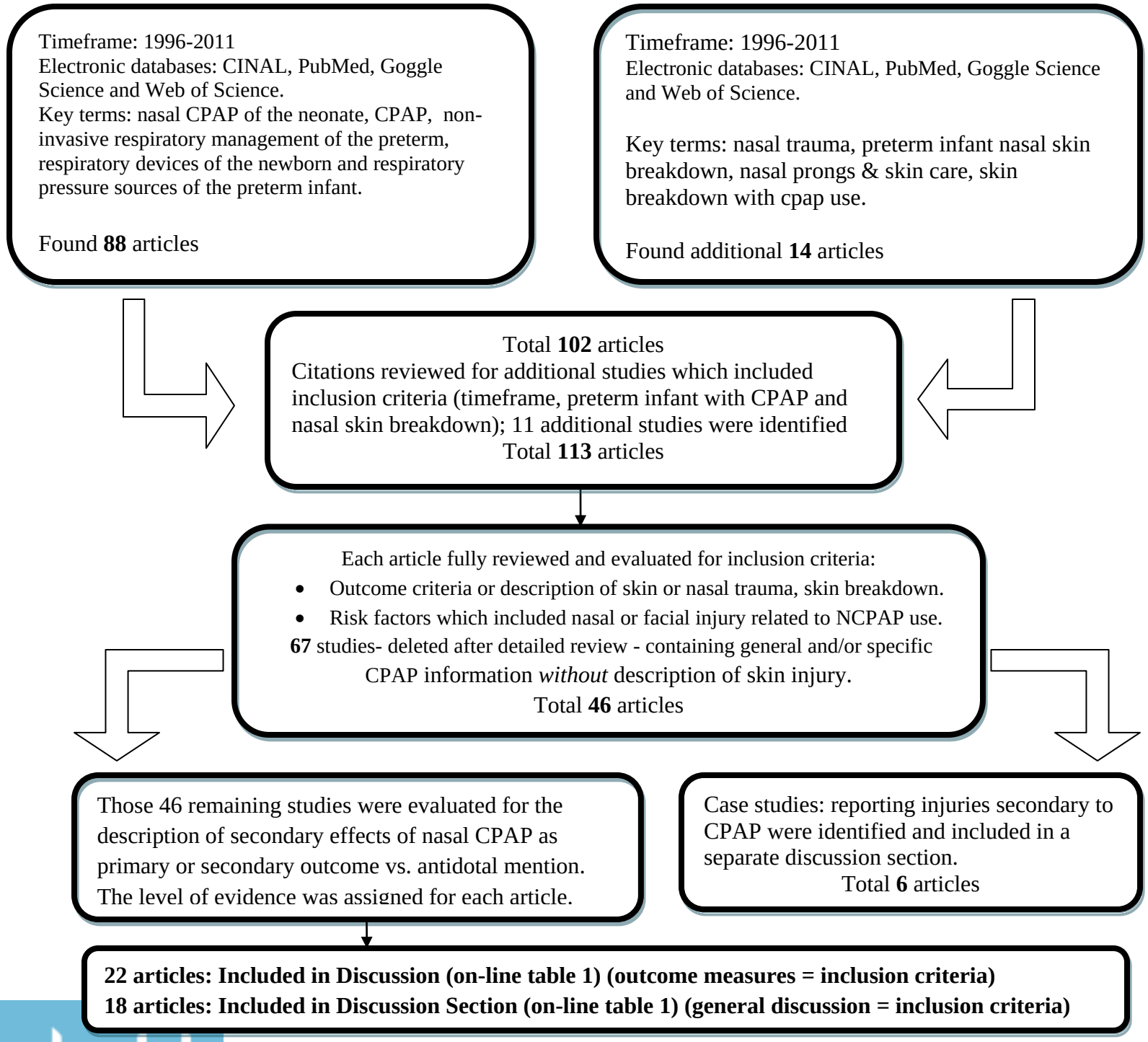

Figure 1: Decision Tree for inclusion/exclusion in the Integrative Review

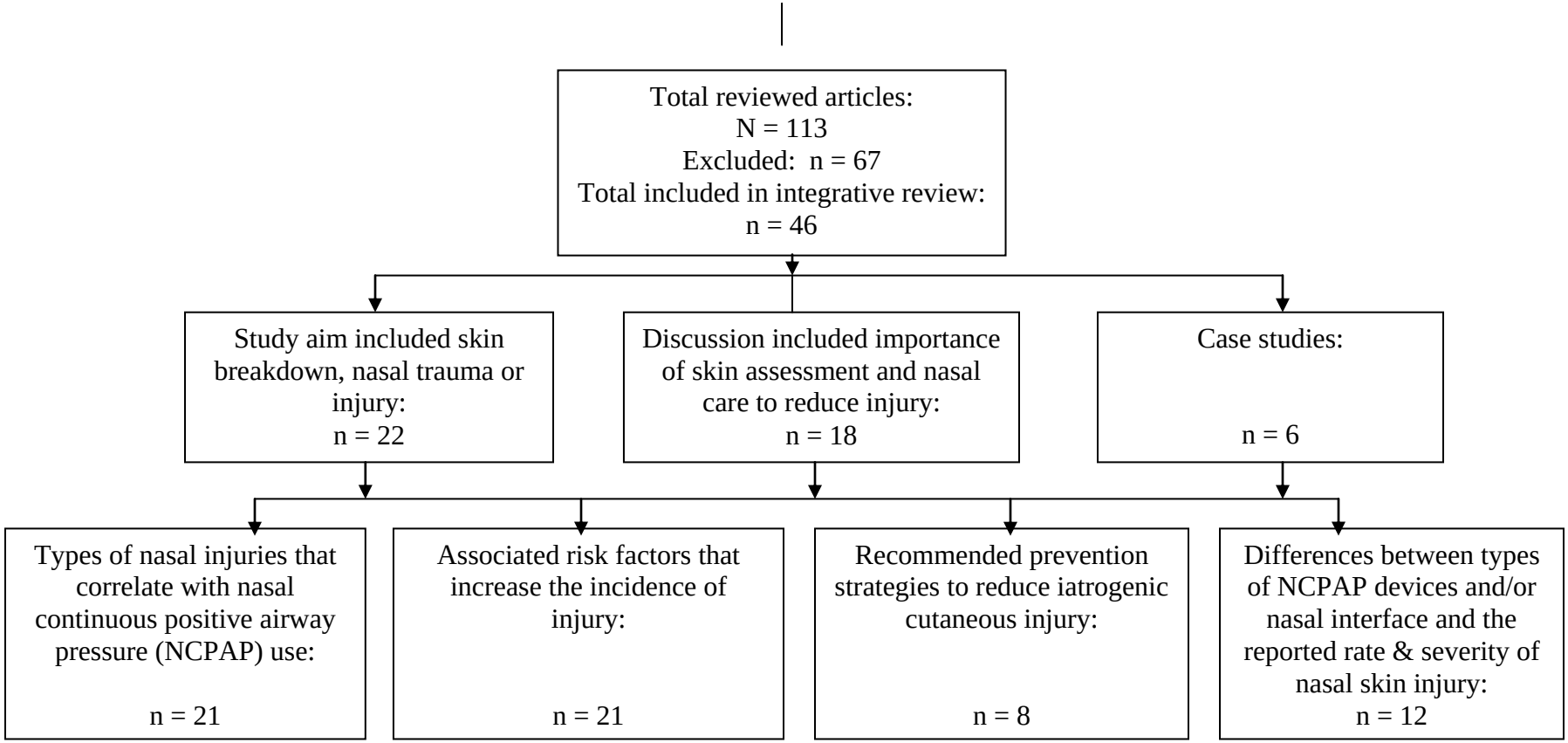

Figure 2: Decision Tree (articles categorized into 3 major topical headings, then delineated into four subject categories)
Note: There were 16 articles that included information applicable to more than a single subject category and, thus, are listed within more than one subject category.

Supportive Tables and Figures for Chapter 2

A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

Table 1: sample representation for each stratified birth weight per group with comparisons among groups for consistency

Table 2: Demographic variables for total sample

Table 3: Demographic for each nasal interface group. Comparisons between groups conducted with p value reported for each comparison.

Table 4: Variable correlation table

Table 5a: Independent variables entered into the multiple regression model

Table 5b: Predictors of skin breakdown risk factors during nasal CPAP use in the neonate <1500 grams

Figure 1: Consort table for study screening and enrollment

Block Stratification according to birth weight	Continuous Mask	Continuous Prongs	Rotation Mask/Prongs	p value
ELBW #1 (500-750 grams)	13 (37.1%)	4 (19%)	6 (27.3%)	0.123
ELBW #2 (751-1000 grams)	16 (45.7%)	10 (47.7%)	9 (47.9%)	0.67
ELBW #3 (1001-1250 grams)	5 (14.3%)	4 (19%)	7 (31.8%)	0.99
VLBW #1 (1251-1500 grams)	1 (2.9%)	3 (14.3%)	0 (0%)	0.114
Total sample	N = 35	N = 21	N = 22	

Table 1: sample representation for each stratified birth weight per group with comparisons among groups for consistency.

Variable	N	Mean	Minimum	Maximum	SD
Birth weight (grams)	78 Δ	873.36	500	1460	220.70
Birth gestational age (weeks)	78 Δ	26.77	23.00	32.00	1.90
Current weight (grams)	730●	1065.24	720	3170	373.99
Current age (weeks)	726●	3.87	0.14	14.43	3.23
Time to CPAP initiation (weeks)	726●	3.87	0.14	14.43	3.23
Number of CPAP days	730●	4.32	1	16	3.22
CPAP temperature	730●	36.38	0	38	2.70
CPAP flow rate (lpm)	730●	5.35	4	7	0.66
Oxygen supplementation (%)	730●	0.25	0.21	0.60	0.6
Amount of humidity provided (C)	730●	25.59	0	86	34.26

Table 2: Demographic variables for total sample

Δ Total number of participants in the study

● Number of data collection episodes

Table 3: Demographics for each nasal interface group. Comparisons between groups conducted with resulted p value for each comparison

Groups (→)	Continuous Mask (N = 35)			Continuous Prongs (N = 21)			Rotation Mask/Prongs (N = 22)			P value
Variable (↓)	Mean	Minimum	Maximum	Mean	Minimum	Maximum	Mean	Minimum	Maximum	
Birth gestational age (grams)	26.65	23.29	31.14	27.26	24.00	32.00	26.51	23.00	30.14	0.388
Birth weight (grams)	826	500	1420	941	610	1460	884	520	1170	0.164
Current weight during CPAP (grams)	934	520	1720	1142	750	2145	1196	710	3170	0.000*
Post menstrual age during CPAP (weeks)	2.32	0.14	9	2.90	0.14	14.14	3.33	0.14	9.86	0.109
Mean FIO2 administered (%)	0.26	0.21	0.60	0.24	0.21	0.47	0.24	0.21	0.34	0.189
Time to NCPAP (weeks)	3.47	0.14	10.71	3.47	0.14	14.43	4.65	0.14	11.00	0.109
Number of CPAP days	4.79	1	15.50	3.45	1.50	8.50	5.68	1.50	15	0.093
CPAP temperature (C)	36.20	0	38.00	36.10	0	37.30	36.70	26.00	37.50	0.173
CPAP flow rate in LPM	5.38	4.38	6	5.59	4.50	6.50	5.30	4.58	6.07	0.037*
Incubator humidity during CPAP (C)	37.15	0	81.67	29.44	0	81.25	29.37	0	72.60	0.287
Developmental positioning	1.81	1	2	1.77	1	2	1.83	1	2	0.229
Nasal suctioning	0.94	0	5	0.70	0	4	0.80	0	4	0.323
Use of Normal Saline during suction	2.78	1	3	2.90	1	3	2.83	1	3	0.059
NSCS score (erythma)	1.31	1	2	1.28	1	2	1.18	1	3	0.001*
NSCS score (excoriation)	1.19	1	3	1.18	1	3	1.10	1	3	0.007*
Summary NSCS score	4	3	7	4	3	7	4	3	7	0.716

(*) denotes significance level of 0.05 or less

Variable	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1. Birth gestational age (gr)	--															
2. Birth weight (grams)	.716	--														
3. Current weight during CPAP (gr)	.140	.311	---													
4. PMA during CPAP (weeks)	-.555	-.560	.523	--												
5. Mean FIO2 administered (%)	-.467	-.369	-.080	.151	--											
6. Time to NCPAP (weeks)	-.555	-.560	-.523	1.00	.155	--										
7. Number of CPAP days	.000	.000	.051	.255	-.068	.255	--									
8. CPAP temperature (C)	.085	-.084	.025	.067	.045	.067	-.002	--								
9. CPAP flow rate in LPM	.054	.012	-.011	.154	.126	.192	.126	-.250	--							
10. Incubator humidity (%)	.165	.383	.366	-.325	.727	.253	.727	.310	-.047	--						
11. Developmental positioning	.099	.037	.026	-.033	-.089	-.033	.039	.037	.001	.042	--					
12. Nasal suctioning	-.037	-.029	-.061	.031	.074	.031	.024	.058	-.012	-.062	.008	--				
13. Use of Normal Saline w/suctioning	.085	.091	-.003	-.040	-.023	-.040	-.100	-.010	-.023	.047	.014	.269	--			
14. NSCS score (erythma)	-.107	-.054	-.093	-.053	-.004	-.053	.207	.046	-.021	.061	.003	.009	.035	--		
15. NSCS score (dryness)	-.284	-.292	-.167	.394	.128	.394	.301	.022	-.191	-.461	.032	.039	.093	.034	--	
16. NSCS score (excoriation)	.057	.071	-.073	-.041	-.008	-.041	.216	.038	-.002	.040	0.63	.022	.088	.571	.055	--
17. Summary NSCS score	.290	-.282	.015	.176	.065	.176	.360	.051	-.060	-.210	.045	.007	.105	.747	.594	.727

Table 5a: Independent variables entered into the multiple regression model

Independent Variables	β	t - statistic	p value
Birth weight	-0.070	-0.534	0.595
Number of CPAP days	0.031	2.808	0.006
CPAP flow rate in LPM	-0.049	-0.433	0.667
Mean incubator temp	-0.170	-1.097	0.276
Mean post menstrual age at time of nasal CPAP	0.030	2.414	<0.001
Percent nasal suctioning	0.073	0.680	0.499
Percent oral suctioning	-0.052	-0.473	0.637
Percent nasal/oral suctioning	0.014	0.131	0.896
Developmental position utilized	-0.004	0.033	0.974

Dependent variable: Mean NSCS sum score

Table 5b: Predictors of skin breakdown risk factors during nasal CPAP use in the neonate <1500 grams

Model	R	R square	Standard error	Df1	Df2	F	p-value
Model 1 - Mean post menstrual age at time of nasal CPAP (constant)	0.399	0.159	0.48	1	73	13.82	<0.001
Model 2 - Mean post menstrual age at time of nasal CPAP; number of CPAP days (constant)	0.492	0.221	0.46	1	72	11.51	0.006

Dependent variable: Mean NSCS sum score

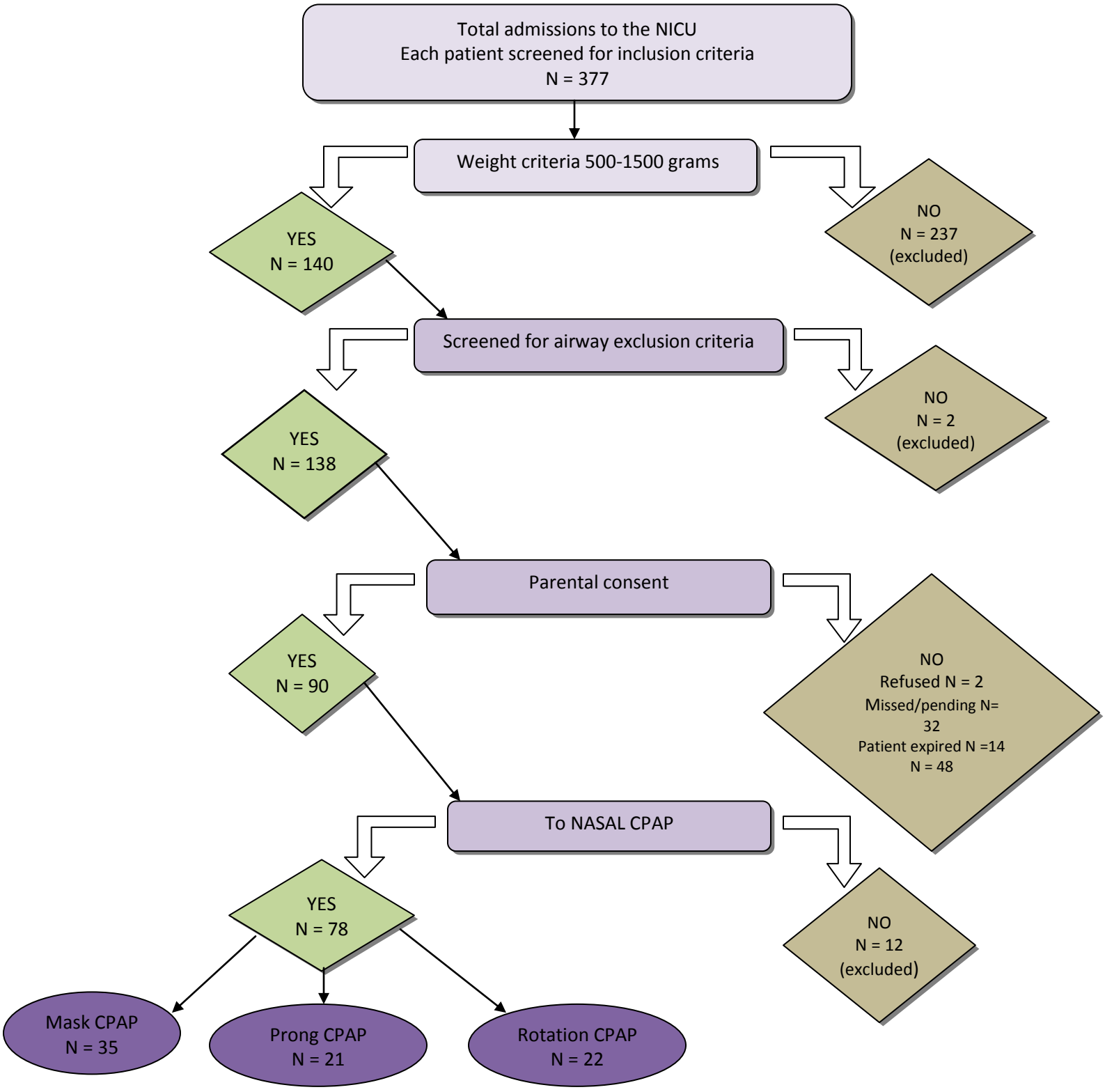

Figure 1: Consort table for study screening and enrollment

Appendix A.

The following published research plan was submitted to and approved by the Virginia Commonwealth University Institutional Review Board

VCU IRB
FULL and EXPEDITED STUDY INITIAL REVIEW SUBMISSION FORM

IRB NUMBER: _____

DO NOT DELETE SECTIONS OF THIS FORM

SECTION 1: PRINCIPAL INVESTIGATOR AND OTHER VCU PROJECT PERSONNEL

1. PRINCIPAL INVESTIGATOR: LIST NAME AS IT EXISTS IN THE HUMAN RESOURCE SYSTEM (HRS)

NOTE: See guidance on who can serve as PI at **HTTP://WWW.RESEARCH.VCU.EDU/IRB/WPP/FLASH/IX-1.HTM**)

Name (Last, First, MI):	McGrath, Jacqueline M.
PI Title and Degrees:	Associate Professor of Nursing, PhD, RN, NNP, FNAP
VCU Department:	School of Nursing
VCU P.O. Box # (must provide 6-digit box #):	PO Box 980567
Phone/Pager/Fax #'s:	**(804) 828-1930**
VCU Email:	**MCGRATHJM@VCU.EDU**

2. PROJECT PERSONNEL TO BE INCLUDED IN CORRESPONDENCE: These persons may be copied on correspondence from the IRB. (ALL project personnel are to be listed on a separate *VCU IRB Study Personnel Roster*)

RESEARCH COORDINATOR (if applicable):

Name (Last, First, MI), Degrees:		Email:	

TRAINEE (Postdoctoral Scholar, Fellow or Resident) (if trainee project):

Name (Last, First, MI), Degrees:		Email:	

STUDENT (if student project):

Name (Last, First, MI), Degrees:	Newnam, Katherine M., PhD (c), RN, NNP, CPNP	Email:	**NEWMANKM2@VCU.EDU**

SECTION 2: PROJECT INFORMATION

1. PROJECT TYPE (check one):

☐ **BIOMEDICAL** — Research involving medical interventions and/or FDA-regulated products

SOCIAL-BEHAVIORAL (check one): — Social or behavioral research that does **NOT** involve medical interventions or FDA-regulated products

- ☐ **SOCIAL-BEHAVIORAL QUALITATIVE**
- ☒ **SOCIAL-BEHAVIORAL QUANTITATIVE**
- ☐ **SOCIAL-BEHAVIORAL QUALITATIVE & QUANTITATIVE**

2. TITLE OF PROTOCOL SUBMISSION:
A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

3. Are there any **IRB-APPROVED PROTOCOLS ASSOCIATED** with this submission? ☐ YES ☒ NO
If YES, please list the associated VCU IRB Protocol #'s:
Note: If this submission is associated with other new projects submitted to the IRB (but not yet approved), please attach a cover memo to your submission noting related projects.

4. Is this a **TRAINEE OR STUDENT PROJECT** in which activities will be carried out by that individual under your supervision? ☒ YES ☐ NO

SECTION 3: TYPE OF SUBMISSION

Please check all categories that apply to the study being submitted for IRB review.

☒ **RESEARCH PROJECT**

☐ **FDA REGULATED RESEARCH***

* FDA regulated research includes:
a) any research involving a drug or biologic intended for human use (other than the use of an approved drug in the course of medical practice);
b) any research designed to test the safety and effectiveness of a device; or
c) research involving ANY FDA regulated product where the intent is to submit data to the FDA in support of a research or marketing application. Regulated products include foods & dietary supplements, infant formulas, food & color additives, and electronic products.

☐ **CLINICAL TRIAL**

See definition of clinical trial at http://www.cto.vcu.edu/about/index.html#ClinicalTrialDefinitition

☐ **HUMANITARIAN USE DEVICE**

See guidance at http://www.research.vcu.edu/irb/wpp/flash/XVI-2.htm

☐ **TREATMENT USE OF INVESTIGATIONAL DRUG/DEVICE**

See guidance at http://www.research.vcu.edu/irb/wpp/flash/XVI-5.htm

SECTION 4: TYPE OF REVIEW

REVIEW TYPE REQUESTED (check one):

☐ **FULL BOARD REVIEW**

NOTE: Industry-sponsored research **MUST** be submitted to Western IRB (WIRB) for review. See instructions available at http://www.research.vcu.edu/forms/wirb.htm

☒ **EXPEDITED REVIEW**

* **EXPEDITED CATEGORIES:** Type 1

* Identify the expedited category or categories in which your research falls (See Expedited Review Guidance at http://www.research.vcu.edu/irb/reviewtypes.htm)

NOTE: For projects requesting exempt review determination, use the exempt review submission form, available at http://www.research.vcu.edu/forms/vcuirb.htm.

SECTION 5: SPONSOR DATA

1. Does the research project involve a **DIRECT FEDERAL AWARD** made to VCU (or a research funding proposal for such)? ☐ YES ☒ NO

2. Have you submitted a related research funding proposal(s) to the VCU Office of Sponsored Programs (OSP)? ☐ YES ☒ NO

If YES**,** you must provide (a) **NAME OF THE FUNDING SOURCE** AND (b) **PT/PD #** for each related proposal **(regardless of the funding source)**:

(1) **(2)** **(3)**

NOTE: Federal regulations require IRB approval of **NEW**, **RESUBMISSION**, or **COMPETING CONTINUATION** FEDERAL RESEARCH FUNDING PROPOSALS. If there is a new, resubmission, or competing continuation VCU federal research funding proposal associated with this research project, you must include a copy of your ENTIRE proposal (exclusive of appendices) and OSP Internal Approval Form with this submission. Failure to do so may delay your research award start date. Other sponsors also may require IRB approval of research proposals. It is the investigator's responsibility to determine whether this review is needed. If the sponsor does not require IRB approval of research proposals, DO NOT submit them to the IRB for review. If you have questions about whether your sponsor requires IRB approval of your research funding proposal, please contact OSP.

SECTION 6: STATEMENTS OF COMPLIANCE

PRINCIPAL INVESTIGATOR STATEMENT OF COMPLIANCE:

I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including myself, sub/co-investigators, research coordinators, trainees, and students have completed the VCU required training on human subjects protection. I agree to a continuing exchange of information with the VCU IRB including the requirements to (i) obtain IRB approval before making non-emergency changes/revisions to the project, except where necessary to eliminate apparent immediate hazards to subjects or others, (ii) provide progress reports to the VCU IRB at their request (and at least annually), and (iii) report promptly to the IRB all unanticipated problems and serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the IRB).

SIGNATURE OF INVESTIGATOR: **DATE OF SIGNATURE:**

TRAINEE OR STUDENT INVESTIGATOR STATEMENT OF COMPLIANCE (IF APPLICABLE):

This is a student or trainee project, which will potentially be presented outside the classroom and/or published. I understand that I may not proceed with the research without first receiving a formal written letter of approval from the VCU IRB. I certify that I have completed the VCU required training on human subjects protection.

SIGNATURE OF TRAINEE OR STUDENT: **DATE OF SIGNATURE:**

DEPARTMENT/DIVISION CHAIRPERSON OR DEAN STATEMENT OF COMPLIANCE*see NOTE:

I certify that the research project referenced in this document (check one of the following):

☐ Has been subjected to scrutiny within a VCU Committee (i.e., Massey Cancer Center Protocol Review, Clinical Research Center [CRC]) or sponsor study group (i.e., NIH or other agency with appropriate scientific expertise) and found to be scientifically acceptable.

☐ Has been subjected to scrutiny by my designee or me according to criteria that include the following, as applicable: appropriate power and sample size, currency of literature review, and relevance of hypothesis or research question and found to be scientifically acceptable.

PRINT NAME, DEGREES, TITLE OF DEPARTMENT/DIVISION CHAIRPERSON OR DEAN:

SIGNATURE OF DEPARTMENT/ DIVISION CHAIRPERSON OR DEAN: **DATE OF SIGNATURE:**

***NOTE:** Department/Division Chairperson cannot sign if he/she is a co-investigator on the project. In these instances, a Dean's signature is required. If a designee is signing the Statement of Compliance, his/her name, degrees, and title should be listed.

SECTION 7: PROJECT DETAIL

ANSWER ALL OF THE FOLLOWING QUESTIONS (by marking the appropriate box to the right):

1. Will DRUG(S), BIOLOGIC(S), OR DEVICE(S) be utilized for this project? ☐ YES ☒ NO*
If NO, skip to Question 7.

2. Will DRUG(S) be administered in this project? If YES, supply the following information (attach a separate sheet if necessary): ☐ YES ☐ NO

DRUG NAME(S): _____

2-A. If drug is INVESTIGATIONAL or involves an IND, please complete the following:
IND #: _____ **HELD BY** (check one): ☐ SPONSOR ☐ INVESTIGATOR ☐ N/A

- If IND is held by the SPONSOR, provide copy of the INVESTIGATOR'S BROCHURE and the SPONSOR'S PROTOCOL
- If IND is held by the INVESTIGATOR, provide copy of the IND APPLICATION submitted to the FDA and safety information
- Attach copy of FDA FORM 1572

3. Will BIOLOGIC AGENTS be used in this project? If YES, supply the following information: ☐ YES ☐ NO

BIOLOGIC NAME(S):

4. Will the VCU/VCUHS INVESTIGATIONAL DRUG SERVICE PHARMACY (IDS) be utilized? (required for all inpatient projects) ☐ N/A** ☐ NO*

***If NO, you must submit a descriptive plan regarding appropriate drug storage and dispensing for an investigational drugs or biologic agents/drugs used in the research to the Investigational Drug Service (IDS) Pharmacy. Guidance and the form for describing the management plan is located at http://www.investigationaldrugs.vcu.edu. Submit the form to the IDS. Upon IDS's receipt of the plan, an email response containing the plan is generated. Include the IDS confirmation or receipt with this submission. For assistance, please call the Investigational Drug Pharmacy at 828-7901.

**Submitting a plan to the IDS is not required if: 1) no drugs are used in the study, 2) the drug used in the study is FDA-approved, considered standard of care and is a patient-charge item, 3) off-label use of such a drug is not being studied and 4) there is no protocol requirement for specific management of the drug.

5. Are you evaluating MARKETED MEDICAL DEVICE(S) (including 510k devices) in this project? If YES, supply the following information: ☐ YES ☐ NO

DEVICE NAME(S): _____

NAME OF MANUFACTURER: _____

NOTE: In addition, provide any supporting documentation regarding LEVEL OF RISK (SIGNIFICANT vs. NON-SIGNIFICANT RISK)

6. Are you evaluating INVESTIGATIONAL MEDICAL DEVICE(S) or a NEW USE FOR MARKETED MEDICAL DEVICE(S) in this project? If YES, supply the following information: ☐ YES ☐ NO

DEVICE NAME(S): _____

NAME OF MANUFACTURER: _____

IDE #: _____ **HELD BY** (check one): ☐ SPONSOR ☐ INVESTIGATOR ☐ N/A

- **If IDE is held by the SPONSOR**, provide a copy of the INVESTIGATOR'S BROCHURE and the SPONSOR'S PROTOCOL
- **If IDE is held by the INVESTIGATOR**, provide a copy of the IDE APPLICATION submitted to the FDA

NOTE: In addition, provide any supporting documentation regarding LEVEL OF RISK (SIGNIFICANT vs. NON-SIGNIFICANT risk)

7-A. Does this project involve the use of any procedure(s) that will expose the research subject to IONIZING RADIATION?
☐ YES (Proceed to 7-B) ☒ NO (Proceed to Question 8)

7-B. If all of these procedures are for the direct clinical benefit of the research subject/patient, check YES. If any of these procedures are of research interest only and will not affect the clinical management of the research subject, check NO.
☐ YES (no further information required) ☐ NO (Proceed to 7-C)

7-C. RADIATION SAFETY COMMITTEE (RSC) approval is required if you answered NO to item 7-B. Do you have RSC approval for this project?
☐ YES (Attach copy of RSC Approval Letter) ☐ NO (Contact the Radiation Safety Section at 828-9131 for approval information)

NOTE: See also http://www.vcu.edu/oehs/radiation/humanuseguide.pdf

8-A. Does this project involve the use of RECOMBINANT DNA, BIO-HAZARDOUS SUBSTANCES including pathogenic or potentially pathogenic viruses and bacteria (e.g., Adenovirus, HIV, Hepatitis B), CARCINOGENS OR ACUTE CARCINOGENS, MUTAGENS, TERATOGENS, ACUTE TOXINS, OR SELECT AGENT MATERIALS?
☐ YES (Proceed to 8-B) ☒ NO (Proceed to Question 9)

8-B. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) approval is required if you answered YES to this question. Do you have IBC approval for this project?
☐ YES (Attach copy of IBC Approval Letter) ☐ NO (Contact CHEMICAL AND BIOLOGICAL SAFETY OFFICE at 828-4866 for approval information)

NOTE: See also http://www.vcu.edu/oehs/chemical/

9. Does this project involve GENE THERAPY? ☐ YES ☒ NO

10-A. Does this study involve cancer patients, their families, or their health care providers? ☐ YES * ☒ NO

10-B. Is this a Cancer Prevention Study? ☐ YES * ☒ NO

* If YES TO 10-A OR 10-B, the research project must be reviewed and approved by the MASSEY CANCER CENTER PROTOCOL REVIEW AND MONITORING COMMITTEE before IRB Review, and a copy of the approval letter provided. For information, see http://www.massey.vcu.edu/research/?pid=2013 or call the PRMC Coordinator at 628-1924.

11. Will this project be conducted in the CLINICAL RESEARCH CENTER (CRC)? ☐ YES * ☒ NO
* If YES, please review information for investigators available at http://www.vcuhealth.org/crc/

12. Is your project: (1) involving human subject activities conducted by Navy and Marine Corps personnel; (2) involving naval military personnel and Department of Navy (DoN) employees as research subjects; (3) supported by naval activities through any agreement (e.g., contract, grant cooperative agreement, development agreement [CRADSs], or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification; or (4) using DoN property, facilities or assets? ☐ YES * ☒ NO
* If YES, you must ensure that your project meets the additional Department of Defense (DoD)-Department of the Navy (DoN) requirements for human subject protection. Guidance on additional requirements can be found at [http://www.research.vcu.edu/irb/wpp/flash/XVII-12.htm]

13. Will this project be conducted in a VCUHS patient care area or involve VCUHS patients? ☐ YES* ☒ NO
*If YES, I have reviewed and agree to comply with the CONDUCT OF CLINICAL RESEARCH IN VCU HEALTH SYSTEM PATIENT CARE AREAS policy on this page: http://www.research.vcu.edu/irb/guidance.htm.

14. HIPAA Regulatory Compliance

14-A. Will this study use or access protected health information (PHI)?* ☒ YES ☐ NO**

*See Decision Tree 1: Determining when HIPAA Applies to Research at http://www.research.vcu.edu/irb/hipaa-guidance.htm

**If no, go to Question 15

14-B. Select all of the ways PHI will be used for this study.

