IMPACT OF COMMON MORBIDITY ON ATTAINMENT OF ORAL FEEDING SKILLS IN A MODERN COHORT OF INFANTS BORN PREMATURELY: A RETROSPECTIVE ANALYSIS

by

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ABSTRACT

Feeding during infancy is a complicated, multidimensional task involving dynamic coordination between sucking, swallowing, and breathing (Wolf & Glass, 1992). The synactive theory of infant development discusses the influence of the autonomic, motor, and state systems on the resulting stability and homeostasis of newborns (Als, 1982). The synactive theory proposes that the core of stability for all developing infants is the autonomic nervous system, especially the respiratory, circulatory, and digestive systems. The motor system supports the development of the state system – levels of arousal that range from deep sleep to a vigorous cry. The ability to attend and to actively process incoming stimuli is supported by the ability to maintain stability in the autonomic and motor systems and remain alert (Ross, 2012). By the synactive theory, feeding can be conceptualized as a developmental skill that emerges when the coordination for sucking/swallowing/breathing is present at approximately 35 weeks post gestational age along with maturation of the state system (Ross, 2012). Previous research has established that many common newborn morbidities, such as those that impact the cardiac and respiratory systems, can delay the post gestational age at which infants born prematurely achieve full oral feeding competency. The purpose of this project is to establish the impact of common newborn morbidities, as measured by the Morbidity Assessment Index for Newborns, on the resulting transition time and post conceptual age at which a modern cohort of preterm infants attain the skills and coordination necessary to support nutritional intake by exclusive oral means.

DEDICATION

This thesis is dedicated to everyone who helped me and guided me through the trials and tribulations of creating this manuscript. In particular, my family, supervisor, and close friends who stood by me throughout the time taken to complete this masterpiece.

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1. INTRODUCTION

Infants born less than 32 weeks gestational age at increased risk for delayed achievement of feeding competence. This can result in prolonged hospitalization and increased cost of hospital stay (Ross, 2012). Young infants feed by sucking which is a complicated, multidimensional task involving a dynamic coordination between sucking, swallowing, and breathing dependent upon many interrelated factors. These interrelated tasks help encourage development of sucking skills in newborns. Nutritive sucking is rarely fully developed or coordinated before 34 weeks of gestation (Bernbaum et al., 1983). Non-nutritive sucking however, is present in utero as early as 15 weeks gestation (Delaney and Arvedson, 2008). Recent literature has inconsistent information regarding the gestational age at which a preterm infant attains feeding skills (Dalton, 2017; Delany & Arvedson, 2008; Foster et al, 2017; Hack, 1985; Morris, 1982; Pinelli & Symigton, 2011). The purpose of this project is to establish the impact of common newborn morbidities, as measured by the Morbidity Assessment Index for Newborns, on the transition time or the post gestational age at which a modern cohort of preterm infants attain the skills and coordination necessary to support nutritional intake by exclusive oral means. This study will shed light on when oral feeding will be obtained for infants in level II –III Neonatal intensive care units (NICUs) as well as when interventions may be beneficial.

2. BACKGROUND AND LITERATURE REVIEW

Typical Infant Feeding.

Embryonic Period. The anatomical structures for swallowing include the nose, mouth, pharynx, airways, and esophagus. Studies of embryonic development have determined that the central nervous system and neural folds begin developing as early as 3 weeks gestation (Dalton, 2017). The head and tail folds form the primordium of the brain by the beginning of the 4th gestational week, along with tissue differentiation that forms various organ systems (Moore & Persaud, 2008). By 24 days gestation, the first pair of pharyngeal arches has appeared, with four pairs visible by 28 days gestation (Moore & Persaud). Growth of the head is caused by the rapid development of the brain and facial prominences during the 5th week of development. Also beginning to develop in week 5 are the arytenoids, epiglottis, cranial nerves, lung buds, larynx, esophagus, and trachea (Dalton). These are all significant in the development of suck, swallow, breathing coordination in infants. The face contacts the heart prominence during this time. During the sixth week, the head is much larger relative to the trunk and is bent over the large heart prominence due to the bending in the cervical, neck region. Lip and palate components of the upper lip begin developing in the embryo as early as the 7th week gestational age, with the tongue and rounded head appearing by the 8th week gestational age. The scalp vascular plexus appears and forms a characteristic band around the head during the 8th week of gestation. By the end of the 8th week the nose and mouth are present, along with other human characteristics (Moore & Persaud).

Fetal Period. Shallow grooves above the taste bud primordium appear on the tongue during week 10, with maximum synapses between cells and afferent nerve fibers occurring between weeks 12 and 13, and taste pores developing during week 14 to 15 (Hill, 2017). The hard and soft palates begin to fuse by week 12 gestation. (Dalton, 2017). Facial skeleton remodeling begins of the head during the second trimester, which clinically begins at the 14th week gestational age (Hill). The head becomes erect is also during the 14th week of gestation that the head becomes erect (Moore & Persaud, 2008).

The pharyngeal swallow is present between weeks 13 and 16 and continues to strengthen throughout the remainder of the fetal development (Dalton, 2017). The fetus is capable of sucking and swallowing amniotic fluid in utero indicating that the motor program for these acts is functioning long before gestation is complete (Hack, 1985). Sucking appears at 15 weeks gestation but is not sufficient for survival of the fetus outside of the womb (Pinelli et al, 2011). Sucking and swallowing are fully present by 28 weeks gestation, although not fully coordinated until about 32 to 34 weeks gestation (Pinelli et al). Young infants feed primarily by sucking, which is composed of two components: compression (positive pressure on the nipple/ source of nutrients) and suction (negative pressure created when the jaw drops down while the tongue maintains contact with the nipple, creating a change in pressure and drawing the fluid into the mouth (Ross, 2012; Wolf & Glass, 1992). However, three processes – sucking, swallowing, and breathing – are the cornerstones of infant feeding. By 21 to 36 weeks gestation, behaviors associated with the development of arousal states begin, with the latest behaviors to develop including focused awareness, social reciprocity, and object play (Ross, 2012).

Extrauterine Environment. The anatomical structures responsible for sucking, swallowing, and breathing are physically close in proximity and overlap in function (Wolf &

Glass, 1992). The nose (nasal cavity), mouth (oral cavity), pharynx (combined channel), airways (larynx and trachea), and esophagus provide a conduit for passage of both air (into and out of the lungs) and food (to the stomach). Air may pass through the food passages (pharynx and esophagus) with little impact, but when food enters the air passages (pharynx, larynx, and trachea) serious consequences may result (Wolf & Glass).

Throughout the processes of sucking, swallowing, and breathing, there are numerous muscular connections between the structures of the mouth, pharynx, larynx, skull, and shoulder girdle. These are the basis for the reciprocal influences between feeding, swallowing, and breathing, and head and neck posture. The key role in this relationship is the muscular attachments to the hyoid bone. It is the site for muscular interface between the mandible (jaw), tongue, temporal bone, cervical vertebrae, laryngeal cartilages, and scapulae (Wolf & Glass, 1992).

