The Impact of Nasogastric Indwelling versus Oral Intermittent Tube Feeding Methods on Premature Infants

By

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Dedication

To The Creator,

Who made life majestic, intricate… then entwined it with the abstract.

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Abstract

Both intermittent oral gavage tube placement (OG) and indwelling nasogastric tube placement (NG) are acceptable methods for feeding preterm infants. A randomized controlled pilot study was conducted to examine the impact of OG versus NG placement on premature infant feeding transition. Twenty healthy premature infants were enrolled and thirteen completed the study. The results were not statistically significant. Age at last tube feed averaged 35 weeks gestational age (GA) for the intermittent group and 35+4 weeks GA for the indwelling group (p=0.181). Infants in both groups were discharged at an average of 36 weeks GA (p=0.836) and average suckled volumes at 35 weeks GA was 134.4 cc/kg/day for the intermittent group versus 111.8cc/kg/day for the indwelling group (p=0.240).

Infant feeding patterns were analyzed descriptively and found to be consistently variable. The lack of consistency in feeding development has implications for feeding plan development and feeding transition care.

CHAPTER 1

Statement of the Problem

This thesis was designed to examine the impact of two different tube feeding methods on premature infant feeding behavior. The first chapter introduces two different types of tube feeding methods commonly used to feed premature infants and presents the differences as the statement of the problem. Chapter two commences the literature review. It covers physiological principles that impact premature infant feeding, explains feeding transition, and reviews the factors involved in premature infant feeding transition. A section on tube feeding effects completes the literature review. Als' Synactive Theory of Development is presented as the theoretical framework used to develop the hypotheses in chapter three. The methods follow in chapter four. The results and discussion elucidate the thesis findings. Appendix E descriptively analyzes premature infant feeding patterns.

Background and Significance of the Problem

The ability to ingest nutrition is a vital activity of daily living and is of great clinical importance for the premature infant to master. Discharge from hospital is dependent on the infant's ability to take full oral feedings, maintain respiratory and cardiovascular stability, and achieve good weight gain (Medoff-Cooper, 2000).

For the premature infant, feeding is a complex neurodevelopmental task that takes time, practice and stamina to accomplish. The ability to coordinate sucking and swallowing with breathing does not begin to develop until around 32 weeks gestation (Medoff-Cooper, 1991). Even then, the premature infant usually does not have the coordination or stamina to maintain nutritional requirements solely by oral feeding without the help of medical intervention.

The medical intervention required by preterm infants for enteral nutrition is tube feeding. Tube feeding bypasses the premature infant's sucking and swallowing processes and allows nutritional substrates to be delivered to the infant's stomach for growth and development. Preterm infants who are born at 25 weeks gestation may require tube feeding for 10 weeks or more, and if the infant has other medical complications, the feeding process can take even longer (Bazak, 1990). For premature infants, tube feeding is a necessary medical intervention, and in essence, a daily lifeline.

Infant gavage feeding or tube feeding is usually done by two different methods: an intermittent method, or an indwelling method. In intermittent tube feeding, a nutritional substrate is given to the infant through an intermittently-placed feeding tube. The tube is inserted into the infant's mouth or nose and pushed into the infant's stomach prior to each feed, and then removed immediately after each feed. Intermittent nasogastric (NG) tube insertion lost popularity many years ago and is no longer practiced at Health Sciences Center (HSC) Neonatal Intensive Care Unit (NICU) or Intermediate Care Nursery (IMCN). Recent research has shown that NG tube insertion is as painful as a heel stick for premature infants (McCullough, Halton, Mowbray & Macfarlane, 2007), and this finding lends support for the decision to abandon intermittent nasogastric tube insertion. However, intermittent oral gastric (OG) tube insertion remains the most popular tube feeding method for a sub-group of premature infants transitioning from gavage feeding to oral feeding at HSC.

Intermittent OG tube insertion can have negative effects on the preterm infant. It can induce life-threatening events such as apnea, bradycardia and desaturation with each tube insertion procedure (Haxhija, Rosegger & Prechtl, 1995). Gagging and emesis may also occur with the tube insertion and removal, and these events can be experienced up to 8 times a day with routine feedings that are scheduled every three hours. Very little tube feeding research is available, so it is not known if intermittent tube insertion interferes with the infant's neuro-feeding development and feeding skill acquisition, creates undesirable associations with feeding, or if it delays the premature infant's ability to take full oral feeds.

In contrast, the indwelling tube feeding method provides a route for nutritional substrate administration through a tube which is inserted for long-term placement. A gavage tube is advanced into the infant's nose or mouth and down to the stomach. Then it is secured to the infant's face with tape or a barrier device and tape to reduce skin irritation. The indwelling feeding tube is only replaced once every three days or every month, depending on the type of material the tube is made of; thereby, greatly decreasing the number of potentially aversive tube insertion procedures. However, the feeding tube is constantly present and research shows that infants who endured indwelling feeding tubes for more than three weeks displayed delayed feeding development at 11 and 17 months of age (Dodrill, McMahon, Ward, Weir, Donovan, Riddle, 2004). Also, an indwelling NG tube can negatively impact the infant's delicate respiratory system and decrease the volume of milk the infant suckles (Shiao, Brooker, & Difore, 1996; Shiao, Youngblut, Anderson, Difore, & Martin, 1995). Currently little research is available about the effects of an indwelling feeding tube on the preterm infant's ability to transition to full oral feeds.

There are currently few guidelines for tube feeding practice in the literature (Daley & Kennedy, 2000; Hawes, McEwan & McGuire, 2005; Mears, 2001; Rogahn, 1998; Shiao & Novotny, 1998), and little is known about the discomfort or impact of different tube feeding methods on feeding behaviors. Hence, it is the bedside nurse, physician or institutional preference that guides the frequency of tube insertion and preference for indwelling versus intermittent tube feeding methods (Chant, 1999; Shiao & Difiore, 1996; Shiao, et al., 1995; Symington, Ballantyne, Pinelli, & Stevens 1995).

The Health Sciences Centre NICU (in Winnipeg, Manitoba) currently utilizes only indwelling feeding tubes while the IMCN (also at Health Sciences Center) uses a combination of NG (preferred method) or OG indwelling feeding tubes, and intermittently-placed oral feeding-tubes. Indwelling tubes are often used for preterm infants, who are not yet feeding orally, and for orally-feeding infants who feed poorly and have medical conditions that require long-term tube feeding. Whereas intermittent oral tube placement is mostly practiced for preterm infants beginning to feed orally who do not have medical conditions or feeding difficulties that require long-term tube feeding. The assumption that premature infants will reach full oral feedings faster, and will have fewer feeding difficulties with intermittent tube placement supports the intermittent OG tube placement practice of this unit. It is not known if this sub-group of preterm infants who are beginning to feed orally would benefit from NG indwelling tubes during the transition from gavage to oral feeding. Hence the question: which tube feeding method promotes an expedited transition from gavage to oral feeding in premature infants and supports oral feeding behavior?

Purpose of the Study

The purpose of this pilot study is to compare the impact of intermittent oral tube insertion versus NG indwelling feeding-tube placement on the healthy preterm infant's length of hospital stay, and ability to transition to full oral feeds without medical intervention. The information gathered from this study will be used to raise awareness about tube feeding issues, provide new knowledge, determine the feasibility of a larger study, gather information pertinent to determine sample size in a full study, and ascertain adequacy of the proposed research approach (Polit & Hungler, 1999).

CHAPTER 2

Review of the Literature

Principles important to the tube feeding dilemma will be discussed using some review articles and some original studies. The purpose of this section is to provide the reader with a basic understanding of the concepts contributing to the complexity of premature infant feeding.

Principles of Premature Infant Feeding

Premature infant feeding is a complex process that depends on physiological structures needed to suckle and their neurological maturity. It is also a dynamic process involving growth and development. Anatomic structures essential for competent feeding skills must be accompanied by neurologic maturation and cardio-respiratory stability. As premature infants begin the feeding process, experiential learning, and infant health further shape the feeding behavior (Medoff-Cooper, McGrath, & Shults, 2002).

Infant Feeding Physiology

Infant feeding differs from an adult feeding both structurally and functionally. Some infant feeding physiology is specifically designed for sucking, and a basic knowledge is essential to understanding infant feeding and the potential impact of feeding tubes on infant feeding. The pharynx is divided into three compartments: the nasopharynx, oropharynx and the hypopharynx. The nasopharynx is part of the respiratory tract and the oropharynx and hypopharynx are both part of the alimentary and respiratory tracts. When a nasogastric tube is in place, the respiratory tract now has a foreign connection to the gastrointestinal system and the respiratory tract is sharing valuable space for feeding purposes.

Each compartment of the pharynx has specific motor functions and the neural networks of those compartments have different maturation times (Bosma, 1985; as cited in Stevenson & Allaire, 1991). The premature infant is dependant on these neural maturational time lines and may exhibit some feeding behaviors prior to the readiness of the other neural systems. Thus, feeding development is complex and feeding activity is inconsistent across different gestational ages. To complicate the matter further, premature infants feeding by indwelling NG or orogastric feeding tubes have the added stimulation of a foreign object in contact with highly sensory areas which are still developing and which are designed to protect the airway, provide respiration, and transport liquid to the stomach. According to neurophysiological principles, when a persistent stimulus such as a feeding tube is present, it may diminish neural responses due to accommodation (as cited in Haxija et al., 1995) and it is not known if the continued presence of a feeding tube versus the intermittent placement of the feeding tube will impact the intricate feeding system and infant feeding development.

Structurally, the tongue and soft palate are much larger in the infant proportionally than in an adult, and take up significantly more space. A large section of the mid-tongue is sensitive to stimulation (Wolf & Glass, 1992) therefore the placement of an OG tube easily elicits the gag reflex and may cause emesis. Not only is the tongue a sensory organ, it also plays an important part in sealing the oral cavity and compressing the nipple against the palate to create positive pressure for liquid extraction from the nipple. Additionally, it creates negative suction pressure with the downward movement of the jaw (Wolf & Glass, 1992).

Another feature that aids infant feeding is the large fatty sucking pads that further reduce the size of the oral cavity, provide stability and help with bolus formation. The infant's larynx is higher and the epiglottis touches or overlaps the soft palate to help prevent aspiration by directing the liquid around the laryngeal opening. This relationship makes the recumbent position ideal for feeding the infant (Stevenson & Allaire, 1991). Finally, the soft palate prevents reflux to nasopharynx.

The premature infant is disadvantaged as an oral feeder in many aspects. The premature infant has less body fat, muscle bulk and poorly developed sucking pads which change the structure and stability of the oral cavity (Glass, & Wolf, 1994). Weaker labial and facial muscles decrease the ability to create a tight seal on the nipple and make feeding more difficult for the infant. To make matters worse, the infant may have an indwelling feeding tube which may impact the infant's seal on the nipple, and suction pressures, and may impact oral stability. Also, with an NG tube in place nasopharyngeal integrity may not be maintained. Any deviations in feeding structures may impact infant feeding, and any foreign object being placed for a feed or in place during the feed may impact infant feeding.

Premature Infant Sucking

Sucking begins early in gestation, and has been seen at around 15 weeks' gestation (Ianniruberto & Tajani, 1981). There are two phases of sucking: a positive pressure caused by compressing the nipple, and a negative pressure caused by a good seal on the nipple and a downward motion of the jaw which lowers the tongue and enlarges the oral cavity to create negative intra-oral pressure that pulls liquid into the mouth (Wolf & Glass 1992). Generally, all infants begin sucking with compression only. However, the term infant progresses very quickly (in about one hour) to combining compression and suction (Wolf & Glass, 1992), whereas the preterm infant may continue to use compression as a primary phase of sucking, even after full oral feeds are achieved (Lau, Sheena, Shulman & Schanler, 1997).

Another important concept that characterizes sucking in the infant is that it is also a reflex. Sucking changes to a volitional act with the process of encephalization after birth (as cited in Stevenson & Allaire, 1991) and is believed to change to full volitional control by four to six months (Wolf & Glass, 1992). Sucking is further described in terms of nutritive and nonnutritive. Nonnutritive sucking is a highly organized repetitive pattern of bursts and pauses with a ratio of six to eight sucks to one swallow (Wolff, 1968; as cited in Glass, & Wolf, 1994) with no nutritional ingestion. Nutritive sucking begins the process of ingesting liquid. It is more complex than nonnutritive sucking and is comprised of two patterns—continuous and intermittent sucking. Continuous sucking is the feeding pattern that all infants begin each feed with. It consists of long sucking bursts with few brief pauses. The change in pattern from a continuous sucking burst to an intermittent pattern is thought to be triggered by sensitivity to decreased arterial oxygen saturation. Gradually, over the course of the feeding, the infant shifts to an intermittent pattern which is characterized by shorter sucking bursts and longer pauses (Glass, & Wolf, 1994). It remains unknown if an indwelling feeding tube or an intermittently-placed feeding tube will impact the sucking reflex and affect the volume intake of a nutritional substrate.

Both sucking patterns can pose difficulties for premature infants. During the continuous sucking pattern, premature infants can struggle with apnea as they attempt to balance continuous sucking with breathing. Mathew (1988) found that apnea was even more prevalent during the intermittent sucking pattern. Also, preterm infants feed for shorter periods of time, exhibit lower sucking pressures and generally have shorter sucking bursts (as cited in Thoyre 2003). Between 28 - 33 weeks gestation, premature infants begin to demonstrate immature sucking patterns that continue to develop and mature. Around 35-36 weeks gestation (Mathew, 1988), most healthy preterm infants demonstrate adequate sucking patterns.

Some important observations were made by Medoff-Cooper, et al., (2002) about the development of nutritive sucking patterns in premature infants that further our understanding of premature infant feeding. Medoff-Cooper, et al. found that infants born between 30-32 weeks gestation developed more competent sucking patterns by 40 weeks gestational age than term infants who were 48 hours old. This group of healthy preterm infants born at 30-32 weeks gestation also had better sucking patterns than infants born at 24-29 weeks gestation. In fact, these preterm infants born at 24-29 weeks gestation did not develop feeding patterns of the same type or even at the same rate.

Medoff-Cooper et al., (2002) concluded that the group of later born preterm infants' (30-32 weeks gestation) feeding experiences shaped their feeding development, and that learning was critical to their feeding performance. However, the poor feeding behavior of very early preterm infants born at less than 29 weeks gestation was reflective of poorer health status, and the maladaptive feeding patterns seen in this group developed as a consequence of poorer health status. Therefore, health status has a major influence on premature infant sucking-pattern development. Consequently, this pilot study will control for infant health by selecting study participants following stringent selection criteria.

Infant Swallowing

Infant swallowing is a highly complex, coordinated action of the nervous system and muscles innervating the mouth, pharynx, larynx and esophagus. The oral phase is under voluntary control, but pharyngeal and esophageal phases are involuntary. Once enough liquid has accumulated in the midline depression of the tongue, it stimulates receptor sites of the tongue, soft palate, pharyngeal walls and faucial arches, and triggers the involuntary phase of swallowing. The cortical and hypothalamic regions may over-ride the swallowing action, and stimulation of the same regions can also evoke different motor responses such as gagging or vomiting. Another factor that affects swallowing is respiration, and the timing of the swallow may be altered by respiratory disease (Wolf & Glass 1992).

If the swallowing reflex is supported by the neural-network, the liquid passes into the hypopharynx where the larynx elevates and moves under the tongue. The laryngeal adductors contract, the soft palate closes off the nasopharynx, the epiglottis closes the larynx, and the cricoesophageal sphincter relaxes for a about one second or less, allowing the liquid into the esophagus. The muscular esophageal tube, which is normally collapsed, begins squeezing the liquid in peristaltic contraction toward the lower esophageal sphincter which opens briefly to allow the food to pass into the stomach. In optimal conditions, the infant performs these actions without compromising the respiratory system (Mathew, 1991; Rombeau & Caldwell 1990).

Feeding Rhythms

The smooth integration of sucking, swallowing, and breathing during nutritive feeding allows the infant to feed efficiently. If a problem is present in any component of the suck-swallow-breath cycle, feeding may be compromised. The central mechanisms that coordinate these three functions into a smooth rhythmic cycle must be intact. In some cases, even healthy term infants can have some difficulty with maintaining a rhythm during feeding, and it is not uncommon for them to struggle with coordinating breathing and swallowing (Mathew, 1988).

A normal sucking pattern consists of a burst. A burst usually contains one suck and one swallow, followed by one breath. Between a run of bursts, the infant pauses for a segment of rapid breathing, and then re-enters a run of bursts with a 1:1:1 ratio of sucking, swallowing, and breathing. As the infant matures, the ratio of suck to swallow may increase to 2:1 or 3:1, with one or more breaths occurring after the swallow (Wolf & Glass, 1992).

Premature infants struggle with maintaining coordinated breathing patterns with sucking and swallowing. Premature infant feeding patterns are not rhythmic but fall into three different types of categories. One type of premature feeding is characterized by short sucking bursts where the preterm infant makes one to three bursts before pausing. However, the pauses are too frequent and too long thus compromising and liquid intake. This pattern may indicate difficulty with swallowing, or respiration, or with poor oral-motor control in forming the bolus, or an impeded swallowing reflex speed (Wolf & Glass, 1992).

In the disorganized sucking pattern, the burst may not include adequate breaths, and since the run of sucking bursts are not rhythmic, choking is frequently associated with this feeding pattern. Causes of this feeding pattern may be a disorganized state, neurologic deficits, respiratory difficulties or incompatible nipple-flow rates.

Lastly, in a prolonged sucking pattern the premature infant does not exhibit any normal bursts. The infant simply sucks and swallows without taking a breath. This pattern causes apnea and leads to desaturation if the infant does not pause to breathe. The premature infant cannot maintain this pattern for long and exhaustion prevents the infant from taking adequate volumes (Wolf & Glass 1992).

Typically, as the preterm infant matures, the sucking pattern becomes rhythmic by 35 to 36 weeks gestation. Although coordination skills advance with age as a general rule, there is wide variation in skills between premature infants at the same gestational age (Lau, Alagugurusamy, Schanler, Smith & Shulman, 2000; Medoff-Cooper, 1991). The preterm infants most likely to maintain the immature sucking rhythms beyond 36 weeks gestation and to experience significant delays in attaining mature sucking patterns are infants with bronchopulmonary dysplasia (Gewolb, Bosma, Taciak, & Vice, 2001), and early born infants with gestational ages of 24- 29 weeks (Medoff-Cooper, et al., 2002).

Immature Breathing Patterns

The premature infant encounters many respiratory challenges which make feeding even more difficult; however, the infant must maintain respiratory stability during feeding to remain physiologically stable. The premature infant has immature respiratory patterns that are characterized by irregular periods of respiration, brief apnea, and apnea of prematurity. Apnea and premature breathing patterns are known to be a reflection of the infant's premature neurological status, a self-limiting condition that resolves with central nervous system maturation.

During feeding a premature infant can have central, obstructive or mixed apneic events. Central apnea is primarily caused by an infant's breath-holding during the nutritive suck-swallow pattern, or secondarily to an obstructive event. In central apnea, the infant does not attempt to breath. If apnea is secondary to an obstructive event, it is called a mixed apneic event. Mathew (1988) found that the majority of apnea during infant feeding was caused by mixed apnea. Respiratory effort is made, but no air flow is exchanged. This type of apnea can be caused by respiratory effort taking place before the airway is open, mucosal adhesive forces, tracheomalacia, laryngospasm, gastroesophageal reflux, or laryngeal chemoreflexes. In the premature infant, the immature laryngeal chemoreflex causes rapid, prolonged swallowing and apnea with suppressed coughing. As the infant matures, the reflex diminishes and is changed into a coughing reflex (Thach, 2001; Thach, 2007). As well, premature infants who have more periods of irregular respiration tend to have prolonged airway closure associated swallowing (Wilson, Thach, Brouillette & Abu-Osba , as cited in Wolf & Glass 1992). The immature laryngeal chemoreflex and prolonged airway closure in the premature infant further complicates the feeding process.

During periods of apnea the infant's physiological status may be threatened. The infant may be able to self-resolve the apnea, but if not, will require the feeder's assistance to recover. The feeder can resolve the apnea by providing some stimulation such as rubbing the infant's back, tipping the infant forward so that any liquid in the mouth moves away from the airway, or by removing the infant's bottle. These methods help the infant recover from apnea, desaturation or bradycardia, and are referred to as infant-pacing techniques (Wolf & Glass 1992). The pacing techniques may also be used to prevent an apneic episode from occurring by providing a breathing pause for the infant who continues to have immature feeding patterns.

