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# THE EFFECT OF NURSING INTERVENTIONS ON THERMOREGULATION AND NEUROMOTOR FUNCTION IN VERY LOW BIRTHWEIGHT INFANTS.

A thesis submitted in fulfilment of the requirements for the degree of

PhD in Nursing

School of Nursing and Public Health

Faculty of Communications, Health and Science

Edith Cowan University, Western Australia

Leanne Monterosso RN B Nursing(Hons) RM NNT

February 25, 1999

#### **ABSTRACT**

The prone position is used routinely in neonatal intensive care units worldwide in the nursing of preterm infants because of reported beneficial physiological effects. This position can, however, lead to development of flattened posture in very low birthweight (VLBW) infants and contributes to both short and longer term implications for functional motor development of upper and lower extremities. To date, limited research has been undertaken to investigate methods of reducing flattened posture and its related negative outcomes.

Temperature instability is also a problem for VLBW infants and no nappy exists that meets postural, size and thermoregulation requirements.

The purpose of this study was to demonstrate the effect of a nursing care model designed for the primary prevention of neuromotor problems and temperature instability in VLBW infants. The theoretical framework was based on two bodies of knowledge, thermoregulation and neuromotor development. A two phase study was used to test two hypotheses: (1) use of a cloth postural support nappy (N) with an inner absorbent nappy liner would improve temperature stability in VLBW infants nursed in incubators on infant servo control (ISC); and (2) use of a postural support roll (R) with or without a N, would improve neuromotor development in the short and longer term.

In Phase 1, a sample of 23 infants < 31 weeks gestation nursed in incubators on ISC was recruited over two months to a randomised, observer blind, crossover trial. Infants were randomised to commence wearing either a N with or without an inner absorbent liner, and alternated wearing each nappy for a 24 hour period over four days. Eight hourly per axilla (PA) temperatures and hourly measurements of infant handling, skin and incubator temperatures were recorded. Infants in both groups were well matched for birth and postnatal variables.

Findings showed that nursing infants in a N with an inner absorbent liner experienced clinically and statistically significant higher skin and lower incubator temperatures. In addition, a prediction model for PA temperature was developed that showed it was possible to predict PA temperatures from skin temperatures.

In Phase 2, a sample of 123 infants < 31 weeks gestation was recruited to a randomised, observer blind, controlled trial. Infants were randomised to one of three treatment groups (i.e., N only, N and R, or R only). Measurements of neuromotor development were performed at three assessment periods (i.e., from birth to term conceptional age, then at four and eight months conceptional age). Randomisation was effective. Findings confirmed previous study findings that use of a N improves hip posture up to term conceptional age. The major finding was that use of a R while VLBW infants are nursed in the prone position in a NICU improved hip and shoulder posture up to eight months conceptional age. In addition, an Infant Posture Evaluation Tool (IPAT) was developed that will enhance the clinical skills of health professionals involved in the care of these infants.

The findings contribute to neonatal nursing theory development in thermoregulation and neuromotor development and function in VLBW infants. Practice implications focus on promoting temperature stability and normal neuromotor function in VLBW infants up until eight months conceptional age. Longer term research will determine the effect of postural interventions on gait and foot progression angles. Testing and validation of the IPAT will facilitate future research related to infant posture.

#### **DECLARATION**

I certify that this thesis does not, to the best of my knowledge and belief:

- (i) incorporate without acknowledgement any material previously submitted for a degree or diploma in any institution of higher education;
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Signature:		
	Leanne Monterosso	

Date: February 25, 1999

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#### **CHAPTER 1**

#### Introduction

Advances in perinatal and neonatal medicine have resulted in increased survival rates for preterm infants (Hack, Klein, & Taylor, 1995). The survival rate for the very low birthweight (VLBW) preterm infant (i.e., an infant with a birthweight of less than 1500g) has improved dramatically over the past 10 years from 40% to approximately 90% (Bennett & Scott, 1997; Gee, 1996; Hack et al., 1995).