Air and food are moved through the system of chambered organs through muscular activity and changing pressure gradients (Kennedy & Kent, 1988). To accommodate the transport of air and food through the same and adjacent structures in a safe manner, a system of "valves" channels food and air in the proper direction at the proper time (Morris, 1982). The resting position of these valves favors respiration, with most valves changing position to allow swallowing (Wolf & Glass, 1992). The lips close, keeping the food in the mouth while changing the intra-oral pressure. This pressure change facilitates bolus organization and movement, which plays a role in initiating swallowing (Wolf & Glass). The soft palate and tongue work together to form a valve between the oral cavity and the pharynx. The soft palate approximates the tongue at rest and channels air from the nasal pharynx directly through the pharynx into the larynx/trachea. The soft palate is elevated to seal the nasopharynx during swallowing and the tongue forms a deep median groove to direct food into the pharynx (Wolf & Glass). The epiglottis is elevated at rest and allows air to flow freely into the larynx and trachea. It folds down during swallowing to seal the larynx against food. The cricopharyngeal sphincter remains tonically closed to keep previously swallowed food in the esophagus and prevent it from reentering the pharynx (Wolf & Glass).

As the baby matures, there is a shift from positional stability provided by the close proximity of various structures and the infant's large amount of subcutaneous fat to postural stability where the structures are supported by increase amounts of connective tissue, cartilage, and more highly specialized muscle control as the structures move further apart (Wolf & Glass, 1992). Relatively large amounts of subcutaneous fat, including fat pads or sucking pads, provide firm consistency and puffy profile of the infant's cheeks. Bosma (1972) describes this subcutaneous fat as providing a functional "exoskeleton" to support oral and pharyngeal function, particularly for mandibular movement. As the infant matures, the oral cavity enlarges to allow for a large variety of tongue movements used in mature feeding skills (Wolf & Glass). As the sucking pads diminish, mandibular stability is provided by increased muscular control and development of more rigid connective tissue. The reduction in the mass of the cheeks allows for greater and more active mobility of the lips and cheeks (Wolf & Glass).

There is also considerable overlap in the neural control of these functions. The oral, nasal, pharyngeal, laryngeal, and respiratory structures are primarily innervated by branches of cranial nerves V, VII, IX, X and XII, and branches of the upper cervical nerve roots. Inherent in the activities of sucking, swallowing, and respiration are rhythmic patterns, each being characterized by its own rhythmic pattern that is highly coordinated (Wolf & Glass, 1992). Literature has described the presence of a "central rhythm generator" with functions involving facilitation jaw depression/elevation in an alternating rhythmic pattern, generating appropriate rhythmic patterns to drive oscillating inspiratory and expiratory neurons for respiration, and perhaps initiating sequencing swallowing (Wolf & Glass).

Sucking. Sucking is the primary means for receiving nutrition. It can also provide calming and pacification, and is an initial method of exploring the environment (Wolf & Glass, 1992). Fetal swallowing is important for the regulation of amniotic fluid volume from the fetal environment and maturation of the fetal gastrointestinal tract and has been reported between 10 and 14 weeks gestation (Delaney & Arvedson, 2008). By 15 weeks, ultrasound studies reveal non-nutritive sucking and swallowing in most fetuses, and the fetus absorbs some amniotic fluid. Forward tongue thrusts have been reported by 21 weeks gestation, tongue cupping by 28 weeks gestation, and anterior-posterior tongue movements between 18 and 24 weeks gestation. Consistent swallowing is seen by 22 to 24 weeks gestation and near term infants swallows amniotic fluid at a volume of about 500-1,000 ml/day (Delaney & Arvedson). In the extrauterine environment, mouthing activity can be observed around 27 to 28 weeks, though in a disorganized and random pattern with "sucks" which are quite weak. By 32 weeks, stronger sucking is noted and a burst-pause pattern is emerging, though stability is not established until 34 weeks. Sucking and related components necessary for effective feeding are generally not reported to be present until 34 or 35 weeks gestation (Wolf & Glass).

Sucking Pressure. Literature has described sucking as a pumping system with the mouth as the pump and a pump being defined as a device that pushes or draws fluid out of something by differential pressure (Wolf & Glass, 1992). During infant feeding, fluid moves primarily because of changes in pressure. Positive pressure, compression, "pushes" fluid out of something. The tongue compresses the nipple, positive pressure is created, and liquid is expelled. Negative pressure, suction, “draws” fluid out of something. To produce suction, the oral cavity must be completely sealed so that the jaw and tongue movements to enlarge the oral cavity and increase the negative intra-oral pressure will be effective (Wolf & Glass).

Movement Sequence during Sucking. The tongue, jaw, lips, cheeks, and palate work together to produce the smooth, rhythmic movements that characterize sucking and allow the infant to take in adequate substance for nourishment (Wolf & Glass). The tongue forms a central groove along its longitudinal axis to receive the nipple. The lips and tongue close around the nipple and the posterior portion of the tongue elevates to maintain contact with the soft palate. Laterally, the cheeks approximate the tongue and nipple. The medial portion of the tongue produces a wavelike motion in the anterior-posterior direction. During this peristaltic movement, the nipple is initially compressed between the anterior portion of the tongue and palate. The posterior portion of the tongue is depressed, the sealed oral cavity is enlarged creating negative pressure and suction and propelling the bolus of fluid toward the pharynx (Wolf & Glass).

Nutritive Sucking. Nutritive sucking is the process of obtaining nutrition with a rate of one suck per second, and is constant over the course of feeding. The purpose is to obtain nutrition in the form of breast milk or formula (Foster et al, 2016). It involves the intake of fluid due to the alternation of expression and suction (negative intraoral pressure that occurs when the tongue and jaw become lower and the soft palate closes the nasopharynx) (Harding et al, 2012). The nutritive sucking pattern is more complex but varies in a predictable way throughout the feeding period (Wolf & Glass, 1992). There is an initial sucking burst that lasts at least 30 seconds to 60 or 80 seconds. The infant then transitions to a period of intermittent sucking. The duration and number of each sucking burst steadily declines while the length of the pauses steadily increases (Wolff, 1962). The sucking rate averages about one suck per second and remains constant over the course of feeding, the actual number of sucks per minute decreases as the number and length of pauses increases at the end of feeding. The nutritive sucking rate is slower to allow for the swallow to occur (Wolf & Glass). During feeding, there is a 1:1 ratio of sucking to swallowing. A swallow follows almost every suck. This changes, and by the end of feeding, the ratio is 2:1 or 3:1 in younger infants. Older infants can take several sucks before swallowing (Wolf & Glass). The suck:swallow ratio are dependent on the rate of flow of liquid and the size of the oral cavity (Colley, 1958). When the flow of liquid is high, swallowing follows each suck. When the flow of liquid is low, sucking pressure diminishes and the ratio decreases (Wolf & Glass). As the infant matures, the oral cavity enlarges. This allows more space for the infant to fill, which requires more sucks to trigger the swallowing response (Wolf & Glass).

Coordination of Sucking, Swallowing, and Breathing. Even as each task occurs in relative isolation, in infant feeding they must act together for safe and efficient feeding. Swallowing suppresses respiration. During a smooth rhythm of sucking, respiration becomes synchronized with sucking, however it is unlikely that this rhythm will remain stable throughout the entire feed (Wolf & Glass, 1992). Swallowing is initiated by the presence of a bolus in the oral cavity and oropharynx. During non-nutritive sucking, there is no fluid flow, just the accumulation of oral secretions, the ratio of sucking to swallowing is high. During nutritive sucking, the infant may begin eagerly feeding, the fluid flow is rapid requiring one swallow for each suck. As the infant fatigues the rate of fluid flow declines, several sucks may be needed to accumulate a sufficiently large liquid bolus to initiate the swallow (Wolf & Glass). In the first few days of life, dysthrythmic sucking and poor coordination of sucking, swallowing, and breathing are common in full-term infants (Wolf & Glass). Feeding patterns are reported to be smooth by five to eight days of life (Weber et al, 1986).