☐ Determine study feasibility [COMPLETE REVIEW PREPARATORY TO RESEARCH FORM]
☐ Identify and recruit potential study participants from within the VCUHS system or other covered entity[COMPLETE APPENDIX A: HIPAA FOR RESEARCH]
☒ Collected and maintained in medical record or research records (prospective collection) [COMPLETE APPENDIX A: HIPAA FOR RESEARCH]
☐ Collected from medical records within the VCUHS system or other covered entity (retrospective collection) [COMPLETE APPENDIX A: HIPAA FOR RESEARCH]

Access HIPAA guidance information here: http://www.research.vcu.edu/irb/hipaa-guidance.htm

15. Does this project involve the creation of or contribution to a Research Registry? (A registry is an organized collection of retrievable, identifiable information (pertaining to living humans) that is intentionally maintained for use as a prospective instrument for the conduct of research. ☐ YES* ☒ NO**

* If YES, you must follow guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-4.htm and answer 15-A and 15-B.
**If NO, skip to Question 16

15-A. Will the registry be maintained at VCU? ☐ YES ☐ NO

15-B. Does the registry include any identifiers? ☐ YES ☐ NO
See list of 18 identifiers here: http://www.research.vcu.edu/irb/hipaa-guidance.htm

16. Do you plan to involve NON-VCU INSTITUTIONS (i.e., institutions [or employees or agents of the institutions] that are not under the authority of VCU or VCU Health Systems and are located within the United States or a United States territory) in your research project? ☒ YES * ☐ NO
* If YES, you must follow guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm

17. Do you plan to involve FOREIGN RESEARCH SITES (i.e., institution or non-institutional setting)? ☐ YES * ☒ NO
* If YES, you must follow guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-11.htm

18. Do you plan to involve INDEPENDENT INVESTIGATORS (i.e., individuals who are not representatives of VCU or any other institution or facility) in your research project? ☐ YES * ☒ NO
* If YES, you must follow guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-15.htm

19. Does this project involve GENETIC TESTING, that is, testing human tissue samples for heritable characteristics or storing human tissue samples for possible future such testing? ☐ YES * ☒ NO
* If YES, you must follow guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-5.htm

SECTION 8: RESEARCH SUBJECT INFORMATION

VULNERABLE SUBJECTS:

1. Do you plan to allow for the inclusion of data on subjects who are children? ☐ YES * ☒ NO
* If YES, include the VCU IRB CHILDREN-SUBJECT FORM with your submission. The form is available at http://www.research.vcu.edu/forms/vcuirb.htm
NOTE: In Virginia, children are those under the age of 18 and not emancipated.

2. Do you plan to allow for the inclusion of data on subjects who are PREGNANT WOMEN, HUMAN FETUSES, or NEONATES? ☒ YES * ☐ NO
* If YES, include the VCU IRB PREGNANT WOMEN, FETUSES, NEONATES-SUBJECT FORM with your submission. The form is available at http://www.research.vcu.edu/forms/vcuirb.htm

3. Do you plan to allow for the inclusion of data on subjects who are, or may become a PRISONER? ☐ YES * ☒ NO

* If YES, you must follow the VCU IRB PRISONER-SUBJECT GUIDANCE and include the VCU IRB PRISONER-SUBJECT FORM with your submission. The guidance and form are available at http://www.research.vcu.edu/forms/vcuirb.htm

SUBJECT ENROLLMENT PLAN:

Anticipated # OF SUBJECTS (if this is a multi-center project, list only subjects under this IRB approval): 72
Is this a **MULTI-CENTER PROJECT**? ☐ YES ☒ NO
If YES, please provide:
(1) # OF SITES: **(2)** # OF SUBJECTS ACROSS ALL SITES:

CONSENT DOCUMENTATION: (Mark the type of consent process/documentation planned):

☒ **STANDARD CONSENT FORM:** A copy of the proposed consent form(s) is attached to this submission.

☐ **CONSENT FORM FOR PRISONER SUBJECTS:** A copy of the proposed consent form for prisoners is attached to this submission.

☐ **WAIVER OF SOME OR ALL ELEMENTS OF CONSENT OR PARENTAL PERMISSION: NOTE:** Waiver is not allowed for FDA-regulated research unless it meets FDA requirements for Waiver of Consent for Emergency Research (see below). A request is being made to waive the requirement to obtain prospective informed consent from subjects or permission from parents. Your research synopsis should explain why: (1) the research involves no more than minimal risk to the subjects, (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, (3) the research could not practicably be carried out without the waiver or alteration; **AND** (4) whether or not subjects will be debriefed after their participation. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XI-1.htm.

☐ **WAIVER OF DOCUMENTATION OF CONSENT, PARENTAL PERMISSION:**
A request is being made to waive documentation of consent. The IRB may waive this requirement if it finds either: (1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Subjects will be asked whether they want documentation linking them with the research, and each subject's wishes will govern; or (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Your research synopsis should include a justification for waiver based on one of these two elements and include a description of the information that will be provided to participants. If you are proposing to use a verbal consent statement, the proposed consent script should be attached to this submission. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XI-2.htm

☐ **ASSENT FORM:** A copy of the assent form for children or decisionally-impaired persons is attached to this submission. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm. and http://www.research.vcu.edu/irb/wpp/flash/XVII-7.htm.

☐ **WAIVER OF ASSENT:** A request is being made to waive the requirement to obtain prospective assent from children age 7 or higher, or decisionally-impaired persons. Your research synopsis should explain (1) why some or all of the individuals age 7 or higher, or decisionally-impaired will not be capable of providing assent based on their developmental status or impact of illness; (2) the research holds out a prospect of direct benefit not available outside of the research; **AND/OR** (3) [a] the research involves no more than minimal risk to the subjects, [b] the waiver or alteration will not adversely affect the rights and welfare of the subjects, [c] the research could not practicably be carried out without the waiver or alteration; **AND** [d] whether or not subjects will be debriefed after their participation. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm.

☐ **WAIVER OF CONSENT FOR EMERGENCY RESEARCH:** Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XVII-16.htm.

SECTION 9: VCU RESEARCH PLAN

You must use the VCU Research Plan Template that can be found at http://www.research.vcu.edu/forms/vcuirb.htm, Use of this template is required to provide your VCU Research Plan to the IRB. Your responses should be written in terms for the non-scientist to understand. If a detailed research protocol (e.g., sponsor's protocol) exists, you may reference that protocol by including the specific location (section # or small page range) within the protocol where the requested information can be found.

NOTE: **If that protocol does not address all of the issues outlined in each Section Heading, you must address the remaining issues in this Plan. It is NOT acceptable to reference a research funding proposal.**

NOTE: A roster of all study personnel is to be provided utilizing a *VCU IRB Study Personnel Roster*. Information regarding each study personnel is to be submitted using the *VCU IRB Study Personnel Information and Change Form*. These forms can be found at http://www.research.vcu.edu/forms/vcuirb.htm.

SECTION 10: SUBMISSION CHECKLIST

The following elements are reminders of steps and documentation that must be included with your submission packet.
NOTE: If required documents are missing and multi-page documents are not individually stapled or clipped, your review may be delayed.

This checklist must be included as the last page of the IRB INITIAL REVIEW SUBMISSION FORM
If not applicable, indicate "N/A."

☐ **1. VCU IRB INITIAL REVIEW SUBMISSION FORM**

☐ **2. VCU RESEARCH PLAN**
Required with ALL submissions and **MUST follow the template and include version number or date, and page numbers** [see SECTION 9 of this form]. Review of your protocol will be delayed if the template is not followed.
NOTE: A research funding proposal cannot substitute for the VCU Research Plan

☐ **3. VCU IRB STUDY PERSONNEL INFORMATION AND CHANGE FORM**
Required with ALL submissions and **MUST** be completed for each project personnel [see SECTION 9 of this form].

☐ **4. VCU IRB STUDY PERSONNEL ROSTER**
Required with ALL submissions and **MUST** follow the template and include version number or date, and page numbers [see SECTION 9 of this form].

☐ ___ **5. MEASURES (e.g., surveys, questionnaires, instruments, appendices)**
Measures **MUST include title, version number or date, and page numbers**

☐ N/A **6. SPONSOR'S PROTOCOL**
If a sponsor's protocol exists, it must be submitted with the VCU Research Synopsis.
NOTE: A research funding proposal is not considered a Sponsor's protocol

☐ N/A **7. ADVERTISEMENTS/SUBJECT RECRUITMENT MATERIALS**
If approval is sought for advertisement/subject recruitment materials at this time. Materials **MUST include version number or date**

☐ ___ **8. INFORMED CONSENT/ASSENT DOCUMENT(S)**
Informed consent document(s) should follow a version of the VCU IRB CONSENT TEMPLATE and **MUST include version number or date, and page numbers**

☐ N/A **9. VCU IRB CHILDREN-SUBJECT FORM**

☐ ___ **10. VCU IRB PREGNANT WOMEN, FETUSES, AND NEONATES-SUBJECT FORM**

☐ N/A **11. VCU IRB PRISONER-SUBJECT FORM**

☐ N/A **12. FDA FORM 1572**
If investigational drugs are involved in the research

☐ N/A **13. INVESTIGATIONAL DRUG PHARMACY PLAN**
If a drug or biologic agent/drug will be used in the research and IDS will not be used, confirmation from IDS that a plan has been received is required with this submission [see SECTION 7(4) of this form]

☐ N/A **14. IND OR IDE APPLICATION**
If a drug or device is used in the project and IND or IDE is held by the investigator [see SECTION 7(2) or 7(6) of this form]

☐ N/A **15. INVESTIGATOR'S BROCHURE**
If a drug or device is used in the project and the IND or IDE is held by the sponsor [see SECTION 7(2) or 7(6) of this form]

☐ N/A **16. DOCUMENTATION REGARDING LEVEL OF RISK (when evaluating a device)**
If an investigational medical device or a new use for marketed medical device is being evaluated [see SECTION 7(5) or 7(6) of this form]

☐ N/A **17. RADIATION SAFETY COMMITTEE APPROVAL** If required [see SECTION 7(7) of this form]

☐ N/A **18. INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW** If required [see SECTION 7(8) of this form]

☐ N/A **19. MASSEY CANCER CENTER PROTOCOL REVIEW AND MONITORING SYSTEM APPROVAL**
If required, [see SECTION 7(10) of this form]

☐ **20. CONFLICT OF INTEREST DISCLOSURE STATEMENT**
This form and explanatory supplement (if applicable) is required for the PI and all others who have responsibility for the design, conduct, or reporting of the research.

☐ N/A **21. RESEARCH FUNDING PROPOSAL**
If required [see SECTION 5 of this form] The entire proposal (exclusive of appendices) and VCU Office of Sponsored Programs (OSP) Internal Approval Form must be included.

☐ **22. PRINCIPAL INVESTIGATOR CV (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**
If submitting a biosketch, the NIH biosketch form (398) must be used. The biosketch form is available at http://grants.nih.gov/grants/funding/phs398/biosketch.pdf. Additional instructions are available at http://grants1.nih.gov/grants/funding/phs398/phs398.html.

☐ ___ **23. CV OF DOCTORAL STUDENT, POSTDOCTORAL SCHOLAR, FELLOW, OR RESIDENT (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**

☐ N/A **24. MEDICALLY RESPONSIBLE INVESTIGATOR CV (not to exceed 5-6 pages) or a BIOSKETCH (2-3 pages)**

☐ N/A **25. REVIEW PREPARATORY TO RESEARCH FORM** If required [see SECTION 7(14) of this form]

☐ ___ **26. APPENDIX A: HIPAA FOR RESEARCH** If required [see SECTION 7(14) of this form]

27. OTHER: _____

In addition, please ensure the following:

- All key project personnel, including the principal investigator, sub/co-investigators, project coordinators, and students have completed **VCU REQUIRED TRAINING ON HUMAN SUBJECTS PROTECTION**. The exam can be accessed from the following website http://www.research.vcu.edu/irb/education.htm
- Principal Investigator, Trainee or Student (if applicable) and Department/Division Chairperson or Dean have **SIGNED THE APPROPRIATE STATEMENTS OF COMPLIANCE** [see SECTION 6 of this form]
- The **REVIEW TYPE REQUESTED** [see SECTION 4 of this form] has been checked

NUMBER OF COPIES REQUIRED

NOTE: If required documents are missing, multi-page documents are not individually stapled or clipped, or the documents are not provided in the order noted below, your review may be delayed.
Double-sided documents are encouraged; but it is recommended that one (original) copy of consent/assent forms and recruitment documents be submitted as single sided to ensure that documents returned to the PI with an IRB approval stamp are legible.

I. If review type requested is **EXPEDITED**, submit **(4) COLLATED SETS** containing the following documents in the order noted.

1) VCU IRB Initial Review Submission Form
2) VCU Research Plan
3) Appendix A: HIPAA for Research
4) VCU IRB Study Personnel Information and Change Form(s)
5) VCU IRB Study Personnel Roster
6) Sponsor's Protocol (if applicable)
7) Advertisements/Subject Recruitment Materials (if applicable)
8) Informed Consent/Assent Documents(s) (if applicable) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent/assent documents)
9) VCU IRB Children-Subject Form (if applicable)
10) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable)
11) VCU IRB Prisoner-Subject Form (if applicable)
12) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable)
13) FDA Form 1572 (if applicable)
14) IND or IDE Application (if applicable)
15) Investigator's Brochure (if applicable)
16) Radiation Safety Committee Approval Letter (if applicable)
17) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable)
18) Conflict of Interest Disclosure Statement (s) and supplement(s) if applicable
19) Research Funding Proposal (if applicable)
20) Principal Investigator CV or Biosketch
21) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable)

II. If review type requested is **FULL BOARD**, follow the instructions below:

A) **All Full Board Initial Review submissions will undergo a pre-review process** - Submit 1 **COLLATED SET** containing the following documents for the **pre-review** process:

1) VCU IRB Initial Review Submission Form (signatures are not required for pre-review)
2) VCU Research Plan
3) Appendix A: HIPAA for Research
4) VCU IRB Study Personnel Information and Change Form(s)
5) VCU IRB Study Personnel Roster
6) Sponsor's Protocol (if applicable)
7) Advertisements/Subject Recruitment Materials (if applicable)
8) Informed Consent/Assent Document(s) (if applicable) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent /assent documents)
9) VCU IRB Children-Subject Form (if applicable)
10) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable)
11) VCU IRB Prisoner-Subject Form (if applicable)
12) Conflict of Interest Disclosure Statement**.** Submit Conflict of Interest Disclosure Statement AND Disclosure Supplement Form(s) IF any of the investigators answered YES to one of the questions. Signatures are required.
13) Principal Investigator CV or Biosketch
14) FDA Form 1572 (if applicable)
15) IND or IDE Application (if applicable)
16) Investigator's Brochure (if applicable)
17) Documentation of Level of Risk (if applicable)

18) Radiation Safety Committee Approval Letter (if applicable)
19) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable)
20) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable)
21) Research Funding Proposal (if applicable)
22) Medically Responsible Investigator CV or Biosketch (if applicable)
23) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable)

AND

B) **Once all outstanding items are addressed through the pre-review process and you have received confirmation that the submission is considered complete -** Submit 25 **COLLATED SETS** containing the following documents (only 4 of the 25 sets need to include the documents noted in items 11-22 below):

1) VCU IRB Initial Review Submission Form (signatures are required - 25 copies)
2) VCU Research Plan (25 copies)
3) VCU IRB Study Personnel Information and Change Form(s) (25 copies)
4) VCU IRB Study Personnel Roster (25 copies)
5) Sponsor's Protocol (if applicable – 25 copies)
6) Advertisements/Subject Recruitment Materials (if applicable – 25 copies)
7) Informed Consent/Assent Document(s) (if applicable – 25 copies) (**NOTE:** If this is a DHHS protocol, you **MUST** include the DHHS-approved consent/assent documents)
8) VCU IRB Children-Subject Form (if applicable – 25 copies)
9) VCU IRB Pregnant Women, Fetuses, Neonates-Subject Form (if applicable – 25 copies)
10) VCU IRB Prisoner-Subject Form (if applicable – 25 copies)
11) Conflict of Interest Disclosure Statement**.** Submit Conflict of Interest Disclosure Statement AND Disclosure Supplement Form(s) IF any of the investigators answered YES to one of the questions. (signatures are required - 25 copies)
12) Principal Investigator CV or Biosketch (4 copies)
13) FDA Form 1572 (if applicable – 4 copies)
14) IND or IDE Application (if applicable – 4 copies)
15) Investigator's Brochure (if applicable – 4 copies)
16) Documentation of Level of Risk (if applicable – 4 copies)
17) Radiation Safety Committee Approval Letter (if applicable – 4 copies)
18) Massey Cancer Center Protocol Review and Monitoring System Approval Letter (if applicable – 4 copies)
19) Confirmation of receipt of management plan from Investigational Drug Pharmacy (if applicable – 4 copies)
20) Research Funding Proposal (if applicable – 4 copies)
21) Medically Responsible Investigator CV or Biosketch (if applicable – 4 copies)
22) CV of Doctoral Student, Postdoctoral Scholar, Fellow, or Resident (if applicable – 4 copies)

VCU RESEARCH PLAN TEMPLATE

Use of this template is required to provide your VCU Research Plan to the IRB. Your responses should be written in terms for the non-scientist to understand. If a detailed research protocol (e.g., sponsor's protocol) exists, you may reference specific sections of that protocol. NOTE: **If that protocol does not address all of the issues outlined in each Section Heading, you must address the remaining issues in this Plan**. **It is NOT acceptable to reference a research funding proposal**.

ALL Sections of the Human Subjects Instructions must be completed with the exception of the Section entitled "Special Consent Provisions." Complete that Section if applicable. When other Sections are not applicable, list the Section Heading and indicate "N/A."

NOTE: The Research Plan is required with ALL Expedited and Full review submissions and MUST follow the template, and include version number or date, and page numbers.

DO NOT DELETE SECTION HEADINGS OR THE INSTRUCTIONS.

I. TITLE

A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

II. RESEARCH PERSONNEL

A. PRINCIPAL INVESTIGATOR

List the name of the VCU Principal Investigator

Jacqueline M. McGrath, PhD, RN, NNP, FNAP

B. STUDY PERSONNEL

NOTE:

1. **Information pertaining to each project personnel, including their role, responsibilities, and qualifications, is to be submitted utilizing a *VCU IRB Study Personnel Information and Changes Form.* This form is available at http://www.research.vcu.edu/forms/vcuirb.htm.**
2. **A roster of all project personnel, including the principal investigator, medically responsible investigator, and non-VCU personnel, is to be maintained as a separate study document which is retained with the Research Plan, and is to be updated as necessary. This template document, entitled *VCU IRB Study Personnel Roster,* is available at http://www.research.vcu.edu/forms/vcuirb.htm.**

C. Describe the process that you will use to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions.

NICU personnel including the bedside registered nurses and respiratory care therapist will be informed of the research study including study aims, recruitment and planned research protocol using both group and individual in-service format before the study enrollment is initiated. The Core Research team (see VCU IRB Study Personnel Information and Changes Form and Personnel Roster) will be updated weekly using a written report to include number of participant's recruited, current number of participants and potential study participants pending informed consents.

III. CONFLICT OF INTEREST

Describe how the principal investigator and sub/co-investigators might benefit from the subject's participation in this project or completion of the project in general. Do not describe (1) academic recognition such as publications or (2)

grant or contract based support of VCU salary commensurate with the professional effort required for the conduct of the project

Conflict of Interest:
There is no identified conflict of interest on the part of the Principal Investigator (PI) or the student investigator.

IV. RESOURCES

Briefly describe the resources committed to this project including: (1) time available to conduct and complete the research, (2) facilities where you will conduct the research, (3) availability of medical or psychological resources that participants might require as a consequence of the research (if applicable), and (4) financial support.

1) Available time:
The student investigator will maintain an on- site presence as needed for participant recruitment, consenting and data collection. The PI for the project is a full time VCU faculty member whose position supports ongoing nursing research as well as the support of mentored PhD student projects.

2) Study Site:
The neonatal Intensive care unit at the Children's Hospital of the King's Daughters (CHKD) in Norfolk Virginia will be utilized as the study site for this project. This is a 62 bed level III NICU that serves a large geographic territory from Northern North Carolina to Williamsburg, Virginia. Based on unit statistics from January through June, 2011 (see appendix 2) there were 58 patients admitted to the CHKD NICU who required nasal CPAP and who met the inclusion criteria for birth weight 500-1500 grams. The range of CPAP days based on these statistics show that these patients used nasal CPAP from 1-16 days for a total of over 900 CPAP days. The average patient's birth weight was 833.6 grams. This data was collected as a feasibility projection for the planned study sample of ELBW infants less than 1500 grams.

3) N/A

4) N/A

V. HYPOTHESIS

Briefly state the problem, background, importance of the research, and goals of the proposed project.

Introduction:

The use of nasal CPAP has become widely accepted by health care providers who care for preterm infants in the treatment of respiratory distress syndrome (RDS), yet few studies have used comparative effectiveness research to examine the performance of various nasal interfaces within this group to determine differences in either the incidence or severity of nasal skin breakdown, a well described side effect of this useful treatment.

Following a systematic literature review of 111 articles related to the use of nasal CPAP on the preterm infant, only a single study was reviewed which included the study aim of comparing nasal interfaces to determine the frequency of skin breakdown (Rego and Martinez 2002). This research study, conducted in Sao Paulo, Brazil evaluated the performance of two types of nasal prongs, Argyle and Hudson, to deliver nasal CPAP to preterm infants. The conclusion of the study was the prongs were found to be equally effective in the delivery of CPAP, the Argyle prong was more difficult to maintain in the infant's nares and had a higher incidence of nasal hyperemia, the first sign of skin breakdown when compared to the Hudson prong. No comparison studies were reviewed between prongs, mask or a rotation of devices that have been described antidotally as a strategy to reduce pressure on nasal skin during the use of nasal CPAP (Robertson, McCarthy et al. 1996; McCoskey 2008; Squires and Hyndman 2009). Additionally, there is universal agreement that nasal injury is a potential risk factor when using the nasal interfaces with CPAP delivery with clear directives for attention to skin assessment and increased nursing care and expertise which was mentioned in 44 of the 111 reviewed articles.

Study Goals:

The primary aim of this study will be to determine differences in the frequency, severity and specific types of

nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask) used to treat respiratory distress syndrome. These outcome measures will be calculated based on nurses recording information included in the skin condition score (NSCS), a three parameter tool that evaluates skin breakdown, erythma and dryness. A secondary aim of the study will be to identify those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration. Lastly an exploratory aim will be to identify and describe nursing strategies that can support the reduction of nasal injuries in this vulnerable population during nasal CPAP administration. Additional data will be collected during the study which will include the agitation levels of the infants during nasal CPAP administration and the respiratory stability of the patients as measured by blood gases. These measures will be used to explore other potential factors associated with nasal injury and skin breakdown.

VI. SPECIFIC AIMS

For this Comparative Effectiveness Study the Hypotheses are:

1) Is there a difference in the incidence and/or severity of skin breakdown of the ELBW preterm neonate (less than 1500 grams) when nasal CPAP is administered using three types of nasal interfaces: 1) continuous nasal prongs, 2) continuous nasal mask or 3) alternating the nasal mask and prongs every 4 hours?
2) Are the differences in the incidence and/or severity of skin breakdown related to other predisposing risk factors such as gestational age, birth weight, length of therapy, environmental humidity level, amount of CPAP flow administered and/or nursing interventions that include positioning techniques, nasal suctioning devices and the use of nasal saline during suctioning?
3) Will the frequency and severity of nasal injury be accurately measured with the NSCS?
4) Is there a correlation between agitation scores as measured by the N-PASS and the incidence and/or severity of nasal injury during the use of nasal CPAP in the ELBW preterm neonate?
5) Is there a correlation between blood gas results, specifically respiratory acidosis reflected in the pH, CO2 and base excess levels and the incidence of nasal injury in the ELBW preterm neonate?

VII. BACKGROUND AND SIGNIFICANCE

Include information regarding pre-clinical and early human studies. Attach appropriate citations.

Background and Significance:

The dynamic approach to respiratory care of the preterm neonate has progressed following scientific evidence which clearly demonstrates advantages to early nasal continuous positive airway pressure (CPAP) or early extubation to nasal CPAP in this population. It is now well understood that reduced mechanical ventilation in high-risk preterm infants has many advantages which includes; decreased chronic lung disease, decreased incidence of ventilator associated pneumonia as well as overall reduction in blood stream infections, reduction in the incidence of periventricular luekomalacia (PVL) previously associated with long term ventilation, improved neurodevelopmental outcomes and shortened hospital length of stay (De Paoli, Davis et al. 2008; Squires and Hyndman 2009). These small infants however require some adjunct to maintain functional residual capacity (FRC) as well as improve the symptoms of respiratory distress syndrome (Buettiker, Hug et al. 2004). Nasal continuous positive airway pressure (CPAP) is often used to support this need.

Nasal CPAP is a non invasive method for providing a constant distending pressure during both the inhalation and exhalation phase of respiration. Used in the spontaneously breathing preterm infant it provides stability of the infant's FRC, improves oxygenation, conserves surfactant, aids in the prevention of atelectasis, improves gas exchange and aids in the prevention of obstructive and central apnea (Davis, Jankov et al. 1998; Diblasi 2009; Squires and Hyndman 2009). First described in 1914 in a German textbook about the diseases of the newborn, a system of hoses placed into a water filled receptacle, a face mask with a gas source was used on a newborn who had symptoms of respiratory distress to provide continuous airway pressure (Diblasi 2009). Ventilator delivered

CPAP first was reported in the late 1970's and 1980's that were adapted from adult models (Gregory, Kitterman et al. 1971); then in the 90's free standing nasal CPAP delivery systems were designed and widely adapted into routine practice (Verder 2007; Diblasi 2009).

Three major types of nasal CPAP are used in the neonatal population, traditionally classified by the technique used to control the gas flow to the patient (Gupta, Sinha et al. 2009). These include constant flow or bubble CPAP, variable flow which are devices that have fluidic control to maintain the CPAP pressure and finally ventilator delivered CPAP generally delivered through an endotracheal tube (ETT) or a long single nasal pharyngeal tube. All devices share in four components, 1) a heated/humidified blended gas source, 2) a nasal interface, 3) a patient circuit and 4) a pressure-generating apparatus (Diblasi 2009).

Risks attributed to the use of nasal CPAP in this population have also been described. These include abdominal distension, inability to provide enteral nutrition secondary to gut disturbance, slightly increased incidence of necrotizing enterocolitis (NEC), pneumothorax and nasal injury or nasal mucosal damage (Verder 2007; Squires and Hyndman 2009) The current CPAP devices are effective in maintaining needed positive end expiratory pressure (PEEP) but also place constant pressure on the nares, nasal septum and forehead leading to decreased skin integrity and injury (De Paoli, Davis et al. 2008). Research is needed to 1) compare nasal CPAP interfaces commonly used to determine differences in frequency and severity of skin break down and 2) to identify strategies to reduce skin breakdown during nasal CPAP use in extremely low birth weight (ELBW) infants.

The overall clinical management of preterm infants whose respiratory status is supported through the use of nasal CPAP is based on anecdotal experience and unit standards rather than on scientific evidence. Nursing skill level and experience with positioning, frequent assessment and intervention, all of which takes significant nursing time has been well described by nearly half of the 111 reviewed articles. Practices vary widely from unit to unit making standardization of nursing care to protect vulnerable preterm infant skin during this therapy difficult.

We clearly understand the advantages of using nasal CPAP in this population which outweighs the observed risk to this therapy. We must now examine the different delivery methods and nasal interface devices while providing non-invasive nasal CPAP to preterm infants to best manage the preterm infant's respiratory distress syndrome using scientific evidence to create and test best clinical practices. In a meta analysis completed on the devices and pressure sources for the administration of nasal CPAP, implications for further research included determining which nasal interface device is the least traumatic to the infant nose, particularly the very low birth weight infant (De Paoli, Davis et al. 2008). Additionally, a systematic review of non-invasive ventilation strategies described nasal prongs and newer nasal masks for use in the neonate. The masks were described to require less pressure to remain in place but "will need empiric testing to determine safety in this population" (Courtney and Barrington 2007).

Empiric evidence based on current scientific literature is needed to support nursing interventions to reduce iatrogenic skin injury of the nose, face and head during nasal CPAP administration to provide improved long term outcomes. Specific attention to those details of nursing care to this patient population to addresses strategies for optimal outcomes are clearly needed.

VIII. PRELIMINARY PROGRESS/DATA REPORT

If available.

N/A

IX. RESEARCH METHOD AND DESIGN

Include a brief description of the project design including the setting in which the research will be conducted and procedures. If applicable, include a description of procedures being performed already for diagnostic or treatment purposes.

Research Method and Design:

A three group prospective randomized experimental study design is currently planned. This would include recruitment into the study following admission to the neonatal intensive care unit (NICU) when infants are typically intubated during the mechanical ventilation phase of treatment. Upon extubation to nasal CPAP (the typical care for these infants) the participants would be randomized into three groups to include, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. All infants will be managed with the same type of nasal CPAP delivery system. Infants transported from the delivery room or outlying hospital that are initially treated with nasal CPAP would be considered for enrollment if consent was obtained and randomization could occur within 8hours.

Following parental consent, infants would be clearly identified by a star placed at the infant's bedside to remind caregivers to enroll participants as the medical condition of the patient was appropriate for transition from current therapy to nasal CPAP following physician or neonatal nurse practitioner (NNP) order to extubate the patient. Infants who meet study inclusion criteria and who have been consented and self extubate will also be randomized for nasal CPAP trial if medically appropriate as dictated by physician or nurse practitioner order. No infants will be placed on nasal CPAP unless medically warranted; therefore patients who are extubated to high flow or regular nasal cannula will be excluded unless nasal CPAP is used in those patients at a later time as medically indicated.

Following parental consent the infants recruited for the study will be block stratified according to weight into four categories according to birth weight: < 750 grams, 750-1000 grams, 1001-1250 grams and > 1251-1500 grams. Known differences in the skin integrity have been demonstrated with the lowest birth weights proven the most vulnerable. Stratification according to infant's birth weight will keep the groups more homogeneous as it is expected that the smallest group will have the least patients. After stratified the subjects will be randomly allocated into the three groups, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. Randomization will accomplished using serially numbered opaque sealed envelopes developed by the researcher which will be located close to the storage area which houses the CPAP equipment within the NICU.

A flow diagram (algorithm) will be placed beside the aforementioned sealed envelopes to provide a quick reference to the respiratory team collecting the necessary equipment for the infants ordered transition to nasal CPAP (see appendix 1). This diagram will visually describe the information required (birth weight) in order for the respiratory therapist to determine from which group of envelops they should select from which will determine group assignment. This diagram will be located on the respiratory care clipboard, not visible to patient's families or visitors. The equipment would then be collected by the respiratory staff to place the infant on nasal CPAP with continuous nasal prongs, continuous nasal mask or alternating each device every four hours based on randomization.

Routine skin assessments will be completed every 3-4 hours which is consistent with current care practice. This skin assessment is primarily a nursing responsibility but collaboration between the bedside nurse and respiratory therapist will be encouraged. A small group of skin experts, described as the Core Research Team, which includes seven senior staff RN's and advance practice nurses will be responsible for twice a day skin care evaluations on enrolled participants. These skin evaluations will be scheduled during the infant's routine nursing care. This will be accomplished through communication with the bedside nursing staff to coordinate assessment times in an effort to protect the infant's quiet environment.

X. PLAN FOR CONTROL OF INVESTIGATIONAL DRUGS, BIOLOGICS, AND DEVICES.

Investigational drugs and biologics: IF Investigational Drug Pharmacy Service (IDS) is not being used, attach the IDS

confirmation of receipt of the management plan.

Investigational and humanitarian use devices (HUDs): Describe your plans for the control of investigational devices and HUDs including:
(1) how you will maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product(s);
(2) plan for storing the investigational product(s)/ HUD as specified by the sponsor (if any) and in accordance with applicable regulatory requirements;
(3) plan for ensuring that the investigational product(s)/HUDs are used only in accordance with the approved protocol; and
(4) how you will ensure that each subject understands the correct use of the investigational product(s)/HUDs (if applicable) and check that each subject is following the instructions properly (on an ongoing basis).

N/A

XI. DATA ANALYSIS PLAN

For investigator–initiated studies.

Data Analysis Plan

Demographic information from each participant will be collected for descriptive purposes and the means of each group will be compared using a one way analysis of variance (ANOVA) to identify group differences. Data analysis will be performed at both the individual and group levels for descriptive and comparison purposes. Specific intended study analysis will be discussed according to study aim:

1) The primary aim of this study will be to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs, mask or alternating prong/mask) used to treat respiratory distress syndrome. Analysis will be conducted using the previously described NSCS scores every 10-12 hours with an incidence of skin breakdown classified as mild, moderate or severe. Incidence of breakdown per group will be calculated for all three groups and one-way ANOVA will be used to analyze continuous variables. The frequency of nasal breakdown per group will be determined by the number of cased of nasal breakdown divided by the total number within the group.

2) A secondary aim of the study will be to identify those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration. This descriptive analysis will examine those factors such as gestational age, birth weight, nutritional support, liter per minute of CPAP flow, length of CPAP therapy, environmental humidity and nursing factors such as infant positioning, suctioning practices and suctioning frequency in each group. Inferential statistics will be used to examine individual factors using ANOVA for continuous variables and logistic regression for dichotomous variables.

