# HYPERTONIC LOWER EXTREMITIES IN INFANTS: CORRELATION TO MOTOR FUNCTION SCORES AT THIRTEEN MONTHS OF AGE

by

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## This manuscript has been read and accepted by the Graduate Faculty in Nursing in satisfaction of the dissertation requirement for the degree of Doctor of Philosophy.

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#### Abstract

#### HYPERTONIC LOWER EXTREMITIES IN INFANTS:

#### CORRELATION TO MOTOR FUNCTION SCORES

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by

#### Susan Jean Brillhart

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Exploring a large data set, hypertonicity of the lower extremities has been incidentally identified as occurring in one out of every five infants, whether term or preterm. This retrospective, longitudinal, descriptive, quantitative study examined data from 463 functionally and structurally normal infants and identified infants that were considered to be hypertonic at either hospital discharge and at one month of corrected gestational age to determine what their motor capabilities were at 13 months of age. Understanding the correlation will assist in determining whether early intervention is indicated for these infants. Multiple statistical analyses revealed no correlation between hypertonicity as a young infant and the Bayley-II motor function score at 13 months of age. The Roy Adaptation model was used as the conceptual framework of the study and ordinal regression was utilized to analyze the data.

#### **Dedication**

This dissertation would not exist without the village of people that surrounded me and cheered me on.

First, it is dedicated to my parents. I am so very fortunate that the Lord chose me to be theirs! Their unconditional love and constant support was critical throughout this 21 year journey to completion. They encouraged my siblings and I to learn, explore, investigate, and build, and then taught us how to fly so that we could each make a positive impact in the world, surrounding us in prayer each step of the way. My siblings Sandy, Steve, and Sheri, and spouses Glenn and Rennell, have provided home-cooked meals, edited revisions, kept little ones at bay while I slept late, let me borrow their washer, and picked up my share of family responsibilities when I was swamped..... while giving smiles, hugs, and words of encouragement.

Joanne Singleton has been a mentor, friend, sister, teacher, editor, cheerleader, chef, and many other things throughout the last 25+ years. You would not be reading this without her persistent, usually gentle, nudges. Rolf, Jon and Dai have lovingly hugged the tired lump on the couch, refilled my ice cream bowel, and provided lots of laughter.

Martha Whetsell, as my dissertation advisor, became a cherished member of the family, providing love, support, guidance, food, hugs, and so much more. Thank you!

My doctoral sisters – Mary, Marge, Bernadette, Jeanne, Valerie, Danna, Sondra, and Anne. You provided the laughter, the tissues, the perspective, the daily support, and made the journey SO much more meaningful than the goal. Thank you for memories that will last a lifetime, and encouragement that will be treasured forever.

Dr. Judy Gardner and Dr. Bernie Karmel – researchers that became cherished friends.

You trusted me with very important things - your babies and your data. You shared generously

and willingly, showing me how incredible researchers could be. And who knew learning SPSS could produce so much laughter? Thank you for being such wonderful teachers!

My dissertation faculty advisors – Dr. Keville Fredickson, Dr. Donna Nickitas, Dr. Gary Krasilovsky, and Dr. Joanne Singleton. Thank you for your edits, your patience, your encouragement, and your suggestions. They were invaluable. And to all the other Graduate Center Nursing faculty- there is a bit of you in here, as each of you helped mold me into a scholar.

To those special individuals who were so important every day in the way you supported my efforts to complete this degree, whether through boxes of Godiva arriving in the mail, teaching a class for me when I was overwhelmed, or making me laugh when I wanted to cry – every single bit of support was exactly what I needed at that moment. Kathryn, Pat, Dorothy, Edna. Judy, Jessica, Dorothy, Virginie, Kent, Karina, Unice, Michael, and the MANY others – Thank you for being the angel that I needed at that moment. You made the difference every day, and I couldn't have done it without you!

And, to the precious little ones in my life – Sam, Alex, Maddy, Kara, Jon, Dai, Madison, Katie, Tori, Patrick, Hannah, Ryan, Izzy, Emily, and Kallie – you provided laughter, joy, and hugs. Thank you to your parents for letting me borrow you, and the furry things that come with you!!!

I am so very blessed.

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#### **Chapter One**

#### Aim of the Study

Hypertonicity of the lower extremities, also known as tightening of the muscles in the legs, can interfere with normal infant development (Jeng et al., 2008). Rolling over, sitting, standing, and walking are all infant developmental tasks that require the use of legs, and increased muscle tone in the legs may lead to difficulty mastering those skills (Jeng, Yau, Liao, Chen, & Chen, 2000). Infants are frequently assessed for growth in weight and height throughout the first year, as well as growth in their developmental behaviors. The ability of the infant to perform these behaviors, such as smiling, cooing, sitting, and walking is further defined as neurodevelopmental behavior (American Academy of Pediatrics, 2005; Khan et al., 2013).

Neurodevelopmental behaviors are ideally assessed using standard assessment tools, and basic screening is done at health care visits frequently throughout the child's first several years of life and then annually during school-age years (AAP Section on Developmental and Behavioral Pediatrics, 2010). Because developmental experiences during the first years of life may affect future cognitive, social, emotional, and physical development later in life (Halfon, 2009; Liu et al., 2010; Poon, Larosa, Pai, 2010), the current American Academy of Pediatrics (AAP) recommendation for assessing healthy growth and development includes honed assessment skills since excellent assessment is critical for proper evaluation of both normal and abnormal behaviors (AAP, 2006; Radecki, Sand-Loud, O'Conner, Sharp, Olson, 2011). Early identification of developmental deficits is viewed as part of routine screening for pediatric health promotion and disease prevention. If any concerning developmental issues are identified, the child requires further evaluation and early corrective action, so optimal developmental outcomes may be achieved (Blauw-Hospers & Hadders-Algra, 2005; Miller, 2013). A challenge for

today's practitioner is to identify when a neurodevelopmental behavior is not being mastered as expected, instead of waiting until there is an obvious delay (AAP, 2006; Miller, 2013).

Mild abnormal neurodevelopmental behavior can be seen at any time along the spectrum of infant/child development. A classic example of abnormal neurodevelopmental behavior in the otherwise normal child is a child who does not crawl in the normal opposite-hand-and-knee pattern. Instead, children may walk on their knees, scoot along the floor, or execute a crawl where one foot steps while the other leg crawls (Teitelbaum, Teitelbaum, Nye, Fryman & Maurer, 1998; WHO, 2006). The ability to understand the significance of an abnormal finding and the projected trajectory, including the possible influence of that abnormality on other areas of development, is crucial for clinicians that work with children. Abnormal findings, then, possibly merit specialist referrals for further assessment and evaluation (AAP Section on Developmental and Behavioral Pediatrics, 2010; AAP, 2002).

#### **Relevance to Nursing**

One of the comprehensive initiatives of *Healthy People 2020* (U.S. Department of Health and Human Services, 2010) is to optimize health promotion and disease prevention across the lifespan is spelled out in. Nurses are crucial to the successful implementation of the *Healthy People 2020* tenents for early detection, since they are directly involved in health screening and education at the individual, family, and community levels. Early screening, evaluation, and enrollment in early intervention services for children with possible developmental delays is articulated in Maternal, Infant, and Child Health Objective 29 (MICH-29) of *Healthy People 2020*. Consequently, this research study will address the MICH-29 objective for infants with hypertonic lower extremities at hospital discharge and age one month.

Nurses are often the first health care providers an infant/child encounters and are essential in screening, evaluating, and referring for specific developmental or medical therapies (Cervasio, 2010; Spicer, Pinelli, Saigal, Wu, Cunningham, & DiCenso, 2008). A vital step in systematically reducing national health risks and disabilities are ensuring the ability of nurses as well as other health care professionals to effectively identify, assess, and utilize brief reliable screening methods (U.S.D.H.H.S., 2010).

#### **Problem Statement**

When hypertonicity is present in the infant at both hospital discharge and one month of age, does this predict lower extremity hypertonicity at age 13 months?

#### Operational definitions.

For the purpose of this study, the following operational definitions will be used to describe the meaning and application of these terms.

Hypertonicity: Abnormally increased resistance to externally imposed movement about a joint (Jethwa et al., 2010; Task Force on Child Motor Disorders, Sanger, et al, 2003). Level of hypertonicity will be measured by the Rapid Neonatal Neurodevelopmental Assessment (RNNA) rating scale (Gardner, Karmel, Magnano, Norton, & Brown, 1990).

*Normal tone:* Defined by the RNNA score of zero (0).

*Mild/moderate hypertonicity:* Defined by the RNNA score of one (1).

Severe hypertonicity: Defined by the RNNA score of two (2).

Lower extremity: Lower limb or leg.

*Infants:* Children younger than 365 days old.

*Preterm:* Infants born before the end of week 37 of gestation (American College of Obstetricians and Gynecologists/ACOG, 2009).

Post-term: Infants born beginning week 43 of gestation (ACOG, 2009).

*Full-term:* Infants born from week 38 through week 42 of gestation (ACOG, 2009).

Gestational age: Amount of time the child has been developing since conception (ACOG, 2009). Estimated prenatally by menstrual dates and ultrasound, but actually determined by the pediatrician after delivery utilizing the Dubawitz scoring system (Dubawitz, Dubawitz, & Mercuri, 1999).

Corrected age: Age the infant would be if he/she was born at 40 weeks gestation (ACOG, 2009). All measurement points will be stated as corrected age (Bayley, 1993; D'Agostino, 2010). The one month corrected age visit is at 44 week gestational age (40 + 4 = 44), and the 13 month correct age visit is at 96 weeks gestational age (40 + 56 = 96).

Hospital discharge age: The gestational age at which the infant was discharged home from the hospital after birth.

Structurally normal newborn: A baby without obvious physical structural deficits as determined by the pediatric team and has a normal cranial head ultrasound (CHU) of the brain. Cranial head ultrasounds are performed through the anterior fontanelle and allow visualization of the brain structure (Phan, 2010) by the study team, and results are recorded as normal (0) or abnormal (1).