Prematurity. The World Health Organization defines prematurity as birth before 37 completed weeks of gestation (Vogel et al., 2016). Preterm birth is sub-classified into extreme preterm (<28 weeks gestation), very preterm (28 to <32 weeks gestation), and moderate to late preterm (32 to <37 weeks gestation) (Platt, 2014). Most (85%) of preterm births occur after 31 weeks (Platt, 2014). The most recent study published in 2012 by Blencowe and colleagues estimated that 14.9 million babies were born premature in 2010, accounting for 11.1% of all live births worldwide. According to the Centers for Disease Control (CDC) in 2015, preterm birth affected about 1 of every 10 infants born in the United States (Preterm Birth, 2016). Factors that contribute to premature birth include pre-existing maternal medical conditions (diabetes, obesity, undernourishment), pregnancy-related medical conditions (pregnancy-induced hypertension), maternal age, a history multiple gestations, socio-economic status, and demographics (Platt, 2014). Worldwide, preterm birth is the most common cause of neonatal death, although there are dramatically different patterns in survival rates across the world. In high-income countries, about 50% of preterm infants born at 24 weeks survive the neonatal period (the first 28 days of life), while at 28 weeks chances of survival rise to 90% (Platt). In low-income countries only those born at 34 weeks or later have a 50% chance of survival (Platt).

Infants born prematurely are at greater risk of complications in both the short and long term periods after birth (Platt, 2014). A developing baby goes through important growth throughout pregnancy, especially in the final weeks and months (Preterm Birth, 2016). If an infant is born early, certain structures are not able to develop sufficiently to function for survival without intervention. These include insufficient fat stores, poorly developed body/organ systems, underdeveloped neuromotor control (Hack, 1985). Areas that can be affected by premature birth include breathing, feeding, cognitive development, vision, and hearing (Preterm Birth). Often, when an infant is born prematurely, they are not able to feed orally due to immature gastrointestinal systems and poor coordination of suck, swallow, and breathing coordination. Common co-morbid factors with prematurity that may contribute to difficulty achieving oral feeding are summarized in Appendix 1.

Synactive Theory of Development

According to Als (1982), "Clinical work with infants necessitates a theory from which to understand the individual and his/her development (pg. 232)." Her process-oriented theory focuses on how the individual infant appears to handle him/her through subsystem interaction (Als, 1982). These interactions are viewed through the development synactive, Because the various subsystems of functioning exist side by side. These systems include the autonomic system, the motor system, the state-organizational system, the attention and interaction system, and a self-regulatory, balancing system the functioning of which are reliably observable without instrumentation (Als).

According to Synactive Theory (Illistration 1), the four concentric cones are in simulataneous connection, if not interaction. According to Als, these cones are supporting one another and infringing on one another's relative stability. The innermost cone is the autonomic system; it controls baseline functioning. Around the autonomic system is the motor system, with recognizable flexor posture, limb, and trunk movements. Finally, is the state-organizational system is, monitoring the distinct states of consciousness. Around this lies the gradual differentiation of the awake state into more elaborated, subtly branched and finely tuned nuances of affective and cognitive receptivity and activity (Als).

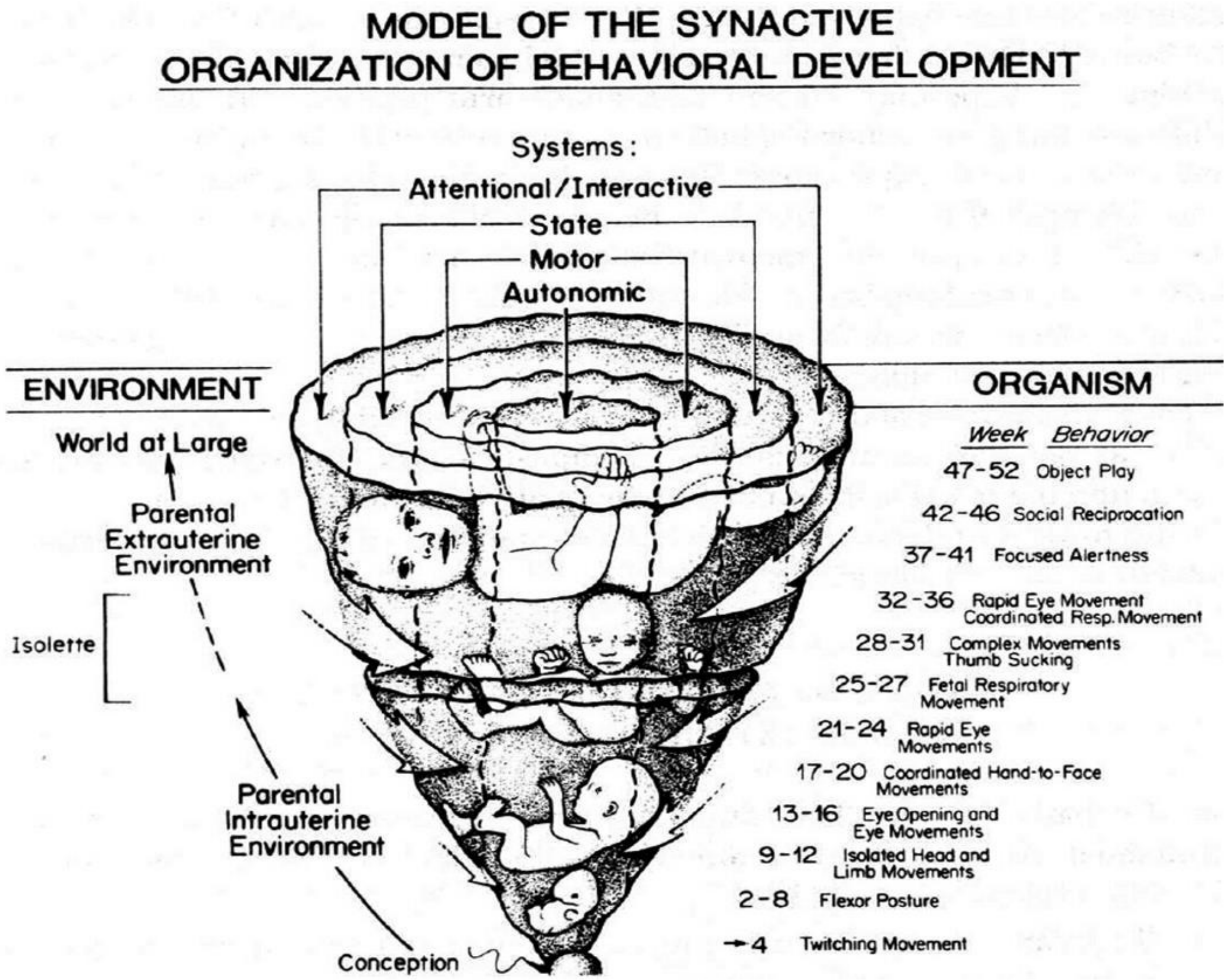

Illustration 1. Model of Synactive Theory of Development (Als, 1982)

We can apply this theory to the development of a preterm infant. A preterm infant has been taken out of the sensory deprived-maternal environment and thrust into a sensory overloaded-mechanical, technological setting that is attempting to save and best support their life before they are properly prepared developmentally to handle all the sensory stimulations. On the basis of this synactive theory approach to development, individualized environmental structuring to maintain maximal development and to reduce developmental defense becomes possible. For some babies, "complete elimination of nearly all stimulation may be necessary and strict stress precautions may be appropriate, depending on the infant's level of sensitivity and fragility of current subsystem integration" (Als, pg 237). The goal of intervention using this approach is to decrease the stress of these manipulations and increase the infant's positive functional strategies.