3) Will the frequency and severity of nasal injury be accurately measured with the NSCS? The Core research team will be scoring the NSCS every 10-12 hours who have expertise in use and scoring guidelines of the tool (see Appendix 4 and 5). At least 10% of the study sample will be tested by multiple core researchers to provide inter rater reliability data. This data will be collected weekly (see Appendix 6).Analysis will be on both tool and interrater reliability using Cohen's Kappa and chronbach's alpha.

4) Is there a correlation between agitation scores as measured by the N-PASS and the incidence and/or severity of nasal injury during the use of nasal CPAP in the ELBW preterm neonate? The Neonatal Pain, Agitation and Sedation Scale (N-Pass) was developed as a clinically relevant tool to assess primarily acute or chronic pain as well as sedation level in preterm infants who are not capable of self report (Hummel, Puchalski et al. 2008). This scale (see appendix 7) has been well validated in the preterm population and is currently used as a measure of agitation at the proposed research site; therefore information will be extrapolated from the medical record.

5) Is there a correlation between respiratory acidosis as defined by blood gas results and the incidence of nasal injury in the ELBW preterm neonate? The presence of respiratory acidosis will be defined as pH < 7.25 with CO2 reading >55 in the preterm population and when these conditions are present the participant will be

classified as respiratory acidosis. Cases which have been identified as breakdown present will be filtered for inclusion for analysis. ANOVA will be completed to establish correlation between groups 1, 2 or 3 with identified breakdown and the presence of respiratory acidosis.

XII. DATA AND SAFETY MONITORING

- **If the research involves greater than minimal risk and there is no provision made for data and safety monitoring by any sponsor, include a data and safety-monitoring plan that is suitable for the level of risk to be faced by subjects and the nature of the research involved.**
- **If the research involves greater than minimal risk, and there is a provision made for data and safety monitoring by any sponsor, describe the sponsor's plan.**
- **If you are serving as a Sponsor-Investigator, identify the Contract Research Organization (CRO) that you will be using and describe the provisions made for data and safety monitoring by the CRO. Guidance on additional requirements for Sponsor-Investigators is available at http://www.research.vcu.edu/irb/wpp/flash/X-2.htm**

No greater than minimal risk without current provision for data and safety monitoring.

XIII. MULTI-CENTER STUDIES

If VCU is the lead site in a multi-center project or the VCU PI is the lead investigator in a multi-center project, describe the plan for management of information that may be relevant to the protection of subjects, such as reporting of unexpected problems, project modifications, and interim results.

N/A

XIV. INVOLVEMENT OF NON-VCU INSTITUTIONS/SITES (DOMESTIC AND FOREIGN)

1. **Provide the following information for each non-VCU institution/site (domestic and foreign) that has agreed to participate:**
   - **Name of institution/site**
   - **Contact information for institution/site**
   - **Engaged in Research or not (if YES AND the research involves a DIRECT FEDERAL AWARD made to VCU, include FWA #). See OHRP's guidance on "Engagement of Institutions in Research" at http://www.hhs.gov/ohrp/policy/engage08.html.**
   - **Request for the VCU IRB to review on behalf of the Non-VCU institution?** See requirements found at http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm.
   - See VCU WPPs:
     http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm and
     http://www.research.vcu.edu/irb/wpp/flash/XVII-11.htm.

Name of Institution	Contact Information for Site	Engaged (Y/N) and FWA # if applicable	Request for VCU IRB to review on behalf of the non-VCU institution (Y/N)*
Children's Hospital of the King's Daughters, Norfolk, Virginia	**Katherine Newnam PhD (c), RN, NNP-BC at (757) 668-7452 (NICU) or (757) 567-5334 (cell number)**	**Engages--Yes FWA—N/A**	**No-IRB application will be submitted to the Eastern Virginia Medical School.**

*NOTE: If a Non-VCU site is engaged in the research, the site is obligated to obtain IRB review or request that the VCU IRB review on its behalf.

2. **Provide a description of each institution's role (whether engaged or not) in the research, adequacy of the facility (in order to ensure participant safety in the case of an unanticipated emergency), responsibilities of its agents/employees, and oversight that you will be providing in order to ensure adequate and ongoing protection of the**

human subjects. You should only identify institutions that have agreed to participate. If additional institutions agree to participate at a later time, they must be added by amendment to the protocol.

The primary site for the proposed research study is a large Neonatal Intensive Care Unit located within a teaching hospital, The Children's Hospital of the Kings Daughters.

XV. HUMAN SUBJECTS INSTRUCTIONS

ALL sections of the Human Subjects Instructions must be completed with the exception of the section entitled "Special Consent Provisions." Complete that section if applicable.

A. DESCRIPTION

Provide a detailed description of the proposed involvement of human subjects or their private identifiable data.

Privacy of Participants:

The privacy of the participants will be supported through the use of participant identifier as described in section "Confidentiality of Data". The group that each patient is randomized which dictates the type of nasal interface utilized to deliver nasal CPAP will be recorded as part of the health care record which is standard care for patients receiving nasal CPAP. All research records with all patient identifiers removed will be removed from the patient's bedside daily and placed into a secure location on the unit for later analysis.

Confidentiality of Data:

All information will be de-identified by assignment of research assigned patient number which will be used on all study records. The process of assignment will start with the number (N) 001 through (N) 024 for the first patient in the continuous nasal prong group; (M) 101 through (M) 123 for the continuous nasal mask group, and (R) 201 through (R) 224 for the rotation group. This patient identifier will be recorded on all maintained study records. The consent which will contain patient names and medical record number will be related to assigned patient identifier as described above using a key which will be available to the PI and student investigator only. This information will be kept under lock and key in the Virginia Commonwealth University School of Nursing and will be destroyed following the data analysis phase of the research project. De-identified data will be maintained for an undetermined length of time.

B. SUBJECT POPULATION

Describe the subject population in terms of sex, race, ethnicity, age, etc., and your access to the population that will allow recruitment of the necessary number of participants. Identify the criteria for inclusion or exclusion of all targeted populations and include a justification for any exclusion. Explain the rationale for the involvement of special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable. If you plan to allow for the enrollment of Wards of the State (or any other agency, institution, or entity), you must specifically request their inclusion and follow guidance in VCU IRB WPP XV-3: Wards and Emancipated Minors available at http://www.research.vcu.edu/irb/wpp/flash/XV-3.htm.

Human Subjects:

Inclusion criteria: Infants who are initially treated with or weaned from mechanical ventilation to nasal CPAP and who are birth weight 500 grams to 1500 grams. Infants with a birth weight under 500 grams will not be considered based on documented overall concerns with skin integrity in this group (Sardesai, Kornacka et al. 2011) which could influence study results.

Exclusion criteria: Infants who have been diagnosed with major cardiac disease or congenital malformation which could impair the nasal CPAP performance would be excluded. Patients who are not consented within 8 hours of nasal CPAP initiation or who had nasal skin breakdown at enrollment would be excluded and patients outside of the weight inclusion would not be included.

Mothers less than 18 years of age: Mothers who are under the age of 18 that have infants that meet

inclusion criteria for this research project will be excluded secondary to informed consent limitations.

Recruitment Plan:

Parents or guardians of those patients who are admitted to the NICU and who meet the study inclusion criteria will be approached by a member of the Core Research Team following admission to the unit. All members of this Research Team are employed as staff within the study site. The research study will be explained to each family providing adequate time to answer questions related to the proposed research plan. Those parents who are unable to visit the NICU because of geographic or other barriers will be contacted by phone to explain the research study and invite participation.

A power analysis using a significance level of $p < 0.05$ was performed (see appendix 8) to meet the described primary aim of the study which was to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask) used to treat respiratory distress syndrome in the preterm infant less than 1500 grams. The analysis was focused on the frequency parameter of this aim and a total sample size of 72 with 24 in each of the three groups (continuous nasal prongs, continuous nasal mask or alternating nasal mask and prongs every 4 hours) was adequate to determine significant differences between groups.

C. RESEARCH MATERIAL

Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

1) Data Collection Form; Enrollment/Daily and Weekly (Appendix 4/5 and 6) which will include the following information which is extrapolated from the medical record. Each of these items were shown through the literature review to be factors related to skin breakdown in the preterm infant during nasal CPAP use.
   a) Patient's birth weight
   b) Patient's current weight
   c) Patient's gestational age at birth
   d) Patients current age
   e) Length of CPAP use
   f) CPAP flow rate
   g) Amount of FIO2 required
   h) Incubator humidity
   i) Type of nasal interface
   j) Suctioning requirements
   k) Saline use during suctioning
   l) Bleeding with suctioning
   m) Blood gas results
   n) Skin injury location
   o) Skin injury reported to the medical team
   p) Intervention provided for skin injury
   q) Additional clinical issues/concerns
   r) Care strategies per standard of care complied with (pectin barrier, developmental position and CPAP hat placement)
2) Neonatal Skin Condition Scale (NSCS) which will be collected by the Core Research team every 10-12 hours in coordination with routine infant care/assessment performed every 3-4 hours (see Appendix 3). This information will be collected for research purposes.
3) Neonatal Pain, Agitation and Sedation Scale (N-PASS) is a scale (see appendix 7) has been well validated in the preterm population and is currently used as a measure of agitation at the proposed research site; therefore information will be extrapolated from the medical record.

D. RECRUITMENT PLAN

Describe <u>in detail</u> your plans for the recruitment of subjects including:
(1) how potential subjects will be identified (e.g., school personnel, health care professionals, etc),
(2) how you will get the names and contact information for potential subjects, and
(3) who will make initial contact with these individuals (if relevant) and how that contact will be done.
If you plan to involve special cases of subjects, such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable, describe any special recruitment procedures for these populations.

Recruitment Plan:
1) Subjects will be identified based on current respiratory management (mechanical ventilation or nasal CPAP) and birth weight 500-1500 grams.
2) Parents or guardians of those patients who are admitted to the NICU and who meet the study inclusion criteria will be approached following admission to the unit. The research study will be explained to each family providing adequate time to answer questions related to the proposed research plan. Those parents who are unable to visit the NICU because of geographic or other barriers will be contacted by phone to explain the research study and invite participation.
3) The initial contact with the parent will be made by the Core Research Team if the neonate meets inclusion criteria.

E. PRIVACY OF PARTICIPANTS

NOTE: Privacy refers to individuals and their interests in controlling access to their identities, their physical person, and how and what kind of information is obtained about them. Privacy also encompasses the interests of defined communities (e.g. those with a certain diagnosis or social circumstance) in controlling access to the group identity and information about the group or individuals as part of the group.

Describe how the privacy interests of subjects (and communities, if appropriate) will be protected including:
(1) in the research setting (e.g., in the identification, recruitment, and intervention settings) and
(2) with the information being sought and the way it is sought. For example, providing drapes or barriers, interviewing in a private room, and collecting only the amount of sensitive information needed for identification, recruitment, or the conduct of the study.

Privacy of Participants:
The privacy of the participants will be supported through the use of participant identifier as described in section "Confidentiality of Data". The group that each patient is randomized which dictates the type of nasal interface utilized to deliver nasal CPAP will be recorded as part of the health care record which is standard care for patients receiving nasal CPAP. All research records with all patient identifiers removed will be removed from the patient's bedside daily and placed into a secure location on the unit for later analysis.

Confidentiality of Data:
All information will be de-identified by assignment of research assigned patient number which will be used on all study records. The process of assignment will start with the number (N) 001 through (N) 024 for the first patient in the continuous nasal prong group; (M) 101 through (M) 123 for the continuous nasal mask group, and (R) 201 through (R) 224 for the rotation group. This patient identifier will be recorded on all maintained study records. The consent which will contain patient names and medical record number will be related to assigned patient identifier as described above using a key which will be available to the PI and student investigator only. This information will be kept under lock and key in the Virginia Commonwealth University School of Nursing and will be destroyed following the data analysis phase of the research project. De-identified data will be maintained for an undetermined length of time.

F. CONFIDENTIALITY OF DATA

NOTE: Confidentiality refers to the way private, identifiable information about a subject or defined community is

Check all of the following precautions that will be used to maintain the confidentiality of identifiable information:

[X] Paper-based records will be kept in secure location and only accessed by authorized study personnel
[X] Electronic records will be made available only to those personnel in the study through the use of access controls and encryption
[X] Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location)
[ ] For research involving web-based surveys, data is secured via passwords and encryption
[ ] Audio or video recordings of subjects will be transcribed and then destroyed to prevent audio or visual identification. Note the date of destruction (e.g., 3 months from close of study; after transcription is determined to be error free).
[ ] Obtaining a Certificate of Confidentiality
[ ] Other precautions:

G. Potential Risks

Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

Potential Risks:

There are no anticipated risks or discomforts associated with participation in this research study. Individual risk to individual patients are considered minimal and consistent with the risk experienced with current standard nasal CPAP care for the identified population within the NICU.

H. Risk Reduction

Describe procedures for protecting against or minimizing potential risk. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events to the subjects. Describe the provisions for monitoring the data collected to ensure the safety of subjects, if any.

Risk Reduction:

Frequent patient skin assessment (at least every 4 hours) by the bedside registered nurse and/or respiratory care therapist is required by both unit and research protocol. Signs of hyperemia, erythma or excoriation will be reported to the health care team and treatment ordered as necessary which is consistent with current medical care. Intolerance to nasal CPAP treatment will be addressed in the usual manner with increased medical care to include escalating respiratory support up to and including endotrachael intubation. All three described nasal interfaces are currently in use within the NICU research setting. No changes in the standard unit care are anticipated based on the use of the type of nasal interface during the administration of nasal CPAP in the preterm infant.

I. Additional Safeguards for Vulnerable Participants

Describe any additional safeguards to protect the rights and welfare of participants if you plan to involve special cases of subjects such as children, pregnant women, human fetuses, neonates, prisoners or others who are likely to be vulnerable.

Safeguards to protect the rights and welfare of participants might relate to Inclusion/Exclusion Criteria: ("Adults with moderate to severe cognitive impairment will be excluded." "Children must have diabetes. No normal controls who are children will be used.") Consent: ("Participants must have an adult care giver who agrees to the participant taking part in the research and will make sure the participant complies with research procedures." "Adults must be able to assent. Any dissent by the participant will end the research procedures.") Benefit: ("Individuals who have not shown benefit to this type of drug in the past will be excluded.").

Neonates who meet inclusion criteria will be considered eligible for the research study if the adult care giver

(parent) agrees to the participant taking part in the study which consist of the neonate being randomized into a specific nasal interface group and data collection from pertinent items from the medical record as well as serial skin assessments during the nasal CPAP use. Clear discussion with the adult care giver regarding the consent not pertaining to the use of nasal CPAP with nasal prongs, nasal masks and alternating devices as this is standard of care within the NICU as part of respiratory management of the preterm infant.

J. RISK/BENEFIT

Discuss why the risks to participants are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and supply the FDA approval letter.

Risk/Benefit:

There are no direct benefits to the study participants at present; however, changes in how nasal CPAP is administered to this patient population may provide benefits in future neonatal care.

K. COMPENSATION PLAN

Compensation for participants (if applicable) should be described, including possible total compensation, pro-rating, any proposed bonus, and any proposed reductions or penalties for not completing the project.

Compensation Plan for Study Participants:

No compensation is planned for study participants or their families.

L. CONSENT ISSUES

1. CONSENT PROCESS

Indicate who will be asked to provide consent/assent, who will obtain consent/assent, what language (e.g., English, Spanish) will be used by those obtaining consent/assent, where and when will consent/assent be obtained, what steps will be taken to minimize the possibility of coercion or undue influence, and how much time will subjects be afforded to make a decision to participate.

Consent Process:

Informed consent will be obtained by the researcher or his/her designees (identified as the Core Research Team) which are advanced practice nurses or physicians experienced in obtaining informed consent. Each parent or guardian of the qualifying patients will be asked to sign a consent form which will describe the study aim, the study design and various steps to be employed during the study (see appendix 4). Parents of the participants will be encouraged to discuss any items or words that are unclear or that they do not understand during the consent process. The parents of the participants will be provided a copy of the signed consent with contact information including the primary investigator (PI) as well as student researcher. The Internal Review Board (IRB) contact information will be included for parental questions not answered by the PI or research team. Languages other than English will be translated using the translation language line currently used as the standard method in which to communicate with Non-English speaking parents of NICU patients. This method will provide a full reading of the consent in the parent's native language with the ability to answer questions, raise and concerns regarding the study.

2. SPECIAL CONSENT PROVISIONS

If some or all subjects will be cognitively impaired, or have language/hearing difficulties, describe how capacity for consent will be determined. Consider using the VCU Informed Consent Evaluation Instrument available at http://www.research.vcu.edu/irb/guidance.htm. If you anticipate the need to obtain informed consent from legally authorized representatives (LARs), please describe how you will identify an appropriate representative and ensure

that their consent is obtained. Guidance on LAR is available at http://www.research.vcu.edu/irb/wpp/flash/XI-3.htm.

N/A

3. ASSENT PROCESS
If applicable, explain the Assent Process for children or decisionally impaired subjects. Describe the procedures, if any, for re-consenting children upon attainment of adulthood. Describe procedures, if any, for consenting subjects who are no longer decisionally impaired. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm and http://www.research.vcu.edu/irb/wpp/flash/XVII-7.htm.

N/A

4. REQUESTS FOR WAIVERS OF CONSENT (COMPLETE IF REQUESTING ANY TYPE OF WAIVER OF CONSENT OR ASSENT)

Not requesting waiver of consent

4-A. REQUEST TO WAIVE SOME OR ALL ELEMENTS OF INFORMED CONSENT FROM SUBJECTS OR PERMISSION FROM PARENTS: A waiver of informed consent means that the IRB is not requiring the investigator to obtain informed consent OR the IRB approves a consent form that does not include or alters some/all of the required elements of consent. **Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XI-1.htm. NOTE: Waiver is not allowed for FDA-regulated research unless it meets FDA requirements for Waiver of Consent for Emergency Research (see below).**

4-A.1. Explain why a waiver or alteration of informed consent is being requested.

4-A.2. Describe how this study meets ALL FOUR of the following conditions for a waiver or alteration:

- The research involves no more than minimal risk to the participants. → Explain how your study meets this criteria:
- The waiver or alteration will not adversely affect the rights and welfare of participants. → Explain how your study meets this criteria:
- The research could not practicably be carried out without the waiver or alteration. → Explain how your study meets this criteria:
- Will participants be provided with additional pertinent information after participation?
  ☐ Yes
  ☐ No → Explain why not:

4-B. REQUEST TO WAIVE DOCUMENTATION OF CONSENT: A waiver of documentation occurs when the consent process occurs but participants are not required to sign the consent form. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm#XI-2.htm. One of the following two conditions must be met to allow for consenting without signed documentation. Choose which condition is applicable and explain why (explanation required):

☐ The only record linking the participant and the research would be the informed consent form. The principal risk to the participant is the potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participants wishes will govern. → Explain how

your study fits into the category:

☐ The research presents no more than minimal risk of harm to participants & involves no procedures for which signed consent is normally required outside of the research context. → Explain how your study fits into the category:

4-C. REQUEST TO WAIVE SOME OR ALL ELEMENTS OF ASSENT FROM CHILDREN ≥ AGE 7 OR FROM DECISIONALLY IMPAIRED INDIVIDUALS: A waiver of assent means that the IRB is not requiring the investigator to obtain assent OR the IRB approves an assent form that does not include some/all of the required elements. Guidance is available at http://www.research.vcu.edu/irb/wpp/flash/XV-2.htm.

4-C.1. Explain why a waiver or alteration of informed consent is being requested.

In order for the IRB to approve a request for waiver of assent, the conditions for 4-C.2, 4-C.3, OR 4-C.4 must be met. Check which ONE applies and explain all required justifications.

4-C.2. ☐ **Some or all of the individual's age 7 or higher will not be capable of providing assent based on their developmental status or impact of illness**. → Explain how your study meets this criteria:

4-C.3. ☐ **The research holds out a prospect of direct benefit not available outside of the research**. → Explain how your study meets this criteria:

4-C.4. ☐ **Describe how this study meets ALL FOUR of the following conditions**:

- The research involves no more than minimal risk to the participants. → Explain how your study meets this criteria:

- The waiver or alteration will not adversely affect the rights and welfare of participants. → Explain how your study meets this criteria:

- The research could not practicably be carried out without the waiver or alteration. → Explain how your study meets this criteria:

- Will participants be provided with additional pertinent information after participation?
  ☐ Yes
  ☐ No → Explain why not:

4-D. REQUEST TO WAIVE CONSENT FOR EMERGENCY RESEARCH: Describe how the study meets the criteria for emergency research and the process for obtaining LAR consent is appropriate. See guidance at http://www.research.vcu.edu/irb/wpp/flash/XVII-16.htm.

N/A

5. GENETIC TESTING
If applicable, address the following issues related to Genetic Testing.

5-A. FUTURE CONTACT CONCERNING FURTHER GENETIC TESTING RESEARCH
Describe the circumstances under which the subject might be contacted in the future concerning further participation in this or related genetic testing research.

N/A

5-B. FUTURE CONTACT CONCERNING GENETIC TESTING RESULTS

If planned or possible future genetic testing results are unlikely to have clinical implications, then a statement that the results will not be made available to subjects may be appropriate. If results might be of clinical significance, then describe the circumstances and procedures by which subjects would receive results. Describe how subjects might access genetic counseling for assistance in understanding the implications of genetic testing results, and whether this might involve costs to subjects. Investigators should be aware that federal regulations, in general, require that testing results used in clinical management must have been obtained in a CLIA-certified laboratory.

N/A

5-C. WITHDRAWAL OF GENETIC TESTING CONSENT

Describe whether and how subjects might, in the future, request to have test results and/or samples withdrawn in order to prevent further analysis, reporting, and/or testing.

N/A

5-D. GENETIC TESTING INVOLVING CHILDREN OR DECISIONALLY IMPAIRED PARTICIPANTS

Describe procedures, if any, for consenting children upon the attainment of adulthood. Describe procedures, if any, for consenting participants who are no longer decisionally impaired.

N/A

5-E. CONFIDENTIALITY OF GENETIC INFORMATION

Describe the extent to which genetic testing results will remain confidential and special precautions, if any, to protect confidentiality.

N/A

VCU IRB STUDY PERSONNEL ROSTER

(for Expedited and Full Board Research)

PRINCIPAL INVESTIGATOR:	Jacqueline M. McGrath, PhD, RN, NNP, FNAP	VCU EMAIL:	mcgrathjm@vcu.edu
RESEARCH COORDINATOR:		VCU EMAIL:	
VCU IRB #:			
TITLE OF PROJECT:	A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate		

General Instructions – List all project personnel*, including Principal Investigator, individuals from other institutions, and independent investigators. (Add rows as necessary). This roster is to be kept current throughout the approval period with the IRB, and is to be retained within the investigator's study documentation. This roster is intended to serve as an ongoing list of all personnel who are currently engaged in the project, as well as those who have been, but are no longer, involved. Individual *Personnel Information and Change Forms* are also required for each project personnel.

Submission Instructions - See Submission Instructions on next page

**Project Personnel* *includes anyone 'engaged' in the research (VCU & non-VCU personnel), including independent investigators. Engaged means interacting or intervening with research participants and/or having access to identifiable private information about participants. See OHRP's guidance on "Engagement of Institutions in Research" at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08/html.*

STUDY PERSONNEL ROSTER

	FIRST NAME	LAST NAME	ROLE IN STUDY - (entry should match information on *Study Personnel Information and Change Form*)		DATE ADDITION PROPOSED TO IRB:	DATE REMOVAL PROPOSED TO IRB:
1)	Jacqueline	McGrath	Principal Investigator	If *Other*, list:	11/21/11	
2)	Katherine	Newnam	Student	If *Other*, list:	11/21/11	
3)	Thape	Jan	Research Assistant	If *Other*, list:	11/21/11	
4)	Deborah	Quast	Research Assistant	If *Other*, list:	11/21/11	
5)	Lynetta	Cox	Research Assistant	If *Other*, list:	11/21/11	
6)	Melinda	Bissett	Research Assistant	If *Other*, list:	11/21/11	
7)	Yvette	Conyers	Research Assistant	If *Other*, list:	11/21/11	
8)	Morit	Leonardo	Research Assistant	If *Other*, list:	11/21/11	
9)	Ortiz	Angela	Research Assistant	If *Other*, list:	11/21/11	
10)			(Choose an Item)	If *Other*, list:		
11)			(Choose an Item)	If *Other*, list:		
12)			(Choose an Item)	If *Other*, list:		
13)			(Choose an Item)	If *Other*, list:		
14)			(Choose an Item)	If *Other*, list:		
15)			(Choose an Item)	If *Other*, list:		
16)			(Choose an Item)	If *Other*, list:		
17)			(Choose an Item)	If *Other*, list:		
18)			(Choose an Item)	If *Other*, list:		
19)			(Choose an Item)	If *Other*, list:		
20)			(Choose an Item)	If *Other*, list:		

Roster Version Date: 11.21.11 *(Insert updated version date)*

STUDY PERSONNEL ROSTER INSTRUCTIONS

THE FOLLOWING INSTRUCTIONS DO NOT NEED TO BE SUBMITTED TO THE IRB

SUBMISSION INSTRUCTIONS

Initial Review Submission:

- List all personnel currently 'engaged' in this study. This includes the Principal Investigator, Medically Responsible Investigator, and non-VCU personnel (if applicable).
- At the time of Initial Review, submit 4 copies of the following to ORSP, attached to the *Initial Review Submission Form* and accompanying documents:
  - *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer)
  - *VCU IRB Study Personnel Information and Change Forms* for all project personnel

Existing Studies Only (during the phase-in of this new process):

- NOTE: For existing studies, implementation of this process will be required upon submission of the next continuing review. This continuing review will not be approved until a *VCU IRB Study Personnel Roster* is on file for the existing study.
  - Following IRB approval of the roster, the investigator is requested (upon submission of the next amendment to the Research Plan) to update section *II. Research Personnel* of the Research Plan to list only the Principal Investigator.
- List all personnel currently involved in this study. This includes the Principal Investigator, Medically Responsible Investigator, and non-VCU personnel (if applicable).
- If list of personnel varies from the previously approved protocol/research plan (adding or removing personnel), also follow instructions below under *To Add or Remove Personnel from a Study.*
- For existing studies only (during the phase-in process) - The IRB is not requiring that the initial roster include personnel who are no longer involved in the study; list only those currently involved (including the Principal Investigator and the Medically Responsible Investigator, if applicable).
- For existing studies only (during the phase-in process) - Investigators are not required to submit the *VCU IRB Study Personnel Information and Change Forms* for currently approved personnel. All project personnel must be listed on the *VCU IRB Study Personnel Roster*, however.
- At the time of Continuing Review (during phase-in and subsequent continuing reviews), submit 4 copies of the following to ORSP, attached to the Continuing Review Submission Form and accompanying documents:
  - *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer)

Add or Remove Personnel from a Study:

- All changes in research personnel must first be submitted to, and approved by, the IRB.
- To add or remove personnel (including a change to the Principal Investigator and/or Medically Responsible Investigator), revise the *VCU IRB Study Personnel Roster* to note personnel who are being added and/or removed. Include updated version date in footer. NOTE: When removing personnel from a study, do not delete name(s) from this roster, but enter the date of removal in the appropriate column. When updating the roster to add or remove personnel, also submit the appropriate *VCU IRB Study Personnel Information and Change Form(s)*.
- A change to the Principal Investigator also requires (in addition to the Personnel documents noted above) submission of a *Change in Research Submission Form* and applicable amended documents (i.e. Protocol/Research Plan, ICF, etc).
- For changes that involve Non-VCU sites – In addition to the *VCU IRB Study Personnel Roster* and *VCU IRB Study Personnel Information and Change Form*, personnel changes that involve non-VCU sites must also be addressed within the protocol/research plan (Section XIV. *Involvement of Non-VCU Institutions/Sites*). Changes to the protocol/research plan are to be submitted via a *Change in Research Submission Form*, along with any other applicable document(s).
- If adding Independent Investigators, follow instructions for the addition of Independent Investigators available at http://www.research.vcu.edu/forms/vcuirb.htm. .
- To make changes to study personnel, submit 4 copies of the following to ORSP:
  - Revised *VCU IRB Study Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer). Also provide the most recent IRB-approved Roster.
  - *VCU IRB Study Personnel Information and Change Form*(s), noting personnel who are being added and/or removed.
  - Conflict of Interest Disclosure Statement(s) for all personnel being added.
  - Curriculum Vitae for addition of Principal Investigator and/or Medically Responsible Investigator
  - Additional applicable documents, as noted above, and per instructions.

VCU IRB STUDY PERSONNEL INFORMATION AND CHANGE FORM

(for Expedited and Full Board Research)

PRINCIPAL INVESTIGATOR:	Jacqueline M. McGrath, PhD, RN, NNP, FNAP	VCU EMAIL:	mcgrathjm@vcu.edu
RESEARCH COORDINATOR:		VCU EMAIL:	

VCU IRB #:

TITLE OF PROJECT: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

1. Does this change involve a change to the Principal Investigator? Yes* ☐ No ☒
   *If YES, submit this form along with an updated *Personnel Roster* and the *Change in Research Submission Form*. Also see #2 below.

2. Does this change require additional changes to the research plan, consent, or other study documents? Yes* ☐ No ☒
   *If YES, also submit *Change in Research Submission Form* and appropriate documents for changes to study documents

3. STUDY PERSONNEL TO BE REMOVED - - IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL FORM AND CHECK HERE ☐

   A) 1. First Name: Last Name:
   2. First Name: Last Name:
   3. First Name: Last Name:

   B) Does the Principal Investigator confirm that the personnel remaining on this study have the expertise needed to conduct this study? Yes ☐ No ☐

4. STUDY PERSONNEL TO BE ADDED – - IF SPACE IS NEEDED FOR ADDITIONAL PERSONNEL, PLEASE USE CONTINUATION PAGE AND CHECK HERE ☒
   - ENTER TOTAL NUMBER OF PERSONNEL ADDITIONS INCLUDED WITH THIS SUBMISSION:

   A)

First Name: Jacqueline		Last Name: McGrath	Degrees: PhD, RN, NNP, FNAP
Email Address: mcgrathjm@vcu.edu		Phone: (804) 828-1930	VCU eID:
Mailing Address/VCU PO Box: 1100 East Leigh Street, Richmond, VA 23298 PO BOX 980567			
Affiliate Status:	VCU Affiliate ☒	School/Department: School of Nursing	
	Non-VCU Affiliate – Affiliated with a non-VCU institution/site ☐	Name of Institution/Site: * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
	Independent Investigator – Not affiliated with VCU or any other institution ☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
Role in the Study: Principal Investigator If *Other*, list:			
Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)*			
Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.*			

   B) Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* Yes ☒ No ☐
   Non-VCU research personnel may provide proof of training from their home institution.

Signature of Principal Investigator or Designee:	Date:

Continuation Page for Addition of Personnel

4.	A)	First Name: Katherine		Last Name: Newnam	Degrees: PhD c), RN, NNP-BC, CPNP
		Email Address: newmankm2@vcu.edu		Phone: (757) 546-7497	VCU eID: V004-1830
		Mailing Address/VCU PO Box: 1104 Hillston Court, Chesapeake Virginia 23322 PO Box 980567			
		Affiliate Status:	VCU Affiliate ☒	School/Department: School of Nursing	
			Non-VCU Affiliate – Affiliated with a non-VCU institution/site ☐	Name of Institution/Site: * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
			Independent Investigator – Not affiliated with VCU or any other institution ☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Student If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* On site responsibility to include participant identification, obtaining informed consent from parent, participant enrollment and data collection, weekly reports to the Core Research Team and data analysis.			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* NNP currently employed at the Study site as an advanced practice nurse, enrolled in PhD program at VCU with knowlegde of conducting research.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

4.	A)	First Name: Thape		Last Name: Jan	Degrees: MS, RN
		Email Address: Jan.Thape@chkd.org		Phone: (757) 668-7448	VCU eID: N/A
		Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507			
		Affiliate Status:	VCU Affiliate ☐	School/Department:	
			Non-VCU Affiliate – Affiliated with a non-VCU institution/site ☒	Name of Institution/Site: Children's Hospital of the King's Daughters * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
			Independent Investigator – Not affiliated with VCU or any other institution ☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Research Assistant If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Data collection			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Advanced Practice nurse who has completed previous research and has expertise using the skin assessment tool (NSCS) planned for the study.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

STUDY PERSONNEL INFORMATION AND CHANGE FORM

(The following instructions do not need to be submitted to the IRB)

SUBMISSION INSTRUCTIONS:

The *VCU IRB Study Personnel Information and Change Form* is to be used to add and remove project personnel* from the study, and is used in conjunction with the *Study Personnel Roster*, which is intended to serve as an ongoing list of all personnel who are currently involved in the project, as well as those who have been, but are no longer, involved.

**Project Personnel* *includes anyone 'engaged' in the research (VCU & non-VCU personnel), including independent investigators. 'Engaged' means interacting or intervening with research participants and/or having access to identifiable private information about participants. See OHRP's guidance on 'Engagement of Institutions in Research' at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08/html.*

Initial Review Submission – *For submission at the time of Initial Review of a new study*

- Complete the *VCU IRB Study Personnel Information and Change Form* for each project personnel, including Principal Investigator, Medically Responsible Investigator, and non-VCU personnel (if applicable). Use the Continuation Page for additional personnel, if needed.
- *Note:*
  - Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
  - Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- At the time of Initial Review, submit 4 copies of the following to ORSP, attached to the *Initial Review Submission Form* and accompanying documents:
  - *VCU IRB Study Personnel Information and Change Forms* for all project personnel
  - *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer).

