STABILITY OF THE INFANT CAR SEAT CHALLENGE AND RISK FACTORS FOR OXYGEN DESATURATION EVENTS

A Dissertation Presented

by

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DEDICATION

This dissertation is dedicated to Douglas K. Richardson M.D. M.B.A.

His passion for knowledge is fondly remembered.

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ABSTRACT

STABILITY OF THE INFANT CAR SEAT CHALLENGE AND RISK FACTORS FOR OXYGEN DESATURATION EVENTS

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Research suggests that infants with poor neck and upper torso muscle tone experience lateral slouching and a compromised airway when placed in the semi-upright seating position. Studies reveal that 4-60% of premature infants (born at less than 37 weeks gestation) may experience oxygen desaturation events when in their child safety seats (CSS), potentially resulting in adverse neurodevelopmental outcomes. Therefore, the American Academy of Pediatrics recommends that premature infants be tested in their CSS prior to hospital discharge. However, neonatal healthcare providers are concerned that this method of testing might not be reliable. No formal studies have investigated the outcomes of repeat testing of premature infants, and little is known about the risk factors for oxygen desaturation events. Therefore, the purpose of this descriptive, non-experimental, observational study was to explore the stability of the one-point Infant Car Seat Challenge (ICSC) and risk factors that may be associated with oxygen desaturation events. A sample of 49 premature infants was used to explore the following variables: 1) pass/fail rates following two (ICSC) observation points, 2) oxygen saturation and desaturation patterns, sleep/wake activity, and a measure of head lag (using the pull-to-sit maneuver) during two ICSCs, and 3) the association between head lag, chronological age, time spent sleeping in the CSS and oxygen desaturation events. Data were analyzed by descriptive and nonparametric statistical tests. This study's

findings indicated that 86% of premature infants had stable results, 8% passed ICSC 1 but not ICSC 2, and 6% failed ICSC 1 and passed ICSC 2. In addition the odds for oxygen desaturation events increased in infants that are born at a gestational age ≤ 34 weeks, were discharged home at a chronological age of > 7 days and had a corrected gestational age of ≥ 37 weeks. Neither head lag or sleep time influenced the ICSC outcomes. Furthermore the ICSC success rate for identifying at risk infants was equal to or better than that of other screening tests for newborn medical conditions. These findings will assist neonatal healthcare providers in making appropriate recommendations for safe travel.

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CHAPTER I

INTRODUCTION

Introduction

Since the early 1980s child safety seats (CSS; see Table 1) have played a major role in the safe travel of the youngest motor vehicle passengers in the U.S. However, with the growing use of CSSs, researchers recognized that premature and low birth-weight infants do not fit securely into some of the currently available models, thereby increasing the risk for injury (Bull & Stroup, 1985; Bull, Stroup, & Gerhardt, 1988a; Bull, Weber, & Stroup, 1988b). In addition, studies have shown that some premature infants, although considered medically stable for discharge, experience a variety of symptoms known as oxygen desaturation events, i.e., apnea, bradycardia, periodic breathing and oxygen desaturation (see Table 1), when placed in the semi-upright seating position of a CSS (Bass & Mehta, 1995; Bass, Mehta, & Camara, 1993; Dawson & Stainton, 2004; Dollberg, Yacov, Mimouni, & Ashbel, 2002; Hertz, Aggarwal, Rosenfeld, & Greensher, 1994; Merchant, Worwa, Porter, Coleman, & deRegnier, 2001; Mullen & Courts, 2002; Nagase, Yonetani, Uetani, & Nakamura, 2002; Smith & Turner, 1990; Willett, Leuschen, Nelson, & Nelson, 1986; 1989). Moreover, this same problem affects a number of full-term infants (Bass & Mehta, 1995; Merchant et al., 2001). Although the cause of CSS-related oxygen desaturation events is not known, their etiology is believed to differ from that of apnea of prematurity, which is caused by an immature respiratory control center and/or obstruction from a weakened or poorly developed airway and resolves as the infant matures (Martin & Fanaroff, 1998; Martin, Miller, & Waldemar, 1986; Miller & Martin, 1998).

Table 1

Key Words and Phrases

Key Word or Phrase	Definition
Apnea	Pause in breathing for ≥ 20 seconds (Bass et al., 1993)
Bradycardia	Heart rate of ≤ 80 beats per minute (Bass et al., 1993)
Child safety seat (CSS)	Restraint device used for transporting infants (Block, Hanson, & Keane, 1998). These devices differ from the basic type of infant seat in that they are designed to protect the occupant in a crash (NHTSA, 2004). Child safety seats must meet federal guidelines and be crash tested to be approved for use during transport (NHTSA 2004).
Oxygen desaturation	A reduction in the oxygen saturation of blood to < 93% (Bass et al., 1993)
Infant car seat challenge (ICSC)	Observation of premature infants in a CSS prior to hospital discharge. This term, used by The Children's Hospital of Boston (K. Gustafson, personal communication, April 22, 2004), was chosen by the researcher for this dissertation. There is no nationwide standard term for this test. This name was selected because the predischarge observation procedure is specific to infants and "challenge" means a trial of strength (Oxford English Dictionary Online, 2002). Infants must have sufficient neck and torso strength to successfully pass the ICSC (Tonkin, 1998; Tonkin et al., 2003).
Neurodevelopmental disability	One or more of the following: 1) cerebral palsy, 2) legal blindness, 3) hearing loss, 4) convulsive disorder, and 5) cognitive delay (Cheung, Barrington, Finer, & Robertson, 1999).
Oxygen desaturation event	The constellation of symptoms (apnea, periodic breathing, bradycardia and oxygen desaturation) that happens when an infant is placed in a CSS.
Periodic breathing (PB)	Short pauses in breathing of less than 3 seconds interrupted by bursts of rapid shallow respirations (Barrington & Finer, 1990). Similar to apnea.
Premature infant	Infant born at less than 37 weeks gestation (American Academy of Pediatrics [AAP], 1991)
Stability (when applied to a measure)	The consistency of repeated measures of the same attribute using the same scale or instrument (Burns & Grove, 2001)

Due to the difficulties with the semi-upright seating position, the American Academy of Pediatrics (AAP, 1991, 1996, 1999) has recommended that every infant born at less than 37 weeks gestation undergo a period of observation in their CSS prior to hospital discharge. However, there are concerns that a one-time predischarge observation period, called the Infant Car Seat Challenge (ICSC; Table 1), is not sufficient to identify all at-risk infants (Pilley & McGuire, 2005; R. Pye, personal communication, May 5, 2004).

The AAP (1991, 1996, 1999) also recommends car bed travel for infants who experience oxygen desaturation events in their CSS. When traveling in a car bed, infants are positioned supine or on their sides (Weber, 2000). For most premature infants, being placed in a more reclined or horizontal position resolves oxygen desaturation events (Nagase et al., 2002; Willett et al., 1989; Young, Shapira, & Finer, 1996). However, car beds are not recommended for all infants (Weber, 2000). It is believed, though not proven, that infants in car beds may be more vulnerable to injury because the entire side of their bodies are exposed to the force of a crash (Weber, 2000). Young children have immature bones and neck muscles that may deform or separate (atlantooccipital dislocation) during a crash, leaving no structural support between the head and torso (Fuchs, Barthel, Flannery, & Christoffel, 1989; Weber, 2001). The shell of the rear-facing CSS protects the infant's head from the extreme forces generated during a crash, as shown by crash tests results and from examinations of infants following motor vehicle crashes (Fuchs et al., 1989; Weber, 2001). Thus, the rear-facing, semi-upright seating position is considered the safest position for young children (AAP, 1999; NHTSA 2004). Nevertheless, it is also clear that the rear-facing, semi-upright seating position of the CSS

places some infants at risk for oxygen desaturation events, which can result in adverse cognitive, behavioral and motor outcomes.

No formal studies have investigated outcomes of a repeat ICSC for stability on premature infants. In addition, little is known about the risk factors for oxygen desaturation events. Since car beds are not the best option for all infants, it is essential to identify infants at risk for oxygen desaturation events, so that neonatal clinicians can make appropriate recommendations for travel. Therefore, the purpose of this descriptive study was to explore the stability of the one-point ICSC by observing premature infants (born at less than 37 weeks gestation) during a second ICSC and risk factors that may be associated with oxygen desaturation events.

Background

Several important issues stimulated this investigation. First, a large number of premature infants may be affected by oxygen desaturation events. Second, oxygen desaturation events may lead to adverse behavioral, cognitive and motor outcomes that could require long-term medical and psychological interventions for both infants and their family members. Third, some oxygen desaturation events may not be detected through visual inspection by the parent. Fourth, information is lacking on risk factors (e.g., sleep, head lag, and chronological age) that may contribute to oxygen desaturation events. Fifth, the ICSC used for identifying at-risk premature infants is not consistently performed nationwide. Although premature infants are not discharged from the hospital until they are apnea free (Eichenwald, Aina, & Stark, 1997; Martin & Fanaroff, 1998; Martin et al., 1986; Miller & Martin, 1998), infants who experienced oxygen desaturation events in their CSS were apnea free at the time of discharge. These five important issues

provide the rationale for examining the stability of the one-point ICSC and the associated risk factors for oxygen desaturation events.

Numbers Affected

No large scale studies have investigated the number of infants that experience oxygen desaturation events when placed in a car seat. As a result, the number of premature infants who experience oxygen desaturation events can only be estimated. To obtain this estimate the number of premature infants that survive per year must first be determined. The latest statistics reveal that of the 4,021,726 infants born in the U.S. during 2002, 480,812 (12.1 %) were born prematurely (Martin et al., 2003). Furthermore, the National Vital Statistics datasets classify infant deaths by cause only, not by gestational age (Anderson & Smith, 2003). In 2001, there were 27, 568 infant deaths, of which 4,410 (16 %) were attributed to prematurity or low birth weight. However, some premature infant deaths may have been attributed to other causes such as respiratory failure (Anderson & Smith, 2003). Thus, using only the number of infant deaths caused by prematurity would overestimate the number of premature infant survivors. On the other hand, the total number of infant deaths includes full-term infants, so that using the total number of infant deaths underestimates the number of premature infant survivors. Therefore, the number of premature infant survivors is estimated to be between 450,000-476,000 yearly.

To determine how many of these survivors experience oxygen desaturation events, the percentage of premature infants affected by this problem must be calculated. Early studies reported that up to 60% of premature infants experienced oxygen desaturation events in their CSS (Willett et al., 1986; 1989), while a more recent study

reported that 4% experienced this problem (Mullen & Courts, 2002; Willett et al., 1986; 1989). This large discrepancy in percentages of infants affected over the past two decades may be due to changes in car seat design, differences in testing procedures across studies, and/or advances in neonatal care. Nonetheless, most surviving premature infants will travel home in a CSS at hospital discharge. Based on the frequency of events (4-60%; M = 27%) and the number of survivors (450,000-476,000), 121,500-128,520 premature infants per year are estimated to be at risk for oxygen desaturation events.

Adverse Outcomes

Impaired oxygenation, such as happens during apnea of prematurity and oxygen desaturation events, can cause harmful physiological changes. In adults, impaired oxygenation causes depressed mental activity, reduced capacity of working muscles, and eventually cell death (Guyton & Hall, 1996a; Miller & Martin, 1998). Similarly, the clinical signs and symptoms of inadequate oxygenation in children include tachypnea, tachycardia, dyspnea, hypertension, behavioral changes, somnolence, and hypotension (Pasterkamp, 1998). However, advanced monitoring is required to detect oxygen desaturation events in premature infants because they routinely exhibit varying levels of muscle tone and strength, decreased levels of activity, and lack verbal communication abilities.

No investigations have looked at adverse outcomes of premature infants with a history of oxygen desaturation events in a CSS. However, several investigations have found that poor oxygenation in infancy leads to undesirable neurodevelopment, validating the previous beliefs of many practitioners (Newburger, Silbert, Buckley, & Flyer, 1984). For example, a study of a cohort of 38 children 6 months to 6 years old at

time of surgery) with transposition of the greater arteries (and chronic hypoxemia) found that delaying surgical correction resulted in poorer scores for cognitive function (Newburger et al., 1984). Also, 6 week-old infants with sleep apnea syndrome and low transcutaneous oxygen values have been shown to have lower neurological test scores than infants without sleep apnea syndrome (Loscher et al., 1990). Moreover the seminal work of Cheung and colleagues (1999) demonstrated an association between mean oxygen desaturation and frequency of apnea in premature infants (<32 weeks gestation), and undesirable neurodevelopment in early childhood (15-64 months of age).

These findings suggest that severe apnea in infants before discharge from the hospital is a marker for poor neurodevelopmental outcomes. Collectively, these studies have increased health care providers' awareness of the potential adverse outcomes associated with apnea and/or impaired oxygenation. Some infants have been reported to spend up to 16 hours a day in their CSS or similar seating device (Callahan & Sisler, 1997). It is not known how many of these infants experience impaired oxygenation. Therefore it is important that oxygen desaturation events, even if not overtly manifested, be detected and prevented. The potential for adverse neurological outcomes in premature infants makes identifying at-risk infants a priority.

Parental Observation

Observing the premature infant for oxygen desaturation events by skin color has been shown to be an unreliable form of detection (Cifuentes, Haywood, Ross, & Carlo, 1998; Lynam, 1991; Miller & Martin, 1998). For example, as apnea ensues, oxygen desaturation and bradycardia may be noted, but cyanosis in response to deoxygenated blood may not be evident until a significant level of hypoxemia has occurred (Cifuentes

et al., 1998; Lynam, 1991; Miller & Martin, 1998). Newborns, including premature infants, have varying levels of red blood cells, which affect skin color and may limit a parent's ability to identify an oxygen desaturation event (Lees, 1970; Miller & Martin, 1998). In polycythemia, a condition of increased amounts of red blood cells, there may be an adequate amount of oxygen in the blood, but the patient may appear cyanotic because not all the hemoglobin may be saturated (O'Brodovich & Haddad, 1998). In contrast, patients with anemia, a condition of decreased amount of red blood cells, may have inadequate oxygen in the blood, yet their skin may appear pink (O'Brodovich & Haddad, 1998). The red blood cells are saturated with oxygen, but a lower than normal number of them is circulating.

Both polycythemia and anemia are conditions that affect the premature infant. Thus, parents cannot rely on the premature infant's color or physical appearance to detect an oxygen desaturation event. Cellular damage from inadequate oxygenation may begin before parents see visible signs and symptoms, especially if the infant is anemic. Furthermore, recognition of color changes in infants with darker skin tones may be even more difficult to detect. This issue is particularly important because over half (54%) of the approximately 440,000 premature infants born in 2003 had darker skin tones, including 17.8% black non-Hispanic, 11.9% Hispanic, and 24% American Indian or Asian (Centers for Disease Control and Prevention, 2004). Therefore, identifying those infants who will experience problems and finding alternative methods for transporting them may prevent these harmful events.

Risk Factors

In addition to the concerns about identifying at-risk infants, little is known regarding risk factors for oxygen desaturation events. To date, the potential risk factors identified for oxygen desaturation events in CSSs are the semi-upright seating position (necessitated by the traditional car seat) (Smith & Turner, 1990; Willett et al., 1989), sleep (Hertz et al., 1994), genetic disorders (Bass & Mehta, 1995), and the amount of time spent in the CSS (Merchant et al., 2001). However, no published studies were found that adequately addressed all potential risk factors. Infant chronological age and head lag (a measure of head control) have never been studied. Additionally, few studies have examined the effect of sleep while infants are positioned in their CSS (Hertz et al., 1994; Nagase et al., 2002).

Head lag, chronological age, and sleep are three potential risk factors that may be associated with oxygen desaturation events. Head lag is important to assess in premature infants because their diminished head/upper torso control prevents them from repositioning their heads when experiencing poor oxygenation from a positional ventilatory abnormality (Lester & Tronick, 2002). Chronological age, a measure of the infant's age beginning at birth (Holditch-Davis, Edwards, & Wigger, 1994), can be helpful when comparing infants of the same gestational age, but with different birth dates. Infants may exhibit differing degrees of maturation depending upon the amount of time spent outside the womb (Forslund & Bjerre, 1983; Mercuri et al., 2003). Older infants may exhibit more developed neck muscles (Forslund & Bjerre, 1983; Mercuri et al., 2003). Furthermore, two infants can have the same gestational age but different chronological ages and exhibit different responses to being positioned in the CSS.

Moreover, during sleep the body relaxes. With relaxation, the infant's already slouched position may be further compromised (Hertz et al., 1994; Nagase et al., 2002). During sleep infants are also less likely to respond to the body's biofeedback mechanisms that would enable them to correct poor body alignment (Gaultier, 1990; Holditch-Davis et al., 1994). Therefore head lag, chronological age, and sleep warrant further exploration as potential risk factors.

Standardization & Stability of the ICSC

The AAP and National Highway Traffic Safety Administration (NHTSA) are the guiding agencies for addressing issues of transporting infants. Acknowledging the difficulties in identifying infants at risk for oxygen desaturation events, the AAP (1991; 1996; 1999) recommends advanced monitoring of all premature infants before hospital discharge to detect which infants will experience these events. More specifically, the AAP recommends that every infant born at less than 37 weeks gestation be observed in a CSS. The AAP's recommendation was based on five small studies (Bass et al., 1993; Bull & Stroup, 1985; Bull et al., 1988b; Willett et al., 1986; 1989). One of the studies examined the fit of premature and low birth weight infants in the traditional CSS (Bull & Stroup, 1985). Another looked at the issue of CSS misuse (such as improper positioning or securing infant in the seat) (Bull et al., 1988b), while the remaining three studies focused on oxygen desaturation events experienced by premature infants when positioned in the CSS (Bass et al., 1993; Willett et al., 1986; 1989). Subsequently, the AAP (1999) added that all hospitals should have policies in place that ensure infants are discharged in an appropriate CSS.

The predischarge observation period or ICSC has become standard practice in approximately 75% of U.S. hospitals (Williams & Martin, 2003). Following the lead of the U.S., other countries have also instituted the practice of predischarge ICSC (Fetus and Newborn Committee, 2000; Mullen & Courts, 2002; Nagase et al., 2002). Many institutions nationwide have complied with the AAP recommendation for the predischarge observation period even though no standardized guidelines have been established. Due to this lack of standardized guidelines, hospitals have developed their own policies and procedures for performing the ICSC, including how often to repeat it if an infant fails the initial period of observation (Mullen & Courts, 2002; Williams & Martin, 2003).

These independent criteria and procedures have led to inconsistencies in criteria for observing infants, pass and fail criteria, and duration of observation (Williams & Martin, 2003). Inclusion criteria for infants to be observed include prematurity, weight, respiratory conditions, and current or past oxygen needs (Williams & Martin, 2003). Most providers perform a 30- to 90-minute test, replicating the criteria of past research studies (Bass & Mehta, 1995; Bass et al., 1993; Willett et al., 1986; 1989). Although pass/fail criteria have not been formally researched, it is typical for either the practitioner or institution itself to set these parameters (K. Gustafson, personal communication, April 22, 2004; S. Young, personal communication, May 5, 2004).

Furthermore, although many healthcare providers have complied with the AAP recommendations, others have chosen not to perform predischarge ICSC because current methods have never been tested for stability, are not standardized, and may not identify all at-risk infants (Pilley & McGuire, 2005; R. Pye, personal communication, May 5,

2004). A key issue for those institutions that do not observe premature infants in their CSS before discharge is lack of evidence that a one-point measure is stable.

To date no empirical evidence has been found to support the standard one-point ICSC of premature infants. Passing a one-point ICSC does not guarantee that an infant will pass a repeat ICSC during the short time between being deemed medically ready for discharge and actual discharge. Anecdotal evidence indicates that two-point ICSCs have yielded varying results in institutions that repeat an initial failed ICSC (S. Young, personal communication, May 5, 2004). In some institutions, premature infants are tested twice if the first test is failed. A car bed is recommended if both tests are failed (S. Young, personal communication, May 5, 2004). With two tests, it has been found that some infants will fail the initial test but pass the second. These inconsistent results indicate the need for further investigation.

Significance of the Problem

Some premature infants experience difficulty in maintaining stable blood oxygen saturation when positioned in their CSS, yet it is not clear whether all at-risk infants are successfully being identified by a one-point ICSC. To date, no investigations have examined the stability of the one-point ICSC. It is not known whether repeat observations of premature infants will yield similar or different results compared to the one-point ICSC. In addition, the relationships between risk factors and oxygen desaturation events when premature infants are positioned in their CSS have not been fully explored. Little is known about the effects of head lag, chronological age, and sleep on the occurrence of oxygen desaturation events.

This study has important implications for neonatal healthcare providers who perform the ICSC and provide parental education at discharge. Determining the stability of the ICSC will help ensure that healthcare providers do not convey false reassurance to parents of premature infants at discharge. Also, knowing more about the risk factors and their relationship to oxygen desaturation events will help neonatal healthcare providers make appropriate recommendations for safe travel at hospital discharge. Lastly, the acquisition of more accurate methods for identifying at-risk premature infants may contribute to better behavioral, cognitive and motor outcomes for this population.

Purpose Statement

The purpose of this descriptive, non-experimental, and observational study was to explore the stability of the one-point ICSC by observing premature infants (born at less than 37 weeks gestation) during a second ICSC and risk factors that may be associated with oxygen desaturation events. The specific aims of this study were to describe 1) the pass/fail rates of premature infants following two (ICSC) observation points, 2) oxygen saturation and desaturation patterns, sleep wake activity, and a measure of head lag for premature infants over the course of two ICSCs, and 3) the association between head lag, chronological age, time spent sleeping in the CSS and oxygen desaturation events experienced by premature infants during ICSCs.

Summary

Approximately 450,000-485,000 premature infants born yearly are sent home in CSSs. Almost one third of these infants may be at risk for oxygen desaturation events, which can lead to adverse behavioral, cognitive and motor outcomes (Newburger et al., 1984; Perlman & Volpe, 1985). Parental observation is insufficient to detect these

events. The AAP (1991; 1996; 1999) has recommended that every infant born at less than 37 weeks gestation be tested in a CSS prior to hospital discharge. Despite these recommendations, little is known about the risk factors for oxygen desaturation events and many questions remain regarding the stability of predischarge testing methods. By investigating the stability of the ICSC and the risk factors for oxygen desaturation events, this research study will help neonatal healthcare providers make appropriate recommendations for safe travel at hospital discharge. In addition, this research study will help to answer three important questions about the ICSC:

Research Questions

1) What are the pass/fail rates of premature infants who have undergone two ICSCs?
2) What are the oxygen saturation and desaturation patterns, sleep wake activity, and measures of head lag for premature infants who undergo two ICSCs?
3) Are variations in head lag, chronological age, and time spent sleeping associated with oxygen desaturation events of premature infants in CSSs?

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

This chapter will present the theoretical framework for this study, based on Roy's Model of the Person as an Adaptive System (Roy, 1984; Roy & Andrews, 1999), and review the relevant literature on the infant car seat challenge (ICSC) and on risk factors for oxygen desaturation events of premature infants in a child safety seat prior to hospital discharge.

Adaptation

As soon as full-term infants are born, they face challenges in the extrauterine environment (Prechtl, 2001). Premature infants, who exit early from the womb, are at an even greater risk for difficulties in meeting environmental demands. Although premature infants occasionally remain hospitalized for a prolonged period, 6 months or more, some may still not be ready for the environmental challenges at discharge. Premature infants may take considerably longer to catch up to their full-term peers (McCormick, 1989). The survival of premature infants in the extrauterine environment is constantly threatened. One form of environmental threat is positioning them in the semi-upright seating position of the traditional CSS. Without successful adaptation to the CSS, the premature infant is at risk for oxygen desaturation events, and subsequent adverse behavioral, cognitive, and motor outcomes. Furthermore the infant's survival may be jeopardized by unstable blood oxygenation resulting from being positioned in a CSS. The prevention of oxygen desaturation events in premature infants when positioned in their CSS ensures successful adaptation to their new environment. Therefore, Roy's

(1984) Model of the Person as an Adaptive System provides a suitable framework for this investigation.

Roy's Model of the Person as an Adaptive System

Adaptation, a concept used in biology, psychology, sociology, literature, music, religion, and nursing, refers in the simplest sense to adjustment to environmental conditions (Mish, 2003). The biological concept of adaptation, perhaps the most commonly recognized, conveys the idea that living organisms inherit the capacity to develop structures and functions for carrying out such processes of life as assimilation of new matter, capture of energy, and reproduction (Oxford English Dictionary Online, 2002; The New Encyclopaedia Britannica, 1998; World Book Encyclopedia, 2002). This biological or hereditary form of adaptation is passed on through modifications of, or variations in genetic material that enable a species to feed, reproduce, and protect themselves and their offspring (Bahr & Johnston, 1993). The nonhereditary attributes of adaptation that enable survival include personal acclimatization or the habituation of organisms (deBeer, 1978).

Sister Callista Roy, a nurse theorist, integrated the concept of adaptation into a framework for use by the nursing profession. Roy has described individuals as biopsychosocial beings required to adapt to environmental stimuli and to meet five physiological needs: oxygenation, nutrition, elimination, activity and rest (Roy & Andrews, 1999). The Model of the Person as an Adaptive System proposes that humans meet these needs by using four primary adaptive modes: 1) physiologic-physical, 2) self-concept, 3) role function, and 4) interdependence (Roy & Andrews, 1999). Although

Roy uses the term "physiologic," the preferred spelling "physiological" (Mish, 2003) will be used in this dissertation.

Physiological-Physical Mode

The physiological-physical adaptive mode that applies to this study is concerned with the physical and chemical processes integral to human function and activities of daily living (Roy & Andrews, 1999). According to Roy, when a person's physiological-physical needs are met, physiological integrity is achieved. The compensatory function of the lungs serves as a perfect example of how physiological integrity can be achieved via a physiological-physical adaptive mode. When a human's acid-base balance is disturbed, the body can become acidotic (Guyton & Hall, 1996d). In response to this acidosis, the body's biofeedback system (a chemical process) is activated, resulting in an increased respiratory rate (a physical process) (Guyton & Hall, 1996d). This increase in respiratory rate permits carbon dioxide, which makes the blood acidic, to be released from the lungs to the air, helping to restore the body's acid-base balance to normal, thereby restoring the body's physiological integrity (Guyton & Hall, 1996d). Roy explains that nurses must know about these types of normal body processes and recognize compensatory and compromised processes of physiological adaptation so that necessary steps can be taken to maintain health (Roy & Andrews, 1999).

Roy's model of adaptation has been used as a framework for physiological studies on premature infants (Harrison, Leeper, & Yoon, 1990; Modrcin-Talbott, Harrison, Groer, & Younger, 2003; Norris, Campbell, & Brenkert, 1982). According to Roy and Andrews (1999), the goal of nursing is to contribute to the overall aim of healthcare, which is to promote the health of individuals and society. Roy explains that adaptive

behavior promotes the integrity, or degree of wholeness, of the human system, but that ineffective responses to change can disrupt this integrity (Roy & Andrews, 1999).

Theoretical Framework

Positioning premature infants in the semi-upright position in their CSS constitutes a change in their environment, to which their bodies try to adapt. Maladaptation is observed when premature infants experience oxygen desaturation events, thus threatening their physiological integrity. Within Roy's model, the premature infant's physiological integrity is maintained or achieved through a system of four interrelated parts: input, control processes, effectors, and output (Roy, 1984) (see Table 2; Appendix A).

Table 2

Definitions for Roy's Model of the Person as an Adaptive System

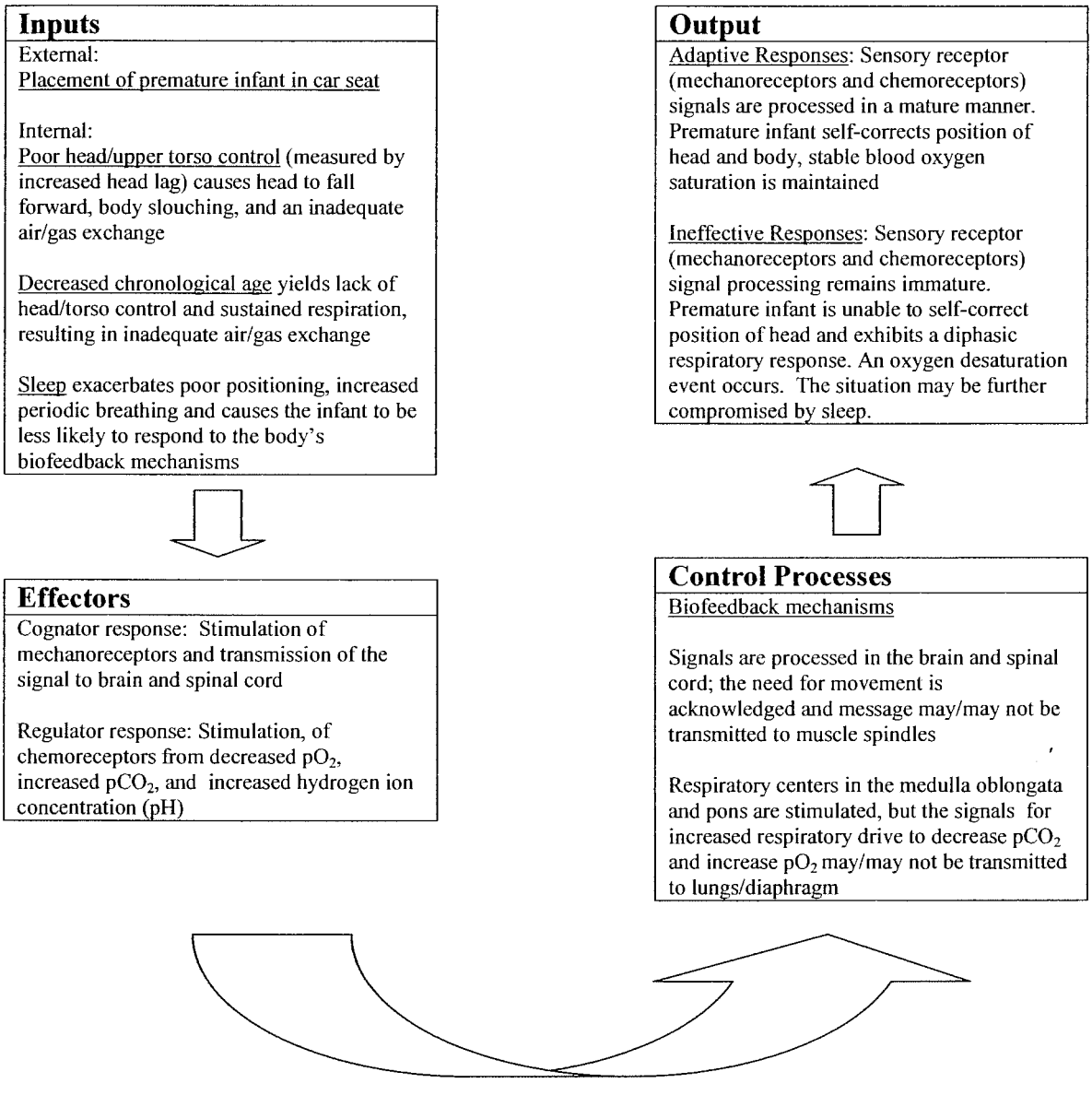
Input	Stimuli derived internally (from the self) and externally (from the environment).
Control Processes	Biological abilities enabling an individual to cope with a changing environment; also called coping mechanisms. 1. Cognator: A coping mechanism that responds through learned behavior to input of complex processes of perception and information processing. 2. Regulator: A coping mechanism that responds automatically to input through neural chemical endocrine processes.
Effectors	Physiological responses to control processes.
Output	Adaptive or ineffective responses to input. 1. Adaptive responses: responses that promote integrity of a person in terms of human system goals such as survival, growth, reproduction and mastery. 2. Ineffective responses: responses that do not contribute to adaptive goals.