Preterm Feeding.

Enteral Feeding. From a clinical perspective, the ability to feed depends upon a coordinated sucking, swallowing, and breathing pattern. In preterm infants less than 32 weeks gestation, the ability to suck-swallow-and-breath is not usually effective enough to sustain full oral feeds. Until then, infants are fed by gavage tube (Pinelli et al, 2011). There are many options to get nutrients into the infants system (Wolf & Glass, 1992). Each feeding process is unique and developed according to the infant's needs. A clinical feeding evaluation should be carried out early to allow careful observation of the infant's feeding skills and determine the best methods in which the infant may obtain nutrients. At the beginning, most preterm infants are fed non-orally through enteral feedings or parenteral feedings due to their poorly developed nutrient sucking skills. Enteral feedings move nourishment through the digestive tract, while in parenteral feedings nutrients enter the circulatory system directly through intravenous lines or central arterial lines. Enteral nutrition is done using a gavage tube that is passed through either the nose or the mouth into the stomach and can be removed and replaced with each feeding or taped and left "indwelling" for several days. Liquids can be delivered via bolus (over a 15 to 20 minute period) or via continuous drip feedings (set at a specified rate for a portion of the day or over 24 hours). Ideally, the infant will be moving from tube to oral feeding throughout the whole process (Wolf & Glass, 1992). Enteral feeding is a standard method of providing nutritional support for vulnerable infants until they are ready to attempt oral feeding. It can help support weight gain, and reduce the parental stress of maintaining weight through oral feeding alone. (Harding et al, 2012). Achieving safety, efficacy, and success in oral feeding early on during hospitalization will naturally lead to a more rapid transition from tube to independent oral feeding (Lau, 2012).

Readiness Factors. Four factors should be considered in determining if a premature infant is ready to attempt oral feeding. The infant should be at least 32 weeks gestation, although success is more likely at 34 weeks gestation or later. The infant's medical condition should be relatively stable, particularly the respiratory status. The infant should be tolerating enteral feedings and breathing should not be labored. The infant should be able to maintain, at least briefly, a wakeful state. Lastly, the infant should be able to present and easily maintain a rhythmic pattern of non-nutritive sucking (Wolf & Glass, 1992). These criteria provide the infant with the best chance to make a smooth transition to oral feeding. An infant who meets only one or two of these criteria is not likely to be successful at oral feeding, and may be more successful if postponed one to two weeks (Wolf & Glass). Due to premature birth and subsequent medical complications, some premature infants may be slower to progress in the maturation of the coordination required during feeding yet still acquire skills within a "normal" time range (Wolf & Glass). The progression to nipple feeding must be completely individualized and carefully monitored to be most successful (Wolf & Glass).

Gestational Age Dodrill and colleagues (2008) documented the ages at which preterm neonates began suckle-feeds and attained exclusive suckle-feeding as well as the time taken to transition from commencement of suckle-feeds to exclusive suckle-feeding. They conducted a chart review over a twelve month period for all neonates < 37;0 weeks GA admitted to a tertiary level perinatal facility (n= 735). Complete data relating to attainment of feeding milestones were available on 472 neonates (Dodrill, et al, 2008). Correlation analysis indicated that both a low GA at birth and a high neonatal morbidity rating were statistically correlated with an increased transition time from commencement of suckle-feeds to exclusive suckle-feedings (Dodrill, et al). Specifically, extremely premature neonates and mildly premature neonates along with preterm neonates with a mild degree of morbidity or an extremely high degree of morbidity were found to be more mature at commencement of suckle-feeds than moderately preterm neonates or neonates with a moderate degree of morbidity (Dodrill, et al). Cox regression analysis indicated that both of these variables were statistically significant risk factors for a delayed GA at attainment of exclusive suckle-feeding. Dodrill and colleague's research provides evidence that is in contrast to the "traditional idea that all preterm neonates are capable of attaining suckle-feeding milestones at specific Gas" (Dodrill, et all). Further, more modern research needs to be completed to continue to develop understanding in preterm feeding development.

Transition Time. Researchers have looked into different interventions to encourage the development of feeding skills in premature infants. Fucile and colleagues (2009) found that a vacuum-free bottle improved the physiologic stability and reduced the transition time to exclusive oral feeds, though it did not affect the gestational age at attainment of exclusive oral feeding (36.3 +/- 1.5 days gestational age vs 36.8 +/- 2.0, $P = 0.425$). Chang et al., (2007) and Matthew (1991) looked into the effects breathing patterns and nipple cuts on feeding efficiency and physiologic state in premature infants. They both found that slow flow bottle nipples improved physiologic stability during feeds, but were not clear as to the effect they had on gestational age at attainment of full oral feeding or transition time (Chang et al, 2007; Matthew 1991). Feeding positions and techniques have also been studied to see if they improve the transition time to achievement of full oral feeding. These include external pacing, and placing the infant in side-lying position. Law Morstatt and colleagues (2003) found that external pacing (tipping the bottle back to prevent the infant from over filling his mouth so as to allow for better sucking, swallowing, breathing coordination) improved physiologic stability during feeding, and Park et al., (2014) and Dawson et al., (2013) found that side lying improved physiologic stability during feeding. Thoyre and colleagues (2016) found that coregulation (the combination of external pacing and side-lying positon during feeding) was associated with improved physiologic stability during feeding. It is important to note though that all of these studies did not evaluate the impact of these approaches on the gestational age at the attainment of full oral feeding or on the length of time to achieve full oral feeding in relation to gestational age at achievement of full oral feeding which is still around 36 weeks gestational age based on what we know by the time they regularly coordinate sucking, swallowing, and breathing together. Further research is needed to investigate the impact of intervention and respiratory and cardiac illness on the attainment of full oral feeding and transition time to achieve full oral feeding.

Specific Aim:

The purpose of this project was to establish the impact of common preterm morbidities as measured by the Morbidity Assessment Index for Newborns, gestational age at birth, time spent on mechanical ventilation, high flow nasal cannula, and CPAP, on the resulting transition time and post conceptual age at which a modern cohort of preterm infants attain nutritional intake by exclusive oral means.

Hypotheses:

Hypothesis 1: There will be a significant impact of gestational age on the time needed to transition to full oral feeding.

Hypothesis 2: There will be a significant impact of respiratory support on the time it takes to transition to full oral feeding.

These hypotheses were tested utilizing multiple regression analysis.

3. METHODS AND PROCEDURE

Participants

Data was collected from a retrospective chart review for 229 neonates born < 37 weeks gestational age who were admitted to either DCH Regional Medical Center or Northport Medical Center over a 12-month period from January 2013- December 2013. No specific interventions other than standard medical care were provided to these infants during this period. Both centers are Level II-III care hospitals. According to the American Academy of Pediatrics, Level II and III Neonatal Intensive Care Units (NICUs) consist of special care nurseries that provide sustained life support for infants less than or between 32 - 35 weeks gestational age and provide a range of respiratory support including mechanical ventilation and non-invasive support (Academy of Pediatrics, 2012). An Example of the level of acuity in the NICU setting can be seen in Figure 2 below. Infants were excluded if they expired or were transferred to another hospital before achieving oral-feeding milestones. Two-hundred and twenty-three infants were used in the final analysis of this paper. Figure 1 illustrates the selection process for the included 223 participants. Chart reviews of hand-written and electronically entered, bedside notes were conducted by two researchers who achieved at least 90% agreement with one another and with the Principal Investigator (PI). This was reached on collection of chart review items (during review of 5 consecutive charts) following training by the project's PI. Errors that prevented the researchers from reaching 100% agreement included illegible handwriting, missing information from the notes, or disagreement between the two researchers in interpretation of the notes/math. At least two weeks following the conclusion of data collection 20% of the charts were reviewed again to establish intra and inter-rater agreement. Again, there was at least 90% agreement for intra and inter-rated measures. Items in the chart review consisted of binary, yes or no responses or items that were calculated by the researchers using dates provided in the medical history.