Impact of Infant Respiration on Feeding

Feeding can impact breathing as discussed above, however the reverse has also been found to be true. Since respiration can be suppressed during suckling, the infant who is already experiencing some respiratory distress in the form of increased work of breathing or increased respiratory rate, must find a way to compensate. In order to compensate for this loss of breathing time, the premature infant takes breathing pauses between abnormal sucking rhythms and becomes tachypneic (Wolf & Glass, 1992). Abnormal respiratory patterns are associated with immature sucking patterns that can last beyond 36 weeks gestation, and are hypothesized to contribute to the development of abnormal feeding rhythms often seen in infants with bronchopulmonary dysplasia (Gewolb, et al., 2001).

In summary, infants who have breathing difficulties will be the most affected by the demands of feeding, will take longer to develop mature sucking patterns (Gewolb, et al., 2001), and are at a greater risk for apnea, fatigue, aspiration and inefficient feeding (Wolf & Glass, 1992). Therefore, it is important to investigate which type of tube feeding method will cause the infant the least amount of respiratory distress because it may impact feeding behavior.

Preterm Infant Oral Feeding Readiness and Skill

Currently, the assessment of preterm infant feeding skills is based on the bedside nurse's experience, skill, and knowledge of preterm infant feeding. Preterm infant feeding assessment scales are being developed (Thoyre, Shaker & Pridham, 2005) and some neonatal care facilities are beginning to incorporate them into nursing care plans. However, Health Sciences Center does not currently utilize a feeding assessment scale for infants. As the body of literature regarding infant feeding readiness accumulates, infant feeding assessment scales verified by research will become more popular and become a part of neonatal practice.

Oral feeding readiness and skill are not based on the infant's gestational age or oral structural and functional integrity alone, but are influenced by many more factors. The infant must also have the ability to maintain an alert state and have the energy to stay engaged in feeding, as well as express the desire to feed (Gisel, Birnbaum & Schwartz, 1998). Some less-obvious factors that influence feeding readiness and feeding skill are the infant's environment and the skills of the infant's feeder (Thoyre, 2003; Thoyre, et al., 2005; Wolf & Glass 1992). For example, any environmental factor that stresses the infant can impact the infant's energy level, desire to feed or level of alertness. Simple things such as over-stimulation, noise levels, lighting, bundling for feeding, poor infant positioning, pacing, and procedures performed on the infant prior to a feeding can all impact the infant's feeding skill (Bazak, 1990; Thoyre, 2003; Wolf & Glass, 1992). Finally, the caregiver's interaction and feeding technique in attending to infant behavior during feeding, can impact the infants feeding ability.

Tube Feeding

Delivering a nutritional substrate to promote growth and development in an individual who is incapable of taking in the required nutrients is the function of tube feeding, and it is usually viewed as a task that is necessary and beneficial. Harm and discomfort are not the typical associations attributed to tube feeding, but these associations will be examined in greater detail in another section of the literature review. In this section, the essence of tube feeding as it relates to premature infants will be described.

The tube can be made of many types of materials, each of which has potential benefits and detriments. Tubes are made of polyvinyl chloride (PVC), silicone or polyurethane, and come in sizes as small as 3.5 French (Fr) to 8 Fr for preterm infants. The size represents the outer diameter, and one Fr. unit equals 0.33mm. The tubes are made with one or more side holes which are beneficial because they can minimize tube clogging during feeding, and stomach tissue injury when the tube is aspirated.

PVC tubes are recommended for short-term use only because they harden over time. When PVC tubes come in contact with gastric enzymes, the plasticizers leak out of the tubing and increase the likelihood of perforating the gastrointestinal tract. The plasticizer in many PVC medical supplies that keeps them flexible is a phthalate derivative called diethylhexylphthalate (DEHP). It easily migrates out of the PVC tube into the surrounding tissues and can have multiple effects on the liver, testis, kidney, lung and heart. Since the 1980’s, polyadipate was introduced as a less expensive alternative to phthalate and it leaks significantly less DEHP into the body. However, not all suppliers of PVC feeding tubes have switched to using polyadipate (Subotic, Hannmann, Kiss, Brade, Breitkopf & Loff, 2007).

The length of time recommended for PVC tube replacement varies from six hours to seven days (Mears, 2001; Rogahn, 1998; Shiao & Difiore, 1996; Shiao & Novotny, 1998). PVC is thought to be the least comfortable type of feeding tube because it is less flexible. Although the more rigid property of the PVC makes it easier for the nurse to insert, it also carries an increased risk for perforating the premature infant's gastrointestinal track when it is being inserted (Shiao & Novotny, 1998). PVC tubes are used for both intermittent and indwelling tube feeding methods.

Silicone and polyurethane tubes are strong, durable, do not contain plasticizers, and can be used for up to one month. They can be more difficult to insert because of their increased flexibility but are beneficial because they carry a decreased risk for gastrointestinal perforation, and they are thought to be more comfortable. Silicone can collapse during gastric aspiration and is known to break (Shiao & Novotny, 1998). Another possible deterrent to the use of these tubes is their cost, so they are normally used for an indwelling feeding method.

Surgically-placed gastrostomies or percutaneously-placed gastric feeding tubes are not used in the premature infant population. Only infants who demonstrate an inability to change over to oral feedings during the normal transition period are considered candidates for gastrostomy placement. Therefore, premature infants are left with few feeding options—indwelling tube feeding placement or intermittent tube feeding placement.

Indwelling feeding tubes can be placed nasally or orally with the tubes secured to the infant's face. The tubes may be made of PVC, in which case they are typically replaced every two to seven days. If they are made of silicone or polyurethane, they are changed every month. In contrast, infants fed by the intermittent tube feeding method are fed with a PVC tube that is placed prior to each feed and is removed immediately after each feed. In the intermittent method the infant can experience the tube insertion procedure 56 times in a week; however the indwelling tube is constantly present, so it may be a source of constant irritation.

The nose is a sensitive structure that has an intricate and delicate network of cells which detect pain, scent, and provide filtration, humidification and temperature control to the inspired air. The nose also contains a combination of vessels, glands and mucous-producing cells, and ciliary cells that are designed to move particles toward the posterior nasopharynx for disposal via the esophagus. When a nasogastric tube is placed, excess mucous may be produced and the vascular permeability of the nasal venous valve-less system may predispose the nasal cavity and sinuses to infection (Naclerio, Durham, & Mygind, 1999). Also as obligate nasal breathers, infants lose valuable airflow space to a tube, and an abnormal connection is created between the nasal cavity and the stomach.

Feeding Transition: From Gavage to Oral Feeding

The preterm infant receives nutrition via parenteral route initially, and then begins receiving enteral nutrition via gavage tube. The process of changing from parenteral to enteral feeding can be a long and slow process that depends on the infant's physiological toleration of enteral feeds. Exclusive tube feeding continues until the infant is ready to begin oral feeding, and the bedside nurse decides when the infant can be challenged with this complex task. Transitioning is the period of time when the infant begins to feed orally till the time the infant is successfully able to maintain nutritional requirements solely by oral feeding, and no longer requires tube feeding intervention. Many factors affect infant transitioning; it is not just a matter of time as has been stated (Lemons & Loughead, 2001). Those factors affecting transition will be discussed based on a review of feeding transition literature.

Oral feeding is one of the final competencies that the infant needs to attain prior to discharge, and there are obvious reasons of interest in seeing the infant feeding independently. Earlier discharge reduces the cost of hospitalization and the risks associated with prolonged hospitalization. The benefits of earlier infant feeding are the decreased time the infant must experience the tube feeding intervention and its associated risks, and greater opportunities for parental bonding when the parent can participate in infant feeding.

Physiological Factors

As previously discussed, there are many infant physiological factors such as the integrity of the infant’s oral structures and neurological functions that are necessary for successful infant feeding. In order to further explore and define the physiological factors or infant profiles that would impact premature infant feeding transition, a literature search on Medline was conducted.

In an ex post facto research design, Bazyk (1990) retrospectively reviewed 100 infants’ charts to determine medical factors associated with prolonged transition to oral feeding. Through correlational and multiple regression analyses, Bazyk found a number of medical complications significantly correlated with the length of feeding transition.

Complications in the following list of physiological systems were correlated with an increased feeding transition time: number of digestive conditions, necrotizing enterocolitis, number respiratory conditions, bronchopulmonary dysplasia, number of congenital cardiac defects, number of neurological conditions, and the number of medical complications.

In another study, infants who were identified with sucking disabilities at 35 weeks gestation had the following medical conditions: infant number1 had neonatal pneumonia, diaphragmatic paralysis and necrotizing enterocolitis; infant number 2 had respiratory distress syndrome, bronchopulmonary dysplasia and laryngotracheomalacia; infant number 3 had a hypoplastic left heart; infant number 4 had perinatal asphyxia, pneumonia, and a patent ductus arteriosus; infant number 5 had bronchopneumonia, BPD, and pulmonary arterial hypertension; infant number 6 had obstructive apnea with gastroesophageal reflux and prematurity; infant number 7 had perinatal asphyxia, and atrial-septal defect; infant number 8 had a diaphragmatic hernia and pneumonia; infant number 9 had necrotizing enterocolitis; infant number 10 had Status epilepticus, lissencephaly, and cerebral atrophy (Rendon-Macias, Cruz –Perez, Mosco-Peralta, Sariaba-Russsell, Levi-Tajfeld & Morales-Lopez, 1999). The list goes on and becomes somewhat repetitive, but what is striking is the similarity to Bazyk’s (1990) list of factors that predict a prolonged transition to oral feeding. Almost every infant listed above has more than one medical diagnosis or had a medical condition that fit into one of Bazyk’s (1990) categories that predicted a lengthened feeding transition.

Pickler, Mauck and Geldmaker (1997) used a different approach to study which preterm infants would take longer to transition to full oral feeds. In an ex post facto design, they studied 40 preterm infants' morbidity rating (using the Neonatal Medical Index) to predict feeding transition times. Similar to Bazyk's (1990) study, Pickler et al. found that infants with the most medical complications took the longest to transition to full oral feedings. Infants who took the longest to transition fit into the fifth medical rank description. Criteria of the fifth Neonatal Medical Index rank are: a birth weight of less than 1,000 grams, assisted ventilation for more than 29 days, meningitis, seizures or grade III or IV periventricular hemorrhage/ intraventricular hemorrhage (PVH/IVH), or periventricular leukomalacia (PVL). Infants who qualified to fit into this rank took two to five weeks longer to transition. The Neonatal Medical Index was significantly predictive of feeding transition time.

Mandich, Ritchie and Mullett (1996) studied the impact of premature infant apnea, and treatment with or without aminophylline, on the feeding transition of 65 premature infants aged 28-34 weeks gestation. The preterm infants were ventilated less than 48 hours and did not have any of the high risk factors discussed above. Mandich et al. found that these healthy preterm infants, who had apnea during transition regardless of whether they were or were not on aminophylline, had the strongest correlation with longer transition times. The factors that ranked beneath apnea were birth weight, and age at which oral feeding began. Although the results of this study appear promising for being able to predict that premature infants with apnea will take longer to transition to full oral feeding, the study is a chart review which does not control for bias. The authors acknowledged that the infants without apnea differed significantly in the following characteristics; first, the infants with apnea were one to two weeks younger in gestational age than the infants without apnea, secondly, the group of infants without apnea and not on aminophylline had the heaviest birth weights, and third, the age of the first feeding was significantly later for the group of infants without apnea. Since apnea is associated with neurological immaturity and neurological injury, and given that the infants in this study with apnea were younger in gestational age and had lower birth weights, these results must be accepted cautiously. Also, the transition time was counted in days from the first feeding to full oral feeds and the gestational age at full feeding is not mentioned, so it makes these results difficult to interpret. The knowledge that breathing patterns do impact feeding patterns is an important consideration for any future feeding studies examining feeding transition.

Respiratory function has already been identified as a factor that prolongs feeding transition, and the following studies support this finding. Gewolb, et al. (2001) found that infants with BPD did not mature their sucking and swallowing rhythms with increasing gestational age as anticipated. As well, when examining groups of BPD infants for variables that impacted feeding transition, Pridham, Sondel, Chang, and Green (1993) found that BPD infants of younger gestational age who required more days of supplemental oxygen and ventilation and had more severe lung disease, also had longer transition times. In Pridham, Brown, Sondel, Green, Wedel and Lai's (1998) retrospective study examining infants with respiratory distress syndrome (RDS) or BPD and days to full feeds, Pridham et al.,(1998) found that infants with RDS, and no history of apnea, had a significantly shorter transition time. Pridham et al. also found that infants who were treated at one of two hospitals included in the study had significantly shorter transition times. This implies that the different practices in hospitals can also lengthen transition times. The study furthermore found that breast feeding did not affect transitioning and that the number of tube-fed days increased transitioning days.

Environmental Factors

Some environmental factors have also been studied that impact infant transitioning. They include non-nutritive sucking, oral stimulation, and feeding premature infants at earlier gestational ages. Studies examining these factors will be reviewed, using some original studies and some review articles.

Non-nutritive sucking and oral stimulation.

Non-nutritive sucking has been identified as a factor that is beneficial and supports feeding transition. Infants who have been provided with a pacifier are known to exhibit less behavioral distress, spend less time in a fussy active state and return to sleep significantly faster than infants who do not engage in non-nutritive sucking (DiPietro, Cusson, Caughy and Fox, 1994). Soothers are available for non-nutritive sucking and it is practiced in the IMCN and in the NICU at HSC unless the mother declines a soother for her infant.

Premji and Paes (2000) conducted a systematic review of randomized controlled trials that examined the effect of non-nutritive sucking on the maturation of the sucking response, gastric emptying, weight gain and time to discharge from hospital. The studies that were reviewed took place between1979 and 1996. In their conclusion, Premji and Paes report finding that the effects of non-nutritive sucking were inconclusive in all the outcome measures except for early hospital discharge. Infants who received non-nutritive sucking benefited from the intervention by achieving an earlier hospital discharge. Many of those studies did not examine feeding transition as an outcome, and the authors criticized some of the studies for a lack of sufficient power and lack of stratification to control for variables. Therefore, these results must be accepted cautiously and further study is needed.

Rocha, Moreira, Pimenta, Ramos and Lucena (2007) found that infants who received sensory-motor-oral stimulation and non-nutritive sucking accomplished full oral feeds in fewer days of life, and had a significantly earlier hospital discharge at an earlier gestational age than infants who did not receive the sensory-motor-oral stimulation and non-nutritive sucking. The study was a double-blind randomized clinical trial where 98 infants were stratified based on gestational age ranges. The days of life at the first introduction to feeding was also significantly earlier, but gestational age in weeks (35.2 +/- 1.7 - 36.0 +/- 1.7) at the first introduction to feeding was not significantly different according to statistical calculations. This may indicate that the statistical significance noted for the days of life at the first feed is influenced by the type of measure used. In order to clarify this situation, measuring the infant's gestational age in weeks would provide a clearer picture for the reviewer and make comparisons between future studies simpler.

The authors Fucile, Gisel and Lau (2002) also reviewed studies that examined oral stimulation and then they conducted their own research. The beneficial effects of oral stimulation in the cited studies were an enhanced sucking rate when an infant's cheek was stroked, increased liquid volume intake during sucking when an infant's cheek and chin were supported during feeding, improved scores on the Neonatal Oral Motor Assessment Scale, and decreased hospital stay. Based on the results of the studies reviewed, Fucile et al decided to test the assumption that oral stimulation and non-nutritive sucking provided to preterm infants prior to 30 weeks gestation would also improve oral feeding performance. They studied 32 stable premature infants aged 26 to 29 weeks that were stratified with a block size of four and randomized based on gestational age to ensure similar groups. The experimental group experienced oral stimulation while the control group received sham stimulation. The infants began oral feedings at similar gestational ages, days of life and weights, and the health statuses of the infants were similar. With the variables well controlled for, the results of this study showed that the intervention group achieved a higher milk transfer-rate, and had an overall better intake. They also achieved oral feedings significantly earlier when measured in the number of days from complete tube feeding to independent oral feeding. However, when the outcome was measured in the number of weeks post menstrual age, there was no significant difference between the groups, and the length of hospital stay was not significantly different.

It is plausible to expect that infants with sensory-motor oral stimulation associated with non-nutritive sucking will begin feeding earlier, have positive oral reinforcement that leads to earlier attainment of full oral feeding, and earlier hospital discharge.

Early feeding opportunities and semi- demand feeding.

Other strategies that have been explored to shorten feeding transition are earlier exposures to oral feeding and the use of semi-demand oral feeding protocols. According to research done by Simpson, Schanler and Lau (2002), infants who began feedings at earlier gestational ages attained full oral feeds earlier. The study's sample size was 29 and only 13 infants were in the experimental group. The experimental group of healthy preterm infants born at less than 30 weeks gestation began feeding orally at an average

age of 31.1 weeks +/- 1.3 weeks gestation, compared to the infants in the control group, who began oral feedings at 33.7 +/- 0.09 weeks gestation. The experimental group was feeding all feeds orally at an average postmenstrual age of 34.5 weeks, significantly earlier than infants in the control group who attained full oral feedings at 36.0 weeks postmenstrual age. The control group and experimental infants differed in a couple of ways. The control group had an average weight of 1000 grams and the experimental group weighed about 1200 grams also the control group required three weeks of oxygen and the experimental group only required two weeks of oxygen. Thus, the experimental may have had a slight advantage. The groups did not differ significantly in gestational age at birth, days ventilated or in episodes of feeding-related oxygen desaturations and bradycardia. Age at discharge from hospital was not significantly different. Since the sample size is small and control group spent more days on oxygen and had a lower birth weight, the results of this study need to be accepted cautiously.

McCain, Gartside, Greeenberg and Lott (2001) studied the impact of semi-demand feeding and non-nutritive sucking on healthy preterm infants aged 28.9 to 32 weeks gestation. The post-conceptual age at entry into the study was similar for both groups. The transition period was measured in days to full oral feedings. The authors found that infants in the experimental group took fewer days to transition. They also discovered that triplets and quadruplets required significantly more days to achieve full feedings in both control and intervention groups, and that the average transition days of singletons and twins were similar.

Cue-based feeding shares similar principles to semi-demand feeding except that unmet total fluid requirements are not supplemented by tube feeding. Puckett, Grover and Sankaran (2008) conducted a quazi- randomized trial on cue-feeding and found similar results to McCain. Premature infants were able to stop tube feeding on entrance to the study and were discharged significantly earlier than control infants.

In a systematic Cochrane review of semi-demand feeding versus scheduled feeding (Tosh & McGuire, 2006), only two trials reported an earlier hospital discharge, and only McCain et al. (2001) reported a significant difference in feeding transition. The authors concluded that insufficient data existed to support semi-demand feeding as beneficial for preterm infants and recommended that further clinical trials with larger sample sizes and standardized outcome measures be conducted.

Feeding Transition Summary

In summary, physical factors that impact premature infant feeding include: neurological impairments, multiple diagnoses, necrotizing enterocolitis or other digestive conditions, multiple respiratory conditions, BPD, apnea of prematurity, lower birth weights less than 1000 grams, and major congenital defects, including major cardiac defects. Infants of alcoholic mothers (Van Dyke Mackay & Ziaylek, 1982), and infants of diabetic mothers have been observed to have longer feeding transition times as well (McCain et al., 2001). Environmental factors are also influential in decreasing transitioning times. Noteworthy environmental factors include non-nutritive sucking and gestational age at which oral feeding begins. Feeding protocols, hospital feeding practices (Howe, Sheu, Hinojosa, Lin & Holzman, 2007; Pickler & Reyna, 2003) and oral stimulation may also be important in decreasing feeding transition times. Finally, caution must be taken when forming conclusions about feeding transition interventions when multiple factors are involved in premature infant feeding.

Effects of Tube Feeding

Gavage feeding the premature infant is a life-saving nursing procedure, but it is associated with numerous risks for the premature infant and impacts the infant's experience in the NICU. Because there is limited literature about the effect of naso/oral gastric tubes on premature infants, this literature review also includes articles describing the effect of feeding tubes on adults. The variety of articles included in this review provides a foundational understanding about gavage tubes and tube feeding, and gives insights that may be applicable to the premature infant's tube feeding experience or feeding behavior.

Disadvantages of NG indwelling and OG intermittent Tube Insertion

Bradycardia, desaturation and apnea, gagging and emesis are well-known side effects of NG or OG insertion (DiPietro & Porges, 1991; Rombeau & Caldwell, 1990). The infant can experience one or all these effects each time the procedure is performed. In nursing practice, the indwelling feeding tube is used to overcome the risks of frequently eliciting the strong vagal response in those infants who become very distressed with intermittent tube insertion (Haxhija, et al., 1995; Shiao & DiFore, 1996). If an indwelling tube is used, it may continue eliciting a vagal response, but it is believed that the response diminishes through the self-regulatory properties of the infant's autonomic nervous system (DiPietro & Porges, 1991). In support of the neurologic habituation principle, Symington, Ballantyne and Stevens's (1995) study showed that there was no significant difference in apnea or bradycardia over a six-day period in non-orally feeding infants who received nutrition via indwelling tube placement versus intermittent tube placement.