Functionally normal newborn: An infant without obvious physical functional deficits as determined by the pediatric team and has a normal Brainstem Auditory Evoked Response (BAER) test. A BAER test is done with a speaker emitting specified sounds into one ear of the infant while electrodes attached to the scalp with gel are attached to a computer. Then, the

computer program records brain response to the auditory stimulus, and the results are recorded as normal (0) or abnormal (1) (Phan, 2010).

*Motor Function Scores:* Measured and calculated according to the Bayley Scales of Infant Development-II (Bayley-II, Bayley, 1993).

*Early Intervention:* A set of services funded under federal initiative, administered by each state, and available to children who are disabled or at risk for becoming disabled.

#### Assumptions.

The main assumption of this study is that an infant with functional or structural abnormalities may have an underlying cause for deviations on a neurobehavioral assessment.

A second assumption is that in order to achieve an accurate testing result, the corrected gestational age must be properly calculated and used for every measurement.

#### Delimitations.

Neurodevelopmental assessment data exists for a group of 5000+ neonates examined over time by Gardner and Karmel and their research team at the New York State Institute for Basic Research, Department of Infant Development (Karmel, 2010). Nested within the overall data set is data on over 1000 otherwise healthy infants. These are neurologically functionally and structurally normal newborns, as measured by Brainstem Auditory Evoked Response (BAER) tests and cranial head ultrasounds (CHU) that are both within normal limits. Excluded from the study are data from any infant with cranial ultrasounds or BAER tests considered abnormal by protocol, or infants with obvious physical abnormalities.

#### **Conceptual Framework**

According to Roy and Andrews (1999), an individual is a bio-psycho-social being in constant interaction with a changing environment. To cope with this changing environment, an

individual has certain innate and acquired mechanisms that are biological, psychological, and social in origin. Health and illness are considered an inevitable dimension within a person's life and effective coping is considered adaptive. The individual's adaptive mechanisms help them to cope with the changing environment. To cope, according to Roy and Andrews (1999), individuals may change themselves, their environment, or both. Environment is viewed as anything external to the organism or external to any subsystems within a system (Roy & Andrews, 1999).

When Roy (2003) analyzes an individual as an adaptive organism, she further describes four adaptive modes. These modes are theorized to provide observational (assessment) data of the internal functioning of the regulator and cognator mechanisms that transform system inputs into system outputs. The two mechanisms (cognator and regulator) are viewed as the means by which an adaptive organism transforms inputs from its environment into outputs or behaviors. The four ways or adaptive modes expressed by an adaptive system are the following: physiological, self-concept, role function, and interdependence (Roy & Andrews, 1999). Of particular concern for this study is the physiological mode.

The condition of the individual relative to adaptation is called his/her adaptation level.

Adaptation level is determined by the pooled effect of three classes of stimuli, and the organism's responses and outcomes to those stimuli. The three classes of stimuli within the Roy Adaptation Model are the following: the *focal* stimulus, which is an event or situation immediately confronting the person; the *contextual* stimulus, which are all other stimuli thought to immediately surround the event or situation and thought to influence or contribute to the focal stimuli's effects on the organism; and the *residual* stimulus, which includes beliefs, attitudes, experiences, or traits, which are thought to have an effect on the organism's responses to focal

and contextual stimuli (Roy & Andrews, 1999). Adaptation is the ability to change in response to environmental pressures (Roy & Andrews, 1999). The idea of adaptation suggests that all systems have constraints within which they function. Constraints are not to be viewed as negative but rather as the effects of internal and external influences upon an organism or its subsystems.

Within Roy's Model, the idea constraint is found, implicitly, in the theorized effects of contextual and residual stimuli on the adaptive organism. These stimuli influence the organism's response to focal stimuli or the transformation of such stimuli into behaviors. Implicitly, contextual and residual stimuli can be viewed as constraining the organism's responses to focal stimuli as inputs and/or to the transformations of such inputs by either modifying the organism's initial reaction to focal stimuli or by modifying the organism's transformation of an input into an output, or both. Expressing stimuli explicitly as constraints (having the ability to influence or to modify an adaptive organism) expands Roy's original Adaptation Model's perspective of such stimuli but keeps it well within the open systems and the adaptive theoretical framework of the model (Whetsell, 2011).

The primary focal stimulus for this study is hypertonicity of the legs of the babies. The goal of nursing, using the Roy Adaptation Model, is to facilitate an individual's adaptation by the manipulation of one or more of the classes of stimuli in order to modify the organism's coping response (Whetsell, 2011). Since the immediate focal stimuli of leg hypertonicity cannot be removed, a way of reducing hypertonicity, and thereby enhancing adaptation to normal walking, may be through the identification of the focal stimuli and early treatment intervention. The Roy Adaptation Model provides the theoretical underpinnings for this empirical study. The effects of final identification of one or all three classes of stimuli in order to enhance adaptation are what

guide this study.

#### Rationale

Infant neurobehaviorist Judith Gardner and neurobiological specialist Bernard Karmel have led a team that has completed neurodevelopment assessments on more than 5000 babies over the past 25 years (Karmel & Gardner, 2010; Gardner et al, 2006; Gardner, Karmel & Freedland, 2001; Gardner, Karmel, Magnano, Norton, & Brown, 1990). Gardner used a unique screening tool, the Rapid Neonatal Neurodevelopmental Assessment (RNNA), to assess infants at hospital discharge and at 44 weeks post-conceptual age. Lasting less than ten minutes, the screener elicits reflexive movements such as stepping, and purposeful movements, such as turning the head toward sound. The RNNA is a brief but thorough test when administered by a skilled clinician (Gardner, Karmel, Magnano, Norton, & Brown, 1990). Infants found to have deficiencies on their assessment were referred to the Early Intervention program coordinator for further evaluation and then carefully monitored. Early Intervention is one of the services available at the study site, so children can be easily evaluated, served, and monitored if needs are identified during routine assessments by the study team.

During RNNA testing of over 5000 babies, an incidental finding of hypertonicity was discovered. The cumulative data revealed that approximately 20% of otherwise normal infants have some level of hypertonicity, or muscle tightness, in the lower extremities when discharged home after birth (Gardner, et al, 2006). Neurological development is in a cephalocaudal (head-to-toe) and proximal distal (core-to-farthest point) direction (Hockenberry & Wilson, 2013). It is anticipated that an infant's legs will neurodevelopmentally mature later than the arms or trunk. The finding of hypertonicity is not surprising for preterm infants because of potential for incomplete neurological maturation, secondary to premature birth (Bucher, Killer, Ochsner,

Vaihinger & Fauchere, 2002). However, hypertonicity is not noted in the literature for otherwise normal term infants.

Upon preliminary analysis of the overall RNNA data by Karmel & Gardner (2010), only one test item had a consistently high rate of abnormal findings for both term and preterm infants; hypertonicity of the lower extremities. The Rapid Neonatal Neurodevelopmental Assessment (RNNA) (Gardner, Karmel & Freedland, 2001) consists of 30 individually scored items. For 29 of 30 individual items, only 8% of all infants tested scored in the abnormal range for those items. The hypertonicity of the lower extremities item had 20% of the babies scoring in the abnormal range, an abnormality level 150% higher than any other individual test item, a level that demands further investigation once discovered.

In other words, this finding of hypertonicity of the lower extremities is a data outlier where 92% of the babies scored in the normal range on all indicators on the RNNA except for hypertonicity of the lower extremities. Therefore, hypertonicity of the legs appears to be very different from every other individual neurodevelopmental task item. Instead of at least 92% of infants having a normal score on this item, only 80% scored normally (Karmel & Gardner, 2010). A decrease from a 92% normal rate on all other items to the 80% normal rate on hypertonicity of the legs means one out of five babies has hypertonicity of the lower extremities, while fewer than one in ten babies had any other neurodevelopmental problem identified by the RNNA. Hypertonicity of the lower extremities was identified more than twice as often as any other neurodevelopmental finding. This difference is what merited study of the reported longitudinal results.

#### **Research Question**

What is the correlation between a set of two predictors (age and hypertonicity of lower extremities) and the outcome of Bayley-II Motor Function Scores at 13 months of age?

#### **Need for Study**

Objectives for *Healthy People 2020* specifically address the need for early screening, evaluation, and enrollment in early intervention services for children with possible developmental delays (MICH-29, U.S.D.H.H.S., 2010). This study addresses the Maternal Infant Child Health (MICH) objective number 29 for the population of infants with hypertonic lower extremities at age one month. The analysis of data also attempts to answer the following Healthy People 2020 related question: Is the finding of persistent hypertonicity of the lower extremities in the otherwise normal one-month-old an early indicator of lower extremity motor function delay for which early intervention is indicated? A brief, effective screening test performed by an experienced infant nurse or other experienced infant health professional may guide future need for additional screening or testing for that infant. Most importantly, the developmental and economic significance of the finding of hypertonicity may be meaningful, and the retrospective exploration of a large set of nested longitudinal data may provide additional guidelines for pediatric clinicians (including pediatric nurses, pediatricians, PNP's, pediatric physical therapists, infant development specialists, and others), in their practice when they encounter this finding.

#### **Chapter Two**

#### **Review of the Literature**

Abnormal tone is a key component of many chronic motor disorders of childhood (Jethwa et al., 2010; Sanger, et al, 2003). An increase in tone is called hypertonia, and the Task Force on Childhood Motor Disorders specifically recognized "mechanisms that lead to increased tone may also contribute to poor voluntary motor performance" (Sanger, p. e91). The literature concerning hypertonia and hypertonicity in infancy has multiple studies of hypertonia connected to obvious neurological deficits and cerebral palsy (Elenjickal, Thomas, Sushamabai & Ahamed, 2009; Liu et al, 2010; Pedersen, Sommerfelt & Markestad, 2000; Smith & Kurian, 2012), maternal cocaine use (Belcher, et al., 1999; Chiriboga et al., 1995; Delaney-Black, et al, 1996; Dempsey, et al., 2000, Karmel, Gardner & Freeland, 1998), and specific toxins (Balamtekin, Gulgun, Sarici, Unay, & Dundaroz, 2010; Singer et al., 2012; Wagner & Orwick, 1994). Most of the related studies were conducted by researchers in the fields of infant development, physical therapy, occupational therapy and rehabilitative medicine, with very few conducted within the field of nursing, and an extensive review of the literature revealed very few studies of hypertonicity in the otherwise normal term or preterm infant.