Figure 1. Participant Inclusion for Regression Analysis

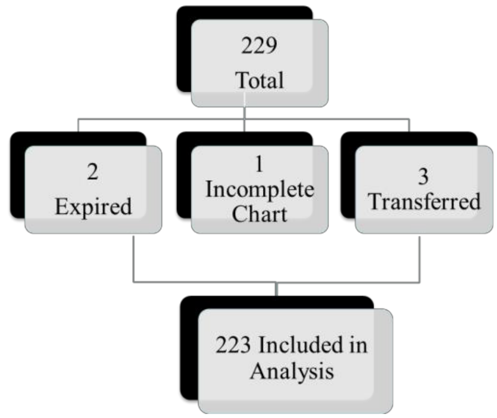

Figure 2. Level of Acuity in Neonatal Intensive Care Unit (NICU) setting

Level	Description	Characteristics
I	Basic Newborn Care	Healthy, full-term babies. Stabilize babies born near term to get ready to transfer to facilities that provide advance care
II	Advanced Newborn Care	Born at greater than 32 weeks gestation or recovering from serious conditions
III	Subspecialty Newborn Care	Born <32 weeks GA or with critical illness. Facilities offer readily available access to a range of pediatric medical subspecialties including respiratory support and advanced imaging
IV	Highest Level of Neonatal Care	Can provide surgical repair of complex congenital or acquired conditions

Assessments and Measures

This study examined the impact of comorbidities on typical feeding development in preterm infants by analyzing the length of time from start of oral feed to mastery of oral feed for each neonate. Medical history of participants including birthweight, gestational age at birth, age at initiation of oral feeding, age at achievement of full oral intake, and information relating to the number and type of medical comorbidities experienced during the neonatal period was determined from medical chart reviews. An example of the chart review tool used can be found in Appendix 1. The degree of morbidity was assessed using the Morbidity Assessment Index for Newborns (MAIN) described below.

MAIN Score

The MAIN Score is a measurement tool that is used to assess the morbidity (illness) in very low birth weight or low gestational age infants. It captures the full range of morbidity, from minimal to severe in a numerical index, and is sensitive enough to show subtle differences according to gestational age, birthweight, sex, maternal influences, and the impact of adverse prenatal exposures (Verma, 2005). The items included in the measure are clinical and laboratory data that can be easily collected from clinical records (Strobino, 2006). The inventory includes 47 clinically relevant pathophysiologic items describing morbidity at birth, based on 24 attributes that include the APGAR Score (Appearance, Pulse, Grimace, Activity, and Respiration), Respiratory Illness, Central Nervous System functioning, Blood, etc. (Strobino, 2006). It consists of binary test items, which can be scored from information routinely available in neonatal medical charts (Dodrill et al., 2008). Test items are weighted to reflect the severity of the medical condition they relate to. An overall MAIN score is calculated for each child by totaling the weighted scores from each of the test items that the child scored positively on (Dodrill et al).

The higher the score, the greater the degree of overall morbidity demonstrated (Dodrill et al). The MAIN scores range from 0 to 150 (no/minimal morbidity), 151 to 500 (mild), 501 to 800 (moderate), and ≥ 800 (severe), (Verma).

Independent and Dependent Variables

The independent variables included gestational age at birth, MAIN score, total days on ventilation, total days on continuous positive airway pressure (CPAP), and total days on high flow nasal cannula (HFNC). The Dependent variables include post- gestational age at achievement of full oral feeding, and time to transition to full oral feeding. Age was measured relative to time of conception (GA) and time of birth (chronological age). The start of oral feeding is defined as the first attempt to feed where sufficient volume is taken to justify a reduction in the volume of a tube feed (Dodrill et al., 2008). Attainment of feeding is defined as when all feeds are consumed by mouth, followed by two consecutive days of exclusive oral feeding (Dodrill et al.). Transition time was calculated by subtracting age at commencement of oral-feeding from age at of attainment at full oral feeding. An overall MAIN score is calculated for each child by totaling the weighted scores from each of the test items that the child scored positively on (Dodrill et al). Total days on ventilation, CPAP, and HFNC were recorded directly from the chart reviews.

Statistical Analysis

Statistical analyses included descriptive and regression analyses. Descriptive measures provided the mean and standard deviation of all variables of interest. Regression analysis was used to determine which factors impacted the post-conceptual age at attainment of full oral feeding and the time required to achieve full oral feeding as defined by the time to transition measured for this cohort of premature infants. A regression analysis is a prediction statistical test completed to assess the linear relationship between two continuous variables to predict the impact of one variable on the other. The regression analysis determines if there is a linear relationship between the variables, if the relationship is significant, and how much variation in the dependent variable can be explained by the independent variables (Laerd Statistics, 2015). For all regression analyses, gestational age (GA) was measured in completed weeks. IBM SPSS Statistics version 24, a statistical package for the social sciences, was used for statistical analyses.

4. RESULTS

Table 1 describes the 223 participants in the study and the facility where they were born. There were 135 infants from Regional Medical Center and 88 infants from Northport Medical Center. Time to transition to oral feeding for facilities was normally distributed, as assessed by Shapiro-Wilk's test ($p > .05$) and the test showed a mean difference between facilities of .037 (95% CI, 0.20 to 0.54), $t(221) = 1.917$, $p = .057$. No significant difference in time to transition to oral feeding between participants from the two hospitals. The distribution of birthweight (BW) and gestational age (GA) in the study sample group approximated that of the American preterm population from which they were drawn (Birthweight and Gestation, 2017). Neonates varied in terms of birthweight (BW) from 400 to 4300 g (mean 1900 ± 729), with GA at birth ranging from 23 to 36 (mean 32.4 ±3.4). Lower GA at birth was associated with higher MAIN score (r = -696, $p < .0001$). Mean transitional time by gestational age at birth is presented in Table 2.

Table 1.
Birth Location, Gender, and Ethnicity Descriptives

	n	%
Northport Medical Center	88	39
Tuscaloosa Regional Medical Center	135	60
Male	114	51.1
Female	109	48.9
African American	110	49.3
Caucasian	106	47.5
Hispanic	5	2.2
Other	2	0.9

Table 2.
Descriptive Statistics for combined groups

	Mean (SD)	Range
GA at Birth Completed Weeks	32.4 (3.4)	(19.3, 45.3)
MAIN Score	700.2 (600.8)	(366.7, 1033.7)
Birthweight (Grams)	1900.0 (729.6)	(1510, 2290)
PGA at Start PO Intake (Weeks)	34.9 (1.6)	(21.75, 48.05)
Days to Reach Full PO	10.26 (12.07)	(0.56, 19.96)
PGA at Reach of Full PO	36.4 (1.9)	(23.68, 49.68)
PGA at Discharge Converted to Weeks	37.6 (2.2)	(22.2, 53)

Across all of the participants, the mean age at start of oral feeding was 34.8 ± 1.6 weeks PGA; the mean age at attainment of full oral feeding was 36.3 ± 1.8 weeks GA; the mean transition time was 10.2 ± 12.0 days PGA (Table 3). No significant differences were found between neonates who received exclusive breastmilk, formula, or a combination of breastmilk and formula. At discharge, 8.5%, N= (19), of neonates received breastmilk, 67.7%, N= (151), received formula alone, and the remaining 23.8%, N= (66), received combined breastmilk and formula. Of the 223 neonates, only 2 (0.9%) were discharged on oxygen via nasal cannula.