Another important concern relevant to indwelling tubes and premature infants is reflux. When the feeding tube crosses the lower esophageal sphincter there is a significant increase in reflux (Peter, Wiechers, Bohnhorst, Silny & Poets, 2002); however, the reflux associated with the placement of an indwelling tube is not significantly associated with apnea, bradycardia or desaturation in the infant (Peter, Sprodowski, Bohnhorst, Silny & Poets, 2002).

In a crossover repeated-measures study done by Daga, Lunkad, Daga and Ahuja (1999) of four stable term newborns and six stable preterm infants aged 31-35 weeks, Draga et al. examined oxygen saturations during NG versus OG insertion. Infants had significantly lower mean oxygen saturations during NG insertion than during OG insertion, and the lower mean oxygen saturations continued for the duration of the tube feed. In orally feeding infants, lower oxygen saturations may mean that less oxygen is available for energy consumption during feeding. Therefore the infant may tire sooner, have decreased co-ordination with the suck-swallow-breathe pattern, and may have an increased number of desaturations during the feed. Since the investigational period only lasted 30 minutes, and the infants were not orally fed, the prolonged implications of an indwelling NG on oxygen saturations and premature infant energy levels during oral feedings are not known. The sample size was small and the other adverse effects of OG and NG insertion were not addressed.

Haxhija, et al. (1995) focused only on intermittent OG insertion and commented on the change in heart rate, oxygen saturation, respiration and cerebral blood flow velocities of the procedure. In this study, a change in cerebral blood flow velocity was only significant if the heart fell below 80 beats/minute. Oxygen desaturation correlated strongly with bradycardia and no episodes of apnea were noted in any of the 21 observations. They also found that vagal responses were minimized when the OG was inserted slowly over 10-15 seconds.

Baserga, Gregory and Sola, (2003) also studied changes in cerebral hemodynamics and oxygenation in infants receiving intermittent OG tube feedings. They found that there was a transient decrease in heart rate and oxygen saturations after OG insertion, but that the decrease was not statistically significant. Furthermore, they found that the valsalva maneuver associated with OG insertion was similar to the response initiated by a premature infant crying, so its significance is not known. Further study of intermittent OG tube insertion and its effects on preterm infant feeding behavior would offer evidence to support or halt the practice of intermittent tube placement.

As previously discussed, the pain of NG tube insertion in premature infants has been recently studied. McCullough, et al., (2007) have found that NG tube insertion is as painful as a heel stick and that sucrose administration significantly reduced the behavioral and physiological pain responses. The discomfort associated with oral gastric tube insertion is not known and requires more research, as does the discomfort that may be associated with an indwelling tube. If OG tube insertion or indwelling NG tubes cause significant pain or distress in preterm infants, their feeding behaviors may be affected.

Other possible effects reported by a number of studies on the insertion of OG or NG tubes are trauma of the pharynx, esophagus and stomach, which vary from minor injury to full-thickness perforation. Esophageal perforation is becoming recognized as a serious iatrogenic problem in the NICU and may increase infant morbidity. The infants at most risk of tube insertion trauma are low birth weight and very premature infants. (Ibe

& Ugbam, 1994; Krasna, Rosenfeld, Benjamin, Klein, Hiatt & Hegyi, 1987; Rogahn,1998; Shiao & Novotny, 1998; Soong, 2007). Thus a feeding tube insertion procedure carries risks that must be considered when a feeding method for premature infants is chosen.

Another risk of NG/OG insertion is tube placement error. Fifteen percent of children had a tube placement error on radiographs. OG tubes had a higher probability of misplacement than NG tubes (Ellett, Maahs, & Forsee, 1998). According to Ellett's et al. review of the literature, 39 – 55.6% of feeding tubes are misplaced in the premature infant. The risk of a low-placed feeding tube is mal absorption; conversely, aspiration is a risk for high tube placement. All these risk factors must be considered when deciding on a feeding method. It is not known how tube misplacement affects the comfort of the infant, or if frequent tube placement (intermittent) increases the risk of tube misplacement versus indwelling placement.

Comparison of Indwelling and Intermittent Gavage Tube Placement

Short term consequences of a nursing practice are often more apparent than the long term consequences and research studies examining the longer term effects of intermittent and indwelling tube placement will be reviewed here.

Infection is not often considered when the type of tube feeding method is chosen. Intermittently placed tubes that are discarded after one use are not considered an infectious risk. Indwelling tubes, on the other hand that are in place for as little as six hours can act as loci for bacterial attachment and multiplication. Hurrell, et al. (2009) found that 76% of feeding tubes were colonized by the following most common isolates: Enterobacter cancerogenus (41%), Serratia marcescens (36%), E. hormaechei (33%), Eshcerichia coli (29%), Klebsiella pneumoniae (25%). The danger associated with some of these isolates was that they were resistant to 3rd generation cephalosporins ceftazidime and cefotaxime and they pose an infectious risk to premature infants.

No statistical difference was found between premature infants nursed with intermittent tube placement and indwelling NG placement on weight gain, apnea and bradycardia events over a six day period. This study had a sample size of 93 infants and used blocking and random selection to ensure equal representation in each group (Symington, Ballantyne, Pinelli & Stevens, 1995). Symington et al. (1995) concluded that the tube feeding methods would remain the choice of the caregiver and that further study was necessary to assess which tube feeding method was less irritating to the infant.

One study was found that examined the effect of an indwelling NG tube placement on the infant's ability to feed. The study was a crossover design and was conducted on one day. Sixteen infants were fed one feeding with an NG tube in place, and later that day they were fed again without the NG tube. The study showed that an NG tube decreased the sucking pressure, sucking time, and amount of milk the infant took. It also showed that minute ventilation, tidal volume and pulse rate were lower in infants with an NG in place (Shiao, Youngblut, Anderson, Difore & Martin, 1995). Oxygen saturations were also lower during the oral feeding with an NG in place, and the oxygen desaturations were prolonged when they occurred (Shiao, Brooker & Difore, 1996; Shiao, et al., 1995). Although these studies show that an indwelling NG does have negative effects during oral feeding and on feeding behavior, it only looks at a short term effect. In order to fully understand the impact of an NG on feeding behavior and infant transition, the long term implications must be investigated. Neurologic habituation to the presence of the feeding tube may minimize the effects of the NG placement over the long term, and may prove to be a superior method of nutritional supplementation during the transition period.

A few other studies examined the effects of an indwelling NG on airway resistance. Stocks (1980) found that infants weighing 2 kg and less who had an indwelling NG had increased nasal resistance and total airway resistance. Greenspan, Wolfson, William & Shaffer (1990) also found that infants weighing less than 2 kg with an NG demonstrated increased pulmonary resistance and hypoventilation. However, an indwelling OG did not affect pulmonary function in the infant weighing less than 2 kg, and infants wearing a palatal appliance to secure an OG tube had significantly less periodic breathing, central apnea and restlessness than infants with NG tubes (van Someren, Linnett, Stothers & Sullivan, 1984). Infants weighing more than 2 kg with an NG or OG had no change in pulmonary function. Since respiratory function is known to impact feeding patterns, the orally feeding infant weighing less than 2 kg who has an NG in place may experience greater difficulty during feeding.

No studies were found that examined the negative effects of an indwelling OG feeding tube. One reference that discussed tube feeding practices mentioned that prolonged use of an OG tube was negatively associated with feeding (Rogahn, 1998). Another article that discussed tube feeding practices in premature infants briefly mentioned that nurses chose to feed infants who had a strong vagal reflex with NG tubes instead of OG tubes to reduce the number of times the gag reflex was elicited (Shiao & Difiore, 1996). No articles or studies were found examining the premature infants' experiences with indwelling OG feeding tubes.

Oral Aversion

Oral aversion is a well-known phenomena associated with prolonged NG feeding tubes (Gisel, et al., 1998; Senez, et al., 1996). Dodrill et al., (2004) found that infants fed with an NG for more than 3 weeks displayed significantly more facial defensive behavior, and had significantly more delays in feeding development than pre-term infants who received less than 2 weeks of NG feedings. Feeding dysfunctions such as panic attacks with the introduction of food, and swallowing and chewing difficulties lasting up to one year or longer, have also been associated with long-term nasogastric tube feeding (Bazyk, 1990; Kamen, 1990; Mason, Harris & Blissett, 2005; Strologo, et al., 1997).

The hypothesized cause of the feeding dysfunction may be a conditioned dysphagia from aversive nasopharyngeal and esophageal NG tube irritation (Bazyk, 1990; Kamen, 1990). Moreover, chronic pharyngeal stimulation of an indwelling tube can decrease the sensitivity of the protective airway mechanisms (Gomes, Pisani, Macedo & Campos, 2003) or alter the swallowing reflex (Morris, 1989) In fact, the larger the feeding tube the greater the impact on the swallowing reflex in young healthy adults (Huggins, Tuomi & Young 1999). Even a fine-bore feeding tube slowed the swallowing response.

Oral-feeding deprivation in infancy may lead to deficits in cortical development because motor and sensory pathways between the oropharynx and the cortex are not established (Mason, et al., 2005), and nutritive sucking practice has been shown to be necessary for the development of oral feeding. Non-nutritive sucking practice did not result in the skills necessary for nutritive sucking (Mizuno & Ueda, 2001). Fortunately for premature infants, they have a strong sucking reflex and feeding may be largely reflexive during a critical period of infancy. Therefore, oral aversion may not be of great significance until reflexive feeding comes under volitional control (Mason, et al., 2005).

Long Term use of NG Tubes in Pediatrics and Adults

Nasogastric tubes are associated with the following complications in the pediatric population: rhinitis, sinusitis, purulent otitis media, esophageal and nasal septum ulcers (Asfaw, Miles, & Caplan, 2000; Rombeau & Caldwell, 1990; Royce, Tepper, Watson & Day, 1951). Later in life, preterm infants who required a nasal-tracheal tube placement may have an increased risk for chronic otitis media, and children with nasal-tracheal tube placement had an increased risk of otitis media. However, nasogastric tubes were considered a lower risk for otitis media in premature infants and children (Engel, Mahler, Anteunis, Marres & Zielhuis, 2001; Persico, Barker & Mitchell, 1985).

In the adult population, indwelling NG tubes were found to impact the swallowing reflex of normal healthy adults by slowing the swallowing process (Huggins, et al., 1999). Other documented side-effects included bleeding, pharyngeal and nasal irritation, necrosis of the nasal septum, larynx and pharynx; sinusitis and otitis media; as well as esophageal and gastric ulcers (Rombeau & Caldwell, 1990). The incidence of vocal cord paralysis, esophageal strictures and tacheoesophageal fistula was considered low (Vanek, 2002), and esophageal perforation was considered to be rare (Gruen, Cade & Vellar, 1998). Negative middle ear pressure was observed in 84% of patients, and they showed tympanometric and otscopic changes within five days of NG insertion (Vento, Durrant, Plamer & Smith, 1995). Nasogastric tube syndrome-vocal cord paralysis and severe post-cricoid ulceration are life threatening effects of NG tube placement, but fortunately they are rare events (Brousseau & Kost, 2006; Sofferman, Haisch, Kirchner, Hardin, 1990).

The emotional experience of indwelling NG tubes in children is not well researched (Crellin & Johnston, 2005). Moore and Greene (1985) informally stated that patients described wearing a non-reactive NG tube as no more annoying than wearing clothing. However, Sandler, Evans and Ein (1998) informally stated that the children in their study did not like the NG tube and cited discomfort as a major reason. In a study of NG tube insertion in the pediatric population, Crellin and Johnston (2005) found that half of the children reported the procedure as severely painful. Further research about the experience of wearing an NG in the pediatric and neonatal population is needed.

Wearing an NG tube was rated by adults as more painful than mechanical ventilation (Morrison, et al., 1998; Resnick & Morrison, 2004). In other studies, 70% of adults complained of marked discomfort and 4% had their NG tubes removed early because of intolerable discomfort (Perl, Valea, fisher & Chalas 1996). Forty-three percent found the NG tube most inconvenient (Hoffmann et al., 2001), and an indwelling NG was also documented as irritating and causing swallowing problems (Baeten & Hoefnagles, 1992). Padilla et al., (1979) found that an NG tube was moderately painful in the adult population, and Hansen, Noyes and Lehman (1991) informally found that many of their surgical patients complained that the discomfort of the NG tube was not responding well to the patient-controlled morphine infusion, even though they were satisfied with the post-op pain control. More over, nasogastric tube insertion is known to be painful in the adult population, and research has been conducted to lessen the pain experienced during the procedure (Ducharme, & Matheson, 2003; Singer, Richman, Kowalska & Thode, 1999).

Summary of Tube Feeding Effects

In review of the literature, the respiratory effects of indwelling tubes have been studied in the premature infant population to some degree; however, the long term effect of an indwelling tube on the infant's feeding transition is not known. Even though the pain with indwelling NG tubes has been documented in the adult population, it is not known if an indwelling tube is painful for the preterm infant. Nor is any information available about pain the infant may experience during intermittent OG tube insertion. Both indwelling NG and OG intermittent tube placement have advantages and disadvantages, and the pros and cons have been identified and studied to some degree. Currently indwelling NG placement and intermittent OG placement appear to be practiced primarily on the opinions of caregivers rather than on evidence. What is lacking in the literature is the impact of the different feeding methods on the infant's ability to attain full oral feeds.

CHAPTER 3

Theoretical Framework

The purpose of basing research on a theoretical framework is to explain the relationship between the concepts being studied, guide the research design and hypotheses, and provide some predictive ability for the outcomes. In this section, Als' Synactive Theory of Development will be described in detail and the origins of the theory identified. Then the concepts of the theory will be explained in relation to the premature infant tube feeding dilemma; namely, which tube feeding method best supports the infant's development to full oral feeding.

Als' Synactive Theory of Development

Previous work which gave direction to infant developmental theory and infant developmental care was Piaget's concepts of assimilation and accommodation of an infant's perceptual experiences. These concepts identified the environment's impact on the developing infant (Pressler, Turanage-Carrier & Kenner, 2004). Dr. Brazelton, a physician and professor of pediatrics and chief of the child development unit at Boston Children's Hospital Medical Center, studied and examined the infant's reflexes and responses to specific environmental stimuli. Eventually, he developed the Brazelton Neonatal Behavioral Assessment Scale from his work.

In his journey toward studying infant behavior, Dr. Brazelton realized that the infant could control its state and respond to both positive and negative stimuli. This knowledge influenced Dr. Brazelton to change his focus from infant reflex behavior to viewing behavior as a stimulus for generating responses from the caregiver or environment (Brazelton, 1978). He also identified state control (which means that the infant can change from a crying state to a quiet alert state) as a critical developmental task that reflected central nervous system *differentiation* and could predict future development (Parker & Brazelton, 1981).

Als, an assistant professor in pediatrics from the Department of Psychology at Harvard Medical School, began her work studying the infant's behaviors and the mother's response to the infant's attempt to interact. Through her work, Als describes how the infant cycles through three *levels* of communication by gaining help from the mother with *modulating* 'state control communication'. If the communication input becomes too intense, the infant can self-regulate to decrease the input and reorganize for further communication (Als,1977). Hence, from the work and observation of infant behavior by Als and Brazelton, the basis for the synactive theory was formed (Als & Brazelton, 1981).

A new philosophy now emerged from Als' and Brazelton's work which recognized the infant as an active participant, capable of directing the care. This new philosophy shifted the control of care giving from the caregiver to the infant. The infant's behaviors became conceptualized in terms of a mode for communicating and directing care, and the behaviors became an indication of developmental level.

The four general laws or principles from which Als' Synactive Theory developed are as follows: The principle of phylogenetic Bauplan which provides a species-specific view of organizational potential or adaptedness in the developmental process that evolves, but may be limited by environmental disturbances (Als & Brazelton, 1981). This principle is supported by Blurton (1974,1976), Hinde (1970), Hinde and Spencer-Booth (1967), and Towen (1984), as cited in Als (1992).

The second principle relates to the continuous cultural and environmental interaction of the infant and its ability to catch up (Als & Brazelton 1981). This principle is supported by Bertalanffy (1968), Dobbing (1971) and Waddington (1939), as cited in Als & Brazelton (1981); and Piaget (1952), Sherrington (1940), Patterson, Potter and Furshpan (1978), Hunt (1963), Fowler and Swenson (1979), and Bunge, Johnson and Ross (1978), as cited in Als (1992).

The third principle is the ontogenetic sequence of development which proceeds from a global state to one of increasing differentiation, articulation and hierarchic integration. The third principle is supported by Bruner (1968, 1974), Coghill (1962), Gesell (1946), Gesell and Armatruda (1945), Hooker (1936,1942), McGraw (1945), Piaget (1952), and Werner (1957), as cited in Als (1992).

The fourth principle is the principle of dual antagonist integration which means that an organism strives for smooth integration and has the ability to move toward or withdraw from its environment, depending on the stimulation threshold of the organism. This final principle is supported by Denny-Brown (1962, 1966), Schneirla (1959, 1965), and Schneirla and Rosenblatt (1961, 1963), as cited in Als (1992).

In summary, Als' Synactive Theory of Development is a developmental theory that was deductively derived and based on the natural sciences, and developmental and behavioral psychology. A new philosophy unfolds in this theory, focusing on the infant as the director of care. As well, it is guided by empirical philosophy as evidenced by its generalizability to describe and identify repeated patterns of infant behavior in a predictable manner, and by dividing the developmental process into subsystems which then describe the whole developmental process. Furthermore, it operationalizes the concept into measurable components and places importance on reliability and validity (Als & Brazelton 1981; Als, Butler, Kosta & McAnulty, 2005; Brazelton, 1978; Pressler, Helm, Hepworth & Wells, 2001).

Model Introduction

Als' theory is framed within past work which recognizes that infants have sensory, cognitive and social capacities or competencies (Als 1982). Her work specifically focuses on describing these capacities and answering the question of how the infant uses them to interact with the environment. Her theory describes the preterm infant's developmental process as well as the environment's potential effect on the infant and the infant's developmental process. Her model will now be explained by describing its three main concepts which are: development, systems and environment.

Development

Development is the main concept in this theory. Als (1982, p.230) states that the focus of development in this model is on how "the infant appears to handle the experience of the world around him/her". The definition of development is not explicitly stated but is implied by the underlying assumptions previously discussed; namely, explaining development as a process that is species-specific, constantly interacting with the environment, increasing in differentiation as gestational age increases, may be interrupted by environmental conditions, and is a process where the organism actively strives to accomplish the next level but may withdraw from because of adverse environmental conditions.

Premature infant development is further characterized by three words: *level, differentiation* and *modulation*. The *level* refers to infants' current abilities to organize their behaviors in an environment. The degree of *differentiation* measures how flexible/rigid or specialized the infant's behavior is. It also describes the process of interaction and integration of the other subsystems. *Differentiation* is also a process that progresses over time, but may be limited by environmental stimuli. Thirdly, the degree of *modulation* examines how sustained the newly emerging developmental behavior is and how difficult the new behavior is to attain (Als & Brazelton 1981).

The words differentiation, modulation and level are associated with the five subsystems described in Als synactive theory of development (Als, 1986). Each of the five subsystems goes through the process of differentiation, modulation and level attainment. For example, in the autonomic system, the respiratory pattern of a premature infant differentiates from a periodic respiratory pattern to a regular respiratory pattern as maturation takes place, and the system shows modulation by being able to maintain regular breathing during a stressful event. For example, feeding may be a stressful event for the infant; the infant shows modulation by being able to maintain regular breathing while feeding. This accomplishment places the infant at a certain level of development, namely independent feeding. Conversely, an infant who has periodic breathing and becomes stressed by feeding, stops breathing and turns blue, is less differentiated, has poorer modulation ability and is clearly at a lower developmental level than the first infant. Consequently, the words differentiation, modulation and level are reflective of infants' current states and developmental processes, and are used as parameters of the infant's behaviors that describe the developmental process through abstract theoretical definitions. Finally, the word development is always associated with words such as 'synactive', 'interactive' and 'process' (Als, 1982).

Systems

The systems represent the infant's behaviors and are the infant's modes of communication (Als, 1986; Als, Lawhon, et al., 1986). There are five systems (behavior groups) in Als' Synactive Theory of Development. They are the autonomic, motor, state, attentional/interactive and regulatory systems (Als, 1982). The systems represent concrete concepts which are the observable behaviors of the infant, and have been catalogued and recorded in the Newborn Individualized Developmental Care Assessment Program (NIDCP). Theoretically, by interpreting these behaviors, nursing care can be specifically designed for the individual premature infant to the extent that it is believed to support normal development, and prevent or lessen the insult of premature birth (Pressler, et al., 2004).