Input

Inputs are stimuli that can be internal (from within the human) or external (from the environment). Although many inputs may influence the premature infant's tolerance to the CSS, this study will focus on three internal inputs: head /upper torso control, chronological age, and sleep (see Figure 1).

Figure 1

Model of Theoretical Framework



All three internal inputs can partially or fully occlude the upper airway and compress the chest, leading to an oxygen desaturation event (Carlo, Beoglos, Siner, & Martin, 1989; Tonkin, 1998). A partially or fully occluded airway and chest compression lead to inadequate lung expansion and decreased tidal volume, which lead to oxygen desaturation. Oxygen desaturation can lead to myocardial hypoxia, which is exhibited by bradycardia (Scanlon, 1994) or a slowed heart rate. This unstable cardiorespiratory status is expressed in the premature infant by symptoms such as apnea and/or periodic breathing, bradycardia and a reduction in oxygen saturation (Poets, Rau, Neuber, Gappa, & Seidenberg, 1997), symptoms of an oxygen desaturation event. However, each of the three inputs that can lead to the development of oxygen desaturation events, do so by a slightly different mechanism.

The first internal input is head/upper torso control. Infants who lack sufficient head/upper torso control develop a partially or fully occluded upper airway from their head falling forward onto their chest (Carlo et al., 1989; Tonkin, 1998; Tonkin et al., 2003). In addition, infants who lack head/upper torso control may lack chest/torso control, which can lead to chest compression as well. In response to upper airway occlusion and chest compression, the lungs of premature infants fail to adequately exchange oxygen and carbon dioxide.

The second internal input is chronological age, which is a measure of time that an infant has spent outside the womb (extrauterine age) (Holditch-Davis et al., 1994). Some studies suggest that prolonged extrauterine exposure may accelerate maturation (Forslund & Bjerre, 1983; Majnemer, Brownstein, Kadanoff, & Shevell, 1992). Therefore chronologically older infants may better tolerate being positioned in a CSS than those

who are chronologically younger. This better tolerance may be due to the older infant's mature responses to the environment, e.g., maintaining good body alignment (Forslund & Bjerre, 1983) and a stable respiratory status. In contrast, a less mature (chronologically younger) peer exhibits diminished strength and respiratory control and may therefore experience difficulty maintaining stable body alignment and a stable cardiorespiratory status when placed in a CSS (Amiel-Tison, 1968; Eichenwald et al., 1997).

The third internal input is sleep, which can also lead to cardiorespiratory compromise of the premature infant when placed in a CSS. During sleep, the infant's body relaxes and may slump over into a poor position for cardiorespiratory function (Hertz et al., 1994; Smith & Turner, 1990; Tonkin, 1998; Tonkin et al., 2003). Furthermore, the sleeping premature infant is more prone to periodic breathing and apnea and is less likely to respond to the body's biofeedback mechanisms that would normally signal the infant to readjust his or her body position (Hertz et al., 1994; Holditch-Davis et al., 1994; Nagase et al., 2002). Hence, the premature infant develops an oxygen desaturation event.

Control Processes and Effectors

An oxygen desaturation event, also referred to as cardiorespiratory compromise, can activate control processes that stimulate centers in the infant's spinal cord and brain, which in turn direct the body's response. Control processes or coping mechanisms include cognators and regulators (Roy, 1984). Activation of the control processes by inputs results in stimulation of the sensory receptors. Two types of sensory receptors that may be activated during an oxygen desaturation event are mechanoreceptors (cognators) that control body position and chemoreceptors (regulators) that control breathing and gas

exchange (Guyton & Hall, 1996b). Stimulation of the mechanoreceptors sends signals to the brain indicating the need for a change in body position (Guyton & Hall, 1996c), whereas stimulation of the chemoreceptors (by hypoxemia, hypercapnia, and/or hypoxia) signals to the brain indicating the need for a change in respiration (Guyton & Hall, 1996d). Following activation of the control processes, a signal is sent to the effectors.

The effectors are physiological responses to the control processes. However, the premature infant's physiological responses may be immature and unreliable. Premature infants may not have the physical strength to change their position. Furthermore, in terms of their respiratory status, most mammals in the early neonatal period have been shown to have a diphasic response to sustained hypoxia (Gaultier, 1990). This response begins with an initial increase in ventilation (tachypnea), followed by a secondary decrease in ventilation (apnea) (Gaultier, 1990; Kattwinkel, 1977; Manning & Stothers, 1991). The extent to which the premature infant experiences a diphasic response depends upon his/her gestational age and degree of maturation.

Output

When the four-part interrelated system of inputs, control processes, effectors and output is working appropriately, the effectors respond adaptively by directing the premature infant to self-correct his/her head and body position. In this case, the infant responds to an unstable respiratory condition with sustained respirations, averting the diphasic response and maintaining stable blood oxygen saturation. Therefore, the output maintains the infant's physiological integrity. In order for the infant to achieve physiological integrity (adapt to the CSS), he/she must have some degree of independent head/upper torso control and strength derived from a developed nuchal musculature. In

addition, the infant must have the neurological maturity that permits sustained respiration and the ability to respond to the body's cues even during sleep (Holditch-Davis et al., 1994).

When the system is not working correctly, it responds ineffectively and physiological integrity is not achieved. Ineffective responses are expressed through upper airway occlusion and chest compression, leading to an unstable condition evidenced by hypoxemia/hypercapnia (abnormally high levels of carbon dioxide in the blood)/hypoxia. The premature infant initially responds to this unstable condition by increasing respiratory drive during the first phase of a diphasic response (Gaultier, 1990; Kattwinkel, 1977; Manning & Stothers, 1991). However, as the second phase of the diphasic response is activated, the premature infant responds to the hypoxemic/hypercapnic/hypoxic condition by becoming apneic or by experiencing an oxygen desaturation event (Gaultier, 1990; Kattwinkel, 1977; Manning & Stothers, 1991). Also, the oxygen desaturation event may become worse during sleep. As discussed earlier, during sleep the premature infant is more prone to periodic breathing and apnea (Holditch-Davis et al., 1994) and is less likely to respond to biofeedback mechanisms that would normally signal the need for readjusting body position (Hertz et al., 1994; Holditch-Davis et al., 1994; Nagase et al., 2002).

Stability of the Infant Car Seat Challenge

When properly installed, CSSs reduce the risk of infant death by 71% (NHTSA, 2002). As a result, all states have laws requiring that infants and young children travel in federally approved CSSs (NHTSA, 2004). However, studies have shown that some premature infants, considered medically stable for discharge, experience oxygen

desaturation events when placed in the semi-upright seating position (Bass & Mehta, 1995; Bass et al., 1993; Dollberg et al., 2002; Hertz et al., 1994; Merchant et al., 2001; Mullen & Courts, 2002; Nagase et al., 2002; Smith & Turner, 1990; Willett et al., 1986; 1989). Therefore, the AAP (1991; 1996; 1999) has recommended that infants born at less than 37 weeks gestation undergo a period of observation (ICSC) in their CSS prior to hospital discharge. Many hospitals have complied with these recommendations, yet the stability of the one-point ICSC has never been tested.

Several studies have performed repeat observations of premature infants in their CSSs prior to hospital discharge (Dawson & Stainton, 2004; Dollberg et al., 2002; Nagase et al., 2002; Smith & Turner, 1990; Willett et al., 1989). However, in these studies the observations were not repeated to look at the stability of the one-point ICSC. Instead, repeat observations were performed in order to determine the etiology of oxygen desaturation events or to test an alternative position/support device. More specifically, observations were repeated to examine infant responses to 1) different angles of recline, including while positioned in a crib (Dawson & Stainton, 2004; Nagase et al., 2002; Smith & Turner, 1990; Willett et al., 1989; Young et al., 1996), 2) different head supports (Dollberg et al., 2002; Tonkin et al., 2003), 3) an alternative child restraint device (Nagase et al., 2002), or 4) modifications in position, such as adding blanket rolls (Mullen & Courts, 2002). No studies could be found that used a consistent procedure to examine and evaluate the stability of the one-point ICSC.

It is not known whether repeat observation of premature infants in their CSS will yield consistent results. Throughout the course of a single day, infants exhibit varied muscle tone, activity and states of wakefulness. Sleepy infants display diminished

muscle tone, while agitated infants have increased muscle tone (Amiel-Tison, 1968). These variations in tone may lead to inconsistent physiological responses when infants are positioned in CSSs. If the one-point ICSC lacks stability, some infants at risk for oxygen desaturation events may not be identified.

Pass/Fail Rates of the Infant Car Seat Challenge

To date, 10 studies have examined the pass/fail rates of oxygen desaturation events for infants when positioned in their CSS (Bass & Mehta, 1995; Bass et al., 1993; Hertz et al., 1994; Merchant et al., 2001; Mullen & Courts, 2002; Nagase et al., 2002; Smith & Turner, 1990; Willett et al., 1986; 1989; Young et al., 1996). Eight of these studies included premature infants in their samples (Bass et al., 1993; Hertz et al., 1994; Merchant et al., 2001; Mullen & Courts, 2002; Smith & Turner, 1990; Willett et al., 1986; 1989; Young et al., 1996). All of the studies examining premature infants were descriptive. Four studies had 50 or less premature infants in their samples (Hertz et al., 1994; Merchant et al., 2001; Smith & Turner, 1990; Willett et al., 1986; 1989). Only two studies had sample sizes of 100 or more premature infants (Mullen & Courts, 2002; Young et al., 1996).

The samples for all eight studies included premature infants with gestational ages ranging from 26-37 weeks (Bass et al., 1993; Hertz et al., 1994; Merchant et al., 2001; Mullen & Courts, 2002; Smith & Turner, 1990; Willett et al., 1986; 1989; Young et al., 1996). Missing from the samples were infants born at less than 25 weeks gestation. Most of the studies included male and female premature infants (Merchant et al., 2001; Mullen & Courts, 2002; Willett et al., 1986; 1989; Young et al., 1996); while others did

not report the numbers of male and female subjects (Bass et al., 1993; Smith & Turner, 1990; Young et al., 1996).

The ICSC failure rate for premature infants in their CSS ranged between 4% (Mullen & Courts, 2002) and 60% (Willett et al., 1986) (see Table 3). Several factors may explain the lowest failure rate. First, that study was conducted in England, while the others were conducted in the US. Though AAP recommendations were followed for positioning infants in the CSS, there may be differences in CSS design between England and the US, as suggested by the car seat pictured in the journal article. Second, the make and model of monitoring instruments used by Mullen and Courts could not be determined from their report. Some models of cardiorespiratory and oximetry monitoring devices may not identify oxygen desaturation events as accurately as others. For instance, newer models of oximeters can distinguish between venous and arterial blood movement, resulting in more accurate oxygen saturation readings (Masimo Corporation, 2004; Nellcor Puritan Bennett Inc, 2004). Also, newer models of cardiorespiratory and oximeter monitors can filter artifact associated with movement, decreasing the chance of false positive or negative readings (Corometrics, 2004; Masimo Corporation, 2004; Nellcor Puritan Bennett Inc, 2004). Third, heart rate, respiratory rate, and blood oxygen saturation were recorded when the infants were first placed in the CSS, and every 15 minutes thereafter (Mullen & Courts, 2002). Therefore, it is possible that some oxygen desaturation events were missed during the remaining 14-minute intervals. Of the nine studies that examined this phenomenon in premature infants, eight obtained continuous readings of these variables (Bass et al., 1993; Dawson & Stainton, 2004; Hertz et al., 1994; Merchant et al., 2001; Smith & Turner, 1990; Willett et al., 1986; 1989; Young et

al., 1996). Fourth, the sample of infants tested by Mullen and Courts may not have been representative of the entire neonatal population. Sicker premature infants may have a lower survival rate in England than other countries such as the US (Tin, Wariyar, & Hey, 1997). This possibility would mean that the infants in Mullen and Courts' sample could have been generally healthier.

In contrast to the Mullen and Courts (2002) study, Hertz et al. (1994) and Willett et al. (1986) both found that a large percentage (54% and 60%, respectively) of premature infants experienced oxygen desaturation events when positioned in their CSS. Hertz et al. (1994) used blanket roles to position the infants per AAP recommendations, although the CSS were minimally reclined (75 to 85 degrees). This minimally reclined position may explain the increased frequency of oxygen desaturation events, since angle of CSS recline has been identified as a risk factor for oxygen desaturation events (Nagase et al., 2002; Smith & Turner, 1990; Willett et al., 1989). In fact, infants who are positioned more upright in a CSS are more likely to experience adverse effects (Smith & Turner, 1990; Willett et al., 1989; Young et al., 1996). Consequently, to minimize the occurrence of oxygen desaturation events, the AAP (1991) recommends a 45-degree angle of recline (semi-upright position).

Table 3

Studies of ICSC Failure Rates for Premature Infants in CSS

Authors/year	Country	Sample Size	Recording Duration	Angle of Recline	Failure Rate (%)
Bass et al., (1993)	US	87	90 min continuous	Semi-reclined seating position per AAP	18
Hertz et al. (1994)	US	28	290 min continuous (time in CSS not reported)	65-75° (105-115°)	54
Merchant et al. (2001)	US	50	90 min continuous	Not reported	12
Mullen & Courts (2002)	England	100	90 min intermittent	45°	4
Smith & Turner (1990)	US	14	30 min continuous	85° (95°) 110° (70°) 140° (40°)	21
Willett et al., (1986)	US	12 infants < 37 weeks w/ treatment for apnea[a] 8 infants < 37 weeks w/o apnea	30 min continuous	Semi-upright seating position per manufacturer's instructions	60
Willett et al., (1989)	US	31 infants < 32 weeks 22 infants 32-36 weeks	30 min continuous	Semi-upright seating position per manufacturer's instructions	26
Young et al., (1996)	Canada	141	90 min continuous	Semi-reclined seating position per AAP	24

[a]Infants treated with methylxanthine

Similarly, several factors may explain the increased frequency of oxygen desaturation in the Willett et al. study (1986). First, all the infants in group I (n = 12), were being treated for apnea of prematurity with methylxanthines, which are believed to

increase respiratory output by stimulating the respiratory center of the brain (Martin et al., 1986). Therefore, one could argue that infants being treated with methylxanthines have not sufficiently matured neurologically, were not ready to be placed in a CSS, and were not candidates for hospital discharge.

The second factor that may explain the increased frequency of oxygen desaturation events witnessed by Willett et al. (1986) is that the angle of CSS recline was not measured. According to Willett et al. (1986), a semi-upright seating position was used in accordance with the manufacturer's instructions. As a result, anything less than 90 degrees could have been considered semi-upright. Using an angle of recline closer to 90 degrees, rather than the AAP-recommended 45 degrees could have increased the frequency of ICSC failures.

In the remaining studies (see Table 3), failure rates for the ICSC ranged between 12% (Merchant et al., 2001) and 26% (Willett et al., 1986). Young, Shapira and Finer (1996) completed the largest and most rigorous study to date. In contrast to the other researchers, Young et al. (1996) maintained tight control over the study variables. Their sample included infants with birth weights between 380-3225 grams and gestational ages from 26-36 weeks. These premature infants were required to meet strict discharge readiness criteria, and AAP guidelines for positioning infants in the CSS were followed. Furthermore, the ICSC failure criteria were clearly articulated and not much different from those used in other studies. Additionally, the car seats used were limited to those that enabled proper restraint of smaller infants (Young et al., 1996).

Although they maintained tight methodological control, Young and colleagues (1996) detected a 24% ICSC failure rate. Infants who failed the ICSC had varied birth

weights and gestational ages. In addition, failure rates were associated with number of days on the ventilator and with lower baseline blood oxygen saturation in the CSS (Young et al., 1996). Moreover, these authors demonstrated that even following a strict procedure for positioning, oxygen desaturation events occurred in a large percentage of premature infants.

Risk Factors for Oxygen Desaturation Events

Several risk factors have been associated with oxygen desaturation events (Bass et al., 1993; Hertz et al., 1994; Merchant et al., 2001; Mullen & Courts, 2002; Nagase et al., 2002; Smith & Turner, 1990; Tonkin et al., 2003; Willett et al., 1986; 1989; Young et al., 1996). To date, these risk factors include male gender (Willett et al., 1989; Young et al., 1996), a history of respiratory problems (Willett et al., 1986; 1989; Young et al., 1996), the semi-upright seating position (necessitated by the traditional car seat) (Dawson & Stainton, 2004; Smith & Turner, 1990; Willett et al., 1989), genetic disorders affecting tone and breathing (Bass & Mehta, 1995), and the amount of time spent in the CSS (Merchant et al., 2001). Although sleep has been identified as a potential risk factor (Hertz et al., 1994; Nagase et al., 2002), it has not been adequately investigated, and other potential risk factors such as chronological age and head lag (a measure of head and upper torso control) have never been explored.

Chronological Age

Control of breathing and muscular strength are two important factors that signify maturation of the premature infant (Amiel-Tison, 1968; Eichenwald et al., 1997). Following birth, premature infants are not only more prone to periodic breathing (Holditch-Davis et al., 1994), but also respond to hypoxemia less consistently than older

children and adults (Goddard-Finegold, 1998). Adults respond to hypoxemia by increasing their ventilatory drive (Guyton & Hall, 1996a), while full-term infants show an initial increase in ventilation followed by a decrease (Goddard-Finegold, 1998). In contrast, the late gestation fetus (equivalent to the premature infant) becomes apneic in the face of hypoxemia (Goddard-Finegold, 1998).

In addition to respiratory instability, premature infants also lack physical strength and control (Alyward et al., 1984). Infant maturation is believed to occur in a sequential, well-defined, caudocephalad pattern from lower to upper extremities and from distal to proximal (Allen & Capute, 1990), yet some studies suggest that extrauterine exposure may accelerate maturation (Forslund & Bjerre, 1983; Majnemer et al., 1992).

Gestational age, which measures the infant's age beginning at conception, is most frequently used to assess the neurobehavioral status of infants (Alyward et al., 1984). However, gestational age is not always the best measure of infant maturation, because time outside the womb is also important to maturation. Using chronological age as a measure of maturation distinguishes infants of the same gestational age but with different birth dates. Premature infants demonstrate a wider range of responses to items on standardized neonatal neurological exams than their full-term peers (Mercuri et al., 2003). This difference in responses occurs because two infants of the same gestational age may have spent different amounts of time outside of the womb. Thus, comparison of two infants with same gestational age but different birth dates may show that the two infants exhibit very different levels of maturation. In fact, the chronologically older premature infant may tolerate the CSS better than a chronologically younger premature or full-term infant.

Currently, it is not known whether chronologically older infants may better tolerate being positioned in a CSS than chronologically less mature infants. Therefore research is needed to determine whether chronological age is a variable for identifying infants at risk for oxygen desaturation events in their CSS.

Head/Torso Control

In 1993, Bass et al. were the first to suggest that the physical exam characteristics of infants may be useful in determining their readiness to be placed in a CSS. Pediatricians were asked to recommend full-term infants for a study that would test their ability to maintain stable blood oxygen saturations when positioned in their CSS (Bass et al., 1993). Four of the 28 infants chosen for participation had chromosomal aberrations, resulting in low muscle tone and poor head control. All of the infants with these chromosomal aberrations failed to maintain stable oxygenation. Furthermore 46% of the selected full-term infants had either demonstrated oxygen desaturation events or had borderline ICSC results (Bass et al., 1993). These results demonstrate that skilled clinicians may have the ability to detect at-risk infants based on physical exam characteristics.

Research on infant development has shown that preterm infants demonstrate varying degrees of head lag when pulled to a sitting position (Allen & Capute, 1990; Iloeje, Obiekwe, & Kaine, 1991; Koumudi, Barve, & Chaudhari, 1997; Molteno, Magasiner, Sayed, & Karplus, 1990). Mature responses to head lag are not usually seen until a premature infant reaches term gestation (40 weeks) or beyond (Allen & Capute, 1990; Iloeje et al., 1991; Koumudi et al., 1997; Molteno et al., 1990). Some researchers have found that premature infants may have less well-developed head/upper torso control

than their full-term peers at hospital discharge due to lower scores on nuchal flexor and extensor muscle tone (Allen & Capute, 1990; Mercuri et al., 2003) However, others have shown that head/upper torso control in the sitting position may actually be better in some preterm infants than in their full-term counterparts (Forslund & Bjerre, 1983). Infants with more head/upper torso control may better tolerate being positioned in a CSS (Brazelton, 1984).

Infant head/upper torso control can be measured by the degree of head lag, a widely used marker of neurobehavioral status (Brazelton, 1984; Lester & Tronick, 2002; Prechtl & Beintema, 1965). To date, no investigations were found on the relationship between head/upper torso control and oxygen desaturation events of premature infants. Two devices designed to provide head support in CSS have been tested for their ability to prevent oxygen desaturation events (Dollberg et al., 2002; Tonkin et al., 2003) (see Appendix B), yet neither device was proven completely successful. The failure of these head support devices to prevent oxygen desaturation events may be due to their suboptimal design. The investigators failed to take into consideration that as infants relax, their bodies can shift downward, causing lung compression. In both studies, the support devices were designed to support the infant's head but not the torso.

Infants lacking sufficient head/ upper torso control may be at increased risk for airway occlusion and oxygen desaturation events when in the semi-upright seating position (Carlo et al., 1989; Tonkin, 1998; Tonkin et al., 2003). A measurement of head lag, such as the pull-to-sit maneuver, allows researchers to assess the strength of both the head control (nuchal musculature) and upper body strength (torso musculature) of an infant (Brazelton, 1984; Lester & Tronick, 2002; Prechtl & Beintema, 1965). Two

commonly used measures of head control and upper body strength are the pull-to-sit maneuver and the traction test (Brazelton, 1984; Lester & Tronick, 2002; Prechtl & Beintema, 1965). An increase in head lag indicates poor head/upper torso control, whereas decreased head lag indicates better head/upper torso control.

Most neonatal clinicians who are trained to perform newborn physical exams already possess the skill to evaluate head/upper torso control. Identification of a relationship between the measure of head/upper torso control in premature infants and oxygen desaturation events in CSSs could provide a valuable indicator of at-risk infants. In the future, measurement of the infant's head lag may be used with other risk factors and ICSC testing to assess whether an infant should travel in a CSS or car bed at hospital discharge.

Sleep

Callahan and Sisler (1997) found that infants considered too young to sit, spend approximately 0-16 hours a day (M 5.7 +/- 3.5 hours) in a seating device. New CSSs enable parents to transfer infants in the seating device from the car, stroller, plane, or house without disturbing the infant's sleep (Elite Car Seats, 2000-2004). This method of handling an infant represents a significant change in infant care, and the developmental effects of this change are not presently known (Callahan & Sisler, 1997).

The role of sleep in relationship to body position and breathing has been researched extensively (Holditch-Davis et al., 1994; Manning & Stothers, 1991; Mok et al., 1988; Orr et al., 1985). During sleep, the body relaxes and can slump over, resulting in poor positioning (Hertz et al., 1994; Nagase et al., 2002). Furthermore, laboratory studies have shown that poor positioning during sleep can lead to posterior mandibular

movement and airway occlusion (Tonkin, 1998). In addition, breathing pauses are prolonged when premature infants sleep, which can contribute to a hypoventilatory state (Holditch-Davis et al., 1994). Furthermore, the sleeping infant is less likely to respond to biofeedback mechanisms that enable him/her to correct poor alignment of the body and breathing problems (Hertz et al., 1994; Nagase et al., 2002). Despite this knowledge, few studies have examined the sleep/wake activity of infants in their CSS.

When in the semi-upright position of a CSS, infants have been noted to slouch forward (Smith & Turner, 1990). This already compromised position may become worse during sleep (Hertz et al., 1994; Nagase et al., 2002). To date, only two small studies have examined the effect of sleep on breathing when infants are positioned in CSSs. Hertz et al. (1994) concluded that sleep, rather than position, accounted for the increased incidence of abnormal breathing events when 28 premature infants were positioned in CSSs. This conclusion was based on finding that the infants experienced more periodic breathing and spent more time sleeping in the car seat as opposed to the crib (Hertz et al., 1994). In contrast, Nagase et al. (2002) found that infants slept more in their car seats, and that there was a greater incidence of oxygen desaturation episodes and lower mean blood oxygen saturation levels when 15 full-term infants were in the car seat versus the car bed or cot. Thus, the role of sleep in relation to oxygen desaturation events of premature infants positioned in their CSS remains unclear.

As mentioned above, seating devices are currently (and frequently) being used in the US as a replacement for holding the infant or as an alternative to the crib (Callahan & Sisler, 1997). As a result, the effect of sleep in relation to oxygen desaturation events in infants placed in CSSs or other seating devices is an important matter. Continued

investigation into this phenomenon is needed to provide neonatal healthcare providers the information they need to adequately educate parents about risk factors for oxygen desaturation events. Parents also need to know if using seating devices may have long-term implications for their infant in terms of behavioral, cognitive, and motor outcomes.

Summary

In 2003 Williams and Martin reported that 75% of institutions nationwide perform some method of predischarge testing to identify premature infants at-risk for CSS related oxygen desaturation events. This large percentage confirms that neonatal healthcare providers are concerned about the safety of premature infants during travel, yet an extensive literature review revealed no investigations on the stability of the one-point ICSC. One cannot be certain that a premature infant who passes a one-time ICSC will pass the test a second time.

The proposed study was designed to shed new light on the issues of car seat safety for the premature infant. If the ICSC is found to yield stable results upon repeat testing, then neonatal healthcare providers will be more confident about using the ICSC as a predischarge screening tool. In contrast, if the ICSC is not found to be stable, then neonatal healthcare providers could consider discontinuing or combining it with other measures. Moreover, this study provides a greater understanding about the frequency of oxygen desaturation events in relation to such factors as chronological age, head/upper torso control, and the length of time infants spend sleeping in their CSS.

CHAPTER III

PILOT STUDY

Introduction

Participation in this study required that parents agree to have their infants 1) tested in their car seats on two separate occasions, 2) tested using a pull-to-sit maneuver, and 3) medical record reviewed by the researcher. Because it was not known how parents would respond to these procedures, a pilot study was conducted. The purpose of the pilot study, conducted between December 5 and December 31, 2004, was to ensure that the research plan and procedures for the formal investigation could be operationalized. This chapter will identify which procedures were examined, the results of this preliminary investigation, and how they influenced the formal investigation.

Purpose

The purpose of the pilot study was to evaluate the exact procedures that were to be used in the formal investigation, including:

1. education of medical and nursing staffs
2. obtaining parental consent
3. conducting ICSCs and pull-to-sit maneuvers
4. data documentation
5. staff and parental notification of ICSC results and securing a car bed for travel

Sample

Three premature infants who met the inclusion/exclusion criteria (Table 4) were recruited by convenience sampling. These infant participants had similar ages, both gestational (32-33 weeks) and chronological (17-22 days), but their races/ethnicities and

medical diagnoses differed (Tables 5 and 6). Besides the diagnoses listed in Table 6, participants were assessed for and found not to have apnea of prematurity, hypoglycemia, hypotension, intraventricular hemorrhage grades I – IV, necrotizing enterocolitis, patent ductus arteriosus, persistent pulmonary hypertension of the newborn, pneumonia, pneumothorax, and retinopathy of prematurity.

Table 4

Pilot Study Inclusion/Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Premature infants born to English-speaking parents preparing for their initial discharge home from the NICU or newborn nursery • Medical clearance by healthcare team • No apnea, bradycardia, or oxygen desaturation event for at least 48 hours • Anticipated discharge date of less than one week	• Orthopedic support / brace • State custody • Treatment with methylxanthines • Discharge home on oxygen

Table 5

Demographics of Participants in Pilot Study ($N = 3$)

ID#	Gender	Race/Ethnicity	Gestational Age		Chronological Age (days)
			at Birth (weeks)	at Discharge (weeks)	
100	F	W	32 0/7	35	22
103	F	W	32 5/7	35 2/7	17
105	M	B	33 4/7	36 2/7	19

Table 6

Delivery Routes and Medical Histories of Pilot Study Participants

	Participant ID#:		
	100	103	105
Delivery Route			
C-Section		X	X
Vaginal Delivery	X		
Discharge Diagnosis			
Anemia	X	X	X
Artrial Septal Defect		X	
Hyperbilirubinemia	X	X	X
Respiratory Distress Syndrome	X		
Respiratory Distress			
Sepsis Confirmed			
Sepsis Presumed	X	X	X
Transient Tachypnea of the Newborn			X

Setting

The pilot study was conducted at an urban-based tertiary care medical center with a Level I Newborn Nursery and Level III Neonatal Intensive Care Unit. The setting was the same medical center used for the formal study. Before the pilot study was implemented, it was approved by the Institutional Review Board (IRB) at the medical center.