Table 3.
Mean Transition time by Gestation Age at Birth

Gestational age at birth (completed weeks)	**n**	**PGA at Start of PO Intake Weeks Mean (Std. Deviation)**	**PGA at Reach of Full PO Weeks Mean (Std. Deviation)**	**Transition Time (PGA at Reach - PGA at Start) weeks**
Less than or Equal to 25 wks	12	33.44 (2.46)	38.88 (3.6)	5.44
26	9	34.29 (3.85)	37.99 (3.22)	3.7
27	9	34.25 (.80)	35.63 (1.67)	1.38
28	7	34.50 (1.26)	37.71 (3.5)	3.21
29	5	34.23 (.99)	35.34 (.63)	1.11
30	5	33.62 (.59)	36.422 (2.79)	2.8
31	10	33.76 (1.2)	35.66 (1.73)	1.9
32	21	34.17 (.98)	35.59 (1.2)	1.42
33	35	34.12 (.74)	35.34 (.94)	1.22
34	40	34.91 (.53)	35.86 (1.15)	0.95
35	36	35.79 (.75)	36.50 (1.15)	0.75
36	34	36.71 (.72)	37.26 (.93)	0.55

PGA= post gestational age, GA= gestational age, PO= by way of the opening/by mouth

Regression Analysis:

A multiple regression was run to predict the impact of MAIN score, total ventilation days, CPAP days, high flow ventilation days, and gestational age at birth on transition time to achieve full oral feeding. The multiple regression statistically significantly predicted time needed to transition to full oral feeding, $F(5,217) = 25.794$, $p < .0001$, adj. $R2 = .36$. Total days on ventilation and gestational age at birth significantly added to the prediction, $p < .05$. Regression coefficients and standard errors can be found in the table below (Table 4).

Table 4. Regression coefficients and Standard Errors

Variable	β	Std. Error	Sig.
MAIN Score	-0.001	0.002	0.682
Total Days on Vent	0.253	0.074	0.001
NCPAP Days	0.035	0.139	0.800
High Flow Days	-0.045	0.082	0.580
Gestational Age at Birth	-1.191	0.395	0.003

5. DISCUSSION

The mean gestational age that ex-preterm infants achieved full oral feeding was 36.4 weeks. On average all of the infants born prematurely, regardless of variables, achieved full oral feeding from 35.44 weeks gestational age to 38.88 weeks gestational age as stated in in table 3. This data provides further evidence for full oral feeding achievement as a developmental skill. That is, once the medical co-morbidities have been managed, the infant develops the needed suck, swallow, and breathe coordination in a predictable, developmental time frame without additional intervention.

This project provides support to the synactive theory of development. On the basis of the synactive theory, infants need time to stabilize and develop their autonomic, sensory, and motor systems before being ready to safely participate in a more complex task, like feeding, that requires the integration of these sub-systems. The autonomic system is essentially protective; often we see that sleep has the biggest impact on development (Als, 1982). Therefore, it would appear that the initial goal of therapy needs to be to decrease the stress that the infant experiences and increase the infant's positive functional interactions, as medically appropriate. Therapy and intervention need to focus on stabilization of the infant.

Much of what is currently published for encouraging successful feeding for infants in NICU focuses on how feeding exercise paradigms, like oral motor interventions including nonnutritive sucking and/or oral stimulation, along with motorized devices to encourage sucking behaviors such at the Ntrainer (Arvedson et al, 2010; Barlow et al, 2014) decrease the time it takes to reach full oral feeding, but it does not provide the gestational age at which they actually reached full oral feeding. Without knowing the gestational age that the infants finally reach full oral feeding, it is impossible to know if the currently available interventions significantly decreased the age at which they achieve the oral feeding milestone.

The data provided here allows a guiding range to inform parent and professional expectations for when infants in Level II – III NICUs will likely achieve full oral feeding without any intervention. This includes expectations for infants to achieve oral feeding between the ages of 35 and 38 weeks regardless of gestational age or days on respiratory support. A number of intervention methods have been implemented in hospitals to encourage earlier development of oral feeding skills. One such intervention includes the use of non-nutritive sucking in various times to increase sucking behaviors. Bernbaum and colleagues (1983) discovered that the use of non-nutritive sucking did not correlate to an increase in nutritive sucking behaviors. Barlow and colleagues in 2013 found that the use of a vibrating pacifier at various levels during non-nutritive opportunities did not statistically encourage the development of nutritive feeding skills. Other interventions that have been tried in the preterm population include oral motor exercises such as tongue, lip and jaw movements, although there has been no evidence the prove efficacy in them as of yet (Harding, 2009). When family members are in the NICU with their infant, they can be scared and become concerned about the length of time it takes for their infant to feed. With the information found in this study we can explain that while the infant might not be feeding at the moment, we can expect them to feed within a certain time frame. We can also use this information in discussion with the medical professionals when discussing goals for feeding success for the infant.

Gestational age at birth, morbidity at birth (measured by the MAIN), days on ventilator support, days on HFNC, and days on CPAP significantly predicted the transition time to achieve full oral feeding for a modern cohort of preterm infants cared for in a Level II – III NICU. Gestational age at birth and days on ventilator support had the strongest relationship to transition time on gestational age at attainment of full oral feeding. This evidence supports the information previously found by Dodrill and colleagues looking at these factors in a level IV NICU.

Limitations

There are inherent limitations to retrospective studies that include bias in participant selection and bias from review of reported data. In order to limit bias in participant selection, the participant population was defined prior to beginning chart reviews. The variables of interest for this study were calculated from collected data in order to reduce bias from previously reported data. Other limitations include failure to train and monitor data abstractors. This study provided both training and monitoring of data collectors along with a secondary check of all data entered into the database to reduce bias from human error.

Future Directions

Future research should incorporate the results of this study into the analysis of therapeutic interventions to determine if the intervention significantly shortens transition time for full oral feeding in preterm infants. The result of this study may also be used in quality monitoring for the impact of various clinical procedures that are introduced to the NICU to evaluate their impact on oral feeding. Finally, future research in the area of oral feeding in the NICU should focus on decreasing the length of time needed on respiratory support to evaluate the potential impact on the time needed to transition to oral feeding.

Conclusions:

This study found that gestational age at birth and days on ventilator support had the strongest relationship to transition time on gestational age at attainment of full oral feeding and that gestational age at birth, morbidity at birth (measured by the MAIN), days on ventilator support, days on HFNC, and days on CPAP significantly predicted the transition time to achieve full oral feeding for a modern cohort of preterm infants cared for in a Level II – III NICU. The results suggest that infants born with greater prematurity and those that spend more time on respiratory support take longer to transition to full oral feeding.