The five systems are described as interactive and synactive with each other and the environment. They develop in a hierarchal pattern with increasing differentiation and are in constant interaction with the environment to attain new levels. Each new level is negotiated on the backdrop of a previously differentiated and modulated subsystem. The systems mature in layers (with the exception of the regulatory system because each system contains a regulatory system), with the autonomic subsystem as the innermost layer, and the attentional/interactive layer as the outermost layer. The maturation processes of the systems are influenced by the ontogenesis of the species and their interaction with the environment (Als, 1986).

Als' model is pictured as an inverted cone shape and describes how the infant's systems (*autonomic*, *motor*, *state, attentional/interactive* and *regulatory*) develop in an ascending order, correlating with increasing gestational age. The model also portrays how the systems develop from the core to the periphery. Although it is not clear in the model portrayal, the relationships between the systems are synactive and depend on the stability of the core system. For example, the *autonomic* system is the centre circle of four concentric circles and is characterized by respiration and color change and other autonomic functions. The *motor* system is the second circle around the autonomic system and is characterized by muscle movements like finger-splaying and arm extension. The third circle is *state*, and it reflects the infant's sleeping or crying behaviors. *Attentional/interactive* behaviors characterize the infant's ability to use *state* to elicit modification from the environment. Finally, the *regulatory* system is part of each system, and it demonstrates the infant's ability to modulate each of the systems to maintain a balanced state.

In order to describe the infant's systems in relation to feeding behavior, the following example is provided. Since the autonomic system is at the centre of the infant's behaviors, it must be stable in order for any of the other systems to function. For example, the infant must be breathing in order for the motor, state, and attentional/interactive systems to be functioning. Clearly, the infant will not be able to bottle feed if breathing is not present. As well, the infant must be able to display motor control and sucking behavior to feed. However, if the infant is sleeping, the state system will interfere with the motor system. The regulatory system modifies the infant's state system by making the infant feel hungry. More over, the regulatory system modifies the infant's state by waking up the infant, and then modifies the motor system by causing the infant to begin sucking on nearby objects. Therefore all the systems are interactive, depend on each other, and the caregiver can observe the behaviors and provide the infant with the care needed.

Environment

The concept of environment is given a very simple descriptive definition in this theory. It is referred to as extrauterine or intrauterine, and is interpreted as supportive or non-supportive of infant development (Als, 1982). Als gives examples of supportive environments and nursing procedures that benefit infants' development although she does not provide a clear measurable definition of the concept (Als, 1986). Rather, environment is used as a modifiable variable that affects the developmental process. For the purpose of this study, tube feeding is the environmental variable that will interact with the infant, and the infant will respond to the variable by developing mature feeding behaviors with the least amount of delay or aversive behaviors.

According to the theory, the infant will continue to strive for the next level of development. The environment can support the development or delay the development by destabilizing the infant's systems. As the research study done by Shiao, et al. (1995) showed, an NG tube decreased the sucking pressure and destabilized the infant's motor system in a short-term crossover design. However, further research is needed to explore the infant's regulatory ability to modulate that behavior and accomplish a level of independent feeding with the feeding tube present. More over, the theory stresses the infant's (systems) constant interaction with the environment and its ability to self-regulate under environmental influences. Furthermore, the theory demonstrates that the environment can impact the infant's development directly or indirectly through the infant's systems.

Identifying Relational Statements

Als Synactive Theory of Development attempts to provide an explanatory and predictive theory of development that will guide research questions whose answers will improve the developmental outcome of the premature infant. Unfortunately, the theory remains partly undeveloped. However, based on the definitions provided, the relationships between the concepts will be explored in the following discussion.

1. Very low birth-weight infants benefit medically and developmentally from individualized behavioral care (Als, Lawhon, et al., 1986; Als, Lawhon, Duffy, McAnulty, Gibes-Grossman & Blickman, 1994; Westrup, Kleberg, von Eichwald, Stjernqvist & Lagercrantz, 2000; Becker, et al. 1993; Becker, et al. 1999; Becker, Grunwald, Moorman & Stuhr, 1991; Als, Duffy et al., 2004). In other words, modifying the environment and nursing care (another component of environment) directly affects the systems (infant's behavior) and development (the process of differentiating, modulating and attaining a new level). The relationship between the environment and systems is associational because the environment is positively correlated with the systems. However, the relationship is a complex one because the environment stimulus may just target one subsystem of the systems. For example, ventilating a premature infant will stabilize the autonomic system, but over time the ventilation itself will injure the lungs and disrupt the developmental process of feeding, as seen in infants with BPD. As well, while the ventilator is stabilizing the autonomic system, the sensory stimulation of having a foreign object in the oral/respiratory tract may destabilize the motor, state, attentional/interactive and self-regulation systems. The concepts are indeed interactive;

however, as a general rule, a developmentally appropriate environment will have a positive effect on the systems.

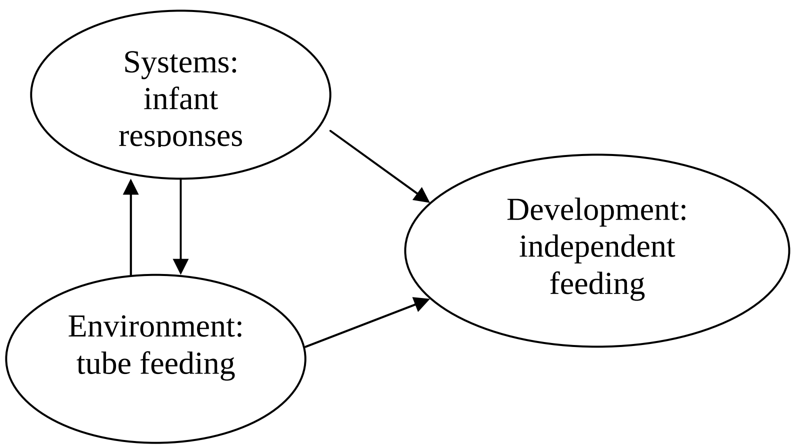
A second relationship noted in this statement is the relationship between the systems and development. This relationship also has a positive correlation. If the systems are balanced, they will be able to differentiate, modulate and develop to the next level.

2. The system (of the infant) has the ability to interact with the environment in an observable manner, and it can show behaviors of avoidance or approach (Als, 1982; Holsti, Grunau, Oberlander & Whitfield, 2004, Stevens, Johnston, Petryshen, & Taddio, 1996). Through this behavioral display, the infant can direct nursing care. The relationship between the system and the environment here shows an association of interaction. As the infant interacts with the environment on a constant basis, the relationship will be a positive correlation. For example, if an infant is feeding orally with an indwelling tube placement without showing avoidance behaviors, that infant is communicating adaptability to the feeding method and developing to the next level of independent feeding.

3. Developmental level can be determined by assessing the infant's response to the environment (Mouradian, Als & Coster, 2000). This statement shows that a relationship between the system and the environment can determine the developmental level. For example, an infant who is displaying premature sucking patterns and breathing patterns is developmentally immature or delayed. Therefore, the relationship between system and the environment produce a result that is positively correlated to development. All of the above statements appear to be linear; this can be assumed until proven

otherwise. The statements are used consistently and reflect the definitions or the assumptions underlying the definitions. In fact, each of the above statements shows a positive correlation between the *environment*, *system* and *development* concepts. Figure 1 shows the relationships of the concepts and depicts the integration of the research question into the theory.

Figure 1: Relationships between concepts in Als' Synactive Theory of Development



In conclusion, Als and Brazelton have demonstrated that infants are capable of responding to and communicating with the environment through the systems. This theory has the potential to revolutionize the care of premature infants and generate research about nursing practices that support infant development. Infant feeding practices continue to vary from one care facility to another because there is no conclusive research evidence to guide the practice, and it is not known how the infant responds to the different feeding practices. However, the difference in practice is felt by the infant, and the infant is capable of directing care by displaying withdrawal or engaging behaviors.

These behaviors are measurable and observable. For the purpose of this study, the feeding tube will be viewed as an environmental factor that interacts with the infant's systems and will support or delay transition to the level of independent oral feeding. Nutritive sucking behavior is observable and can be measured by the amount of nutrition the infant consumes orally. The developmental level is also measurable and is evidenced by the infant's ability to feed full nutritional requirements orally in order to meet weight and growth standards. Therefore, Als' Synactive Theory of Development will guide the investigation into the relationship between indwelling NG tube placement and oral intermittent tube placement on the infant's feeding transition to full oral feeding.

Hypotheses

Based on the literature review, indwelling NG tubes were associated with lower sucking pressures and decreased suckled volumes. The NG has also been shown to lower oxygen saturations, increase airway resistance and impact minute ventilation in the premature infant. In healthy young adults the swallowing reflex slows down when an NG tube is placed and it has been associated with swallowing difficulty and pain. Since adequate respiration and coordination of the suck-swallow-breath sequence are important principles of premature infant feeding, feeding without an NG tube may benefit the premature infant's transition period by reducing aversive stimuli during oral feeds. Hence the following hypotheses were proposed:

1. Preterm infants born at 30-33+ 6/7 weeks gestation who are healthy, and are beginning to transition from gavage to oral feedings via oral intermittent gavage tube insertion, will achieve full oral feeds by bottle/breast at an earlier gestational age (in weeks) than infants transitioning to oral feedings via nasogastric indwelling tubes

during their stay in the Intermediate Care Nursery and will be ready for earlier discharge.

2. Premature infants receiving intermittent oral gavage feeds during the gavage to oral feeding transition period will feed more ml/kg/day (in gestational age) than infants feeding with indwelling nasogastric tubes during the gavage to oral feeding transition period.

CHAPTER 4

Methods

Research methods must be carried out in an ethical manner and the protection of human rights is the goal of ethical research (Polit & Beck, 2004). In order to protect the rights of premature infant's in this study, the following considerations were incorporated to maintain dignity, privacy, beneficence, and justice.

Ethics

Respect for Human Dignity and Privacy

The premature infant is a vulnerable member of society who cannot make an informed decision or understand the concept of being a research subject. In order to protect the infant's rights, the research proposal was sent to the Biomedical Research Ethics Board for approval (Appendix A), and it was approved by the Pediatric Research Coordinating Committee (Appendix A). The Personal Health Information Act (PHIA) of Manitoba was also signed in order to access personal health information for the research and protect the infant's privacy and right to confidentially (Appendix A). Finally, the infant's right to self-determination and full disclosure was protected by providing an invitation to the parent and by obtaining the legal guardian's voluntary informed consent (Appendix B).

Beneficence

As evidenced in the literature review, both feeding regimes have advantages and disadvantages, although it is not currently known which feeding regime is less harmful for the premature infant. Currently, both intermittent OG tube placement and indwelling NG placement are widely practiced but the basis of the practice is supported by opinion rather than evidenced-based research. According to Shiao and Difore (1996), fifty percent of neonatal units use indwelling tube placement only, and forty-five percent of neonatal units use a combination of indwelling and intermittent tube placement. The IMCN at HSC falls into the category of using a combination of tube feeding methods while the NICU at HSC uses only indwelling tubes.

Expert opinion is divided on which method of tube feeding is best for the infant, and is based on two different schools of thought. Those who favor indwelling tube placement believe it is superior to intermittent tube placement because the infant's anatomy and physiology (A & P) differs from an adult's A & P and, therefore, may not an irritant to the infant. Also, because feeding is strongly reflexive, the underlying belief is that the presence of the tube will not interfere with oral feeding. The intermittent tube placement is viewed as a barbaric method that causes the infant distress eight times a day and is an unnecessary procedure that is costly in tube feeding supplies.

On the other hand, the opinion supporting intermittent tube placement is based on the belief that the indwelling tube placement is an irritant for the premature infants, negatively impacting their feeding behavior and delaying independent oral-feeding attainment. The group which supports intermittent tube placement believes that infants get used to the procedure, and that it is not as distressing for the premature infant. However, they do believe that once a premature infant approaches term gestation, the intermittent tube insertion procedure becomes an irritant to the infant. That is why they choose to feed term infants with an indwelling tube, and consequently, both tube feeding methods will be used in the same unit, even though the rationale lacks consistency. A feeding methodology should not be based on opinion. Currently, both feeding methods are acceptable in institutions caring for the premature infant population, and both feeding methods are thought to be equally beneficial and harmful.

Beneficence is also promoted by ensuring that the investigator is competent; this is evidenced by the investigator's knowledge and educational activities to keep up-to-date in the field of neonatology. The design was carefully planned and the measurement method carefully chosen according to recommendations of previous research studies investigating feeding transition. The benefit/harm ratio was considered in this investigation. Finally, a summary of this study's results were made available to the subject's legal guardian upon request.

Justice

Justice ensures that all subjects are treated equally. Justice also carries with it the idea of not excluding particular groups in research. This was addressed in the sample section by inclusion of all races and sexes. Infants for the study were selected based on the exclusion criteria derived from the literature. Since this RCT was a pilot study, as many variables as possible were controlled to ensure valid and reliable results. In a full study, the criteria can be relaxed because the larger numbers in the study will balance out the infants who are expected to have difficulty transitioning, and those who are at a greater risk for transitioning can be evaluated separately.

Study Design

A prospective randomized controlled pilot trial was conducted to explore the impact of NG indwelling versus OG intermittent tube feeding methods on premature infants. The pilot study was conducted in the IMCN at HSC in Winnipeg, Manitoba, Canada. The IMCN has 27 beds for infant care and three triage beds. The unit admits term and preterm infants who require monitored intermediate care. Infants who require ventilatory support are transported to the NICU.

The unit was chosen for convenience and receptivity of management to the study. In preparation for the study, the investigator met with the manager, educator and clinical nurse specialist. The investigator also met with each nurse on the unit to discuss the study protocol, and assess receptivity to the study. Both methods of tube feeding, NG indwelling and OG intermittent are practiced on the unit and the same size and type of tube feeding materials (a # 5 French PVC) are used for both the NG indwelling and OG intermittent placement thus controlling for feeding tube size and type bias. Furthermore investigator conflict of interest and bias was limited because the investigator does not work in this unit making it a good choice for a research site.

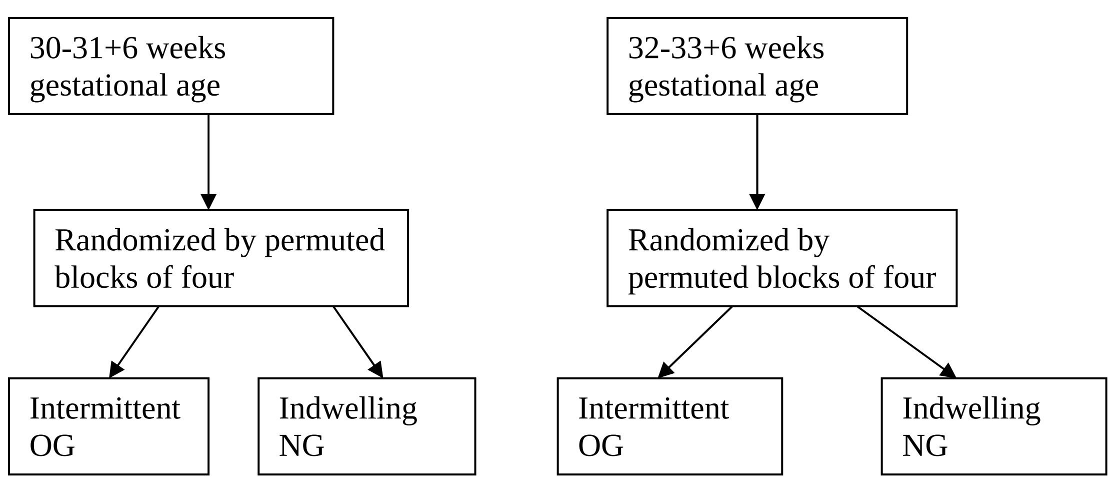
Twenty infants were recruited over the 18 month time period allotted for the study. The recruitment total was just four participants short of the targeted goal for this pilot study. Thirteen infants completed the study. Participants remained in the study until discharge, unless, the infant became unstable or parents decided to withdraw the infant from the study.

Premature infants enrolled in the study were eligible according to the following criteria: 30 to 33^{+6} weeks gestation at birth and not more than 34^{+3} weeks old on the enrolment day, generally appropriate for gestational age, any race or sex, and required tube feeding. Gestational age (GA) was determined by the mothers last menstrual period and by the pre-natal ultra-sound record if it was available. Infants were excluded if they had neurological abnormalities or insults, IVH greater than a grade two, PVL, birth asphyxia, seizures, cord gas of <7.0 ph, or chest compressions, or required abstinence scoring. Infants were also excluded if they had major congenital anomalies, major genetic anomalies that impacted feeding ability such as diaphragmatic hernia and cleft palate, major cardiac defects, infants who were NPO for more than five days, infants who developed necrotizing enterocolitis, infants who received more than 14 days of intubation or CPAP or oxygen, and infants of diabetic or alcoholic mothers. These inclusion and exclusion criteria were chosen to decline infants who may have prolonged feeding transitions.

Procedure and randomization

A letter of invitation (see Appendix C) was placed at the patient's bedside and the researcher was contacted if the legal guardians were interested in having their infant participate or wanted to speak to the researcher. Upon enrolment into the study, infants were stratified by GA into the following GA categories: 30 -31^{+6} weeks and 32-33^{+6} weeks. They were then randomized by using permuted sequence blocks of four into the control group (intermittent tube feeding) or the intervention group (NG indwelling tube feeding). See figure 2.

Figure 2: Randomization



Caregivers were not blinded to the infant's feeding group assignment. A green sticker was placed in the infant's bedside kardex (the infant's care plan) as well as inside the charge kardex notifying the nurse of the infant's designated feeding method. A green card was also attached to the infant's bedside in full view for parents and nurses. It stated the infant's designated feeding method and was used as a *prompt card* in an effort to control for caregiver feeding bias (see Appendix D). There is a 'feeding culture' in each different nursery, and it is very likely that the feeding practices of the nurses in this unit will be more similar than different. Research is still developing feeding assessment tools to determine infant feeding readiness (Thoyre, et al., 2005) and the HSC IMCN did not use a feeding assessment tool. The bedside nurse and legal guardian were encouraged to feed the infant according to the guidelines on the prompt card and the infant received standard hospital policy care by nurses who worked in the unit. The researcher followed the study infants and visited daily or every few days to document the infant's progress, answer staff questions, or problem-solve issues that arose around the feeding study.

After enrollment of the second infant, the investigator noted that the infant's feeding method was frequently changed. On consultation with some of the nursing staff, a *decorative kite* made out of yellow colored paper was taped to head of the infant's crib or isolette to help nurses identify the infant's designated feeding method in the study. Furthermore, a *highlighted information sheet* describing the infant's feeding method was on taped on the front of each infant's chart and kardex (see Appendix D).

Measurement Methods

According to Al's Synactive Theory of Development, the infant's systems have the ability to interact with the environment in an observable manner to attain the next developmental level (Als, 1982). Therefore, premature infants who are transitioning from gavage tube feedings to full oral feedings will display measurable behaviors that will indicate their ability to achieve full oral feedings. Nutritive sucking is an objective measurable behavior that is sustained by the infant's other systems. The success of nutritive sucking can be measured by the amount of nutritive liquid that the infant consumes in a day. The amount of nutritive liquid that infants of differing weights ingest can be standardized by measuring it in milliliters, per kilogram, per day (ml/kg/day). Therefore, infants' nutritive sucking behaviors in both feeding groups were recorded in ml/kg/day of GA.

Breast fed volumes were also recorded. Infants in each group were weighed prior to breast feeding, once they demonstrated a good latch and suck at the breast. Infants often do not latch or suck well at the breast for the first few feedings therefore the bedside nurse determined when the infant needed to be weighed prior to breast feeding. Even though weighing the infant post breast feeding is not considered the best way to measure intake (Savenije & Brand, 2007) it is currently the standard of practice in the nursery and was the best option for this pilot study.

The attainment of a developmental level is also measurable. The infant's ability to accomplish full oral feeds is measurable by counting the number of days it takes infants of similar gestational ages and similar feeding introduction dates to transition to full oral feedings. The number of days it takes an infant to transition to full oral feedings can also be standardized by counting the days or weeks in gestational age. Therefore, the infants' attainment of full oral feedings in the two different tube feeding groups were assessed by comparing their earliest gestational ages when they reached full oral feedings. Transitioning days were also assessed by comparing the number of days it took an infant to transition to full oral feeds beginning with the first feed offered and ending with the last day of required tube feeding.

Another measure that is often used to assess an infant's response to nutrition and development is weight gain. Therefore, the infant's weight gain in both feeding groups was compared to ensure that the different feeding methods do not negatively impact the infant's weight gain.