#### **Hypertonicity**

The studies of infant neurodevelopment that specifically assessed for hypertonicity were generally conducted in the 1990's and were related to assessing the effects of intrauterine cocaine exposure, as maternal crack cocaine use had become a significant public health problem (Dempsey, et al., 2000). Findings of increased jitteryness and hypertonicity (Chiriboga, et al., 1995; Delaney-Black, et al., 1996; Karmel, Gardner & Freedland, 1998), increased leg tone (Belcher, et al., 1999), and delayed acquisition of walking (Belcher, et al., 1999) were common in

this population. Dempsey, et al. (2000) also examined cocaine-exposed infants for nicotine levels and found that tone abnormalities in these babies were dose-dependent on nicotine levels.

There was a decrease in the specific evaluation of hypertonia in full-term infants by researchers after the number of cocaine exposures began to decrease and the effects of intrauterine cocaine exposure were more clearly understood. In the last decade, studies of full-term infants are usually related to disease-based case studies rather than large longitudinal studies. Atypical trisomy 21 presentation (Keppler-Noreuil, Welch, Major, Qiau, Jordan & Patil, 2002), buprenorphine withdrawl syndrome (Kayemba-Kay's, & Laclyde, 2003), neurologic events in infants undergoing cardiac surgery (Chock, Reddy, Bernstein & Madan, 2006), presentation of mitochondrial disorders (Moran, M. M., Allen, Treacy & King, 2011; Tulinius & Oldfors, 2011) and the use of baclofen for hypertonia (Moran, L. R., Cincotta, Krishnamoorthy, & Insoft, 2005; Schulz & Mathew, 2012) are the topics of some of those studies. These studies are helpful in understanding the hypertonicity in children with these diseases, but are not generalizable to normal infants, further supporting the need for large longitudinal studies.

#### **Motor Evaluation: Walking**

Motor evaluation studies tend to focus on the very premature infant rather than the otherwise healthy term and preterm infant. Attainment of independent walking has been shown to be influenced by, and also not influenced by, several variables, especially in the preterm infant. A low gestational age at birth does affect walking age, but intrauterine growth retardation (de Groot, de Groot & Hopkins, 1997; Geva, Leitner, & Harel, 2012; Johnson, Goddard, & Ashurst, 1990; Pedersen, Sommerfelt, & Markestad, 2000; Peter, Vainder, & Livshits, 1999), gender, and socioeconomic status have no effect on age of walking for preterm infants (Cioni, et al., 1993; Kimura-Ohba et al., 2011; Largo, et al., 1985, Restiffe & Gherpelli, 2012).

Interestingly, black preterm infants generally walk earlier than white preterm infants (Allen & Alexander, 1990).

Marin, et al. (2009) examined 694 very-low-birth-weight (<1500 g) preterm infants who had normal motor development at age two years. The preterm infants sat unsupported and walked independently later than their full-term peers, with a mean walking independent age of 13.6 months instead of 12.1 months (p=<0.0001). Jeng, Yau, Liao, Chen & Chen (2000) also reviewed walking attainment in very low birth weight (VLBW) infants and found that the median age of walking was 14 months, with significant risk factors for delay, including intraventricular hemorrhage, neonatal respiratory distress, and retinopathy of prematurity. Infants with these risk factors would not meet the criteria for inclusion in this current study, and were not included.

Jeng, et al (2008) then removed health variables and studied 58 healthy term and preterm infants to assess for independent walking attainment. Mean preterm gestational age was 32.8 weeks and full mean age was 38.8 weeks. Twenty four percent of preterm babies were walking by 12 months corrected age, while 48% of term babies were walking by the same age. Gestational age was significant (p= 0.03) in attainment of walking, with preterm infants median age 12.5 months (range 9.8-16.5 months) and term infants median age 12 months (range 10-14.5 months), confirming that gestational age effects walking age. However, an age of 13 months was chosen for assessment for this study to accommodate this effect.

Restiffe & Gherpelli (2012) examined 101 low-risk preterm infants and 52 healthy full-term infants, using the Alberta Infant Motor Scale (AIMS). The criteria for inclusion were almost identical to the study this author conducted, with thorough screenings and exclusion of any infants with potential for neurological deficits. The preterm infant walked a mean of 13 days

later (381.6 days) than the full-term infants (368.6 days), a difference that is significant (95%CI-1.268-0.162; p<0.05) but not critical, as the 13 month assessment in this study was done around day 396. Therefore, as in Jeng et al. (2008) above, the majority of both groups of infants would be walking.

The World Health Organization (WHO, 2006) conducted a Multicenter Growth Reference Study, gathering longitudinal data from 816 infants in five different parts of the world. The Motor Development Study portion of the data revealed the mean timeframe for walking alone is 12.1 months, with 75% of children achieving this milestone by 13.1 months. Therefore, evaluating data from an assessment at 13 months of age is appropriate because 75% of children are expected to have reached the milestone of walking at this time. This 13 month evaluation falls at a sensitive time and may discriminate easily between those infants with motor delays and those without.

#### **Cranial Ultrasound Results and Neurodevelopment**

Neurodevelopmental outcomes of the very small premature infant are still being explored because medical advancements continue to increase their survival rate. Patra, Wilson-Costello, Taylor, Mercuri-Minich & Hack (2006) examined 362 infants with birth weights under 1000 grams using a classic ultrasound machine to visualize the brain through the open anterior fontanel, and compared those with normal cranial ultrasounds to those with findings of low-grade (grade I-II) intraventricular hemorrhage (IVH) on cranial ultrasound. A Bayley Scales of Infant Development II (Bayley-II) test was conducted at 20 months corrected age to assess for neurodevelopmental differences. Even after adjusting for confounding factors, infants with grade I-II IVH had significantly poorer neurodevelopmental outcomes than those with normal cranial ultrasounds.

Pinto-Martin, et al. (1995) examined 1105 infants born under 2 kg and compared those without intraventricular hemorrhage (IVH) on cranial ultrasound to those with low-grade (grade I-II) IVH. At age 2 years, disabling cerebral palsy was found in 24.8% of infants with low-grade IVH, compared to 3.8% of those without IVH. Jeng, Yau, Liao, Chen & Chen (2000) found IVH to be a significant (p=<0.001) risk factor for late walking in the VLBW infant. These studies reinforce the delimitation of normal cranial head ultrasound for study subjects so that scores will not be skewed by babies already identified as high risk. Babies with abnormal cranial head ultrasounds, as determined by the Infant Development study team, were excluded from this study.

#### **Brainstem Auditory Evoked Response (BAER) Testing**

Analysis of electrical brain activity in the newborn to assist with evaluation of functional central nervous system (CNS) integrity via brainstem auditory evoked response (BAER) testing is a non-invasive, relatively rapid, and inexpensive method to evaluate CNS functioning at the bedside (Karmel, Gardner, Zappulla, Magnano, & Brown, 1988). Karmel, Gardner, Kapadia & Harin (1998) found that infants with abnormal BAER test results were at high risk for significant motor and cognitive delays, and need to be carefully monitored. Karmel, Gardner, Lennon, et al. (2002) utilized a combination of neurodevelopmental assessments, cranial head ultrasounds, and BAER testing to identify children at greatest risk for delay.

BAER testing in neonates is done on a contentedly sleeping baby, preferably after feeding. Three round conductive surface electrodes are placed, respectively, at the middle forehead, the ipsilateral earlobe, and the contra-lateral earlobe. (Jiang, Wu, & Wilkinson, 2009). A small headset earphone is attached over the infant's ear, and a series of clicking sounds is generated by the computer into the headset. The electrodes measure conduction of the auditory

pathways between the cochlea nerve and the primary auditory cortex of the brain. Abnormal latency or amplitude of the received waveforms may indicate incomplete neurological connections in an infant. Abnormal results excluded the neonate from the study.

#### **Correcting for Gestational Age**

The process of correcting for gestational age when conducting a developmental assessment is a common one, and gives the assessor a true picture of the infant's ability. Because the corrected age is the age the infant would be if he/she was born at 40 weeks gestation, each infant was neurologically equal at his/her 44 week/1month and 96 week/13 month assessments for this study. Flieshman, Oinuma, & Clark (2010) outline how babies that are born at "term" (37-41 weeks gestation) are not all alike, and "early term" (37-38 weeks gestation) babies are at significantly higher for infant mortality and neonatal morbidity risk than 40 week gestation babies. Mally, Bailey, & Hendricks-Munoz (2010) outline many of the same issues when they discuss the late preterm infant, detailing how this infant who appears reasonably mature can be at risk if not watched closely. Clearly, babies born earlier and at risk should not be neurodevelopmentally assessed with the same expectations as gestationally older newborns, and standard infant assessment tools require age correction (Pin, Eldridge, & Galea, 2010).

El-Dib, Massaro, Glass, & Aly (2012) describe the effectiveness of the Neonatal Intensive Care Unit Network Neurobehavioral Scale (NNNS) for predicting mental (P=0.011) and psychomotor (P= 0.002) delays on future assessments when the NNNS was done at a corrected age of 40 weeks, but the scale is only predictive if corrected age is used. The Bayley Scales of Infant development also require that age be corrected, and this was a rule for each version (Bayley-I, 1969; Bayley-II, 1993; Bayley-III, 2006).