Existing Studies Only (during phase-in of this new process) – *For first time submission of the VCU IRB Study Personnel Roster for previously approved studies.*

- NOTE: For existing studies, implementation of this process will be required upon submission of the next continuing review. This continuing review will not be approved until the *VCU IRB Study Personnel Roster* is on file for the existing study.
- For existing studies only (during the phase-in process) - Investigators are not required to submit *VCU IRB Study Personnel Information and Change Forms* for currently approved personnel. All personnel must be listed on the *VCU IRB Study Personnel Roster*, however.
- If the personnel on the *VCU IRB Study Personnel Roster* vary from the previously approved protocol/research plan (adding or removing personnel), also follow instructions below under *To Add or Remove Personnel from a Study.*

To Add or Remove Personnel from a Study – *For personnel changes following initial VCU IRB Study Personnel Roster review*

- All changes in research personnel must first be submitted to, and approved by, the IRB.
- To add or remove personnel (including a change to the Principal Investigator and/or Medically Responsible Investigator), submit the appropriate *VCU IRB Study Personnel Information and Change Form(s)*, accompanied by an updated *VCU IRB Study Personnel Roster*. Use the Continuation Page of the *VCU IRB Study Personnel Information and Change Form* if needed for additional personnel.
- A change to the Principal Investigator also requires (in addition to the Personnel documents noted above) submission of a *Change in Research Submission Form* and applicable amended documents (i.e. Protocol/Research Plan, ICF, etc).
- *Note:* Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
- Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- For changes that involve Non-VCU sites – In addition to the *VCU IRB Study Personnel Information and Change Form* and *VCU IRB Study Personnel Roster*, personnel changes that involve non-VCU sites must also be addressed within the protocol/research plan (Section XIV. *Involvement of Non-VCU Institutions/Sites*). Changes to the protocol/research plan are to be submitted via a *Change in Research Submission Form*, along with any other applicable document(s).
- If adding Independent Investigators, follow instructions for the addition of Independent Investigators available at http://www.research.vcu.edu/forms/vcuirb.htm.
- To make changes to study personnel, submit 4 copies of the following to ORSP:
  - *VCU IRB Study Personnel Information and Change Form(s)*, noting personnel who are being added and/or removed
  - Revised *VCU IRB Study Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer). Also provide the most recent IRB-approved roster.
  - Conflict of Interest Disclosure Statement(s) for all personnel being added.
  - Curriculum Vitae or NIH Biosketch for new Principal Investigator and/or Medically Responsible Investigator, if applicable- (CV should not to exceed 5-6 pages; BIOSKETCH should be 2-3 pages. If submitting BIOSKETCH, the NIH BIOSKETCH form 398 must be used.
  - Additional applicable documents, as noted above, and per instructions.

VCU IRB STUDY PERSONNEL INFORMATION AND CHANGE FORM

(for Expedited and Full Board Research)

PRINCIPAL INVESTIGATOR:	Jacqueline M. McGrath, PhD, RN, NNP, FNAP	VCU EMAIL:	mcgrathjm@vcu.edu
RESEARCH COORDINATOR:		VCU EMAIL:	

VCU IRB #:

TITLE OF PROJECT: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

1. Does this change involve a change to the Principal Investigator? Yes* ☐ No ☒
   *If YES, submit this form along with an updated *Personnel Roster* and the *Change in Research Submission Form*. Also see #2 below.

2. Does this change require additional changes to the research plan, consent, or other study documents? Yes* ☐ No ☒
   *If YES, also submit *Change in Research Submission Form* and appropriate documents for changes to study documents

3. STUDY PERSONNEL TO BE REMOVED - - IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL FORM AND CHECK HERE ☐

   A) 1. First Name: Last Name:
   2. First Name: Last Name:
   3. First Name: Last Name:

   B) Does the Principal Investigator confirm that the personnel remaining on this study have the expertise needed to conduct this study? Yes ☐ No ☐

4. STUDY PERSONNEL TO BE ADDED – - IF SPACE IS NEEDED FOR ADDITIONAL PERSONNEL, PLEASE USE CONTINUATION PAGE AND CHECK HERE ☐
   - ENTER TOTAL NUMBER OF PERSONNEL ADDITIONS INCLUDED WITH THIS SUBMISSION:

   A)

First Name: Deborah	Last Name: Quast	Degrees: RN
Email Address: Deborah.Quast@chkd.org	Phone: 757) 668-7448	VCU eID: N/A
Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507		

Affiliate Status:			
	VCU Affiliate	☐	School/Department:
	Non-VCU Affiliate – Affiliated with a non-VCU institution/site	☒	Name of Institution/Site: Children's Hospital of the King's Daughters * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).
	Independent Investigator – Not affiliated with VCU or any other institution	☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.

Role in the Study: Research Assistant
If *Other*, list:

Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Data Collection

Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Full time Research nurse within the NICU

   B) Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* Yes ☒ No ☐
   *Non-VCU research personnel may provide proof of training from their home institution.

Signature of Principal Investigator or Designee:	Date:

Continuation Page for Addition of Personnel

4.	A)	First Name: Lynetta	Last Name: Cox		Degrees: MS, RN, NNP-BC
		Email Address: Lynetta.Cox@chkd.org	Phone: (757)668-7452		VCU eID: N/A
		Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507			
		Affiliate Status: VCU Affiliate	☐	School/Department:	
		Non-VCU Affiliate – Affiliated with a non-VCU institution/site	☒	Name of Institution/Site: * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
		Independent Investigator – Not affiliated with VCU or any other institution	☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Research Assistant If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Obtaining informed consent from parents of eligible participants and data collection			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Advanced practice nurse who is knowledgable with informed consent and expert in neonatal assessment including skin.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

4.	A)	First Name: Melinda	Last Name: Bissett		Degrees: MS, RN, NNP-BC
		Email Address: Melinda.Bissett	Phone: 757) 668-7452		VCU eID: N/A
		Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507			
		Affiliate Status: VCU Affiliate	☐	School/Department:	
		Non-VCU Affiliate – Affiliated with a non-VCU institution/site	☒	Name of Institution/Site: Children's Hospital of the King's Daughters * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
		Independent Investigator – Not affiliated with VCU or any other institution	☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Research Assistant If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Obtaining informed consent from parents of eligible participants and data collection			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Advanced practice nurse who is knowledgable with informed consent and expert in neonatal assessment including skin.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

STUDY PERSONNEL INFORMATION AND CHANGE FORM

(The following instructions do not need to be submitted to the IRB)

SUBMISSION INSTRUCTIONS:

The *VCU IRB Study Personnel Information and Change Form* is to be used to add and remove project personnel* from the study, and is used in conjunction with the *Study Personnel Roster*, which is intended to serve as an ongoing list of all personnel who are currently involved in the project, as well as those who have been, but are no longer, involved.

**Project Personnel* *includes anyone 'engaged' in the research (VCU & non-VCU personnel), including independent investigators. 'Engaged' means interacting or intervening with research participants and/or having access to identifiable private information about participants. See OHRP's guidance on 'Engagement of Institutions in Research' at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08/html.*

Initial Review Submission – *For submission at the time of Initial Review of a new study*

- Complete the *VCU IRB Study Personnel Information and Change Form* for each project personnel, including Principal Investigator, Medically Responsible Investigator, and non-VCU personnel (if applicable). Use the Continuation Page for additional personnel, if needed.
- *Note:*
  - Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
  - Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- At the time of Initial Review, submit 4 copies of the following to ORSP, attached to the *Initial Review Submission Form* and accompanying documents:
  - *VCU IRB Study Personnel Information and Change Forms* for all project personnel
  - *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer).

Existing Studies Only (during phase-in of this new process) – *For first time submission of the VCU IRB Study Personnel Roster for previously approved studies.*

- NOTE: For existing studies, implementation of this process will be required upon submission of the next continuing review. This continuing review will not be approved until the *VCU IRB Study Personnel Roster* is on file for the existing study.
- For existing studies only (during the phase-in process) - Investigators are not required to submit *VCU IRB Study Personnel Information and Change Forms* for currently approved personnel. All personnel must be listed on the *VCU IRB Study Personnel Roster*, however.
- If the personnel on the *VCU IRB Study Personnel Roster* vary from the previously approved protocol/research plan (adding or removing personnel), also follow instructions below under *To Add or Remove Personnel from a Study.*

To Add or Remove Personnel from a Study – *For personnel changes following initial VCU IRB Study Personnel Roster review*

- All changes in research personnel must first be submitted to, and approved by, the IRB.
- To add or remove personnel (including a change to the Principal Investigator and/or Medically Responsible Investigator), submit the appropriate *VCU IRB Study Personnel Information and Change Form(s)*, accompanied by an updated *VCU IRB Study Personnel Roster*. Use the Continuation Page of the *VCU IRB Study Personnel Information and Change Form* if needed for additional personnel.
- A change to the Principal Investigator also requires (in addition to the Personnel documents noted above) submission of a *Change in Research Submission Form* and applicable amended documents (i.e. Protocol/Research Plan, ICF, etc).
- *Note:* Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
- Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- For changes that involve Non-VCU sites – In addition to the *VCU IRB Study Personnel Information and Change Form* and *VCU IRB Study Personnel Roster*, personnel changes that involve non-VCU sites must also be addressed within the protocol/research plan (Section XIV. *Involvement of Non-VCU Institutions/Sites*). Changes to the protocol/research plan are to be submitted via a *Change in Research Submission Form*, along with any other applicable document(s).
- If adding Independent Investigators, follow instructions for the addition of Independent Investigators available at http://www.research.vcu.edu/forms/vcuirb.htm.
- To make changes to study personnel, submit 4 copies of the following to ORSP:
  - *VCU IRB Study Personnel Information and Change Form(s)*, noting personnel who are being added and/or removed
  - Revised *VCU IRB Study Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer). Also provide the most recent IRB-approved roster.
  - Conflict of Interest Disclosure Statement(s) for all personnel being added.
  - Curriculum Vitae or NIH Biosketch for new Principal Investigator and/or Medically Responsible Investigator, if applicable- (CV should not to exceed 5-6 pages; BIOSKETCH should be 2-3 pages. If submitting BIOSKETCH, the NIH BIOSKETCH form 398 must be used.
  - Additional applicable documents, as noted above, and per instructions.

VCU IRB STUDY PERSONNEL INFORMATION AND CHANGE FORM

(for Expedited and Full Board Research)

PRINCIPAL INVESTIGATOR:	Jacqueline M. McGrath, PhD, RN, NNP, FNAP	VCU EMAIL:	mcgrathjm@vcu.edu
RESEARCH COORDINATOR:		VCU EMAIL:	

VCU IRB #:

TITLE OF PROJECT: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

1. Does this change involve a change to the Principal Investigator? Yes* ☐ No ☒
   *If YES, submit this form along with an updated *Personnel Roster* and the *Change in Research Submission Form*. Also see #2 below.

2. Does this change require additional changes to the research plan, consent, or other study documents? Yes* ☐ No ☒
   *If YES, also submit *Change in Research Submission Form* and appropriate documents for changes to study documents

3. STUDY PERSONNEL TO BE REMOVED - - IF MORE SPACE IS NEEDED, PLEASE ATTACH ADDITIONAL FORM AND CHECK HERE ☐

   A) 1. First Name: Last Name:
   2. First Name: Last Name:
   3. First Name: Last Name:

   B) Does the Principal Investigator confirm that the personnel remaining on this study have the expertise needed to conduct this study? Yes ☐ No ☐

4. STUDY PERSONNEL TO BE ADDED – - IF SPACE IS NEEDED FOR ADDITIONAL PERSONNEL, PLEASE USE CONTINUATION PAGE AND CHECK HERE ☐
   - ENTER TOTAL NUMBER OF PERSONNEL ADDITIONS INCLUDED WITH THIS SUBMISSION:

   A)

First Name: Yvette	Last Name: Conyers	Degrees: MS, RN
Email Address: Yvette.Conyers@chkd.org	Phone: 757) 668-7448	VCU eID: N/A
Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507		

Affiliate Status:			
	VCU Affiliate	☐	School/Department:
	Non-VCU Affiliate – Affiliated with a non-VCU institution/site	☒	Name of Institution/Site: Children's Hospital of the King's Daughters * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).
	Independent Investigator – Not affiliated with VCU or any other institution	☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.

Role in the Study: Research Assistant
If *Other*, list:

Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Data Collection

Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Advanced practice nurse who serves the NICU as a clinical specialist, knowledgable regarding neonatal skin assessment and conducting research.

   B) Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* Yes ☒ No ☐
   *Non-VCU research personnel may provide proof of training from their home institution.

Signature of Principal Investigator or Designee:	Date:

Continuation Page for Addition of Personnel

4.	A)	First Name: Leonardo		Last Name: Morit	Degrees: BS, RN
		Email Address: Leonardo.Morit@chkd.org		Phone: (757)668-7448	VCU eID: N/A
		Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507			
		Affiliate Status:	VCU Affiliate ☐	School/Department:	
			Non-VCU Affiliate – Affiliated with a non-VCU institution/site ☒	Name of Institution/Site: * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
			Independent Investigator – Not affiliated with VCU or any other institution ☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Research Assistant If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Data Collection			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Staff nurse in the NICU who is qualified to perform serial skin assessments on preterm neonates and currently serves on the hospital research committee.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

4.	A)	First Name: Angela		Last Name: Ortiz	Degrees: BS, RN
		Email Address: Angela.Ortiz		Phone: 757) 668-7448	VCU eID: N/A
		Mailing Address/VCU PO Box: 601 Childrens Lane, Norfolk, Virginia 23507			
		Affiliate Status:	VCU Affiliate ☐	School/Department:	
			Non-VCU Affiliate – Affiliated with a non-VCU institution/site ☒	Name of Institution/Site: Children's Hospital of the King's Daughters * NOTE: Personnel changes that involve non-VCU sites must also be addressed within the research plan (Section XIV). Changes to the research plan are to be submitted to the ORSP, via a *Change in Research Submission Form*, along with an amended research plan and any other applicable document(s).	
			Independent Investigator – Not affiliated with VCU or any other institution ☐	* NOTE: If an independent investigator is "engaged," and the research involves a DIRECT FEDERAL award made to VCU (or application for such), the independent investigator must sign a formal written agreement with VCU certifying terms for the protection of human subjects. For an agreement to be approved: (1) the PI must directly supervise all of the research activities, (2) agreement must follow the ORSP template, (3) IRB must agree to the involvement of the independent investigator, AND (4) agreement must be in effect prior to final IRB approval.	
		Role in the Study: Research Assistant If *Other*, list:			
		Responsibilities in the Study: *Describe the duties of the individual (i.e. consenting, interviewing, data analysis, data collection)* Data Collection			
		Qualifications: *Describe how the individual is qualified to carry out study related responsibilities.* Staff nurse in the NICU who is qualified to perform serial skin assessments on preterm neonates and currently serves on the hospital research committee.			
	B)	Does the Principal Investigator confirm this individual has current CITI training in Human Participant Protections.* **Non-VCU research personnel may provide proof of training from their home institution.*		Yes ☒	No ☐

STUDY PERSONNEL INFORMATION AND CHANGE FORM

(The following instructions do not need to be submitted to the IRB)

SUBMISSION INSTRUCTIONS:

The *VCU IRB Study Personnel Information and Change Form* is to be used to add and remove project personnel* from the study, and is used in conjunction with the *Study Personnel Roster*, which is intended to serve as an ongoing list of all personnel who are currently involved in the project, as well as those who have been, but are no longer, involved.

**Project Personnel* *includes anyone 'engaged' in the research (VCU & non-VCU personnel), including independent investigators. 'Engaged' means interacting or intervening with research participants and/or having access to identifiable private information about participants. See OHRP's guidance on 'Engagement of Institutions in Research' at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08/html.*

Initial Review Submission – *For submission at the time of Initial Review of a new study*

- Complete the *VCU IRB Study Personnel Information and Change Form* for each project personnel, including Principal Investigator, Medically Responsible Investigator, and non-VCU personnel (if applicable). Use the Continuation Page for additional personnel, if needed.
- *Note:*
  - Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
  - Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- At the time of Initial Review, submit 4 copies of the following to ORSP, attached to the *Initial Review Submission Form* and accompanying documents:
  - *VCU IRB Study Personnel Information and Change Forms* for all project personnel
  - *VCU IRB Study Personnel Roster* listing all project personnel (insert version date in footer).

Existing Studies Only (during phase-in of this new process) – *For first time submission of the VCU IRB Study Personnel Roster for previously approved studies.*

- NOTE: For existing studies, implementation of this process will be required upon submission of the next continuing review. This continuing review will not be approved until the *VCU IRB Study Personnel Roster* is on file for the existing study.
- For existing studies only (during the phase-in process) - Investigators are not required to submit *VCU IRB Study Personnel Information and Change Forms* for currently approved personnel. All personnel must be listed on the *VCU IRB Study Personnel Roster*, however.
- If the personnel on the *VCU IRB Study Personnel Roster* vary from the previously approved protocol/research plan (adding or removing personnel), also follow instructions below under *To Add or Remove Personnel from a Study.*

To Add or Remove Personnel from a Study – *For personnel changes following initial VCU IRB Study Personnel Roster review*

- All changes in research personnel must first be submitted to, and approved by, the IRB.
- To add or remove personnel (including a change to the Principal Investigator and/or Medically Responsible Investigator), submit the appropriate *VCU IRB Study Personnel Information and Change Form(s)*, accompanied by an updated *VCU IRB Study Personnel Roster*. Use the Continuation Page of the *VCU IRB Study Personnel Information and Change Form* if needed for additional personnel.
- A change to the Principal Investigator also requires (in addition to the Personnel documents noted above) submission of a *Change in Research Submission Form* and applicable amended documents (i.e. Protocol/Research Plan, ICF, etc).
- *Note:* Study personnel are required to complete the CITI human research protection training before involvement in the research project. For information about mandatory training requirements for study personnel, read WPP V-1 or Required Education.
- Study personnel are required to submit a signed Conflict of Interest Disclosure Statement.
- For changes that involve Non-VCU sites – In addition to the *VCU IRB Study Personnel Information and Change Form* and *VCU IRB Study Personnel Roster*, personnel changes that involve non-VCU sites must also be addressed within the protocol/research plan (Section XIV. *Involvement of Non-VCU Institutions/Sites*). Changes to the protocol/research plan are to be submitted via a *Change in Research Submission Form*, along with any other applicable document(s).
- If adding Independent Investigators, follow instructions for the addition of Independent Investigators available at http://www.research.vcu.edu/forms/vcuirb.htm.
- To make changes to study personnel, submit 4 copies of the following to ORSP:
  - *VCU IRB Study Personnel Information and Change Form(s)*, noting personnel who are being added and/or removed
  - Revised *VCU IRB Study Personnel Roster*, noting personnel who are being added and/or removed (update version date in footer). Also provide the most recent IRB-approved roster.
  - Conflict of Interest Disclosure Statement(s) for all personnel being added.
  - Curriculum Vitae or NIH Biosketch for new Principal Investigator and/or Medically Responsible Investigator, if applicable- (CV should not to exceed 5-6 pages; BIOSKETCH should be 2-3 pages. If submitting BIOSKETCH, the NIH BIOSKETCH form 398 must be used.
  - Additional applicable documents, as noted above, and per instructions.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

VCU IRB NO.:

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY:

To provide breathing assistance to your preterm baby, nasal CPAP is often used immediately after delivery or when your baby is taken off the ventilator. Nasal CPAP is a respiratory machine that is secured to your babies' nose through the use of either short soft nasal prongs, a soft nasal mask or a rotation between the mask and prongs in order to provide constant air flow or air pressure into the baby's nose and airways to help the baby breath more effectively. Although both the nasal prongs and mask are effective in providing respiratory support to your baby and is routinely used in our Neonatal Intensive Care Unit (NICU) we would like to know if one device is more comfortable for your baby or may cause less skin irritation where the skin comes in contact with the respiratory machine.

You are being asked to participate in this study because you have a preterm infant between the birth weight of 500 and 1500 grams who is currently treated with nasal CPAP or may be treated with nasal CPAP after your baby is taken off the ventilator.

DESCRIPTION OF THE STUDY AND YOUR (YOUR CHILD'S) INVOLVEMENT:

RISKS AND DISCOMFORTS:

There are no anticipated risks or discomforts above what is currently associated with nasal CPAP use therefore no additional risks or discomforts are expected with the participation in this research study. All study team members will maintain confidentiality of completed skin assessments and medical record information collected. Skin assessments will be performed in conjunction with nursing care therefore no additional interruption of infant rest or additional handing is anticipated. Other data collection will be extrapolated from the infant's medical record without interruption of bedside care.

BENEFITS TO YOU AND OTHERS

There are no direct benefits to you or your infant at the present time; however the information collected will be used to improve nasal CPAP care in our NICU and therefore might benefit other infants who have nasal CPAP therapy.

COSTS:

There are no financial costs associated with participation in this research study.

PAYMENT FOR PARTICIPATION:

There is no payment for participation in this research study.

ALTERNATIVES

The alternative is to not participate in this research study.

CONFIDENTIALITY

Potentially identifiable information about your infant will consist of this consent form. Skin assessment data will be collected on a data collection form by the research team which will be associated with an enrollment number and not your babies name. This data is being collected for research purposes only. All consent forms will be kept in a secure area and electronic data files will be kept in a password-protected computer. All personal identifying information will be deleted in accordance with state and federal regulations and guidelines. Data will be kept indefinitely. Access to all study materials will be limited to study personnel.

****We will not tell anyone the answers you give us; however, information from the study and information from your medical record and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. What we find from this study may be presented at meetings or published in papers, but your name will never be used in these presentations or papers.

IF AN INJURY HAPPENS

This study is minimal risk and no more than currently expected during the current standard of care during the administration of nasal CPAP.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. Your decision to participate or not participate in this research study will involve no penalty or loss of care, service or benefits to which you are otherwise entitled from this agency/service provider.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Jacqueline M. McGrath, PhD, RN, NNP, FNAP
Associate Professor of Nursing
School of Nursing
Viriginia Commonwealth Univeristy
11100 East Leigh Street
Richmond, VA 23298
(804) 828-1930

Mailing Address:
PO Box 980567
Richmond, VA 23298-0567

Katherine Newnam RN, MS, NNP-BC
Children's Hospital of the Kings Daughters
601 Children's Lane
Norfolk, Virginia 23507
(757)668-7452

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at http://www.research.vcu.edu/irb/volunteers.htm.

CONSENT

I have been given the chance to read this consent form. I understand the information about this research study. Questions that I wanted to ask about the research study have been answered. My signature says that I am willing to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

Participant name printed	Participant signature	Date

Name of Person Conducting Informed Consent Discussion / Witness (Printed)

Signature of Person Conducting Informed Consent Discussion / Witness — Date

Investigator Signature (if different from above) — Date

VCU IRB
APPENDIX A: HIPAA FOR RESEARCH

PRINCIPAL INVESTIGATOR:	McGrath, Jacqueline M.
EMAIL:	McGrathJM@vcu.edu
RESEARCH COORDINATOR:	
EMAIL:	
P.O. BOX #:	PO Box 980567
STUDY TITLE:	A COMPARATIVE EFFECTIVENESS STUDY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) RELATED SKIN BREAKDOWN WHEN USING DIFFERENT NASAL INTERFACES IN THE EXTREMELY LOW BIRTH WEIGHT (ELBW) NEONATE.

SECTION A: GENERAL INFORMATION

1. Describe the health information that will be obtained or used in this research.

1) Data Collection Form; Enrollment/Daily and Weekly (Appendix 4/5 and 6) which will include the following information which is extrapolated from the medical record.

a) Patient's birth weight
b) Patient's current weight
c) Patient's gestational age at birth
d) Patients current age
e) Length of CPAP use
f) CPAP flow rate
g) Amount of FIO2 required
h) Incubator humidity
i) Type of nasal interface
j) Suctioning requirements
k) Saline use during suctioning
l) Bleeding with suctioning
m) Blood gas results
n) Skin injury location
o) Skin injury reported to the medical team
p) Intervention provided for skin injury
q) Additional clinical issues/concerns
r) Care strategies per standard of care complied with (pectin barrier, developmental position and CPAP hat placement)

2) Neonatal Skin Condition Scale (NSCS) which will be collected by the Core Research team every 10-12 hours in coordination with routine infant care/assessment performed every 3-4 hours (see Appendix 3). This information will be collected for research purposes following skin assessment.

3) Neonatal Pain, Agitation and Sedation Scale (N-PASS) is a scale (see appendix 7) has been well validated in the preterm population and is currently used as a measure of agitation at the proposed research site; therefore information will be extrapolated from the medical record

2. Indicate the source(s) of the health information. (check all that apply)

☐ VCUHS medical records
☒ Non-VCUHS health care provider medical records
☐ PHI held by a component of the VCU ACE (other than VCUHS)
☒ Directly from the research participant (e.g., physical exams, diagnostic results, interviews and questionnaires)
☐ Records open to the public
☐ Other (please specify):

3. Explain how the PHI collected or used in this research is the minimum necessary to accomplish the research.
The data included on the Data Collection Form (Enrollment/Daily and Weekly--Appendix 4/5 and 6) include items were shown through the literature review to be factors related to skin breakdown in the preterm infant during nasal CPAP use and are critical to examination of this identified side effect of nasal CPAP use in this population.

4. Select all of the identifiers that will be used in this research.

- [X] Names
- [X] Dates (e.g., birth, admission, death)
- [ ] Phone numbers
- [ ] Fax numbers
- [X] Ages ≥ 89
- [ ] Geographic subdivisions smaller than state (e.g., city, county, zip)
- [ ] Social security numbers
- [ ] Medical record numbers
- [ ] Health plan beneficiary numbers
- [ ] Device identifiers & serial numbers
- [ ] Full-face photos or comparable
- [ ] Account numbers (e.g., bank, invoice#, credit card #)
- [ ] IP addresses
- [ ] License numbers
- [ ] Internet URLs
- [ ] Vehicle ID & serial numbers
- [X] Biometric identifiers
- [X] Other unique identifying #, code, or characteristic
- [ ] None of the above

5. Select all pathways this research will employ or use to access PHI.
De-identified data [FINISHED WITH THIS FORM AFTER THIS QUESTION]

- [X] All identifiers removed (safe harbor)
- [ ] Statistical analysis verifying no possibility of re-identification [SUBMIT ATTESTATION FROM STATISTICIAN WITH THIS FORM]
- [ ] Limited Data Set (may ONLY include city, state, zip code, dates, and ages) [COMPLETE DATA USE AGREEMENT]
- [ ] Waiver of Authorization [COMPLETE SECTION B]
- [ ] Partial Waiver of Authorization for Recruitment (allows access to PHI to contact potential participants who will sign consent and authorization upon enrollment) [COMPLETE SECTION C]
- [ ] Signed Authorization from participants in a combined Informed Consent and Authorization form [FINISHED WITH THIS FORM]
- [ ] Signed Authorization from participants in a separate Authorization form [FINISHED WITH THIS FORM]

SECTION B: WAIVER OF AUTHORIZATION

1. Describe how the use of PHI in this study poses no greater than minimal risk to participants' privacy.

2. When will identifiers be destroyed? (Identifiers must be destroyed at earliest opportunity)

- [ ] End of the study
- [ ] years after the end of the study (enter # of years)
- [ ] Other (please specify):

3. Other than the PI and research personnel, who else will have access to the health information?

4. Explain why this research cannot practicably be conducted without the use of PHI.

5. Explain why this research cannot practicably be conducted without a waiver of authorization.

Assurances
In applying for a waiver of authorization, I agree to the following:

A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in the research application), except as required by law.
B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB.
C) I will comply with VCU HIPAA policies and procedures and with the use and disclosure restrictions described above.
D) I assume responsibility for all uses and disclosures of the PHI by members of the study team.

SIGNATURE OF PRINCIPAL INVESTIGATOR OR DESIGNEE:		DATE OF SIGNATURE:	

SECTION C: PARTIAL WAIVER OF AUTHORIZATION

1. Describe how the use of PHI for recruitment poses no greater than minimal risk to participants' privacy.

2. When will identifiers be destroyed? (Identifiers must be destroyed at earliest opportunity)

☐ Following participant contact
☐ Following participant enrollment
☐ Upon reaching study accrual objectives
☐ Other (please specify):

3. Other than the PI and research personnel, who else will have access to the health information?

4. Explain why this recruitment cannot practicably be conducted without the use of PHI.

5. Explain why the recruitment cannot practicably be conducted without the partial waiver of authorization.

Assurances

In applying for a partial waiver of authorization, I agree to the following:

A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in the research application), except as required by law.
B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB.
C) I will comply with VCU HIPAA policies and procedures and with the use and disclosure restrictions described above.
D) I assume responsibility for all uses and disclosures of the PHI by members of the study team.

SIGNATURE OF PRINCIPAL INVESTIGATOR:		DATE OF SIGNATURE:	

VCU IRB SUBMISSION FORM ADDENDUM

REQUIRED FOR RESEARCH INVOLVING

CHILDREN

PRINCIPAL INVESTIGATOR:	
Name (Last, First, MI):	McGrath, Jacqueline M.
Department:	Nursing
VCU Box # (must provide 6-digit #):	PO Box 980567
Study Title:	A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.
VCU IRB #:	
CHILDREN: AGE RANGE	Preterm infants from birth to 8 weeks of age.

The purpose of this VCU IRB form addendum is to assist the principal investigator in complying with the regulations unique to Children and to guide the reviewer in the review documentation.

An overview of special considerations to review prior to completing this form:

- In Virginia, children (those under the legal age of 18 and not emancipated) are also termed minors. Children are a special class of research participants and classified as vulnerable populations, with unique protections under DHHS regulations at 45 CFR 46 Subpart D and 21CFR50 Subpart D.
- Use this submission form addendum to ensure that the requirements of Subpart D are met if research will involve children, as defined in the Virginia Code or according to the law of the jurisdiction where the research will be conducted.
- Definitions: See Section B *Definitions*, in **WPP XV-1** for federal definitions of child, parent, guardian, assent and permission. In contrast to federal law, Virginia Code does not specifically define 'assent', 'permission' or 'parent' or 'guardian.'
- Legally Authorized Representatives for Children: For purposes of research with unemancipated minors, individuals who may serve as 'LARs" for children/ unemancipated minors are: 1) "the parent or parents having custody of a prospective subject who is a minor, 2) 'the legal guardian of a prospective subject,' or 3) 'any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research' (for children in state- or court-appointed custody).
- Court-appointed and State Custody: *Due to the specific requirements related to the involvement in human subjects research of children in court-appointed and state custody, such children ARE EXCLUDED from VCU IRB consideration, unless a specific request has been made to include children in court-appointed or state custody.* ***Section V*** on this form specifically addresses the inclusion of such children. To request the research participation of children in court-appointed or state custody, Section V ***MUST*** be completed. *See alsoIRB* ***WPP XV-3 "Children in Court-Appointed or State Custody and Emancipated Minors."***
- Legally-Emancipated Minors: Note that in Virginia, an individual below the age of 18 years of age who is legally emancipated (with legal documentation to verify such status) is permitted to make all decisions concerning research participation as would someone 18 and older who is also decisionally capable. Such an individual is no longer considered a 'child'

under Virginia law or federal definitions. Consequently, the individual's consent, not assent, is obtained and parental or guardian permission is not relevant to the research.

I. PERMITTED RESEARCH CATEGORIES:

Guidance for this section:

- Check one or more of the following categories of research that best describe your research study (404, 405, 406 or 407) and answer the questions in that section.
- NOTE: Subsequent sections of this form will refer to the category you select, below (be careful to fully consider ALL aspects of your research protocol).

Complete the following, Section I:

☒ **[404] NO GREATER THAN MINIMAL RISK:** Research involving no greater than minimal risk to children with adequate provisions for soliciting the assent of the children and permission of their parents or guardians (as set forth in Sec **46.408**) [**46.404**].

NEXT: Go to Section II – Assent of Children

☐ **[405] GREATER THAN MINIMAL RISK with Direct Benefit:** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. [**46.405**].

The principal investigator should provide brief protocol-specific information in support of each of the following 3 required conditions:

1. Explain how the risk is justified by the anticipated benefit to subjects:

2. Explain how the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

3. Briefly explain how you plan to ensure that provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. **46.408**.

NEXT: Go to Section II – Assent of Children

☐ **[406] GREATER THAN MINIMAL RISK with No Direct Benefit:** Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition **[46.406]**.

The principal investigator should provide brief protocol-specific information in support of each of the following 4 required conditions:

1. Explain how the risk represents only a minor increase over minimal risk.

2. Explain how the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

3. Explain how the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder, or condition.

4. Briefly explain how you plan to ensure that provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408.

NEXT: Go to Section II – Assent of Children

☐ **[407] NOT OTHERWISE APPROVABLE:** Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children **[46.407]**.

*The principal investigator should provide brief protocol-specific information in support of each of the following 2 required conditions [**NOTE:** if the research is not HHS funded, then only the first condition must be met]:*

1. Explain how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. (Note: The IRB will also have to make this finding, so be clear and include protocol-specific information).

2. **(For HHS Supported Research ONLY):** The Secretary, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment has made its required determinations under Sec. **46.407**. The OHRP Guidance Document: **Special Protections for Children as Research Subjects (45 CFR 46.407 Process)** will be followed by the VCU IRB. Not until the Secretary has issued determinations in writing back to the IRB (as documented in the official record) will the IRB be able to fully review the research and consider it approval status.