Lastly, infant discharge to home is a milestone marking the infant's readiness and the parent's ability to care for the infant outside the hospital environment. The discharge criteria were based on the hospital guidelines. The infant must be gaining weight consistently prior to discharge, no longer require tube feeding, and be able to maintain oxygen saturations and heart rate while sitting in a car-seat. Even though many factors impact the discharge date, the type of tube feeding method may also contribute to the infant's length of hospital stay. Therefore, hospital discharge dates were included in this feeding study. The infant's GA was measured at discharge, and the two different tube feeding groups were compared for earliest discharge.

Data analysis

The data were entered into SPSS and checked for consistency by a technical assistant at the University of Manitoba. The categorical demographic data were reported using percentages and continuous data was reported as mean +/-standard deviation. The differences between the groups were analyzed using the Mann-Whitney U. The Mann-Whitney U test was chosen because the NG indwelling and oral intermittent groups were small samples, independent, and nonparametric. The Mann-Whitney U test is designed to detect a significant difference where data are nonparametric and are easily ranked. A two tailed test was utilized and level of significance was set at ‘p’ equal to or less than 0.05.

CHAPTER 5

Results

Results are discussed as follows: descriptive statistics depict the study population, participants are analyzed for homogeneity, and hypotheses are tested for significance. Although twenty patients were recruited into the study, attrition was high. A total of seven patients were removed from the study for various reasons. Three patients developed medical complications, one patient was continuously switched between the two feeding methods, and one patient only remained in the study about ½ a day and then became completely independent with oral feeds. The other two patients were withdrawn because the bedside nurse and/or parent felt that the assigned feeding method was not appropriate for the patient. These seven patients were excluded in the statistical analysis. A separate review of these patients will take place in the discussion section.

Through the data gathering process, premature infant feeding patterns were uncovered and although this study did not set out to focus on infant feeding patterns, the data that was gathered is pertinent to feeding transition and merits further consideration. See Appendix E.

Characteristics of Participants

Seven preterm infants were allocated to the intermittent tube feeding group and six preterm infants were assigned to the indwelling tube feeding group by randomization as previously described. Table 1 displays the demographics of the infants in the study and also provides approximate percentages of the group's characteristics. About half of the premature infants were Caucasian and about half were of another ethnic descent. There were more males than females in the study and most of the males were in the intermittent group. An appropriate size for gestational age is a relevant indicator of normal intrauterine growth and table 1 shows the size categories the study infants fit into. The infants' five minute Apgar scores were all greater than seven and the cord ph's ranged between 7.14 and 7.36. These factors are reflective of appropriate adaptation to the birth process.

Table 1. Infant demographics

	Intermittent n (%)	Indwelling n (%)	Total % n (%)
Ethnicity			
Caucasian	4 (57)	3 (50)	7 (53.8)
First Nations	0	2 (33)	2 (15.4)
Black	1 (14)	1 (17)	2 (15.4)
Other	2 (29)	0	2 (15.4)
Total	7 (100)	6 (100)	13 (100)
Sex			
Male	5 (71)	3 (50)	8 (62)
Female	2 (29)	3 (50)	5 (38)
Total	7 (100)	6 (100)	13 (100)
Size for gestational age			
3^{rd} %	1(14)	0	1 (8)
$>10^{th} <50^{th}$ %	3 (43)	2 (33)	5 (38.5)
50^{th} %	2 (29)	3 (50)	5 (38.5)
$>50^{th} <90^{th}$ %	1 (14)	1 (17)	2 (15)
Total	7 (100)	6 (100)	13 (100)

n-refers to the number of infants

Feeding Transition Variables

The infants' ages at birth are not significantly different between the two groups, nor are the birth weights (as shown in Table 2). Gestational age at birth ranged between 30^{+1} – 33^{+5} for the intermittent group and 30^{+4} -33^{+5} for the indwelling group. Birth weights ranged from 954 grams to 2326 grams in the intermittent to 1528 grams to 2020 grams in the indwelling group. Enrolment into the study also occurred at similar gestational ages. The intermittent group was enrolled between 33-34^{+3} weeks GA and infants in the indwelling group were enrolled between 32^{+3}-34^{+1} weeks of GA. This difference was not statistically significant.

Premature infants in the indwelling group started feeding on average almost one week earlier at 32^{+5} with a range of 30^{+6} - 33^{+5} weeks GA. Half of the infants in the indwelling group began feeding orally by 32^{+3} weeks GA. The other half of the infants in the indwelling group had some feeding start dates starting later than infants in the intermittent group. Hence, the Mann-Whitney U showed no significant differences between the two groups with respect to gestational age of first feed.

Infants in the intermittent group started oral feeds at an average age of 33^{+4} weeks with a range of 33 – 34^{+2}. According to the literature (Simpson, et al., 2002) the indwelling group should have had an advantage in attaining earlier feeding transition because of earlier introduction to oral feeds. One infant did, benefit from an earlier feeding start date in the indwelling group but the other two infants in that group did not. The infant that benefited from an earlier start date transitioned to full oral feeds by 34^{+6} weeks GA and the other two infants transitioned at 35^{+5} and 36^{+5} weeks GA. The infant in the indwelling group who transitioned at 34^{+6} weeks GA and the infant in the same group who transitioned at 36^{+5} weeks GA, had very similar histories. They were born at 30+4 weeks GA, had good apgar scores and cord ph's, required less than 3 days of CPAP, and had moderate to frequent ABD's during the feeding transition period. The infant with the longest transitioning period breast fed frequently whereas the other infant did not breast feed. There does not appear to be a logical reason for the feeding transition delay between the two infants, unless the breast feeding infant experienced more handling and possibly more fatigue. Overall the variables relevant to feeding transition in each group were not significantly different as shown in Table 2.

Table 2. Feeding transition variables

	Intermittent n = 7 M (SD)	Indwelling n = 6 M (SD)	Mann-Whitney Exact Sig. P (2-tailed)
Age at birth	31.77 (1.4)	31.93 (1.2)	.836
Birth weight	1601 (519)	1729 (207)	.534
Study start age	33.65 (0.5)	33.38 (0.6)	.534
First oral feed	33.55 (.53)	32.67 (1.16)	.234

n- refers to the number of infants M- mean (SD)- standard deviation

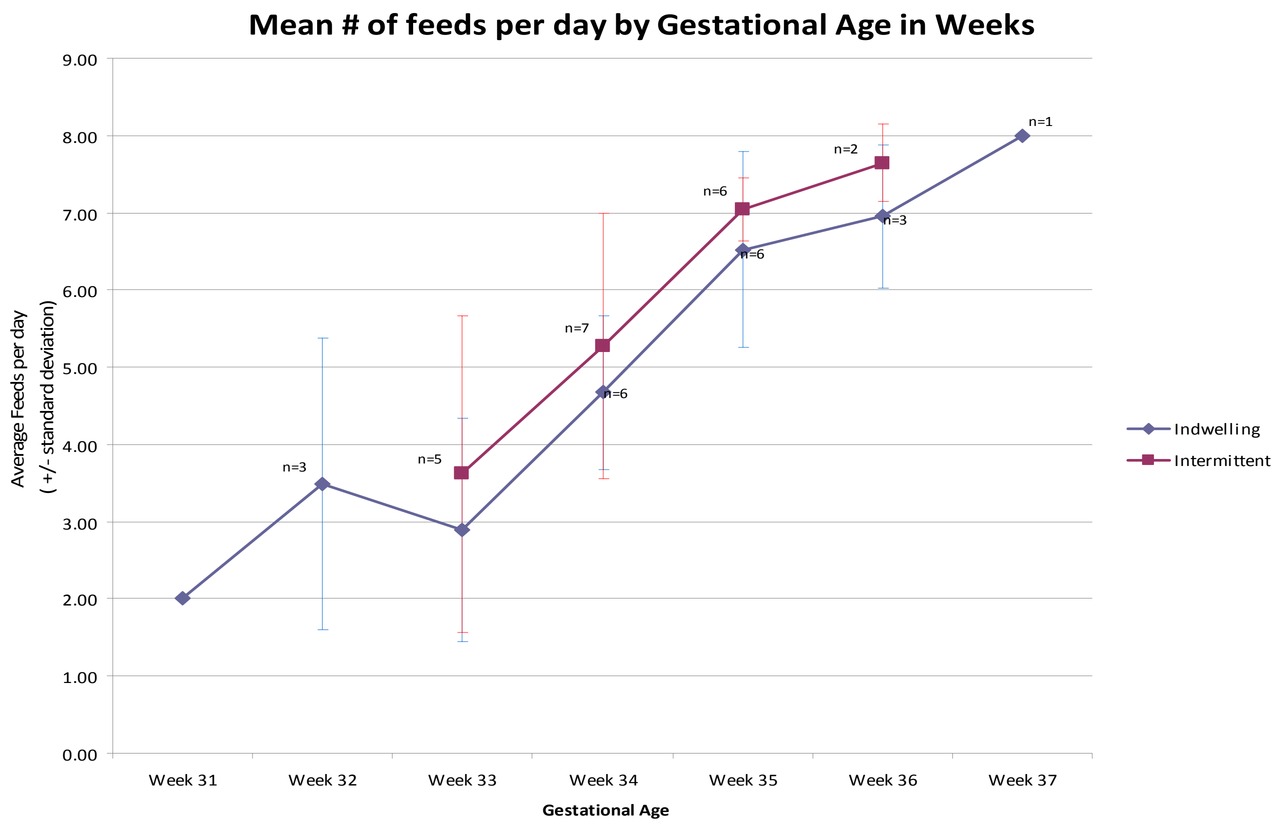
The numbers of feeds offered per day to each group were also recorded to insure equal feeding opportunities (Table 3). Nine out of the thirteen infants began feeding orally prior to enrolling in the study. Three infants in the indwelling group began suckling by 32 weeks gestational age (prior to being enrolled), and took an average of 3.5 feedings per day with a standard deviation of 1.9. This result mirrors the infants in the intermittent group who began feeding one week later and had a similar mean of 3.6 feedings per day with a standard deviation of 2.0. Both groups began feeding transition with attempting approximately three feedings per day and although the intermittent group began feeding about one week later, the older infants did not begin feeding transition by attempting more feeds per day. As shown in Figure 3, the indwelling group begins to lag behind at 33 weeks gestation and does not catch up to the intermittent group until around 35-36 weeks GA. Although there appears to be a slightly more feeds on average being offered to the intermittent group, there is no statistical difference between the feeding opportunities of the groups once both groups are 33 weeks gestational age.

Table 3. Feeding opportunities

	Intermittent		Indwelling		Mann-Whitney
	(n)	M (SD)	(n)	M (SD)	Exact Sig. P (2-tailed)
Number of feeds/day					
32-32+6	(0)	0	(3)	3.5 (1.9)	n/a
33-33+6	(5)	3.6 (2.0)	(5)	2.9 (1.4)	1.0
34-34+6	(7)	5.3 (1.7)	(6)	4.7 (1.0)	.731
35-35+6	(6)	7.0 (.4)	(6)	6.5 (1.3)	.485
36-36+6	(2)	7.6 (.5)	(3)	7.0 (.9)	.40

n/a- not applicable (n)- refers to the number of infants M- mean (SD)- standard deviation

Figure 3.



n = number of infants Standard deviation is illustrated by the cross bar

The number of times breast feeding was offered by mothers was recorded in each group as well. Both groups had infants who breast fed. Infants who breast fed moderately attained full oral feeds at 34 – 35^{+2} days of GA in the intermittent group versus 35^{+5} -36^{+5} for the indwelling group. Breast feeding has not been identified as a factor that impacts feeding transition in the literature, however breast feeding volumes were generally much lower than bottled volumes in this sample and appear to have contributed to a lower total fluid intake on some days. Table 4 summarizes the number of infants in the study who were breast feeding.

Table 4. Breast feeding summary

	Intermittent n (%)	Indwelling n (%)	Total % n (%)
None	1 (14)	2 (33.33)	3(23.08)
Rare	3 (43)	2 (33.33)	5 (38.46)
Mod	3 (43)	2 (33.33)	5 (38.46)
Total	*7 (100)*	*6 (100)*	*13 (100)*
	6/7 breast feeding 86%	4/6 breast feeding 67%	

n- refers to the number of infants

Key
Rare – breast feeding less than once a day
Mod (moderate) – breast feeding once a day or more often

Approximately 71% of infants received some ventilatory support in the intermittent group versus 33% in the indwelling group as shown in Table 5. However, less than two weeks of ventilatory support is not considered to have an adverse impact on feeding transition (Pickler et al., 1997). Some infants in both groups required caffeine for a breathing stimulant and two infants in each group experienced moderate – frequent ABD (apnea, bradycardia and desaturations). The two infants who experienced moderate – frequent ABD in the intermittent group reached full oral feeding at 35^{+2} & 35^{+3} weeks GA versus infants in the same group who had rare ABD; they reached full oral feeds between 34 – 35^{+4} weeks GA. Whereas infants in the indwelling group who had moderate - frequent ABD reached full oral feeds between 34^{+6} days to 36^{+5} days, infants who experienced rare ABD reached full oral feeds between 35^{+3} – 36 weeks GA. There was no clear trend of infants with ABD's having a later gestational age to attain full oral feeding in this study.

Table 5. Respiratory summary

	Intermittent		Indwelling		Total %
	n (%)	mean days (SD)	n (%)	mean days (SD)	n (%)
<u>Respiratory support</u>					
Vent or cpap or 02	4 (57.1)	4.8 (4.2)	2 (33.3)	2 (0)	6 (46)
N/P (no 02)	1 (14.3)	2	0 (0)	0	1 (8)
No support	2 (28.6)	n/a	4 (66.7)	n/a	6 (46)
Total	*7 (100)*		*6 (100)*		*13 (100)*
<u>Breathing stimulant</u>					
Caffeine	5 (71)		3 (50)		8 (62)
No caffeine	2 (29)		3 (50)		5 (38)
Total	*7 (100)*		*6 (100)*		*13 (100)*
<u>ABD</u>					
None- rare	5 (71)		4 (67)		9 (69)
Mod- freq	2 (29)		2 (33)		4 (31)
Total	*7 (100)*		*6 (100)*		*13 (100)*

n- refers to the number of infants n/a- not applicable (SD)- standard deviation

Key
ABD – (apnea, bradycardia or desaturation)
Vent – intubated with assisted ventilation
Cpap – constant positive airway pressure
N/P – room air flow via nasal prongs
02 – supplemental oxygen
None-rare – One ABD every two – five days
Mod-freq – One or more ABDs per day

Days to Full feed and Weight Gain

Another method of analyzing feeding transition in premature infants is to count how many days it takes an infant to attain full feeding from the first day oral feeding commenced to the last day of tube feeding (see Table 6). Early feeding opportunities and more feeding opportunities are associated with fewer feeding transition days (Pickler, Best, & Corsson, 2009, Simpson, et al., 2002). However, the maturity of the infant at the first oral feeding, and gestational age at birth, are also factors that impact the length of the feeding transition time (Dodrill, Donovan, Cleghorn, McMahon & Davies, 2008). For example, a set of twins who were randomly assigned to different feeding methods both took eight days to transition to full oral feeds. The twin who was more awake and alert began feeding three days earlier than the sibling, and became independent with oral feeds at 34^{+6} weeks GA, while the sibling became independent with oral feeds three days later at 35^{+2} weeks GA. Even though the transition days were the same, one infant transitioned at an earlier gestational age. When the groups were examined as a whole, the infants fed by intermittent tube placement had on average a shorter, but not statistically significant transitioning time as measured in days. The intermittent group did begin feeding at an older GA (but not too late to delay feeding transition) and that may explain the fewer transition days. There may be a critical window to begin oral feeds that optimizes feeding transition and perhaps beginning feeds prior to or after that critical window may impact the transition time. The fewer number of days it took infants in the intermittent group to transition is nearing significance.

Weight gain during the feeding study was also measured to find out if the type of feeding method would impact weight gain. The weight gain was calculated in grams per kilo per day. Infants who are being fed by the indwelling method gained on average the same amount of weight as infants in the intermittent group. The result is not statistically significant.

Table 6. Days to full feed and weight gain

	Intermittent n = 7 M (SD)	Indwelling n = 6 M (SD)	Mann-Whitney Exact Sig. P (2-tailed)
Days to full feed	10 (4.7)	20.5 (11.5)	.051
Weight gain during transition (g/kg/day)	16.5 (5.6)	17.8 (3.8)	.295
Weight gain to discharge (g/kg/day)	17.1 (2.8)	17.7 (3.7)	.445

n- refers to the number of infants M- mean (SD) - standard deviation

Hypotheses

The hypotheses are addressed and summarized in Table 7. The last day of tube feeding signified the last day of feeding transition and was measured in gestational age so that comparisons could be easily made. Infants in the intermittent group transitioned to full oral feeds at an average age of 34^{+6} weeks versus 35^{+4} weeks for the indwelling group. The result was not statistically significant; however, a five-day difference may have some clinical importance.

Both groups were discharged around the same gestational age. Three infants in the intermittent group had a delayed discharges ranging from 11 – 13 days. They were delayed for one or both of the following reasons they weighed less than1800 grams, and/or continued to have ABD's. Two infants in the indwelling group had delayed discharged ranging from 4 – 8 days. One infant had difficulty passing the car-seat test and one infant had a delayed discharge because of a bradycardia event with an oral vitamin administration.

The last hypothesis question addresses the oral volume suckled. Infants in the intermittent group took slightly higher average volumes measured in milliliters per kilo per day (cc/kg/day) than infants in the indwelling group. See table 7 and figure 4. However, this result was also statistically not significant.

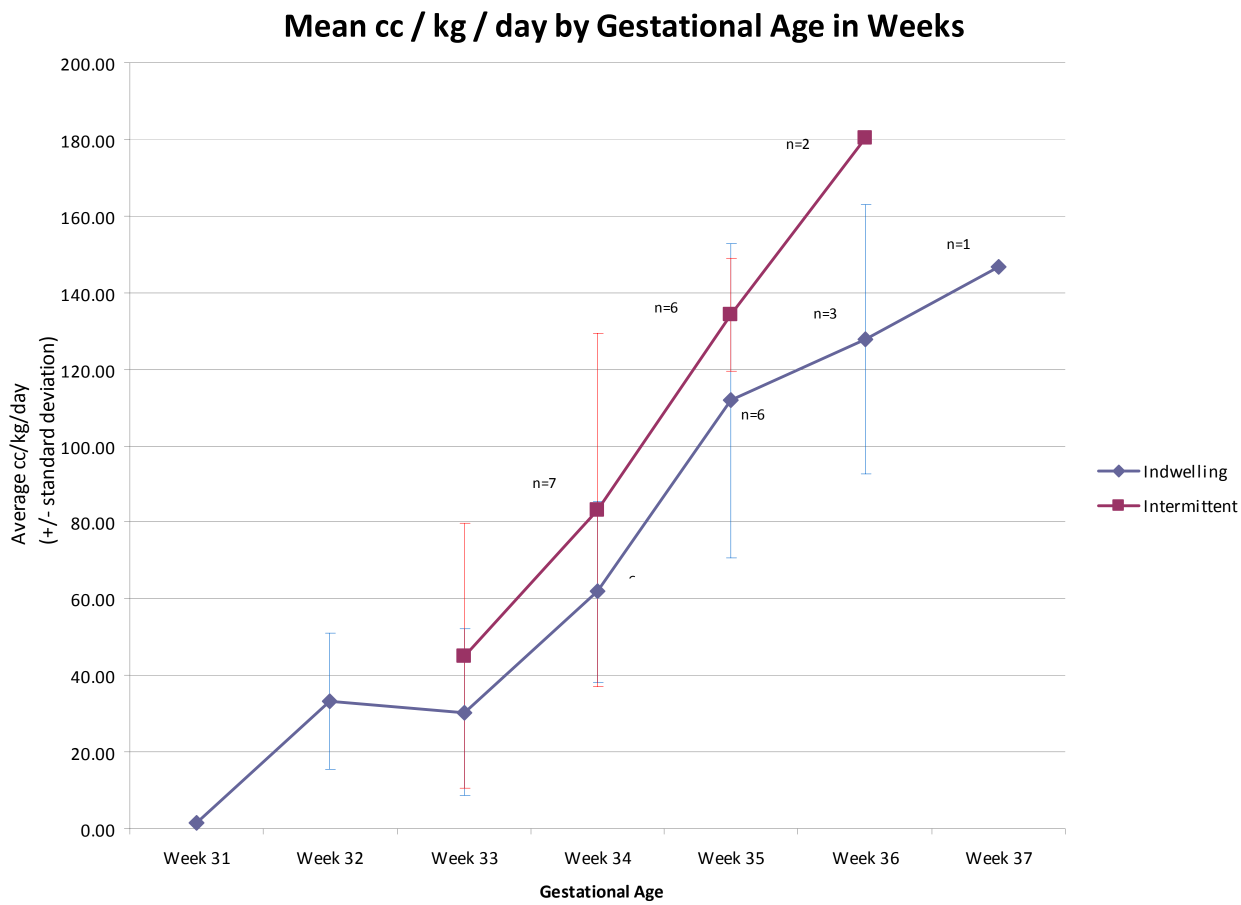
Table 7. Infant feeding transition and discharge

	Intermittent (n)	M (SD)	Indwelling (n)	M (SD)	Mann-Whitney Exact Sig. P (2-tailed)
Last TF	(7)	34.89 (0.64)	(6)	35.6 (0.71)	.181
Discharge	(7)	35.92 (0.91)	(6)	36.1 (0.81)	.836
Mean cc/kg/day					
33-33+6	(5)	45.1 (34.7)	(5)	30.4(21.6)	.690
34-34+6	(7)	83.0 (46.1)	(6)	61.8 (23.6)	.628
35-35+6	(6)	134.4 (14.7)	(6)	111.8 (40.9)	.240

(n) – number of infants M – mean (SD) – standard deviation

Key
TF – tube feed

Figure 4



n = number of infants

Cost

The number and cost of tube feeding supplies were also recorded and calculated. Infants in the intermittent feeding group required 65 days of tube feeding during the study period for a cost of $286.26 dollars and infants in the indwelling group required a total 93 days of tube feeding during the study period for an approximate cost of $28.86 dollars. Where data were missing for the indwelling group, the tube change was not counted. Therefore the actual cost may be slightly higher for the indwelling group. The intermittent group did not have missing data. The frequent change of feeding tubes in the intermittent group increases the cost of tube feeding supplies for premature infants during the transition period. See Table 8.