D'Agostino et al. (2011) examined the provider usage of corrected age during health supervision visits for premature infants at a major children's teaching hospital, and found that developmental assessments and recommendations were often (74%) made based on chronological age, rather than corrected age. When causation was reviewed, the electronic medical record was found to calculate based on chronological age, and not have a provision for corrected age. Therefore, providers using electronic medical records are cautioned to consistently manually correct age for assessments, growth, nutritional counseling, and developmental referrals.

Restiffe & Gherpelli (2006) studied 43 low-risk preterm infants to evaluate the need for correction of gestational age during gross motor assessments and found an overlap of gross motor skill score confidence intervals between corrected and chronological ages at 13 months/96 weeks. This suggests that correction for prematurity is usually no longer necessary for low-risk premature infants after 13 months/96 weeks. However, correction should be made in the first year of life, and electronic medical records, especially at children's hospitals, should have a provision for corrected age.

This study used 13 months/96 weeks as the follow-up point because of the overlap in confidence intervals between corrected and chronological ages. Thirteen months is when the differences between the term and low-risk preterm infant dissolve and is an optimal time for assessment, as the infants have shown their ability to adapt and "catch up." However, to ensure consistency, all infants had corrected gestational age used at every assessment point, as required by the Rapid Neonatal Neurobehavioral Assessment (RNNA), and the Bayley Scales of Infant Development-II (Bayley-II, 1993).

#### Roy's Adaptation Model: Physiologic Research

Adaptation is a daily event in the life of an infant, as they adapt from intrauterine to extrauterine life, adapt to their environment, and then adapt so they can become mobile and communicate and explore the world around them. Early research examining physiologic results of adaptation was common for the infant population. Cheng & Williams (1989) explored oxygenation rates during chest physiotherapy of very-low-birth-weight infants, Shogan & Schumann (1993) examined the effect of environmental lighting on the oxygen saturations level of preterm infants in the NICU, and Garcia & White-Traut (1993) ascertained the preterm infants' responses to taste/smell and tactile stimulation during apneic episodes. Utilizing the Roy Adaptation Model framework (Roy & Andrews, 1999) to explore physiologic adaptation for the infant has been a consistent application of this theoretical framework. Touch and the preterm infant was studied from the viewpoint of adaptation by Kitchin and Huthinson (1996), who qualitatively explored touch during resuscitation of the preterm infant. Harrison, Leeper, and Yoon (1990) reviewed the effects of early parental touch on the heart rates and oxygen saturation levels of preterm infants, with results that varied from infant to infant. Velasco-Whetsall, Evans, and Wang (1992) continued with touch, exploring containment post-suctioning for the neonate. These early physiological mode studies paved the way for continued research with infants utilizing the Roy Adaptation Model as a framework, and this study will add to the body of knowledge.

Disciplines that are concerned with credibility in the application of evidence based practice honor their theories, demand a scientifically rigorous research methodology that it is directed by their own theoretical models so that new findings can be applied according to the scientific evidence, and can make a distinction between describing and explaining. Theory

demands explanation of what is being described. It is impossible to test theory based on description. Searching for an explanation provides the basis for an experiment which, in turn, gives validity to the research, which is the key to for scientific theories. Reviewing the nursing literature, it is obvious as the majority of the research is developed, nursing doesn't try to explain phenomena. Nursing is satisfied to collect descriptions of behavior. This study will begin describing the behavior of hypertonicity as young infants, but then continue to explain whether that hypertonicity significantly affects motor function scores as these young toddlers are beginning to walk, and provide thoughts for future research.

#### **Chapter Three**

#### Methodology

#### **Research Design**

A nested, retrospective, longitudinal, descriptive design was used to explore the effects of hypertonicity in early infancy on the acquisition of gross motor milestones at 13 months of age, as measured by the Bayley-II Motor Function Score. All data was previously gathered by the Infant Development Research (IDR) Team (Karmel & Gardner, 2010) and was shared with this researcher after de-identification so that previously unexplored data could be examined and assessed. Bayley-II Motor Function Score results may be predicted by Rapid Neonatal Neurodevelopmental Assessment (RNNA) lower extremity hypertonicity results. To answer this question, the correlations were explored to determine if they are significantly related to each other. The linear regression model for this study was as follows:

Model Variables

1 age

2 hypertonicity

Regression was used for exploration and prediction. It is a flexible technique that allows the use of categorical and continuous variables, and is one of the most powerful techniques.

$$R^2 = 1 - (1 - R^2) \frac{n-1}{n-k-1}$$

#### Rationale.

Mining of data nested within a single data set was used to analyze existing data from a large number of infants assessed by a single research team over time. This data was used to answer research questions not currently addressed in the literature in order to guide care of infants. This single data set was used because of the high level of internal validity. The internal

validity is the result of over 99% of the newborn assessments being performed by a single researcher. With this single-researcher data gathering, inter-rater reliability is very high (Gardner, et al, 2006).

#### **Population and Sample**

#### Sampling technique.

Sampling was done retrospectively, with only data from functionally and structurally normal infants, extracted from the larger set of data gathered by the Infant Development Research team. Within this nested data set, the longitudinal data of infants who were assessed at 44 weeks using the Rapid Neonatal Neurodevelopmental Assessment (RNNA) was analyzed. As per Nunnelly & Bernstein (1994), ten subjects per predictor are needed, so this sample would require 20 subjects. Sample size was obtained using Cohen's (1987) formula:

$$N = \frac{L(1-R^2)}{R^2} + U + I$$

where N = total sample size

L= effect size index

U = number of independent variables.

L is obtained from a standard power table and is defined by Cohen (1987) as a function of power and number of independent variables at a given level of alpha. Power = 0.80, Alpha = 0.05. The desired effect was derived from the following standard (Munro, 2005)

Small effect  $R^2 = 0.02$ 

Moderate effect  $R^2 = 0.13$ 

Large effect  $R^2 = 0.30$ 

With two independent variables a sample size of 463, Alpha = .05, and effect = 0.30, the power will be .999. This is clearly strong enough to analyze data.

#### **Description of subjects.**

Healthy neonates from 24 to 42 weeks gestational age were included in the primary datagathering study conducted by the Infant Development Research team. They were evaluated with the RNNA at both hospital discharge and at 44 weeks gestational age. Healthy infants assessed by the RNNA at 44 weeks/1 month were the subjects of this study. Preterm infants admitted to the Neonatal Intensive Care Unit were first evaluated with the RNNA while in the hospital, with follow-up RNNA evaluations conducted at the research center at 44 weeks/1month of age. For term infants, all evaluations, including BAER and cranial ultrasound, were conducted post discharge at the research center. The New York State Institute for Basic Research in Developmental Disabilities (IBR) Infant Development Follow-up Program Neurobehavioral Laboratory is supervised by Dr. Judith Gardner and located within five miles of the hospital NICU. The IBR lab is easily reached by car and a car service is provided for those who need assistance with transportation to the research site.

#### Source of subjects.

The data for this study was a sample of 44 week old newborns drawn from a larger data set. The primary data set was a convenience sample gathered by Karmel & Gardener (2010) over multiple years for longitudinal research programs.

#### **Selection process.**

All infants born at the chosen urban hospitals were eligible for inclusion into the primary data set, with special efforts made to recruit 100% of the infants admitted to the Neonatal ICU. The data set for this study was limited to 44 week newborns who were structurally and functionally normal as determined by Karmel & Gardener's (2010) Infant Development Research team.

#### Number of subjects.

The number of subjects available for this study was based on the inclusion criteria for selection of data for study from the primary data set. The data from 1145 infants meet the initial criteria and were evaluated for inclusion in this study.

#### Criteria and rationale.

This study retrospectively examined previously gathered infant assessment data nested within a larger data set. Parameters for sampling and inclusion in the primary data set were determined by the previous research team. Therefore, the subjects available for the secondary analysis were constrained by available data. However, 1145 subjects met structural and functional criteria for inclusion in this secondary analysis and their data provided a reasonably sized initial sample set.

#### **Instruments**

Two instruments were used to assess the study subjects. The *Rapid Neonatal Neurodevelopmental Assessment* (RNNA) (Gardner, Karmel &Freedland, 2001) was performed at both hospital discharge and 44 weeks gestational age (also known as 1 month corrected age). At 96 weeks gestational age, also known as 13 months corrected age, the *Bayley Scales of Infant Development* (Second Edition) (Bayley-II, Bayley, 1993) was used to assess motor skills. Each tool will be addressed in this section.

#### Bayley scales of infant development second edition (Bayley-II).

To neurodevelopmentally assess the motor skills of 13-month-olds, the *Bayley Scales of Infant Development (Second Edition)* (Bayley-II, Bayley, 1993) was used. The Bayley-II is a standardized, norm-referenced, individually administered developmental assessment for children from ages one to 42 months old and is a revision of the original Bayley (Bayley-I), first

published by Bayley in 1969. There is another recently released version of the Bayley test (Bayley-III, Bayley, 2006), but the Bayley-II was used to assess all the infants whose data was analyzed, and the researchers decided to continue utilizing the Bayley-III for consistency. Also, there are published cautionary reports that the Bayley-III is underestimating developmental delay in the first several years of life, a critical time for identification of delay (Anderson et al., 2010; Msall, 2010), so transition to the Bayley-III will be deferred. Because the larger data set included infants evaluated during a 25 year span, data from infants assessed with the original Bayley (Bayley-I, 1969) instead of Bayley-II (1993) was removed during data cleaning, after IRB approval was received.

The Bayley-II was chosen by the Infant Development researchers originally gathering data for depth of data gathered and wide acceptance as a standard assessment (Karmel, 2010). The Bayley-I and Bayley-II have long been considered the criterion standard for the developmental assessment of infants and toddlers (Johnson, et al., 2004) and are described as the most widely used measure of infant cognitive and motor development (Cherny, et al., 1994). The 13 month/ 96 week visit consists of 16 items, beginning with "stands alone," and has 12 lower-body gross-motor-skill items that are conducted while standing, including walking, standing on one foot, walking up stairs, and walking backward. There are also four upper-body motor skills that are conducted with the child seated, including grasping a pencil and holding a piece of paper while drawing.