In Western Australia prematurity accounts for 6.7% of all live births, 1% of which are classified as very low birthweight (Gee, 1996). These figures concur with current worldwide trends. However, although the figures reflect the ability of medical technology to save small infants, they also raise questions regarding short and longer term developmental outcomes (de Groot, Hopkins, & Touwen, 1995; Vohr & Msall, 1997).

Traditionally, the focus of care for VLBW infants has been to meet their immediate survival needs (Desmond, Wilson, Alt, & Fisher, 1980; Turill, 1992). This has prompted research resulting in significant perinatal and neonatal therapeutic and technological advances. Most of the advances relate to the respiratory, cardiovascular, neurological and gastrointestinal systems. Recently, the following improvements have been made: administration of prenatal steroids to mature fetal lung development; administration of exogenous surfactant during the early neonatal period in association with the introduction of new ventilatory techniques to reduce the incidence and severity of respiratory distress syndrome; administration of prophylactic indomethacin for prevention of intraventricular haemorrhage; and improved nutritional management to facilitate growth and development (Bennett & Scott, 1997; Hack et al., 1995; Vohr & Msall, 1997).

#### Thermoregulation

Many problems related to the immediate survival needs of VLBW infants have been well researched. However, the maintenance of thermal stability in these infants continues to be a significant problem despite the routine use of incubators and overhead warmers (Okken, 1991; Thomas, 1991; Thomas, 1994).

Thermoregulation is a critical physiologic function that is closely related to the VLBW infant's survival and transition to extrauterine life (Hurgoiu, 1992; Okken, 1991; Poland, 1995; Roncoli & Medoff-Cooper, 1992; Thomas, 1991). Due to immaturity of their thermoregulation ability, VLBW infants rely on environmental temperature to maintain thermal stability (Mok, Bass, Ducker, & McIntosh, 1991; Okken, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994).

Immediate attention to this problem can improve outcomes; therefore, it is vital that interventions that conserve body heat and reduce heat loss be incorporated as a primary focus of care (Poland, 1995; Roncoli & Medoff-Cooper, 1992; Thomas, 1994).

One of the major causes of heat loss in VLBW infants is evaporation caused by wet nappies. Anecdotal evidence suggests that use of disposable nappies reduces temperature instability in VLBW infants (Graham, 1992). Attempts to create a more thermally stable environment have led to the widespread use of disposable nappies in place of traditional cloth nappies. The reported benefits of disposable nappies in the maintenance of temperature are anecdotal and remain unsubstantiated by empirical research. Furthermore, the bulky shape of these nappies may contribute to neuromotor problems such as *flattened* posture (Petty, Hemingway, & Wylie, 1993).

The first phase of this study empirically tested a nappy that provided both optimal temperature maintenance and postural support to prevent the development of *flattened* posture in the lower extremities.

#### Neurodevelopment

Despite increased survival rates and advances in perinatal care, preterm infants are still at risk for neurodevelopmental problems, particularly those related to the neuromotor system (Bennett & Scott, 1997; de Groot, 1993; de Groot et al., 1995; Georgieff & Bernbaum, 1986; Vohr & Msall, 1997).

Although the majority of VLBW infants may have normal outcomes, as a homogenous group they generally have higher rates of abnormal growth, illness, and neuromotor problems (de Groot et al., 1995; Hadders-Algra, Huisjes, & Touwen, 1988; Piper, Byrne, Darrah, & Watt, 1989). It is well documented that these problems are increased in infants of extremely low birthweight (Bennett & Scott, 1997; de Groot et al., 1995; Hack et al., 1995).

The rate of both major and minor neuromotor problems in VLBW survivors has not changed in the last 20 years (Hack et al., 1995; Vohr & Msall, 1997). Of greater concern is evidence suggesting that the rate of functional limitations (i.e., including neuromotor disorders) may be increasing (Anderson & Auster-Liebhaber, 1984; Vohr & Msall, 1997). These findings are of concern to all health carers working in Neonatal Intensive Care Units (NICUs) whose traditional focus has been the immediate survival needs of preterm infants. Although research to further decrease the delivery rates of low birthweight infants must remain a primary focus, ongoing study of neuromotor outcomes, together with intervention strategies to ameliorate these problems is warranted (Hack et al., 1995).