Table 8. Cost of tube feeding supplies

	Intermittent n = 7	Indwelling n = 6
Number of TF days in the study	65	93
Number of tubes used	367	37 (approx)
Cost ($0.78/tube)	$286.26	$28.68
Cost per day	$4.40	$0.31

n – number of infants

Key
TF- tube feeding

Summary

The results of the study were not statistically significant but did accomplish the goals of this pilot study. The intermittent and indwelling groups were similar in many characteristics. The randomization method that was used to equally distribute infants born at younger and older gestational ages into the indwelling and intermittent groups worked very well. The goal of maintaining homogeneity between the two groups was accomplished. The hypotheses were tested and infants in the intermittent group had an earlier mean feeding transition time of five days as measured in gestational age, fed on average more cc/kg/day, had on average the same weight gain, as the indwelling group. The number of infants disqualified after enrollment was higher than expected and this finding will need to be considered in future studies. Enrollment was a slow process because the enrollment criteria were restrictive and some parents declined to participate because they did not want to be randomized into a tube feeding method.

Cost was significantly higher for the intermittently placed tube fed infants. Under conditions of fiscal restraint cost may be an important factor in choosing a feeding method. If scientific evidence fails to support a medical intervention, cost will likely play a role in determining practice.

In order to gain information about future sample size requirements with a power of 80% and a 5% type 1 error rate, a power analysis was performed. This power analysis does not negate the results of this study, and does not guarantee a statistically significant difference between the two feeding methods in the future. The analysis provides size estimations for future studies based on the results of this pilot study. According to these estimations, about 28 infants may be required to explore if a difference in the mean age of last tube feeding exists, 76 infants may be required for further study to explore if a difference in the mean total nutritional substrate suckled as measured by cc/kg/day exists. This study did not only explore the feasibility of a similar future study; however, it provided insight into the research question and hypotheses, and also provided information about premature infant feeding patterns.

CHAPTER 6

Discussion

The discussion herein is divided into several parts. First I elaborate on the infants who were removed from the study for various reasons, and also on those infants who experienced ABD's. The results are then discussed in context of the literature findings. Finally I examine the limitations of the study, suggest areas for future research and provide some practical applications to nursing practice.

Disqualified Infants

Complications of prematurity occurred in each group. It is appropriate to summarize those complications and discuss infants who were removed from the study. A total of ten infants were recruited into the indwelling group and ten were recruited into the intermittent group. Three infants were disqualified from the intermittent group and four infants were disqualified from the indwelling group.

Of those three infants who were disqualified from the intermittent group, the disqualifications occurred for the following reasons. One mother declined from the study the same day of enrollment because her infant gagged with oral tube insertion, pulled at the tube during feeding and had reflux during the oral tube feeding procedure. The mother also stated that nursing staff had recommended that the infant remain on the indwelling method.

The second infant was disqualified from the intermittent group because of short duration in the study. The infant's last tube feed occurred on the first day that the infant was fed only by intermittent tube feeding. The six days prior to being enrolled the infant fed by the indwelling method (see Table 9 in Appendix F). On the first day of the study, the infant was fed half the day with indwelling and half of the day by intermittent. The volumes the infant suckled half of the day with the indwelling tube in place were very similar to the volumes the infant suckled without the indwelling tube present. The infant fed very well the on the first day of being completely in the intermittent group and only required three tube feedings. The following day the infant fed all feeds orally and no longer required tube feeding.

The third infant, a twin was removed from the study after developing necrotizing enterocolitis (NEC). The twin's sibling who was randomly assigned to the indwelling group also developed NEC and was removed from the study three days later. Premature infants disqualified from the intermittent group for the following reasons: NEC, short duration in the study and one mother declined because of her infant's response to intermittent oral tube feeding.

There were four infants in the indwelling group who were disqualified from the study. The first infant was removed from the study because the infant did not consistently remain in the indwelling group. The nurses changed the infant to their desired method of feeding, or the infant pulled the feeding tube out and the nurse did not replace it. The second infant, a twin, developed NEC as previously mentioned.

The third infant (weighing more than 2kg) who was on caffeine and having ABDs had 27 ABDs at rest and five ABDs associated with feeds eight days prior to starting the study. In the eight day period after study enrollment, the infant had 32 ABDs at rest and seven ABDs associated with feedings. The infant was also started on nasal prongs three days after enrollment. The nurses were concerned that the infant was having reflux and increased ABDs related to the indwelling tube placement and decided to take the baby off the study. I spoke with the mother later, and she agreed with the nurse's opinion that the indwelling tube was causing more ABDs and wanted to have the infant switched to intermittent tube feeding. During the study period, that the infant was feeding orally, the infant suckled variable amounts ranging from 0 – 41 cc's. The infant seemed to be progressing along as expected.

The fourth infant was 31^{+4} weeks GA on the date of enrollment, weighed less than 2 kilos and also had difficulty with ABDs prior to enrolling in the study. The infant was on nasal prongs on room air which were discontinued four days after study enrollment. On the tenth day of the study the infant was restarted on nasal prongs and on the twelfth day the infant had a partial septic workup and enteral feeds were discontinued. A chest x-ray showed that the infant had developed atelectasis and as a result was transported back to the neonatal intensive care unit for continuous positive airway pressure (CPAP) therapy. Therefore the infant was disqualified and removed from the study. Premature infants were disqualified from the indwelling group for the following reasons: atelectasis requiring CPAP, the nurse's opinion that ABDs were related to the indwelling method, NEC and the nurse's inconsistency in maintaining indwelling tube feeding.

Apnea of Prematurity

Apnea, bradycardia and desaturations (ABD) are common complications of prematurity and can interfere with feeding transition. Two infants in the intermittent group and two infants in the indwelling group experienced moderate to frequent ABDs. The first infant in the intermittent group had difficulty with ABDs prior to the study and had been treated with caffeine. Four days after enrolling in the study the infant had 11 ABD's, required a caffeine load and was re-started on maintenance. More than half of the infant's ABD episodes were feeding related. Four occurred during rest and seven were associated with feeding. Once the caffeine was discontinued the infant continued to have zero to two feeding related ABD's per day till 48 hours prior to discharge. The infant progressed quickly with feeds (8 transition days) and was completely independent with feeds after 35^{+3} weeks GA.

The second infant also had ABDs prior to entering the study but had not been treated with caffeine. The infant was treated with nasal prongs on room air for two days prior to the start of the study. Forty-two of this infant's ABDs happened at rest and ten were feeding related over a twenty day period. This infant transitioned to full oral feeds in eleven days and was completely independent with oral feeds after 35^{+2} weeks GA. After transitioning to full oral feeds, the infant continued to have one to four ABDs at rest and zero to four ABDs per day with feeding till 48 hours prior to discharge.

The indwelling group's experiences did not reveal many differences. Two of these infants also had ABDs prior to being enrolled in the study. The first infant was treated with caffeine prior to study enrollment. Subsequently, eight days after study enrolment the infant was placed on nasal prongs for three days and received a caffeine load for increased ABDs. Twenty-four of the ABD's occurred at rest and eight ABDs were related to feeding during that eight day period post study enrolment. The infant responded well to the treatment and only had a total of 3 ABDs in the following six days after the caffeine load. The infant transitioned to full oral feeds after 21 days and no longer required tube feeding after 34^{+6} weeks GA. The nurses commented that this infant was sleepy and not very motivated to feed. Sleepiness is also common for preterm infants and this infant did not progress to ad lib demand feeds for that reason.

The second infant in the indwelling group having ABDs had a caffeine load two days prior to enrolling in the study and was on caffeine maintenance. After enrollment, the infant had 22 ABDs at rest and 14 ABDs that were associated with feeds over a 28 day period. Hence the infant was only having about one ABD per day associated with rest or a feed. The infant began breast feeding at 30^{+6} weeks GA and began bottling about one week later. The total transition time was 41 days and the infant was independent with feeds after 36^{+5} weeks GA. Another complication encountered by this infant was emesis post feeds, and the infant developed oral thrush on the last day of tube feeding. This infant was very inconsistent with feeding and progressed slowly. Other than breast feeding frequently, no factor was apparent for the slow progress in feeding transition.

ABDs did not appear to be associated with either feeding method and did not seem to impact feeding transition. Although, ABDs are a common complication of prematurity they are also barriers to discharge, and did contribute to attrition.

Theory Application, Literature Findings and Study Results

It was hypothesized that infants in the intermittent group would attain full oral feeds sooner than the indwelling group; take on average more cc/kg/day than infants in the indwelling group, and be ready for an earlier discharge. The study results did not support these hypotheses. Al's Synactive Theory of development predicts that an infant will show avoidance or approach behaviors to environmental stimuli, which in turn will impact development. The premise of each hypothesis was that the indwelling feeding method would be more aversive to the infant and therefore the infant would respond with avoidance behaviors which would slow the developmental progress of feeding. When the complications of prematurity are viewed as the infant's avoidance response to environmental stimuli and are set within the context of the literature reviewed and results of this study, it is apparent that there were maladaptive behaviors in both groups. The cause of those behaviors is beyond the scope of this paper; however, a discussion of what was seen in this pilot study has merit.

Indwelling NG tubes have previously been scrutinized and studied for negative affects. According to Greenspan et al., (1990), Shiao et al., (1995), and van Someren et al. (1984) the physical presence of an NG tube passing through the respiratory and feeding structures may lead to a compromise in respiratory status. Greenspan and associates further speculated that suckled volumes and weight gain may also be compromised due to indwelling NG tube placement. The results of this study did not show support for those speculations since infants did not differ significantly in feeding transition, and weight gain, and infants in both groups were able to suckle large volumes.

A discussion on tube feeding necessitates consideration of ABDs. ABDs were recorded as *per* nursing record and were examined for their impact on feeding rather than being examined for their relationship to NG tubes. However, because the tube feeding literature discusses the relationship between indwelling tubes and respiratory compromise observations of ABDs in infants and the relationship between feeding methods will be discussed here.

Infants who did not have difficulties with ABDs before entering the study did not appear to be impacted by the type of feeding method, even those infants weighing less than 2000 grams. Whereas those infants who had difficulty with ABDs prior to entering the study, continued to have ABDs during the study period whether they were assigned to the intermittent group or the indwelling group. No apparent differences in ABDs were observed between feeding methods and these observations reflect the findings of Bohnhorst, Cech, Peter & Doerdelmann, 2010 and Symington, et al., 1995 who found that there were no significant differences with regard to ABDs between infants fed with indwelling nasogastric tubes and those tube fed by an alternate oral route. As well, infants in both groups who had ABDs at rest also had ABDs associated with feeds. Furthermore, the impact of ABDs on feeds was not obvious. Infants with ABDs were still able to take large volumes during oral feeds and their feeding progression patterns appeared no different than infants without ABDs. Also, the presence of an indwelling tube did not appear to impact ABDs during feeding in this sample. The only factor that appeared different but was not statistically significant for infants in the indwelling group was the slightly fewer number of feedings taken during the transition period. The fewer number of feeds taken in the indwelling group may be related to nurse's influence or to the infant's lack of feeding cues.

The other parameter speculated to be negatively impacted by indwelling tube feeding was weight gain. However, infants in the indwelling group and intermittent groups had similar average weight gains.

Infants have a strong instinct to feed and I speculate that innate drive overcomes and adapts to the feeding method being provided. Also, the type of tube feeding method may not present enough of a barrier to interfere with the feeding progression. Another study examining the impact of NG indwelling versus intermittent oral tube insertion on feeding transition would support or negate the hypotheses of this study and provide direction for future tube feeding practices. Overall, the maladaptive behaviors, or complications of prematurity expected to be accentuated with the indwelling tube feeding method, was not supported by this study and feeding transition was not significantly impacted.

Limitations of the Study

A major limitation of the study was its sample size of thirteen. The study was a pilot from its inception, the purpose of which was, gathering information and raising awareness about tube feeding issues. A contributing factor to the small sample size was attrition. Attrition was expected, but the high attrition rate in this study was not anticipated. A lack of equipoise between nurses' opinions in favor of NG or OG tube feeding methods were initially thought to be a benefit; however those opinions impacted parental views and resulted in the loss of one patient from the intermittent group and one patient from the indwelling group.

Another limitation that emerged was the lack of consistency at the start of the first feeding and that could possibly have given one group a feeding advantage. Although three infants in the indwelling group began feeding earlier than infants in the intermittent group only one of those infants seemed to benefit from the early start and achieved full oral feeds by 34^{+6} weeks. For the other two infants who began feeding early, there did not appear to be an advantage because they completed feeding transition in third last and last place. A feeding assessment tool may have standardized feeding initiation and the feeding start times may have had greater consistency thereby equalizing initial feeds. Moreover, a feeding assessment tool may have provided an explanation for the fewer feeds offered to the indwelling group or added a control mechanism to equalize the feeding opportunities of each group.

A third limitation of the study is the difficulty of accurately determining the gestational age of the infants. Although the last menstrual period was used to calculate gestational age as well as fetal-assessment ultrasound data when it was available, the true gestational age remains an estimated calculation and a large sample size would diminish the impact of the GA calculation error.

Implications for Future Research and Nursing Practice

There is much to be learned about tube feeding methods, feeding transition and infant feeding patterns. Each study adds to the knowledge base and this pilot study examined two different types of tube feeding methods and described premature infant feeding patterns. There remain gaps in the knowledge regarding tube feeding methods and their potential associations with the complications seen in prematurity. Investigation into the association of tube feeding methods with emesis, infection, trauma, pain, oral aversion, and oxygen saturations during feeding is needed. Studies done in the past are short term or have very few participants or are retrospective and good evidence is still required to answer questions about the impact of NG indwelling tubes and intermittent tube feeding on the premature infant. The association of ABDs and tube feeding methods has been studied to some degree, however; a long term study comparing the association between ABDs and indwelling NG tube feeding and ABDs with oral intermittent tube feeding is still required. Furthermore, the long-term feeding outcomes of tube feeding methods post discharge also deserve investigation. Tube feeding remains an unnatural means of providing nutrition that may cause discomfort, pain or infection. Awareness of the potential negative impacts imposed on the infant during the tube feeding period, and observing the infant’s systems (or responses) will guide nurses’ care plans. Furthermore, nurses are front line workers who observe the impact of feeding methods on the infants in their care and their observations and opinions provide an excellent source for research questions.

Conclusion

Premature infants who may require up to 10 weeks or more of gavage tube feeding are often seen as the least capable of directing their own care. However, Als' Synactive Theory of Development proposes that infants are capable of providing direction for their care through their *systems* and are able to adapt to their environment. The results of this study were inconclusive and that may be a reflection of the infant's ability to adapt to the feeding environment, or that both feeding methods are equally aversive to the infant and therefore equally impact feeding transition. Many questions regarding feeding transition remain unanswered. Moreover, controversy remains over which tube feeding method, intermittent or indwelling are best for premature infants, and strongly held opinions rather than research maintain the current tube feeding practices. While much premature infant feeding research is still needed, premature infants requiring tube feeding must endure the current methods we impose on them and wait until we discover how to help them through the trying time of tube feeding.

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APPENDIX A

Biomedical Research Ethics Board Approval Form

UNIVERSITY OF MANITOBA

BANNATYNE CAMPUS
Research Ethics Boards

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Tel: (204) 789-3255
Fax: (204) 789-3414

APPROVAL FORM

Principal Investigator: Ms. J. Kublick
Supervisor: Dr. W. Diehl-Jones

Protocol Reference Number: B2008:072
Date of REB Meeting: May 26, 2008
Date of Approval: May 27, 2008
Date of Expiry: May 26, 2009

Protocol Title: "The Impact of Nasogastric Indwelling versus Oral Intermittent Tube Feeding Methods on Premature Infants"

The following is/are approved for use:

- **Protocol dated May 12, 2008 including appendices A to D**
- **Research Participant Information and Consent Form, Version 3 dated May 26, 2008**

The above was approved by Dr. Nicholas Anthonisen, Chair, Biomedical Research Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your letter dated May 27, 2008. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations.*

This approval is valid for one year from the date of the meeting at which it was reviewed. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval should be sought from the relevant institution, if required.

Sincerely yours,

Nicholas Anthonisen, MD, Ph.D
Chair,
Biomedical Research Ethics Board
Bannatyne Campus

Please quote the above protocol reference number on all correspondence.
Inquiries should be directed to the REB Secretary
Telephone: (204) 789-3255/ **Fax:** (204) 789-3414

www.umanitoba.ca/faculties/medicine/research/ethics

Biomedical Research Ethics Board Annual Approval Form

UNIVERSITY OF MANITOBA

BANNATYNE CAMPUS
Research Ethics Boards

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Tel: (204) 789-3255
Fax: (204) 789-3414

APPROVAL FORM

Principal Investigator: Ms. J. Kublick
Supervisor: Dr. W. Diehl-Jones

Ethics Reference Number: B2008:072
Date of Approval: October 27, 2009
Date of Expiry: May 26, 2010
****Original Anniversary Date****

Protocol Title: "The Impact of Nasogastric Indwelling versus Oral Intermittent Tube Feeding Methods on Premature Infants"

The following is/are approved for use:

- **Annual Approval**
- **Research Participant Information and Consent Form, Version #3 dated 26/05/08**

The above was approved by Dr. Nicholas Anthonisen, Chair, Biomedical Research Board, Bannatyne Campus, and University of Manitoba on behalf of the committee per your letter dated October 4, 2009. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations of Canada.*

This approval is valid until the expiry date only. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval should be sought from the relevant institution, if required.

Sincerely yours,

Nicholas Anthonisen, MD, Ph.D
Chair,
Biomedical Research Ethics Board
Bannatyne Campus

Please quote the above Ethics Reference Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255/ **Fax:** (204) 789-3414

Pediatric Research Coordinating Committee

Health Sciences Centre
Winnipeg

Arthritis Centre

Pediatric Rheumatology & Immunology
Office: (204) 787-2020
Clinic: (204) 787-2674
Fax: (204) 787-2475

September 17, 2008

Dr. B. Diehl-Jones, Academic Advisor
Faculty of Nursing and Department of Zoology
University of Manitoba
Helen Glass Center for Nursing
WINNIPEG, MB
R3T 2N2

Dear Ms. Kublick and Dr. Diehl-Jones:

Re: Research protocol RI08:077 "The impact of nasogastric indwelling versus oral intermittent tube feeding methods on premature infants."

Your study was reviewed at the Pediatric Research Coordinating Committee meeting on September 15, 2008. N. Kostiuk advised that the ward clerk staff will place the information sheets on the admission package and parents will contact you if they are interested in the study. We have, therefore, approved this study.

Please inform the Pediatric Research Coordinating Committee of the dates data collection is started and completed (at time of completion).