   Has the Secretary issued a written determination? ☐ YES ☐ NO

NEXT: Go to Section II – Assent of Children or Waiver of Assent (Request)

II. ASSENT OF CHILDREN OR WAIVER OF ASSENT (REQUEST):

Guidance for this section:

- The principal investigator should provide briefly describe the assent plan (including any request for waiver of assent (for certain ages or situations) below.
- Protocol specific information must be provided in support of each item below (page numbers are helpful, but should not be provided in lieu of specific information) [s***ee VCU IRB WPP#: XV-2 for detailed guidance].***
- Unless age-specific waiver of assent is requested and approved, children of age 7 and higher are expected to be part of the discussion about the research. To request a waiver of assent for some or all participants, due to age or anticipated condition, the PI must provide a sufficient justification. Child

participants not meeting the age or condition specified must give assent. An IRB approved waiver of assent for children below age 7 is not required.

Complete the following, Section II:

1. Completely describe the provisions in place for soliciting the assent of children (when the IRB determines capability to do so). Please note that the IRB may consider waiver of assent for certain age groups (if requested and justified by the PI here). Generally, the VCU IRB anticipates assent appropriate for children 7 and older.
   N/A.

   1(a). Exactly how do the provisions for assent take into account, ages, maturity, and psychological state for decisions made on behalf of all children or each child (IRB will review and determine if this is appropriate).

   1(b). For research which holds a prospect for direct benefit (available only through the research), indicate if assent be ***required*** for the research to proceed.

   NOTE: Assent of children to participate in research may be waived by the IRB for children above the age of 7 (in agreement with PI justification) in cases where the research holds out the prospect of direct benefit to the health or well-being of the children, and is available to them only in the context of the research. In such circumstances, children should be informed about the research, but should be told that their assent will not be solicited. Indicate if the waiver of assent will apply to all children regardless of age or condition. If the waiver will only apply to some children, give examples and explain why their assent is to be waived.

2. Indicate if the waiver of assent will apply to all children or some children. If the waiver will only apply to some children, give examples and explain why their assent is to be waived, eg. a) some/all children will not be capable of providing assent based on their age, maturity, psychological, or physical state, the capability of some or all children may be so limited that they could not reasonably be consulted, c) the research holds out the prospect of direct benefit that is important to the health or well-being of some or all children and is only available in the context of the research, and/or d) the criteria for waiver of consent apply to the waiver of assent ((45CFR46.116.d) See WPP XI-1 Consent Process, Elements, Waiver of Element(s), and Modification).

III. WAIVER OF PARENTAL/GUARDIAN PERMISSION:

Guidance for this section:

- Parental/guardian permission may not be waived for FDA-regulated research except for emergent or life-threatening situations, either individually or as a group (see 21CFR 50.23 and 24, respectively).
- For non-FDA regulated research all of the requirements of 45CFR46.116 concerning informed consent apply to parental permission, including the general and required elements.
- See WPP XI-1 CONSENT PROCESS, ELEMENTS, WAIVER OF ELEMENT(S), AND MODIFICATION. The elements of informed parental permission can be modified or waived entirely in accord with 45CFR46.116 (d).

Complete the following, Section III:

A. Is a waiver of parental or guardian permission requested?

☐ YES – Continue to "B"

☒ NO – Skip the remainder of this section, Continue at Section IV.

B. The principal investigator should provide brief protocol-specific information in support of each of the following ONLY IF WAIVER OF CONSENT/permission IS REQUESTED:

1. The PI/IRB must find/document that the requirement for parental permission is not reasonable in order to protect the subjects (e.g., abused, neglected children).

2. The IRB/PI must ensure that an appropriate mechanism for protection of the children is substituted.

3. Consideration must be given to the nature of the research, risks and benefits, and the subject's age, maturity, status, and condition.

4. Indicate that the 4 elements for waiver of some or all elements of parental permission/informed consent are addressed (45CFR46.116.d) See *WPP XI-1* CONSENT PROCESS, ELEMENTS, WAIVER OF ELEMENT(S), AND MODIFICATION.

IV. DOCUMENTATION OF PARENTAL/GUARDIAN PERMISSION AND ASSENT

Guidance for this section:

- Documentation of parental permission is determined according to 45CFR46.117, or 21 CFR50 Subparts B and D. See WPP XI-2 Informed Consent Documentation, Waiver of Documentation, and Required Signatures.
- For Categories 404 and 405: If the Research involves categories 404 and 405, The IRB may find that the permission of one or both parents is adequate/necessary. For Categories 406 and 407: If the research involves categories 406 and 407, the IRB must find that the permission of BOTH parents is necessary unless one parent is deceased, unknown, incompetent, not reasonable available, or not a custodial parent.
- Consent forms should be drafted to allow for BOTH parents to provide permission for a child to participate in research. The inclusion of two consent signature lines will help to ensure that both parents are encouraged to provide and document their permission in all cases, if so desired.

Complete the following, Section IV:

A. Parental/Guardian Permission: Indicate your plan for obtaining parental signatures (see guidance, above):

[X] We will require that ONE parent/guardian to sign permission (research under category 404 or 405). Justification: Category 404—No greater than minimal risk to the infant as nasal CPAP with all three types of nasal interfaces are currently used at the study site (CHKD NICU) for the administration of nasal CPAP, which is a universally accepted method of respiratory support for the preterm infant. The randomization into one of three groups for the research project for the purpose of correlation between nasal interface type and the incidence and severity of skin injury is the study purpose with skin assessment every 10-12 hours during the nasal CPAP use by a skilled nursing professional who is currently employed at the research site. The skin assessments will be coordinated with routine infant care so that additional interruption of the infants sleep will be minimized. Additionally collected data will be extrapolated from the medical record and will require no additional patient testing or manipulation.

[ ] We will require that TWO parents/guardians sign permission (research under category 404 or 405) when both parents/guardians are reasonably available. Justification:

[ ] We will require that TWO parents/guardians sign permission (research under category 406 and 407) unless one parent is deceased, unknown, incompetent, not reasonably available, or not a custodial parent. Justification:

B. Assent Signature: Indicate your plan for obtaining assent of the child (provide a brief justification where required).

1. **Is a signature of assent required for ages 7 and older (standard practice)?**
   - [ ] **YES**
   - [ ] **NO:** If assent signature is not required for all children, ages 7 and older, please answer the following:

     a. Indicate the *age range* for assent (e.g. ages 10 and older) and explain why this age range was chosen:

     b. Explain how the investigator will record assent (in the case where a signature is not required)

     c. If a signature of assent will be required on a case-by-case basis, explain how it will be determined which children will be asked/required to sign an assent document.

2. **Indicate the type of assent document:**
   - [ ] Assent Form (Separate from Parental/Guardian Permission)

☐ Assent Combined with Parental/Guardian Permission Form (additional signature block on the parent/guardian document).

V. SPECIAL REQUEST/JUSTIFICATION FOR THE INVOLVEMENT OF CHILDREN (OR AN INDIVIDUAL CHILD) IN COURT-APPOINTED OR STATE CUSTODY

Guidance for this section:

- Children in court-appointed or state custody (frequently termed 'wards of the state') are viewed as highly vulnerable research subjects. Plans for their involvement are to be considered accordingly.
- *Please see* ***VCU IRB WPP #XV-3:*** **Children in Court-Appointed or State Custody and Emancipated Minors**.

Complete the following, Section V:

☒ Check here to indicate that this research will ***EXCLUDE*** children in court-appointed or state custody (*Skip this section V*). ***Form ends.***

OR

☐ Check here to indicate that this research will ***INCLUDE*** children in court-appointed or state custody (***Complete this section***).

Categories ☐ [404] *OR* ☐ [405] ONLY: *(Be sure to use the same category you selected in section I of this form!)*

Ensure that all 5 criteria are addressed (regulations require justification using protocol-specific information):

☐ (1) The research is submitted under category 404 or 405 and qualifies based upon the following brief information:
Justification:

☐ (2) The research is therapeutic with the prospect of direct benefit to the child or if non-therapeutic, represents no more than minimal risk to the subject**.**
Justification:

☐ (3) For children in court-appointed or state custody (as vulnerable research subjects), the research does not pose additional risks to and/or could not reasonably be accomplished without their inclusion.
Justification:

☐ (4) For children in court-appointed or state custody (as vulnerable research subjects), the LAR does not over-ride known or reasonably known religious or value restrictions of the child in court-appointed or state custody (or parents or guardians) and otherwise acts in accordance with the laws of the Commonwealth.
Justification:

☐ (5) Assent is requested of the child, as appropriate given the age and maturity of the child.
Justification:

Categories ☐ [406] *OR* ☐ [407] ONLY: *(Be sure to use the same category you selected in section I of this form!)*

Ensure that all 9 criteria are addressed (regulations require justification using protocol-specific information):

☐ (1) The research is submitted under category 406 or 407 and qualifies based upon the following brief information:
Justification:

☐ (2) The research is a study focused on evaluating the status of wards OR conducted in a setting where the majority of children involved as subjects are NOT in court-appointed or state custody.
Justification:

☐ (3) The research is therapeutic with the prospect of direct benefit to the child or if non-therapeutic, represents no more than minimal risk to the subject.
Justification:

☐ (4) The research does not pose additional risks to children in court-appointed custody (as vulnerable research subjects) and/or could not reasonably be accomplished without their inclusion.
Justification:

☐ (5) The LAR does not over-ride known or reasonably know religious or value restrictions of the child in state custody and otherwise acts in accordance with the laws of the Commonwealth.
Justification:

☐ (6) An advocate is appointed for each child who is in court-appointed or state custody (the advocate may serve on behalf of more than one child at a time and must be prepared to document appropriate background and experience to act in the best interests of the child for the duration of the research, document their willingness accept the role of advocate for the child, document that they have no other association with the research/investigator(s)/guardian organization, except as the role of advocate or member of the IRB.
Justification:

☐ (7) Explain whether the parents of a child in court-appointed custody are to be informed of the child's possible involvement in research and whether parental refusal may be considered.
Justification:

☐ (8) Assent is requested of the child, as appropriate given the age and maturity of the child.
Justification:

☐ (9) If a child(ren) in court-appointed or state custody is/are eligible for enrollment, but the study was not approved by the IRB to involve children in court-appointed or state custody, include the rationale, and process to allow such children as participants in the research (attach the VCU IRB Change in Research form to mark the submission).
Justification:

VIRGINIA COMMONWEALTH UNIVERSITY

Conflict of Interest Disclosure Statement

No.:_____
Rec'd by:_____
Date:_____
Actions:
To COIRC:_____
To File:_____

Under VCU Research Policy, the Principal Investigator and all others who have responsibility for the design, conduct, or reporting of research, must disclose financial interests in any external entity that is related to the work to be conducted under the proposed project or is interested in the results of the project. Providing this information is mandatory. Any individual who voluntarily discloses financial interests related to extramurally supported research projects should also use this form. Under the Virginia Public Records Act, this information may be made available to the public upon request.

Principal Investigator: Jacqueline M. McGrath PhD, RN, NNP, FNAP, FAAN School/Dept: School of Nursing, Maternal Child Health
Funding Entity: N/A Contract/Grant No: N/A
Title of Research Project: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when Using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

Reason for Disclosure: ☒ New Proposal ☐ Additional Support ☐ New Protocol ☐ New Investigator ☐ New Interest Obtained
☐ Revisions to Grant/Contract ☐ Grant/Contract Continuation

Disclosure and Certification

By signature below, each individual certifies that either no Financial Interest exists or that a complete listing of all financial interest is provided on a Disclosure Supplement form. All individuals named below further acknowledge their responsibility to disclose any new Financial Interest obtained during the term of the award.

The Principal Investigator's signature certifies that all individuals required to make disclosures have been listed below.

A. Do you, your spouse, or dependent children have a Financial Interest in an external entity related to the work to be conducted under the project or interested in the results of the project? (See reverse for definitions of Financial Interests.) – Check response below adjacent to your signature.

B. If the project is funded, to the best of your knowledge, does any VCU employee have a financial interest, including an ownership or equity interest, in the sponsor? Check response below adjacent to your signature.

C. Project is Unfunded: ☒

1. Jacqueline M McGrath 12/5/11
Signature (PI) Date
Jacqueline M. McGrath
Print or Type Name of **Principal Investigator**
A. ☒ NO ☐ YES, Supplement Form attached
B. ☐ NO ☐ YES, Name

2. Katherine M Newnam 11/30/11
Signature Date
Katherine Newnam
Print or Type Name of Investigator
A. ☒ NO ☐ YES, Supplement Form attached
B. ☐ NO ☐ YES, Name

3. 12/5/11
Signature Date
Rebecca Tucker
Print or Type Name of Investigator
A. ☒ NO ☐ YES, Supplement Form attached
B. ☐ NO ☐ YES, Name

4. Melinda Bissett 12/5/11
Signature Date
Melinda Bessett
Print or Type Name of Investigator
A. ☒ NO ☐ YES, Supplement Form attached
B. ☐ NO ☐ YES, Name

5. Lynetta Cox 12/5/2011
Signature Date
Lynetta Cox
Print or Type Name of Investigator
A. ☒ NO ☐ YES, Supplement Form attached
B. ☐ NO ☐ YES, Name

(please attach additional pages as required)

10/15/04 (over)

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME McGrath, Jacqueline M.	POSITION TITLE Faculty, Associate Professor
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Akron, Akron, OH	BSN	1984	Nursing
Kent State University, Kent, OH	MSN	1989	Nursing – Parent-Child
University of Pennsylvania, Philadelphia, PA	NNP	1998	Post-Grad NNP
University of Pennsylvania, Philadelphia, PA	PhD	1999	Nursing

A. PERSONAL STATEMENT

The proposed prospective single-arm pilot study will provide feasibility data that is necessary to conduct a future RCT of an innovative mother-participative massage intervention for very preterm infants (VPIs). My background of more than 25 years in neonatal nursing with almost 15 years of research experience has focused on the integration of developmental interventions for high-risk infants during their stay in the neonatal intensive care unit (NICU). My research experience began at the University of Pennsylvania where I was the project director for two large NIH funded studies (#2-RO1-NR02093-06 & SBIR funded by NIH/Heart & Lung) related to understanding the neurologic organization of preterm infant sucking and oral feeding. I coordinate all aspects of data collection and entry; including hiring and trained of personnel and maintenance as well as integrity of the study protocol. Coupled with this experience and my work in the NICU, I developed and recently completed the reliability and validity testing of the Feeding Readiness and Progression in Preterms Scale (FRAPPS) (R15 NR09235-02). Like the intervention proposed in this application, feeding readiness is developmental in nature. Both interventions address the need to provide care that is age appropriate and uses physiologic and behavioral cues as a means to gauge intervention effectiveness. I am trained as an infant massage specialist and considered a clinical expert in developmental care; as such I am the coordinator for the Neonatal Developmental Specialist Designation implemented by the National Association of Neonatal Nurses. Completion of this designation demonstrates excellence in neonatal developmentally supportive caregiving. I am also the Co-Editor of *Developmental Care for Infants and Newborns: A Guide for Health Professionals 2nd edition (2010).*

As the Principal Investigator, I will be responsible for overseeing and coordinating all aspects of the research. I will work closely with the study collaborators and research team on all phases of the research. I will lead preparation of manuscripts and future study development. This feasibility study is the result of our recent R01 submission where we received a score of 47 with a percentile of 29%. We believed the best way to address reviewer comments and concerns were more data. We plan to resubmit as soon as we have the data analysis completed for this research. Future studies will include extending the intervention into a multi-site trial with follow-up through the 1st year of life as well as with different populations/cultures especially the US Latino population. In addition we plan to add more long term follow-up with objective evaluation of infant parent interactions as an outcome and as well as in-depth cost analysis of the intervention in comparative effectiveness studies. Inclusion of fathers in future research aims will also be a priority.

B. POSITIONS/HONORS

POSITIONS AND EMPLOYMENT

1989-1994	Maricopa Integrated Healthcare System -- Infant Developmental Specialist, NICU
1993-1994	Department of Maternal-Child Health- NICP -- Infant Developmental Consultant AZ
1994-1998	Children's Hospital of Philadelphia, PA -- Staff Nurse NICU, Developmental Team
1998-1999	Delaware County Memorial Hospital, Drexel, PA -- Neonatal Nurse Practitioner
1994-1999	University of Pennsylvania, SON -- Nutritive Sucking Research, Project Director
1999-2005	Arizona State University, College of Nursing -- Assistant Professor
2000-2006	Arizona State University, College of Nursing -- Coordinator, Neonatal Track
2005-2006	Arizona State University, College of Nursing -- Associate Professor
2006-Present	Virginia Commonwealth University, SON -- Associate Professor
2006-2009	P-20 Center for Biobehavioral Research, SON -- Center Affiliate
2009-Present	P-30 Center for Excellence in Biobehavioral Research, SON -- Center Affiliate

PROFESSIONAL CERTIFICATIONS

NDCSD	Neonatal Developmental Care Specialist Designation, National Association of Neonatal Nurses, summer 2008
CCNS	Certified Neonatal Clinical Nurse Specialist, AACN, May, 1999.
LEND	Fellowship - Leadership Education in Neurodevelopmental & Disabilities – 1999.
NCAST	Nursing Child Assessment Satellite Training, University of Washington, May 1988.
NIDCAP	Neonatal Individualized Developmental Care and Assessment, October 1990, 1992.

GRANT REVIEW BOARDS

AWHONN – Association of Women's Health, Obstetrical, and Neonatal Nurses
Present- 2008 Research Advisory Panel – Corresponding Member
National Institute of Health
2009, June Stage 1 NIH Challenge Grant applications; mail reviewer
American Nursing Foundation
2010-2008 Stage 1; Grant Reviewer
2010 Grant Review Board
2011 Vice Chair, Grant Review Board
2012 Chair, Grant Review Board
Health Resources & Services Administration: Bureau of Health Professions
2002, April Nursing Education Grant Review Panel
2003, July Advanced Nursing Education Grant Review Panel
2003, March Advanced Nursing Education Grant Review Panel
2010, August Advanced Nursing Education Grant Review Panel

HONORS/AWARDS

1999 Marian R. Gregory Dissertation Award: University of Pennsylvania, School of Nursing, Philadelphia, PA.
1999 Henry O. Thompson Prize in Ethics - for distinction: University of Pennsylvania, School of Nursing, Philadelphia, PA.
2001 Outstanding Alumni, College of Nursing, University of Akron, Akron, OH.
2004 Excellence in Leadership STTI, Beta Upsilon Chapter, ASU College of Nursing, Tempe, AZ
2004 Joyce Finch Faculty Achievement Award, ASU College of Nursing, Tempe, AZ
2005 Fellow of the National Academies of Practice
2006 Research Dissemination Award, ASU College of Nursing, Tempe, AZ
2006 JPNN Publication Award: "State of the Science: Feeding Readiness in the Preterm Infant"
2007 Fellow American Academy of Nursing
2008 Distinguished Service in Neonatal Nursing Award – National Association of Neonatal Nurses
2010 Faculty Mentor for the Sigma Theta Tau International: Nurse Faculty Mentored Leadership Development Program (NFMLD).

C. Selected peer reviewed PUBLICATIONS (in chronological order)
(Selected from 70 peer-reviewed publications)

1. Medoff-Cooper, B., **McGrath, J. M.**, & Shults, J. (2002). Feeding patterns of Full term and preterm infants at forty weeks post-conceptional age. *Developmental and Behavioral Pediatrics,* 23(4), 231-236. PMID: 12177569
2. Hughes, M. B., Shults, J., **McGrath, J. M.**, & Medoff-Cooper, B. (2002). Temperament characteristics of premature infants during the first year of life. *J Dev & Behavioral Pediatrics, 23*(6), 430-435. PMID: 12476073
3. **McGrath, J. M.,** & Medoff-Cooper, B. (2002). Alertness and feeding competence in extremely early born preterm infants. *Newborn and Infant Nursing Reviews, 2*(3), 174-186.
4. **McGrath, J. M.,** & Braescu, A. V. B. (2004). State of the Science: Feeding Readiness in the Preterm Infant. *Journal of Perinatal and Neonatal Nursing, 18(4),* 353-370. PMID: 15646306
5. **McGrath, J. M**., Records, K., & Rice, M. (2008). Maternal depression and infant temperament characteristics. *Infant Behavior and Development,* 31(1), 71-80. doi:10.1016/j.infbeh.2007.07.00 PMCID: PMC2268864
6. Samra, H. A., & **McGrath, J. M**. (2009). Pain Management during retinopathy of prematurity eye exams: A Systematic Review. *Advances in Neonatal Care, 9*(3), 99-110.PMID: 19542771
7. **McGrath, J. M.** (2009). Touch and massage in the newborn period: Effects on biomarkers and brain development. *Journal of Perinatal and Neonatal Nursing, 23*(4), 304-306. PMID: 19915411
8. Pickler, R. H., Brown, L. **McGrath, J. M.,** Lyons, D. E., Rattican, D., Cheng, C.Y., Howell, L., Jallo, N., (2010). Integrated review of the association of cytokines in maternal cord and newborn blood to adverse outcomes in preterm infants: Part II. *Biological Research for Nursing. 11,* 377-386. doi: 10.1177/1099800409344619 PMID: 20028689
9. Melnyk, B., Bulluck, T., **McGrath, J.,** Kelly, S. Jacobsen, D., & Baba, L. (2010). Translating the Evidence-based NICU COPE Program for Parents of Premature Infants into Clinical Practice: Impact on Nurses' EBP and Lessons Learned. *Journal of Perinatal & Neonatal Nursing,* 24(1), 74-80. doi: 10.1097/JPN.0b013e3181ce314b PMID: 20147834
10. Ho, Y. J., & **McGrath, J. M.** (2010). A review of the psychometric properties of breastfeeding assessment tools. *JOGNN: Journal of Obstetrical, Gynecological and Neonatal Nursing, 39*(4), 386-400. doi:10.1111/j.1552-6909.2010.01153.x PMID: 20697246
11. **McGrath, J. M.**, Samra, H. A., Zukowsky, K., & Baker, B. (2010). Parenting after infertility: Issues for families and infants. *MCN: The American Journal of Maternal Child Nursing, 35*(3), 157-164. doi: 10.1097/NMC.0b013e3181d7657d PMID: 20453593
12. Samra, H. A., **McGrath, J. M.**, Wey, H., & Roe, T. (2010). Are former late preterm children at risk for perceived vulnerability and overprotection? *Early Human Development,* 86,557-562. doi:10.1016/j.earlhumdev.2010.07.005 PMID: 20696540
13. Baba, L., **McGrath, J. M.**, & Liu, J. (2010). The efficacy of vibration analgesia for relief of heel stick pain in the term and near-term neonate. *Journal of Perinatal and Neonatal Nursing, 24*(3), *24*(3), 274-283. doi: 10.1097/JPN.0b013e3181ea7350 PMID: 20697246
14. Newnam, K,. M., & **McGrath J. M.** (2010, in press). Understanding the inflammatory response of the neonate: Clinical implications for caregivers in the NICU. *Newborn and Infant Nursing Reviews, 10*(4),
15. Pickler, R. H., **McGrath, J. M.,** Reyna, B. A., McCain, N., Lewis, M., Cone, S., Best, A., Wetzel, P. (2010, in press) A Model of Neurodevelopmental Risk and Protection for Preterm Infants. *Journal of Perinatal and Neonatal Nursing. 24(4),*

D. RESEARCH SUPPORT

ONGOING RESEARCH SUPPORT

Improving outcomes for preterm infants through holding during gavage feedings
Phoenix, Children's Hospital; Phoenix, AZ 2006-2010
This research examines the benefits of an evidence-based holding intervention during gavage feeding in the NICU. PI: Peters, A. ROLE: Co-Investigator

FUNDED TRAINEES

F31NR011268 Baker (Fellow) 2009-2011
NINR, NIH Understanding Late Preterm Mothers and Infants
ROLE: Sponsor

COMPLETED RESEARCH SUPPORT

P20 NR008988 McCain (PI) 07/01/07-06/30/09
NINR Biobehavioral Research in Critical Health Experiences
Pilot study: Safety & Feasibility of a Touch and Massage Intervention; NICU-PLAY
ROLE: Pilot Study Investigator 2007-2009

R15 NR09235-02 McGrath (PI) 03/01/06-02/28/09
Feeding Readiness and Progression in Preterms Scale (FRAPPS)
NIH/National Institute of Nursing Research
This research is the validity and reliability testing for the FRAPPS in the NICU. This 10 item pen and paper instrument is designed to predict the appropriate initiation of oral feeding and provide an assessment of how progression should best occur for preterm infants in the NICU. Ongoing analysis of the FRAPPS will provide: additional reliability and validity data; further the understanding of the interrelationship of physiologic and neurobehavioral feeding variables; and, increased potential to identify infants feeding readiness, and thus, progression to full feedings. The next phase of the FRAPPS research is a quasi-experimental design to test the predictive validity of the FRAPPS (planned submission October, 2011). ROLE: Principal Investigator

NICU Implementation of Massage Survey McGrath (PI)
Children's Medical Ventures Manager Meeting Spring 2009
Distribution of this questionnaire provided more understanding of the obstacles and barriers to integrating a parent-delivered massage intervention into the caregiving provided routinely in the NICU. ROLE: Principal Investigator

COPE in the NICU: A Dissemination Pilot Study
Phoenix, Children's Hospital; Phoenix, AZ 03/01/06-04/30/07 Melnyk (PI)
This research is a pilot study to examine two different dissemination approaches for the COPE intervention in the NICU. ROLE: Co-Investigator

Parent Delivered Gentle Infant Massage: Program Evaluation
Phoenix Children's Hospital, NICU 2005-2006
This research provided the beginning data to develop a massage intervention for VLBW infants in the NICU. ROLE: Co-Principal Investigators Thillet, M. & McGrath, J. M.

CITI Collaborative Institutional Training Initiative

Basic/Refresher Course Human Subjects Research Curriculum Completion Report
Printed on 10/25/2010

Learner: Jacqueline McGrath (username: jmmcgrath)
Institution: Virginia Commonwealth University
Contact Information Richmond, VA
Department: NURSING
Phone: 804-828-1930
Email: jmmcgrath@vcu.edu

Social and Behavioral: *This course is suitable for Investigators and staff conducting SOCIAL / HUMANISTIC / BEHAVIORAL RESEARCH with human subjects. Unless previously completed you **MUST** take the Basic Course.*

Stage 1. Basic Course Passed on 10/25/10 (Ref # 5044884)

Required Modules	Date Completed	Score
Introduction	10/25/10	no quiz
History and Ethical Principles - SBR	10/25/10	2/4 (50%)
Defining Research with Human Subjects - SBR	10/25/10	5/5 (100%)
The Regulations and The Social and Behavioral Sciences - SBR	10/25/10	5/5 (100%)
Assessing Risk in Social and Behavioral Sciences - SBR	10/25/10	5/5 (100%)
Informed Consent - SBR	10/25/10	5/5 (100%)
Privacy and Confidentiality - SBR	10/25/10	3/3 (100%)
Research with Prisoners - SBR	10/25/10	4/4 (100%)
Research with Children - SBR	10/25/10	3/4 (75%)
Research in Public Elementary and Secondary Schools - SBR	10/25/10	4/4 (100%)
International Research - SBR	10/25/10	3/3 (100%)
Internet Research - SBR	10/25/10	4/4 (100%)
Virginia Commonwealth University	10/25/10	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Katherine Newnam 1104 Hillston Court, Chesapeake, VA 23322

Employment/ Experience

Jan. 2007 to present Neonatal ICU CHKD

Neonatal Nurse Practitioner

Assessment, diagnosis and treatment for the critical ill neonate within the ICU under the direct supervision of the neonatologist.

1994-2001 and 2005-2007 Neonatal ICU CHKD

Staff Nurse

Continual assessment and treatment of neonates under the direction of the neonatologist, resident staff and /or neonatal nurse practitioner. Assist with additional staffing when needed. Participate in the family support committee to enhance family centered care within the NICU.

2000-2005 Renaissance Pediatrics Chesapeake, VA

Certified Pediatric Nurse Practitioner

With the oversight of a supervising physician I assessed, diagnosed and treated patients including prescriptive authority. Patient load was approximately 22 assigned pediatric patients daily from newborn to age 21 years. Focus on well and preventative care with a focus in lactation and asthma support and teaching. Supervised office nursing and support persons while assigned to assist in my daily functions. Phone triage at night as assigned; weekly and hospital visits as required.

2001-2006 Hospital Lactation Support CHKD

Lactation consultant

Assist with any lactation issues throughout the inpatient units and the Emergency department. Hands on participation with latch techniques and pumping equipment and support.

1988-1994 Progressive Care Unit CHKD

Unit Director, Progressive Care Unit

Twenty four hour accountability for the operation of the Progressive Care Nursing Unit. This included staffing, patient care, education, budget analysis and development, policy development and departmental representation for the Progressive Care Unit. Implemented departmental relocation to the third floor and unit expansion from 10-13 beds. Directly supervised and evaluated the performance of fifty professionals and paraprofessionals with the assistance of two assistant nurse managers.

1986-1988 Assistant Unit Director NICU

1983-1986 Staff Nurse Infant & Toddler Unit/NICU

Education

May 1983	Old Dominion University	Norfolk, VA
Bachelor of Science	Nursing	
August 1990	Old Dominion University	Norfolk, VA
Master of Science	Nursing Administration	
December 1999	Old Dominion University	Norfolk, VA
Post Master's Certification	Certified Pediatric Nurse Practitioner	
December 2006	East Carolina University	Greenville, NC
Post Master's Certification	Neonatal Nurse Practitioner	
August 2008-Current	VA Commonwealth Univ.	Richmond, Va.
(graduation 2/2013)	PhD in Nursing	

Professional Affiliations

NAPNAP National and Local Chapter
NANN National and Local Chapter

Certifications

Basic Life Support (BLS)
Neonatal Advanced Life Support (NALS)
Pediatric Advanced Life Support (PALS)
Certified Pediatric Nurse Practitioner (CPNP)
Certified Neonatal Nurse Practitioner (NNP)
Lactation Consultant (IBCLC)

Publications/ Presentations

Newnam, K.M. & Parrott, J. (2013). The NICU graduate; Implications for Pediatric Primary Care. Newborn & Infant Nursing Reviews. Accepted for publication (June, 2013).

Newnam, K. M., McGrath, J.M., Jallo, N., Sayler, J., Estes, T, & Bass, W.T. (2012). An Integrative Review of Skin Breakdown in the Preterm Infant Associated with Nasal Positive Airway Pressure. Journal of Obstetric, Gynecologic & Neonatal Nursing. Accepted with revisions.

Newnam, K. M. (2012). Understanding the mystery of adrenal insufficiency in the preterm infant & Continuous Positive Airway Pressure (CPAP): What Do We Know in 2011? 28th National Association of Neonatal Nurses (NANN) 27th Annual Educational Conference, Palm Springs, Ca. Podium Presentations.

Newnam, K. M., McGrath, J.M., Jallo, N., Sayler, J., Estes, T, & Bass, W.T. (2012). Continuous Positive Airway Pressure (CPAP), State of the Science. Council of the Advancement of Nursing Science (CANS), 2012 SOS Congress-Nursing Research, Washington, DC. Poster Presentation.

Newnam, K. M. (2012). Sharing Science as a method to increase breast feeding rates in the NICU. NANN Research Summit, Scottsdale, AZ.

Newnam, K. M. (2012). Strategies to Reduce Skin Injury related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants. 26th Annual Conference of the Southern Nursing Research Society (SNRS), Podium presentation.

Newnam, K. M. (2011). Prevention of Skin Injury Related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants, An Evidence Based Approach. 25th Anniversary Research Symposium of the National Institute of Health/National Institute of Nursing Research (NINR), Washington DC, Poster Presentation.

Newnam, K. M. (2011). Prevention of Skin Injury Related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants. 6th Annual Research Summit of the National Association of Neonatal Nurses (NANN), Orlando, Fl. Paper Presentation.

Newnam, K. M. & DeLoach, D. L. (2011). Neonatal Hypothermia: A Method to Provide Neuroprotection After Hypoxic Ischemic Encephalopathy. Newborn and Infant Nursing Reviews. Vol. 11 (3), 113-124.

Newnam, K. M. & McGrath, J. M. (2011). Following the Diagnosis of Neonatal Hypoxic Ischemic Encephalopathy: A Family-Centered Approach. Newborn and Infant Nursing Reviews. Vol 11 (3), 98-101.

Newnam, K. M. (2011). Prevention of Skin Injury related to Continuous Positive Airway Pressure (CPAP) in Preterm Infants. NANN Research Summit, Scottsdale, AZ.

Newnam, K. M. & McGrath, J. M. (2011). Integrated Review of findings related to Neonatal Skin Care. Southern Nursing Research Society (SNRS), Jacksonville, Fl., Poster Presentation.

Newnam, K. M. & McGrath, J. M. (2010). Understanding the Inflammatory Response of the Neonate: Clinical Implications for Caregivers in the Neonatal Intensive Care Unit. Newborn and Infant Nursing Reviews. Vol. 10 (4), 165-176.

Newnam, K. M. & McGrath, J. M. (2010). Families and the Sepsis Work-up: Considering their Fears. Newborn and Infant Nursing Reviews. Vol. 10 (4), 160-162.

Newnam, K. M. Improving Fluid Management and Decreasing PDA by improving the Neonatal Environment. Poster presentation for National Association of Neonatal Nurses (NANN), Annual conference 10/07.

Newnam, K. M. Hyperbilirubinemia: Guidelines for Care in the Newborn. Presentation to Tidewater Area Lactation Consultant Association (TALCA) in 9/2005.

Newnam, K. M. Hyperbilirubinemia: Guidelines for Care in the Newborn. Repeated presentation for NICU staff educational session, 10/2005.