Neuromotor problems in preterm infants are caused by imbalances between active and passive muscle power that occur as a result of early removal from the uterine environment (Bennett & Scott, 1997; de Groot, 1993; de Groot et al., 1995; Georgieff & Bernbaum, 1986).

Following exposure to the extrauterine environment, the following environmental and physiological factors contribute to muscle group imbalances: positioning for prolonged periods on the flat surface of an incubator mattress, neuromuscular immaturity, global hypotonia, gravitational force, and the caudocephalic direction of neurological development (Anderson & Auster-Liebhaber, 1984; de Groot et al., 1995; Downs, Edwards, McCormick, Roth, & Stewart, 1991; Dunn, 1991; Georgieff & Bernbaum, 1986). Mobility, which is vital for the development of normal posture is, therefore, impeded in the preterm infant.

In the NICU of the major perinatal tertiary referral centre for Western Australia as in many NICUs worldwide, preterm infants are routinely nursed in the prone position (Katz, Krikler, Wielunski, & Merlob, 1991; Lacey, Henderson-Smart, & Edwards, 1990; Perez-Woods, Malloy, & Tse, 1992; Turill, 1992; Updike, Schmidt, Macke, Cahoon, & Miller, 1986). When comparisons are made between infants nursed in a supine position with infants nursed prone, those in the prone position are reported to benefit from many physiological effects including more rapid gastric emptying and less incidence of reflux (Blumenthal & Lealman, 1982; Blumenthal & Pildes, 1979; Vandenplas & Sacre-Smits, 1985; Yu, 1975). Other significant benefits associated with the prone position compared with the supine position are decreased energy expenditure and increased time spent asleep (Amemiya, Vos, & Prechtl, 1991; Masterson, Zucker, & Schulze, 1987).

In addition, the prone position has a beneficial effect on neurobehavioural systems including improved state organisation and improved self calming (Als et al., 1986; VandenBerg, 1990). The prone position also increases lung compliance and tidal volume, decreases the rate of breathing, increases the regularity of breathing, decreases asynchronous chest wall movement, and increases partial pressure of oxygen (Brackbill & Douthitt, 1973; Heimler, Langlois, Hodel, Nelin, & Sasidharan, 1992; Martin, Herrell, Rubin, & Fanaroff, 1979; Masterson et al., 1987; Wagaman et al., 1979).

Although the prone position is most physiologically beneficial for preterm infants, it results in the deformation of malleable tissues and can lead to development of *flattened* posture affecting all extremities (Davis, Robinson, Harris, & Cartilidge, 1993; Fay, 1988; Heimler et al., 1992; Konishi, Kuriyama, Mikawa, & Suzuki, 1987; Montfort & Case-Smith, 1997). This posture results in the development of the "W" position in the upper extremities, characterised by elevation and adduction of the scapula, causing shoulder retraction and abduction with the upper extremities in external rotation (Davis et al., 1993; Georgieff & Bernbaum, 1986; Turill, 1992; Updike et al., 1986). In the lower extremities *flattened* posture results in external rotation and wide abduction of the hips, lack of pelvic elevation and hip flexion of greater than 90 degrees (Davis et al., 1993; Konishi et al., 1987).

Flattened posture has both short and longer term implications for the functional motor development of the upper extremities for as long as 18 months or more. The infant's ability to reach for and manipulate objects, sit without support, and bear and shift weight on the forearms when prone may be affected. Without this ability, crawling and supported standing will be delayed (Georgieff & Bernbaum, 1986).