Staff Education

Before recruiting subjects, the researcher educated the medical and nursing staffs in the Level I Newborn Nursery and Level III Neonatal Intensive Care Unit. This education entailed informing the staff of their role in this study. All staff members were given a research protocol pamphlet (see Appendix C) and asked to help identify potential study participants.

Recruitment

As planned, staff members who had been educated about the study identified the potential participants and approached mothers to ask if they would be interested in hearing about the study. All six mothers that were approached by the staff agreed to hear about the study.

Consent Procedure

The 6 mothers met with the researcher, who explained the study and the procedure for consent. Three mothers agreed to have their infants participate, and 3 mothers declined. The mothers who declined participation cited several reasons:

1. The infant had "been through too much already."
2. "Ninety minutes in the car seat was too long" a time.
3. Father of baby refused participation after reading in the parent handout that some infants, though rare, experience life threatening events in the child car seat (CSS) and that these events may require resuscitation.

During the consenting process, each mother was given a parent handout describing the study (see Appendix D), a consent form (see Appendix E), and a Health Insurance Portability Accountability Act (HIPAA) form (see Appendix F) to review in private. Most mothers shared this information with their significant others. After the materials had been reviewed, the consent and HIPAA forms were signed by either the mother, father (if married), or sometimes both parents with the researcher present. The original consent and HIPAA forms were placed in the medical record. Two copies of each form were made; one copy was given to the parents, and the other was retained by the researcher. Once consent was obtained, the researcher informed the medical and

nursing staffs that the infant would be participating in the study. When the infant participants were approaching discharge, a member of the medical and nursing staffs notified the researcher.

ICSC and Pull-to-Sit Procedures

Participation in the study required that each participant undergo two ICSCs (24 hours +/- 12 hours between tests) (see Appendix G), observation of sleep/wake state (state observation; see Appendix H), and a single pull-to-sit maneuver (see Appendix I). The ICSC measures the infant's tolerance to being placed in the semi-upright seating position and the pull-to-sit maneuver measures head lag (a measure of head/upper torso control). Participants had to be in an appropriate sleep/wake state for the pull-to-sit maneuver to be considered accurate; therefore an assessment of sleep/wake state was also performed before obtaining that measure. Once a prospective discharge date was secured, the researcher notified the research assistant (RA) and the participant's parent(s) of the schedule for the ICSCs and pull-to-sit maneuver.

The parent(s) of the 3 participating infants were asked to bring in their CSSs for the ICSC tests. No difficulties were encountered in obtaining the infants' own CSS from their parents. All 3 infants were positioned according to the AAP recommendations. Each participant completed two ICSCs with a range of 12-22 hours from ICSC 1 to ICSC 2. In addition, an RA performed a single pull-to-sit maneuver preceded by a state observation for each premature infant participant. All of the ICSCs and pull-to-sit maneuvers were performed during the appropriate timeframe; though some difficulty was encountered in scheduling the pull-to-sit exams because 2 of the 3 infants were discharged home on the weekend, when the RA was not available.

Documentation

The researcher completed two ICSC Data Collection Forms (see Appendix J; the first form documented the baseline ICSC, and the second form recorded the repeat ICSC) and one Infant Demographics and General Data Collection Form (see Appendix K) for each infant. During data collection, the researcher realized that the demographic data collection form had no place to document the birth and discharge weights. In addition, a problem arose in printing out the recordings from the Hewlitt Packard Viridia 24CT cardiorespiratory monitor, leading to complete sets of printouts for only 2 of 3 infants. This problem developed because the cardiorespiratory monitor had been accidentally turned off before obtaining one of the monitor printouts. In contrast, recordings from the Masimo Radical Oximeter were obtained for all 3 infant participants without incident.

Furthermore, the RA completed a single pull-to-sit measure (see Appendix L) for each of the 3 participants. As outlined in the research plan, the researcher remained blinded to the pull-to-sit maneuver findings. The RA had no difficulty performing the pull-to-sit maneuvers. However, the researcher recognized that scheduling the pull-to-sit exams for infants being discharged on a weekend would pose difficulties since the RA was unavailable on weekends.

Notifying Parents and Staff of ICSC Results and Securing Car Bed for Travel

The parents of all 3 infant participants were notified about the ICSC results. Two infants passed both ICSCs and were discharged home in their CSSs. The parents of these infants were given a handout explaining the limitations of the ICSC and educating them about the use of child car seats (see Appendix M). The other infant participant failed both ICSCs and was recommended for discharge home in a car bed. The parents of this

infant were given a different handout explaining the limitations of the ICSC and the AAP recommendation that their infant travel in a car bed at discharge (see Appendix N). This handout also explained how to secure a car bed for travel if desired. At the parents' request, the researcher assisted them in obtaining a car bed.

In addition, the nursing and medical staffs caring for each study participant were notified of the ICSC results. One physician did not want to be informed of the ICSC results because he felt that knowledge of failed ICSC tests would delay the hospital discharge for those participants. Another problem that surfaced was the inability of the study monitor, a staff physician, to execute his role of overseeing recruitment procedures and reviewing failed ICSCs with the researcher. This inability was due to the physician being overextended and not available for consultation.

In contrast, no problems arose when dealing with the nursing staff. One nurse caring for the infant who had failed the ICSC reported that the infant experienced intermittent oxygen desaturation events for approximately 30 minutes following the ICSC test while positioned in a crib. This nurse reported that it was helpful to know the result of the ICSC and that some infants undergo a period of recovery following a failed ICSC. No problems were reported for the two infants who passed their ICSC.

Procedure Evaluation

No problems were encountered related to staff education, obtaining parental consent, or securing a car bed for travel. However, the pilot study did inform the researcher about five procedural problems related to conducting the ICSC, pull-to-sit maneuvers, study monitor supervision, documentation and the notification of staff and

parents about the ICSC results. These five problems and their resolutions are discussed below.

Problem 1: Cardiorespiratory Monitor Recordings

While conducting one of the ICSCs, the Hewlitt Packard Monitor was accidentally shut off; the on-off switch had been pushed instead of the alarm silence button when transitioning the infant from the car seat back to the crib. This error resulted in loss of study data, i.e., a recording of cardiorespiratory activity. Identifying this problem during the pilot study raised the researcher's awareness of the two switches, thus preventing another accidental shutdown from happening a second time.

Problem 2: Pull-to-Sit Maneuver

The RA responsible for performing all pull-to-sit examinations was available Monday thru Friday. Two participant discharges were scheduled over a weekend when the RA was not working. The RA's unavailability posed a challenge for ensuring that the pull-to-sit maneuvers would be completed in the specified timeframe (within 36 hours of the first ICSC). By scheduling the ICSCs to be completed at the beginning or end of a weekend, all 3 pilot study participants were able to have pull-to-sit maneuvers completed during the designated timeframe. Given this problem however other times were anticipated when the RA would be unavailable to complete the pull-to-sit maneuver within the designated timeframe; therefore an alternative plan was needed.

This problem was addressed by three options. The first option was to train two alternate research assistants. The second option was to accept missing data for the pull-to-sit exams. The third option was to extend the timeframe for obtaining the pull-to-sit measure. Extending the timeframe by 24-48 hours would have required consulting a

developmental expert to help the researcher determine whether infants would experience a significant change in head control in that timeframe.

After exploring these options with the research committee, the first option was chosen. This option was deemed the best because additional RAs would ensure that the pull-to-sit maneuver would be completed not only during weekends, but also during unexpected absences and vacations.

Two experienced registered nurses (RNs) volunteered to serve as additional RAs. One was a neonatal nurse practitioner with 29 years experience caring for infants; she worked every weekend. The other was a bachelor's-prepared RN with 35 years of experience in the neonatal field. Both of these individuals completed the necessary IRB procedures and training for the sleep/wake state observations and pull-to-sit maneuver sections of Neonatal Intensive Care Unit (NICU) Network Neurobehavioral Score (NNNS). The researcher provided each RA many opportunities to observe and practice these procedures. Once comfortable with the procedures, the RAs were observed performing the procedures, with the researcher present, until they achieved interrater reliabilities of at least 0.80 (see Appendix O).

Problem 3: Study Monitor Supervision

During the pilot study, the researcher and study monitor recognized that the monitor could not fulfill the requirements of this position. The monitor therefore withdrew from the position, which was filled by an alternate member of the medical staff. This physician completed all necessary IRB requirements to serve as the study monitor. To solidify this change, the researcher completed an IRB study protocol amendment

form. Subsequently, this amendment was approved by the IRB. All pilot study procedures and results were reviewed with the new study monitor.

Problem 4: Demographic and Medical History Data Documentation

The original Infant Demographics and General Data Collection Form did not include a place to record the participating infants' birth and discharge weights. Therefore, the researcher submitted an application to the IRB requesting permission to add birth and discharge weights to this form. Since the HIPAA consent form (see Appendix F) stated that the researcher would have access to the discharge summary, which included both the birth and discharge weights. The changes in the Data Collection Form were approved by the IRB.

Problem 5: Reporting Study Results to Staff and Parents

The institution where the study was conducted did not routinely perform ICSC testing of premature infants prior to discharge. During the pilot study, one physician became concerned that knowledge of infant study results would extend the hospital stay of infants who failed the ICSC, and requested that the study be blinded to medical and nursing staffs. Furthermore, this same physician requested that the results of ICSCs also be blinded to parents of infants participating in the study since it was not known whether the ICSC was a stable test. However, the researcher immediately recognized that withholding this information, particularly from parents, would be unethical.

To resolve this ethical issue, several discussions were held between the researcher, medical staff at the study site, and members of the dissertation committee. The conclusion of these discussions was that blinding the study results from medical and nursing staffs and from parents could jeopardize infant safety during and after the study.

ICSCs are standard practice in 75% of institutions nationwide. Although the stability of ICSCs has not been proven, ICSC testing does provide parents with some information about how their infant will tolerate being placed in a CSS during travel. If difficulties in breathing are detected during the ICSC, the AAP recommends that the infant be transported in a car bed rather than a car seat. Failure to inform parents of the ICSC results and to provide them the option to transport their infant in a car bed may place infants at risk for future breathing problems when in their CSS. For these reasons, it would have been unethical to withhold the findings of the ICSCs from parents.

In addition to safety concerns during future travel, other issues about blinding the study results were discussed. Infants have been reported to take approximately one-half hour to completely recover from an oxygen desaturation event (Willett et al., 1986). Therefore, infants who fail the ICSC must be closely observed for residual problems, making it important for the medical and nursing staffs to know the ICSC results. Also, parents of infants participating in the study wanted to discuss the study results with the medical and nursing staffs intimately involved in their infant's care. Such discussions would not have been possible if the staff were blinded to the ICSC results. Moreover, it would have been nearly impossible to blind the medical and nursing staffs to the ICSC results. When preparing for discharge, parents of infants who had failed the ICSC were to be given the option of transporting their infant in a car bed. Transporting an infant in a car bed at discharge would clearly convey the study results to staff, even if the study results had not been openly discussed.

Due to these ethical and safety concerns, and because blinding the study was nearly impossible, a decision was made to conduct the investigation as originally

planned. The parties involved in this decision included the researcher, dissertation committee members, the NICU medical director, and the Chair of Pediatrics.

Summary

After the pilot study was completed, the researcher presented a descriptive report of the findings to the dissertation committee. The report contained an overview of the pilot study and a description of the five problems encountered. Changes to the research plan as described in this chapter were made upon advisement of the dissertation committee. The pilot study report and revised research plan were then submitted to the medical center's IRB for review before proceeding with the formal investigation.

CHAPTER IV

METHODS

Introduction

Premature infants may be at risk for oxygen desaturation events when they are positioned in their CSS. Oxygen desaturation events may lead to hypoxemia and, if undetected, may be associated with adverse behavioral, cognitive and motor outcomes (Newburger et al., 1984; Perlman & Volpe, 1985). Parental observation of the infant's skin tone is insufficient to detect these events due to varying skin tones and hematocrits (Lees, 1970; Miller & Martin, 1998). Thus, the American Academy of Pediatrics (1991; 1996; 1999) recommends that all infants born at less than 37 weeks' gestation be observed in their CSS prior to hospital discharge. This observation period, called the Infant Car Seat Challenge (ICSC), is used to evaluate the need for travel in a car bed instead of a CSS, but the stability of this test has never been studied.

This chapter presents the methodology for investigating the stability of the ICSC and risk factors (i.e., sleeping in the CSS, chronological age, and head lag) that may be associated with oxygen desaturation events experienced by premature infants in their CSS. The study design; sample recruitment and characteristics; setting; procedures; and data collection, management and analysis are described in this chapter.

Study Design

This study's design was descriptive, non-experimental, and observational; there was no manipulation of the independent variable, i.e., the two ICSCs of premature infants (Polit & Hungler, 1995). A non-experimental, descriptive research design fits the specific aims of this study and was used to describe 1) the pass/fail rates of premature

infants following two observation points (ICSCs), 2) oxygen saturation and desaturation patterns, sleep/wake activity, and a measure of head lag for premature infants over the course of two ICSCs, and 3) the association between head lag, chronological age, time spent sleeping in the CSS and oxygen desaturation events experienced by premature infants during two ICSCs. This investigation was underpinned by four hypotheses:

Hypotheses

1. Premature infants who undergo two ICSCs will pass one test but not the other.
2. Premature infants with increased head lag will experience oxygen desaturation events in their CSS.
3. Premature infants of decreased chronological age will experience oxygen desaturation events in their CSS.
4. Premature infants who spend more time sleeping in their CSS will experience oxygen desaturation events.

Sample

A convenience sample of 73 premature infants was initially targeted for recruitment into this study. This sample size was calculated for the primary research question (stability of the infant car seat challenge) using a 95% confidence interval around an estimated 5% failure rate ranging between 0% (lower limit) and 10% (upper limit) when the number of infants tested is 73. However, the study was terminated early because during data collection, it was realized that most infants had stable ICSC test results. Upon consultation with the statistician, Dr. Carol Bigelow, it was determined that the primary research question could be adequately answered with data from 50 participants. While a total of 52 participants had completed all study procedures, a

miscommunication between the researcher and dissertation committee members regarding whether or not pilot study data (N=3) could be included in the final analysis resulted in a final sample size of 49 infants and a lower power for statistical analysis.

All 49 premature infants participating in the study underwent two ICSCs in their own CSS. All participants were studied in infant style CSSs with a 3-point (n = 5, 10%) or 5-point harness (n = 44, 90%) system, and were positioned at a 45-degree angle of recline. This angle was achieved either by using the car seat base when available (n = 30, 61%), or firm rolls when not available (n = 19, 38%). Head supports were used only if they were manufactured as part of the original car seat design (n = 24, 49%). Lateral blanket rolls (head to pelvis) were used along both sides of the premature infants (n = 49; 100%) to help maintain a midline position. Also, when needed, crotch rolls were used to prevent the infants from sliding downward (n = 30; 61%). The time between the two ICSCs ranged from 11 to 25 hours (M= 17.35, SD= 4.423).

The sample included infants from gestational ages between 24 and 36 weeks (Tables 7 and 8). At the time of ICSC testing (hospital discharge), the corrected gestational ages of the infants ranged between 34 and 40 weeks. Four infants were only one-day-old when they participated; none of the infants were less than 1 day old. Fourteen (29%) of the 49 premature infants were only 2 days old when they participated in the study, and the oldest infant was 95 days old (Table 9). More than half (61%; n = 30) of the infants were less than 8 days old, with the remaining infants (39%; n = 19) 8 days or older at the time of the ICSC.

Table 7

Chronological, Gestational and Corrected Gestational Ages of Participants

	Mean	Median	Mode	Range
Chronological Age (days)	13.8	4	2	1-95
Gestational Age (weeks)	33.82	35	36	24-36
Corrected Gestational Age (weeks)	35.82	36	36	34-40

Table 8

Participants' Gestational Age at Birth

Gestational Age at Birth (weeks)	Frequency	Percent	Valid Percent	Cumulative Percent
24	1	2	2	2
25	1	2	2	4.1
26	1	2	2	6.1
27	1	2	2	8.2
29	2	4.1	4.1	12.2
32	3	6.1	6.1	18.4
33	4	8.2	8.2	26.5
34	8	16.3	16.3	42.9
35	11	22.4	22.4	65.3
36	17	34.7	34.7	100.0
Total	49	100	100	

The participants had been assigned various diagnoses commonly found in the premature infant population (Table 10). The most prevalent diagnosis was hyperbilirubinemia (47%, n = 23). Many infants had been evaluated for sepsis (45%, n = 22), but only 12% (n = 6) were presumed to be infected and none had positive bacterial, viral or fungal cultures. At birth, 25% (n = 12) were diagnosed with respiratory distress syndrome, 12% (n = 6) had transient tachypnea of the newborn, and 12% (n = 6) had nonspecific respiratory distress. Furthermore, during their hospitalizations, 18% (n = 9) of the participants were diagnosed with apnea of prematurity, 10% (n = 5) developed

chronic lung disease, and 8% (n = 4) developed pneumothoraces. In addition, five sets of twins (20%) participated in the study, but no infants from other multiple birth variations. The participants' list of diagnoses is similar to that of past NICU patient populations at the study site. However, a detailed comparison of these two groups could not be made because the discharge diagnoses of previous patients were not available.

Table 9

Participants' Chronological Age at Discharge

Chronological Age at Discharge (days)	Frequency	Percent	Valid Percent	Cumulative Percent
1	4	8.2	8.2	8.2
2	14	28.6	28.6	36.7
3	4	8.2	8.2	44.9
4	3	6.1	6.1	51
5	1	2.0	2.0	53.1
6	2	4.1	4.1	57.1
7	2	4.1	4.1	61.2
8	3	6.1	6.1	67.3
9	1	2	2	69.4
12	1	2	2	71.4
14	1	2	2	73.5
15	1	2	2	75.5
18	2	4.1	4.1	79.6
21	1	2	2	81.6
22	2	4.1	4.1	85.7
25	1	2	2	87.8
46	2	4.1	4.1	91.8
62	1	2	2	93.9
66	1	2	2	95.9
74	1	2	2	98
95	1	2	2	100
Total	49	100.0	100.0	

Table 10

Participants' Diagnoses at Discharge

Diagnosis	Frequency	Percent
Hyperbilirubinemia	23	47
Sepsis Suspect	22	45
Anemia	14	29
Respiratory Distress Syndrome	12	25
Twin Gestation	10	20
Apnea	8	18
Hypotension	8	16
Transient Tachypnea of the Newborn	6	12
Presumed Sepsis	6	12
Respiratory Distress	6	12
Hypoglycemia	5	10
Chronic Lung Disease	5	10
Pneumothorax	4	8
Intrauterine Growth Retardation	4	8
Retinopathy of Prematurity	4	8
Other	≤ 2	≤ 4

Table 11

Study Site NICU Patient Admission Diagnoses

Diagnosis	Percent
Respiratory Distress Syndrome	56
Sepsis Suspect	49
Transient Tachypnea of the Newborn	12
Hypoglycemia	9
Intrauterine Growth Retardation	7
Feeding	5
Anemia	4
Apnea	3
Hypotension	2
Other	< 2

Note: Data are from 2003 admissions

Based on past NICU and newborn infant patient demographics at the study site, premature infants participating in the proposed study were expected to have various chronological ages (range= 23 3/7- 36 6/7 weeks), male and female genders, different

races/ethnicities and medical diagnoses (see Table 11). Participants were also anticipated to be born to families from diverse educational and financial backgrounds.

The study sample was representative of the newborn nursery and NICU patient populations at the study site in 2003 (see Table 12). Of the 49 participating premature infants, 23 (47%) were male and 26 (53%) were female. The infants' birth weights ranged between 740-3565 grams (M= 2226.59; SD= 667.59), and their weight at discharge ranged from 1705-3580 grams (M= 2413.33; SD= 392.83). More white infants (78%) participated in this study than other races. In addition, two-thirds of the infants (67%) were born by Caesarean section; the rest were delivered vaginally (32%).

Table 12

Demographics of Participants vs. Other Infants Born at Study Site

	Gender (%)		Race/Ethnicity (%)				
	Male	Female	Asian	Black	Hispanic	White	Other
Study Participants (n)	47 (23)	53 (26)	2 (1)	4 (2)	6 (3)	78 (38)	10 (5)
All Premature Infants at Study Site (NICU, 2003)	57	43	4	7	9	59	21
All Newborns at Study Site (2003)	50	50	9	5	6	70	10

Inclusion Criteria

All premature infants were born to English-speaking parents preparing for their initial discharge from the NICU or newborn nursery, and received medical clearance by their healthcare team to participate. The infants had been free of apnea, bradycardia, and

oxygen desaturation for at least 48 hours. This criterion was determined by reviewing the last 48 hours of the nursing flow sheet located in the infant's medical record.

Exclusion Criteria

Infants were excluded from this investigation if they met any of the following criteria. First, infants that were to be discharged home with an orthopedic support or brace and thus did not fit well into the traditional upright CSS were not enrolled (n = 0). The reason for this criterion was that infants with orthopedic supports or braces are routinely recommended to travel in a specially designed car seat or car bed. Second, infants who were in the custody of the state were excluded since parental consent could not be obtained (n = 1). Third, infants requiring oxygen or methylxanthine treatment (for apnea of prematurity) at the time of discharge were not enrolled (n = 0). Treatment with these substances could have masked breathing problems. Also, apnea, bradycardia and oxygen desaturation experienced by this high-risk group may or may not be associated with being positioned in a CSS. Fourth, full-term infants were not included in this study sample because they were not recommended for routine predischarge ICSC testing by the AAP (1999) at the time of this study. Fifth, infants that were not monitored and who failed the 30-minute oxygen saturation pre-screen test were not enrolled (n = 0). Sixth, infants born to non-English-speaking parents were not enrolled (n = 0). This criterion was established due to a lack of funds for translating reading materials into other languages. Lastly, one infant was diagnosed with a pneumothorax when she was attached to the cardiorespiratory and oxygen saturation monitors; she was immediately referred to the NICU medical team for treatment and entered the study following recovery.

Attrition

As anticipated, attrition was low during the course of the investigation. Only 2 infants were withdrawn from the study after their parents had signed consents to participate. The first infant was withdrawn before any study procedures commenced. The mother of this infant stated that 90 minutes was too long for her infant to spend in the car seat. The second infant was withdrawn after failing the first ICSC because the parents cited concern for their infant's safety and did not want their infant to undergo a second ICSC. This infant was discharged home in a car bed.

Recruitment

Following the pilot study, recruitment into the formal investigation continued without interruption. Recruitment occurred any time after birth and before hospital discharge as long as the infant's condition was not considered life-threatening. For infants who were hospitalized for a prolonged period, no study procedures (i.e., identifying potential subjects by the staff, obtaining permission from the medical team, and obtaining informed consent) were begun until it was determined that the infant was to be discharged home from the study site. This determination was needed because some infants were transferred to institutions closer to home before discharge, which excluded them from the study. In contrast, for infants who were expected to be discharged within 2-4 days of birth, procedures to identify potential participants, to obtain permission from the medical team and to obtain informed consent were completed as soon as possible after birth to leave time to complete their participation in the study.

As planned, the nursing and medical staffs identified potential study participants and notified the researcher. Once the researcher verified that a potential infant participant

met the study criteria and was nearing discharge, the staff nurse or physician asked the mother or both parents if they were interested in hearing about the study. Only two mothers refused to hear about the study. One of those mothers reported having prior experience with car seat testing of twin premature infants and was not interested, but did not elaborate further. The other mother gave no reason for declining. Another five parents (either the mother or both parents) declined to participate after the researcher had explained the study. The reasons for declining to participate were as follows:

1. Two sets of parents said that it was not possible to have their infant car seat available prior to discharge.
2. One mother said that she liked the car seat that she had already purchased.
3. One set of parents never declared their desire to sign consent once they had the opportunity to review it.
4. One mother stated she was having difficulty breast feeding and that the testing procedures would cause further disruption.

Parent(s) of the premature infant participants signed consent and HIPAA authorization forms before any study procedures were begun. Premature infants who met the inclusion criteria and whose parents consented to their participation were enrolled in the study. No infants were excluded from participation based on their gender or race/ethnicity. As noted under exclusion criteria, full-term infants were excluded from this study. At the time data collection was to begin, all 49 premature infant participants had been preparing for hospital discharge, and therefore were in good health.

Informed Consent

The researcher informed parent(s) of infant participants about the purpose of the study and what was expected of them and their infant during the data collection procedure. This information was included in a pamphlet (see Appendix D), which was given to parents along with informed consent (see Appendix E) and HIPAA forms (see next section) to review in private. Each consent form displayed the infant's name, the purpose of the study, risk and benefit information, as well as the procedure for withdrawing from the study. The parent(s) were given the opportunity to ask questions, which were answered by the nurse researcher.

HIPAA Authorization Form

After signing the informed consent, parents of infants meeting eligibility criteria were also asked to sign the HIPAA form (see Appendix F), which authorized the use and disclosure of health information for research purposes. The disclosure data required for this investigation included obtaining medical history and physical health information, and the discharge summary or newborn's medical record if no discharge summary was available. This study did not require the disclosure of highly confidential information. The authorization remained in effect until the researcher reviewed the discharge summary or birth record.

Ethical Considerations

Parents of study participants were informed that participation in this study involved some risks to the infant (see Appendices D and E). The researcher explained that some infants would experience minimal discomfort when the cardiorespiratory and oxygen saturation monitoring leads were removed because they were sticky. This

discomfort was explained as being equivalent to the discomfort felt when a Band-Aid is removed. The researcher also explained that the leads might leave a red mark on the skin, and that this redness usually subsided within a couple of hours.

Also, it was explained to parents that the greatest risk was the rare possibility that an acute life-threatening event (respiratory arrest) would occur when their infant was positioned in a car seat. Therefore, the controlled setting of the NICU had been chosen as the desired site for performing this study. In the NICU, medical staff was immediately available to respond to any life-threatening events. Life-threatening events requiring medical team intervention during data collection procedures were to be reported to the IRB/Human Subjects Committees at the medical center.

One life-threatening event to an infant participant was identified while the monitoring instruments were being set up. The researcher and NICU medical staff diagnosed this infant with a pneumothorax. The researcher and study monitor determined that the pneumothorax was a preexisting condition that had gone unrecognized by the medical personnel caring for the infant. The study monitor and IRB staff determined that this event was not related to the study, but recommended that the event be reviewed by the morbidity and mortality committee within the institution. This committee confirmed the IRB staff and study monitor's determination.

In contrast to these risks, the benefit of participating in this study was that parents gained some understanding of how their infant would do when positioned in his/her car seat at discharge. Parents were informed that identification of problems might prevent their infant from experiencing potentially harmful oxygen desaturation events during travel. No financial incentives were offered to the premature infants or their families for

participating in this study. The risk-benefit ratio assessed for this study was minimal risk and an important benefit.

Data were gathered from the two ICSCs, from the pull-to-sit maneuver, and from observations of sleep/wake activity. Medical records were also reviewed by the researcher for data on infants' date of birth, gender, race/ethnicity, type of delivery, birth/discharge weights, and discharge diagnosis list. The data from testing and the medical record were used only for research purposes. Infant names did not appear on any forms. Instead, all infant participants were identified by identification (ID) numbers to protect their identity.

Permission to conduct this study was obtained from the nurse researcher's dissertation committee, the University of Massachusetts Worcester, and the study site's IRB. In addition, verbal approval of the study was obtained from each participant's attending/covering physician in the NICU or Newborn Nursery.

Setting

This study was conducted between 12/31/04 and 06/02/05 at a large, urban, tertiary healthcare institution that delivered approximately 1500 infants each year. The institution housed a level I Newborn Nursery and a level III NICU, which collectively cared for approximately 300 in-born premature infants and approximately 38 out-born premature infants in 2003. The large number of premature infants served by this institution enabled easy access to potential study participants.

Accessible Population

Of the 112 premature infants born at the study site from 12/1/2004 through 6/2/2005, 3 died and 37 were transferred before discharge to an alternative hospital that

was closer to their home. The remaining 72 premature infants were discharged directly to home. Of these remaining 72 infants, only 1 infant was excluded from the study. Therefore, 71 of the 118 premature infants delivered were eligible for participation.

Data Collection

The nurse researcher and 3 research assistants (RAs) collected the data. The nurse researcher is a certified neonatal nurse practitioner with 20 years of nursing experience and 14 years of experience in caring for premature infants. She was responsible for overseeing the entire research project and for ensuring that it was carried out as outlined in this proposal. Her responsibilities included 1) obtaining IRB approval, 2) managing the financial aspects of the project, 3) recruiting subjects, 4) obtaining signed informed consent and HIPAA authorization from parents(s), 5) performing ICSCs and collecting data, 6) maintaining validity and reliability of procedures, and 7) managing and analyzing data. The 3 RAs were responsible for measuring head lag of all participants using the pull-to-sit maneuver. The RAs chosen for this investigation were a master's-prepared RN and maternal child health educator with 34 years of experience in caring for perinatal patients, an RN, and a neonatal nurse practitioner. The last two RAs each had 30 years of experience caring for neonatal patients. Their experience and availability (7 days a week coverage) made these nurses excellent candidates to serve as RAs.

In addition to the nurse researcher and RAs, medical and nursing staffs were responsible for identifying potential study participants, evaluating each premature infant's readiness for discharge, and asking parents if they would be interested in learning about this study. One attending physician served as the study monitor. The role of this

physician was to review recruitment procedures and any failed ICSCs with the nurse researcher.

Personnel Training

Educating Staff

The researcher provided introductory informational in-service training to the data collection site's ancillary personnel, nursing and medical staffs to acquaint them with all aspects of the study. This information included the purpose of the study, the roles of key personnel, and study procedures. The staffs were given the opportunity to ask questions and have them answered. Contact information and written procedures outlining the study were made available in a research protocol pamphlet (see Appendix C) to each staff member in the NICU and Newborn Nursery.

Educating Research Assistants

The researcher taught the RAs how to perform the state assessment, pull-to-sit maneuver and how to score these measures of several infants before starting the investigation. Examination and scoring of infants continued until the researcher was satisfied that the RAs were performing the assessment and technique correctly, that they had gained a comfort level with the procedure, that they had an opportunity to have questions about scoring answered and until their scoring reached an interrater reliability of 0.80 (see Appendix O).