Yours truly,

Kiem G. Oen, MD, FRCPC
Chairperson
Pediatric Research Coordinating Committee

KGO:jc

c.c. File
Karen Shaw

Adult Office (204) 787-1851 Appointments (204) 787-2392 Fax (204) 787-4595 / Pediatric Office (204) 787-2020 Fax (204) 787-2475
RR149, 800 Sherbrook Street, Winnipeg, Manitoba Canada R3A 1M4 www.hsc.mb.ca

An operating division of the Winnipeg Regional Health Authority Office régional de la santé de Winnipeg

Affiliated with the University of Manitoba

Health Sciences Centre Research Impact Committee

Health Sciences Centre
Winnipeg

Office of the Director of Research

Dial Direct 204-787-2404
Fax 204-787-4547

September 22, 2008

Dear Ms Kublick

RE: THE IMPACT OF NASOGASTRIC INDWELLING VERSUS ORAL INTERMITTENT TUBE FEEDING METHODS ON PREMATURE INFANTS.

ETHICS #: B2008:072 RIC #: RI08:077

The above-named protocol, **has been evaluated and approved** by the HSC Research Impact Committee.

The Department of Research wishes you much success with your study.

Sincerely

Karen Shaw-Allan
Research Protocol Officer
Health Sciences Centre

cc: Director of Research
Ancillary Services, Finance Division

MS7 - 820 Sherbrook Street, Winnipeg, Manitoba Canada R3A 1R9 www.hsc.mb.ca

An operating division of the Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg

Affiliated with the University of Manitoba

The Personal Health Information Act of Manitoba

Page 1

original

HSC Research Department Use Only
RI#: 08:077

The Personal Health Information Act of Manitoba

AGREEMENT FOR
ACCESS TO PERSONAL HEALTH INFORMATION
FOR RESEARCH PURPOSES

BETWEEN:

WINNIPEG REGIONAL HEALTH AUTHORITY - Health Sciences Centre Site
(hereinafter referred to as the "HSC")
-and-

Judy Kublick
(hereinafter referred to as the "Principal Investigator")

This agreement is used once a proposal to access personal health information for research purposes has been approved by the HSC. Once the person conducting a health research project ("Principal Investigator") has signed this form and the terms and conditions of access have been approved by the HSC, it becomes a legal agreement between the Principal Investigator and the HSC. The HSC Research Impact Approval Application and the University of Manitoba Research Ethics Boards Approval letters must be appended to this agreement and form part of the legal agreement.

The collection of the information referenced on this Application is authorized *by The Personal Health Information Act* and will be used only to administer the research project. The Director of the HSC Research Department, 7th Floor Thorlakson Building, Health Sciences Centre, 820 Sherbrook Street, Phone: 787-2404 can answer any questions concerning this agreement or the collection of the information on this form.

Title of Research Proposal: The impact of nasogastric indwelling versus oral intermittent tube feeding methods on premature infants

Please provide the following additional information (if applicable):

Institutional Affiliation and/or Department: University of Manitoba

Position: Graduate student Academic Advisor (if student): Dr. Bill Diehl-Jones

The Personal Health Information Act of Manitoba

Page 2

1. The Principal Investigator has requested access to the following records that contain personal health information and are in the custody or under the control of the HSC for the proposal as identified below:

   Describe the Records that will be used in this research proposal:

   Information in the infant's current (bedside) chart will be used for data collection.

   (the "records")

2. The Principal Investigator agrees to the following terms and conditions:

   a not to publish the personal health information requested in a form that could reasonably be expected to identify the individuals concerned.

   b to use the personal health information requested solely for the purposes of the above-named research project;

   c to destroy the information or remove all identifying information at the earliest opportunity consistent with the purpose of the project.

   - Specify when identifying information will be destroyed: Identifying information will be removed as soon as the data collection is complete. (At infant discharge.)
   - Specify procedures to destroy identifying information:
     The infant's name will be cut off the data collection form and disposed of in the confidential waste bin in the IMCN. If a computer is used for data collection the infant's name will be deleted from the computer when the infant is discharged.

   d to use reasonable safeguards to protect the confidentiality and security of the personal health information:

   - Specify safeguards: All personal information will be locked in the Principle Investigator's (PI) filing cabinet and if a computer is used for data collection, it will be locked in the PI's closet.
   - Attach the REB submission form and specify area where this is stated.
     Refer to pages 11 & 13 for plans to handle confidential information

3. The HSC agrees to grant access to the records on the terms and conditions set out in paragraph 2.

HSC Research Department approval is dependent upon the Principal Investigator providing a copy of the REB final approval letter to the HSC Research Department.

Signed at: this day of , 20

Principal Investigator
Name:
Judy Kublick

Director HSC Research Department
Name:

- *ORIGINAL AGREEMENT TO BE RETAINED IN HSC RESEARCH DEPARTMENT*
- *SIGNED COPY TO BE FORWARDED TO PRINCIPAL INVESTIGATOR.*

APPENDIX B

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: The Impact of Nasogastric Indwelling versus Oral Intermittent Tube Feeding Methods on Premature Infants

Protocol number: B2008:072

Principal Investigator: Judy Kublick
University of Manitoba Faculty of Nursing
Helen Glass Centre for Nursing
Winnipeg, Manitoba, R3T 2N2
Voice mail #
Supervisor: Dr. William Diehl-Jones
University of Manitoba Faculty of Nursing
Helen Glass Centre for Nursing
Winnipeg, Manitoba, R3T 2N2
Phone #
Sponsor: *Winnifred Ruane Graduate Student Research Grant for Nurses*

You are being asked to participate in a clinical trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with the study nurse. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study nurse to explain any words or information that you do not clearly understand.

The study nurse is receiving financial support to cover study costs.

Purpose of Study

This Clinical Pilot Trial is being conducted to learn more about the infant's feeding behavior while being fed by indwelling nasogastric tube placement or by intermittent oral tube placement. Currently we do not know which of these two commonly-used tube feeding methods is best for premature infants who are learning how to feed. This study will not definitely answer the question "Which tube feeding method is best for the premature infant learning how to feed?" but it will provide us with very important information that is needed for future research.

A feeding tube is used to feed a baby when the baby is too immature, too tired or too sick to feed by bottle or breast. In the indwelling feeding tube placement method, the feeding tube is guided into the baby's nose or mouth and placed into the baby's stomach. The tube is taped to the baby's cheek to help it stay in place. The bedside nurse will test the liquid in the feeding tube before each feed and decide if the feeding tube is correctly placed as per current hospital policy. It is changed every two or three days. In the intermittent feeding tube placement method, the feeding tube is guided into the baby's mouth and placed into the baby's stomach every time the baby is unable to feed by bottle or by breast. The bedside nurse will test the liquid in the feeding tube before each feed and decide if the feeding tube is correctly placed as per current hospital policy. It is taken out immediately after the feed is finished. Both tube feeding methods are being used to feed premature infants in this hospital and your infant may have experienced both feeding methods already.

Your infant is being asked to take part in this study because he/she is a healthy growing preterm infant who will be learning to feed by breast and/or bottle.

A total of 24 infants will participate in this study.

A cost analysis of both tube feeding methods will also be performed**.**

Study Procedures

In this study, your infant will be "randomized" into one of *2* study groups described below. "Randomized" means that your infant is put into a feeding group by chance, like flipping a coin. Your infant will have an *equal, one in two* chance of being fed by intermittent oral tube placement or by indwelling nasogastric tube placement while he/she learns to feed. The research nurse will randomly assign your infant's feeding method by opening a sealed envelope that will indicate which feeding method your infant will be assigned to. Your researcher and your nurse will not know which feeding group your baby will be assigned to until the envelope is opened. Your infant will also be encouraged to suck on a soother when appropriate and will receive the same care that the other infant's in this nursery will receive. The researcher will collect feeding related data from your baby's chart.

Participation in the study will continue until your infant is discharged**.**

The researcher may decide to take your infant off this study if he/she is not able to feed by breast or bottle.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the research nurse first.

If your infant participates in this study you may ask for a summary of the results to be sent to you. Please indicate that you would like a summary by checking off the box at the end of this consent form and write your address in the space provided. If you move it is your responsibility to notify the researcher by sending a letter to the above address and notifying the researcher of your new address.

Risks and Discomforts

There are risks and benefits associated with each type of tube feeding method. Feeding tube insertion may be uncomfortable or painful for your baby, may cause tissue injury, gagging or vomiting and a temporary drop in heart rate or temporary change in breathing pattern. Both feeding methods may place your infant at risk for developing feeding difficulties. A benefit of an indwelling tube is that the tube is only changed every two or three days and the infant does not have to experience frequent tube insertion. However, your infant may have slight increased risk for an ear infection and may have a slightly longer dip in oxygen saturation (about 8 seconds longer) during feeding if a dip in oxygen saturation occurs at that time. Premature infants commonly experience a dip in their oxygen saturations when they are learning how to feed and infants in both feeding groups will likely experience oxygen saturation dips during their feeds. Finally, a benefit of intermittent tube feeding is that the feeding tube is not constantly present. It is not known if an indwelling tube is uncomfortable for your baby.

Benefits

By participating in this study, you will be providing information to the study nurse about the impact of different tube feeding methods described above on premature infant feeding behaviors. There may or may not be direct medical benefits to your infant from participating in this study. We hope the information learned from this study will benefit other premature infants in the future.

Costs

There will be no cost for the study participation.

You do not have to participate in this study in order for your infant to receive the same care that the other infants in this nursery will receive. If your infant is not in this study, your infant will be fed with the intermittent tube placement method.

Confidentiality

Information gathered in this research study may be published or presented in public forums; however your name and other identifying information will not be used or revealed. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

All study documents related to you will bear only your assigned patient number.

Only infant feeding data and infant name may be entered into a computer for data collection. Once data collection is complete your infant’s name will be deleted from the computer. The feeding data entered into a computer for data analysis will be destroyed once the data analysis is complete.

The University of Manitoba Biomedical Research Ethics Board may review research-related records for quality assurance purposes.

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your infant's name, address or telephone number will be revealed.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your infant's medical care at this site. If your study nurse feels that it is in your best interest to withdraw you from the study, your study nurse will remove you without your consent.

We will tell you about any new information that may affect your infant's health, welfare, in this study.

Medical Care for Injury Related to the Study

In the case of injury or illness resulting from this study, necessary medical treatment will be available at no additional cost to you.

You are not waiving any of your legal rights by signing this consent form nor releasing the investigators or the sponsor from their legal and professional responsibilities.

Questions

You are free to ask any questions that you may have about your infant's feeding method and your infant's rights as a research participant. If any questions come up during or after the study or if your infant has a research-related injury, contact the study nurse Judy Kublick at

For questions about your rights as a research participant, you may contact The University of Manitoba Biomedical Research Ethics Board at (204) 789-3389

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Judy Kublick. I have had my questions answered by her in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to allow my infant to participate in this research study.

I understand that information regarding my infant's personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of University of Manitoba Biomedical Research Ethics Board.

By signing this consent form, I have not waived any of the legal rights that my infant has as a participant in a research study.

Legal guardian's signature_____________________
Date ___________________
(day/month/year)

Legal guardian's printed name: ____________________________

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: ___________________________________
Date ___________________
(day/month/year)

Signature: ____________________________

Role in the study**:** ____________________________

Please send me a summary of the results ☐

My address is _______________________

____

____

APPENDIX C

Invitation to Participate

Would you like your baby to participate in a feeding study?

There is a research nurse studying infant feeding in this nursery.

If your baby was born between 30 to 33 weeks gestation you may have the opportunity to participate.

What is the study all about?

There are different ways to tube feed your baby while he or she is growing and becoming strong enough to breast/bottle feed without help. You may have seen some different methods used already. Some babies are fed with an *indwelling* feeding tube and some babies are fed with an *intermittently* placed feeding tube. The indwelling tube is inserted into the baby's stomach and is taped to the baby's cheek. It is changed every 2-3 days. In the intermittently placed tube feeding method, the nurse will put a feeding tube into the baby's stomach for each feed as needed and remove it after each feed. Currently we do not know if an *indwelling* tube versus an *intermittently* placed tube will impact the baby's feeding progress. This pilot study will examine the impact of an ***indwelling*** nasally-placed feeding tube versus an ***intermittently*** placed oral feeding tube on infant feeding behavior.

How will the study change nursing care?

During the study your baby will receive routine nursing care. Only the tube feeding method may differ or stay the same. Your infant will be randomly assigned to either *intermittent* gavage tube placement or *indwelling* nasogastric tube placement. You cannot ask to be assigned to a particular feeding group. You will be encouraged to breast feed (if you are planning to breast feed) and bottle feed your baby when the nurse thinks your baby is ready to feed. Your baby will also be encouraged to practice sucking on a soother while awake.

How do I find out more?

If you are interested in learning more about this study, or participating in this study you can tell your nurse or you can call the research nurse, or you may place a check mark beside the 'Yes' and the research nurse will contact you and arrange a meeting time at your convenience. If you would like the research nurse to contact you, just leave this letter at your baby's bedside and check off the 'Yes.'
"Yes" I would like more information_______ No thank you, I'm not interested ______

Thank you for taking the time to read this invitation.

This study is being conducted by Judy Kublick RN, BN, and a graduate student at the University of Manitoba. The study is being supervised by Dr. William Diehl-Jones. For more information about the feeding study you may call Judy Kublick at any time and leave a message.
Voice mail #

APPENDIX D

Nursing Prompt card

Infant Feeding Study: **Type of tube feeding method____________**

Oral feeding guidelines as per routine

- may begin oral feeding by breast or bottle if infant is 32 weeks gestation (may begin feeding sooner if infant is ready)

  AND

- rooting
- sucking on soother well
- awake and alert
- stable

Feeding support as per routine

- provide swaddling support as needed
- provide pacing as needed
- provide a soother often

Chart as per routine

- chart breast feeding volumes as per routine
- chart bottled volumes and a bottling attempts as per routine

Remove feeding tube/stop intermittent feeding when:

- the infant has been able to feed full oral requirement in a 48 hr. period as per routine practice

Restart the infant's designated tube feeding method if the infant requires tube feeding.

- do not change the infant's feeding method

The study will end on infant's discharge date.

Highlighted information sheet

Sample of the highlighted information sheet taped on the front of each study infant's chart and kardex.

Sheet for the indwelling NG infant

Feeding Study Infant
I am on the feeding study: indwelling method. If my NG is out for **One** or more feeds please leave a message for the study nurse as soon as possible and let her know the date and time it remained out or clearly chart on the feeding sheet. V*oice mail #*

You may remove my NG if I have bottled/breast fed all my feeds in the last 48 hours or if the doctor writes an order asking you to discontinue my feeding method. Please notify my study nurse **Immediately** if the doctor decides to stop my feeding method.

If I accidentally pull out my tube, please hide my fingers in my sleeper. Please call study nurse if you have questions, interesting observations or frustrations with my feeding method because you may have discovered something important. Thank you! ☺

Sheet for the intermittent OG infant

I am on the feeding study: intermittent method.

Please call my study nurse if you have questions, interesting observations or frustrations with my feeding method because you may have discovered something important. Thank you! ☺
Voice mail #

Sample of Kite attached to the head of the crib

- the infant's feeding method was written with a marker on this card

APPNEDIX E

Infant Feeding Patterns

Suckled amounts were initially recorded in cc/kg/day and later the actual amount that the infant suckled at each feeding was recorded to gain a better understanding of the change in feeding size over the course a day. Just two infants did not have the amounts of each feeding recorded. Breast fed amounts were also recorded and analyzed for a pattern. The first section will discuss breast fed volumes, the second section will analyze the infant's feeding pattern of suckled amounts at each feed during the day, and the last section will examine the cc/kg/day (total fluid intake) the infant fed and show the feeding progression over time.

Breast Fed Volumes

The breast fed volumes were much smaller than the bottle fed volumes as a general rule. Out of the ten infants who were breast feeding, three began nursing first, four began by bottling first, and three began feeding by breast and bottle. The three infants who averaged the highest suckled volumes in one day, usually breast fed twice a day and had the most breast feeding practice. One of the top three breast feeders began breast feeding the same day bottling commenced, the other one began breast feeding prior to bottling and the best breast feeder of the whole group began breast feeding after bottle feeding was established. Two infants out of the ten were able to take one full volume feed prior to discharge, and only one infant was breast feeding well enough to exclusively breast feed at discharge. Generally the breast feeding amounts were variable, and a large volume at one feeding was not predictive of a large volume the next feeding or the next day. The overall cc/kg/day suckled by breast and bottle was affected at times by the smaller breast fed volumes.

Daily Bottled Volumes

Bottled volumes ranged from 0cc to 27cc at the first bottled attempt and volumes tended to be smaller at the beginning of feeding transition and increased over the course of the feeding transition. Infants in the intermittent group were able to take at least one full oral feed one to five days after commencing feeds and infants in the indwelling group were able to take at least one full oral feed two to sixteen days after commencing oral feeds. Like the breast fed volumes, the first bottled volume was not predictive of the second bottled volume. For example one infant took 2cc at the first bottled attempt and took 23cc at the next time the bottle was offered. The reverse could also be true. Another infant took 27cc at the first bottled attempt and then only 17cc at the next offered feeding. The feeding volumes tended to be very inconsistent over the course of the day.

An infant may feed very well once or twice during the day and then very poorly or not at all at other times during the day. A large variable feeding pattern was seen at the beginning of feeding transition; it continued throughout the transitional period, and was also seen post transition. Figures 5 and 6 provide a graphed view of the average volumes suckled at one feed during the day and the bar intersecting the mean denotes the standard deviation of suckled volumes that day. One infant was in the indwelling group (Figure 5) and one infant was in the intermittent group (Figure 6). The indwelling infant was not breast feeding, did not have any recorded ABDs during the study period and was born about one week earlier than the intermittent infant. Both infants began feeding at 33^{+5} weeks GA. The intermittent infant had moderate to frequent episodes of ABDs and breast fed frequently. The greater variability shown by the standard deviation in Figure 6 is reflective of the intermittent infant's breast fed volumes. The infant in the intermittent group completed transition at 35^{+2} weeks GA and the infant in the indwelling group transitioned at 35^{+3} weeks GA. Both infants displayed a range in volumes suckled over the course of a day and their feeding patterns were typical of the feeding patterns seen in the other study-infants.