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APPENDIX 1

	Definitions	Impact on Feeding
Conditions Affecting Respiratory System		
Infants Respiratory Distress Syndrome (IRDS) [a, b, c, d]	• Often due to inadequate amounts of surfactant in the alveoli trigger events that lead to respiratory insufficiency. • Apparent within the first hours of life. • Deep inspirations tend to collapse the chest wall, which is extremely compliant in the premature infant. • Management includes oxygen therapy, correction of acidosis, and maintenance of normal arterial blood pressure, temperature control, and often assisted ventilation.	• T he work of breathing may often be greater, requiring high energy expenditure and leading to frequent fatigue. • Poor development in respiration can lead to apneic episodes in sucking • BPD is common in infants with IRDS and can have negative impacts on feeding development • Receiving adequate nutrition is key to facilitating lung repair and growth, which aid in the recovery from BPD and other respiratory illness
Bronchopulmonary Dysplasia (BPD) [a, e]	• A chronic pulmonary disease process generally seen in neonates after treatment with positive pressure ventilation. • IRDS, also include infants being treated for meconium aspiration, pneumonia, or other respiratory disorders. T he goals of medical treatments of BPD are to minimize damage to the lungs, promote growth of new lung tissue, maintain optimal oxygenation, and prevent additional complications	• Problems of feeding include decreased endurance, poor coordination of sucking, swallowing, and breathing, abnormal oral-motor patterns, swallowing dysfunction, oral-tactile hypersensitivity and " learned" behaviors that interfere with feeding. • T reatment strategies for decreased endurance include decreasing the work of breathing, providing additional oxygen at feeding, and manipulating feeding schedules and nutritional supplements. • Careful monitoring and using a short sucking burst pattern should be facilitated as an adaptive response to high respiratory demands for treatment of poor coordination.. • T reatment strategies include normalization of totally body posture should be emphasized during feeding,
Tracheostomy [a]	• A tracheostomy is performed when prolonged ventilator support is required for a subgroup of infants with BPD. • It eliminates the need for ongoing orotracheal or nasotracheal intubation and the associated discomfort.	• May lead to swallowing dysfunction. • T he tube itself may mechanically restrict upward movement of the larynx, limiting the laryngeal elevation necessary for complete epiglottic closure. • Appropriate pacing of sucking, swallowing, and breathing should be encouraged to help the infant develop an adequate pattern of coordination.
Tracheoesophageal Fistula [a]	• T racheoesophageal Fistula (T EF) is a common congenital anomaly occurring in the neonate. • It is classified according to the presence or absence of fistula and the configuration of the esophagus. • Surgical repair is necessary and long-term complications in infants following repair vary. • Complications include tracheomalacia (inherent structural abnormality of the trachea that causes it to be unusable and prone to collapse).	Feeding problems are most commonly due to long-term complications, associated congenital anomalies, or delayed introduction of foods.

Conditions Affecting GI System	Definitions	Impact on Feeding
Esophageal Atresia [a]	• Congenital anomaly classified according to the presence or absence of fistula and the configuration of the esophagus. • Surgical repair is necessary • A number of complications include: esophageal dysmotility (fluids and liquids progressing more slowly or less organized placing a child at risk for aspiration), stricture formation (some degree of narrowing at the site where esophageal ends join), foreign-body impaction (build-up of food and saliva requiring endoscopic removal), gastroesophageal reflux, associated respiratory complications, and nutritional deficits	Feeding problems are most commonly due to long-term complications, associated congenital anomalies, or delayed introduction of foods.
Gastroesophageal Reflux (GERD) [a]	• The spontaneous return of gastric contents into the esophagus. • There is an interrelationship and interdependency between GER and respiratory disease in children. • Casual Factors of GER include aspiration, reflex bronchospasm, reflex laryngospasm, central apnea and bradycardia, positive abdominal pressure, negative intrathoracic pressure, and lower esophageal sphincter/ gastric acid production.	• Gradually resolves with maturation • Can influence an infant's willingness to feed, effect weight gain, and alter respiration and heart rate. • Treatment is usually aimed at managing the resulting problems and/or treating any of the casual factors and alleviating symptoms so that the infant can thrive. Positional and dietary management is used with antacids and other medications included as needed. Surgery is used in the most severe cases. • Pleasurable oral-tactile experiences may also be helpful if oral aversion becomes generalized.
Necrotizing Enterocolitis (NEC) [a, f]	• Develops between day 3 and day 10 of life • Negative reaction to bacteria commonly found in milk • Any premature infant developing NEC experiences significant setbacks in overall medical progress that can impact other areas. • Depending on the severity, surgery may be required and recovery is prolonged.	• Early diagnostic signs include feeding intolerance, abdominal distension, and gastric retention of feedings. • If necessary, portions of the bowel are removed and enteral feeding is not possible. • Total parenteral nutrition may be required. • Oral feeding skills develop very slowly and are characterized by frequent setbacks. • Encouraging non-nutritive sucking opportunities

Oral Facial Consideration	Definitions	Impact on Feeding
Suck/Swallow/ Breath Coordination [a]	• Rhythm patterns are often abnormal in the premature infant leading to dysrhythmic sucking patterns, irregular sucking bursts, or even periods of apnea	• Treatment strategies include monitoring the infant's respiratory rate, providing external pacing of sucking swallowing and breathing, and changing the nipples or methods of flow.
Sucking Mechanics [a]	• Wide jaw excursions, poorly developed muscles and inefficient tongue movements may compromise sucking strength. • The premature infant, compared with the term infant, has different oral size and structural relationships.	• These differences in sucking mechanics lead to poor positional and postural stability during feeding. • Treatment strategies include treatment techniques for oral control. • Recent literature has reported the use of non-nutritive sucking during enteral feeding to promote sucking development.
Oral Facial Anomalies [a]	• A number of congenital anomalies may interfere with infant feeding including cleft lip, cleft palate, cleft lipand palate, micrognathia, and Pierre-Robin malformation sequence. • A cleft lip results from failure in fusion of the upper lip in the fifth week of embryonic development. • A cleft palate results from failure of the palatal shelves to meet and fuse in the midline during the seventh to eighth week of intrauterine development. Cleft lip and palate may occur individually or together. • Micrognathia refers to a small or posteriorly positioned mandible usually associated with a wide –U shaped cleft of the palate which may lead to glossoptosis, or obstruction of the pharyngeal airway	• A number of factors should be evaluated to determine an appropriate feeding method for infants with these anomalies. • Suction, or the ability of the oral cavity to be completely sealed may not be present, and adequacy of tongue and jaw movements to compress the nipple might not be sufficient to obtain nourishment. • The swallowing mechanism might not have an appropriate response to protect the airway and respiration might be compromised. • There are feeding modifications and devices available for infants with oral-facial anomalies which should be considered when determining
Physiological Consideration	Definitions	Impact on Feeding
Sleepy Baby [a]	• Young premature infants spend most of their time in sleep status with brief spontaneous alerting noted at 32 weeks and poor altering at 37 weeks.	• Feeding is enhanced by an awake state and can be compromised by an inability to maintain wakefulness. • Some infants may use sleep as a defense mechanism to tune out environmental stimuli, resulting in a need for environmental modifications. • Other treatment strategies include arousal, demand feeding schedules, and evaluation and intervention of oxygen saturation.
Decreased Endurace [a]	• Sometimes infants stop feeding before taking the required amount of nutrients often due to reduced endurance. • The primary contributor to reduced endurance is respiratory compromise resulting from infant respiratory distress syndrome.	• If the work to maintain homeostasis is greater the infant may not be capable of the increased respiratory work required in feeding. • Treatment strategies include providing oxygen, modifying feeding schedules or the flow of liquid, or providing nutritional supplements.