Study Variables

Data were collected for the following study variables: 1) testing each premature infant in his/her car seat on two separate occasions (ICSC), 2) state observations of sleep/wake activity, 3) the pull-to-sit maneuver, and 4) medical record review.

Infant Demographics and General Data

Data on the infants' demographics, gestational age, angle of CSS recline, and medical history were collected by the nurse researcher and recorded on the Infant Demographics and General Data Collection Form (see Appendix K).

1) Demographic data included the infant's birth date, birth history, birth weight, discharge weight, chronological age, gender, and race.
2) Gestational age was based on the clinical team's best estimate of completed weeks of gestation.
3) Angle of CSS recline was measured by the researcher during ICSC testing. A Hempe Protractor model #2791 and level were used for this measurement. The CSS make and model were also recorded.
4) Medical history included a list of each infant's medical diagnoses since birth and was collected from the discharge summary or newborn medical record.

Oxygen Saturation/Desaturation

Blood oxygen saturation/desaturation, a continuous variable, is not clinically relevant $\geq$ 93%, but levels below 93% can increase morbidity and mortality. When oxygen saturation levels are kept at $\geq$ 93%, rates of sudden infant death are reduced, weight gain and development is better, pulmonary artery pressure and airway resistance is reduced 50%, and hypoxemic events are reduced (Poets, 1998). As detailed below (see Scoring the ICSC), an oxygen desaturation event was defined as one or more of four conditions that produce oxygen desaturation.

Infant Car Seat Challenge (ICSC). Oxygen desaturation events were measured by the ICSC, a 90-minute predischarge test of the premature infant's tolerance to being

placed in his/her CSS. Infants who experienced at least one oxygen desaturation event in their CSS (see scoring below) failed the ICSC. Pass/Fail outcomes of the two ICSCs were used by the researcher to determine overall ICSC outcomes (see Table 13) and thus an infant's ability to tolerate the CSS. Since no standardized method existed for conducting an ICSC, one was developed specifically for this investigation (see Appendix G). Validation of the ICSC is described below (see ICSC reliability and validity).

Table 13

Possible Scenarios Leading to ICSC Outcomes

ICSC Test #1	ICSC Test #2	Outcome
Pass	Pass	Pass
Fail	Fail	Fail
Pass	Fail	Fail
Fail	Pass	Fail

Infants who had not been monitored in the nursery were monitored in their crib for 30 minutes before each ICSC. This observation ensured that the infants' baseline oxygenation was stable ($\geq$ 93%). If the infant's baseline oxygenation was not stable in the crib or if significant apnea, bradycardia or oxygen desaturation was detected, the infant was excluded from the study and was referred to the medical team for evaluation. No infants were excluded from the study for a baseline oxygen saturation of less than 93%. Infants with stable oxygen saturation in their crib participated in two ICSCs (see Appendix G).

After the 30-minute prescreening test (if applicable), the researcher attached leads and cables to the infant from the cardiorespiratory and oxygen saturation monitoring devices. These measuring instruments, which indirectly measure heart rate, respiratory rate and oxygen saturation, had been chosen because they caused minimal discomfort to

the infant. Cardiorespiratory and oxygen saturation readings were obtained continuously and recorded throughout the ICSC.

The researcher positioned infants in their own CSS at a 45° angle (AAP, 1999). Using the infants' own CSS for this investigation posed both benefits and limitations. One benefit was that parent(s) were given information about how their infant tolerated being in his/her own CSS. Another benefit was that in the "real world" infants are almost always tested in the CSS in which they will travel at discharge (Children's Hospital Boston, 2004). Limitations to using the infants' own CSS were anticipated. One concern that using the infants' own CSS might affect the ICSC test results. Another concern was that it would be difficult to set different seats at a 45° degree angle of recline. In fact the latter limitation was not encountered.

Scoring the ICSC. Because oxygen saturation/desaturation of 93% or above is not clinically meaningful, this variable was scored categorically. Data collected for each 90-minute ICSC were recorded by the nurse researcher on a separate copy of the ICSC Data Collection form (see Appendix J). This form was also used to record total sleep time (sleep/wake activity) during the ICSC.

In this study, an oxygen desaturation event was defined as one or all of the following: 1) apnea for > 20 seconds, 2) more than two consecutive episodes of periodic breathing (lasting 3 to 20 seconds and interrupted by tachypnea [respiratory rate >70]), which are associated with oxygen desaturation of < 93%, 3) bradycardia (heart rate of < 80 beats per minute) without spontaneous recovery, and 4) oxygen saturation of < 93 % without spontaneous recovery. Spontaneous recovery was defined as a consistent rise in heart rate or oxygen saturation within 10 seconds without intervention. A spontaneous

recovery time of 10 seconds was chosen because brief (≤ 4 seconds) decreases in oxygen saturation may be normal for older premature infants and not clinically significant unless repeated (Poets et al., 1991). For premature infants with a persistently low resting heart rate (<100 beats per minute), a fall in heart rate greater than 20% without spontaneous recovery was considered a bradycardic episode. For this study, conservative parameters for apnea, bradycardia and desaturation were based on prior investigations (Bass & Mehta, 1995; Bass et al., 1993; Merchant et al., 2001) and chosen to ensure participant safety until more information is known about safe oxygen levels for infants.

In addition, a plan was in place to watch for premature infants with a persistently elevated respiratory rate (greater than 20% from baseline), short frequent oxygen desaturations, or a labored breathing pattern during the ICSC, but who did not meet criteria for a failed test. Such infants were to be discussed with the medical team to develop recommendations for parents. However, no participant met these criteria. All infants experiencing breathing difficulty met criteria for a failed ICSC.

Any infant who experienced an oxygen desaturation event failed the ICSC, was removed immediately from the CSS, returned to the crib, and monitored until his or her cardiorespiratory status stabilized. Infants who did not experience an oxygen desaturation event during either of the two ICSCs passed the ICSC (Table 13). Thus, a passed ICSC indicated that an infant tolerated the CSS. The parent(s) of infants who passed both ICSCs were given a letter explaining the testing limitations and procedures to keep their infant safe during travel (see Appendix M). Infants who failed either ICSC were recommended for travel in a car bed, and their parent(s) were given a letter discussing the pro and cons about car beds and information about how to obtain a car bed

if desired (see Appendix N). These letters were given to parent(s) by the researcher immediately following the second ICSC.

ICSC reliability and validity. Several steps were taken to ensure the reliability of the monitoring equipment used for the ICSCs. First, before each ICSC, the researcher checked that the biannual electrical safety and performance testing met the manufacturer's guidelines and had been completed by the hospital's clinical engineering department. Confirmation of biannual testing was verified by a label located on each piece of medical equipment. The existence of this label was documented on the ICSC data collection form. Second, a Masimo Radical oximeter with Signal Extraction Technology (SET) was selected for use in this study. The Masimo SET pulse oximeter substantially eliminated problems with motion artifact and low peripheral perfusion (Masimo Corporation, 2004). This oximeter had been clinically validated with 99% SpO_2 sensitivity and 97% SpO_2 specificity (Masimo Corporation, 2004). Third, heart rate was measured by two methods, cardiorespiratory and oxygen saturation monitors, which were compared to detect false readings. This comparison decreased the likelihood of inaccurate readings. Fourth, cardiorespiratory and oxygen saturation recordings strengthened the reliability of this study by enabling the researcher to review questionable events.

Finally, the ICSC procedure used in this study had been validated by four neonatal clinical experts in car seat testing of premature infants. After reviewing the ICSC procedure, all of these experts confirmed that it was similar to the procedure used in their hospitals (J. Bass, personal communication, August 25, 2004; K. Gustafson,

personal communication, September 10, 2004; K. Nash, personal communication, September 20, 2004; S. Young, personal communication, September 17, 2004).

Sleep/Wake Activity and Head Lag

Clinical observations of sleep/wake activity and head lag (as measured by the pull-to-sit maneuver) were scored using the appropriate subscales of the NICU Network Neurobehavioral Scale (NNNS). The NNNS was designed to comprehensively examine full-term, preterm and at-risk infants exposed *in utero* to substances taken by the mother (Lester & Tronick, 2002). These subscales were chosen because they provided more options for scoring sleep/wake activity and head lag than subscales from the more widely-known Neonatal Behavioral Assessment Scale (Brazelton, 1984). The NNNS subscales enabled the researcher and RAs to distinguish subtle differences in infant responses.

Scoring sleep/wake activity. Each infant's baseline sleep/wake activity was measured by the RAs before the pull-to-sit maneuver, and total sleeping time was determined by the researcher during the two ICSCs. Sleep/wake activity was scored using the six state observations (1-6) of Lester and Tronick (2002), where 1 indicates deep sleep, 2-5 indicate increasing alertness, and 6 indicates inconsolable crying (see Appendix H).

The time each infant spent sleeping in the car seat was recorded by the researcher. However, time itself was not a reliable indicator of risk for oxygen desaturation events because time spent in the CSS could vary among the participants. For instance, all infants who passed the ICSC would spend 90 minutes in their CSS, while those who failed the ICSC were removed from their CSS as soon as they met the criteria for failure.

Thus, infants who were tested for longer times could spend more time sleeping merely because they were in their CSSs for longer times. Therefore, to assess whether sleep was a risk factor for oxygen desaturation events, the time (in minutes) spent sleeping in the CSS was normalized by expressing it as a percentage of total time spent in the CSS. This normalized time spent sleeping in the CSS was calculated by adding the time spent sleeping, dividing by the time spent in the CSS, and multiplying by 100. Thus, normalized scores for the time infants spent sleeping in their CSSs ranged from 0-100%.

Scoring the pull-to-sit maneuver. The pull-to-sit maneuver was easily scored from 1-11 (ordinal scale) based on the quality of infant movement observed (Lester & Tronick, 2002). Lower scores (1-4) indicate less mature responses (head can be lifted to but not maintained in an upright position), median scores (5-7) indicate increasingly mature responses (able to hold head upright briefly) and higher scores (8-9) indicate more mature responses (able to maintain head in upright position). Scores of 10-11 suggest abnormal or hypertonic responses.

Sleep/wake activity and pull-to-sit reliability and validity. While the test-retest reliability of the NNNS is available, test-retest reliabilities for the sleep/wake activity and pull-to-sit subscales have not been determined (Lester & Tronick, 2001). In the present study, reliability of the NNNS subscales was assured by having the researcher, a certified NNNS trainer, educate the RAs to perform and score the sleep/wake activity and pull-to-sit assessments. After the 3 RAs had learned to perform the assessments, the researcher along with each of the RAs examined several infants until RAs and the researcher assigned the same sleep/wake activities and pull-to-sit scores 8/10 times (.80). To

enhance the reliability of the pull-to-sit measure, the RAs also worked together on four separate occasions during the study to ensure that they scored infants in the same manner.

Scheduling Data Collection Procedures

Data were collected from each infant over 2-3 days by four procedures: 1) testing in his/her car seat on two separate occasions (ICSC), 2) state observations of sleep/wake activity, 3) the pull-to-sit maneuver, and 4) medical record review. Of these procedures, the first 3 required careful scheduling.

Infant Car Seat Challenge

Once recruitment was completed, the researcher scheduled each infant for two ICSCs to be done within 1 week of hospital discharge. Scheduling ICSCs required considering infant feeding times and other infant-related procedures. The ICSCs were scheduled 24 $\pm$ 12 hours apart. Willett et al. (1986) reported that the recovery period for infants after being placed in a CSS was >30 minutes. Allowing 12-36 hours between ICSCs provided an extended washout period, while helping to ensure that infant maturation between the ICSCs did not affect the study results. In addition, the selected timeframe (12-36 hours) had been approved by a pediatric pulmonologist and accomplished car seat safety researcher (T.B. Kinane, personal communication, June 6, 2004). Once an ICSC was scheduled, the researcher alerted the RAs about the need to perform the pull-to-sit maneuver during the appropriate timeframe. Based on these scheduling parameters, the researcher estimated that at least five months were needed to complete data collection for all 49 infant participants (see Appendix P).

For infants failing one or both ICSCs, the time spent in the CSS varied (see Table 14, Appendix Q). Eleven of the ICSCs were failed at less than 30 minutes into the ICSC,

5 were failed between 30-60 minutes, and 1 was failed between 60-90 minutes. One participant demonstrated extreme intolerance to the CSS; he spent less than 4 minutes in his CSS for both ICSCs.

Table 14

Time to ICSC Failure

Time to Failure (min)	Mean	Median	SD	Range
ICSC #1	28.13	17.5	27.72	3-75
ICSC #2	21.11	13	18.66	0-54

State Observations (Sleep/Wake Activity)

Since the pull-to-sit maneuver is ideally completed when the infants are in an alert (4 or 5) state (Lester & Tronick, 2002), the RAs assessed the infant's sleep/wake activity (see Appendix H) before performing the pull-to-sit maneuver. During the 36-hour time frame when the ICSCs were to be done, the RAs asked the bedside nurses caring for the infant to contact them when the infant was alert. If the infant was not in state 4 or 5, the pull-to-sit maneuver was postponed. However, because infants exhibit frequent changes in state, it was sometimes necessary to perform the exam in a suboptimal state.

Pull-to-Sit Maneuver

The RAs used the pull-to-sit maneuver (see Appendix I) to measure the head lag of infant participants (Lester & Tronick, 2002), but this maneuver also assessed their upper torso strength. The pull-to-sit maneuver was done by placing one's thumbs in both of the infant's palms while holding onto the infant's wrists as he/she was lying supine in the crib. The examiner then pulled to extend the infant's arms, initiating the infant's

automatic grasp of the examiner's thumbs, and pulled the infant to a sitting position (Lester & Tronick, 2002). Infants with an optimal response (score of 8-9) showed increased tone and muscular resistance as they were pulled to the sitting position. These infants would attempt to right the head so that it was midline with the trunk. For infants who were not fully developed, the head would lag behind the body and head righting was not always possible (scores < 7). Once in the sitting position, the infant was further observed for the ability to bring the head up to midline (Lester & Tronick, 2002).

Data Management

Participant Identification

To ensure participant anonymity, names did not appear on any data collection forms; only participant identification numbers were recorded. During the study, the nurse researcher maintained a log book with the participants' names and corresponding identification numbers. After the study was completed, the log book was destroyed.

Organizing Data

Separate folders were maintained for each participant to hold all his/her data collection forms (Pull-To-Sit Measure, Infant Demographics and General Data Collection Form, and two ICSC Data Collection Forms). Also, the original signed consent form was placed in the infant's medical record, a copy was placed in the individual study folder, and a second copy was given to the infant's parent(s). Participant identification numbers were documented on each folder and on the data collection forms. A label on the front of each folder had boxes that were checked when the consent had been secured, the two ICSCs were completed, and the pull-to-sit maneuver had been done.

The data from the pull-to-sit maneuvers were not made known to the researcher, who was performing the ICSCs. This blinding to outcomes was assured by having the RA place the completed Pull-To-Sit Measure in a sealed envelope before returning it to the infant's folder. The RA signed her name across the envelope seal to thwart any tampering with the results.

Storing Data

When not in use, the log book and folders were kept in a locked file cabinet that was only accessible to the researcher in her private office at the study site. Once the data collection procedures had been completed, the researcher moved the log books and data collection folders to a locked file in her home.

Codebook

A codebook was developed by the researcher to code demographic information and data obtained during the ICSC (see Appendix R). The researcher entered all data into the Statistical Package for the Social Sciences (SPSS), version 11, except the data from the pull-to-sit maneuver. These data in their sealed envelopes were given to a graduate student who checked that the envelopes had not been tampered with and entered the data into the SPSS program. The RAs' intact signature indicated that the results had been protected, and that the researcher remained blinded to the results. No results were discarded due to absence of a signature. The accuracy of data entry for every fifth participant was checked by a second graduate student. Several errors in data entry detected by this graduate student prompted a review of data entries for all 49 subjects. Inaccurate entries were corrected prior to data analysis.

Missing Data

Data collection continued until complete data sets were obtained for 49 participants.

Comorbidity and Respiratory Illness Variables

To assess differences between study groups, the participants' medical histories first needed to be quantified. Available methods for scoring illness severity such as the Score for Neonatal Acute Physiology (SNAP) (Richardson, Corcoran, Escobar, & Lee, 2001) or the National Therapeutic Intervention Scoring System (NTISS) (Gray, Richardson, McCormick, Workman-Daniels, & Goldman, 1992) did not meet the needs of this study. These illness severity scores are traditionally used to predict long-term complications or well-being and are not used retrospectively. Therefore, the researcher developed two scoring systems to describe the medical histories of the study sample: a comorbidity score and a respiratory illness score. The researcher recognized that these unweighted scores would only roughly estimate the level of illness for each study participant. The comorbidity score was calculated by adding the number of diagnoses assigned to each participant at hospital discharge. The respiratory illness score was calculated by adding the number of respiratory illnesses experienced by each participant. Each score was used as a categorical measure in data analysis.

Skewness/Recoding

Prior to analysis, data measured on a continuous scale was examined for normal distribution using Fisher's Measure of Skewness (Duffy & Jacobsen, 2001). Variables with a skewness coefficient value of +/-1.96 were considered to be skewed; while normally distributed data had a skewness coefficient value close to zero. Several

variables were found to be skewed: gestational age, corrected gestational age, chronological age, mean oxygen saturation (1), percent sleep time (1&2), comorbidity score and the respiratory illness score (as previously discussed) (see Table 15). All of these data were recoded categorically except for mean oxygen saturation (1), which was used for descriptive purposes only.

Table 15

Evaluating Variables for Skewness

Label	Fisher's Skewness	Significant Y/N	Kurtosis	Significant Y/N
*Gestational age	-5.74	Y	4.89	Y
*CGA	3.34	Y	4.78	Y
*Chronological age	6.99	Y	7.95	Y
Mean O2 1	6.23	Y	8.55	Y
Mean O2 2	-1.83	N	-0.93	N
*Percent Sleep Time test 1	-2.36	Y	-1.04	N
*Percent Sleep Time test 2	2.90	Y	-0.92	N
Time Between Tests	0.54	N	-2.0	N
Birth Weight	-1.59	N	-0.27	N
Discharge Weight	2.05	N	0.92	N
*Number Comorbidities	2.93	Y	0.57	N
*Number Respiratory Illnesses	3.69	Y	1.37	N

* Recoded to categorical variables

The recoding of these six variables was guided by several rationales. First, two separate categories were developed for the gestational age of infants at birth (see Table 16). One category included infants born at 24-34 weeks gestation, while the other included infants born at 35-36 weeks gestation. This distinction was based on the minimal prematurity of infants born at 35-36 weeks gestation; they often do not require advanced care and are admitted into the newborn nursery following birth. Second, corrected gestational age was also coded into two categories: $\leq$ 36 weeks and $\geq$ 37 weeks at discharge. These categories were based on infants being considered premature at

discharge if their corrected gestational age is less than 37 weeks, whereas infants with a corrected gestational age of 37 weeks or greater are considered to have reached term gestation. Third, chronological age was also coded into two categories: ≤ 7 days and > 7 days of life at discharge. The basis for this distinction was that all infants in the first week of life undergo a period of rapid transition into the extrauterine environment and may be more vulnerable than older infants to extrauterine stressors such as being placed in the CSS. Fourth, percent of sleep time was recoded into 2 categories: infants who spent $< 80\%$ of the time sleeping in the CSS and infants who spent $\geq 80\%$ of the time sleeping in the CSS. This categorization was dictated by the median percent sleep time for ICSC 1 (median 78 %) and 2 (median 83%). Median was chosen instead of the mean because the data distributions were multimodal. This recoding enabled sleep time and occurrence of oxygen desaturation events to be examined. Fifth, comorbidity and the respiratory illness scores were also divided into two categories. This distinction was based on infants with one or more comorbidities or who experienced at least one respiratory illness during their hospitalization being considered sicker than infants with only one comorbidity or no respiratory illness.

In addition to recoding continuous variables, the categorical variable head lag was recoded into two categories: head lag < 5 and head lag ≥ 5. This re-categorization enabled the researcher to differentiate between infants with immature head control and those with moderate to mature head control. The cut point was dictated by the mean head lag score ($M = 4.53$ or 5) and by the head lag score that divided immature (increased; score < 5) and more mature (decreased; score ≥ 5) head lag.

Data Analysis

Data were analyzed by a combination of descriptive statistics and nonparametric statistical tests. The decision to use nonparametric statistical methods instead of data transformations was based on two characteristics of nonparametric analyses: 1) they always provide valid inferences and do not rely on the underlying shape of the distribution, and 2) they curtail the burden of meeting assumptions and analyzing data on a transformed landscape. A small sample size and irregular data distributions further dictated the need for nonparametric analyses. A detailed data analysis plan was developed for each research question as follows:

Research Question #1

1) What are the pass/fail rates of premature infants who have undergone two ICSCs?

The researcher identified and described infants who 1) passed both ICSCs, 2) passed one and failed the other ICSC, and 3) failed both ICSCs. In addition, differences among infants in these 3 ICSC pass/fail groups were examined by Kruskal Wallis testing of outcomes by demographic information and medical histories. The findings are summarized in Chapter 5.

Research Question #2

2) What are the oxygen saturation and desaturation patterns, sleep/wake activity and measures of head lag for premature infants who undergo two ICSCs?

Descriptive statistics (mean, standard deviation, and selected percentiles) and graphical summaries are used in Chapter 5 to summarize oxygen saturation values of infants in their CSS. Descriptive statistics (mean, standard deviation, and selected percentiles) and graphical summaries are also used to describe the time that study

participants spent sleeping in their CSS and the percentage (frequency) of infants that exhibited mature and immature head lag.

Table 16

Recoding Skewed Variables Categorically

Variable	Range	Categorical	n	%
Gestational Age	24-36 weeks	1 = 24-34 weeks 2 = 35-36 weeks	21 28	43 57
Corrected Gestational Age	34- 40 weeks	1 = 34-36 weeks 2 = 37-40 weeks	40 9	82 18
Chronological Age	1-95 days	1 = ≤ 7 days of life 2 = > 7 days of life	30 19	61 39
Percent Sleep Time 1	0-100%	0 = < 80 percent sleep time 1 = ≥ 80 percent sleep time	26 23	53 47
Percent Sleep Time 2	0-100%	0 = < 80 percent sleep time 1 = ≥ 80 percent sleep time	22 27	45 55
Comorbidity Score	0-10	0 = 0-1 comorbidity 1 = 2 or more comorbidities	16 33	33 67
Respiratory Illness Score	0-4	0 = 0 respiratory illness 1 = 1 or more respiratory illness	22 27	45 55
Head Lag	1-11	< 5 = immature ≥ 5 = moderately mature to mature	22 27	45 55

Research Question #3

3) Are variations in head lag, chronological age, and time spent sleeping associated with oxygen desaturation events of premature infants in CSSs?

Bivariate analyses were developed to explore three hypothesized relationships. 1) In unadjusted analyses, premature infants with less head control (as measured by greater head lag) are at higher risk of an oxygen desaturation event during an ICSC than infants with greater head control. 2) In unadjusted analyses, premature infants with lower gestational age, corrected gestational age and chronological age are at higher risk for an oxygen desaturation event during an ICSC than their older counterparts. 3) In unadjusted

analyses, infants who spend more time sleeping in their CSS are at higher risk for an oxygen desaturation event during an ICSC than those who sleep less.

CHAPTER V

RESULTS

Introduction

The purpose of this descriptive, nonexperimental, and observational study was to explore the stability of the one-point ICSC by observing premature infants during a second ICSC and risk factors associated with oxygen desaturation events. The specific aims were to describe 1) the pass/fail rates of premature infants following two (ICSC) observation points, 2) oxygen saturation and desaturation patterns, sleep/wake activity, and head lag over the course of two ICSCs, and 3) the association between head lag, chronological age, time spent sleeping in the CSS and oxygen desaturation events experienced by premature infants during ICSCs. In this chapter, the results of the formal investigation are presented.

Research Question #1

1) What are the pass fail rates of premature infants who have undergone two ICSCs?

The 49 premature infant participants had three ICSC outcomes: passed both ICSCs (group 1), failed both ICSCs (group 2), or failed one ICSC (group 3) (Table 17). The first group of infants (n = 37, 76%) passed both ICSC tests and therefore were discharged home in their car seats. Only 5 (10%) infants failed both ICSCs, whereas 7 (14%) infants had pass/fail or fail/pass combinations. Of the 7 infants with pass/fail combinations, 3 (6%) failed the first ICSC and 4 (8%) failed the second. Infants failing one or both of the ICSCs were discharged home in car beds. Overall, 86% (n = 42) of study participants had stable findings (pass/pass or fail/fail) from ICSC 1 to ICSC 2.

Therefore the majority of premature infants had stable findings over the course of the two test points.

Table 17

ICSC Outcomes ($N = 49$)

Group	ICSC Test #1	ICSC Test #2	Frequency %	n	Outcome
1	Pass	Pass	76	37	Pass
2	Fail	Fail	10	5	Fail
3	Pass	Fail	8	4	Fail
	Fail	Pass	6	3	

Comparing ICSC Outcome Groups by Gender, Birth Route, and Race/Ethnicity

The 3 outcome groups did not differ significantly in gender, birth route and race/ethnicity (p = 0.213, 0.775, 0.874, respectively; Kruskal-Wallis test; Table 18). When the participants were divided into two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was still no statistical difference in gender, birth route and race/ethnicity (p = 0.809, 0.52, 0.61, respectively; Kruskal-Wallis test). Therefore gender, birth route, and race/ethnicity did not influence the ICSC outcomes in this sample of premature infants.

Comparing ICSC Outcome Groups by Age

Comparison of the gestational age, corrected gestational age, and chronological age of participants in the 3 outcome groups revealed two statistically significant findings (Table 19). The infants' gestational ages at birth were significantly different among the three outcome groups (p = 0.012, Kruskal-Wallis test). The mean gestational age of

infants in group 2 (M = 32) was significantly lower than that of infants in group 1 (M = 33.78) and group 3 (M = 35.29) (p = 0.014 and 0.005, respectively; Mann-Whitney test). In addition, the chronological ages of infants in the 3 outcome groups differed significantly (p = 0.008, Kruskal-Wallis test). The infants in group 2 (M = 26.20) were significantly older chronologically than the infants in groups 1 (M =14.16) and 3 (M = 3) (p = 0.007 and 0.005, respectively; Mann Whitney test). In contrast, the corrected gestational ages of infants were not significantly different among the 3 study groups (M = 35.81, 36, 35.71, groups 1, 2 and 3, respectively) (p = 0.424; Kruskal-Wallis test). Also, when the participants were divided into two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was no statistical difference in gestational age, corrected gestational age, and chronological age (p = 0.569, 0.499, 0.363, respectively; Kruskal-Wallis test). In summary infants failing their ICSC on two separate occasions were born between 24-34 weeks gestational age and were hospitalized for longer than 1 week.

Comparing ICSC Outcome Groups by Health History

Infants in the 3 outcome groups were diagnosed with a variety of illnesses during their hospitalizations (Table 20). Each participant was assigned a comorbidity and respiratory illness score. All infants in group 2, the fail/fail group, experienced at least 2 comorbidities but the comorbidity scores of infants in the 3 outcome groups were not statistically different (p = 0.12, Kruskal-Wallis test). In addition, the respiratory illness scores of infants in the 3 groups were not significantly different (p = 0.2; Kruskal-Wallis test). Moreover, when the participants were divided into two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was no statistical difference in

comorbidity and respiratory illness scores (p = 0.954, 0.686, respectively; Kruskal-Wallis test). Thus, the ICSC pass/fail rate was not influenced by the number of comorbidities or the presence of respiratory illness.

Table 18

Gender, Birth Route and Race/Ethnicity of Participants by ICSC Outcome Group (*N* =49)

	ISCS Outcome Group					
	Pass/Pass		Fail/Fail		Pass/Fail	
	n	%	n	%	n	%
All Participants	37	76	5	10	7	14
By Gender						
Male	17	74	4	17	2	9
Female	20	77	1	4	5	19
By Birth Route						
Vaginal	13	81	1	6	2	13
Caesarean	24	73	4	12	5	15
By Race/Ethnicity						
Asian	1	100	0	0	0	0
Black	2	100	0	0	0	0
Hispanic	2	67	1	33	0	0
White	28	74	4	10	6	16
Other	4	80	0	0	1	20

Comparing ICSC Outcome Groups by Time between ICSCs and by Harness Types

The times between ICSC 1 and 2 were not significantly different among the 3 outcome groups (M = 17.16, 16.80, 18.71, groups 1, 2 and 3, respectively) (p = 0.742; Kruskal-Wallis test) nor were the CSS harness types (M = 1.86, 2, 2, groups 1, 2 and 3, respectively) (p = 0.413; Kruskal-Wallis test). When the participants were divided into

two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was still no statistical difference in times between ICSC 1 and 2, nor in the CSS harness types (p = 0.648, 0.184, respectively; Kruskal-Wallis test). Therefore neither the time between the ICSCs nor the type of car seat harness influenced the ICSC outcomes.