Flattened posture of the lower extremities may have implications for children as old as six years of age or more, as it may be disadvantageous for the weight-bearing forefoot. This problem can lead to delays in motor skills such as walking, crawling and sitting (Fay, 1988). Furthermore, this posture can cause infants to walk with a marked out-toeing gait until they are as old as six years of age. This may also be cosmetically displeasing to children and their parents (Davis et al., 1993; Desmond et al., 1980; Dunn, 1991; Katz et al., 1991).

Although postural abnormalities are well described, there are only two published studies that have examined the effect of specific interventions on the development of postural problems. These studies describe supportive positioning techniques designed specifically for lower extremities (Downs et al., 1991; Monterosso, Coenen, Percival, & Evans, 1995).

Downs and colleagues (1993) reported a randomised controlled study of 45 infants < 33 weeks gestation to investigate the effects of rolled sheets or beanbags for prone, side-lying and supine placement on the development of *flattening* in the lower extremities. Findings demonstrated that *flattening* was virtually abolished in the group of most vulnerable infants between 24 and 28 weeks gestation. Dunn (1991), however, argued that such postural supports may increase hip pathology from adduction of the hips caused by weight-bearing through the anterior knee rather than medial knee. In addition, reduced lower limb mobility may impede normal postural development (Saint-Anne Dargassies, 1979). This argument is further supported by Oehler (1993) and Perez-Woods (1992) who recommend that restraints should not be used to maintain position.

A recent randomised, controlled, observer blind study of 68 infants less than 31 weeks gestation investigated the short term effect of a postural support nappy (N) on infants nursed in the prone position (Monterosso et al., 1995).

This simple intervention promoted movement and flexion of the lower extremities, without the associated disadvantages of the postural supports used in the Downs and colleagues (1991) study. Monterosso and colleagues (1995) found that use of the N when VLBW infants must be nursed in the prone position, significantly reduced the features of *flattened* posture of the lower extremities at the time of hospital discharge. Specifically, the N increased the angle of pelvic elevation, and reduced the angle of external rotation of the hips and the weight-bearing surface area of the inner aspect of the thigh and knee. The short term results of this study were significant and use of the N has been implemented as a nursing protocol in the study NICU of the study hospital.

Further research is required to determine the longer term effects of this intervention. Phase 2 of the present study extended the work of Monterosso and colleagues (1995) by evaluating the short and longer term effect of postural supports on both upper and lower extremities.

#### Statement of Purpose

The purpose of this study, therefore, was to create an environment that promoted the maximum short and longer term physiological and developmental outcomes by utilising appropriate postural supports and materials.

To achieve this aim, a two phase study was undertaken. Phase 1 investigated the effect of the N with a fixed inner absorbent liner on skin and incubator temperatures in infants < 31 weeks gestation nursed in incubators on infant servo control. Phase 2 investigated the relationship between nursing the preterm infant in a N with or without a postural support roll (R), and the reduction of the features of *flattened* posture of the upper and lower extremities in the short and longer term.

The term *conceptional age* has been used in the following hypotheses and throughout this study. For clarity, it has been defined as the gestational age of an infant at birth plus actual age from birth (Howard, Parmalee, Kopp & Littman, 1976).

#### Hypotheses

#### Phase 1 Hypotheses.

- 1. Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent liner will demonstrate lower incubator temperatures compared with those infants nursed in a cloth postural support nappy without an absorbent liner, when in an incubator on infant servo control.
- 2. Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent liner will demonstrate higher skin temperatures compared with those infants nursed in a cloth postural support nappy without an absorbent liner when in an incubator on infant servo control.