[a]Wolf and Glass, 1992, [b]Hack, 1985, [c] Rosen, 1984, [d]Moore & Persaud, 2008, [e]Brooks, 1989, [f]Yu, 1997

Date of Birth		Birth weight (g)	
Date of Discharge		Discharge Weight (g)	

GA @ Birth in weeks		Delivery: 1= Vaginal 2= C-Section	**Multiple Birth:** 1= No 2= Y	Define if Yes:

Gender: 1= Male 2= Female	Facility 1 = Regional 2 = Northport	***APGAR _____ @1*** ***APGAR _____ @5*** ***APGAR _____ @10***	**Small for Gestational Age** 1=N 2=Y	**Intrauterine Growth Retardation** 1=N 2=Y	**Degree of Prematurity** 1= extreme prematurity <28 weeks 2= very preterm 28 to <32 weeks 3= moderate to late preterm 32 - <37 weeks

Race: 1=AA, 2= Caucasian, 3= Hispanic, 4= Other: ________	*Facial or Peripheral nerve injury @ birth* 1=No 2=Yes	*Bone long bone/ clavicle/skull* 1=No 2=Yes	*Hypoglycemia (<2.2 mmol/L)* 1=N 2=Y	*Low systol. BP (< 30 mm Hg for 28-32 weeks; <40 mm Hg for 32-42 weeks)* 1=N 2=Y	*Low urine op (<2ml/ kg/h)* 1=N 2=Y	*Persistent Vomiting* 1=N 2=Y

Cord Blood pH or Not Reported (NR):	***Resusc @Birth w/ Intubation:*** 1= No 2=Yes	Intubation @ Birth: 1= No 2=Yes	***Meconium Aspiration:*** 1= No 2= Yes	***Report of (circle):*** *Dusky* *Central Cyanosis*

Feeding History	**Start Parenteral (date)**	**Stop Parenteral (date)**	**Start Enteral (date)**	**Reach full enteral (date)**	**Start Oral (PO) 5ml or 5m (date)**	**Reach full oral (date)**

Discharged on: Breastmilk = 1 Formula = 2	**Type of formula:**	**Volume of formula per feeding (ml):**	**Number of feedings per day or 1= ad lib:**

Discharged on:	1=Bottle	2= Breast	3= Bottle and Breast	4= Tube	5 = Tube & oral

Discharged w/ Respiratory Support	1= No 2= Yes	**If yes, define:**
Respiratory Rate:	<30 @ 3-24 h or >60 @ 3-24 h 1= No 2=Yes	>100 @ 3-24 h 1= No 2=Yes
CPR any time 1= No 2=Yes	***Apnea & need for oxygen*** 1= No 2=Yes	***Apnea corrected w resuscitation*** 1= No 2=Yes
Days on HFOV:	***Days on CMV:***	***Days on High Flow:***
Days on NIMV:	***Days on SIMV:***	***Days on Nasal Cannula:***

Bronchopulm. Dysplasia (BPD)	1= No 2= Yes	**Severity** (Mild 1, Mod 2, Severe 3):	
Hyaline Membrane Disease (HMD)	1= No 2= Yes	**Severity** (Mild 1, Mod 2, Severe 3):	
Surfactant	1= No 2= Yes	**Number of doses**: _______	
Lasix	1= No 2= Yes	**Other:**	
Anomaly	1= No 2= Yes	**If yes, describe PDA/ASD/PFO/VSD, etc...:**	
Indomethacin/Indocin Doses: _______	**Ligation** 1= No 2= Yes	**Pulmonary Hypertension** 1= No 2= Yes	***Pulse*** HR < 100 BPM HR >160 BPM HR >200 BPM
NEC 1= No 2= Yes	**Feeding Intolerance** 1= No 2= Yes	**Reflux** 1= No 2= Yes	
Central Apnea/ Apnea of Prematurity/ A&Bs 1= No 2= Yes	**Caffeine** 1= No 2= Yes	***Intraventricular Hemmorhage (IVH)*** 1= No 2= Yes	***Grade (1-4)***: _____ Bilat or Unilat
Level of Consciousness: ***Drowsy / Lethargic / Stupor / Obtundation / Coma***			
Hypoxic Ischemic Encephalopathy (HIE) 1= No 2= Yes	***Seizures*** 1= No 2= Yes	If yes: *Single seizure/tremors* *Multiple seizures* *Multiple & >2 drugs needed*	***Subdural or Intracranial Hematoma*** 1= No 2= Yes
Neonatal Abstinence Syndrome (NAS) 1= No 2= Yes	**Periventricular Leukomalacia** 1= No 2= Yes Bilat Unilat	***Subdural or Intracranial Hematoma*** 1= No 2= Yes	***Bacterial Culture of CSF-Positive*** 1= No 2= Yes

Flaccidity @ 1-120 Hours 1=No 2=Yes	***Hypotonia@ 1-120 Hours*** 1=No 2=Yes	***Hypotonia beyond 120 Hours*** 1=No 2=Yes	***Poor sucking within 24 hours*** 1=No 2=Yes	***Poor sucking @24 hours -7 days*** 1=No 2=Yes	***Poor sucking beyond 7 days*** 1=No 2=Yes	Other:
Thrombo-cytopenia 1=No 2=Yes	***Anemia*** 1=No 2=Yes	***PBRC Transfus*** 1=No 2=Yes	**Platelet Transfus** 1=No 2=Yes	**Plasma Transfus** 1=No 2=Yes	***Hyperbilli (Jaundice)*** 1=No 2=Yes	***Photo Tx*** 1=No 2=Yes
Osteopenia 1=No 2=Yes	**Neutropenia** 1=No 2=Yes	**Maternal DM** 1=No 2=Yes	**Hyper-Glycemia** 1=No 2=Yes	**Hypo-Glycemia** 1=No 2=Yes	**Bac culture of blood + (sepsis)** 1=No 2=Yes	**Other:**

IRB CERTIFICATE

THE UNIVERSITY OF ALABAMA®
Office of the Vice President for
Research & Economic Development
Office for Research Compliance

January 17, 2018

Memorie M. Gosa, PhD, CCC-SLP, BCS-S
Assistant Professor
Department of Communicative Disorders
College of Arts & Sciences
Box 870242

Re: IRB # 15-OR-089-ME-R3 "Achievement of Oral Feeding Skills in Preterm Infants"

Dear Dr. Gosa:

The University of Alabama Institutional Review Board has granted approval for your renewal application.

Your renewal application has been given expedited approval according to 45 CFR part 46. You have been granted the requested waiver of patient authorization to use PHI in research as well as a waiver of the requirement to obtain informed consent. Approval has been given under expedited review category 5 as outlined below:

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

Your application will expire on January 16, 2019. If your research will continue beyond this date, complete the relevant portions of the IRB Renewal Application. If you wish to modify the application, complete the Modification of an Approved Protocol Form. Changes in this study cannot be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to participants. When the study closes, complete the appropriate portions of the IRB Study Closure Form.

Should you need to submit any further correspondence regarding this proposal, please include the above application number.

Good luck with your research.

Sincerely,

Director & Research Compliance Officer
Office for Research Compliance

358 Rose Administration Building | Box 870127 | Tuscaloosa, AL 35487-0127
205-348-8461 | Fax 205-348-7189 | Toll Free 1-877-820-3066