Table 19

Gestational Age, Corrected Gestational Age and Chronological Age by ICSC Outcome Group

Group	Age	n	Range	Mean	SD
1	Gestational Age (weeks)	37	24-36	33.78	3.181
	Corrected Gestational Age (weeks)		34-40	35.81	1.126
	Chronological Age (days)		1-95	14.16	22.194
2	Gestational Age (weeks)	5	27-34	32.00	2.915
	Corrected Gestational Age (weeks)		35-38	36.00	1.414
	Chronological Age (days)		8-66	26.20	22.961
3	Gestational Age (weeks)	7	33-36	35.29	1.113
	Corrected Gestational Age (weeks)		34-37	35.71	0.951
	Chronological Age (days)		1-8	3.00	2.38

Table 20

Frequency of Discharge Diagnoses for the Three ICSC Outcome Groups

Diagnosis	Group 1		Group 2		Group 3	
	n	Frequency %	n	Frequency %	n	Frequency %
Hyperbilirubinemia	16	43	4	80	3	43
Sepsis Ruled Out	16	43	3	60	3	43
Anemia	11	30	3	60	—	
Respiratory Distress Syndrome	8	22	3	60	—	
Apnea	7	19	2	40	—	
Hypotension	7	19	1	20	—	
Conjunctivitis	—		2	40	—	
Transient Tachypnea of the Newborn	1	16	—		—	
Patent Ductus Arteriosus	1	3	1	20	—	
Hypoglycemia	5	14	—		—	
Presumed Sepsis	5	14	1	20	—	
Twin Gestation	6	16	1	20	3	43
Chronic Lung Disease	4	11	1	20	—	
Intrauterine Growth Retardation	4	11	—		—	
Respiratory Distress	4	11	1	20	1	14
Retinopathy of Prematurity	3	8	1	20	—	
Intraventricular Hemorrhage	2	5	—		—	
Pneumothorax	2	5	1	20	1	14
Pneumonia	—		1	20	—	
Feeding Disorder	1	3	—		—	
Heart Murmur	—		1	20	—	
Hyperglycemia	1	3	1	20	—	
Necrotizing Enterocolitis	1	3	—		—	
Stridor	1	3	—		—	

Comparing ICSC Outcome Groups by Birth Weight and by Discharge Weight

The birth weights of infants in the 3 outcome groups were not significantly different (M = 2244.97, 1713, 2496.29, groups 1, 2 and 3, respectively) (p = 0.124; Kruskal-Wallis test) nor were their discharge weights (M = 2448.32, 2187, 2390, groups 1, 2 and 3, respectively) (p = 0.347; Kruskal-Wallis test). When the participants were divided into two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was still no significant difference in birth weights or in discharge weights (p = 0.508, 0.218, respectively; Kruskal-Wallis test). Hence, ICSC outcome was not influenced by the birth weight or discharge weight of study participants.

Research Question #2

2) What are the oxygen saturation and desaturation patterns, sleep/wake activity, and measures of head lag for premature infants who have undergone two ICSCs?

Oxygen Saturation/Desaturation Patterns

Continuous oxygen saturation levels were recorded with the Masimo Radical 4 oximeter during each ICSC. Mean oxygen saturation (SpO_2) for all premature infant participants during both ICSCs was 98% (Table 21). While the mean oxygen saturation for group 1 was also 98%, the mean oxygen saturation levels for groups 2 and 3 were 95% and 97% respectively. The difference in mean oxygen saturation for the three outcome groups can be attributed to several factors. First infants in groups 2 & 3 had saturations of less than 93% for a longer period of time than group 1 resulting at least one failed ICSC and overall lower mean saturation. Also due to their failed ICSCs infants in group 2 & 3 spent less time in their CSS further influencing their mean oxygen

saturations. Third there were many more infants in group 1 (n = 36) compared to group 2 (n = 5) and group 3 (n = 7) which may have also contributed to the difference in mean oxygen saturation.

The oxygen saturation nadir (SpO_2) was 82% during ICSC 1 and 83% during ICSC 2 for infants in all 3 outcome groups (Table 22) (Figures 2 and 3). When the means were compared for the 3 outcome groups, a significant difference was noted (p = 0.004, Kruskal-Wallis test) during ICSC 2. During ICSC 2, the mean oxygen saturation nadir for groups 2 and 3 was significantly lower than that for group 1 (p = 0.018 and 0.004, respectively; Mann-Whitney test). Moreover, when groups 2 and 3 were combined, the oxygen saturation nadir of groups 2 and 3 together was significantly lower than that for group 1 during ICSC 2 (p = 0.001; Kruskal-Wallis test), but not for ICSC 1. Therefore, while all study participants experienced brief desaturations, infants who failed at least one ICSC had significantly lower oxygenation nadirs than infants passing both ICSCs. However the oxygen nadir could have also been influenced by differences in testing time and the unequal sizes of the ICSC outcome groups.

Table 21

Mean Oxygen Saturation (SpO_2) Values by ICSC Outcome Group

	ICSC 1			ICSC 2		
	N	% SpO_2	SD	N	% SpO_2	SD
All	48	97.8	1.80	48	97.95	1.63
Group 1	36	98.40	1.01	36	98.44	1.35
Group 2	5	94.58	3.08	5	95.76	1.52
Group 3	7	96.96	1.23	7	96.96	1.45

Table 22

Oxygen Saturation Nadir (SpO_2) by ICSC Outcome Group

	ICSC 1				ICSC 2			
	n	SpO_2	Range	SD	n	SpO_2	Range	SD
All	48	82.46	68-95	6.51	49	83.188	62-97	8.33
Group 1	36	83.83	68-95	7.19	36	85.67	73-97	6.76
Group 2	5	80.40	77-84	2.70	5	74.20	62-89	9.73
Group 3	7	79.86	72-85	4.56	7	76.86	64-85	7.84

Figure 2

ICSC 1: Oxygen Saturation Nadir by ICSC Outcome Group

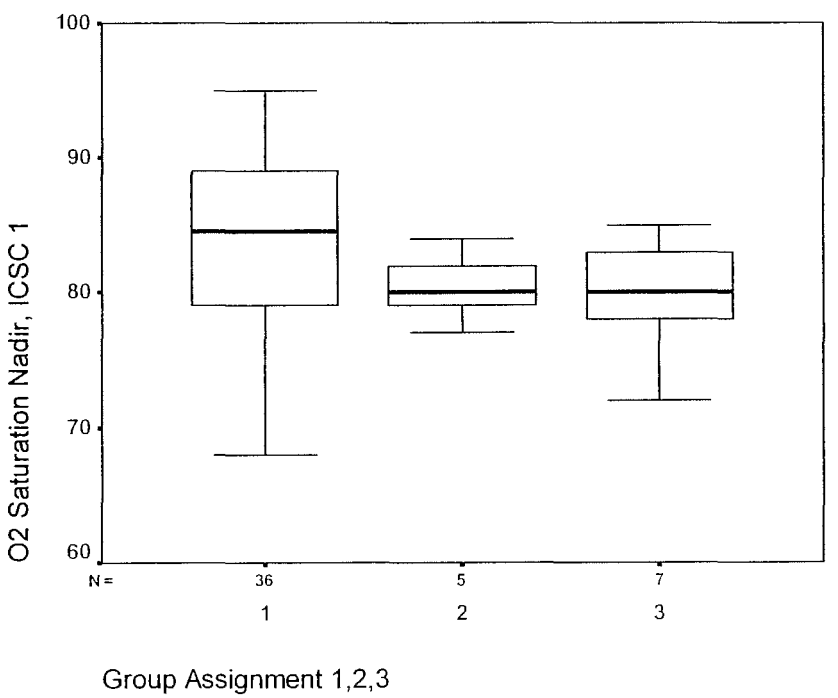
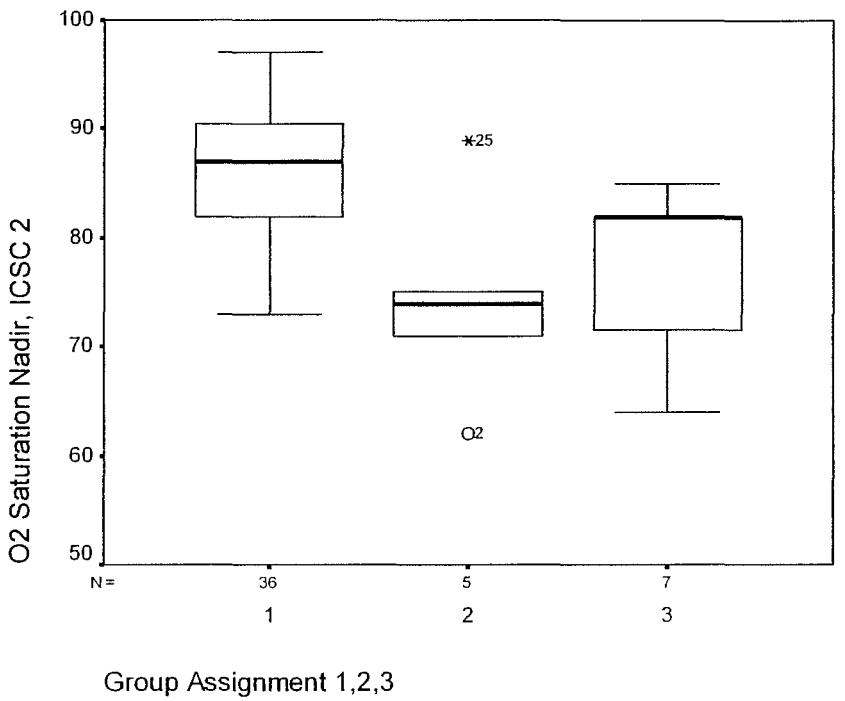


Figure 3

ICSC 2: Oxygen Saturation Nadir by ICSC Outcome Group



Sleep/Wake Activity

The time that the infants spent sleeping (states 1 and 2) during each ICSC was recorded and converted to percentage of sleep time relative to total time in the CSS. Sleep time varied widely among participants (Table 23), but mean sleep time for ICSC 1 and 2 did not differ significantly among the 3 outcome groups ($p = 0.416$ and 0.546, respectively; Kruskal-Wallis test) (Figures 4 and 5). Furthermore, when groups 2 and 3 were combined, sleep time for ICSC 1 and 2 did not differ between infants who passed both ICSCs (group 1) and those who did not (groups 2 and 3) ($p = 0.282$ and 0.287, respectively; Kruskal-Wallis test). Therefore percent of time participants spent sleeping did not influence the ICSC outcomes.

Table 23

Time Participants Spent Sleeping in their CSSs ($N = 49$)

Group	n		Percent Sleep Time ICSC #1	Percent Sleep Time ICSC #2
All	49	Range	0-100	0-100
		Mean	65.82	68.14
		SD	31.82	35.61
1	37	Range	0-100	0-100
		Mean	68.78	73.89
		SD	30.47	30.49
2	5	Range	0-100	0-100
		Mean	48.80	54.60
		SD	41.07	50.69
3	7	Range	12-100	0-98
		Mean	62.29	47.43
		SD	33.10	44.67

Figure 4

ICSC 1: Percentage of Sleep Time by ICSC Outcome Group

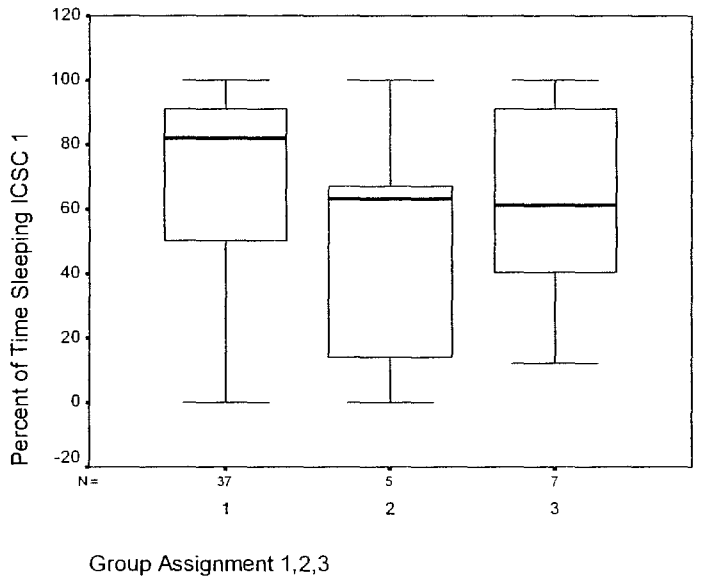
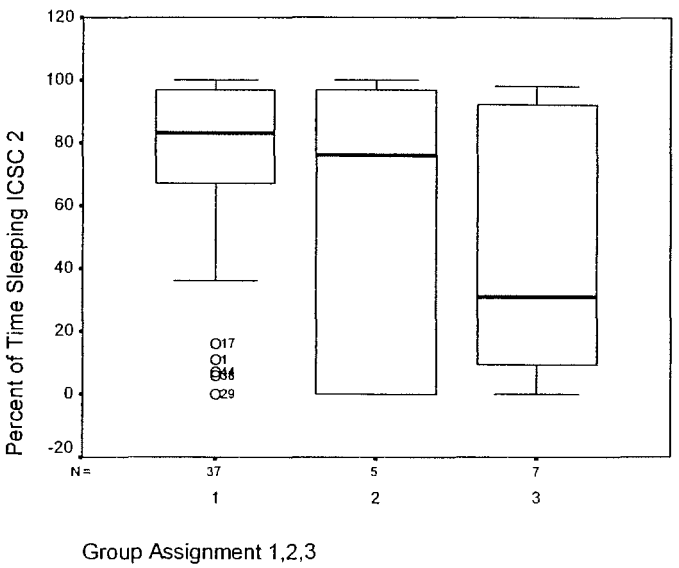


Figure 5

ICSC 2: Percentage of Sleep Time by ICSC Outcome Group



Head Lag

Head lag of all participants was measured by the RAs using the pull-to-sit maneuver. Two infants had their pull-to-sit exams completed outside the 36-hour time frame that was outlined in the research plan. One infant was assessed for head lag 8 hours after the 36-hour time frame and the other was assessed 2 days later.

Efforts were made by the RAs to examine and score for head lag when all premature infants were in an optimal sleep/wake state (state 4 or 5), though this goal was sometimes difficult to meet due to frequent changes in the infants' sleep/wake activity. Of the 49 participants, 77% were in an optimal state (4 or 5) for scoring the pull-to-sit, while 23% were in a sub-optimal state (Table 24). Despite this difficulty, no significant difference was found in sleep/wake state among the 3 outcome groups ($p = 0.44$;

Kruskal-Wallis test). While no difference was detected between outcome groups, sleep/wake state has the potential affect pull-to-sit maneuver results.

Table 24

Participant Sleep/Wake State for Pull-to-Sit Maneuver

Sleep/Wake State	Frequency	Percent	Cumulative Percent
3	10	20.4	20.4
4	28	57.1	77.6
5	10	20.4	98.0
6	1	2.0	100.0
Total	49	100	

The head lag scores for all participants ranged between 1 and 11 (M= 4.53; SD= 1.86) (Table 25). Head lag scores were not significantly different among infants in the 3 ICSC outcome groups (p = 0.778, Kruskal-Wallis test) (Figure 6). This finding did not change when infants with suboptimal sleep/wake states, the infants measured outside of the 36-hour time frame, and the hypertonic infant were removed from the analysis (p = 0.907, 0.951 and 0.799, respectively; Kruskal-Wallis test). While many participants (45%) showed less mature responses (scores of 1-4, ability to lift but not maintain the head in an upright position) over half (51%) of participants demonstrated moderately mature responses to the pull-to-sit maneuver (head lag scores of 5-7, indicating an ability to briefly hold the head upright) (Table 26). Only 2% of participants exhibited more mature responses (scores of 8-9, indicating an ability to maintain the head in an upright position), while another 2% of participants demonstrated an abnormal or hypertonic response to the maneuver (scores of 10-11). Furthermore, when the participants were

divided into two groups, infants who passed both ICSCs (n = 37) and those who did not (n = 12), there was still no statistical difference in head lag scores (p = 0.686; Kruskal-Wallis test). This finding suggests that pull-to-sit exam (head lag score) results do not influence ICSC outcomes.

Table 25

Sleep/Wake State and Head Lag Scores

Group	n		Sleep/Wake State Score	Head Lag Score
All	49	Range	3-6	1-11
		Mean	4.04	4.53
		SD	0.71	1.86
1	37	Range	3-5	1-11
		Mean	4.03	4.54
		SD	0.73	1.91
2	5	Range	3-5	3-5
		Mean	3.80	4
		SD	0.84	1
3	7	Range	4-7	1-7
		Mean	4.29	4.86
		SD	0.49	2.19

Figure 6

Head Lag Scores by ICSC Outcome Group

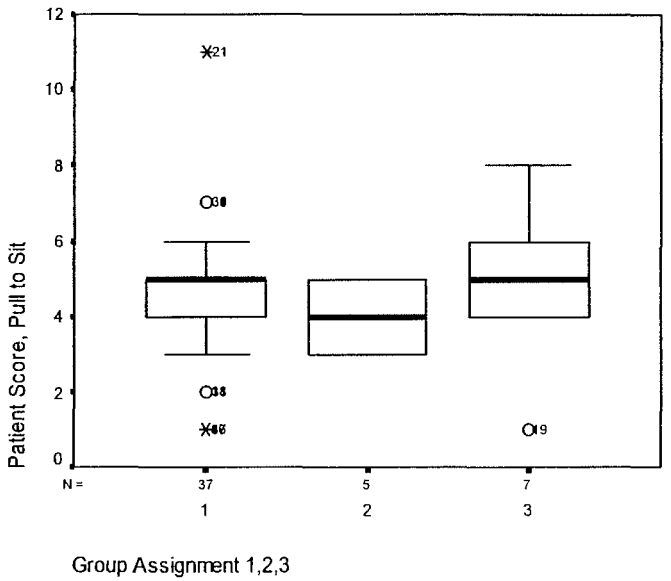


Table 26

Head Lag Scores

Score	Frequency	Percent	Cumulative Percent
1	4	8.2	8.2
2	2	4.1	12.2
3	6	12.2	24.5
4	10	20.4	44.9
5	15	30.6	75.5
6	8	16.3	91.8
7	2	4.1	95.9
8	1	2.0	98.0
11	1	2.0	100
	49	100	

Research Question #3

Are variations in head lag, chronological age, illness, and time spent sleeping associated with oxygen desaturation events of premature infants in CSSs?

In the unadjusted bivariate analyses of data from premature infants, the odds of experiencing an oxygen desaturation event were approximately 50% greater for infants born $\leq$ 34 weeks gestation, 70% greater for infants with corrected gestational ages $\geq$ 37 weeks, and 80% greater for infants discharged home at > 7 days of life (Table 27). In contrast, the odds of experiencing an oxygen desaturation event were 30% less for premature infants with respiratory illness. Moreover, the odds of having an oxygen desaturation event were equivocal for infants with and without comorbid conditions. However, because the 95% confidence interval in each of the analyses includes "one," the findings are not statistically significant.

In addition, while this analysis demonstrates that the odds for experiencing an oxygen desaturation event are 30% greater for infants with increased head lag; caution must be exercised with this interpretation. This is because, no difference among the three outcome groups was previously detected in research question 2; therefore this finding may be a mere artifact from data categorization (or cutting the data). Furthermore, adjusted analysis could not be completed because of the discrepancy in group sizes.

Lastly, in the unadjusted bivariate analysis of percent sleep time and oxygen desaturation events, no association was found between premature infants who slept for 80% of the time or greater and oxygen desaturation events (Table 28). In this analysis, the 95% confidence interval includes "one"; therefore, the findings are not statistically significant. In addition, the large width of the confidence intervals indicates that the

sample size was too small. Furthermore, because of the discrepancy in group sizes, adjusted analysis could not be completed.

Table 27

Bivariate Analyses of Oxygen Desaturation Events with Head Lag, Age, and Illness

	All Participants (N)	Oxygen Desaturation (n)	%	Odds Ratio	95% Confidence Interval
All Participants	49	12	24	-	-
Head Lag					
≥ 5	27	6	22	1.313	(0.356, 4.841)
< 5	22	6	27	Reference	-
Gestational Age (weeks)					
35-36	28	6	21	1.467	(0.396, 5.426)
24-34	21	6	29	Reference	-
Corrected Gestational Age (weeks)					
≥ 37	9	3	33	Reference	-
< 37	40	39	23	1.72	(0.357, 8.264)
Chronological Age (days)					
> 7	19	6	32	Reference	-
1-7	30	6	20	1.845	(0.494, 6.896)
Comorbidities					
0-1	16	4	25	Reference	-
>2	33	8	24	1.041	(0.261, 4.149)
Respiratory Illness					
0	22	6	27	Reference	-
1 or more	27	6	22	1.312	(0.355, 4.83)

Table 28

Bivariate Analyses of Oxygen Desaturation Events with Percent Sleep Time

	All Participants (N)	Oxygen Desaturation (n)	%	Odds Ratio	95% Confidence Interval
All Participants	49	12	24	-	-
Percent Sleep Time, ICSC #1					
< 80%	26	8	31	Reference	-
≥ 80 %	23	4	17	2.11	(0.541,8.26)
Percent Sleep Time, ICSC #2					
< 80%	22	7	32	Reference	-
≥ 80 %	27	5	19	2.053	(0.547,7.69)

Summary of Major Findings

Of the 49 premature infants participating in this investigation, 86% had stable findings from ICSC 1 to ICSC 2, while 14% had inconsistent results, and 8% had false negative results by passing ICSC 1, but failing ICSC 2. Although many risk factors for oxygen desaturation events were explored, no influence on ICSC outcomes was detected for gender, birth route, race/ethnicity, birthweight, discharge weight, number of comorbidities, history of respiratory illness, time between ICSCs, CSS harness types and sleep time. In contrast, infants who were born at a gestational age of ≤ 34 weeks, discharged home at a chronological age of > 7 days, and that had a corrected gestational age of ≥ 37 weeks at discharge were found to be at greater odds for experiencing oxygen desaturation events in their CSSs. Furthermore, while an increase in head lag appeared to be a risk factor for oxygen desaturation events, this finding was likely spurious.

CHAPTER VI

DISCUSSION

Introduction

This chapter will evaluate and interpret the implications of the study findings in terms of the 3 research questions, compare these findings to the work of others and discuss how the findings of this study impact the AAP's recommendations for ICSC testing of premature infants upon hospital discharge. In addition this chapter will present a new theoretical framework for ICSC testing of premature infants, provide recommendations for practice and future study, and discuss how limitations of this study that could affect interpretation of the results.

Research Question #1

Stability of the ICSC

The American Academy of Pediatrics (1991, 1996, 1999) recommends that every infant born at less than 37 weeks gestation undergo a period of observation in their CSS prior to hospital discharge due to breathing difficulties with the semi-upright seating position. However, neonatal healthcare providers have been concerned that a one-point predischarge observation period, i.e., the Infant Car Seat Challenge, might not be sufficient to identify all at-risk infants (Pilley & McGuire, 2005; R. Pye, personal communication, May 5, 2004). Furthermore, anecdotal evidence supported this concern. Therefore it was hypothesized that premature infants would pass one ICSC but not the other.

The findings of this study indicate that the majority of participants (86%, n = 42) had stable results from one ICSC to the next, and only a small number of infants had

unstable results (14%, n = 7). Furthermore, this finding demonstrates that the ICSC is a highly reliable test for detecting breathing problems experienced by premature infants in their CSSs. This success rate for the ICSC is equal to or better than that of other screening tests for problems in newborns. For instance, newborn hearing screens, which are used by a majority of birthing hospitals nationwide to identify hearing loss, have a high percentage of false positive (64%; Clemens, Davis, & Bailey, 2000) and false negative results (12%; Johnson et al., 2005) depending upon the type of screening device used. In addition, the ability to detect cystic fibrosis (CF) in newborns varies widely, depending on the method of testing (Comeau et al., 2004). With single mutation (ΔF508) testing, 50% of CF-affected infants are diagnosed, versus 75% with the multiple-CFTR-mutation screen (Comeau et al., 2004). Improved detection of hearing loss and CF is only noted when additional screens are added.

This study shows that the ICSC is much like other screening tests in that additional ICSCs detect increased numbers of infants with CSS-related breathing problems. However, at this time, it is neither practical nor recommended that all infants undergo more than one ICSC prior to discharge because it is not known how many infants would benefit from additional screens. Moreover, it is not yet known how many ICSCs are needed to identify all infants at risk for oxygen desaturation events. To determine this number would require extending the hospital stay of some (minimally) premature infants beyond the standard 48 hours. Therefore an investigation examining this phenomenon would be costly.

With the stable results found in this investigation, neonatal healthcare providers are reassured that the one-point ICSC is a reliable tool for identifying premature infants at

risk for oxygen desaturation. This new information about the ICSC reaffirms the need to perform routine one-point ICSCs of premature infants prior to hospital discharge. However, the use of the one-point ICSC raises two important issues 1) how to address false positive results (infants who fail the ICSC but do not have a positional ventilatory problem) and more importantly 2) how to address false negative results (infants with a positional ventilatory problem not identified by the ICSC).

False Positive ICSC Results

In this study, 6 % (n = 3) of infants failed ICSC 1 but passed ICSC 2. This finding indicates that one cannot be certain which test result is correct. This researcher believes that infants failing just one of several ICSCs should be considered at risk for a positional ventilatory problem. This researcher's opinion is supported by several rationales: 1) low blood oxygen levels cannot be easily identified upon visual inspection, 2) the consequences of low blood oxygen levels are not fully understood and may be harmful, 3) infant car beds are federally approved and affordable, and 4) no definitive evidence could be found to suggest that car beds are inadequate safety devices for travel. Therefore this researcher recommends, that healthcare providers err on the side of caution by sending any infant who fails even just one properly performed ICSC home in a car bed. However, if the testing technique was not properly performed or if an infant remained hospitalized for an extended period of time resulting in increased maturation following a failed test, then retesting the infant may be appropriate.

False Negative ICSC Results

In this study 8% of infants passed ICSC 1 but failed ICSC 2, indicating that healthcare providers must exercise caution when educating parents because the one-point

ICSC may not be adequate for some infants. Neonatal healthcare providers may want to consider a repeat ICSC for premature infants who pass their first ICSC with borderline results or have multiple risk factors. Also, healthcare providers should warn parents that some infants with potential positional ventilatory problems may not be identified by the one-point ICSC and that the long term effects of these problems remain unclear. In addition parents must be warned that while most infants at risk for oxygen desaturation events are identified by the ICSC, there is no guarantee that infants passing the ICSC will not exhibit future problems. Furthermore, parents should be educated about the variety of travel restraint devices available (car seats and car beds) so that they can make an informed choice when their infant is ready to go home.

If parents choose to transport their infant in a CSS, they need to be told that a parent or another adult must observe the infant in their CSS at all times for labored or periodic breathing, apnea, tachypnea, acute pallor and cyanosis. Infants with these symptoms should be removed from their CSS and assessed by a healthcare provider. Parents should also be cautioned that using other seating devices such as infant seats and swings may lead to similar positional ventilatory problems. These seating devices should only be used when the infant reaches the appropriate age and weight as recommended by the manufacturer. Moreover, parents should be told that the using mirrors to supervise infants during travel is dangerous because 1) the driver's attention may be diverted from the road while looking at the infant in the mirror, resulting in a crash and 2) mirrors can become projectile during a crash resulting in injury.

Research Question # 2

Oxygen Saturation and Desaturation Patterns

At present no consensus has been reached on a safe range for blood oxygen saturation. In this investigation, an oxygen saturation of < 93% was used as the criterion for oxygen desaturation, but others have used different criteria for desaturation, ranging between 85 and 90% (Bass & Mehta, 1995; Tonkin et al., 2003; Willett et al., 1986; Young et al., 1996). The decision to use a more conservative oxygen desaturation criterion had little effect on the outcome of this study. Only one infant failed the ICSC with oxygen saturation values consistently between 90%-92%.

In this study, infants who failed and those who did not fail their ICSCs experienced short episodes of oxygen desaturation with SpO_2 values ranging as low as 60-70% and lasting < 10 seconds. However, the infants in groups 2 and 3 (those that failed their ICSCs) also had prolonged oxygen desaturation events lasting > 10 seconds, necessitating their removal from the CSS. During the oxygen desaturation events, most infants were not overtly symptomatic and few had increased breathing efforts. Some infants became pale but none were cyanotic. Only one infant exhibited labored breathing.

Other investigators have observed apnea and bradycardia (Hertz et al., 1994; Smith & Turner, 1990; Willett et al., 1986; 1989) during the ICSC, yet none of the infants in this study experienced apnea or bradycardia. Some infants became tachycardic, whereas others had a downward trend in their heart rates during oxygen desaturation. Although the reasons for these different findings are not known, they might be explained by variations in discharge criteria, in ICSC procedure, in equipment, car seat design

changes over time, differing NICU populations, and in the timing of the ICSC in relation to discharge.

All infants who failed their ICSC in this study experienced oxygen saturations of less than 90% except for one infant whose oxygen saturation remained between 90-92% for 10 seconds without signs of recovery. When this infant met failure criteria, she was pale in color and she had labored breathing. When oxygen saturation levels are kept $\geq$ 93% in certain infant populations, it has been shown that the rate of sudden infant death decreases, weight gain and development improve, pulmonary artery pressure and airway resistance are reduced by 50%, and the incidence of hypoxemic events is reduced (Poets, 1998). Furthermore, the baseline oxygen saturation for healthy term neonates during the first 4 weeks of life has been shown to be between 92-100% (Poets et al., 1996). Most infants born prematurely are near term or have reached term gestation at hospital discharge. This knowledge, coupled with the finding that one infant in this study experienced a change in skin color at oxygen saturation values of 90-92%, strengthens the argument for a more conservative oxygen desaturation criterion. Therefore, this researcher recommends that an oxygen saturation value of 92-93% serve as a standard criterion for the ICSC of the stable premature or formerly premature infant. This criterion, however, may need to be modified for individual infants with medical conditions requiring higher or lower oxygen saturation thresholds.

Sleep/Wake Activity

Newborn infants spend a large percentage of their day sleeping (Gaultier, 1990). Therefore, newborn sleep has been the focus of numerous investigations. For example, some have investigated the relationship between newborn sleep and physiological

activities, medical conditions and development (Goto et al., 1999; Jeffery & Heacock, 1991; Scher, Johnson, & Holditch-Davis, 2005). In this study infant sleep/wake activity was measured during the ICSCs when participants were secured in their CSSs. In total, 98 ICSCs were performed with 49 infant participants. The percent of time spent sleeping ranged from 0-100% in all 3 outcome groups. During 49% (n = 48) of all 98 ICSCs, infants slept > 80% of the time, while during 21% (n= 14) of all ICSCs infants did not sleep at all. Sleep/wake activity was difficult to measure for some infants due to frequent transitions between sleep and wakefulness. These types of methodological difficulties in coding sleep/wake activity have been reported previously (Sahni, Schulze, Stefanski, Myers, & Fifer, 2004). Sahni et al. (2004) found that coding of infant state improved with the use of EEGs as opposed to observation methods. Therefore, the use of advanced techniques for measuring sleep/wake activity is recommended for future investigation of this phenomenon.