#### Phase 2 - Primary Hypotheses.

- Infants < 31 weeks gestation nursed prone with a postural support roll,
  either with or without a postural support nappy, will achieve higher shoulder
  dependent motor scores at four months conceptional age compared with infants
  < 31 weeks gestation nursed prone with a postural support nappy only.
- 2. Infants < 31 weeks gestation nursed prone with a postural support roll, either with or without a postural support nappy, will achieve higher combined shoulder and hip dependent motor scores at four and eight months conceptional age compared with infants nursed prone in a postural support nappy without a postural support roll.</p>

#### Phase 2 - Secondary Hypotheses.

- 1. At five weeks post intervention and term conceptional age, infants < 31 weeks gestation nursed prone with a postural support nappy and a postural support roll, will demonstrate a reduced area of the weight-bearing surface of the inner thigh and knee, a decreased angle of external rotation of the hip, and an increased angle of pelvic elevation compared with infants < 31 weeks gestation nursed prone with a postural support nappy only, or with a disposable nappy and a postural support roll.
- 2. At five weeks post intervention and term conceptional age, infants < 31 weeks gestation nursed prone with a postural support roll and either a disposable nappy or a postural support nappy, will demonstrate a lower scarf sign score, decreased shoulder retraction and increased spontaneous arm movements, compared with infants < 31 weeks gestation nursed prone in a postural support nappy without a postural support roll.
- 3. Infants < 31 weeks gestation nursed prone with a postural support roll and a postural support nappy will achieve a higher foot progression angle at eight months conceptional age, compared with infants nursed prone in a postural support nappy only, or, a postural support roll only.

#### Background and Significance

The challenge of nursing such fragile infants in an environment that is conducive to the normal development of all body systems is of great concern. Improved survival rates among smaller and more immature preterm infants, in association with increased use of technology and pharmacology, requires increasing nursing attention to the management of body positioning and thermoregulation to promote maximum development potential.

While there is sufficient physiological evidence to support nursing VLBW infants in the prone position, the associated short and longer term positional disorders remain a problem for these infants. Traditionally, priorities for the care of the preterm infant have primarily focused on short term physiological needs rather than longer term postural outcomes (Fay, 1988; Oehler, 1993; Perez-Woods et al., 1992; Turill, 1992).

Although neglected to date, a primary goal of preterm infant positioning is to improve the preterm infant's neuromotor status. There is limited nursing research on positioning and its effect on VLBW infants' motor development. There is a paucity of research to examine the short term effects of postural interventions on the development of *flattened* posture. In addition, no research has been conducted to examine the longer term effects of these or other postural interventions.

Nurses are in key positions for providing care that is both physiologically and developmentally focused to promote maximum development potential. The findings from this study will have implications not only for nurses, but for clinical practice generally, as the care of the VLBW infant involves a dedicated team approach. The interdisciplinary focus of this study will facilitate transfer of clinically meaningful knowledge between disciplines.

This initial chapter has provided the introduction, purpose, hypotheses, background, and significance of the study. The relevant literature is discussed in Chapter 2, the conceptual framework supporting this study is described in Chapter 3, methods and procedures are presented in Chapter 4, and data analysis and findings in Chapter 5. The discussion is presented in Chapter 6,

followed by conclusions, recommendations and implications in Chapter 7.

Summary of the Chapter and Organisation of Thesis

#### **CHAPTER 2**

#### Literature Review

A review of the published literature relating to thermoregulation in the very low birthweight (VLBW) infant is the first topic of interest to be discussed in this chapter. Specifically, it will include a description of the principles of thermoregulation, the effect of immaturity on heat loss and heat production in the VLBW infant, the neutral thermal environment, and practices used to prevent heat loss and facilitate temperature stability in these infants.

The second component of this chapter will include a review of the effects of preterm birth on body system development. As the most frequently reported disturbances to development in VLBW infants occur in the motor system, this review will specifically focus on: physiological homeostasis, motor development, body positioning practices, postural outcomes, interventions used to improve postural development, and instruments used to measure motor function in the VLBW infant.

The review will provide the background, theoretical and empirical support to show that: (a) temperature stability in VLBW infants is influenced by the relationship between the physiological limitations of prematurity and environmental influences, and (b) motor development in preterm infants is influenced by the relationship between neurological maturation, environmental influences, gravity and positioning practices during the first few weeks of life.

These factors form the theoretical basis that underpins the conceptual model guiding this study.