The Bayley-II is scored on a credit (C) or no credit (NC) scale, where the child receives credit for accomplishing a task. Other options for evaluation are refused (RF), repeat (RPT), and not attempted (0).

The scales were normed on 1700 children total, 100 for each of the 17 age ranges contained within the Bayley-II. Each set of 100 children contained 50 boys and 50 girls. The sample was reflective of the 1988 U.S. Census data in terms of gender, race, ethnicity, educational background of parents, and geographical distribution. There is no data on urban or rural residence, however, and no children classified as disabled were included in the norm sample. The Bayley-II consists of the Motor Scale, Mental Scale, and Behavioral Rating Scale. Of these three scales, only the Motor Scale results will be analyzed for this study, although Mental Score averages will be listed to report full demographic results. The Motor Scale is administered individually over a period of five to 10 minutes for the 13-month-old child, and each item is scored as credit/no credit. This scale has a total of 16 possible individual items for that age child to receive credit for achieving, and assesses both fine motor and gross motor skills. Some of the 16 items may not be completed if the child has not met the individual milestone. A child who is not walking alone will not be able to be evaluated for walking alone with good coordination, walking backwards, or walking sideways, decreasing the possible credited items from 16 to 13. At 13 months/96 weeks, there is a total possible cumulative lifetime score of 76 items achieved. Sixty seven credited items is the norm total raw score, so the average child of this age is unable to accomplish a total of 9 items at this time.

Internal consistency reliability correlations ranged from .78 to .93, and the interscorer reliability correlation was .96. Test-retest reliability was examined at four ages, including ages one and 12 months (.83), with retest intervals of one to 16 days. Content validity was achieved through expert opinion in item development and evaluation of content. Each new item was pilot tested three times and changed as necessary.

Concurrent validity studies were completed for the second edition of the scale and include scales owned by Psychological Corporation. Chronologically, the *McCarthy Scales of Children's Abilities* (McCarthy, 1972), the WPPSI-R (Wechsler, 1989), the *Differential Ability Scales* (Elliot, 1990), and the *Preschool Language Scale, Third Edition* (Zimmerman, Steiner, & Pond, 1992) were among the scales tested and had moderate correlations. Other studies have since been conducted and include studies statistically significant for stability of the Bayle-II over time (r=0.49, p<0.001) (Harris, Megans, Backman, & Hayes, 2005).

# Rapid neonatal neurodevelopmental assessment (RNNA).

To neurodevelopmentally test neonates, the Rapid Neonatal Neurobehavioral Assessment (RNNA) was used. The RNNA is a categorical clinical evaluation of sensory and motor systems designed to assess those neurofunctional behaviors that differentiate brain injury in neonates (Gardner, et al, 2006). Taking less than 10 minutes to administer, the RNNA includes visual, auditory, and motor items, and utilizes the infant's natural behavioral responses to elicit and assess behaviors. The current RNNA (Gardner, Karmel, & Freedland, 2001) consists of over 30 individually scored items, with scoring done on a 3-point scale for abnormalities: none/normal (0), mild/moderate (1), and severe (2). The scale was developed by Gardner, et al., (1990) and refined over time specifically for the sick neonate that is easily overstressed, and accurately assesses differing types and severity of CNS injury with minimal stress to the infant. Previous versions of the RNNA had utilized a 2-point scale of normal (0) and abnormal (1), and infants evaluated using the older, narrower system were removed from the data set.

Hypertonicity is specifically assessed when the examiner both fully extends the extremity and assesses amount and strength of recoil, and fully flexes the extremity and notes the amount and strength of extension. The examiner is experienced in handling infants, and examines the

baby in a normothermic environment without clothing on the legs so that muscle tone can easily be felt during the exam.

The RNNA is a modification of two procedures: (1) the Einstein Neonatal Neurobehavioral Assessment Scale (ENNAS) (Kurtzberg, et al., 1979), and (2) the assessment of elicited movement patterns described by Katona (1983) (Karmel & Gardner, 2005). Items selected and modified from ENNAS have been shown to differentiate pre-term from full-term neonates at term age (Kurtzberg, et al., 1979). Katona (1983) assessed more active skills to reveal head and trunk control as well as the amount and quality of extremity movements (Gardner, Karmel & Freedland, 2001).

The RNNA was validated on 248 NICU infants, with high inter-observer reliability ratings (94%) and an average Cohen's kappa of .81. High internal consistency is maintained as the categories provide information not considered redundant indicated by low correlation coefficients. Concurrent validity was replicated with both an independent sample of NICU infants (n=901) and a second population of healthy term infants (n = 317) (Gardner, Karmel & Freedland, 2001).

Over 5000 individual infants have been assessed utilizing the RNNA at this time, with most infants receiving assessments at hospital discharge and 44 weeks gestational age. The assessments in the data set were all done by a single individual, so there is an exceptionally high level of consistency and validity in the data.

## **Description of Treatment or Intervention**

This was a longitudinal, retrospective, descriptive study that examined a nested data set.

There were no treatments or interventions used with this population by this researcher or the

Infant Development Research team gathering the original data.

#### **Data Collection Procedures**

The primary investigator (PI) obtained approval as per policy from the Institutional Review Board (IRB) of Lehman College, City University of New York, the primary college of her sponsor, to examine previously gathered data. The approval was in place throughout data gathering, analysis, and defense. The data previously gathered was done so under IRB approval from the State of New York concurrent with IRB approval from the baby's birth hospital. The IRB approval for the Infant Development Research primary study included parental consent for the study participants. Blinded, de-identified data for this study was acquired after entry into a computerized data program, and all analysis of the blinded data took place within the data program. Therefore, no separate tool is needed to organize and track data, and there was no paper record of data from individual infants.

## **Protection of Human Subjects**

For this study there was no direct contact, in any form, with any human subjects. This researcher completed Protection of Human Subject training (CITI), as did every member of the Infant Development Research team gathering original data. The original Infant Development Research team received IRB approval throughout data gathering and continues to have current IRB approval from all appropriate institutions focusing on the vulnerable population of infants and children. The rights of human subjects were protected within the study. This researcher did not have any original records or identifying data, as all data was previously numerically coded and entered into a computerized data program with the original researchers holding all identifying files in locked cabinets in an appropriate setting. This researcher only had access to de-identified computer-generated coded data. Any further data needed to clarify missing data

from the data set will be retrieved by the original Infant Development Research team and submitted in coded form.

# **Data Analysis**

Analysis of this retrospective longitudinal data was done within the computerized data program SPSS (SPSS, 2011). This researcher expected to utilize regression because of the flexibility and strength of the analysis, in addition to other procedures. The data reflects a 20% rate of hypertonicity at hospital discharge, but the persistence rate of hypertonicity was unknown at this point in the study. Additional statistical methods were chosen to confirm the accuracy of results and further assess possible correlations.

## **Chapter Four**

#### Results

#### **Data Collection Results**

Data from 1145 otherwise healthy neonates (983 preterm and 162 term) was examined after Human Subject Clearance was obtained. This large data set, gathered over a 25 year period, allowed for excellent power analysis so data was carefully chosen for inclusion in final statistical analysis. Because heath disparities are a major concern, especially in large urban areas, analysis of self-reported ethnicity data for the mother was desired. However, there were major gaps in data, and the researchers had chosen not to risk losing a baby from the study just because the mother declined to answer the ethnicity question when most or all other demographic questions had been completed. Therefore, since the ethnicity data did not meet the standard of rigor for this study, analysis was deferred for future study.

Some of the babies had been evaluated with the original Bayley Scale of Infant

Development (Bayley-I), and with the original Rapid Neonatal Neurological Assessment

(RNNA). While both of these scales are accurate, the norms and raw scores between the Bayley-I and Bayley-II are slightly different. The RNNA has also slightly changed over time, from evaluating items like hypertonicity on a 2-step scale of normal=0, and abnormal=1, to evaluating these items on a 3-step scale of normal=0, slightly- moderately abnormal=1, and severely abnormal = 2. The 3-step scale is currently the norm when clinically evaluating items like hypertonicity on a 2-step scale of normal=0, and abnormal=1, to evaluating these items on a 3-step scale of normal=0, slightly- moderately abnormal=1, and severely abnormal = 2.

When clinically evaluating physiological actions of infants the 3-step scale is currently the norm, with the most classic example being the APGAR scoring system performed on a newborn at 1 and 5 minutes of life, which assesses heart rate, respiratory effort, reflex irritability,

muscle tone, and color with scores ranging from zero to two (Apgar, 1953). Although evaluation with a 5-point or 10-point scale would seem to be ideal from a statistical significance and analysis perspective, the wider the scale the greater the potential for error. Therefore, clinical assessments of this type are generally criterion-referenced and often utilize narrower scoring systems to maintain a higher degree of reliability, as the broader the scale the more opportunity for error (Waltz, Strickland, & Lenz, 2010).

To ensure consistency, babies included for final analysis needed to have been evaluated with the 3-step scale Rapid Neonatal Neurodevelopmental Assessment (RNNA), and evaluated at both hospital discharge and at 44 weeks gestational age. They also needed to have been assessed utilizing the Bayley Scale of Infant Development - II (Bayley-II) at 13 months corrected age. Specifying the 3-step scale RNNA and Bayley-II decreased the data set from 1145 babies to less than 650 babies. Next, the set was examined for any missing data, as missing lower extremity motor data from any of these three visits would exclude the baby from the study, and some infants had already been lost to follow-up before the 13-month visit. However, those infants were usually infants that had not had any developmental issues identified at any point during their hospital discharge, 44 week/1 month, 4 month, 7 month or 10 month visits and would be considered developmentally normal (Karmel, 2010). Eighty two babies had data missing from the 13 month visits. Fourteen babies were also identified by the original researchers as having genetic issues diagnosed after birth that could impact neuromuscular functioning and development and they were excluded from the data set, as they no longer met the criteria of "otherwise healthy."