Head Lag

In this study a range of head lag measures (scores of 1-11) were observed using the pull-to-sit exam. Among all study participants, only 2% (n = 1) had mature scores (8-9), whereas 51% (n = 25) had moderately mature scores (5-7) and 45% (n = 22) had immature scores (1-4). However, 22% (n = 11) of infants were not in the correct sleep/wake state at the time of their pull-to-sit exams. That is, some infants were too sleepy or fussy; thus, their head lag score may have been inaccurate. When these infants were removed from the analysis, there was little change in the distribution of scores; 3% (n = 1) of infants had mature scores, 52% (n = 20) had moderately mature scores, and 24% (n = 17) had immature scores. The mean corrected gestational ages of the entire

study sample and the sample subset (infants in the correct sleep/wake states) was 36 weeks. In addition, both the sample and sample subset had a corrected gestational age range of 34-40 weeks.

Few studies have documented normative findings on the neurological assessment of preterm infants and even fewer have reported specifically on the findings of the pull-to-sit exam in the preterm infant population. Only 3 studies that included premature infants in their sample were found for comparisons. Mercuri et al. (2003) found a wide range of responses to an exam of head control. In fact, these authors reported that none of the infants were mature on exam. Similarly, Allen and Capute (1990) reported that more than half of premature infants studied at term continued to demonstrate head lag. In addition, Forslund and Bjerre (1983) showed that formerly premature infants had a greater tendency toward head lag. These findings are consistent with head lag measures observed in this study. No studies were found that demonstrated decreased head lag in the premature infant population.

Furthermore, in previous studies some investigators measured head lag and head control separately (Forslund & Bjerre, 1983; Mercuri et al., 2003) and obtained contradictory results. Forslund and Bjerre (1983) found that premature infants had better head control than their term peers, whereas Mercuri et al. (2003) found the opposite. In the present study, these variables were measured simultaneously, so separate comparisons could not be made.

Research Question #3

Head Lag and Oxygen Desaturation

The findings of this study did not support the hypothesis that premature infants with increased head lag (less head and upper body control) would experience oxygen desaturation events in their CSS. While premature infants with increased head lag scores were found to be at 30% greater odds for experiencing oxygen desaturation events in their CSSs, this finding did not reach statistical significance and is likely spurious due to categorization of the data. However despite these findings, related research suggests that increased head lag may lead to a compromised airway.

Prior studies on infant head lag, infant airway anatomy and observations made during this investigation suggest that extra caution should be taken when placing premature infants who demonstrate increased head lag or poor head control in a CSS. The airway anatomy of infants has been shown to be very different from that of adults (Tonkin, 1998; Tonkin et al., 2003). Infants have a narrowed airway space due to a prominent occiput, an unstable temporomandibular joint and a toothless jaw (Tonkin, 1998; Tonkin et al., 2003). When the back of the infant's shoulders and occiput are forced into a straight line, such as when infants are placed into a CSS, the head is flexed forward on the neck and chest. This posture results in airway compromise (Tonkin et al., 2003). Furthermore, it has been well documented that truncal tone and ventral suspension emerge closer to term and that many premature infants evaluated at term gestation demonstrate persistent head lag when pulled to the sitting position (Allen & Capute, 1990; Forslund & Bjerre, 1983; Mercuri et al., 2003). Due to an increase in head lag, infants do not have the physical/physiological capacity to correct this situation. The

inability to self-correct by repositioning themselves to keep their small airways patent places premature infants at great risk for impaired oxygen saturation.

With this knowledge, neonatal healthcare providers should exercise caution when selecting a car restraint device for infants exhibiting increased head lag until this phenomenon can be studied further. However, the findings on head lag exam should not be the only criterion for choosing a restraint device for travel because head lag exams may not be fully reliable. To perform the pull-to-sit maneuver, infants must be in an ideal state (state 4-5; Lester & Tronick, 2002) which may not always be possible. Moreover, head lag findings have been shown to vary according to serum glucose levels (Linder et al., 1998). Therefore, when determining whether an infant needs a restraint device, healthcare providers should consider findings of increased head lag in conjunction with findings from the ICSC and infant history.

Chronological Age and Oxygen Desaturation

It was hypothesized that premature infants of decreased chronological age would experience oxygen desaturation events in their CSS. This hypothesis was not supported by the data. Infants experiencing oxygen desaturation events fell into 2 outcome groups: those who failed both ICSCs (group 2) and those who failed one ICSC (group 3). The infants in group 3 had inconsistent or unstable ICSC results (pass/fail and fail/pass). The mean chronological age of these infants at the time of their first ICSC was ≤ 7 days of life. In contrast, infants in group 2, the fail/fail group, were of increased mean chronological age, ranging between 8-66 days of life. Moreover, infants in group 1 (passing both ICSCs) had highly variable chronological ages.

Despite the lack of a definitive association, however, some important findings emerged about chronological age. First, the study findings indicate that infants at greatest risk (fail/fail combinations) for oxygen desaturation events in their CSS were chronologically older at discharge (8-66 days) and were born at gestational ages less than $\leq$ 34 weeks (27-34 weeks). These findings are consistent with reports that infants born at an early gestational age and hospitalized for longer periods due to severe prematurity and illness were at increased risk for oxygen desaturation events (Mullen & Courts, 2002; Young et al., 1996).

The findings of this study also suggest that premature infants discharged home in the first week of life may be at increased risk for oxygen desaturation events. All premature infants with pass/fail, fail/pass combinations had a mean chronological age of 3 days (range 1-8 days). These findings are consistent with those of others who showed that some near term and term infants experience oxygen desaturation events (Merchant et al., 2001) and that oxygen saturation improves as infants approach term gestation (Mok et al., 1988). Though it is unclear at this time why this group of infants had inconsistent ICSC test results, one can speculate that they had not fully transitioned into the extrauterine environment. This finding is of particular concern because in 2003, only 22% of level I newborn nurseries in the U.S., which sometimes care for minimally premature infants, did not have the equipment, trained personnel or policies in place to perform ICSC testing (Williams & Martin, 2003).

Sleep and Oxygen Desaturation

Premature infants experience periodic breathing and apnea, two problems that have been associated with impaired oxygenation (Barrington, Finer, & Li, 1996;

Carbone, Marrero, Weiss, Hiatt, & Hegyi, 1999; DiFiore et al., 2001; Eichenwald et al., 1997; Prechtl, Fargel, Weinmann, & Bakker, 1979). In addition, certain sleep states have been associated with increased incidence of periodic breathing, apnea and impaired oxygenation (Hertz et al., 1994; Holditch-Davis et al., 1994). Moreover, increased active sleep with periodic breathing has been attributed to breathing abnormalities of premature infants when positioned in their CSSs (Hertz et al., 1994). In this study, infant sleep time was recorded to explore the relationship between sleep and oxygen desaturation events.

It was hypothesized that premature infants who spent more time sleeping in the CSS would experience oxygen desaturation events. This hypothesis was not supported by the study findings. Some infants were observed having oxygen desaturation events when they were awake, while others were sleeping during their events. These observations and lack of statistically significant findings indicate that sleep may not be a risk factor for oxygen desaturation events in CSSs.

Despite these findings, however, it can be argued that more information is needed regarding the relationship between sleep and oxygen desaturation events in CSS. First, this study's small sample size and the unsophisticated tool for measuring sleep time may have contributed to the lack of association between sleep and oxygen desaturation events. Second, during infants' sleep their ability to maintain stable blood oxygenation is affected by physical and physiological changes: 1) the body relaxes and can slump over, resulting in poor positioning (Hertz et al., 1994; Nagase et al., 2002), 2) posterior mandibular movement can lead to airway occlusion (Tonkin, 1998), and 3) prolonged breathing pauses can contribute to a hypoventilatory state (Holditch-Davis et al., 1994). Moreover, sleeping infants are less likely to respond to biofeedback mechanisms that

enable them to correct poor alignment of the body and breathing problems (Hertz et al., 1994; Nagase et al., 2002). Third, although anecdotal evidence from parents indicates that infants sleep better in their CSSs, some infants were noted during the course of this investigation to have frequent state transitions. Frequent state transitions in the supine position have been hypothesized to protect infants from sudden infant death syndrome (Goto et al., 1999). The rationale for this hypothesis is that premature infants have more frequent changes in sleep/wake activity and more heart rate variability when positioned supine than when prone, resulting in less time spent in sleep states associated with breathing irregularities (Goto et al., 1999). Fourth, the association between sleep and oxygen desaturation events has important implications for current U.S. child care practices. Parents use seating devices as a replacement for holding infants or placing them in a crib (Callahan & Sisler, 1997). These CSS-bound infants are sometimes left sleeping in these devices for prolonged periods; sometimes even throughout the night (personal communication, J. Stewart, November 11, 2005). Thus, based on these important facts, additional investigations are needed on the relationship between sleep time and oxygen desaturation events.

Roy's Model of the Person as an Adaptive System

The theoretical framework for this study was based on Roy's Model of the Person as an Adaptive System (Roy, 1984; Roy & Andrews, 1999). In the proposed framework, it was hypothesized that oxygen desaturation events would be experienced by premature infants 1) with poor head control as evidenced by increased head lag, 2) of decreased chronological age, and 3) who slept more while positioned in their CSSs. While Roy's Model provided the structure needed to guide this study, the findings indicate that sleep

time and decreased chronological age may not be risk factors for oxygen desaturation events in the CSS. Rather, the results of this study suggest that infants are at increased risk for oxygen desaturation events if they 1) are discharged home after the first 7 days of life, 2) are born at $\leq$ 34 weeks gestation, and 3) have corrected gestational ages greater than 37 weeks at discharge. Subsequently, a modification of the proposed theory was necessary (see Figure 6). Modifications to the theoretical framework included removing sleep, head lag and decreased chronological age as internal inputs and replacing them with increased chronological age, decreased gestational age, and increased corrected gestational age.

This modified theoretical framework provides a better understanding of risk factors for oxygen desaturation events experienced by premature infants when positioned in their CSSs because it is evidence based. However, this theoretical framework and the theories presented are still in the formative stage. Although illness history (Willett et al. 1986; 1989), time spent in the CSS (Merchant et al., 2001) and sleep (Nagase et al., 2002) had previously been identified as risk factors for CSS oxygen desaturation events, these potential risk factors were not validated by this study. The present study found instead that illness history, head lag and time spent sleeping did not increase the odds for oxygen desaturation events, and infants failing their ICSC spent various amounts of time in their CSSs. Additional investigations with larger sample sizes are needed to identify all risk factors and to secure theoretical validation.

Implications for Practice

The findings of this study indicate that most infants have similar ICSC results when tested on two separate occasions. The findings also demonstrate that the odds for

experiencing oxygen desaturation events in CSSs are greater for infants 1) discharged home after the first 7 days of life, 2) born at $\leq$ 34 weeks gestation, and 3) with corrected gestational ages greater than 37 weeks at discharge. Thus, these findings provide neonatal healthcare providers with new information about the stability of the ICSC and infant populations at risk for oxygen desaturation events. Healthcare providers can now consider these risk factors when they are making recommendations for travel at discharge. They can also use this information to educate parents about the importance of the ICSC, to warn them that a small number of infants at risk for oxygen desaturation events will not be identified, and that continued close supervision in the CSS is imperative.

Implications for Education

Anecdotal evidence obtained during the course of this investigation suggests that many neonatal healthcare providers and parents of premature infants lack basic knowledge regarding risk factors for oxygen desaturation events, do not completely understand the importance of the ICSC, and do not know about alternative travel devices for infants who fail the ICSC. These issues were highlighted by one specific problem that developed during this investigation, the acquisition of car beds by parents. Soon after the formal study began, a nationwide shortage of infant car beds developed. Similar difficulties in obtaining car beds have been found by others (Pilley & McGuire, 2005). In response to this problem, the researcher purchased several car beds that were still available so that the study would not be interrupted.

At the beginning of this study, the researcher explained to parents that if their infant failed one of the two ICSCs, car bed travel would be recommended and they would

need to purchase a car bed (if they chose to comply with the recommendation). After purchasing car beds due to the shortage, the researcher changed the information given to parents during enrollment. Parents were told that a car bed would be provided if needed. The researcher perceived that more parents declined participation when they were told they would need to purchase a car bed. This anecdotal evidence suggests either the parents did not fully understand the importance of the ICSC or that car bed cost places a financial burden on some parents. Healthcare providers should be aware of this problem and educate parents about the importance of the ICSC and explain to them that the ICSC is recommended by the AAP. Moreover, healthcare providers should assist parents with limited financial resources to secure car beds if needed.

Furthermore delays in discharging infants who failed their ICSC due to the unavailability of infant car beds could have halted this study, but more importantly could negatively impact the U.S. healthcare system at large. Without car beds for travel, hospital beds that are needed for sick infants will remain occupied by healthy infants who are awaiting sufficient maturation to safely travel in their CSSs (Pilley & McGuire, 2005). Discharge delays will also force private and public insurance companies to spend limited financial resources to support the extended hospital stays of infants with unstable blood-oxygenation capacity when in their CSSs. As long as premature infants can be safely transported home in reasonably priced infant car beds, prolonging their hospital stay is economically untenable. To prevent this delay in hospital discharge the uninterrupted production and distribution of infant car beds should be ensured by the collaborative efforts of the AAP, private and public healthcare institutions, insurance companies, infant car bed manufacturers and other organized groups (parent groups).

It is important that healthcare providers with a full understanding of these issues share their knowledge with others. Including this information in journals designed for healthcare providers and parents, nursing and medical curricula, parenting classes, and presenting this information at local and national medical/nursing conferences, are some examples of how this information may be disseminated. Furthermore, this researcher strongly endorses the recommendation of the AAP (1990) that healthcare institutions develop a program for staff education regarding ICSC testing. Neonatal healthcare providers should participate in yearly mandatory education programs that incorporate new information from research studies such as this one.

Future Research

Although the danger of placing a premature infant in a CSS has been demonstrated by several small studies (Bass & Mehta, 1995; Bass et al., 1993; Hertz et al., 1994; Merchant et al., 2001; Smith & Turner, 1990; Willett et al., 1986; Willett et al., 1989) and a few large scale studies (Mullen & Courts, 2002; Young et al., 1996), many more investigations are needed. As discussed previously, some parents are now using seating devices in place of a crib. This change in childcare practice may place these infants at risk for chronic hypoxia. The relationship between length of time in the CSS and oxygen desaturation was first demonstrated in 2001 (Merchant et al.), and sleep was identified as a risk factor for oxygen desaturation in CSSs in 1994 (Hertz et al.), suggesting a need for additional investigations to validate these relationships. In addition, this study's ambiguous findings on the risk for CSS oxygen desaturation events due to chronological age (< 7 days of life) and head lag indicate that additional studies with larger sample sizes are needed to further explore relationships among these

variables. Furthermore, several pediatricians contacted the researcher during this study for information about transitioning the infants from car beds back to CSSs. They requested advice about when it was safe to make this transition. Although an answer to this important question is desperately needed, no literature addressing this issue could be found.

Implications for Policy

This investigation raises two important ICSC-related, healthcare policy issues: the lack of a standardized ICSC procedure, and difficulties with car bed use.

ICSC Procedure

The overall incidence of oxygen desaturation events experienced by premature infants in their CSSs was 24% (i.e., the infants failed at least one ICSC). This incidence rate falls within the previously reported range: approximately 4-60% of premature infants experience oxygen desaturation events when positioned in their CSSs (Bass et al., 1993; Hertz et al., 1994; Merchant et al, 2001; Mullen & Courts, 2002; Smith & Turner, 1990; Willett et al., 1986; 1989; Young et al., 1996). Premature infants had stable blood oxygen levels in their crib, but exhibited difficulty maintaining stable oxygenation in their CSSs at the time of hospital discharge. Therefore, this study's findings support the AAP's (1991; 1996; 1999) recommendation that infants born at less than 37 weeks gestation undergo a period of observation (ICSC) in their CSS prior to hospital discharge. However, standardization of the ICSC is still needed. The length of time considered appropriate to observe premature infants in their CSSs prior to discharge is still unknown and safe parameters for oxygen saturation (to prevent adverse behavioral, cognitive and motor outcomes) remain elusive. As a result, neonatal healthcare providers are left to

develop their own procedure and pass/fail criteria for testing (Williams & Martin, 2003), creating great variability in ICSC procedures among institutions. A standardized procedure for ICSC testing developed by the AAP would help to alleviate liability concerns for institutions and neonatal healthcare providers (Williams & Martin, 2003), increase compliance with the AAP's recommendations, increase the safety of premature infants during travel, and provide a better mechanism for comparing research study results.

Car Bed Use

After infants were discharged, their parents and pediatricians contacted the researcher about problems associated with using car beds. One family complained that they had no room for their older child in their vehicle because their twin infants needed to travel in car beds. Therefore, their family could no longer travel together in one vehicle. Another mother reported that the seat belts in her vehicle barely fit around the perimeter of the car bed. One pediatrician reported that a parent became nervous because the car bed moved (up and down, laterally) during travel. To address these issues, parents and pediatricians were referred to the local child-passenger safety technicians for immediate assistance and information. In the future, neonatal healthcare providers can play an active role in rectifying these problems by reporting them to governing agencies, e.g., the AAP and NHTSA, and to the manufacturers of the car beds.

Figure 7

Theoretical Framework for CSS-Related Oxygen Desaturation Events

Inputs

External:

- Placement of premature infant in car seat

Internal:

- Chronological Age > 7 days
- Corrected Gestational Age ≥ 37 weeks
- Gestational Age ≤ 34 weeks

These inputs contribute to lack of head/torso control and sustained respiration, resulting in inadequate air/gas exchange

Effectors

Cognator response: Stimulation of mechanoreceptors and transmission of the signal to brain and spinal cord

Regulator response: Stimulation, of chemoreceptors from decreased pO_2, increased pCO_2, and increased hydrogen ion concentration (pH)

Output

Adaptive Responses: Sensory receptor (mechanoreceptors and chemoreceptors) signals are processed in a mature manner. Premature infant corrects body position and increases respiratory effort to maintain stable blood oxygen saturation is maintained

Ineffective Responses: Sensory receptor (mechanoreceptors and chemoreceptors) signal processing remains immature. Premature infant is unable to self-correct position of head/torso and exhibits a diphasic respiratory response. An oxygen desaturation event occurs. The situation may be further compromised by sleep.

Control Processes

Biofeedback mechanisms

Signals are processed in the brain and spinal cord; the need for movement is acknowledged and message may/may not be transmitted to muscle spindles

Respiratory centers in the medulla oblongata and pons are stimulated, but the signals for increased respiratory drive to decrease pCO_2 and increase pO_2 may/may not be transmitted to lungs/diaphragm

Study Limitations

This study had several limitations. First, the sample of premature infants was recruited by convenience, which does not ensure that the sample is representative of the premature infant population at large. Second, differences in CSS design (harness mechanisms and seat contours) may have affected the ICSC results, thereby limiting the study's reproducibility. Third, although sample size and power calculations were considered in the study design, the relatively small sample size resulting from early termination of this study may have precluded achieving statistical significance. Fourth, an unsophisticated method (observation) was used to measure sleep time, whereas a more objective measure would have been polysomnographic recordings (Hertz et al., 1994). Using a subjective measure such as observation may have affected the study results. Fifth, the use of unweighted scores and non-standardized comorbidity scores may have resulted in some measurement error. Sixth, because this study was only partially funded, the researcher participated in data collection and analysis. Therefore, the researcher was not blinded to the ICSC study results, possibly introducing investigator bias.

Lastly, 20% of participants were the products of twin gestations. This researcher did not anticipate such a large number of infants born to multiple gestations. Therefore the data were not collected in a way to allow comparisons between related twins. It would have been helpful to gather and code additional data (for example, birth order) for infants born to multiple gestations so that comparisons could be made between the multiples and to other groups of multiple gestation infants.

Conclusion

This study increases the neonatal healthcare provider's knowledge regarding the ICSC recommended by the AAP. It is the first study to explore repeat testing of premature infants in their CSSs prior to hospital discharge. The findings of this study indicate that 86% of premature infants had stable results from ICSC 1 to ICSC 2. The success rate for identification of oxygen-related desaturation events of premature infants in their CSSs by the ICSC is equal to or better than that of other screening tests for newborn medical conditions.

In addition, this study explored several possible risk factors for oxygen desaturation events. These risk factors included infant age (chronological age, gestational age, and corrected gestational age), head lag, illness history (comorbid conditions and respiratory illness), and sleep time in the CSS. Of these risk factors, those found to be associated with oxygen desaturation events were chronological age > 7 days, gestational age ≤ 34 weeks, and corrected gestational age ≥ 37 weeks. Neonatal healthcare providers can use these findings to educate parents about the importance of ICSC screening and to make recommendations regarding infant travel at discharge.

Premature infants who experience breathing problems in their CSSs are recommended for travel in a federally approved car bed. Car beds allow infants to travel supine, thereby prevent breathing problems. However, car beds are not recommended for all infants (Weber, 2000). Though not proven, infants in car beds may be more vulnerable to injury because the entire side of their bodies are exposed to the force of a crash (Weber, 2000). Furthermore, car beds can be difficult to obtain because of a limited supply, difficult to secure in a vehicle, or can limit available space within the

vehicle. For these reasons, only infants who have demonstrated breathing problems in their CSSs should be recommend for travel in car beds.

When positioned in their CSSs, some premature infants experience only brief oxygen desaturations, which are not considered harmful. Consequently, infants who experience brief desaturations are recommended for travel in a CSS at hospital discharge. However, it is important that parents of premature infants recommended for CSS travel not be given a false sense of security. The ICSC is a one-point observation of their infant in the CSS prior to hospital discharge, and some infants with positional ventilatory abnormalities may not be identified. Healthcare providers must forewarn parents that all infants require adult supervision during travel regardless of the ICSC results or safety device used.

APPENDIX A

ROY'S REVISED MODEL OF THE PERSON AS AN ADAPTIVE SYSTEM

Input -> Control Processes -> Effectors -> Output

Input	Control Processes	Effectors	Output
Placement of premature infant in car seat • Poor head control (measured by head lag) causes head to fall forward, body slouches • Decreased chronological age, yielding lack of head control and sustained respiration, partial or complete obstruction of airway yields decreased PO_2 and increased PCO_2 • Sleep exacerbates poor positioning, and the infant is less likely to respond to the body's biofeedback mechanisms	Cognator Stimulation of sensory receptors and transmission of the signal to brain and spinal cord Regulator Stimulation of chemoreceptors from decreased PO_2, increased PCO_2, and increased hydrogen ion concentration	Head Control Signals are processed in the brain and spinal cord, movement is determined, and message transmitted to muscle spindles Respiration Respiratory centers in the medulla oblongata and pons are stimulated, respiratory drive increases, resulting in decrease CO_2 and increase PO_2	Adaptive Responses Premature infant self corrects position of head and body, stable oxygen saturation is maintained Ineffective Responses Premature infant is unable to self correct position of head, and maintains a diphasic respiratory response. Both situations are further compromised by sleep. Resulting in an oxygen desaturation event

APPENDIX B

HEAD SUPPORT STUDIES

Citation	Purpose	Sample	Design	Instruments	Measurements	Major Findings
Dollberg, Yacov, Mimouni, & Ashbel (2002	To test whether prevention of lateral movement of the head, using a specially designed head support apparatus, would prevent oxygen desaturation events in premature infants restrained in car seats	(N = 16) Premature infants at a postmenstrual age of 34-35 weeks	Prospective	Head support apparatus made of rubber-foam covered cotton material Max Cosi, Holland, Newborn Car Seat Ohmeda oximeter	Each infant studied in 3 different positions (supine decubitus, sitting in a car seat, and sitting in a car seat with the head support) for 20 minutes The percentage of time that the infants spent with oxygen saturation values below 90, 92, 94, and 96 % was measured	The oxygen saturation values were not significantly improved when the infant's heads were supported (ANOVA, student's paired t-test with Tukey's correction, $p > 0.05$)
Tonkin, McIntosh, Hadden, Dakin, Rowley, & Gunn (2003)	To test whether an infant car seat modification to allow the infant's head to rest in a neutral position on the trunk would prevent narrowing of the upper airway and thus reduce oxygen desaturation in preterm infants restrained in car seats	(N = 17)	Prospective	A foam plastic insert was constructed such that when placed on the car seat behind the infant, space was left to accommodate the infant's prominent occiput Polygraphic recordings, Edentec Cardio-respiratory monitoring, MR10 *Excursion *Oronasal thermistor for airflow *2 Pulse oximeters	The number of events (oxygen saturation < 85%, bradycardia < 90 bpm, and arousal defined as a combination of variable respiratory recordings, increased heart rate and muscle activity) were measured for each infant position Obstructive apnea was measured by reduced airflow and increased respiratory effort One inspiratory radiograph of upper airway was taken during each of the 2 monitoring periods	Only 24 events were identified with the insert in place, but 56 with insert removed (56) ($P < 0.05$). Upper airspace was wider when infants were asleep in car seat with the insert in place than without the insert ($P < 0.05$) **Narrowed airway without insert:** Reduced distance between space from nasion to lower incisor (ANOVA, $P < 0.05$) Increased angle between upper incisor to nasion to lower incisor ($P < 0.05$).

APPENDIX C

STAFF PAMPHLET

Pass/Fail Criteria

Determination of a passed or failed test will be the responsibility of the researcher.

Oxygen desaturation event is defined as any one, or all, of the following:

- apnea for > 20 seconds
- more than two consecutive episodes of periodic breathing, interrupted by tachypnea (RR >70) which are associated with oxygen desaturation of < 93%
- bradycardia with a heart rate of < 80 beats per minute without spontaneous recovery (*)
- oxygen saturation of < 93 % without spontaneous recovery*

* Spontaneous recovery is defined as a consistent rise in heart rate or oxygen saturation within 10 seconds time and without intervention.

Parent Education

- The parent(s) of infants who pass both of the ICSC tests will be given an information sheet explaining the testing limitations and steps for keeping their infant safe during travel.
- Infants who fail any of the ICSC tests will be recommended for travel in a car bed.
- The parent(s) of infants recommended for travel in a car bed will be given a pamphlet discussing the limitations to the testing, the pro and cons of car beds, and information about obtaining a car bed if desired.

Contacts

If you have any questions and/or concerns during the course of this investigation, you may contact the following individuals:

Michele DeGrazia RNC, MS, NNP
(office number 617-562-7772; page 617-705-3249)

Dr. Susan Sullivan-Bolyai, UMass Worcester
(office number 508-856-4185)

Study Pamphlet:
Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events

Problem

Some premature infants have difficulty in maintaining stable blood oxygen saturation (called an oxygen desaturation event) when placed in the semi-upright seating position of their child safety seat (CSS). To date, no studies have examined either the stability of the one-point ICSC test or relationships between risk factors and the occurrence of oxygen desaturation events when premature infants are positioned in their CSS.

Purpose

This descriptive, non-experimental and observational study will explore the stability of the one-point ICSC by observing premature infants (born at less than 37 weeks gestation) during a second ICSC and risk factors that may be associated with oxygen desaturation events.

Specific Aims

The study goals are to describe:

1. The pass/fail rates of premature infants from two ICSC tests.
2. Oxygen saturation and desaturation patterns, sleep/wake activity, and a measure of head lag for premature infants during two ICSC tests.
3. The association between head lag, infant age, time spent sleeping in the CSS and oxygen desaturation events in premature infants during two ICSC tests.

Importance

1. Knowing the stability of the ICSC will avoid false reassurances by healthcare providers to parents about safe travel for premature infants.
2. Learning more about the risk factors for oxygen desaturation events will help neonatal healthcare providers make appropriate recommendations for safe infant travel.
3. Finding more accurate methods for identifying at-risk premature infants may contribute to better behavioral, cognitive and motor outcomes for this population.

Design

This study will use a descriptive, non-experimental, and observational research design.

Study variables

The variables for this investigation are oxygen desaturation events, head control, chronological age and sleep.

Setting, Sample & Population

- Caritas St. Elizabeth's Medical Center
- A convenience sample of 73 infants will be recruited for this study
- Premature infants born at less than 37 weeks gestation will be targeted for enrollment into this study

Inclusion Criteria

- Premature infants born to English-speaking preparing for their initial discharge home from the NICU or newborn nursery
- Medical clearance by their healthcare team
- Apnea, bradycardia, and desaturation free for at least 48 hours to participate and must have an anticipated discharge date of less than one week.

Exclusion Criteria

- Orthopedic support / brace
- State Custody
- Treatment with methylxanthines
- Discharge home on oxygen

Key Personnel & Roles

Nurse researcher (Michele DeGrazia)

Responsibilities include 1) obtaining IRB approval, 2) financial management, 3) enrollment procedure for subjects, 4) obtaining informed consent of parent(s), 5) testing and data collection procedures, 7) procedures for maintaining validity and reliability of findings and 8) data management and analysis.

Nurse Data Collector (Pat Mitchell)

Performs the pull-to-sit maneuver

Medical and nursing staffs

Identify potential study participants; evaluate the premature infant's readiness for discharge and participation, and ask parents if they are interested in hearing about the study.

Enrollment Procedure

- Enrollment may occur at any time after birth and prior to hospital discharge as long as the infant's condition is not considered life-threatening.
- Identification of potential study subjects along with permission to recruit participants will be secured from the infant's medical team.
- Members of the medical team will ask the parent(s) of potential study subjects if they would be interested in learning about this investigation.

Informed Consent

Parents of infant's that meet eligibility criteria will be approached by the nurse researcher who will educate them about the study and invite them to participate. They will be asked to sign consent and HIPPA forms stating that they agree to participate in the testing and to permit the researcher to obtain information from their infant's medical record.

Scheduling

Once enrollment procedures are complete and consent is obtained, the researcher will schedule the infant for 2 ICSC tests to be done before to hospital discharge

- When the ICSC schedule is made, infant feeding times and other procedures will be taken into consideration
- The ICSC tests will be scheduled approximately 24 hours apart $\pm$ 12 hours.

Measurements

Scoring is required for three variables

- Infant Car Seat Challenge test (90 minute CR and O2 sat monitoring and observation of infant in the CSS)
- Head Control (pull-to-sit maneuver is performed at anytime during the testing time frame)
- Sleep Wake Activity (measured during the 90 minute ICSC)

Infants from the Well Baby Nursery (WBN)

Non-monitored infants from the WBN will be observed and monitored for an additional 30 minutes in their cribs, before the ICSC, to ensure that they have a stable baseline O_2 saturation of > 92%.