#### Section One

Thermoregulation is a critical aspect of care for every newborn infant, especially the VLBW infant who is particularly vulnerable to cooling (Cheng & Partridge, 1993; Hicks, 1987; Okken, 1991; Perlstein, 1995; Thomas, 1994). The need to keep the VLBW infant warm is well recognised and has created significant research interest in thermoregulation processes.

Hypothermia is the major temperature problem faced by this group of infants and is associated with an increased metabolic rate, hypoglycaemia, poor growth, poor weight gain, increased oxygen consumption and metabolic and respiratory acidosis (Brueggemeyer, 1995; Ducker, Lyon, Ross Russell, Bass, & McIntosh, 1985; Hurgoiu, 1992). Hyperthermia occurs less frequently, but is equally important because it is associated with an increase in apnoea and mortality (Cheng & Partridge, 1993; Hurgoiu, 1992; Perlstein, 1995; Roncoli & Medoff-Cooper, 1992).

Considerably more research has been undertaken in the area of VLBW temperature control than in other areas of concern for these infants (Roncoli & Medoff-Cooper, 1992). The rationale for this continued research interest is obvious in the clinical setting, where the maintenance of optimal temperatures in VLBW infants continues to be a challenging aspect of nursing care.

#### Principles of Thermoregulation

The principles of thermoregulation to be covered in this section include: intrauterine temperature regulation of the fetus, transition of the newborn infant to extrauterine life, hypothalamic temperature control, physiological development of temperature regulation, heat production, thermal regulation, hypothermia, hyperthermia, mechanisms of heat loss and heat gain in VLBW infants (i.e, convection, conduction, radiation and evaporation), the thermal neutral environment, and mechanisms used to provide thermoregulation for VLBW infants.

#### Intrauterine Temperature Regulation.

Prior to birth, the fetus is continuously surrounded by the warmth of the intrauterine environment where the ambient temperature is reported to be between 37.0°C and 37.9°C (Okken, 1991; Roncoli & Medoff-Cooper, 1992). The fetus continuously exchanges energy within the intrauterine environment, where its main source of energy intake is derived from the placenta in the form of glucose, amino acids, and lactate (i.e., substrate). In addition, the fetus takes heat energy from the intrauterine environment and, as a result of its own fetal metabolic processes, produces heat that is dissipated throughout the maternal body (Okken, 1991; Roncoli & Medoff-Cooper, 1992)].

The fetal metabolic rate is presumed to be similar to that of a *fed human*, as the fetus receives a continual supply of substrate from the placenta. The metabolic rate of the fetus, therefore, never reaches a fasting or basal rate and is assumed to be higher than that of the mother. Consequently, the average fetal body temperature can be 1.0°C higher than that of the mother, and is also higher than that of the newborn infant (Okken, 1991; Roncoli & Medoff-Cooper, 1992).

Thus, in normal physiological conditions, energy flows from the fetus to the intrauterine environment because the fetal body temperature is higher than the maternal body temperature (Roncoli & Medoff-Cooper, 1992). Rare events such as maternal fever may cause reversal of this temperature gradient.

It has been shown that in fetal sheep approximately 85% of total fetal heat production is exchanged via the placenta, and the remaining 15% through the fetal skin, amniotic fluid and uterine wall (Gilbert & Power, 1986). This suggests that heat loss is dependent predominantly on umbilical circulation. As a physiological model, the fetal sheep is likened to the human fetus; therefore, it is assumed that the human fetus undergoes a similar process of heat exchange with the mother (Gilbert & Power, 1986).

#### Transition to Extrauterine Life.

At birth, following removal from the thermal stability of the uterus, the umbilical circulation is cut off and the newborn infant is exposed to the extrauterine environment. Within this environment the newborn VLBW infant readily loses heat, predominantly via the skin because of exposure to frequent temperature changes in room air (Hammarlund, Sedin, & Stromberg, 1983). Heat loss from the skin occurs as a result of conduction, convection, radiation and evaporation (Brueggemeyer, 1995; Perlstein, 1995; Razi, Razi, & Zubrow, 1997). Physiological maturity enables the term born infant to cope with heat loss by self regulating body temperature. In contrast, the VLBW infant lacks the ability to respond to thermal challenges because of physiological immaturity (Okken, 1991; Thomas, 1994).