When data set cleaning was complete, 546 infants had data recorded for evaluation of the lower extremities for both the 44 week RNNA visit and the 13 month Bayley-II evaluation while

463 babies had data recorded for all three visits - hospital discharge RNNA, 44 week RNNA, and 96 week/13 month Bayley-II evaluation. To maximize potential for evaluation and strengthen possible correlation, the data set of 463 babies with three data points was used. The mean weeks at evaluation fall within the expected dates of 38-42 weeks at first RNNA evaluation, 42-46 weeks at second RNNA evaluation, and 94-98 weeks for the Bayley-II evaluation. Because all ages were tracked in terms of weeks post-conception, both the terms 13 months and 96 weeks will refer to the 13 month visit. Table 1 shows the results of data collection.

Table 1

Data Collection Results

Evaluation Timing	N	Mean Weeks	Expected Weeks
Hospital Discharge	463	38.80	38-42
44 Weeks/1 month	546	44.61	42-46
13 months/96 weeks	546	97.04	94-98

Data was also requested concerning gender, birth weight, and estimated gestational age for any babies included in the study, to provide a robust data set that could be validated against population norms.

## **Sample Characteristics**

## Gender.

The data was first examined for gender, as boys slightly outnumber girls at birth and during childhood in the US (Mathews & MacDorman, 2013; Smith & Spraggins, 2001). This is upheld in the data set as slightly more than fifty percent of the babies were boys (51.2%, N= 237). Table 2 displays the results.

Table 2

Gender of Participants

Gender	Frequency (N)	Percentage
Boys	237	51.2
Girls	226	48.8
Total	463	100

## Hypertonicity.

The frequency of hypertonic lower extremities was explored next, with separate data points at hospital discharge and 44 weeks gestational age. Hypertonicity was noted in the original study at three levels. No noted hypertonicity was scored as 0, mild or moderate hypertonicity was given a score of 1, while severe hypertonicity was identified with a score of 2. Overall, there was slightly more lower limb hypertonicity noted at hospital discharge (20.3%, N=94) than at 44 weeks (17.9%, N=83). Only 35 of the babies (7.6%) had a score indicating hypertonicity at both hospital discharge and the 44 week visit. Table 3 below presents hypertonicity data from the two exams and shows that the overall level of hypertonicity decreased as the infants progressed in age.

Table 3

Levels of Lower Limb Hypertonicity at RNNA Exam

		Hospital Discharge		44 weeks		
Sco	ore Meaning	Frequency (N)	Percent (%)	Frequency (N)	Percent (%)	
0	None	369	79.9	380	82.1	
1	Mild/Moderate	76	16.4	70	15.1	
2	Severe	18	3.9	13	2.8	

## Bayley-II scores.

Although 369 infants were discharged without hypertonicity some became hypertonic, while others did not. For 347 (74.9%) babies, the level of hypertonicity in their legs did not change from the hospital discharge exam to the 44 week exam. The level increased at the 44 week exam for 55 babies (11.9%), and decreased for 61 babies (13.2%). There were 107 (23.1%) babies that had a hypertonicity level of none (0) at one of the exams, yet did have legs assessed to be hypertonic during the other exam, conveying to this researcher how fluid the neurodevelopment of lower extremity muscles is for the otherwise healthy very young infant, in both directions. Forty eight babies had a hypertonicity level of one (1) at discharge, changing to a level of zero (0) at the 44 week exam. Conversely, 47 babies had a hypertonicity level of zero (0) at discharge and a level of one (1) at 44 weeks, and one baby moved from a level of zero (0) at discharge to a level of two (2) at 44 weeks. Table 4 presents hypertonicity level findings, showing that 61 babies decreased their level of hypertonicity, but a total of 55 increased, further strengthening the need for understanding the impact of these changes on the motor development of the infant.

Table 4

Changes in Levels of Hypertonicity on RNNA Exam for Discharge and 44 weeks/1 month

Level	0 at 44 weeks	1 at 44 weeks	2 at 44 weeks	<u>Total</u>
	N Percent	N Percent	N Percent	N Percent
0 at discharge	321 (69.3%)	47 (10.2%)*	1 (0.2%)*	369 (79.7%)
1 at discharge	48 (10.4%)+	21 (4.5%)	7 (1.5%)*	76 (16.4%)
2 at discharge	11 (2.4%)+	2 (0.4%)+	5 (1.1%)	18 (3.9%)
Total	380 (82.1%)	70 (15.1%)	13 (2.8%)	463 (100%)

<sup>+ =</sup> hypertonicity decreased, \* = hypertonicity increased

Data from the 13 month/96 week Bayley-II exam, displayed below in Table 5, was then reviewed and found to meet population norms, with the population norm raw motor score at 13 months being 67, and the mean raw motor score for this data set being 66.8. The converted population index norm motor score at 13 months is 100, and the mean converted score for this data set is 99.5. The acceptable converted range for the 13 month old is 90-145, as determined by Bayley (1993).

Table 5

Data Set and Population Norm Bayley-II Scores

Bayley-II Scale	Data Raw	Norm Raw	Data Index	Norm Index
Motor	66.8	67	99.5	100
Mental	94	91-93	107.3	100

Because of the concern about neurological and cognitive outcomes possibly affecting motor scores, the mean Bayley-II mental scores for the data set were examined and found to be

above the norm. Raw mental scores at 13 months are 91-93 in the population norm, but this data set had a mean of 94, and the converted population index mental score is 100 while the mean index for this data was 107.3.

The babies, as a group, would be considered to have average motor scores for a 13 month old, and slightly advanced mental scores, consistent with a 14 month old. Therefore, the babies have met population norms with no obvious cognitive reason for neurodevelopmental deficits, so analysis could continue.

### **Statistical Analysis**

The number of subjects available (N=463) meets the criteria for adequate power analysis, with power of .999 at an Alpha = .05 and an Effect size = 0.30 for both Pearsons Correlation tests and regression (G\*Power, 2008). The data was analyzed utilizing SPSS statistical software (Windows v.20, IBM, 2011), and data was again checked for accuracy of entry. Utilizing SPSS FREQUENCIES and SPSS EXPLORE, significant positive skewness (>2.0) was found for the data at hospital discharge visit (HYPERL0 = 2.041) and data at 44 week visit (HYPERL1 = 2.226). The 13 month/96 week visit was not significantly skewed, but was mildly negatively skewed (MOTRAW = -.676). Kurtosis was explored and also found to be >3.0 for the same items that are significantly skewed (HYPERL0 = 3.330, HYPERL1 = 4.281), and normal for the remaining variable (MOTRAW = .819). Transforming the data into Z-scores had no effect on the skewness and kurtosis, so the data was returned to its original form.

These abnormalities would normally prevent the data from being described as normally distributed, but the effects of significant skewness significantly diminish with samples of 100 or more cases, and the underestimation of variation with negative kurtosis significantly diminishes with samples of 200 or more cases (Tabachnick & Fidell, 2012). With a sample size of 463, this

data set is clearly large enough to significantly reduce effects of skewness and kurtosis. However, Mauchly's test of sphericity is still important because that is an indicator of whether tests done on the same subjects, as in the RNNA performed at both hospital discharge and 44 weeks, can be run using parametric procedures. The null hypothesis is tested, and a non-significant result is desired. Unfortunately, this data is highly significant (W= .832, df=2, p=<.001), failing the test of sphericity and indicating data transformation should be attempted or non-parametric procedure should be used.

#### Transformation of data.

The first major transformation needed before analysis was to convert the raw motor scores (MOTRAW) from interval data ranging from 49 to 77 into rank data (MOTRANK) so that the three variables are in similar formats. Scores that are normal and higher (67 and above) represent infants in the 13 month ability range and above and will be assigned a score of "0," scores mildly-moderately low (66-61) represent infants in the 11 and 12 month range and are assigned a score of "1," and scores severely low (60 and below) represent infants in the 10 month ability range and below and will be assigned a score of "2" (Black & Matula, 2000). Table 6 presents scores and transformed scores.

Table 6

13 month MOTRAW scores transformed into MOTRANK scores

MOTRAW	MOTRANK	N	Percent	Cumulative
>=67	0	275	59.4	59.4
61-66	1	148	32.0	91.4
<=60	2	8.0	8.6	100.0
Total		463	100	

Because many statistical calculations do not perform well with "0" as a value, the second transformation increased all scores by a value of one (O'Connell, 2006). This is shown in Table 7, below.

Table 7

Conversion of Scores

Old Score	New Score	
0	1	
1	2	
2	3	

Once the data was converted to rank form and "0" was removed as a variable by adding one to every score, variables were renamed and descriptive statistics were once again run, with Table 8 displaying the results. For academic rigor, skewness and kurtosis were still considered to be an issue with the data, even though the large sample size significantly diminishes the effect.

Table 8

Description of Transformed Data

Old Name	New Name	N	Mean	Skewness	Kurtosis
HYPERL0	HYP0AND1	463	1.2419	2.041	3.330
Hosp. Disch.	Hosp. Disch.				
HYPER1	HYP1AND1	463	1.2073	2.226	4.281
44 weeks	44 weeks				
MOTRANK	MRANKAND1	463	1.4924	.974	178
13 months	13 months				

To explore whether further transforming the data improves the data as far as criteria of normal distribution, a normative log transformation was done. When that data was tested for homogeneity of variance, the motor score was very significant [F(2,460) = 5.276, p < .01], which shows that the variances are significantly different and the assumption of homogeneity has been violated, so the data were returned to its non-log form, and the research question was addressed.