CITI Collaborative Institutional Training Initiative

Basic/Refresher Course Human Subjects Research Curriculum Completion Report
Printed on 9/9/2010

Learner: Katherine Newnam (username: newmankm2)
Institution: Virginia Commonwealth University
Contact Information 1104 Hillston Court
Chesapeake, Virginia 23322
Department: School of Nursing
Phone: 757-546-7497
Email: kathynewnam@cox.net

Biomedical: *This course is suitable for investigtors and staff conducting BIOMEDICAL RESEARCH with human subjects. Unless previously completed you **MUST** take the Basic Course.*

Stage 1. Basic Course Passed on 09/09/10 (Ref # 4911460)

Required Modules	Date Completed	Score
Introduction	09/09/10	no quiz
History and Ethical Principles	09/09/10	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	09/09/10	5/5 (100%)
Informed Consent	09/09/10	4/4 (100%)
Social and Behavioral Research for Biomedical Researchers	09/09/10	4/4 (100%)
Records-Based Research	09/09/10	2/2 (100%)
Genetic Research in Human Populations	09/09/10	2/2 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	09/09/10	4/4 (100%)
Vulnerable Subjects - Research with Prisoners	09/09/10	4/4 (100%)
Vulnerable Subjects - Research Involving Minors	09/09/10	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women and Fetuses in Utero	09/09/10	2/3 (67%)
Group Harms: Research With Culturally or Medically Vulnerable Groups	09/09/10	3/3 (100%)
FDA-Regulated Research	09/09/10	5/5 (100%)
Hot Topics	09/09/10	no quiz
Conflicts of Interest in Research Involving Human Subjects	09/09/10	2/2 (100%)
Virginia Commonwealth University	09/09/10	no quiz

For this Completion Report to be valid, the learner listed above must be

affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Appendix B.

The following published research plan was submitted to and approved by the Eastern Virginia Medical Center Institutional Review Board

OFFICE OF RESEARCH SUBJECTS' PROTECTIONS | WWW.EVMS.EDU
P.O. Box 1980 □ Norfolk, VA 23501-1980 | Phone: 757.446.5854 □ Fax: 757.624.2275

Teaching. Discovering. Caring.™

EVMS
Eastern Virginia Medical School

March 8, 2012

Kathy Newnam, RN, NNP-BC
CHKD
601 Children's Lane
Norfolk, VA 23507

IRB # 12-01-EX-0013

Dear Ms. Newnam:

This form provides additional information to the *Application for Approval of Research Involving Human Subjects* form that accompanies this letter. The Application is the official document that confirms IRB review and type of approval and includes the IRB#, study title, and an appropriate chair, vice-chair or IRB member signature.

☒ IRB Study Title: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

- Protocol: A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate Version Date: No version date

☒ No sponsor has been identified as providing funding for this study or project.

☒ Data Collection Consent Form: Version 1 Dated: 12/22/11
Your consent form has been stamped with the approval date and is/are enclosed for your use until a different consent form supersedes it. Please remember that a signed written consent form is not considered a substitute for discussion, but an educational process including a full explanation of the protocol and consent form to the subject, while allowing time for questions prior to signing. The subject's signature is considered verification of the investigator's explanation of the research prior to, not after, initiation of the research.

☒ Waiver for the Use of PHI has been justified using the following criteria:

- The use or disclosure of PHI involves no more than minimal risk to the individuals, based on, at least, the presence of the following elements:
  a. An adequate plan to protect the identifiers from improper use/disclosure
  b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law
  c. Adequate written assurances that PHI will not be reused/disclosed to any other person or entity, except as required by law, for authorized oversight of research project, or for other research for which use/disclosure of PHI would be permitted by this subpart.
- The research could not practicably be conducted without the alteration or waiver;
- The research could not practically be conducted without access to and use of the PHI.

☒ Data Collection Tools:
Data Collection Form – Enrollment
Data Collection Form – Daily
Data Collection Form - Weekly

This approval is a result of an **Expedited Board** action that specified the following category/categories under 63FR 60364 dated November 9, 1998:

☒ (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☒ (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☒ This study was approved on **January 25, 2012** and may be initiated now that you are in receipt of Final Approval documents.

- IF YOU ARE CONDUCTING YOUR RESEARCH AT ONE OF THE LOCAL HOSPITALS, YOU MUST RECEIVE THE APPROPRIATE APPROVALS FROM THAT HOSPITAL BEFORE INITIATING YOUR STUDY.
- IF YOU ARE CONDUCTING YOUR RESEARCH AT A SITE OTHER THAN EVMS, YOU ARE RESPONSIBLE FOR OBTAINING ANY LOCAL REVIEW NECESSARY FOR THE CONDUCT OF THIS RESEARCH.

☒ **Child Risk Designated by the Board:**
The Board noted that this study using children does not involve greater than minimal risk and that adequate provisions have been made for soliciting the assent of the children, including permission of each subject's parent or guardian. [45CFR46.404]

☒ **Your protocol expiration date is January 24, 2013. Please see the attached form for the due date of the next continuing review submission.**

☒ Please remember that prompt reporting to the IRB of proposed changes in a research activity (e.g., changes to the protocol, consent form(s), advertisements, or other study-related materials) is required. This includes information related to funding sources. In addition, the changes must be reviewed and approved by the EVMS IRB ***before*** the changes can be initiated *except* when it is necessary to eliminate apparent immediate hazards to the subject.

Eastern Virginia Medical School (EVMS) has a Federalwide Assurance (FWA 00003956) from OHRP. The Institutional Review Boards (IRB 00000460 and IRB 00001345) are registered with OHRP and are in compliance with 45 CFR 46, 21 CFR 50, and 21 CFR 56.

Please reference the IRB number, principal investigator and study title in any correspondence regarding this protocol.

Thank you for your continued cooperation with the Institutional Review Board.

Sincerely,

Betsy O. Conner, CIP
IRB Manager

BCC/dms

EASTERN VIRGINIA MEDICAL SCHOOL

APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

EVMS Institutional Review Board

Instructions: Please submit this form to the IRB Office, attaching the IRB protocol, abstract, data collection instruments, consent forms and/or informational letters, letters of approval from agencies, hospital impact statement(s) and other supporting documents.

- ~ HANDWRITTEN DOCUMENTS WILL NOT BE ACCEPTED BY THE IRB OFFICE.
- ~ ALL DOCUMENTS INCLUDED IN THE SUBMISSION MUST BE PAGINATED.

HELP: If you are unsure how to complete a field, press F1 while on the field and a help box will appear.

IRB Number: (If assigned)	12-01-EX-0013

ADMINISTRATIVE INFORMATION

Study Title:	A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.	**Date Submitted:** (IRB USE ONLY) RECEIVED JAN 09 2012 By	
Principal Investigator:	Katherine M. Newnam, PhD (c), RN, NNP-BC		
PI Dept / Address	Children's Hospital of the Kings Daughters, NICU 601 Children's Lane		
City / State / Zip	Norfolk, Virginia 23507		
Phone Number(s):	(757) 668-7452	**E-Mail:**	katherine.newnam@chkd.org
Person Preparing This Submission			
Name:	Katherine M. Newnam, PhD (c), RN, NNP-BC	**Role:**	Investigator
Address:	Children's Hospital of the Kings Daughters, NICU, 601 Children's Lane, Norfolk, Virginia 23507		
Phone Number(s):	(H) 757-546-7497 and (W) 757-668-7452	**E-Mail:**	katherine.newnam@chkd.org

INVESTIGATORS AND/OR RESEARCH TEAM MEMBERS

Name	Department	Address	Status	HIPAA for Research Training Date	Human Subjects Protection Training Date
Rebecca Tucker	Neonatal ICU, CHKD	601 Children's Lane, Norfolk, Virginia 23507	Research Team Member	in process	in process
Melinda Bissett	Neonatal ICU, CHKD	601 Children's Lane, Norfolk, Virginia 23507	Research Team Member	in process	in process
Lynetta Cox	Neonatal ICU, CHKD	601 Children's Lane, Norfolk, Virginia 23507	Research Team Member	in process	in process
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		
			-- Choose One --		

1.	**TYPE OF REVIEW:** Review the sub-categories and check the appropriate box (check only one)
☐	**FULL BOARD REVIEW:** (A $1,500 review fee is charged unless a "Wavier of IRB Fee" form is submitted with this application and approved by the Office of Research Subjects Protections.) **CLICK HERE AND PRESS F1 FOR NUMBER OF COPIES TO SUBMIT: ►**
☒	**EXPEDITED REVIEW:** Insert the Category number below that supports the type of review: 4 & 5 **CLICK HERE AND PRESS F1 FOR NUMBER OF COPIES TO SUBMIT: ► 1 hard copy and electronic submission**
	(1) Clinical Studies of drugs or devices when: [1a] Drugs: IND not required; [1b] Devices: IDE not required. (2) Collection of blood samples. CLICK HERE AND PRESS F1 FOR GUIDANCE: ► (3) Prospective collection of biological specimens for research purposes by noninvasive means. (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. (5) Research involving materials that have been collected, or will be collected solely for non-research purposes. (6) Collection of data from voice, video, digital, or image recordings made for research purposes. (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation human factors evaluation, or quality assurance methodologies.
☐	**EXEMPT REVIEW:** Insert the Category number below that supports the type of review: -- Choose One -- **CLICK HERE AND PRESS F1 FOR NUMBER OF COPIES TO SUBMIT: ►**
	(1) Research in Educational Setting involving normal educational practices. (2) Educational Tests, Survey Procedures, Interview Procedures, or Observe Public Behavior unless subjects can be identified and disclosure place subjects at risk of criminal & civil liability. **[Does not apply to those <18 years old. Therefore, defaults to expedited or Full Board review.]** (3) Educational Tests, Survey Procedures, Interview Procedures, or Observe Public Behavior unless subjects elected/appointed officials or candidates for public office and Federal statute requires maintenance of confidentiality. **[Does not apply to those <18 years old. Therefore, defaults to expedited or Full Board review.]** (4) Collection/Study of Existing Data, Documents, Records, Pathological/Diagnostic Specimens and Subjects Cannot Be Identified. CLICK HERE AND PRESS F1 FOR GUIDANCE: ► (5) Federal Dept/Agency Research & Demonstration projects. (6) Taste & Food Quality Evaluation & Consumer Acceptance Studies.

2.	**REQUIRED TRAINING:**

It is necessary for all investigators, co-investigators, and research team members to complete human subjects protection training in order to receive IRB approval to proceed with research using human subjects, their data, or biological samples. Training opportunities and requirements can be found on the Office of Research web site at http://www.evms.edu/research/office/index.html.

Contact the Office of Research at (757) 446-8480 for additional information on all research training requirements.

Please note that Bloodborne Pathogen Training is mandated annually for **EVMS faculty and staff** with potential exposure to blood/body fluid by the Occupational Safety and Health Administration (OSHA).

Contact the Occupational Health Department at 446-5870 for additional information.

3.	**FINANCIAL STATEMENT:**	
Have you, other family members or any other person responsible for the design, conduct, or reporting of this research received from the sponsor (or a subsidiary or parent company of the sponsor):	**Choose one answer in each row below:**	
Salary, other payments for services (e.g., consulting fees or honoraria), recruitment bonuses, trips, referral fees or other incentives **that are NOT covered by an EVMS grant, contract, or clinical agreement?**	☒ No	☐ Yes

Equity interests (e.g., stocks, stock options, or other ownership interests greater than 3% ownership or greater than $10, 000 per annum of salary, fees, or other continuing payments)?	☒ No	☐ Yes
Intellectual property rights (e.g., patents, copyrights and royalties from such rights)?	☒ No	☐ Yes

If "yes," to any of the above, please provide a written explanation of the situation in this box. You may also be required to submit information to the EVMS Conflict of Interest (COI) Committee through the Office of Research, 446-8480. Refer to Appendix C for Model Language to insert into the consent form.

4. THIS STUDY WILL BE ACTIVE AT THE FOLLOWING LOCAL SITES: (Be sure to list site for ALL phases of the research)

☐ Bon Secours DePaul Medical Center	☐ Bon Secours Maryview Hospital	☒ Children's Hospital of The King's Daughters
☐ Children's Specialty Group	☐ Devine Tidewater Urology	☐ Eastern Virginia Medical School
☐ Sentara Bayside Hospital	☐ Sentara CarePlex Hospital	☐ Sentara Leigh Memorial Hospital
☐ Sentara Norfolk General Hospital	☐ Shore Health Services	☐ Virginia Oncology Associates

(4a.) Other local or international site for this IRB application (specify name and include the complete address):	TYPE
	-- Choose One --
	-- Choose One --
	-- Choose One --
	-- Choose One --

5. OTHER SITES:

In addition to the local sites listed above, is this study also conducted at any national or international sites?	☒ No ☐ Yes

6. TYPES OF PARTICIPANTS (CHECK ALL THAT APPLY):

☒ Children [specify age range(s)]: Newborn to 2 months of age.	☐ Adults [specify age range(s)]: (NOTE: Adults 90 or older must be grouped into one category per HIPAA regulations.	
☐ Students/Employees	☐ Healthy Volunteers	☐ Critically Ill Patients
☐ Cognitively Impaired Individuals	☐ Subjects in Emergency Conditions	☐ Economically Vulnerable Subjects
☐ Pregnant Women	☐ Fetus(es)	☐ In vitro fertilization
☒ Medical Records	☐ Specimens (blood, tissue)	
☐ Other: (specify):		

7. SOURCE OF SUBJECTS: (CHECK ALL THAT APPLY):

☒ My Practice	☐ Referral from Other Physicians	☐ Medical Records
☐ Outpatients/Clinics	☐ Stored/Banked Human Specimens	☐ Other, Explain in Protocol

NOTE: All advertisements or other materials used to recruit subjects must be submitted for IRB approval.

8. CONSENT PROCEDURES: (CHECK ALL THAT APPLY):

8a. CONSENT TO BE OBTAINED FROM:	8b. CONSENT TO BE OBTAINED BY:

☐ Patient/Subject	☐ Principal investigator
☒ Parent(s)/Guardian	☒ Co-investigator(s)
☐ Legally authorized representative	☒ Research Team Members not on protocol (list below)
☐ Assent to be obtained from subjects age **to**	

8c. List others not identified in the protocol who are qualified and authorized to obtain subject consent (e.g., study coordinators, clinical staff, etc.) Any individual listed in this section must meet all appropriate EVMS training requirements.

NAME:	RELATIONSHIP TO THE STUDY:	LIST ALL SPECIFIC QUALIFICATIONS TO CONDUCT THE INFORMED CONSENT PROCESS:
Rebecca Tucker	Research Team Member	Advanced nurse practitioner who has expertise in obtaining informed consent as part of her position in the management of the NICU patient.
Melinda Bissett	Research Team Member	Advanced nurse practitioner who has expertise in obtaining informed consent as part of her position in the management of the NICU patient.
Lynetta Cox	Research Team Member	Advanced nurse practitioner who has expertise in obtaining informed consent as part of her position in the management of the NICU patient.
	-- Choose One --	
	-- Choose One --	
	-- Choose One --	

8d. WITNESS: In most cases, a witness signature is not required unless consent is obtained orally. If a witness signature is preferred by the investigator or sponsor, please explain below and include the appropriate signature box on the subject consent form(s).

9. WAIVER REQUESTS (CHECK ALL THAT APPLY):

Are you requesting that the IRB waive the requirements for obtaining subject consent for this study? If yes, an ***"Application for Waiver of Consent"*** must be completed and attached to ALL copies of the submission. **ALL REQUESTS FOR WAIVER OF SUBJECT CONSENT ARE REVIEWED BY THE FULL BOARD.**	☒ No	☐ Yes
Are you requesting that the IRB allow access to or the use of Protected Health Information (PHI) without obtaining subjects permission? If yes, an ***"Application for Waiver of Authorization for the Use of Protected Health Information (PHI)"*** must be completed and attached to ALL copies of the submission	☐ No	☒ Yes

10. SUBJECT PARTICIPATION: *All items must be answered. If applying for a medical record review, length of active participation and follow-up should be answered as "Not Applicable".

ITEM	INSERT LENGTH OF TIME, NUMBER OR DATE
Length of time for active participation (as defined in protocol)	The infant will be observed during nasal CPAP admistration which according to recent unit statistics (Jan-June, 2011) is between 1 and16 days with a mean of 3.9 CPAP days.

Follow-up (long-term follow-up after study completion)	None anticipated
Number of local subjects or medical records or samples	Anticipated enrollment of 72 patients
Total number of subjects or records or samples across all sites	Anticipated enrollement of 72 patients
Duration of study at this local site	Anticipated duration 7 months
Anticipated Start Date the proposed study will begin (be sure to allow time for IRB review and approval):	February, 2012 **Month / Year**
Anticipated End Date of the proposed study	August, 2012 **Month / Year**

11.	ARE THE FOLLOWING ASSOCIATED WITH THE RESEARCH STUDY?			
	11a. SUPPLEMENTARY DOCUMENTS INCLUDED:			
☐	Subject Diary	☒ No	☐ Yes	If Yes, insert identifier:
☐	Questionnaire or Psychological Instrument	☒ No	☐ Yes	If Yes, insert identifier:
☐	Federal NIH Grant Application	☒ No	☐ Yes	If Yes, insert identifier:
☐	Investigator Brochure	☒ No	☐ Yes	If Yes, insert identifier:
☐	Drug Package Insert	☒ No	☐ Yes	If Yes, insert identifier:
☒	Data Collection Tool (with a key to all field headings)	☐ No	☒ Yes	If Yes, insert identifier:
☐	Advertisements / Flyers / Patient Information Sheets	☒ No	☐ Yes	If Yes, insert identifier:
☐	Other, Please Explain:	☐ No	☐ Yes	If Yes, insert identifier:
☐	Other, Please Explain:	☐ No	☐ Yes	If Yes, insert identifier:
	11b. RESEARCH-RELATED USE OF ANY OF THE FOLLOWING:			
☐	Investigational Drugs/Biologics:	☒ No	☐ Yes	If Yes, insert IND#:
	FDA Approved Drug(s) for an Unapproved Use If Off-Label Use, an IND is not always required. If sponsor cooperating with goal of extending use of drug an IND is required	☐ No	☐ Yes	Comments:
	FDA Approved Drug(s) for an Unapproved Subject Group If Off-Label Use, an IND is not always required. If sponsor cooperating with goal of extending use of drug an IND is required	☐ No	☐ Yes	Comments:
☐	Investigational Devices:	☒ No	☐ Yes	IDE#: and Date:
	Risk Assessed by Sponsor			☐ Significant Risk (SR) ☐ Non-Significant Risk (NSR)
☐	Humanitarian Device Exemption:	☒ No	☐ Yes	HDE #:
	11c. DESIGN OF STUDY:			
☐	Placebo Controlled	☒ No	☐ Yes	Comments:
☐	Blinded	☒ No	☐ Yes	If Yes, ☐ Double Blind **or** ☐ Single Blind
☒	Randomized	☐ No	☒ Yes	Comments: As described in the attached study proposal, the neonates will be randomized to one of three groups (mask, prongs or alternation of mask/prongs every 3-4 hours) when nasal CPAP is medically indicated and initiated.
☐	Anonymous Survey or Questionnaire	☒ No	☐ Yes	Comments:
☐	Banking of Tissue / Specimen / Data	☒ No	☐ Yes	Comments:

☒	Retrospective Review of Records or Information	☐ No	☒ Yes	Comments: NICU admission data will be reviewed for potential study participants every 24 hours which may require retrospective record review.
☐	Registry Study	☒ No	☐ Yes	Comments:
☐	Compassionate Use – Contact IRB office for guidance	☒ No	☐ Yes	Comments:
☐	Other:	☐ No	☐ Yes	Comments:
	11d. SAFETY MEASURES:			
☐	Data/safety monitoring is included in the study.	☒ No	☐ Yes	If yes, details must be provided within the protocol or as an attachment.
	Please specify the type of monitoring:			
☐	Local data and safety monitoring plan in place	☒ No	☐ Yes	Comments:
☐	Sponsor reviews adverse events, interim findings and relevant literature	☒ No	☐ Yes	Comments:
☐	Data Safety Monitoring Board [DSMB], Data Monitoring Committee (DMC) or other similar body in place	☒ No	☐ Yes	Comments:
	Other measures:			
☐	Certificate of Confidentiality *(for genetic research involving identified samples)*	☒ No	☐ Yes	Comments:
☐	Other:	☒ No	☐ Yes	Comments:
	11e. USE OF SPECIMENS OR DATA: Tissue/data banking and genetic research require additional protections for subjects.			
☐	Genetic research will be done on biologic samples.	☒ No	☐ Yes	If Yes, ☐ Samples will be de-identified ☐ Samples will be identified
☐	Gene therapy vectors or recombinant DNA products will be used.	☒ No	☐ Yes	If Yes, EVMS Biosafety Committee Approval # on
☐	Cell lines will be developed	☒ No	☐ Yes	Comments:
☐	Cell lines from unidentified subjects will be used in this research study.	☒ No	☐ Yes	Comments:
☐	Samples/data will be used and kept for the use of **this study only.** The intent is **NOT TO ESTABLISH** a "tissue/data bank.	☒ No	☐ Yes	Comments:
☒	Samples/data will be stored/banked for the use of **the investigators OR others.** The intent is **TO ESTABLISH** a repository or bank.	☐ No	☒ Yes	Comments: The researcher request permission to maintain this dataset for possible future meta-analysis (using this data plus data obtained from future studies). However, this data will only be stored and used by this research team (no others). ☒ Samples will be de-identified ☐ Samples will be identified
	If yes, provide the IRB # for protocol to govern collection and storage of samples:			IRB #:
☐	Certificate of Confidentiality *(for genetic research involving identified samples)*	☒ No	☐ Yes	Comments:
	11f. SPONSOR AND/OR GRANTING AGENCY:			
☐	Sponsor is a Federal granting agency. [If Federally funded by NIH, you must submit the entire grant with this application.]	☒ No	☐ Yes	Name of Sponsor:

☐	Sponsor is a commercial company.	☒ No	☐ Yes	Name of Sponsor:
☐	Sponsor is a non-profit granting entity.	☒ No	☐ Yes	Name of Sponsor:
☐	Sponsor is academic/hospital department or personal funds.	☒ No	☐ Yes	Name of Sponsor:
	IF YES TO ANY OF THE ABOVE, PLEASE ANSWER THE FOLLOWING QUESTIONS Who is the Principal Investigator on the award? To which entity/institution is the primary award made?			
☒	Unsupported, no funding	☐ No	☒ Yes	Comments:

12.	**TO THE BEST OF YOUR KNOWLEDGE, HAS THIS STUDY ALREADY BEEN APPROVED BY AN EVMS IRB UNDER ANOTHER INVESTIGATOR?**		
☒ No	☐ Yes	If yes, provide: Investigator's Name:	and IRB #:

13.	**VERIFICATION OF SCIENTIFIC REVIEW AND ACCEPTANCE STATEMENT:**
It is necessary for each principal investigator to verify the scientific merit of a new study before submitting the study for IRB review. Based on information submitted by the principal investigator, the appropriate department chair (or designee), certifies the conduct of the study under his/her department.	
By signing below, you confirm that you have sufficient staff and facilities to conduct this study	
By signing below, you agree to abide by the EVMS IRB Assurance which specifies compliance with OHRP Regulations for Protection of Human Research Subjects, and you agree to conduct your research: 1) according to the guidelines of this statement, 2) according to human subjects regulations outlined in the human subjects training you have completed, and 3) according to the information you supplied in this Application.	
BY SIGNING BELOW, YOU UNDERSTAND YOU MUST OBTAIN WRITTEN IRB APPROVAL BEFORE INITIATING ANY RESEARCH PROCEDURES OR ACTIVITY.	
PRINCIPAL INVESTIGATOR SIGNATURE:	**DATE OF SIGNATURE**
Katherine N. Newman	12/28/11

14.	**DEPARTMENT CHAIR CERTIFICATION:**		
This protocol has been reviewed by me or an appropriate designee and I agree that this study has scientific merit.			
DEPARTMENT CHAIR OR DESIGNEE OR SIGNATURE:			**DATE OF SIGNATURE**
Signature:	D W Lewis		12/29/11
Printed Name:	D W Lewis	**Department:**	PEDS

THIS SECTION FOR IRB USE ONLY

FINAL DISPOSITION:

REVIEW CATEGORY	ACTION	CONTINUING REVIEW DEADLINE
☐ Exempt	☒ Approved	11/01/12

☒ Expedited		☐ Disapproved	
☐ Full (Convened) Board			
IRB SIGNATURE:		**DATE:**	1/25/12
SIGNED BY:	☐ IRB Chair ☑ IRB Vice Chair ☐ IRB Member		

IRB APPROVAL
DATE: 01/25/12
EXPIRES
DATE: 01/24/13
IRB # 12-01-EX-0013

Application for Approval of Research Involving Human Subjects

DO NOT EXCEED TWO (2) PAGES AND DO NOT INCLUDE EXTRA PAGES

Study Title:	Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate	**IRB Number:**
Principal Investigator:	Katherine M. Newnam, PhD (c), RN, NNP-BC	

1. CLEARLY STATE THE PURPOSE OF THE STUDY:

The primary aim of this study will be to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask) used to treat respiratory distress syndrome. These outcome measures will be calculated based on recorded information included in the neonatal skin condition score (NSCS), a three parameter tool that evaluates skin breakdown, erythma and dryness. A secondary aim of the study will be to identify those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration. Lastly an exploratory aim will be to identify and describe nursing strategies that can support the reduction of nasal injuries in this vulnerable population during nasal CPAP administration. Additional data will be collected during the study which will include the agitation levels of the infants during nasal CPAP administration and the respiratory stability of the patients as measured by blood gases. These measures will be used to explore other potential factors associated with nasal injury and skin breakdown. The hypotheses for this comparative effectiveness study are: 1) Is there a difference in the incidence and/or severity of skin breakdown of the ELBW preterm neonate (less than 1500 grams) when nasal CPAP is administered using three types of (standard-of-care) nasal interfaces: 1) continuous nasal prongs, 2) continuous nasal mask or 3) alternating the nasal mask and prongs every 4 hours? 2)Are the differences in the incidence and/or severity of skin breakdown related to other predisposing risk factors such as gestational age, birth weight, length of therapy, environmental humidity level, amount of CPAP flow administered and/or nursing interventions that include positioning techniques, nasal suctioning devices and the use of nasal saline during suctioning? 3)Will the frequency and severity of nasal injury be accurately measured with the NSCS? 4) Is there a correlation between agitation scores as measured by the N-PASS and the incidence and/or severity of nasal injury during the use of nasal CPAP in the ELBW preterm neonate? 5)Is there a correlation between blood gas results, specifically respiratory acidosis reflected in the pH, CO2 and base excess levels and the incidence of nasal injury in the ELBW preterm neonate?

2. PROVIDE A BRIEF DESCRIPTION OF DESIGN:

A three group prospective randomized experimental study design is currently planned. This would include recruitment into the study following admission to the neonatal intensive care unit (NICU) when infants are typically intubated during the mechanical ventilation phase of treatment. Upon extubation to nasal CPAP (the typical care for these infants) the participants would be randomized into three groups to include, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. All infants will be managed with the same type of nasal CPAP delivery system. Infants transported from the delivery room or outlying hospital that are initially treated with nasal CPAP would be considered for enrollment if consent was obtained and randomization could occur within 8 hours. Following parental consent, infants would be clearly identified by a star placed on respiratory care providers clipboard to remind caregivers to enroll participants as the medical condition of the patient was appropriate for transition from current therapy to nasal CPAP following physician or neonatal nurse practitioner (NNP) order to extubate the patient. Infants who meet study inclusion criteria and who have been consented and self extubate will also be randomized for nasal CPAP trial if medically appropriate as dictated by physician or nurse practitioner order. No infants will be placed on nasal CPAP unless medically warranted; therefore patients who are extubated to high flow or regular nasal cannula will be excluded unless nasal CPAP is used in those patients at a later time as medically indicated. Following parental consent the infants recruited for the study will be block stratified according to weight into four categories according to birth weight: < 750 grams, 750-1000 grams, 1001-1250 grams and > 1251-1500 grams. After stratified the subjects will be randomly allocated into the three groups described above. Randomization will accomplished using serially numbered opaque sealed envelopes developed by the researcher which will be located close to the storage area which houses the CPAP equipment within the NICU. Routine skin assessments will be completed every 3-4 hours which is consistent with current care practice. A small group of skin experts (advanced NP's), described as the Core Research Team, will be responsible for twice a day skin care evaluations on enrolled participants during the infant's routine nursing care as well as completion of the data collection form (de-identified patient data). Patients randomized to the nasal prongs group and conventional prongs are not able to fit according to manufacture guidelines (rare event) will be removed from the study as exclusion.

3. PARTICIPANT INFORMATION:

Duration of individual subject's total involvement (provide all details – active; long-term follow-up, etc.):

Following parental consent the infants recruited for the study will be block stratified according to weight into four categories according to birth weight:<750 grams,750-1000 grams,1001-1250 grams and >1251-1500 grams. After stratified the subjects will be randomly allocated into three groups, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. Randomization will be accomplished using serially numbered opaque sealed envelopes developed by the researcher. Skin assessments will continue every 3-4 hours per unit protocol. Data collection will be completed every 12 hours by the Core Research Team and includes the following assessment tools: 1)Biographical data: to include infant's gestational age, birth weight and current weight. 2) Information collected related to therapy: CPAP liter flow, day of CPAP, humidification of environment as measured on the incubator humidity gauge (Giraffe ©), and temperature of the nasal CPAP humidifier. 3)Neonatal Skin Condition Scale (NSCS) is a skin condition scoring system that was developed for the AWHONN/NANN skin care research based project and adapted using a visual skin scoring system.The tool uses three clinical outcome categories which includes dryness, erythma and breakdown or excoriation of the skin. Each of these categories is graded one through three. The score of one in each category indicates a healthy skin assessment and the score of two or three indicates an increasing level of skin breakdown with a total score of nine (three in each category) being the worse skin evaluation score possible. Pictorial representation of each category with examples of skin that represented each score was developed to use as an aid for the clinician during the assessment of neonatal skin. 4)Agitation levels of the infants will be monitored using the Neonatal Pain, Agitation and Sedation Scale (N-Pass) was developed as a clinically relevant tool to assess primarily acute or chronic pain as well as sedation level in preterm infants who are not capable of self report.5)Blood gases will be recorded in an effort to establish relationships between increased respiratory distress symptoms as demonstrated by increased carbon dioxide levels and skin breakdown measure. Interrater reliability will be tested through the use of two experts assessing 10% of study participants to assure score agreement. Patients will be monitored during nasal CPAP administration only without scheduled follow up after transition to alternate method of respiratory support.

How will subjects be recruited? 1) Subjects will be identified based on current respiratory management (mechanical ventilation or nasal CPAP) and birth weight 500-1500 grams. 2) Parents or guardians of those patients who are admitted to the NICU and who meet the study inclusion criteria will be approached following admission to the unit. The research study will be explained to each family providing adequate time to answer questions related to the proposed research plan. Parents who are unable to visit the NICU because of geographic or other barriers will be contacted by phone to explain the research study, reading informed consent in its entirity and invite participation similar to the process of obtaining blood or operative consents over the phone. In this special case (rare) after reading the consent and answering all questions, copies will be mailed to parents home address. 3) The initial contact with the parent will be made by the Core Research Team if the neonate meets inclusion criteria.

Inducements to participate: None offered

Inclusion Criteria: Infants who are initially treated with or weaned from mechanical ventilation to nasal CPAP and who are birth weight 500 grams to 1500 grams. Infants with a birth weight under 500 grams will not be considered based on documented overall concerns with skin integrity in this group (Sardesai, Kornacka et al. 2011) which could influence study results.

Exclusion Criteria: Infants who have been diagnosed with major cardiac disease or congenital malformation which could impair the nasal CPAP performance would be excluded. Patients who are not consented within 8 hours of nasal CPAP initiation or who had nasal skin breakdown at enrollment would be excluded and patients outside of the weight inclusion described above would be excluded.

4. BENEFITS TO SUBJECTS (DO NOT USE WORDING SUCH AS "YOU", "YOUR", ETC.):

There are no direct benefits to the study participants at present; however, changes in how nasal CPAP is administered to this patient population may provide benefits in future neonatal care.

5. RISKS TO SUBJECTS (DO NOT USE WORDING SUCH AS "YOU", "YOUR", ETC.):

There are no anticipated risks/discomforts associated with participation in this research study. Individual risk to individual patients are considered minimal and consistent with the risk experienced with current standard nasal CPAP use for the identified neonatal population.

6. MEASURES TO MINIMIZE RISKS:

Risk Reduction: Frequent patient skin assessment (at least every 4 hours) by the bedside registered nurse and/or respiratory care therapist is required by both unit and research protocol. Signs of hyperemia, erythma or excoriation will be reported to the health care team and treatment ordered as necessary which is consistent with current medical care. Intolerance to nasal CPAP treatment will be addressed in the usual manner with increased medical care to include escalating respiratory support up to and including endotrachael intubation (current practice). All three described nasal interfaces are currently in use within the NICU research setting. No changes in the standard unit care are anticipated based on the use of the type of nasal interface during the administration of nasal CPAP in the preterm infant.

EASTERN VIRGINIA MEDICAL SCHOOL

APPLICATION FOR WAIVER OF AUTHORIZATON FOR THE USE OF PHI

EVMS Institutional Review Board

NOTES: 1. This application accompanies your "Application for Approval of Research Involving Human Subjects" if you will require access to Protected Health Information to complete your research.

HELP: If you are unsure how to complete a field, press F1 while on the field and a help box will appear.

~ HANDWRITTEN DOCUMENTS WILL NOT BE ACCEPTED BY THE IRB OFFICE.