The intrauterine environment, therefore, is a stable source of heat control for the fetus who is not required to play a major role in thermoregulation. This is in direct contrast to the newborn infant, who, with increasing gestational and conceptional age becomes competent in self thermal regulation (Azaz et al., 1992; Perlstein, 1995). The critical differences in temperature regulation between full term infants and adults compared with VLBW infants require further explanation.

#### Hypothalamic Temperature Control.

Thermoregulation is under the direct control of the hypothalamus. Thermal stimuli provided by sensors located in the spinal cord, skin, and the perioptic area of the hypothalamus provide information to the posterior hypothalamus. The posterior hypothalamus processes this information that describes the thermal status throughout the body and compares it against the temperature *set point* (Okken, 1991; Thomas, 1994). Thomas (1994) defines *set point* as the controlled temperature within the thermoregulatory system that is clinically manifested as normal body temperature. This process results in modification of body heat and temperature through variations in metabolism, muscle tone and activity, vasomotor activity and sweating. The result of the process is either heat gain or heat loss (Thomas, 1994).

#### Physiological Development.

Unlike an adult or a full term infant, the preterm infant's ability to self regulate temperature is extremely limited (i.e., particularly in response to thermal stress). Thermoregulation occurs progressively in the VLBW infant (Cheng & Partridge, 1993; Hurgoiu, 1992; Sauer, Dane, & Visser, 1984; Sauer & Visser, 1984; Thomas, 1994; Wheldon & Hull, 1983).

The ability to self regulate body temperature first emerges in preterm infants at approximately 28 to 30 weeks gestation (Ducker et al., 1985; Perlstein, 1995; Thomas, 1994). Therefore, infants born at lower gestational ages are vulnerable and likely to develop known problems associated with hypothermia and hyperthermia (Brueggemeyer, 1995; Hurgoiu, 1992; Okken, 1991; Perlstein, 1995; Poland, 1995).

#### Heat Production.

As described by Okken (1991), the human body needs a continuous supply of energy because each biochemical reaction will either require or release energy. Most of the required energy is taken up by energy containing compounds (e.g., carbohydrates, fats and protein). The breakdown of these compounds results in heat production. The amount of heat produced by each cell is dependent upon its rate of metabolism. Therefore, variation in heat production between body organs can be explained by differences in metabolic rates.

Okken (1991) maintains the contribution of different organs and tissues to total body mass affects the distribution of heat production in different parts of the body. In adults the brain, liver and kidney together produce 60% to 70% of total body heat production. Conversely, in newborn infants the contribution of organs and tissues to total body mass is quite different: the contribution of the brain is six to seven times higher, and the liver two times higher than that of the adult. In contrast, Okken (1991) states that skeletal muscles in preterm infants contribute approximately half the amount of heat production that they do in adults. In newborn infants the contribution of the brain to heat production is extremely dominant, particularly in VLBW infants where the brain produces the majority of heat. This supports the assumption that with decreasing gestational age, localisation of heat producing body parts moves in the direction of the head.

Okken (1991) and Le Blanc (1991) maintain the rate of metabolism in VLBW infants at birth is initially at a minimum level that increases within the first few hours of life. Further increases occur during the first days and weeks of life due to energy intake. Newborn infants have higher metabolic rates than children or adults because their metabolism reflects the overall energy required to support growth, repair and maintenance. Body heat generated by body mass is lost over body surface area. It is well documented that infants' relatively large surface area compared with body mass ratio requires a higher caloric intake of up to 42% to support temperature balance (LeBlanc, 1991; Okken, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). The smaller the infant, therefore, the greater the imbalance between heat producing ability and heat loss. Posture can also significantly affect surface area and associated heat loss, and extended body posture can increase heat loss by as much as 35% when compared with the fetal position (Okken, 1991; Thomas, 1994).