APPENDIX D

PARENT PAMPHLET

Are there any benefits to participating?

By participating you will gain some understanding about how your infant will do when placed in his/her car seat at hospital discharge.

Also, your participation in this study you will help doctors and nurses
1) find out if car seat testing before hospital discharge is a reliable way to detect breathing problems of premature infants in their car seats, and
2) learn more about how to identify infants at risk for breathing problems in their car seats.

What if I change my mind after I sign the consent?

You can choose to withdraw your infant from the study at any time, even after you have signed the consent. Just ask to speak to the researcher so that your infant can be removed from the study.

Contacts
If you have any questions and/or concerns during the course of this investigation, you may contact the following individuals:

Michele DeGrazia RNC, MS, NNP (617-562-7772)

Dr. Susan Sullivan-Bolyai, UMass Worcester (508-856-4185)

How will I get information about how my infant did during the test?

You will be given an information sheet describing how your baby did during the two car seat tests immediately after the second test is completed.

If your infant passes both car seat tests you will be given an information sheet explaining the testing limitations and what needs to be done to keep your infant safe during travel.

If your baby does not pass one or both of the car seat tests the American Academy of Pediatrics recommends that your infant travel in a car bed at hospital discharge. You will be given an information sheet discussing the limitations of the ICSC test, the pro and cons about car beds, and information about obtaining a car bed (costing between $55-80) if you choose to do so.

Title of this study: Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events

Introduction

Research has shown that some premature infants can have problems breathing when they sit in an infant car seat. These breathing problems can lead to low blood oxygen levels that can be dangerous if not detected. Undetected low blood oxygen level may cause problems in behavior, intelligence and movement as the infant ages. The American Academy of Pediatrics recommends watching all premature infants in their car seat before hospital discharge to see if this breathing problem exists. Specially designed car beds are recommended for infants who have problems breathing when sitting in their car seat.

To date no studies have tested infants in their car seats to see if this is a reliable method of detecting possible breathing problems. It is not known whether or not infants who pass one test, would pass a second test, if they were to be retested. In addition, only a few studies have investigated risk factors for breathing problems experienced by infants in their car seats. More studies are needed to help doctors and nurses identify which infants are at risk for this problem.

This study will investigate if repeat testing of infants in their car seats on two separate occasions leads to the same result. It will also investigate whether or not head control, infant age and sleep are risk factors for breathing problems when infants are placed in their car seats.

This study is important because...

1. Knowing the stability of the car seat test will avoid nurses and doctors giving wrong information to parents of premature infants at hospital discharge.
2. Learning more about the risk factors for breathing problems will help doctors and nurses give parents of premature infant the best advice for safe infant travel.
3. Finding more accurate tests to identify premature infants with possible breathing problems may avoid future behavior, intelligence and movement problems.

What happens if I agree to have my infant participate?

If you choose to have your infant participate you will be asked to sign a consent form. By signing the consent form, you agree to have your infant tested in his/her car seat on two separate occasions, to have your infant tested using the pull-to-sit maneuver, and to have your infant's medical record reviewed by the researcher.

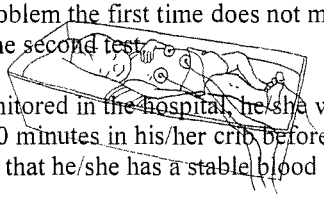
Infant Car Seat Challenge (ICSC)

If you agree to participate in this study, it means that your infant will be brought to the neonatal intensive care unit on two different occasions. When in the neonatal intensive care unit your infant will have monitoring leads placed on his/her chest, lower abdomen and one foot. Then your infant will be placed in his or her car seat for 90 minutes. Your infant will be observed for breathing problems. After your infant has spent 90 minutes in their car seat, the test will be stopped, and your infant will be observed for an additional 30 minutes in his/her crib.

You may go to the neonatal intensive care unit with your infant but other visitors will not be allowed. You must not disturb your infant during the test.

If breathing problems are detected before the full 90 minute test is finished, the test will be stopped and your infant will be immediately removed from the car seat. Your infant will then be monitored in his/her crib until the breathing problems have resolved. The research nurse will then tell you that the American Academy of Pediatrics recommends that your infant travel in a car bed.

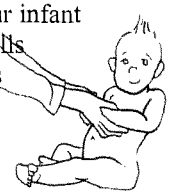
Even if your infant has problems during the first test, he/she will be tested again. Just because your infant had a problem the first time does not mean that he/she will have a problem during the second test.



If your infant has not been routinely monitored in the hospital, he/she will need to be monitored for an additional 30 minutes in his/her crib before being tested in the car seat, to make sure that he/she has a stable blood oxygen level.

Pull-to-Sit

In addition to the car seat test a nurse will perform a specific newborn exam procedure called the pull-to-sit maneuver. This procedure only takes 2-3 minutes to perform. It is done right in your infant's crib. With your infant lying on his/her back the nurse holds your infant's wrists/hands, pulls him/her to a sitting position and watches his/her head control. This procedure will be done only one time.



Medical Record Review

Lastly your infant's medical record will be reviewed. The researcher will need to gather specific information including, date of birth, sex, race, type of delivery, and your infant's discharge diagnosis list.

Will my infant be in any discomfort or danger?

The monitoring leads used in the car seat test will be placed on the surface of your infant's skin and therefore will not cause any discomfort to your infant during the ICSC. However, it is expected that your infant will experience minimal discomfort when the monitoring leads are removed because they are sticky. Your infant's skin may be slightly reddened where the leads were placed. This redness will fade within a few hours to a couple of days.

Your infant could have a drop in blood oxygen level, heart rate or have a change in respiratory rate during the test. This type of event could be severe and your infant may require resuscitation. Specific standards for stopping the car seat test will be used to keep your infant safe.

Many hospitals (75%) in the US routinely test infants in their car seats before hospital discharge. Some infants have had life-threatening breathing problems in their car seat, but these are rare. If your infant experiences a life-threatening problem during the test, he/she will be removed from the car seat, and will be treated by the medical team in the neonatal intensive care unit.

The pull-to-sit maneuver is frequently done during a routine newborn physical exam. This procedure is not expected to cause your infant any discomfort or harm.

Maintaining Privacy

Only the information listed in this pamphlet and on the consent form will be obtained during the medical record review. Your infant's name will not appear on any forms used in this study. Instead, your infant will be identified using a specific participant ID number. This procedure will protect your infant's identity.

What happens if I decide not to have my infant participate?

Nothing will happen. There will be no effect on the care your infant receives in the hospital.

APPENDIX E

INFORMED CONSENT

CARITAS ST. ELIZABETH'S MEDICAL CENTER
INFORMED CONSENT FOR
EXPERIMENTAL PROCEDURE (REVISED 3/28/03)

IRB Approval Stamp

Subject's Name: _____ Date: _____

Home Address:

Home Telephone: Date of Birth:

Research Study Title: Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events

Principal Investigator: Michele DeGrazia RNC, MS, NNP

Study Sponsor(s): Dr. Susan Sullivan Bolyai
University of Massachusetts, Worcester

Participant ID number:

Dear Parent(s),

The purpose of this consent form is to inform you about the nature of the Research Study so that you may make an informed decision as to whether you would like to participate. You are free to decline participation and, should you choose to participate, you are free to withdraw from the Study at any time without penalty or loss of benefits that you otherwise enjoy outside of the Research Study.

5. Invitation: **You are being asked to participate in a research study. Your participation is voluntary.**

Your baby is being invited to participate in a study because he/she was born early. As your baby is getting ready for discharge, babies that are born early sometimes have difficulty breathing when placed in the semi-upright seating position required by traditional infant car seats. However it is not known how reliable the current testing methods for detecting this problem are, so therefore we have designed a study to specifically examine this issue.

2. Purpose: **What is the purpose of this research study?**

This study will help doctors and nurses 1) identify at risk babies, and 2) make appropriate recommendations for safe travel of infants at discharge.

3. Duration: **How long will you be participating in this research study?**

Your baby will participate in this study during the last week of his/her hospitalization, before being discharged to home.

4.Procedures: What will the research study involve?

By signing the consent to participate you agree to having your infant tested in his/her car seat on two separate occasions (called the ICSC test, see below), having your infant examined using the Pull-to-Sit maneuver, and to having your infant's medical record reviewed by the researcher.

Infant Car Seat Challenge Test (ICSC)
If you agree to participate in this study, it means that your infant will be brought to the neonatal intensive care unit on two different occasions. When in the neonatal intensive care unit your infant will have monitoring leads placed on his/her chest, lower abdomen and one foot. Then your infant will be placed in his or her car seat for 90 minutes. Your infant will be observed for breathing problems. After your infant has spent 90 minutes in their car seat, the test will be stopped. If breathing problems are detected before the full 90 minute test is finished, the test will be stopped and your infant will be removed from the car seat immediately.

Regardless of how your infant does in the car seat he or she will be observed closely for 30 minutes after the test.

If your infant experiences difficulties in their car seat, he or she will be recommended for travel in a car bed.

Even if your infant has problems during the first test, he/she will be tested again. Just because your infant had a problem the first time does not mean that he/she will have a problem during the second test.

If your infant has not been routinely monitored in the hospital, he/she will need to be monitored for an additional 30 minutes in his/her crib before being tested in the car seat, to make sure that he/she has a stable blood oxygen level.

Pull-to-Sit
In addition to the car seat test a specially trained nurse will perform a specific newborn exam procedure called the Pull-to-Sit maneuver. This procedure only takes 2-3 minutes to perform. It is done right in your infants crib. With your infant lying on his/her back the nurse, holding your infant's wrists/hands, will pull your infant to the sitting position and watch your infant's head control. This will be done only one time.

Medical Record Review
Lastly your infant's medical record will be reviewed. The researcher will need to gather specific information including, date of birth, sex, race, type of delivery, and your infant's discharge diagnosis list.

6. Risks, Discomforts, Side-Effects and Inconveniences: **What are the risks involved with being enrolled in this study?**

There are several risks, discomforts, side effects and inconveniences you need to know about before deciding to participate and these include:

a. During the car seat test your baby will need to remain in the car seat for the full 90 minutes therefore there may be disruptions in bonding with your baby. You may go to the neonatal intensive care unit with your infant but other visitors will not be allowed. You must not disturb your infant during the test. The researcher will try to minimize the disruptions.

b. Monitor leads will be placed on the surface of your infant's skin and therefore will not cause any discomfort to your infant during the car seat test. Though, it is expected that your infant will experience minimal discomfort with the removal of the monitoring leads, because they are sticky; much like it feels when you have a Band-Aid removed. Your infant may be slightly reddened where the leads were placed. This will subside within a few hours to a couple of days.

c. Your infant could have a drop in blood oxygen level, heart rate or have a change in respiratory rate during the test.

d. Many hospitals (75%) in the US routinely test infants in their car seats prior to discharge. There have been some reports that infants have experienced a life threatening event in their car seat, however these are rare. If your infant experiences a life threatening event during the test, he/she will be removed from the car seat, and will be treated by the medical team in the neonatal intensive care unit. This means that the doctors and nurses may need to give your baby oxygen, use a bag and mask to help your baby breath, and also your baby may require chest compressions to pump the heart. Specific criteria for stopping the ICSC test have been selected in order to keep your infant safe and prevent these rare, but severe events from happening.

e. The Pull-to-Sit maneuver is frequently done during a routine newborn physical exam. This procedure is not expected to cause your infant any discomfort or harm.

f. If your baby does not pass one or both of the ICSC tests the American Academy of Pediatrics recommends that your infant travel in a car bed at discharge. You will be given an information sheet discussing the limitations of the ICSC test, the pro and cons about car beds, and information about how to obtain a car bed (costing between $55-80) if you choose to do so.

6. Benefits: **Are there any benefits from participating in this study?**

By participating you will gain some understanding about how your infant will do when positioned in his/her car seat at discharge.

Also, your participation in this study you will help doctors and nurses 1) find out if car seat testing prior to hospital discharge is reliable for detecting breathing problems of premature infants in their car seats, and 2) learn more about how to identify infants at risk for breathing problems in their car seats.

7. Alternatives: **Therapy is available to you without enrolling in this study. The appropriate alternative procedures or courses of treatment include the following:**

There are no alternative tests used to identify infants at risk for breathing problems in their car seat at this time. If you choose not to participate there will be no effect on the care your infant receives in the hospital.

8. Confidentiality:

Confidential information contained in your medical record may not be given to anyone except to members of the research group and others who must be involved professionally to provide essential medical care. The study sponsor, the Research/Human Subjects Committee (IRB), and federal agencies protecting the welfare of the study participants may view study records.

Your baby's name will not appear on any forms used in this study. Instead, your baby will be identified using a specific participant ID number to protect your infant's identity.

9. Compensation: **Will you be paid to participate in this research study?**

☐ You will be compensated for participating in the research study. You will receive:

[x] You will not receive any sort of compensation for participating in the research study.

10. In Case of Injury.

If your baby becomes sick or injured by directly participating in this research study, medical treatment will be provided to your baby including first aid, emergency treatment and follow-up care as needed. Caritas St. Elizabeth's Medical Center will bill your health insurance for the cost of such care. If your insurance does not pay for your care, or pays only a portion of the cost of such care, Caritas St. Elizabeth's Medical Center may bill you for any unpaid amounts. No special arrangements will be made for the compensation or for the payment of treatment solely because of your participation in this research study. Caritas St. Elizabeth's Medical Center and persons conducting this research study are not admitting fault for your injury or illness by providing or making available medical treatment for your injuries or illness. This paragraph is a statement of the Caritas St. Elizabeth's Medical Center policy and does not waive any of your legal rights. In case of injury contact Michele DeGrazia at 617-562-7772 or 508-946-9887.

11. Costs. **What charges will be paid by the Study Sponsor?**

This study is being funded through a research grant and private/commercial donations. However if your baby does not pass one or both car seat tests you will need to purchase a car bed for your infant, if you choose to take your baby home in one.

You understand that you may have to pay for medicines, devices, and other medical supplies and services related to your participation in the Research Study. Caritas St. Elizabeth's Medical Center will first bill your health insurer for such costs. If your insurance does not pay, or pays only a portion of the costs, Caritas St. Elizabeth's Medical Center may bill you for any unpaid amounts.

12. New Findings. **New Information.**

Any new findings developed during the course of the Research Study, which may affect your willingness to continue participating will be explained to you and you can then decide if you want your baby to continue in this research study, and your consent to continued participation will be required.

13. Number of Subjects.

The number of subjects who will participate in the Research Study at Caritas St. Elizabeth's Medical Center is estimated to be 73.

1. Termination without Consent:

The researcher will terminate your infant's involvement in this study without your consent if your infant is not able to maintain a stable oxygen saturation in his or her crib prior to the car seat test, or if the car seat that you provide does not meet federal motor vehicle safety guidelines.

15. Contacts.

If at any time during this research study, you feel that you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject, or feel under duress to participate against your wishes, you can contact a member of the Research/Human Subjects Committee, who will be available to speak with you during normal working hours (8:30 a.m. to 5:00 p.m.) at:

Institutional Review Board (IRB) Research/Human Subjects Committee
Telephone: 617-789-2804
Address: 736 Cambridge Street
Boston, MA 02135

You may also contact the Principal Investigator or Representative at any time during this Research study for questions and answers regarding the Research study at:

Michele DeGrazia (617-562-7772)

Dr. Susan Sullivan-Bolyai, UMass Worcester (508-856-4185)

The subject has been informed of the nature and purpose of the procedures described above including any risks involved in the research study's performance. The subject has been asked if any questions have arisen regarding these procedures and these questions have been answered to the best of the Caritas St. Elizabeth's Medical Center's ability. A signed copy of this informed consent has been provided to the subject.

Also, any new unforeseen information relevant to the patient that may develop during the course of this research activity will be provided to the subject and the Research/Human Subjects Committee (IRB). I will inform any referring physician(s) of any and all protocol changes, adverse events and/or safety reports.

_____

Investigator's Signature Date
or
Representative's Signature

I have been informed about the procedures, risks, and benefits of this Research Study and agree to participate. I know that I am free to withdraw my consent and to quit the Research Study at any time. My decision not to participate in this Research Study or my decision at any time to withdraw from this Research Study will not cause me any penalty or loss of benefits that I am otherwise entitled to.

I have read and understand the terms of this Consent Form and I have had an opportunity to ask questions about the Study and to discuss the Study with my doctor and other health care providers and my family and friends.

I hereby consent to my medical records relating to this research activity be made available to state and federal agencies (including but not limited to the Department of Health and Human Services' Food and Drug Administration (FDA)), which regulates medical research activity, including this experiment. I understand that while every effort will b e made to keep my identity confidential, there may be occasions when my identity must be made known to sate and federal agencies at their request.

I understand that the Research/Human Subjects Committee (IRB) of Caritas St. Elizabeth's Medical Center (CSEMC) has approved the solicitation of subjects to participate in this research activity.

_____

Signature of Subject Date Printed Name
or Signature of Subject's Legal Representative

_____

Signature of Witness Date Printed Name

APPENDIX F

HIPAA FORM

CARITAS ST. ELIZABETH'S MEDICAL CENTER

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Individual's Name: _____
Last First Middle

Home Address: _____

_____

Home Telephone: _____ **Date of Birth**: _____

SPECIFY INFORMATION TO BE DISCLOSED:

☐ Complete records ☐ Consult ☐ X-Ray ☐ Pathology ☐ Outpatient reports
☐ Physical therapy [X] Discharge summary ☐ Emergency reports ☐ Laboratory
[X] History & Physical [X] Health information to conduct research. [X] All information collected during the research study described in the consent. [X] Other Specified Bedside medical record to assess recent history of apnea, bradycardia or desaturation events.

MY HIGHLY CONFIDENTIAL INFORMATION:

By signing my name next to a category of highly confidential information listed below, I specifically authorize the use and/or disclosure of the type of highly confidential information indicated next to my signature, if any such information will be used or disclosed pursuant to this Authorization:

- Information about a Mental Illness or Developmental Disability

_____

- Psychotherapy Notes _____
- Information about HIV/AIDS Testing or Treatment _____
  (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of such tests were positive or negative)
- Information about Venereal Disease _____
- Information about Substance (i.e., alcohol or drug) Abuse _____
- Information about Abuse of an Adult with a Disability _____
- Information about Sexual Assault _____
- Information about Child Abuse and Neglect _____
- Information about Genetic Testing _____

RECIPIENT: Name of person or class of persons to whom Caritas St. Elizabeth's Medical Center may disclose my health information: Michele DeGrazia RNC, MS, NNP
Address of the recipient or where my health information should be delivered: Neonatal Intensive Care Unit, Caritas St. Elizabeth's Medical Center
TERM: This Authorization will remain in effect:
☐ From the date of this Authorization until the day of , 200 .

☐ Until Caritas St. Elizabeth's Medical Center fulfills this request.
[X] Until the following event occurs: **This authorization will remain in effect for 1 month from the date of my signature.**
☐ Other:

PURPOSE: I authorize Caritas St. Elizabeth's Medical Center to use or disclose my health information (including the highly confidential information I selected above, if any) during the term of this Authorization for the following specific purpose(s): So that my infant will be included in the research study titled Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events.

I understand that my health information may be disclosed as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

I understand that once Caritas St. Elizabeth's Medical Center discloses my health information to the recipient, Caritas St. Elizabeth's Medical Center cannot guarantee that the recipient will not redisclose my health information to a third party. The third party may not be required to abide by this Authorization or applicable federal and state law governing the use and disclosure of my health information.

I understand that Caritas St. Elizabeth' Medical Center may, directly or indirectly, receive payment from a third party in connection with the use or disclosure of my health information.

I understand that I may refuse to sign or may revoke (at any time) this Authorization for any reason and that such refusal or revocation will not affect the commencement, continuation or quality of my treatment at Caritas St. Elizabeth's Medical Center; except, however, if my treatment at Caritas St. Elizabeth's Medical Center is for the sole purpose of creating health information for disclosure to the recipient identified in this Authorization, in which case Caritas St. Elizabeth's Medical Center may refuse to treat me if I do not sign this Authorization. *If my treatment is related to my participation in a research study, I understand that Caritas St. Elizabeth's Medical Center may refuse to allow me to participate in the study if I do not sign this Authorization.*

I understand that this Authorization will remain in effect until the term of this Authorization expires or I provide a written notice of revocation to Caritas St. Elizabeth's Medical Center's Privacy Office at the address listed below. The revocation will be effective immediately upon Caritas St. Elizabeth's Medical Center's receipt of my written notice, except that the revocation will not have any effect on any action taken by Caritas St. Elizabeth's Medical Center in reliance on this Authorization before it received my written notice of revocation.

I may contact Caritas St. Elizabeth's Medical Center's Privacy Office by mail at **Caritas St. Elizabeth's Medical Center, 736 Cambridge Street, Boston, MA 02135, attn: Privacy Office**, by telephone at 617-779-6472.

I have read and understand the terms of this Authorization and I have had an opportunity to ask questions about the use and disclosure of my health information. By my signature below, I hereby, knowingly and voluntarily, authorize Caritas St. Elizabeth's Medical Center to use or disclose my health information in the manner described above.

_____

Signature of Patient Date

If the patient is a minor or is otherwise unable to sign this Authorization, obtain the following signatures:

_____	_____	_____	
Signature of Personal Representative	Description of Authority	Date	CC: Research Subject IRB/Privacy Board

APPENDIX G

ISCS PROCEDURE

Guidelines / Requirements for CSS Use:

- The rear-facing CSS will be age and weight appropriate, never have been in an accident, not have missing or broken pieces, and must meet federal guidelines evidenced by reference on seat.
- CSS with a three or five point harness, a distance of 10 inches from lower harness to bottom, and distance of 5 ½ inches between back and crotch strap.
- Premature and small infants will not be placed in a CSS with shields, abdominal pads, or arm rests.
- Shoulder straps will be in the lowest slots, they should be snug, and retainer clip should be positioned midway on the infant's chest.
- The seat will be reclined to a 45 degree angle.
- No rolls or padding will be placed behind or beneath the infant. The infant will be unwrapped with arms and legs free to be positioned appropriately around restraints and buttocks to back of seat.
- If the CSS does not meet these criteria, one will be provided for testing.

Equipment:

- Infant's own CSS.
- Protractor
- Monitor: Hewlitt Packard Viridia 24CT cardiorespiratory monitor, two 4x4 sterile gauze pads, and sterile water.
- Kendall Foam 4103 prewired neonatal/pediatric monitoring electrodes
- Masimo Radical Oximeter
- Blankets for rolls
- Face cloth or pillow case for small roll

Procedure:

1. Place infant in the CSS to assess need for seat adjustment and rolls.
2. Determine what rolls will be needed and place them accordingly.
3. Use protractor to recline CSS to a 45 degree angle, document on ICSC testing record.
4. Cleanse chest and foot sites for leads/probe.
   On chest apply:
   - White (RA) electrode directly below the clavicle and near the right shoulder
   - Black (LA) electrode directly below the clavicle and near the left shoulder
   - Red/Green electrode directly on the lower left abdomen

   On either foot apply:
   - O_2 transducer probe (Oxysensor II N25); be sure that the light emitter and photodetector are opposite each other.
5. Turn on monitor and select a lead where the ECG wave is completely free from electrical or muscle artifact without baseline wander. Assess for saturation SpO_2 pleth for adequate wave or the presence of artifact. Also assess for good

perfusion to foot with oximeter probe in place and for stable O_2 saturation (>92% in crib).

6. If the infant is not monitored, monitor in crib for 30 minutes to be sure that the baseline O_2 saturation is >92%.
7. If artifact is noted reposition electrodes or O_2 transducer probe.
8. Place infant in CSS with blanket roll, face cloth roll or pillow case roll supports.
9. Complete the ICSC Data Collection Form up to the result section; be sure to document use of rolls and CSS angle of recline.
10. Begin CSS test.
11. Monitor infant for a full 90 minutes unless he/she experiences an O_2 desaturation event; note any unusual findings or circumstances on the CSS test record.
12. Discontinue testing if infant experiences a desaturation event defined as an apnea episode >20 seconds in duration, more than two consecutive episodes of periodic breathing interrupted by tachypnea (RR >70) which are associated with oxygen desaturation of < 93%, bradycardia with heart rate <80 beats per minute without spontaneous recovery, oxygen desaturation of <93% without spontaneous recovery or if other difficulties in breathing are demonstrated. Spontaneous recovery is defined as a consistent rise in heart rate or oxygen saturation within 10 seconds time without intervention.
13. If the infant experiences oxygen desaturation event, he or she will be recommended for discharge home in a car bed. If no desaturation event is experienced the infant will be recommended for discharge home in his/her CSS.
14. After the second ICSC, give parent(s) the letter explaining how infant did during the ICSCs.

APPENDIX H

STATE OBSERVATIONS

Sleep States

State 1: Sleep with regular breathing, eyes closed, no spontaneous activity except startles or jerky movements at quite regular intervals; external stimuli produce startles with some delay; suppression of startles is rapid, and state changes are less likely than from other states; no eye movements and no muscle tone

State 2: Sleep with eyes closed; rapid eye movements can often be observed under closed lids; low activity level, with random movements and startles or startle equivalents; movements are likely to be smoother and more monitored than in state 1; responds to internal and external stimuli with startle equivalents, often resulting change of state. Respiration is irregular, sucking movements occur off and on. Eye opening may occur briefly at intervals.

Awake States

State 3: Drowsy or semi-dozing; eyes may be open but dull and heavy-lidded, or closed, eyelids fluttering; activity level variable, with interspersed, mild startles from time to time; reactive to sensory stimuli, but response often delayed; state change after stimulation frequently noted. Movements are usually smooth. Dazed look, the infant is not processing information and is not "available" to stimulation. This is also considered to be "transitional" and is sometimes difficult to score. Some infants may also show fuss/cry vocalizations in this state. When this happens, state 3 may be difficult to distinguish from state 5 (below). What distinguishes state 3 from state 5 when both are accompanied by fuss/cry vocalizations is the minimal movement in state 3 and considerable movement in state 5.

State 4: Alert, with bright look and appropriate changes in facial expression as stimulation is varied; focuses attention on source of stimulation, such as an object to be sucked, or a visual or auditory stimulus; impinging stimuli may break through, but with some delay in response. Motor activity is at a minimum. There can be glazed look which is easily changed into a brighter look with appropriate stimulation in this state.

State 5: Eyes open; considerable motor activity, with thrusting movements of the extremities, and even a few spontaneous startles; reactive to external stimulation with increase in startles or motor activity, but discrete reactions difficult to distinguish because of general activity level. Brief fussy vocalizations occur in this state. Some infants may transition directly from lower states (1, 2, or 3) directly to state 5. These are often the cases described above in which fuss/cry vocalizations occur and states 5 and 3 are difficult to distinguish unless the differences in motor activity are taken into account.

State 6: Crying characterized by intense, loud, rhythmic, and sustained cry vocalizations which are difficult to break through with stimulation; motor activity is high. It is important to distinguish between crying as a state from the fuss/cry vocalizations that can occur in state 5 and even in state 3. Some infants show repeated episodes of fuss/cry vocalizations in state 5 but may not reach state 6. This may also be a maturational issue as some preterm infants may not have the energy reserves to sustain state 6. In general, state 6 can be distinguished from state 5 by the intensity and sustained quality of the crying (at least 15 seconds) and unavailability of the infant in state 6.

APPENDIX I

PULL-TO-SIT PROCEDURE

1. Place one's thumbs in both of the infant's palms while holding onto the infant's wrists as he/she lies supine in the crib.
2. Pull to extend the infant's arms, initiating the infant's automatic grasp of the examiner's thumbs, and pull the infant to a sitting position. In the seated position the infant's arms can be extended laterally.
3. Observe the infant in the sitting position for his/her ability to bring the head up to midline.
4. Once it is demonstrated that the infant cannot bring the head to midline or cannot maintain the head in a midline position any longer, the procedure ends and the infant is scored.

APPENDIX J

ICSC DATA COLLECTION FORM

Participant Identification Number: Date of Testing:

Positioning	CSS make_____model_____ Clinical Engineering Label Intact/Date:_____ Checks • Safety seat harness secured • Retainer clip (if present) at level of axilla • Harness positioned at lowest level • Seat reclined o Angle of recline:_____degrees
Supports	Check all that apply blanket roll: [ ] head support [ ] right side [ ] left side [ ] between legs [ ] firm wedge placed beneath seat to attain desired tilt [ ] car seat base used
Screening	[ ] ____ minutes spent sleeping in CSS (States 1 & 2) [ ] Infant observed for 90 minutes and did not experience an oxygen desaturation event. [ ] Infant observed for ___ minutes and experienced an oxygen desaturation event. [ ] Infant did experience intolerance to CSS. Explain_____. [ ] Test discontinued due to another reason. Explain_____. Recommendation: [ ] Discharge home in car seat. [ ] Discharge home in car bed. Recommendation report to: _____ MD/NNP. Signature of Researcher:_____.

APPENDIX K

INFANT DEMOGRAPHICS & GENERAL DATA COLLECTION FORM

Participant Identification Number: Date of Testing:

Demographics	DOB_____ Chronological age_____ GA at birth _____ Birth Weight_____ GA at discharge _____ Discharge Weight _____ Sex M [ ] F [ ] Race___ (W-white, B-black, H-Hispanic, A- Asian, O-other)
Medical History	Birth C/S_____ Vaginal_____ Vacuum Assist_____ Forceps_____ Discharge Diagnosis: check all that apply Anemia [ ] Apnea of Prematurity [ ] Hyperbilirubinemia [ ] Hypotension [ ] IVH grade_____ [ ] NEC [ ] PDA [ ] Pneumonia [ ] Pneumothorax [ ] PPHN [ ] RDS [ ] Respiratory distress [ ] ROP [ ] Sepsis Confirmed [ ] Sepsis Presumed [ ] TTN [ ] Other: list _____ _____ _____ _____ _____ _____

APPENDIX L

PULL-TO-SIT MEASURE

Participant ID: _____ Date: _____

Score 1: Head flops completely in pull-to-sit, no attempts to right it in sitting.

Score 2: Futile attempts to right head but shoulder tone increase is felt.