~ ALL DOCUMENTS INCLUDED IN THE SUBMISSION MUST BE PAGINATED.

IRB Number:	

ADMINISTRATIVE INFORMATION

Study Title:	A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.	**Date Submitted:** (IRB USE ONLY)	
Principal Investigator:	Katherine M. Newnam, PhD (c), RN, NNP-BC		
PI Dept / Address	Children's Hospital of the Kings Daughters, NICU 601 Children's Lane		
City / State / Zip	Norfolk, Virginia 23507		
Phone Number(s):	(757) 668-7452	**E-Mail:**	katherine.newnam@chkd.org

I AM REQUESTING A WAIVER OF AUTHORIZATION FOR THE USE OF PROTECTED HEALTH INFORMATION (PHI). THE FOLLOWING VERIFICATION IS PRESENTED IN SUPPORT OF THIS WAIVER:

(ALL SECTIONS MUST BE COMPLETED)

PHI WAIVER JUSTIFICATION

- **Provide a brief description of the specific PHI to which you are requesting access (be sure to list each item).**

DISCUSS IN DETAIL YOUR PLAN:

The specific Protected Health Information (PHI) that will be examined will be the patients name, medical record number, birth weight and current respiratory support (ie mechanical ventilation/nasal CPAP). As part of screening for neonates who meet study criteria following admission to the Neonatal Intensive Care Unit (NICU) each patient's admission information will be retrospectively reviewed every 24 hours. Specifically the birth weight and respiratory support required by that neonate will be screened. If the neonates birth weight is between 500 and 1500 grams and the patient is currently receiving mechanical ventilation or nasal CPAP the parent of that neonate will be contacted for consent to participate in the research study. Following consent the PHI screened will be maintained on the consent form only and then patient information will be de-identified for all other data collection and analysis. This screened information for patients who do not meet study criteria will not be maintained /recorded by the research team unless the patient consent is received and the neonate is enrolled in the study.

- **The research could not practically be conducted without access to and use of the PHI.**

DISCUSS IN DETAIL YOUR PLAN:

Without the described review of pertinent inclusion criteria described above, it would be necessary to consent every admitted infnat to the NICU and then exclude all neonates who do not meet weight or respiratory support inclusion criteria described in the study protocol. This would be a significant burden to the patients parents as well as the study team.

- **The research could not practicably be conducted without the alteration or waiver.**

DISCUSS IN DETAIL YOUR PLAN:

As above

- **The use or disclosure of PHI involves no more than minimal risk to the individuals, based on, at least, the presence of the following elements:**

a. ***An adequate plan to protect the identifiers from improper use/disclosure***

DISCUSS IN DETAIL YOUR PLAN:

The use of PHI involves no risk to the patient as the data will be reviewed only and not recorded in any manner unless the infant meets study criteria and is consented for enrollment in the research study. Of note: all members of the research team who will review admission information of patients prior to contact/consent are members of the advanced practitionter staff in the NICU.

b. ***An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law***

DISCUSS IN DETAIL YOUR PLAN:

As described in the research proposal, all information will be de-identified by the research team. The only link between identified PHI (patinet name/ MR number) and each research participant will be the consent form which will be maintained under lock and key in a secure location to protect confidentiality. No identified recording of patients who do not meet criteria will be completed as study participation is excluded.

c. ***Adequate written assurances that PHI will not be reused/disclosed to any other person or entity, except as required by law, for authorized oversight of research project, or for other research for which use/disclosure of PHI would be permitted by this subpart.***

DISCUSS IN DETAIL YOUR PLAN:

No PHI will be reused/disclosed to any person or entity as described above and in the research proposal. The informed consent which will be the only form to contain the actual patients name with a link to the assigned patient enrollment number (for de-identification purposes) will be held in a locked cabinet in a locked office within the School of Nursing at Virginia Commonwealth University. Until transfer to the VCU School of Nursing the form will be kept in a locked drawer within the Nurse Practitioner office in the NICU. This office is also locked and not accessible to the general public.

THIS SECTION FOR IRB USE ONLY

FINAL DISPOSITION:

REVIEW CATEGORY	ACTION	CONTINUING REVIEW DEADLINE
☐ Exempt	☒ Approved: Above cited justifications meet the criteria required to grant a Waiver of Authorization for the Use of Protected Health Information	11 / 01 / 12
☒ Expedited		
☐ Full (Convened) Board	☐ Disapproved	
IRB SIGNATURE:		**DATE:** 1 / 25 / 12
SIGNED BY:	☐ IRB CHAIR ☒ IRB VICE CHAIR ☐ IRB MEMBER	

IRB APPROVAL DATE: 01/25/12
EXPIRES DATE: 01/24/13
IRB # 12-01-EX-0013

Data Collection Consent Form
Eastern Virginia Medical School (EVMS) Institutional Review Board

Study Title:	A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.
Name of Investigator:	Katherine M. Newnam, PhD (c), RN, NNP-BC
Sponsor:	**N/A**
Name of Subject:	For participants less than 18 years old, all references to "you" in this consent form are referring to "you", "your child" or a "minor for whom you are a legally appointed representative".

You are being asked to participate in a research study involving the collection of information in the form of data from your child's medical record. The purpose of the research project is to compare the different types of equipment that we use to deliver nasal continuous positive airway pressure (CPAP) to your baby who weighs between 500 and 1500 grams at birth. Nasal CPAP is a breathing machine that is secured to your babies' nose through the use of short soft nasal prongs, a soft nasal mask or a rotation between the mask and prongs in order to provide constant air flow or air pressure into the baby's nose and airways to help the baby breath more effectively. Although both the nasal prongs and mask are effective in providing respiratory support to your baby and both types of nasal equipment are routinely used in our Neonatal Intensive Care Unit (NICU) we would like to know if one type is more comfortable for your baby or may cause less skin irritation where the skin comes in contact with the respiratory machine.

Your baby will be randomly placed into one of three groups, the nasal prong group, the nasal mask group or the rotation group which rotates the two nasal devices every 3 to 4 hours during infant care. The random assignment is like flipping a coin with equal choices for the infant to be placed into one of the three identified groups.

During the time your infant is treated with nasal CPAP your infant's skin will be examined by one of the nurses or nurse practitioners to identify any skin redness or skin irritation around the respiratory equipment. Your baby's nurse also examines your infant's skin during nursing care every 3-4 hours with the respiratory therapist. The amount of agitation is also measured by your baby's bedside nurse prior to and during care. These measurements are recorded in the medical record. Routine blood gases are also followed at intervals determined by your baby's medical team. These blood gases help to determine if your infant is tolerating the respiratory treatment of CPAP or may need more or less respiratory support. The blood gas results are also recorded in your child's medical record.

After we measure the amount (if any) of skin irritation we will compare this information between the different group that we are studying to decide if one method of nasal CPAP may be more comfortable or better for infant's skin than the other. If your infant has redness or irritation develops under the nasal CPAP machine your baby will have the skin cared for by your medical team with current standards. Each of the examinations by the research nurses will be conducted during times your baby is awake and handled by the bedside nursing or respiratory staff. When your baby is no longer treated with nasal CPAP according to the medical team, your baby will have completed his/her enrollment in the study. Because all of the requested information is routinely collected as part of nasal CPAP care in the NICU we are asking for permission to record the information from your babies record so that we can look at differences between these nasal CPAP types.

You will not be reimbursed for your participation. There are no additional costs to you associated with taking part in this study.

Although the results of this research may not benefit you directly the researchers hope that the information collected will be used to improve nasal CPAP care in our NICU and therefore might benefit other infants who have nasal CPAP therapy in the future. The final results of this research study will be made available to you upon request.

There are no specific risks related to your infant's participation, but there may be other risks not yet identified.

All protected health information (PHI) will be maintained in strict confidence as required by law and for the purposes of this research your infant's information will be de-identified through the use of an assigned number. The only link between your babies name and the collected PHI will be this consent form which contains your infant's name and assigned patient number. It is also important to understand that your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor or EVMS Institutional Review Board, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
- You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about your infant before the date you cancelled may be used. To cancel your approval, you must notify Katherine Newnam RN, NNP in writing at Children's Hospital of the Kings Daughters (CHKD) Neonatal Intensive Care Unit (NICU), 601 Children's Lane, Norfolk, Va. 23507.
- Your approval for the sharing of personal information about your infant for this study expires at the end of the study.
- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.
- Any research information in your medical record will become a permanent part of that document.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. The only reviewer identified is the Eastern Virginia Medical School Institutional Review Board.

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify your infant.

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time if you revoke your authorization to participate.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

In the event of injury resulting from this research study, Eastern Virginia Medical School (EVMS) provides no financial compensation plan or free medical care

If you have any questions pertaining to this research you may contact Katherine Newnam at 757-668-7452 or Jacqueline McGrath at (804) 828-1930. If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Katherine Newnam at (757) 668-7452. You may also contact Dr. Robert Williams, an employee of Eastern Virginia Medical School, at (757) 446-8423. If you have any questions pertaining to your rights as a research subject, you may contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

SIGNATURE

You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study and accept the risks. *A child who is a ward of the state cannot be enrolled until the IRB has assigned an individual advocate, relative to this potential enrollment, to act on behalf of the child in addition to the guardian or in loco parentis.*

_____ Signature of Participant/LAR	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/ DD/ YY
_____ Signature of Participant/LAR	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/ DD/ YY

WITNESS (required for oral presentations)

This signature must be present if the consent was presented orally to a subject in any manner. The witness may not be an individual named as an investigator or a person authorized to negotiate informed consent.

_____ Signature of Witness ☐ Witnessed Consent Process	_____ Typed or Printed Name	___/___/___ MM/ DD/ YY

STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

_____ Signature of Investigator or Approved Designee	___/___/___ MM/ DD/ YY

IRB APPROVAL
DATE: 01/25/12
EXPIRES
DATE: 01/24/13
IRB # 12-01-EX-0013

"A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate" a research proposal

Katherine Newnam

Introduction:

The use of nasal CPAP has become widely accepted by health care providers who care for preterm infants in the treatment of respiratory distress syndrome (RDS), yet few studies have used comparative effectiveness research to examine the performance of various nasal interfaces within this group to determine differences in either the incidence or severity of nasal skin breakdown, a well described side effect of this useful treatment.

Following a systematic literature review of 111 articles related to the use of nasal CPAP on the preterm infant, only a single study was reviewed which included the study aim of comparing nasal interfaces to determine the frequency of skin breakdown (Rego and Martinez 2002). This research study, conducted in Sao Paulo, Brazil evaluated the performance of two types of nasal prongs, Argyle and Hudson, to deliver nasal CPAP to preterm infants. The conclusion of the study was the prongs were found to be equally effective in the delivery of CPAP, the Argyle prong was more difficult to maintain in the infant's nares and had a higher incidence of nasal hyperemia, the first sign of skin breakdown when compared to the Hudson prong. No comparison studies were reviewed between prongs, mask or a rotation of devices that have been described antidotally as a strategy to reduce pressure on nasal skin during the use of nasal CPAP (Robertson, McCarthy et al. 1996; McCoskey 2008; Squires and Hyndman 2009). Additionally, there is universal agreement that nasal injury is a potential risk factor when using the nasal interfaces with CPAP delivery with clear directives for attention to skin assessment and increased nursing care and expertise which was mentioned in 44 of the 111 reviewed articles.

Specific Aims:

The primary aim of this study will be to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces

(prongs/mask) used to treat respiratory distress syndrome. These outcome measures will be calculated based on nurses recording information included in the skin condition score (NSCS), a three parameter tool that evaluates skin breakdown, erythma and dryness. A secondary aim of the study will be to identify those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration. Lastly an exploratory aim will be to identify and describe nursing strategies that can support the reduction of nasal injuries in this vulnerable population during nasal CPAP administration. Additional data will be collected during the study which will include the agitation levels of the infants during nasal CPAP administration and the respiratory stability of the patients as measured by blood gases. These measures will be used to explore other potential factors associated with nasal injury and skin breakdown and are part of the standard neonatal care while neonates are hospitalized in the NICU.

For this Comparative Effectiveness Study the Hypotheses are:

1) Is there a difference in the incidence and/or severity of skin breakdown of the ELBW preterm neonate (less than 1500 grams) when nasal CPAP is administered using three types of nasal interfaces: 1) continuous nasal prongs, 2) continuous nasal mask or 3) alternating the nasal mask and prongs every 4 hours?
2) Are the differences in the incidence and/or severity of skin breakdown related to other predisposing risk factors such as gestational age, birth weight, length of therapy, environmental humidity level, amount of CPAP flow administered and/or nursing interventions that include positioning techniques, nasal suctioning devices and the use of nasal saline during suctioning?
3) Will the frequency and severity of nasal injury be accurately measured with the NSCS?

4) Is there a correlation between agitation scores as measured by the N-PASS and the incidence and/or severity of nasal injury during the use of nasal CPAP in the ELBW preterm neonate?
5) Is there a correlation between blood gas results, specifically respiratory acidosis reflected in the pH, CO2 and base excess levels and the incidence of nasal injury in the ELBW preterm neonate?

Background and Significance:

The dynamic approach to respiratory care of the preterm neonate has progressed following scientific evidence which clearly demonstrates advantages to early nasal continuous positive airway pressure (CPAP) or early extubation to nasal CPAP in this population. It is now well understood that reduced mechanical ventilation in high-risk preterm infants has many advantages which includes; decreased chronic lung disease, decreased incidence of ventilator associated pneumonia as well as overall reduction in blood stream infections, reduction in the incidence of periventricular luekomalacia (PVL) previously associated with long term ventilation, improved neurodevelopmental outcomes and shortened hospital length of stay (De Paoli, Davis et al. 2008; Squires and Hyndman 2009). These small infants however require some adjunct to maintain functional residual capacity (FRC) as well as improve the symptoms of respiratory distress syndrome (Buettiker, Hug et al. 2004). Nasal continuous positive airway pressure (CPAP) is often used to support this need.

Nasal CPAP is a non invasive method for providing a constant distending pressure during both the inhalation and exhalation phase of respiration. Used in the spontaneously breathing preterm infant it provides stability of the infant's FRC, improves oxygenation, conserves surfactant, aids in the prevention of atelectasis, improves gas exchange and aids in the prevention

of obstructive and central apnea (Davis, Jankov et al. 1998; Diblasi 2009; Squires and Hyndman 2009). First described in 1914 in a German textbook about the diseases of the newborn, a system of hoses placed into a water filled receptacle, a face mask with a gas source was used on a newborn who had symptoms of respiratory distress to provide continuous airway pressure (Diblasi 2009). Ventilator delivered CPAP first was reported in the late 1970's and 1980's that were adapted from adult models (Gregory, Kitterman et al. 1971); then in the 90's free standing nasal CPAP delivery systems were designed and widely adapted into routine practice (Verder 2007; Diblasi 2009).

Three major types of nasal CPAP are used in the neonatal population, traditionally classified by the technique used to control the gas flow to the patient (Gupta, Sinha et al. 2009). These include constant flow or bubble CPAP, variable flow which are devices that have fluidic control to maintain the CPAP pressure and finally ventilator delivered CPAP generally delivered through an endotracheal tube (ETT) or a long single nasal pharyngeal tube. All devices share in four components, 1) a heated/humidified blended gas source, 2) a nasal interface, 3) a patient circuit and 4) a pressure-generating apparatus (Diblasi 2009).

Risks attributed to the use of nasal CPAP in this population have also been described. These include abdominal distension, inability to provide enteral nutrition secondary to gut disturbance, slightly increased incidence of necrotizing enterocolitis (NEC), pneumothorax and nasal injury or nasal mucosal damage (Verder 2007; Squires and Hyndman 2009) The current CPAP devices are effective in maintaining needed positive end expiratory pressure (PEEP) but also place constant pressure on the nares, nasal septum and forehead leading to decreased skin integrity and injury (De Paoli, Davis et al. 2008). Research is needed to 1) compare nasal CPAP interfaces commonly used to determine differences in frequency and severity of skin break down and 2) to

identify strategies to reduce skin breakdown during nasal CPAP use in extremely low birth weight (ELBW) infants.

The overall clinical management of preterm infants whose respiratory status is supported through the use of nasal CPAP is based on anecdotal experience and unit standards rather than on scientific evidence. Nursing skill level and experience with positioning, frequent assessment and intervention, all of which takes significant nursing time has been well described by nearly half of the reviewed articles. Practices vary widely from unit to unit making standardization of nursing care to protect vulnerable preterm infant skin during this therapy difficult.

We clearly understand the advantages of using nasal CPAP in this population which outweighs the observed risk to this therapy. We must now examine the different delivery methods and nasal interface devices while providing non-invasive nasal CPAP to preterm infants to best manage the preterm infant's respiratory distress syndrome using scientific evidence to create and test best clinical practices. In a meta analysis completed on the devices and pressure sources for the administration of nasal CPAP, implications for further research included determining which nasal interface device is the least traumatic to the infant nose, particularly the very low birth weight infant (De Paoli, Davis et al. 2008). Additionally, a systematic review of non-invasive ventilation strategies described nasal prongs and newer nasal masks for use in the neonate. The masks were described to require less pressure to remain in place but "will need empiric testing to determine safety in this population" (Courtney and Barrington 2007).

Empiric evidence based on current scientific literature is needed to support nursing interventions to reduce iatrogenic skin injury of the nose, face and head during nasal CPAP administration to provide improved long term outcomes. Specific attention to those details of

nursing care to this patient population to addresses strategies for optimal outcomes are clearly needed.

Research Method and Design:

A three group prospective randomized experimental study design is currently planned. This would include recruitment into the study following admission to the neonatal intensive care unit (NICU) when infants are typically intubated during the mechanical ventilation phase of treatment. Upon extubation to nasal CPAP (the typical care for these infants) the participants would be randomized into three groups to include, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. All infants will be managed with the same type of nasal CPAP delivery system. Infants transported from the delivery room or outlying hospital that are initially treated with nasal CPAP would be considered for enrollment if consent was obtained and randomization could occur within 8hours.

Following parental consent, infants would be clearly identified by a star placed on the respiratory care provider's bedside chart to remind caregivers to enroll participants as the medical condition of the patient was appropriate for transition from current therapy to nasal CPAP following physician or neonatal nurse practitioner (NNP) order to extubate the patient. Infants who meet study inclusion criteria and who have been consented and self extubate will also be randomized for nasal CPAP trial if medically appropriate as dictated by physician or nurse practitioner order. No infants will be placed on nasal CPAP unless medically warranted; therefore patients who are extubated to high flow or regular nasal cannula will be excluded unless nasal CPAP is used in those patients at a later time as medically indicated.

Following parental consent the infants recruited for the study will be block stratified according to weight into four categories according to birth weight: < 750 grams, 750-1000

grams, 1001-1250 grams and > 1251-1500 grams. Known differences in the skin integrity have been demonstrated with the lowest birth weights proven the most vulnerable. Stratification according to infant's birth weight will keep the groups more homogeneous as it is expected that the smallest group will have the least patients. After stratified the subjects will be randomly allocated into the three groups, 1) a continuous nasal prong group, 2) a continuous nasal mask group or 3) an alternating mask/prongs every 4 hours group. Randomization will accomplished using serially numbered opaque sealed envelopes developed by the researcher which will be located close to the storage area which houses the CPAP equipment within the NICU.

A flow diagram (algorithm) will be placed beside the aforementioned sealed envelopes to provide a quick reference to the respiratory team collecting the necessary equipment for the infants ordered transition to nasal CPAP (see appendix 1). This diagram will visually describe the information required (birth weight) in order for the respiratory therapist to determine from which group of envelops they should select from which will determine group assignment. The equipment would then be collected by the respiratory staff to place the infant on nasal CPAP with continuous nasal prongs, continuous nasal mask or alternating each device every four hours.

Routine skin assessments will be primarily a nursing responsibility but collaboration between the bedside nurse and respiratory therapist for scoring will be encouraged to be consistent with the current standard of practice. A small group of skin experts, described as the Core Research Team, which includes four advance practice nurses will be responsible for twice a day skin care evaluations on enrolled participants using the NSCS, the only additional data collected for study purposes and will be conducted in addition to those skin assessments described by the bedside caregiver. The additional skin evaluations will be completed during the infant's routine nursing care without additional interruption or examination for the neonate. This will be accomplished

through communication with the bedside nursing staff to coordinate assessment times in an effort to protect the infant's quiet environment.

Tool and interrater reliability and of the NSCS (reported as Cohen's Kappa and chronbach's alpha) will be tested through the use of two experts assessing 10% of the study participants in conjunction with scheduled assessments described above (see appendix #5). Skin measurements using the NSCS will continue at the described intervals during the course of nasal CPAP administration. Skin assessment measurements as well as described extrapolated data from the medical record will be imported into an Excel spread sheet for analysis using SPSS.

Assessment Tools:

1) Biographical data: to include infant's gestational age, birth weight and current weight will be extrapolated from the medical record (see appendix #3 and #4).
2) Information collected related to therapy: CPAP liter flow, day of CPAP, humidification of environment as measured on the incubator humidity gauge using the Giraffe ©, and temperature of the humidifier device connected to the nasal CPAP will be extrapolated from the participant's medical record (see appendix #3 and #4).
3) Neonatal Skin Condition Scale (NSCS) is a skin condition scoring system that was developed for the AWHONN/NANN skin care research based project and adapted using a visual skin scoring system originally developed by Lane and Drost (1993). The tool uses three clinical outcome categories which includes dryness, erythma and breakdown or excoriation of the skin. Each of these categories is graded one through three. The score of one in each category indicates a healthy skin assessment and the score of two or three indicates an increasing level of skin breakdown with a total score of nine (three in each category) being the worse skin evaluation score possible. Pictorial representation of each

category with examples of skin that represented each score was developed to use as an aid for the clinician during the assessment of neonatal skin. The tool has been tested for both validity and reliability and for interrater reliability during the project (Lund, Kuller et al. 2001; Lund and Osborne 2004). Skin assessments using the tool will be performed by the Core Research Team of advanced practice nurses every 10 to 12 hours in coordination with the participant's routine nursing care (see Appendix #2 and #5).

4) Agitation levels of the infants will be monitored using the Neonatal Pain, Agitation and Sedation Scale (N-Pass) was developed as a clinically relevant tool to assess primarily acute or chronic pain as well as sedation level in preterm infants who are not capable of self report (Hummel, Puchalski et al. 2008). This scale has been well validated in the preterm population and is currently used as a measure of agitation at the proposed research site; therefore information will be extrapolated from the medical record (see appendix #6).
5) Blood gases typically obtained as part of routine medical care will be recorded in an effort to establish relationships between increased respiratory distress symptoms as demonstrated by increased carbon dioxide levels and skin breakdown measure. No additional blood gas measures will be required of study participants.

This proposed research study will utilize the multidisciplinary expertise from nursing, medicine and respiratory therapy that provide the health care team while these vulnerable patients are in the Neonatal Intensive Care Unit (NICU) during nasal CPAP administration.

Data Analysis Plan:

Demographic information from each participant will be collected for descriptive purposes and the means of each group will be compared using a one way analysis of variance (ANOVA) to

identify group differences. Data analysis will be performed at both the individual and group levels for descriptive and comparison purposes.

Specific intended study analysis will be discussed according to study aim:

1) The primary aim of this study will be to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask) used to treat respiratory distress syndrome. Analysis will be conducted using the previously described NSCS scores every 10-12 hours with an incidence of skin breakdown classified as mild, moderate or severe. Incidence of breakdown per group will be calculated for all three groups and one-way ANOVA will be used to analyze continuous variables.

2) A secondary aim of the study will be to identify those risk those factors associated with nasal injury and skin breakdown during nasal CPAP administration. This descriptive analysis will examine those factors such as gestational age, birth weight, nutritional support, liter per minute of CPAP flow and compare findings between groups using ANOVA. Regression analysis may also be considered.

Study Limitations: The study will employ a convenience sampling method, which may generate a non-representative sample. The study will be conducted at a single NICU site which may not be representative of all neonatal patients in the NICU that are 500-1500 grams and require nasal CPAP. Control for extraneous variables would be impossible during the care of these acutely ill neonates who are cared for in the NICU. Blinding to treatment groups will not be possible and may influence measurements. Data collection phase is estimated to be between 4 and 6 months with multiple changes anticipated in this dynamic environment including the implementation of an electronic medical record (EMR) and staffing pattern changes in the NICU to accommodate the national reduction in resident and intern working hours which impacts neonatal coverage.

Study Site:

The neonatal Intensive care unit at the Children's Hospital of the King's Daughters (CHKD) in Norfolk Virginia will be utilized as the study site for this project. This is a 62 bed level III NICU that serves a large geographic territory from Northeastern North Carolina to Williamsburg, Virginia. Based on unit statistics from 2011 (January-June) there were 58 patients admitted to the CHKD NICU who required nasal CPAP and were birth weight between 500 and 1500 grams. The range of CPAP days was from 1-16 days for a mean of 3.9 CPAP days. The average patient's birth weight was 834 grams. This data was collected as a feasibility projection for this planned research study.

A large evidence based project (EBP) was completed by this researcher earlier this year (2011) using the same proposed data collection site in an effort to standardize routine nursing and respiratory care administered to nasal CPAP patients. This EBP project was aimed at improving patient care outcomes, educating the nursing and respiratory staff on the importance and mechanics of nasal CPAP as well as reducing the extraneous variables which could influence the results of this proposed study.

Human Subjects:

Inclusion criteria: Infants who are initially treated with or weaned from mechanical ventilation to nasal CPAP and who are birth weight 500 grams to 1500 grams. Infants with a birth weight under 500 grams will not be considered based on documented overall concerns with skin integrity in this group (Sardesai, Kornacka et al. 2011) which could influence study results.

Exclusion criteria: Infants who have been diagnosed with major cardiac disease or congenital malformation which could impair the nasal CPAP performance would be

excluded. Patients who are not consented within 8 hours of nasal CPAP initiation or who had nasal skin breakdown at enrollment would be excluded and patients outside of the weight inclusion would not be included.

Parents less than 18 years of age: Mothers and fathers who are under the age of 18 that have infants that meet inclusion criteria for this research project will be excluded secondary to informed consent limitations.

Research material: There will not be any research materials solicited or used for the purposes of this study.

Recruitment Plan:

Parents or guardians of those patients who are admitted to the NICU and who meet the study inclusion criteria will be approached following admission to the unit. The research study will be explained to each family providing adequate time to answer questions related to the proposed research plan. Those parents who are unable to visit the NICU because of geographic or other barriers will be contacted by phone to explain the research study and invite participation.

A power analysis using a significance level of $p < 0.05$ was performed to meet the described primary aim of the study which was to determine differences in the frequency, severity and specific types of nasal injuries described when comparing different nasal CPAP interfaces (prongs/mask) used to treat respiratory distress syndrome in the preterm infant less than 1500 grams. The analysis was focused on the frequency parameter of this aim and a total sample size of 72 with 24 in each of the three groups (continuous nasal prongs, continuous nasal mask or alternating nasal mask and prongs every 4 hours) was adequate to determine significant differences between groups.

Privacy of Participants:

The privacy of the participants will be supported through the use of participant identifier as described in section "Confidentiality of Data". The group that each patient is randomized which dictates the type of nasal interface utilized to deliver nasal CPAP will be recorded as part of the health care record which is standard care for patients receiving nasal CPAP. All research records with all patient identifiers removed will be removed from the patient's bedside daily and placed into a secure location on the unit for later analysis.

Confidentiality of Data:

All information will be de-identified by assignment of research assigned patient number which will be used on all study records. The process of assignment will start with the number (N) 001 through (N) 024 for the first patient in the continuous nasal prong group; (M) 101 through (M) 123 for the continuous nasal mask group, and (R) 201 through (R) 224 for the rotation group. This patient identifier will be recorded on all maintained study records. The consent which will contain patient names and medical record number will be related to assigned patient identifier as described above using a key which will be available to the PI and other research investigators only. This information will be kept under lock and key in the Virginia Commonwealth University School of Nursing (the location of PI's faculty advisor, Dr. McGrath) and will be destroyed three (3) years following the close of the study as required by the IRB. De-identified data will be maintained for an undetermined length of time and may be used in future meta-analysis as described in this protocol.

Use of de-identified data for future publications and presentations are planned by the PI (student researcher). The study findings will be used as part of the requirements for graduation (PhD) at Virginia Commonwealth University (VCU). Electronic submission of the research findings of this study will be filed in the VCU library as part of the researcher dissertation

requirement. Additional secondary analysis as well as future study using this data set for meta-analysis is included as future research plans for the PI.

Potential Risks:

There are no anticipated risks or discomforts associated with participation in this research study. Individual risk to individual patients are considered minimal and consistent with the risk experienced with current standard nasal CPAP care for the identified population within the NICU.

Risk Reduction:

Frequent patient skin assessment (at least every 4 hours) by the bedside registered nurse and/or respiratory care therapist is required by both unit and research protocol. Signs of hyperemia, erythma or excoriation will be reported to the health care team and treatment ordered as necessary. Intolerance to nasal CPAP treatment will be addressed in the usual manner with increased medical care up to and including intubation. If infant's are randomized to the nasal prong group and the smallest size prongs cannot be fit according to manufactures direction (rare event), the infant will be transitioned to the nasal mask for CPAP delivery (current standard-of-care) and removed from the study. No changes in the standard unit care are anticipated based on the use of the type of nasal interface during the administration of nasal CPAP in the preterm infant.

Risk/Benefit:

There are no direct benefits to the study participants at present; however, changes in how nasal CPAP is administered to this patient population may provide benefits in future neonatal care.

Compensation Plan for Study Participants:

No compensation is planned for study participants or their families.

Consent Process:

Informed consent will be obtained by the researcher or his/her designees (Core Research Team) which are advanced practice nurses who are experienced in obtaining informed consent. Each parent or guardian of the qualifying patients will be asked to sign a consent form which will describe the study aim, the study design and various steps to be employed during the study. The parents of the participants will be encouraged to discuss any items or words that are unclear or that they do not understand during the consent process. In special rare circumstances, parents are unable to travel to the NICU because of maternal health following delivery or other barriers that impede travel to Children's Hospital of the Kings Daughters. In these rare cases informed consents may be obtained by phone. The process for the phone consent in these cases will require a full reading of the informed consent including time to answer all parental questions. Witnessed signature will also be required for phone consent. This process will be utilized only when all other means of face-to-face contact by the Core Research Team fails.

The parents of the participants will be provided a copy of the signed consent with contact information for the primary investigator (PI) in person at the conclusion of signing or by mail if phone consent process described above was necessary. The EVMS Internal Review Board (IRB) contact information will be included for parental questions not answered by the PI or research team.