## **Research Question**

#### Pearson correlation.

The research question is "What is the correlation between a set of two predictors (age & hypertonicity of lower extremities) and the outcome of Bayley-II Motor Function Scores at 13 months of age?" Table 9 below shows, via Pearson's Correlation, that there is a significant relationship between the level of hypertonicity at hospital discharge (HYP0AND1) and at the 44 week/1month exam (HYP1AND1) at the 0.01 level (r = .322, p < .001), but no correlation between level of hypertonicity at hospital discharge (HYP0AND1) and score on the 96 week exam/13 month (MRANKAND1) (r = .020, p = .660) nor between level of hypertonicity at the 44 week/1month exam (HYP1AND1) and score on the 96 week /13 month exam (MRANKAND1) (r = .062, p = .185).

Table 9

Correlation of Age, Hypertonicity and Bayley-II Motor Function Scores

Name		HYP0AND1	HYP1AND1	MRANKAND1
Time Frame		Hosp. Disch.	44 weeks	13 months
HYP0AND1	Pearson Correlation	1	.322	020
Hospital	Sig. (2-tailed)		.000**	.660
Discharge	N	463	463	463
HYP1AND1	Pearson Correlation	.322	1	.062
44 weeks/	Sig. (2-tailed)	.000**		.185
1 month	N	463	463	463
MRANKAND1	Pearson Correlation	020	.062	1
96 weeks /	Sig. (2-tailed)	.660	.185	
13 months	N	463	463	463

<sup>\*\* =</sup> significance level < .01

## Spearman's rho correlation.

The data were then analyzed using Spearman's correlation coefficient because even though this is a very large data set and the size should compensate for any parametric deviations, the data technically do not meet the assumptions of normally distributed data. Table 10 displays verification via Spearman's correlation coefficient that there is a positive relationship between the level of hypertonicity at hospital discharge (HYP0AND1) and at the 44 week/1month exam (HYP1AND1) at the 0.01 level ( $r_s = .271$ , p < .001), but no correlation between level of

hypertonicity at hospital discharge (HYP0AND1) and score on the 96 week /13 month exam (MRANKAND1) ( $r_s = -.043$ , p = .357) or between level of hypertonicity at the 44 week/1month exam (HYP1AND1) and score on the 96 week /13 month exam (MRANKAND1) ( $r_s = .050$ , p = .283).

Table 10

Spearman's rho Correlation of Age, Hypertonicity and Bayley-II Motor Function Scores

Name		HYP0AND1	HYP1AND1	MRANKAND1
		Hosp. Disch.	44 weeks	13 months
HYP0AND1	Correlation	1.000	.271	043
Hospital	Sig. (2-tailed)		.000**	.357
Discharge	N	463	463	463
HYP1AND1	Correlation	.271	1.000	.050
44 weeks/	Sig. (2-tailed)	.000**		.283
1 month	N	463	463	463
MRANKAND1	Correlation	043	.050	1.000
13 months/	Sig. (2-tailed)	.357	.283	·
96 weeks	N	463	463	463

<sup>\*\* =</sup> significance level < .01

## **Ancillary Analysis**

Next, the SPSS Ordinal Regression procedure, or PLUM (Polytomous Universal Model) was utilized for further assessment of the data. The PLUM Ordinal Regression procedure is an extension of the general linear regression model to ordinal categorical data. This procedure is a good fit for this data as it can be used with heteroscedastic data. This data set was significant

for, and therefore failed, the test of homoscedasticity, making it heteroscedastic. When plotted on a graph, data that meet the assumptions of linearity and homoscedasticity look like a blob, with points randomly and evenly dispersed. Heteroscedastic data look like a megaphone, with data clumped narrowly on one end, but widely spaced by the other end of the plot (Field, 2005).

#### Goodness of fit.

Examining the model for goodness-of-fit, Table 11 below shows large significance numbers (Pearson p=.198, df = 12; deviance p=.197, df = 12), indicating that this model is a good fit for this data set. The null hypothesis that the model fits is rejected if the significance is small, so statistical significance is not desired in this case, and significance numbers approaching .2 indicate a very good fit between the data and PLUM ordinal regression (Norusis, 2010). Using G\*Power to calculate power for this test, N=463, Alpha = .05, df = 12, and a large effect w=0.5, power was determined to be 1.000, an extremely strong level validating good fit of the data.

Table 11

Goodness-of-Fit Test

	Chi-Square	df	Sig.
Pearson	15.848	12	.198
Deviance	15.870	12	.197

## PLUM ordinal regression.

The PLUM ordinal regression parameter estimates listed below in Table 12 show no significant relationship between the Threshold variable (96 week /13 month exam - MRANKAND1) and any of the Location variables (hospital discharge exam - HYP0AND1, and

44 week/1 month exam - HYP1AND1) at any level (p = .853, .519, .126, and .287), thereby a lack of relationship between hypertonicity of the lower extremeties at hospital discharge or 44 weeks, and motor function scores on the 96 week/13 month Bayley-II exam.

Table 12

PLUM Ordinal Regression Parameter Estimates

	Level	Estimate	Std. Error	Wald	df	Sig.
Threshold	mrankand1 = 1.00	429	.615	.487	1	.485
13 month	mrankand1 = 2.00	1.561	.624	6.259	1	.012*
Location	HYP0AND1 = 1.00	.094	.506	.034	1	.853
Hosp. Disch	HYP0AND1 = 2.00	345	.535	.416	1	.519
	HYP0AND1 = 3.00	0			0	
44 weeks	HYP1AND1 = 1.00	891	.583	2.341	1	.126
	HYP1AND1 = 2.00	650	.611	1.133	1	.287
	HYP1AND1 = 3.00	0	•	-	0	

<sup>\* =</sup> significance level < .05

## Psuedo R-squared tests.

Post-hoc testing is done to look at strength of association, utilizing pseudo *R*-square statistics, to verify regression measurements (Norusis, M. J., 2010). The larger the association, the larger the statistic for the Cox and Snell, Nagelkerke, and McFadden tests listed in Table 13.

All the post-hoc testing statistics are significant ( $R^2 = .009$ , .011 and .005) therefore rejecting that there is any association, and verifying that there is no relationship between hypertonicity of lower extremities at hospital discharge or 44 weeks/1 month and Bayley-II motor function scores at 96 weeks/13 months.

Table 13

Pseudo R-Square Tests

Test	Statistic
Cox and Snell	.009**
Nagelkerke	.011*
McFadden	.005**

<sup>\*\* =</sup> significance level <.01, \* = significance level <.05

### **Additional Analysis**

### Hypertonicity subsets.

The large size of the data set may possibly conceal subtle correlations, so infants that did not have hypertonicity were excluded from the data set, and correlations were again explored. Ninty-four infants were identified as having some level of hypertonicity at hospital discharge, 83 had some level of hypertonicity at 44 weeks/1 month, and 35 of those infants were assessed as hypertonic at both hospital discharge and 44 weeks/1 month. Pearson's correlation was performed, but no correlation between hypertonicity at hospital discharge and score on the 96 week exam/13 month (r = -.026, p = .803, n = 94), hypertonicity at the 44 week/1month exam and score on the 96 week/13 month exam (r = -.170, p = .125, n = 83), or hypertonicity at both hospital discharge and 44 weeks/1 month and score on the 96 week/13 month exam (hospital discharge r = .078, p = .658, n = 35; 44 week/1 month - r = -.314, p = .066, n = 35) was found.

Spearman's correlation coefficient confirmed no correlation between hypertonicity at hospital discharge and score on the 96 week/13 month exam ( $r_s = -.051$ , p = .565, n = 94), hypertonicity at the 44 week/1month exam and score on the 96 week /13 month exam ( $r_s = -.113$ , p = .227, n = 83), or hypertonicity at both hospital discharge and 44 weeks/1 month and

score on the 96 week/13 month exam (hospital discharge  $r_s$  =.093, p = .594, n = 35; 44 week/1 month  $r_s$  = -.329, p = .053, n = 35). This data is presented in Table 14.

Table 14

Correlations - Infants with Hypertonicity to 13 month Motor Function Scores

Age		Pearson's	Spearman's
Hosp. Disch.	Corr. Coeff.	026	051
	Sig. (bilat)	.803	.565
	n	94	94
44 week/1 month	Corr. Coeff	170	
	Sig. (bilat)	.125	.227
	n	83	83
<u>Both</u>		Hosp D 44 wk	Hosp D 44 wk
Hosp. Disch.	Corr. Coeff.	.078314	.093329
and	Sig (bilat)	.658 .066	329 .053
44 week/1 month	n	35 35	35 35

## Birthweight/estimated gestational age correlation.

To further validate the data and results, the birthweight (BW) and estimated gestational age (EGA) scores for the infants included in this data set were analyzed. Estimated gestational age and birth weight are closely tied and well correlated throughout the literature (Alexander, Himes, Kaufman, Mor, & Kogan, 1996; Brenner, Edelman, & Hendricks, 1976; Oken, Kleinman, Rich-Edwards, & Gillman, 2003) and should be highly correlated if the statistical procedures used are correct. The data set was analyzed, and birthweight and estimated

gestational age were found to be very highly correlated (r = .829, p = < .001, N = 462) with Pearson's correlation. Spearman's rho post-hoc testing was done, showing BW and EGA to be very strongly positively correlated ( $r_s = .812$ , p = < .001, N = 462). Birthweight was missing from one infant, so overall n is lower than the regular data set for this study. Table 15 presents these results.

Table 15

Birth Weight and Estimated Gestational Age Correlations

	Type o	of Correlation
BW*EGA	Pearson's	Spearman
Correlation	.829 .829 .856	.812 .704 .837
Coefficient		
Sig. (bilateral)	.000** .000** .000**	**000. **000. **000.
N/n	462 93 82	462 93 82

<sup>\*\* =</sup> significance level <.01

## Summary.

In summary, the level of hypertonicity observed at the hospital discharge exam or the 44 week/1 month exam does not correlate with the Bayley-II motor function score at the 96 week/13 month exam. All variables were positively skewed and were analyzed as ordinal data. The large data set (N = 463) should have offset problems with normal distribution, but ordinal regression and other nonparametric tests were used to ensure accuracy of results.