Score 3: Slight increase in shoulder tone, seating brings head up once but not maintained, no further efforts. Head may pivot briefly through.

Score 4: Shoulder and arm tone increase, seating brings up head, not maintained at midline but there are further efforts to right it.

Score 5: Head and shoulder tone increase as pulled to sit, brings head up once to midline by self as well, maintains it for at least 1-2 seconds

Score 6: Head brought up twice after seated, then can keep it in position 2 seconds or more.

Score 7: Shoulder tone increase but head not maintained until seated, then can keep it in position 10 seconds. When it falls, repeatedly rights it.

Score 8: Excellent shoulder tone, head up for 10 seconds after seated, no head lag as comes up.

Score 9: Head up during lift and maintained for 1 minute after seated, shoulder tone and whole body tone increases as pulled to sit.

Score 10: Hypertonic response; upper trunk and neck rigid, head comes up in vertical plane with back, or legs stiffen and infant pulls to standing position.

Score 11: Infant resists flexion and head righting by arching backward and item cannot be administered.

Score 98: Item not administered because infant is not in an appropriate state.

Score 99: Item not administered due to examiner error.

STATE: _____

SCORE: _____

APPENDIX M

CAR SEAT EDUCATION FOR PARENTS

Dear Parent(s),

Thank you for participating in the study, "Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events." As you know, your infant underwent two tests in his or her own car seat during the study. Your infant passed both tests.

Passing the test means that your infant did not experience breathing problems when in the semi-upright sitting position. Even though this information is reassuring, this test does not guarantee that your infant will not experience breathing problems in the future. It is still recommended that an adult sit in the back seat with your infant to observe him/her during travel.

Please refer to the car seat education handout in your parent folder. This handout has important information about keeping your baby safe during travel.

Read the manufacturer's guidelines for your automobile and for the child restraint device you have chosen to be sure that they can be used together.

It is recommended that you have your child restraint device installed by a trained technician. Many local police and fire departments have child passenger safety (CPS) technicians available to help you.

Send in the registration card that came with your child restraint device so that the company can notify you of any recalls.

If you notice any problem with your infant's breathing when he/she is in the car seat, stop the car, remove your infant from the car seat, and call your infant's pediatrician.

Best Wishes.

APPENDIX N

CAR BED EDUCATION FOR PARENTS

Dear Parent(s),

Thank you for participating in the study, "Stability of the Infant Car Seat Challenge and Risk Factors Associated with Oxygen Desaturation Events." As you know, your infant underwent two tests in his or her own car seat during the study. Your infant did not pass the test during at least one of the two testing periods. Not passing the test means that your infant had some breathing problems when in the semi-upright sitting position. Many babies have this same problem.

The American Academy of Pediatrics recommends that infants who do not pass the Infant Car Seat Challenge test travel in a car bed. Therefore, it is recommended that your infant travel in a car bed. It is also recommended that you do not put your infant in any other seating devices such as an infant seat, swing or upright seat in a stroller.

Car beds have the same FMV approval as car seats but crash testing of car beds is reported to be incomplete. However, car beds are the only available alternative to car seats. As a parent, you can choose whether or not to purchase a car bed for your infant.

It is not clear at this time when it will be safe for your infant to use a traditional style car seat. You should ask your pediatrician about using a traditional car seat when you notice that your infant can hold up his/her head without help. This ability usually comes at about 2 months of age. However, infants who are born prematurely may not hold up their head until they are older than two months.

It is important to read the manufacturer's guidelines for your automobile and for the child restraint device you have chosen to be sure they are compatible. It is important that you have your child restraint device installed by a trained technician. Many local police and fire departments have child passenger safety (CPS) technicians available to help you.

Whatever your choice of child restraint device, it is recommended that you travel in the back seat to observe your infant.

Never position the infant near an active air bag in the car.

Send in the registration card that came with your child restraint device so that the company can notify you of any recalls.

You may purchase a car bed by contacting:

Make/Model	Cost	Contact
Cosco Ultra Dream Ride, fits infants up to 20 lbs., converts to a car seat	$55	Critical Concepts 781-944-1940
Angle Guard by Mercury Distributing, fits infants up to 9 lbs. and 20 inches	$69.38 plus shipping	Mercury Distributing 1-800-815-6330

Best Wishes.

APPENDIX O

PULL-TO-SIT VALIDATION

Research Assistant #1: 90% agreement

Patient #	State	Score
1	4	3
2	3	7
3	5	5
4	3	2
5	5	5
6	3	6
7	2	3
8	¾	5
9	3	5
10	5	5

Research Assistant #2: 90% agreement

Patient #	State	Score
1	4	8
2	5	8
3	4	2
4	5	1
5	3	5
6	5	3
7	3	4
8	5	6
9	4	4
10	¾	5

Research Assistant #3: 90% agreement

Patient #	State	Score
1	3	2
2	3	1
3	5	6
4	4	3
5	5	3
6	4	7
7	5	6
8	6	5
9	3	2/1
10	5	5

APPENDIX P

STUDY TIMELINE

	mo 1	mo 2	mo 3	Mo 4	mo 5	Mo 6	mo 7	mo 8	mo 9	mo 10	mo 11	mo 12	mo 13
Apply for medical center approval to do study	X												
Apply for IRBs at medical center & UMass	X												
Recruit RAs	X												
Train RAs	X	X											
Educate staff		X	X										
Recruit participants (goal = 4/week)			X	X	X	X	X	X	X				
Collect data				X	X	X	X	X	X				
Analyze data									X	X			
Write up findings											X	X	
Defend dissertation													X

APPENDIX Q

SUMMARY OF FAILED ICSCs

ID	Gestational age	Corrected Gestational Age	Chronological Age	Sex	Birth Route	Car Seat Make	Car Seat Model	Restraint type	ICSC #1		ICSC #2		Sleep time min.	
									P/F	min.	P/F	Min.	#1	#2
114	34	38	22	M	C/S	Baby Trend	6000	5 point	F	75	F	54	47	54
118	32	35	21	M	C/S	Graco	8465BKW	5 point	F	3	F	<1	0	0
120	36	36	2	F	C/S	Graco	7411BLB	5 point	P	90	F	40	79	2
121	34	35	8	M	C/S	Graco	8465BKW	5 point	F	58	F	40	39	39
137	33	35	14	M	Vaginal	Graco	864CJG	5 point	F	4	F	16	4	0
134	35	36	2	F	C/S	Evenflow	3751353	5 point	P	90	F	8	35	0
123	36	37	2	F	C/S	Graco	8474HAB	5 point	P	90	F	7	55	1
126	33	34	8	M	Vaginal	Graco	8645CLN	5 point	F	27	P	90	27	88
128	27	37	66	F	C/S	Graco	8446IVY	5 point	F	7	F	12	1	12
147	36	36	4	M	C/S	Eddie Bauer	02-643-MET	5 point	F	43	P	90	38	82
149	36	36	2	F	C/S	Graco	7449BKW	5 point	P	90	F	13	85	4
155	35	35	1	F	Vaginal	Graco	8457THJ	5 point	F	8	P	90	1	84

APPENDIX R

CODEBOOK

Participant ID:_____ Date:

Category		
DOB Position 1-8	XX/XX/XX	___/___/___
Chronological Age Position 9-11	Value (1-200) corresponds with days of life	_____
Gestational Age at birth Position 12-13	23 weeks 24 weeks 25 weeks 26 weeks 27 weeks 28 weeks 29 weeks 30 weeks 31 weeks 32 weeks 33 weeks	34 weeks 35 weeks 36 weeks 37 weeks 38 weeks 39 weeks 40 weeks 41 weeks 42 weeks 43 weeks 44 weeks _____
Gestational Age at discharge Position 14-15	34 weeks 35 weeks 36 weeks 37 weeks 38 weeks 39 weeks 40 weeks 41 weeks 42 weeks	43 weeks 44 weeks 45 weeks 46 weeks 47 weeks 48 weeks 49 weeks 50 weeks 51 weeks _____
Gender Position 16	1 male 2 female	_____
Race Position 17	1 white 2 black 3 Hispanic 4 Asian 5 Other	_____

Category		
Birth Mode Position 18	1 C/S 2 Vaginal 3 Vacuum 4 Forceps	_____
O_2 Desaturation 1,2 Position 19 & 20	1 yes 2 no	_____
Intolerance Position 31	1 yes 2 no	_____
Test discontinued Position 32	1 yes 2 no	
Discharge Diagnosis Position 21-29 1 yes 2 no	Anemia Apnea of Prematurity Hyperbilirubinemia Hypotension IVH NEC PDA Pneumonia Pneumothorax PPHN RDS ROP Presumed Sepsis Sepsis	R/O Sepsis TTN Heart Murmur Stridor Hypoglycemia Conjunctivitis Resp Distress Twin gestation Sacral Dimple IUGR Feeding NAS other **Circle all that apply**
Bed or Seat Position 30	1 seat 2 bed	_____
Minutes sleeping 1 & 2 Position 33 & 34	1-90	_____ 1

Category		
Pull-To-Sit State Position 35	1 state 1 2 state 2 3 state 3	4 state 4 5 state 5 6 state 6
Pull-To-Sit Score Position 36 & 37	1-11 98 99	_____
Hours between tests Position 38 &39	1-36	_____

Harness type Position 40	1 3pt 2 5pt	_____
Discharge weight Position 41-44	400-4000	_____
Birth Weight Position 45-48	1200-5000	_____

BIBLIOGRAPHY

Allen, M. C., & Capute, A. J. (1990). Tone and reflex development before term. *Pediatrics, 85*, 393-399.

Alyward, G. P., Hatcher, R. P., Leavitt, L. A., Rao, V., Bauer, C. R., Brennan, M. J., et al. (1984). Factors affecting neurobehavioral responses of preterm infants at term conception. *Child Development, 55*, 1155-1165.

American Academy of Pediatrics. (1990). Safe transportation of newborns discharged from the hospital. *Pediatrics, 86*(3), 486-487.

American Academy of Pediatrics. (1991). Safe transportation premature infants. *Pediatrics, 87*(1), 120-122.

American Academy of Pediatrics. (1996). *Safe transportation of premature and low birth weight infants*. Retrieved February 21, 2002, from http://www.medem.com/search/article_display.cfm?path=n:mstr=ZZZO1N6ZUCC.html

American Academy of Pediatrics. (1999). Safe transportation of newborns at hospital discharge. *Pediatrics, 104*(4), 986-987.

Amiel-Tison, C. (1968). Neurological evaluation of the maturity of newborn infants. *Archives of Disease in Childhood, 43*, 89-93.

Anderson, R. N., & Smith, B. L. (2003). Deaths: Leading causes for 2001. *Centers for Disease Control, National Vital Statistics Reports, 52*(9).

Bahr, L. S., & Johnston, B. (Eds.). (1993). *Collier's encyclopedia* (Vol. 1). New York: P. F. Collier.

Barrington, K., J., & Finer, N. (1990). Periodic breathing and apnea in preterm infants. *Pediatric Research, 27*(2), 118-121.

Barrington, K., J., Finer, N., & Li, D. (1996). Predischarge respiratory recordings in very low birth weight newborn infants. *The Journal of Pediatrics, 129*(6), 934-940.

Bass, J. L., & Mehta, K. A. (1995). Oxygen desaturation of selected term infants in car seats. *Pediatrics, 96*(2), 288-290.

Bass, J. L., Mehta, K. A., & Camara, J. (1993). Monitoring premature infants in car seats: Implementing the american academy of pediatrics policy in a community based hospital. *Pediatrics, 91*(6), 1137-1141.

Block, D., E., Hanson, T., K., & Keane, A. (1998). Child safety seat misuse: Home visiting assessment and intervention. *Public Health Nursing, 15*(4), 250-256.

Brazelton, T. B. (1984). *Neonatal behavioral assessment scale* (2 ed.). Philadelphia: J.B. Lippincott.

Bull, M. J., & Stroup, K. B. (1985). Premature infants in car seats. *Pediatrics, 75*(2), 336-339.

Bull, M. J., Stroup, K. B., & Gerhardt, S. (1988a). Misuse of car safety seats. *Pediatrics, 81*(1), 98-101.

Bull, M. J., Weber, K., & Stroup, K. B. (1988b). Automotive restraint systems for premature infants. *The Journal of Pediatrics, 112*, 385-388.

Burns, N., & Grove, S. K. (2001). The concepts of measurement. In *The practice of nursing research, conduct, critique & utilization* (4th ed., pp. 389-410). Philadelphia: W. B. Saunders.

Callahan, C. W., & Sisler, C. (1997). Use of seating devices in infants too young to sit. *Archives of Pediatric and Adolescent Medicine, 151*, 233-235.

Carbone, T., Marrero, L., C., Weiss, J., Hiatt, M., & Hegyi, T. (1999). Heart rate and oxygen saturation correlates of infant apnea. *Journal of Perinatology, 19*(1), 44-47.

Carlo, W. A., Beoglos, A., Siner, B. S., & Martin, R. J. (1989). Neck and body position effects on pulmonary mechanics in infants. *Pediatrics, 84*, 670-674.

Centers for Disease Control and Prevention. (2004). Births: Preliminary data for 2003. *53*(9), 1-6.

Cheung, P., Barrington, K., J., Finer, N., N., & Robertson, C., M., T. (1999). Early childhood neurodevelopment in the very low birth weight infants with predischarge apnea. *Pediatric Pulmonology, 27*, 14-20.

Children's Hospital Boston. (2004). Infant car seat challenge, *The Nursing Policy and Procedure Manual* (pp. 1-3).

Clemens, C., J. , Davis, S., A. , & Bailey, A., R. (2000). The false-positive in universal newborn hearing screening. *Pediatrics, 106*(1), p. e7.

Comeau, A., M., Parad, R., Dorkin, H., L., Dovey, M., Gerstle, R., Haver, K., et al. (2004). Population-based newborn screening for genetic disorders when multiple mutation DNA testing is incorporated: A cystic fibrosis newborn screening model demonstrating increased sensitivity but more carrier detections. *Pediatrics, 113*(6), 1573-1581.

Corometrics. (2004). *Corometrics model 556c neonatal monitor general information.* Retrieved May 15, 2004, from http://www.1-medical-equipment.com/Vendors/MEI/Products/556CINFO.HTM

Dawson, J. A., & Stainton, M. C. (2004). The australian safe-n-sound baby safety capsule and its effect on oxygen saturation values in infants ready for discharge home. *Neonatal Network, 23*(4), 25-31.

deBeer, G. (1978). Adaptation. In J. J. Head (Ed.). Burlington, NC: Scientific Publications Division, Carolina Biological Supply Co.

DiFiore, J., M., Arko, M., K., Miller, M., J., Krauss, A., Betkerur, A., Zadell, A., et al. (2001). Cardiorespiratory events in preterm infants referred for apnea monitoring studies. *Pediatrics, 108*(6), 1304-1308.

Dollberg, S., Yacov, G., Mimouni, F., & Ashbel, G. (2002). Effect of head support on oxygen saturation in preterm infants restrained in a car seat. *American Journal of Perinatology, 19*(3), 115-118.

Duffy, M. E., & Jacobsen, B. S. (2001). Univariate descriptive statistics. In B. H. Munro (Ed.), *Statistical methods for healthcare research* (4 ed., pp. 29-62). Philadelphia: Lippincott.

Eichenwald, E., C., Aina, A., & Stark, A., R. (1997). Apnea frequently persists beyond term gestation in infants delivered at 24 to 28 weeks. *Pediatrics, 100*(3), 354-359.

Elite Car Seats. (2000-2004). *Safeline sit 'n' stroll car seat/stroller.* Retrieved May 16, 2004, from http://www.elitecarseats.com/safeline-sit-n-stroll.shtml

Fetus and Newborn Committee, C. P. S. (2000). Assessment of babies for car seat safety before hospital discharge. *Paediatrics & Child Health, 5*(1), 53-56.

Forslund, M., & Bjerre, I. (1983). Neurological assessment of preterm infants at term conceptional age in comparison with normal full-term infants. *Early Human Development, 8*, 195-208.

Fuchs, S., Barthel, M., J., Flannery, A., M., & Christoffel, K., K. (1989). Cervical spine fractures sustained by young children in forward-facing car seats. *Pediatrics, 84*(2), 348-354.

Gaultier, C. (1990). Respiratory adaptation during sleep in infants. *Lung, Supplement*, 905-911.

Goddard-Finegold, J. (1998). The nervous system during birth. In H. W. Taeusch & R. A. Ballard (Eds.), *Avery's diseases of the newborn* (7 ed., pp. 833-838). Philadelphia: W. B. Saunders Company.

Goto, K., Mirmiran, M., Adams, M., M., Longford, R., V., Baldwin, R., B., Boeddiker, M., A., et al. (1999). More awakenings and heart rate variability during sleep in preterm infants. *Pediatrics, 103*(3), 603-609.

Gray, J. E., Richardson, D. K., McCormick, M. C., Workman-Daniels, K., & Goldman, D. A. (1992). Neonatal therapeutic intervention scoring system: A therapy based severity-of- illness index. *Pediatrics, 90*(4), 561-567.

Guyton, A., & Hall, J. (1996a). Respiratory insufficiency-pathophysiology, diagnosis, oxygen therapy. In *Textbook of medical physiology* (9 ed., pp. 537-545). Philadelphia: W. B. Saunders Company.

Guyton, A., & Hall, J. (1996b). Sensory receptors: Neuronal circuits for processing information. In *Textbook of medical physiology* (9 ed., pp. 583-594). Philadelphia: W.B. Saunders Company.

Guyton, A., & Hall, J. (1996c). Somatic sensations: I. General organization; the tactile and position senses. In *Textbook of medical physiology* (9 ed., pp. 595-607). Philadelphia: W.B. Saunders Company.

Guyton, A., & Hall, J. (1996d). Transport of oxygen and carbon dioxide in the blood and body fluids. In *Textbook of medical physiology* (9 ed., pp. 513-523). Philadelphia: W.B. Saunders Company.

Harrison, L., L., Leeper, J., D., & Yoon, M. (1990). Effects of early parent touch on preterm infants' heart rates and arterial oxygen saturation levels. *Journal of Advanced Nursing, 15*, 877-885.

Hertz, G., Aggarwal, R., Rosenfeld, W. N., & Greensher, J. (1994). Premature infants in car seats: Effect of sleep state on breathing. *Journal of Sleep Research, 3*(3), 186-190.

Holditch-Davis, D., Edwards, L., J., & Wigger, M., C. (1994). Pathologic apnea and brief respiratory pauses in preterm infants: Relation to sleep. *Nursing Research, 43*(5), 293-300.

Iloeje, S. O., Obiekwe, W. N., & Kaine, W. N. (1991). Gross motor developments of nigerian children. *Annuals of Tropical Pediatrics, 11*, 33-39.

Jeffery, H., E., & Heacock, H., J. (1991). Impact of sleep and movement on gastroesopahgeal reflux in healthy newborn infants. *Archives of Disease in Childhood, 66*, 1136-1139.

Kattwinkel, J. (1977). Neonatal apnea: Pathogenesis and therapy. *The Journal of Pediatrics, 90*(3), 342-347.

Koumudi, G., Barve, S., & Chaudhari, S. (1997). Early predictors of neurodevelopmental outcome in high risk infants. *Indian Pediatrics, 34*, 491-495.

Lees, M. H. (1970). Cyanosis of the newborn infant. *Fetal and Neonatal Medicine, 77*(3), 484-498.

Lester, B. M., & Tronick, E. Z. (2001). Behavioral assessment scales. In L. T. Singer & P. S. Zeskind (Eds.), *Behavioral assessment of the infant* (pp. 363-379). New York: Guilford Press.

Lester, B. M., & Tronick, E. Z. (2002). *Nicu network neurobehavioral scale (nnns)*.Unpublished manuscript.

Linder, N., Tsur, M., Kuint, J., German, B., Birenbaum, E., Mazkereth, R., et al. (1998). A simple clinical test for differentiating physiological from pathological head lag in full term newborn infants. *European Journal of Pediatrics, 157*(6), 502-504.

Loscher, W., N., Einspieler, C., Klug, E., M., Haidmayer, R., Gallasch, E., Kurz, R., et al. (1990). Neurological status, sleep apnea frequency, and blood oxygenation in six week old infants. *Early Human Development, 24*, 119-130.

Majnemer, A., Brownstein, A., Kadanoff, R., & Shevell, M. I. (1992). A comparison of neurobehavioral performance of healthy term and low-risk preterm infants at term. *Developmental Medicine & Child Neurology, 34*, 417-424.

Manning, D. J., & Stothers, J. K. (1991). Sleep state, hypoxia, and periodic breathing in the neonate. *ACTA Paediatrica Scandinavia, 80*, 763-769.

Martin, J. A., Hamilton, B. E., Sutton, P. D., Ventura, S. J., Menacker, F., & Munson, M. L. (2003). Births: Final data for 2002. *Centers for Disease Control, National Vital Statistics Report, 52*(10), 1-99.

Martin, R. J., & Fanaroff, A. A. (1998). Neonatal apnea, bradycardia, or destaurtion: Does it matter? *The Journal of Pediatrics, 132*(5), 758-759.

Martin, R. J., Miller, M. J., & Waldemar, A. C. (1986). Pathogenesis of apnea in preterm infants. *The Journal of Pediatrics, 109*(5), 733-741.

Masimo Corporation. (2004). *What's the difference*. Retrieved May 15, 2004, from http://www.masimo.com/whymasimo/difference.htm

McCormick, M. C. (1989). Long-term follow-up of infants discharged from neonatal intensive care units. *JAMA, 261*(12), 767-1772.

Merchant, J. R., Worwa, C., Porter, S., Coleman, J. M., & deRegnier, R. O. (2001). Respiratory instability of term and near-term healthy newborn infants in car seats. *Pediatrics, 108*(3), 647-652.

Mercuri, E., Guzzetta, A., Laroche, S., Ricci, D., vanHaastert, I., Simpson, A., et al. (2003). Neurologic examination of preterm infants at term age: Comparison with term infants. *Journal of Pediatrics, 142*, 647-655.

Miller, M. J., & Martin, R. J. (1998). Apnea in infancy, progress in diagnosis and implications for management. *8*(1), full publication.

Mish, F. C. (Ed.). (2003). *Merriam-webster's collegiate dictionary* (11th ed.). Springfield, MA: Merriam-Webster Inc.

Modrcin-Talbott, M. A., Harrison, L., Law, Groer, M., W., & Younger, M. S. (2003). The biobehavioral effects of gentle human touch on preterm infants. *Nursing Science Quarterly, 16*(1), 60-67.

Mok, J., Y, Q., Hak, H., McLaughlin, F., J., Pintar, M., Canny, G., J., & Levison, H. (1988). Effect of age and state of wakefulness on transcutaneous oxygen values in preterm infants: A longitudinal study. *The Journal of Pediatrics, 113*(4), 706-709.

Molteno, C., Magasiner, V., Sayed, R., & Karplus, M. (1990). Postural development in very low birth weight and normal birth weight infants. *Early Human Development, 24*, 93-105.

Mullen, D., & Courts, J. (2002). Monitoring premature babies in car seats: The car seat challenge. *Journal of Neonatal Nursing, 8*(4), 131.

Nagase, H., Yonetani, M., Uetani, Y., & Nakamura, H. (2002). Effects of child seats on the cardiorespiratory function of newborns. *Pediatrics International, 44*, 60-63.

Nellcor Puritan Bennett Inc. (2004). *N-395 pulse oximeter*. Retrieved May 15, 2004, from http://www.nellcor.com/prod/Product.aspx?id=223

Newburger, J. W., Silbert, A. R., Buckley, L. P., & Flyer, D. C. (1984). Cognitive function and age at repair of transposition of the greater arteries in children. *New England Journal of Medicine, 310*, 1495-1499.

Norris, S., Campbell, L. A., & Brenkert, S. (1982). Nursing procedures and alterations in transcutaneous oxygen tension in premature infants. *Nursing Research, 31*(6), 330-336.

O'Brodovich, H. M., & Haddad, G. G. (1998). The functional basis of respiratory pathology and disease. In V. Chernick, T. Boat, F. & J. Flectcher (Eds.), *Kendig's disorders of the respiratory tract* (6 ed., pp. 27-73). Philadelphia: W. B. Saunders Company.

Orr, W. C., Stahl, M. L., Duke, J., McCaffree, M. A., Toubas, P., Mattice, C., et al. (1985). Effect of sleep state and position on the incidence of obstructive and central apnea in infants. *Pediatrics, 75*(5), 832-835.

Oxford English Dictionary Online. (2002). Retrieved March 7, 2002, from http://.../00002392?case_id=Fg9p-UGXJQq-9217&p=&d=1&sp=1&qt=1&ct=0&ad=1&print=

Pasterkamp, H. (1998). The history and physical examination. In V. Chernick & T. Boat, F. (Eds.), *Kendig's disorders of the respiratory tract in children* (6 ed., pp. 85-106): W. B. Saunders Company.

Perlman, J. M., & Volpe, J. J. (1985). Episodes of apnea and bradycardia in the preterm newborn: Impact on cerebral circulation. *Pediatrics, 76*(3), 333-338.

Pilley, E., & McGuire, W. (2005). The car seat: A challenge too far for preterm infants. *Archives of Disease in Childhood Fetal Neonatal Edition, 90*, F452-F455.

Poets, C. F. (1998). When do infants need additional inspired oxygen? A reveiw of the current literature. *Pediatric Pulmonology, 26*, 424-428.

Poets, C. F., Rau, G. A., Neuber, K., Gappa, M., & Seidenberg, J. (1997). Determinants of lung volume in spontaneously breathing preterm infants. *American Journal of Respiratory and Critical Care Medicine, 155*, 649-653.

Poets, C. F., Stebbens, V. A., Alexander, J. R., Arrowsmith, W. A., Salfield, S. A. W., & Southall, D. P. (1991). Oxygen saturation and breathing patterns in infancy. 2: Preterm infants at discharge from special care. *Archives of Pediatric and Adolescent Medicine, 66*, 574-578.

Poets, C. F., Stebbens, V. A., Lang, J. A., O'Brien, L. M., Boon, A. W., & Suthall, D. P. (1996). Arterial oxygen saturation in healthy term neonates. *European Journal of Pediatrics, 155*, 219-223.

Polit, D. F., & Hungler, B. P. (1995). Experimental, quasi-experiemental, and nonexperimental designs. In *Nursing research priniciples and methods* (5 ed., pp. 157-186). Philadelphia: J. B. Lippincott Company.

Prechtl, H. F. (2001). General movement assessment as a developmental neurology: New paradigms and their consequences. *Developmental Medicine & Child Neurology, 43*, 836-842.

Prechtl, H. F., & Beintema, D. (1965). *The neurological examination of the full term newborn infant*. Lavenham, UK: The Lavenham Press LTD.

Prechtl, H. F., Fargel, J. W., Weinmann, H. M., & Bakker, H. H. (1979). Postures, motility, and respiration of low-risk preterm infants. *Developmental Medicine & Child Neurology, 21*, 3-27.

Richardson, D. K., Corcoran, J. D., Escobar, G. J., & Lee, S. K. (2001). Snap-ii and snappe-ii: Simplified newborn illness severity, and mortality risk scores. *The Journal of Pediatrics, 138*(1), 92-100.

Roy, S. C. (1984). *Introduction to nursing an adaptation model* (2 ed.). Englewood Cliffs, NJ: Prentice-Hall Inc.

Roy, S. C., & Andrews, H., A. (1999). *The roy adaptation model* (2 ed.). Stamford: Appleton & Lange.

Sahni, R., Schulze, K., F., Stefanski, M., Myers, M., M., & Fifer, W., P. (2004). Metodological issues in coding sleep states in immature infants. *Developmental Psychobiology, 28*(2), 85-101.

Scanlon, J. (1994). The very-low-birth-weight-infant. In G. Avery, M. A. Fletcher & M. MacDonald (Eds.), *Neonatology pathophysiology and management of the newborn* (4th ed., pp. 399-416). Philadelphia: J. B. Lippinoctt Company.

Scher, M., S., Johnson, M., W., & Holditch-Davis, D. (2005). Cyclicity of neonatal sleep behaviors at 25 to 30 weeks postconceptional age. *Pediatric Research, 57*(6), 879-882.

Smith, P. S., & Turner, B. S. (1990). The physiologic effects of positioning premature infants in car seats. *Neonatal Network, 9*(4), 11-15.

The New Encyclopaedia Britannica. (1998). (15 ed. Vol. 1). Chicago: Encyclopaedia Inc.

Tin, W., Wariyar, U., & Hey, E. (1997). *Changing prognosis for babies of less than 28 weeks' gestation in the north of england between 1983 and 1994*. Retrieved May 22, 2004, from http://bmj.bmjjournals.com/cgi/content/full/314/7074/107?maxtoshow=&HITS=10&hits=...

Tonkin, S., L. (1998). Airway of babies in car seats. *New Zealand Medical Journal*, 372.

Tonkin, S. L., McIntosh, C. G., Hadden, W., Dakin, C., Rowley, S., & Gunn, A. (2003). Simple car seat insert to prevent upper airway narrowing in preterm infants, a pilot study. *Pediatrics, 112*(4), 907-911.

Weber, K. (2000). Crash protection for child passengers. *UMTRI Research Review, 31*(3), 1-28.

Weber, K. (2001). *Rear-facing car seats: What you need to know*. Retrieved May 16, 2004, from

http://www.parentsplace.com/babies/safety/articles/0,10335,240282_263876,00.html

Willett, L. D., Leuschen, M. P., Nelson, L. S., & Nelson, R. M. (1986). Risk of hypoventilation in premature infants in car seats. *The Journal of Pediatrics, 109*(2), 245-248.

Willett, L. D., Leuschen, M. P., Nelson, L. S., & Nelson, R. M. (1989). Ventilatory changes in convalescent infants positioned in car seats. *The Journal of Pediatrics, 115*, 451-455.

Williams, L. E., & Martin, J. E. (2003). Car seat challenges, where are we implementing these programs. *The Journal of Perinatal & Neonatal Nursing, 17*(2), 158-163.

World Book Encyclopedia. (2002). Chicago: World Book Inc.

Young, B., Shapira, S., & Finer, N. N. (1996). Predischarge car seat study for premature infants. *Paediatric Child Health, 1*(3), 202-205.