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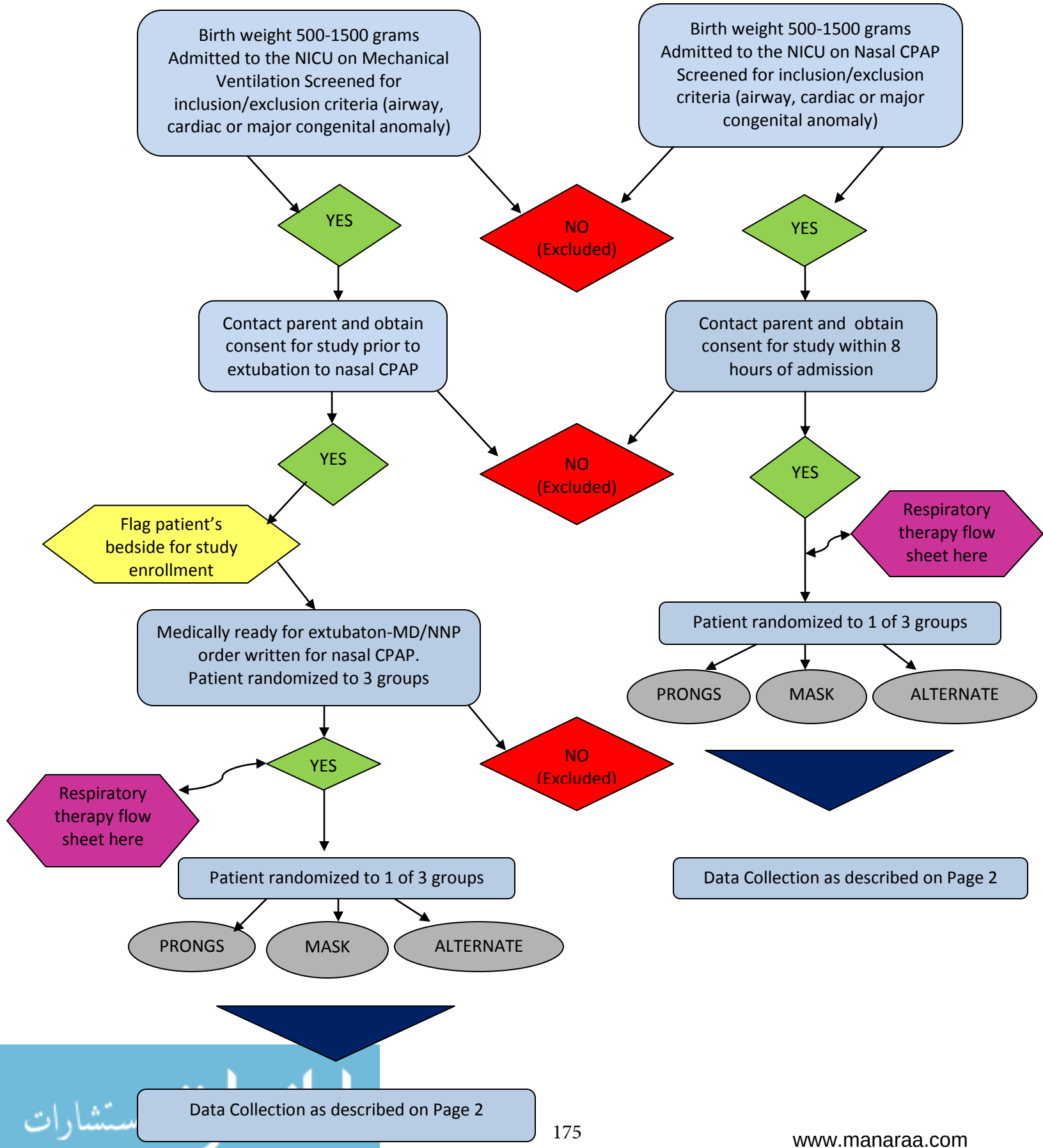
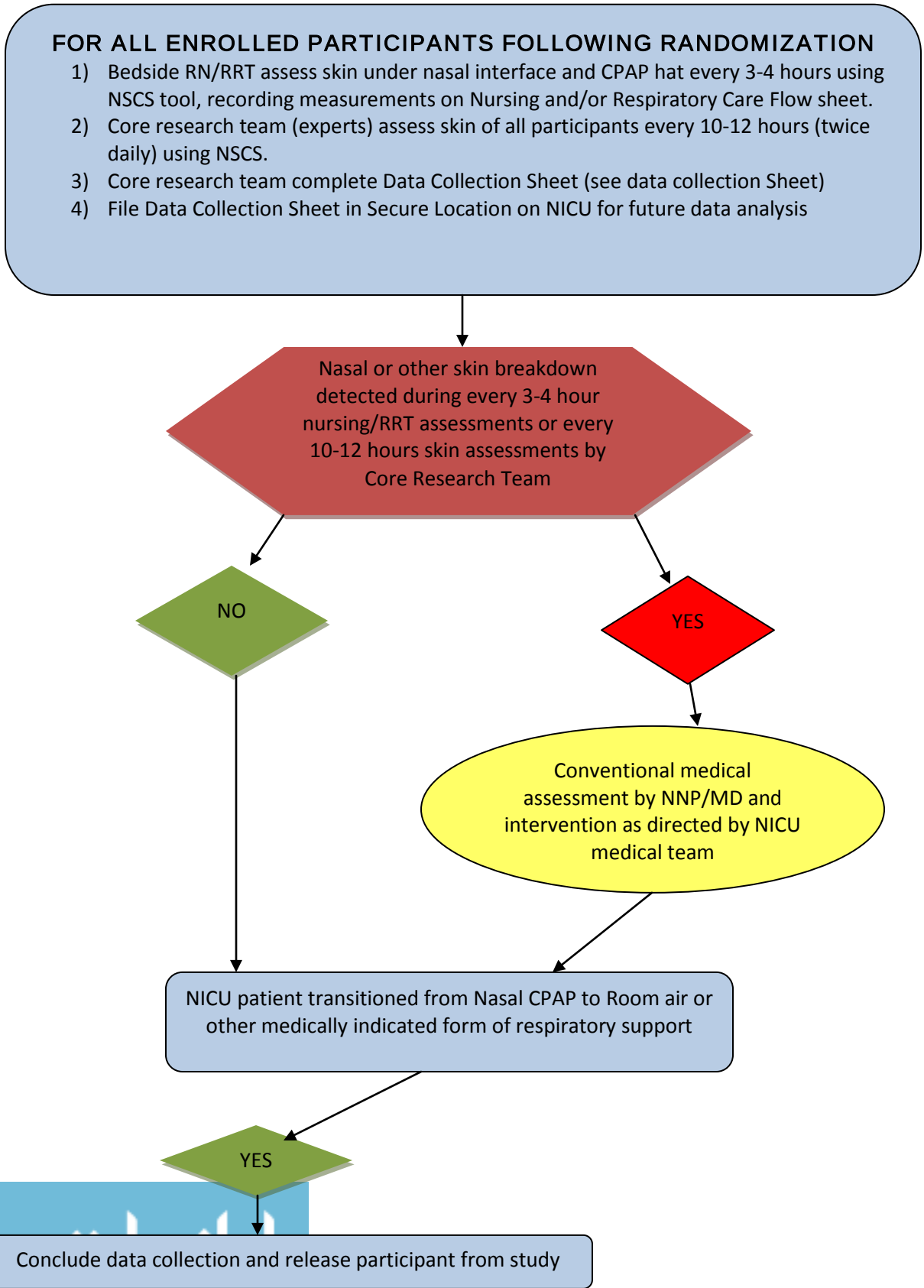
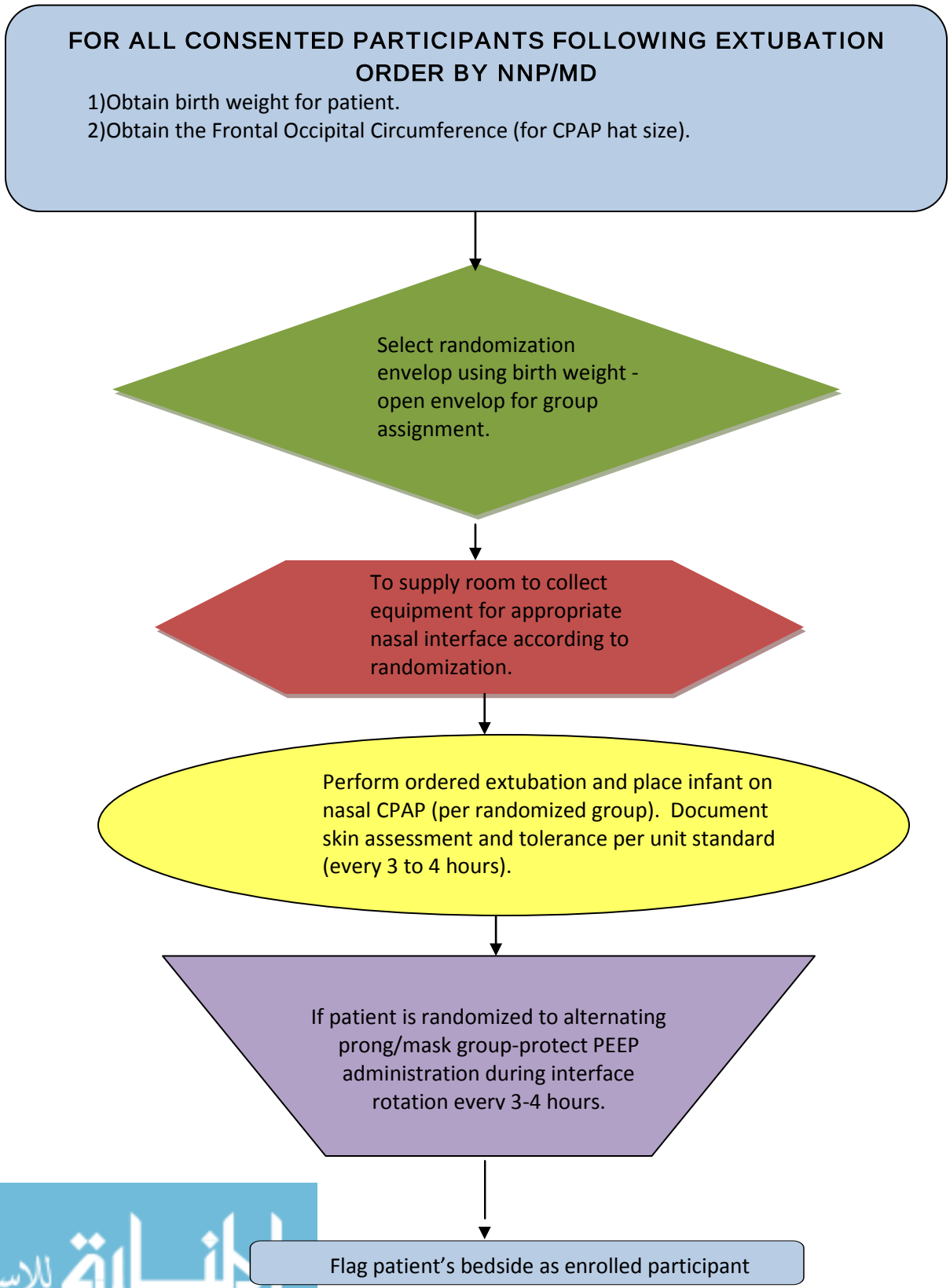
Proposed Algorithm for Study



Page 2-Algorithm for Study--Data Collection



Respiratory Care Algorithm for Study—Appendix 1



Appendix C.

Agreement form between the IRB's of EVMS and VCU

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review:

Eastern Virginia Medical School IRB Registration #: IRB00000460 FWA #: FWA00003956

Name of Institution Relying on the Designated IRB:

Virginia Commonwealth University FWA #: FWA00005287

The Officials signing below agree that may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(X) This agreement is limited to the following specific protocol(s):

Name of Research Project: *"A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate"*

Name of Principal Investigator: Kathy Newnam

Sponsor or Funding Agency: N/A Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of Virginia Commonwealth University's OHRP-approved FWA. The IRB at Eastern Virginia Medical School will follow written procedures for reporting its findings and actions to appropriate officials at Virginia Commonwealth University. Relevant minutes of IRB meetings will be made available to Virginia Commonwealth University upon request. Virginia Commonwealth University remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official Eastern Virginia Medical School:

Robert F Williams Date: March 29, 2012

Print Full Name: Robert F. Williams, PhD, MBA Institutional Title: Associate Dean, Research Subjects' Protections

Signature of Signatory Official Virginia Commonwealth University:

Date: 3/28/2012

Print Full Name: Francis L. Macrina, PhD Institutional Title: Vice President for Research

Appendix D.

Data Collection Instruments

a) Enrollment

b) Daily

c) Weekly

Neonatal Skin Condition Scale (NSCS)

Neonatal Pain and Sedation Scale (N-PASS)

Comparative Effectiveness
Newnam, K. (appendix #3)
Data Collection Form – Enrollment

Patient ID: ☐☐☐
Date: ☐☐/☐☐/☐☐☐☐
Time: ☐☐☐☐

Inclusion/Exclusion criteria assessment:

1. Birth weight between 500 to 1500 grams: ☐ No, not eligible ☐ Yes, eligible
2. No presence of a congenital airway anomaly: ☐ No, not eligible ☐ Yes, eligible

Parental consent obtained? ☐ No ☐ Yes

Must have "yes" for all three above to continue.

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1. Patient's birth weight: ☐☐☐☐ Grams
2. Patient's current weight: ☐☐☐☐ Grams
3. Patient's gestational age at birth: ☐☐ Weeks ☐ Days
4. Patient's current age: ☐☐ Weeks ☐ Days
5. Length of CPAP: ☐☐ Days
6. CPAP flow: ☐ 4L/min ☐ 5L/min ☐ 6L/min ☐ Other_____
7. CPAP temperature: ☐☐.☐ Celsius
8. FiO_2: ☐☐ %
9. Incubator humidity: ☐☐ %
10. Nasal interface: ☐ Prongs ☐ Mask ☐ Alternating prongs and mask
11. Number of times suctioned since last data collection: ☐☐ Times
12. Type of suctioning provided: ☐ Nasal ☐ Oral ☐ Both
13. Was nasal saline used? ☐ No ☐ Yes ☐ Not applicable since no nasal suctioning
14. Is there documented bleeding with suctioning? ☐ No ☐ Yes

Comparative Effectiveness
Newnam, K. (appendix #3)
Data Collection Form – Enrollment

Patient ID: ☐☐☐
Date: ☐☐/☐☐/☐☐☐☐
Time: ☐☐☐☐

15. Has a blood gas been obtained since last data collection? ☐ No ☐ Yes

If so, what are the results?

☐.☐☐ pH

☐☐ CO_2

☐☐☐ Base Excess

16. Was a skin injury reported to the patient's medical team? ☐ No ☐ Yes

17. Was an intervention provided for the skin injury? ☐ No ☐ Yes

18. What type of skin intervention was provided?

☐ Watchful waiting
☐ Ointment applied
☐ Skin massage/pressure relief
☐ Skin care consult
☐ Other:_____

19. Location of nasal or skin injury:

☐ Forehead
☐ Nasal bridge
☐ Nasal septum
☐ Other:_____

Comparative Effectiveness
Newnam, K. (appendix #3)
Data Collection Form – Enrollment

Patient ID: ☐☐☐
Date: ☐☐/☐☐/☐☐☐☐
Time: ☐☐☐☐

20. NSCS score now:

Erythema:	☐ 1	☐ 2	☐ 3
Dryness:	☐ 1	☐ 2	☐ 3
Excoriation:	☐ 1	☐ 2	☐ 3

21. N-PASS score now:

Crying:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Behavior state:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Facial expression:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Extremity tone:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Vital signs:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2

22. Clinical concerns:

- ☐ Sepsis
- ☐ Feeding intolerance
- ☐ Operative procedure
- ☐ Apnea and bradycardia events
- ☐ Other:_____

23. Individual care strategies:

Pectin barrier in place?	☐ No	☐ Yes
Developmental positioning?	☐ No	☐ Yes
Symmetrical hat placement?	☐ No	☐ Yes

Comparative Effectiveness
Newnam, K. (appendix #4)
Data Collection Form – Daily

Patient ID: ☐☐☐
Date: ☐☐/☐☐/☐☐☐☐
Time: ☐☐☐☐

1. Patient's current weight: ☐☐☐☐ Grams
2. Patient's current age: ☐☐ Weeks ☐ Days
3. Length of CPAP: ☐☐ Weeks ☐ Days
4. CPAP flow: ☐ 4L/min ☐ 5L/min ☐ 6L/min ☐ Other _____
5. CPAP temperature: ☐☐.☐ Celsius
6. FiO_2: ☐☐ %
7. Incubator humidity: ☐☐ %
8. Nasal interface: ☐ Prongs ☐ Mask ☐ Alternating prongs and mask
9. Number of times suctioned since last data collection: ☐☐ Times
10. Type of suctioning provided: ☐ Nasal ☐ Oral ☐ Both
11. Was nasal saline used? ☐ No ☐ Yes ☐ Not applicable since no nasal suctioning
12. Is there documented bleeding with suctioning? ☐ No ☐ Yes
13. Has a blood gas been obtained since last data collection? ☐ No ☐ Yes

    If so, what are the results of the latest blood gas?

    ☐.☐☐ pH

    ☐☐ CO_2

    ☐☐☐ Base Excess

14. Was a skin injury reported to the patient's medical team? ☐ No ☐ Yes
15. Was an intervention provided for the skin injury? ☐ No ☐ Yes
18. What type of skin intervention was provided?

    ☐ Watchful waiting
    ☐ Ointment applied
    ☐ Skin massage/remove pressure
    ☐ Skin care consult
    ☐ Other:_____

Comparative Effectiveness

Newnam, K. (appendix #4)

Data Collection Form – Daily

Patient ID: ☐☐☐

Date: ☐☐/☐☐/☐☐

Time: ☐☐☐

19. Location of nasal or skin injury:

- ☐ Forehead
- ☐ Nasal bridge
- ☐ Nasal septum
- ☐ Other:_____

20. NSCS score now:

Erythema:	☐ 1	☐ 2	☐ 3
Dryness:	☐ 1	☐ 2	☐ 3
Excoriation:	☐ 1	☐ 2	☐ 3

21. N-PASS score now:

Crying:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Behavior state:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Facial expression:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Extremity tone:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Vital signs:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2

22. Clinical concerns:

- ☐ Sepsis
- ☐ Feeding intolerance
- ☐ Operative procedure
- ☐ Apnea and bradycardia events
- ☐ Other:_____

23. Individual care strategies:

Pectin barrier in place?	☐ No	☐ Yes
Developmental positioning?	☐ No	☐ Yes
Symmetrical hat placement?	☐ No	☐ Yes

Comparative Effectiveness

Newnam, K. (appendix #5)

Data Collection Form – Weekly

Inter-rater reliability

Patient ID: ☐☐☐

Date: ☐☐/☐☐/☐☐☐☐

Time: ☐☐☐☐

Data Collector Initials: ☐☐

1. NSCS score now:

Erythema: ☐ 1 ☐ 2 ☐ 3

Dryness: ☐ 1 ☐ 2 ☐ 3

Excoriation: ☐ 1 ☐ 2 ☐ 3

Total score: _____

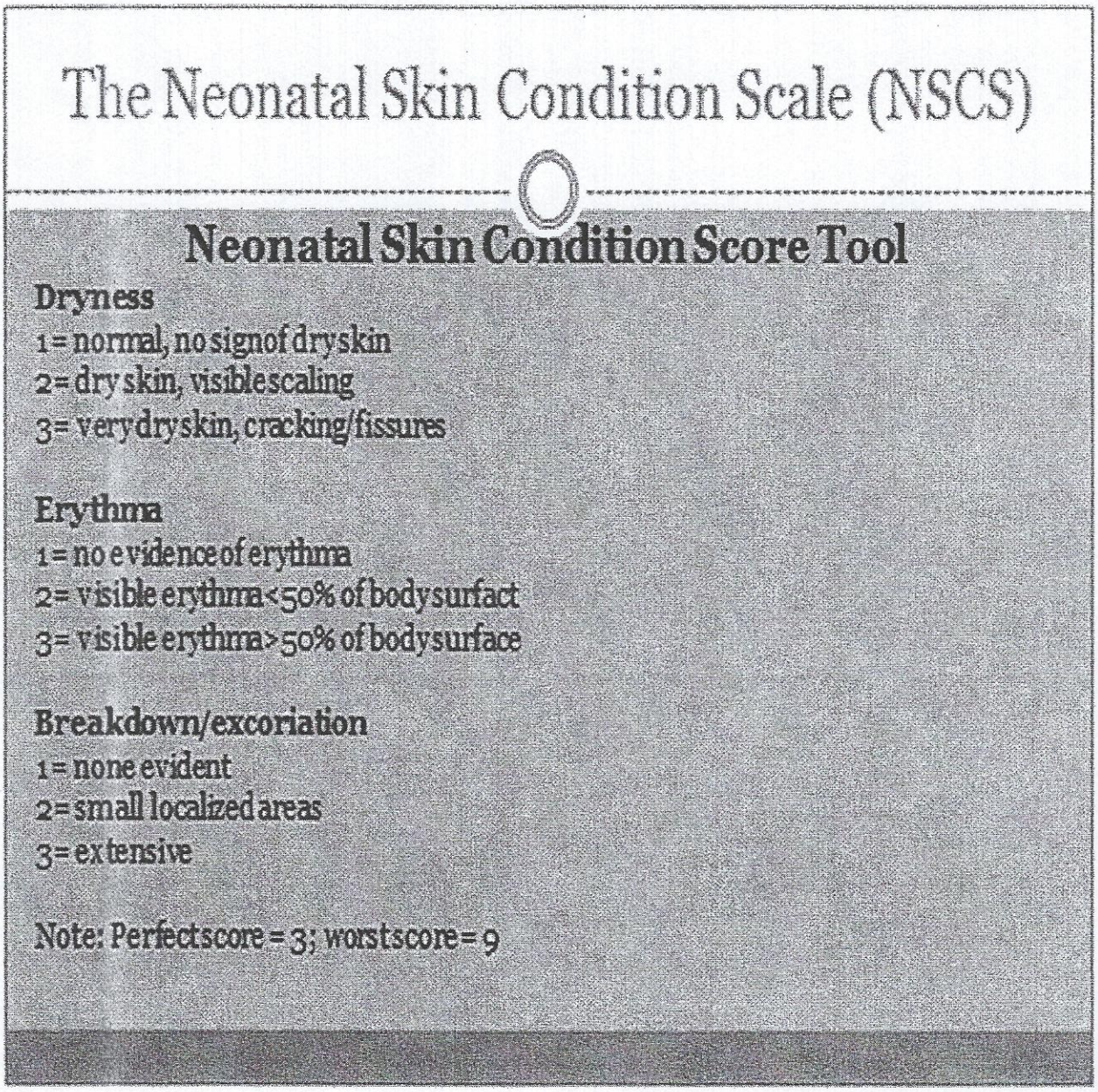
2. N-PASS score now:

Crying:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Behavior state:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Facial expression:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Extremity tone:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2
Vital signs:	☐ -2	☐ -1	☐ 0	☐ 1	☐ 2

Total score: _____

Appendix 2.

A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.



Reference: Lund, C. H. and J. W. Osborne (2004). "Validity and reliability of the neonatal skin condition score." J Obstet Gynecol Neonatal Nurs **33**(3): 320-327.

Reference: Lund, C. H. and J. W. Osborne (2004). "Validity and reliability of the neonatal skin condition score." J Obstet Gynecol Neonatal Nurs 33(3): 320-327.

Appendix 6.

A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate.

Assessment	Sedation		Sedation/Pain	Pain / Agitation	
Criteria	-2	-1	0/0	1	2
Crying Irritability	No cry with painful stimuli	Moans or cries minimally with painful stimuli	No sedation/ No pain signs	Irritable or crying at intervals Consolable	High-pitched or silent-continuous cry Inconsolable
Behavior State	No arousal to any stimuli No spontaneous movement	Arouses minimally to stimuli Little spontaneous movement	No sedation/ No pain signs	Restless, squirming Awakens frequently	Arching, kicking Constantly awake or Arouses minimally / no movement (not sedated)
Facial Expression	Mouth is lax No expression	Minimal expression with stimuli	No sedation/ No pain signs	Any pain expression intermittent	Any pain expression continual
Extremities Tone	No grasp reflex Flaccid tone	Weak grasp reflex ↓ muscle tone	No sedation/ No pain signs	Intermittent clenched toes, fists or finger splay Body is not tense	Continual clenched toes, fists, or finger splay Body is tense
Vital Signs HR, RR, BP, SaO_2	No variability with stimuli Hypoventilation or apnea	< 10% variability from baseline with stimuli	No sedation/ No pain signs	↑↑ 10-20% from baseline SaO_2 76-83% with stimulation – quick recovery ↑	↑↑ 20% from baseline $SaO_2 \leq 75\%$ with stimulation – slow recovery ↑ Out of sync with vent

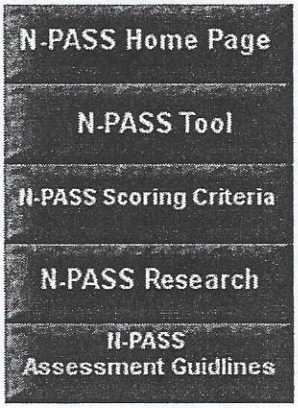
Loyola University Health System, Loyola University Chicago 2009

(rev. 2/10/09) Pat Hummel, MA, APN, NNP, PNP

Premature Pain Assessment +1 if <30 weeks gestation / corrected age.

Appendix 6.
A Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate

Scoring Criteria



Crying / Irritability

-2 → No response to painful stimuli

- No cry with needle sticks
- No reaction to ETT or nares suctioning
- No response to care giving

-1 → Moans, sighs, or cries (audible or silent) minimally to painful stimuli, e.g. needle sticks, ETT or nares suctioning, care giving

0 → No sedation signs or No pain/agitation signs

+1 → Infant is irritable/crying at intervals – but can be consoled
- If intubated – intermittent silent cry

+2 → Any of the following:

- Cry is high-pitched
- Infant cries inconsolably
- If intubated – silent continuous cry

Behavior / State

-2 → Does not arouse or react to any stimuli:

- Eyes continually shut or open
- No spontaneous movement

-1 → Little spontaneous movement, arouses briefly and/or minimally to any stimuli:

- Opens eyes briefly
- Reacts to suctioning
- Withdraws to pain

0 → No sedation signs or No pain/agitation signs

+1 → Any of the following:
- Restless, squirming
- Awakens frequently/easily with minimal or no stimuli

+2 → Any of the following:

- Kicking
- Arching
- Constantly awake
- No movement or minimal arousal with stimulation (noe sedated, inappropriate for gestational age or clinical situation)

Facial Expression

-2 → Any of the following:

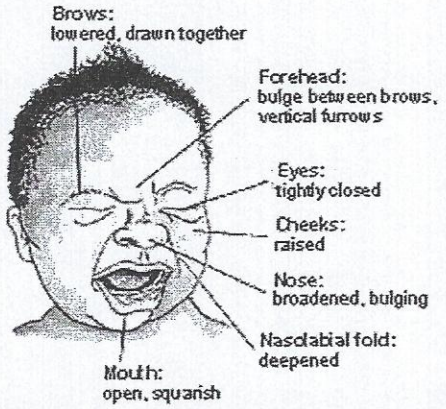
- Mouth is lax
- Drooling
- No facial expression at rest or with stimuli

-1 → Minimal facial expression with stimuli

0 → No sedation signs or No pain/agitation signs

+1 → Any pain face expression observed intermittently

+2 → Any pain face expression is continual



Facial expression of physical distress and pain in the infant

Extremities / Tone

-2 → Any of the following:
- No palmar or planter grasp can be elicited
- Flaccid tone

-1 → Any of the following:
- Weak palmar or planter grasp can be elicited
- Decreased tone

0 → No sedation signs or No pain/agitation signs

+1 → Intermittent (<30 seconds duration) observation of toes and/or hands as clenched or fingers splayed

- Body is *not* tense

+2 → Any of the following:
- Frequent (≥30 seconds duration) observation of toes and/or hands as clenched, or fingers splayed
- Body is tense/stiff

Vital Signs: HR, BP, RR, & O_2 Saturations

-2 → Any of the following:
- No variability in vital signs with stimuli
- Hypoventilation
- Apnea

- Ventilated infant – no spontaneous respiratory effort

-1 → Vital signs show little variability with stimuli – less than 10% from baseline

0 → No sedation signs or No pain/agitation signs

+1 → Any of the following:
- HR, RR, and/or BP are 10-20% above baseline
- With care/stimuli infant desaturates minimally to moderately (SaO_2 76-85%) and recovers quickly (within 2 minutes)

+2 → Any of the following:
- HR, RR, and/or BP are > 20% above baseline
- With care/stimuli infant desaturates severely (SaO_2 < 75%) and recovers slowly (> 2 minutes)
- Out of sync/fighting ventilator

Vita

Katherine Marie Newnam
1104 Hillston Court
Chesapeake, Virginia 23322
newmankm2@vcu.edu

Katherine Newnam was born July 6, 1957 in Norfolk, Virginia as an American citizen.

Employment/ Experience

2007 to present Neonatal ICU CHKD

Neonatal Nurse Practitioner

Assessment, diagnosis and treatment for the critical ill neonate within the ICU under the direct supervision of the neonatologist.

1994-2001 and 2005-2007 Neonatal ICU CHKD

Staff Nurse

Continual assessment and treatment of neonates under the direction of the neonatologist, resident staff and /or neonatal nurse practitioner. Assist with additional staffing when needed. Participate in the family support committee to enhance family centered care within the NICU.

2001-2002 and 2005-2006 Old Dominion University Norfolk, VA

Adjunct Faculty

Taught pediatric dyadic content (Nursing 705; 3 credit course) to family nurse practitioner students under the direction of Graduate Program Director, L. Garzon, PhD. Instruction included on site lecture and testing to students on campus with live feed to distance students across the state of Virginia (10-25 students). Grading of presentations and term papers were also conducted.

2000-2005 Renaissance Pediatrics Chesapeake, VA

Certified Pediatric Nurse Practitioner

With the oversight of a supervising physician I assessed, diagnosed and treated patients including prescriptive authority. Patient load was approximately 22 assigned pediatric patients daily from newborn to age 21 years. Focus on well and preventative care with a focus in lactation and asthma support and teaching. Supervised office nursing and support persons while assigned to assist in my daily functions. Phone triage at night as assigned; weekly and hospital visits as required.

2001-2006 Hospital Lactation Support CHKD

Lactation consultant

Assist with any lactation issues throughout the inpatient units and the Emergency department. Hands on participation with latch techniques and pumping equipment and support.

1988-1994 Progressive Care Unit CHKD

Unit Director, Progressive Care Unit

Twenty four hour accountability for the operation of the Progressive Care Nursing Unit. This included staffing, patient care, education, budget analysis and development, policy development and departmental representation for the Progressive Care Unit. Implemented departmental relocation to the third floor and unit expansion from 10-13 beds. Directly supervised and evaluated the performance of fifty professionals and paraprofessionals with the assistance of two assistant nurse managers.

1986-1988 Assistant Unit Director NICU

1983-1986 Staff Nurse Infant & Toddler Unit/NICU

Education

May 1983	Old Dominion University	Norfolk, VA
Bachelor of Science	Nursing	
August 1990	Old Dominion University	Norfolk, VA
Master of Science	Nursing Administration	
December 1999	Old Dominion University	Norfolk, VA
Post Master's Certification	Certified Pediatric Nurse Practitioner	
December 2006	East Carolina University	Greenville, NC
Post Master's Certification	Neonatal Nurse Practitioner	
August 2008-Current	VA Commonwealth Univ.	Richmond, Va.
(graduation 5/11/13)	PhD in Nursing	

Presentations

Newnam, K. M. Hyperbilirubinemia: Guidelines for Care in the Newborn. Presentation to Tidewater Area Lactation Consultant Association (TALCA), 9/2005.

Newnam, K. M. Hyperbilirubinemia: Guidelines for Care in the Newborn. NICU staff educational podium presentation, 10/2005.

Newnam, K. M. Improving Fluid Management and Decreasing PDA by improving the Neonatal Environment. National Association of Neonatal Nurses (NANN) 24th Annual conference, poster presentation, 10/07.

Newnam, K. M. & McGrath, J. M. Integrated Review of findings related to Neonatal Skin Care. Southern Nursing Research Society (SNRS), Jacksonville, Fl., Poster Presentation, 2/2011.

Newnam, K. M. Prevention of Skin Injury Related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants, An Evidence Based Approach. 25th Anniversary Research Symposium of the National Institute of Health/National Institute of Nursing Research (NINR), Washington DC, Poster Presentation, 3/2011.

Newnam, K. M. Prevention of Skin Injury related to Continuous Positive Airway Pressure (CPAP) in Preterm Infants. NANN Research Summit, Scottsdale, AZ, 4/2011.

Newnam, K. M. Prevention of Skin Injury Related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants. 6th Annual Research Summit of the National Association of Neonatal Nurses (NANN), Orlando, Fl. Paper Presentation, 9/2011.

Newnam, K. M. Strategies to Reduce Skin Injury related to Nasal Continuous Positive Airway Pressure (CPAP) in Preterm Infants. 26th Annual Conference of the Southern Nursing Research Society (SNRS), Podium presentation, 2/2012.

Newnam, K. M., McGrath, J.M., Jallo, N., Sayler, J., Estes, T, & Bass, W.T. Continuous Positive Airway Pressure (CPAP), State of the Science. Council of the Advancement of Nursing Science (CANS), 2012 SOS Congress-Nursing Research, Washington, DC. Poster Presentation, 3/2012.

Newnam, K. M. Understanding the mystery of adrenal insufficiency in the preterm infant, 28th National Association of Neonatal Nurses (NANN) 27th Annual Educational Conference, Palm Springs, CA, Podium Presentation, 10/2012.

Newnam, K. M., Continuous Positive Airway Pressure (CPAP): What Do We Know in 2011? 28th National Association of Neonatal Nurses (NANN) 27th Annual Educational Conference, Palm Springs, Ca. (2) Podium Presentation,

10/2012.

Newnam, K. M. (2012). Sharing Science as a method to increase breast feeding rates in the NICU. 7th annual NANN Research Summit, Scottsdale, AZ.

Newnam, K. M. Comparative Effectiveness
8th annual NANN Research Summit, Scottsdale, AZ. Podium Presentation, 4/2013.

Newnam, K. M. The NICU Graduate: Implications for Primary Care. National Association of Pediatric Nurse Practitioners' (NAPNAP), 34th annual Conference, Orlando, FL. Podium Presentation, 4/2013.

Publications

Newnam, K. M. & McGrath, J. M. (2010). Understanding the Inflammatory Response of the Neonate: Clinical Implications for Caregivers in the Neonatal Intensive Care Unit. Newborn and Infant Nursing Reviews. Vol. 10 (4), 165-176.

Newnam, K. M. & McGrath, J. M. (2010). Families and the Sepsis Work-up: Considering their Fears. Newborn and Infant Nursing Reviews. Vol. 10 (4), 160-162.

Newnam, K. M. & DeLoach, D. L. (2011). Neonatal Hypothermia: A Method to Provide Neuroprotection After Hypoxic Ischemic Encephalopathy. Newborn and Infant Nursing Reviews. Vol. 11 (3), 113-124.

Newnam, K. M. & McGrath, J. M. (2011). Following the Diagnosis of Neonatal Hypoxic Ischemic Encephalopathy: A Family-Centered Approach. Newborn and Infant Nursing Reviews. Vol 11 (3), 98-101.

Newnam, K.M. & Parrott, J. (2013). The NICU graduate; Implications for Pediatric Primary Care. Newborn & Infant Nursing Reviews. Accepted for publication (June, 2013).

Newnam, K. M., McGrath, J.M., Jallo, N., Sayler, J., Estes, T, & Bass, W.T. (2013). An Integrative Review of Skin Breakdown in the Preterm Infant Associated with Nasal Positive Airway Pressure. Journal of Obstetric, Gynecologic & Neonatal Nursing. Accepted with revisions.

Newnam, K. M., McGrath, J.M., Jallo, N., Sayler, J., Estes, T, & Bass, W.T. (2013). Comparative Effectiveness Study of Continuous Positive Airway Pressure (CPAP) Related Skin Breakdown when using Different Nasal Interfaces in the Extremely Low Birth Weight (ELBW) Neonate. Applied Nursing Research, submitted for publication.