## **Chapter Five**

#### Discussion

This study was conducted to investigate if there is any correlation between the level of hypertonicity in the lower extremities of an infant at hospital discharge after birth or at 44 weeks/1 month of corrected age and their motor abilities at 13 months of age as determined by the Bayley Scales of Infant Development (Bayley-II, 1993) motor function scores. Roy's adaptation model is the theoretical basis for this investigation of the infants' adaptive mechanisms. A review of a data set involving over 5000 babies gathered over several decades revealed that twenty percent of infants considered to be otherwise healthy have some level of hypertonicity in the lower extremities at hospital discharge, but the effect on future motor function was unknown, and the need for early therapeutic intervention had not been determined.

A review of the literature revealed multiple studies about hypertonicity related to specific disease entities or abnormalities including findings of: increased jitteryness and hypertonicity (Chiriboga, et al., 1995; Delaney-Black, et al., 1996; Karmel, Gardner & Freedland, 1998), increased leg tone (Belcher, et al., 1999), and delayed acquisition of walking (Belcher, et al., 1999) related to materal cociane use; typical trisomy 21 presentation (Keppler-Noreuil, Welch, Major, Qiau, Jordan & Patil, 2002), buprenorphine withdrawl syndrome (Kayemba-Kay's, & Laclyde, 2003), and neurologic events in infants undergoing cardiac surgery (Chock, Reddy, Bernstein & Madan, 2006). However, there is a sparcity of studies done on otherwise healthy infants of children with isolated hypertonicity after birth. The studies on hypertonicity were conducted by researchers in multiple fields, but nurses were rarely the primary researchers. Physiological studies concerning motor issues, including the ones listed above, were conducted

by professionals representing the fields of medicine, psychology or physical therapy, but not nursing.

## **Summary of Findings**

The nested, retrospective, longitudinal, descriptive design of this study allowed for non-directional exploration of this large data set to determine the current effect hypertonicity has on motor development. The 463 participants fit population norms for gender and age at hospital discharge, and the data set size provided adequate power for analysis.

The level of hypertonicity observed at the hospital discharge exam does not correlate with the Bayley-II motor function score at the 96 week/13 month exam (r = .020, p = .660, N=463), nor does the level of hypertonicity observed at the 44 week/1 month exam (r = .062, p = .185, N=463). However, there is a significant relationship between the level of hypertonicity at hospital discharge and at the 44 week/1 month exam at the 0.01 level (r = .322, p < .001, N = .463). All variables were positively skewed and were analyzed as ordinal data. The large data set (N = .463) should have offset problems with normal distribution, but ordinal regression and other nonparametric tests were used to ensure accuracy of results. The data set was later further split to assess whether the large size was obscuring significance in the smaller number of infants who were positive for hypertonicity at either RNNA assessment, and those correlations were also nonsignificant at the .05 level (r = -.026, p = .803, n = .94; r = -.170, p = .125, n = .83; r = .078, p = .658, n = .85 and r = -.314, p = .066, n = .85).

Ordinal regression was conducted because the data was skewed and failed both the test of sphericity and homogeneity of variance, eliminating the possibility of parametric testing.

Goodness-of-fit testing was passed and indicated that ordinal regression would be very appropriate, but when completed the parameter estimates showed no significant relationship

between the Threshold variable (96 week /13 month exam) and any of the Location variables (hospital discharge exam, and 44 week/1 month exam) at any level (p = .853, .519, .126, and .287). Post-hoc testing confirmed the lack of relationship.

In ancillary analyses, the birthweight and estimated gestational age scores for the infants included in this data set were analyzed, as estimated gestational age and birth weight are closely tied and well correlated throughout the literature and should be highly correlated if the statistical procedures used are correct. Birthweight and estimated gestational age were found to be very highly correlated (r = .829, p = < .001, N = 462 and n = 93) with Pearson's correlation.

The research question is: "What is the correlation between a set of two predictors (age & hypertonicity of lower extremities) and the outcome of Bayley-II Motor Function Scores at 13 months of age?", and the finding of the data analysis is that there is no correlation for this data.

#### **Conclusions**

Given the results of this study, it can be concluded that level the of hypertonicity assessed at hospital discharge or 44 weeks/1 month in an otherwise functionally and structurally healthy infant is not of concern, as it does not significantly affect the child's Bayley-II motor function scores at 13 months of age. When the sample was divided to assess correlations of only those infants positive for hypertonicity, the same results were achieved, confirming that the infants adapt well to the environment and are able to achieve developmental milestones regardless of earlier isolated abnormalities.

## **Implications**

#### Implications for practice.

This was an initial study, and results should be viewed as preliminary. Finding that hypertonicity isolated in the lower extremities in the otherwise healthy infant does not

significantly affect motor function scores at 13 months of age validates the current practice of watchful waiting in the infant age group, and is very reassuring. A significant finding between hypertonicity and motor function scores could have meant that a large number of infants were not being properly referred to Early Intervention in a timely manner, and that pediatric providers as a whole were not providing the best possible care to their infant population.

A lack of correlation may be disappointing to some, but is viewed by this researcher as a finding that can guide practice, reconfirming that every child should be continually evaluated for individual attainment of milestones. However, tightness of the leg muscles in the absence of other factors in the otherwise healthy infant is not a cause for immediate concern and can be carefully monitored developmentally just like any other isolated abnormality. Roy's Adaptation Model (Roy & Andrews, 1999) was utilized as the framework for this study, and the babies showed at every data point that they have increasing adaptive measures within the physiological mode as they increase interaction with their environment, resulting in no significant motor delays by 13 months.

In terms of resource management, a correlation may have drastically increased the number of infants being referred to Early Intervention services, with up to one in every five otherwise healthy infants referred. The astronomical increase would have dramatically impacted both the financial and personnel resources needed to properly care for these infants. A lack of correlation affirms that the current developmental surveillance that is in place is adequate at this time to detect developmental concerns and meet motor function needs for most infants. This infant population was from the New York City metropolitan area, and included infants living in New York, New Jersey and Connecticut. However, the large data set size that met population norms provides good possibility for further study and possible generalization of results.

## Implications for measurement.

Hypertonicity was measured on the infants using a 3-step scale as that is the standard measure for clinical assessment testing on infants at this time, and the APGAR neonatal testing done at 1- and 5- minutes after birth is given as a well known example (Apgar, 1953).

Refinement of the measurement to a 5-step measure would provide the researcher with data that better differentiates the problem, but may come at the expense of good inter-rater reliability.

Therefore, 5-point scoring systems may appear to be ideal, but in the clinical arena they are often too broad to continue to receive accurate data, as the tools require increased training so that users make accurate assessments. In this data set one individual did all the infant testing, so the results are very reliable, and ideal (3-point) measurement techniques provide for development of easily repeatable scoring systems.

### Implication for theory development.

The results of this study support the continued use of the Roy Adaptation Model (Roy & Andrews, 1999) to generate empirically tested nursing theory. The individual's adaptive mechanisms help him/her cope with an ever-changing environment. The physiological adaptive mode was shown to be effective in several ways. First, both the number of overall babies exhibiting hypertonicity decreased between the hospital discharge assessment and the 44 week/1 month assessment, from 94 to 83. Second, the number exhibiting the highest level of hypertonicity decreased between the hospital discharge assessment and the 44 week/1 month assessment, from 18 to 13. Third, the overall number of babies with no hypertonicity noted rose from 369 to 380. Lastly, there was no statistically significant correlation between hypertonicity as a young infant and motor function scores, further reinforcing the theory of physiological adaptation by infants when they are in constant contact with their environment.

#### Recommendations

It is recommended that investigators review other available motor assessments within the larger data set to assess for statistical significance with motor function scores, even though those items did not stand out on initial assessment. Data for hypertonicity of arms is available as is hypotonicity of both arms and legs. A unilateral difference in tone was also noted if present during the RNNA exam. These items were rated as normal in at least 92% of the babies, but may still hold significance for longitudinal development.

It is also recommend that research be done to examine whether the birth statistics, such as estimated gestational age and birthweight, have any significant relationship to motor function scores on a longitudinal basis. The rationale would be to identify infants at-risk for developmental delay early, follow them closely, and place them in Early Intervention at the first sign of possible delay. The research would be ideal to study using Roy's Adaptation Model framework (Roy & Andrews, 1999) within the physiological modes, as was done in this study.

Age and education of the mother has become a topic of interest in the last several years, and the impact of the mother's age and education on motor scores could easily be analyzed. Discriminant analysis could be used when looking back at predictors if two outcome measures are identified. In this study there was only one outcome measure, so discriminant analysis was not an appropriate measure for analysis, but it could be ideal for other methodologies.

## **Future questions.**

The following questions could be asked in future studies with otherwise healthy infants as subjects:

1. What is the correlation of hypotonicity with motor function scores at 13 months?

- 2. What is the correlation of tone differences in the arms to overall motor function scores at 13 months?
  - 3. Does the age or education of the mother affect motor function scores at 13 months?
- 4. Does birthweight, estimated gestational age, or intrauterine growth restriction correlate with lower motor function scores, which would identify the children as high risk for developmental delay?

These are questions that could be explored with the available data set. Another area for exploration is whether the racial group effects motor scores, although only the self-identified racial group of the mother was recorded, and some choose not to identify with any one racial group and left the answer space blank.

## Summary.

In summary, this study with excellent power analysis and a relatively large data set (N = 463) found no statistically significant correlation between the level of hypertonicity in young infants and motor function scores at 13 months in otherwise healthy infants. Roy's Adaptation Model was the framework utilized, and the babies physiologically adapted to their environment nicely, with no significant motor function delays at 13 months of age due to hypertonicity of the lower extremities, and hypertonicity decreasing at every measurement point. This finding supports continued careful assessments of these infants with an isolated abnormality and a stance of watchful waiting to assess for therapeutic early intervention needs.

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