Figure 5. Indwelling group infant – Mean feed size by gestational age

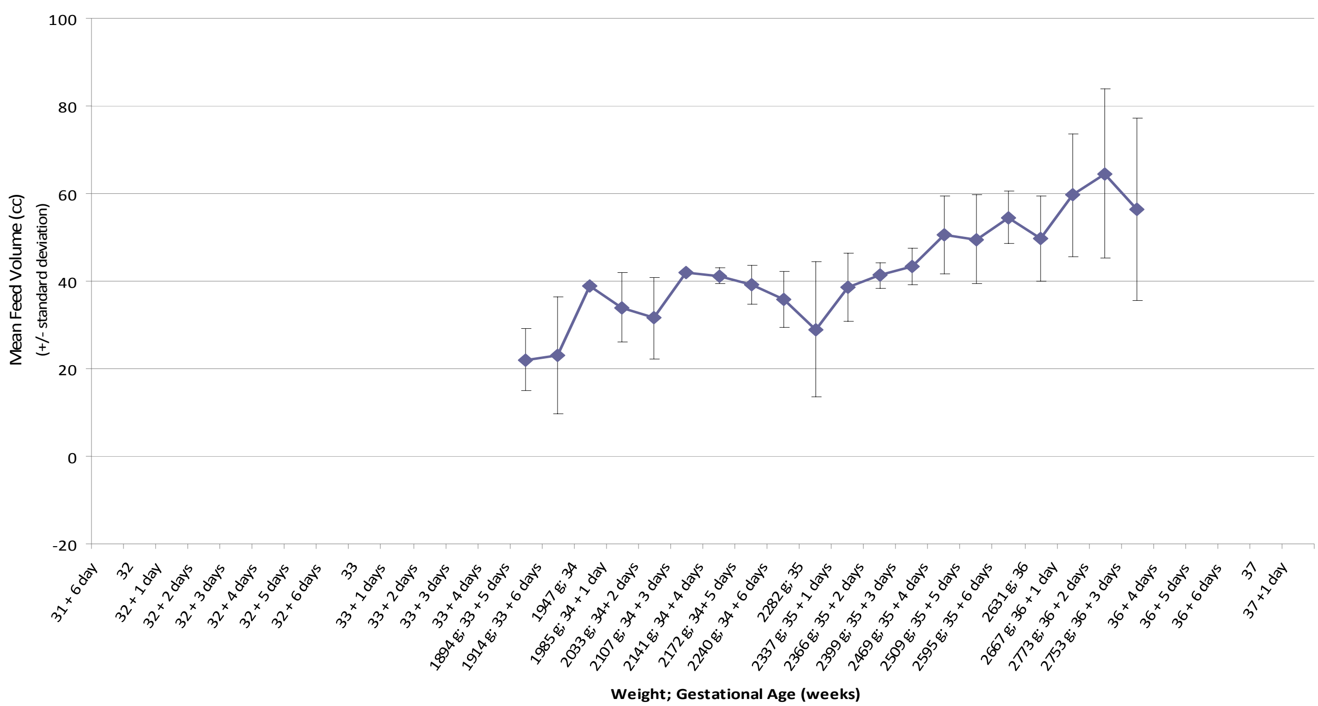
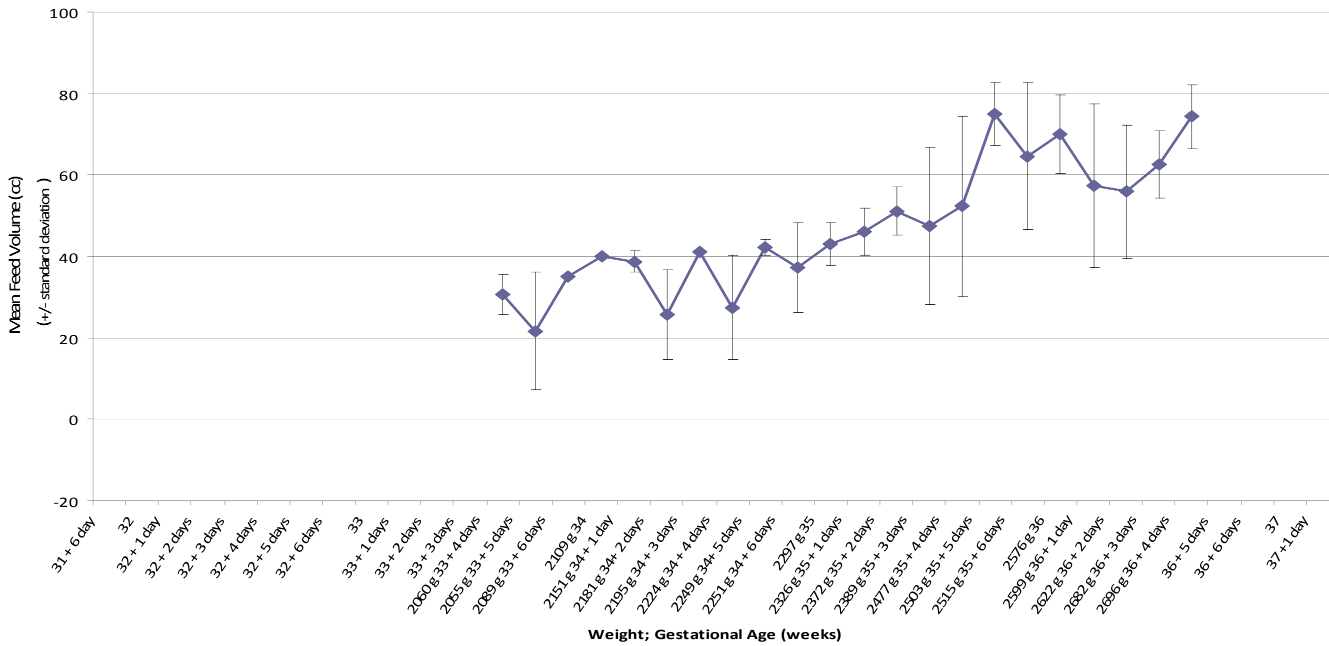


Figure 6. Intermittent group infant - mean feed size by gestational age



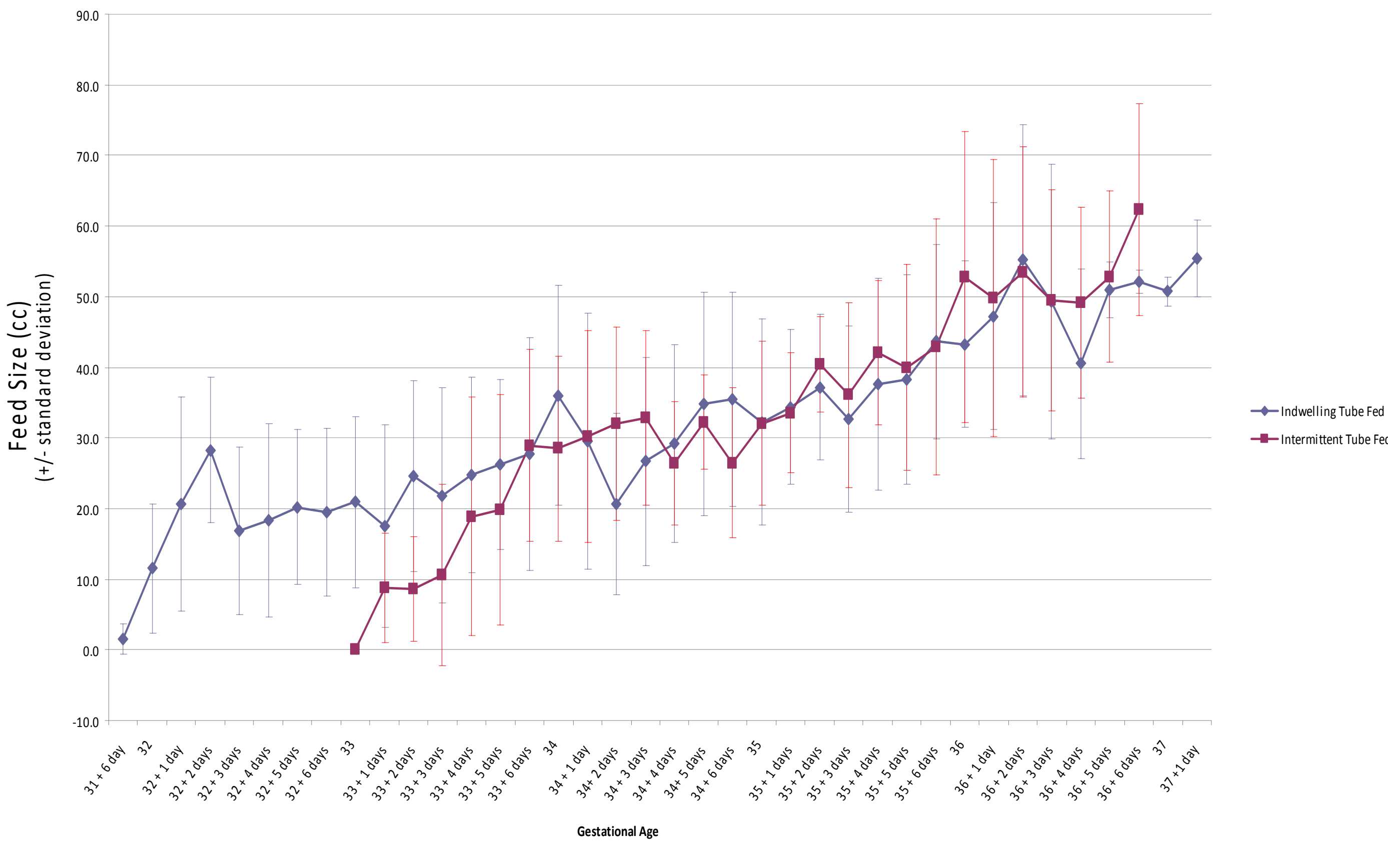
Furthermore, as illustrated, the size of the average feeding for the day increases for a few days (with much variability expressed during the day) and then it decreases for a day, before continuing to increase again over the next few days. The inconsistent progress can be described as 'taking two steps forward and one step backwards'. Of the eleven participants' charts that were recorded with detailed daily suckled volumes, all of them displayed this variable suckling pattern over the course of one day with a backward stepping pattern re-occurring over a few days.

There is one more note worthy observation about individual suckled volumes that raises some questions. Infants in both groups have one or two days of recorded data showing that two or three feeds were offered to an infant in one day and the infant was able to feed the full required oral volume; however, no other feeds were offered to that infant during that day. It is not known if this is a reflection of a nursing decision or if it is a lack of feeding cues from the infant. On other days when the infant bottled two or three full feeds and was offered more opportunities to bottle, the feeds had a smaller volume. It is not known if feeding transition could be hastened if more feeding opportunities were offered or if more feeding opportunities would tire the infant and slow the feeding progress. More research is needed regarding optimum feeding frequency and infant cues.

The next figure (Figure 7) depicts the pooled mean feed size for the intermittent and indwelling groups. The figure also shows how much volume an infant in this pilot study could be expected to feed at a specific gestational age. For example, an infant at 33+6 weeks GA could be expected to take about 28cc at a feeding with a normal range of approx 11cc – 43cc at least once during the day if the infant has had at least one week of feeding practice. Infants in both groups began by taking small volumes orally. Even though the intermittent group began feeding at a later gestational age, they also began the feeding transition period by taking small volumes, and it took them about one week to catch-up to the feed sizes the indwelling group was taking. The expectation that infants at an older gestational age would begin feedings by taking larger volumes was not reflected here. This finding supports Medoff-Copper et al.'s, (2002) assertions that feeding improves with practice and experience shapes feeding development.

Another observation to note in Figure 7 is that infants in both groups are equally capable of taking a large volume at one feed. The type of tube feeding method did not impact that aspect of feeding in this study. Although the indwelling group can take large volumes at a single feeding the ability, desire or opportunity to sustain that volume lags over the course of a day as seen in Figure 10. The intermittent group was able to maintain that volume as reflected in the slightly higher total fluid intake as measured in cc/kg/day. The total fluid intake (TFI) measured in cc/kg/day will be compared in the next section and provides a view of the feeding pattern on a larger scale.

Figure 7. Mean feed size (cc) - Feeds pooled by group



Feeding Patterns Measured in Total Fluid Intake

Figures 8 and 9 look at the larger-scale feeding pattern and measure the TFI suckled in a day (cc/kg/day). The patterns shown in figures 8 and 9 are from the same infants shown in Figures 5 and 6 and resemble the feeding patters of the other infants in this study to some degree. The total suckled cc/kg/day seen here forms the familiar pattern with peaks and valleys, suggesting that the pattern is incremental with a setback which is similar to the patterns seen in the mean feed size suckled in one day of the infants shown in figures 5 and 6. Over one day the variability of the individual feed averages out and does not impact the TFI. However, some days the variability of the feed size takes its toll on the TFI suckled, resulting in the setbacks seen in the feeding progression. Therefore a small volume suckled at one feed is not significant unless the volumes are consistently small. The setback in the feeding progression cannot be explained at this time however possible reasons may be attributed to the infant tiring, having a lack of feeding drive, or having the lack of a feeding opportunity. The indwelling group infant shown in Figure 8 attained unassisted full oral feedings in 12 days and the intermittent group infant shown in Figure 9 attained unassisted full oral feedings in 11 days and both were discharged at 36+ weeks.

Figure 8. Indwelling infant – TFI by gestational age

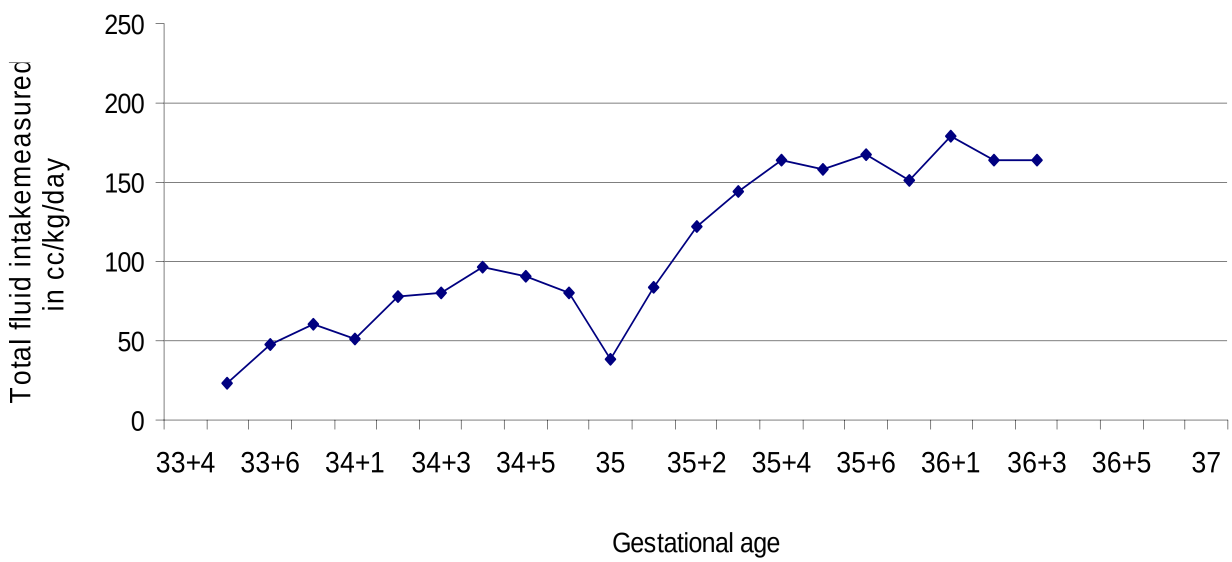


Figure 9. Intermittent infant – TFI by gestational age

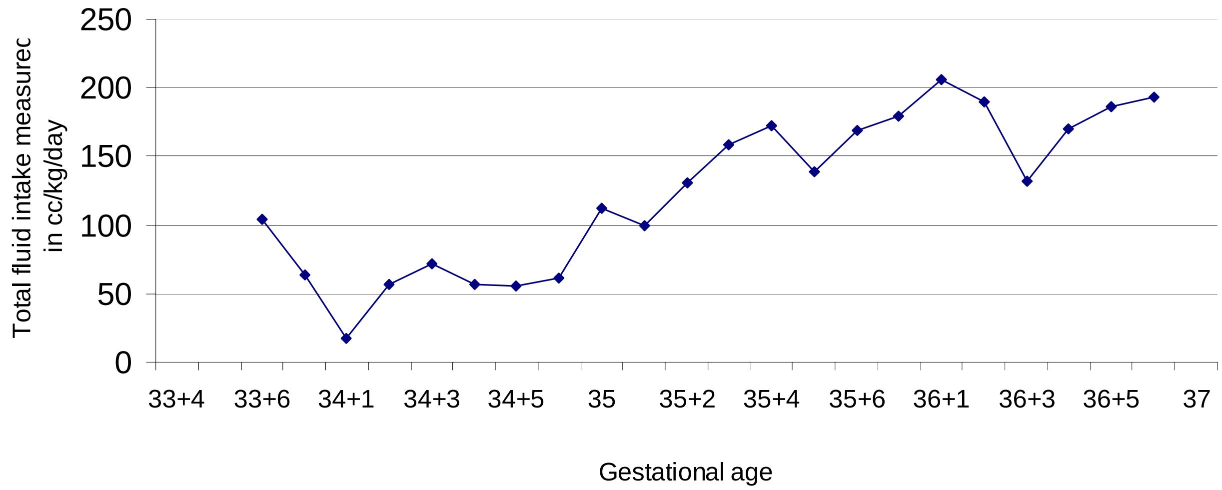


Figure 10. TFI pooled by group

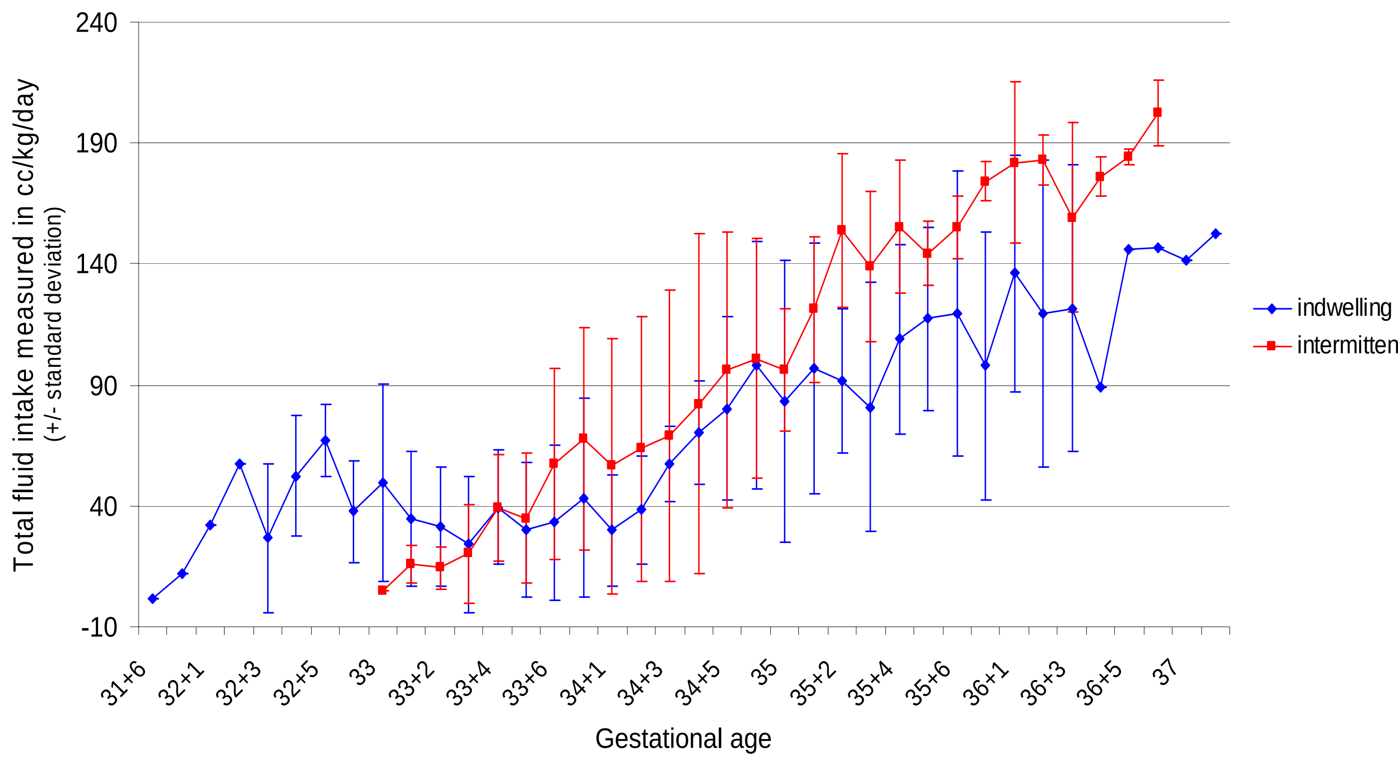


Figure 10 shows mean TFI measured in cc/kg/day and the intersecting bar depicts the standard deviation. One hundred and fifty cc/kg suckled in a day is usually sufficient to support growth and was used as the goal volume to be suckled in one day. The two feeding groups follow each other till about 35 weeks gestation and then the intermittent group surges ahead at 35^{+2} weeks GA. By 35^{+4} weeks GA the indwelling group discharged two infants and the intermittent group had discharged three infants. This surge can be explained to some degree. All infants in the intermittent group no longer required tube feeding and were good feeders at this point but could not be discharged because they needed to gain weigh and/or stop having ABDs. The good feeders in the indwelling group have also been discharged and the poorer feeders of the group still required tube feeding. Even though this surge can be partly explained it does not negate the fact that some infants in the indwelling group had longer transitioning times and were not able to maintain adequate volume intake. The main difference between the two groups that stands out, although it was not statically significant was the slightly fewer feeds taken per day by infants in the indwelling group and the ability of the intermittent group to consistently maintain larger suckled volumes over the course of the day leading to higher daily TFIs.

Conclusion

The description of premature infant feeding patterns was an unintentional outcome of this pilot study. There is much to be learned about premature infant feeding and preterm feeding patterns. Although the description of feeding patterns is likely not new knowledge to any observant neonatal nurse or neonatologist, it provides evidence to validate those clinical observations. Preterm feeding pattern knowledge has implications for future feeding study design. For example if a feeding aid is being evaluated, sufficient evaluation time would be required to determine if an effect was valid or a reflection of a typical feeding pattern. Premature infant feeding data may also be utilized to explore the use of feeding pattern data in predicting feeding difficulties, or developed as a measurement aid to evaluate new feeding methods. In the clinical setting, feeding pattern knowledge provides realistic feeding expectations for the care giver, has implications for feeding assessments and the development of feeding plans.

APPENDIX F

Feeding History

Table 9. Feeding history of the second infant disqualified from the intermittent group

						Study start	Last TF	No TF required
GA	33^{+2}	33^{+3}	33^{+4}	33^{+5}	33^{+6}	34	34^{+1}	34^{+2}
Suckled Volume in cc	2 with NG	4 with NG	0 with NG	36 with NG	8,11 with NG	5,36 (with NG) 8,26 (no NG)	20,36,38 38,38,38 (all no NG)	38,38,38 38,43,38 40,38

GA – gestational age NG – indwelling nasogastric tube TF – tube feed