#### Thermal Regulation.

Body temperature, like many other physiological variables in the human organism is precisely controlled (Thomas, 1991). Temperature is a measure of the balance between heat production and heat loss. A number of factors combine to create a state of thermoregulation where the body constantly maintains an optimal temperature, that is, the measure of the balance between heat gain and heat loss (Perlstein, 1995). When heat loss exceeds heat gain, the human body follows this basic law of physics and becomes cold. Therefore, when heat losses and heat gains are equal, body temperature remains stable.

#### Circadian Rhythm.

Current literature suggests that like adults, preterm infants develop circadian patterns in certain physiologic parameters (Miriman et al., 1990; Updike, Accurso, & Jones, 1985). Body temperature is one of the earliest biorhythms to appear, reflecting a developmental progression to a day/night diurnal pattern (Halberg, 1977). Of note, it has been shown that preterm infants exhibit a cyclic pattern of temperature between day and night periods (Miriman et al., 1990; Thomas, 1991; Updike et al., 1985). While the authors concur that further longitudinal studies of temperature biorhythm are required, their findings are of interest for two reasons. Firstly, the findings refute the belief that a preterm infant's physiologic activity is mostly a constant phenomenon. Secondly, the findings suggest that incubators may be operated in ways that consider the infant's emerging temperature related rhythmicity.

#### Hypothermia.

Birth is a hypothermic event and a newborn infant's temperature can fall as much as 4.5°C immediately after delivery (Roncoli & Medoff-Cooper, 1992; Thomas, 1994). It is not surprising that heat loss is the most frequently reported complication of the delivery and transport of newborn infants and is, therefore, a significant nursing concern (Perlstein, 1995; Roncoli & Medoff-Cooper, 1992; Thomas, 1991).

Full term infants and adults behave like homeotherms and are able to maintain a constant body temperature above that of the environment, despite fluctuations in environmental temperature (Okken, 1991). As Okken (1991) described, when a homeotherm senses a cold environment (i.e., manifested by a decrease in skin temperature), heat production and oxygen consumption increase to maintain body temperature around the normal *set point*.

Constriction of skin blood vessels then occurs, reducing blood flow to the skin. This action decreases skin temperature and reduces the temperature difference between the environment and the skin (i.e., the environment to skin temperature gradient). This temperature gradient is the driving force for heat flow from the organism to the environment (Okken, 1991; Roncoli & Medoff-Cooper, 1992).

As a newborn term infant becomes colder, oxygen consumption and the rate of metabolism can increase to a level three times greater than the basal metabolic rate (Roncoli & Medoff-Cooper, 1992). This increase results principally from non-shivering thermogenesis that utilises brown fat tissue metabolism (LeBlanc, 1991; Perlstein, 1995; Thomas, 1994). This source of metabolism consumes fuel substances, generates free fatty acids, and provides the primary source of heat production in the newborn infant.

In contrast to regular fat cells, brown fat cells have many fat vacuoles, an increased number of mitochondria, and increased glycogen stores (Thomas, 1994). In addition, the blood and sympathetic nerve supplies to these cells are abundant. As described by Thomas (1994), the overall effect of these unique characteristics is an enhanced responsiveness of brown fat tissue to thermal stimuli, and the rapid distribution of heat to other areas of the body.

Brown fat tissue is found in the scapular, axillary, adrenal, and mediastinal regions (Thomas, 1994). It rapidly increases cellular metabolic rates and oxygen consumption; thereby, generating heat and releasing substrates to be used in cellular metabolism. Brown fat cells have been identified at 26 to 28 weeks gestation and continue to multiply for as long as three to five weeks post term conceptional age (Roncoli & Medoff-Cooper, 1992; Thomas, 1994). In the term infant brown fat tissue accounts for 10% of adipose tissue.

Therefore, as purported by Thomas (1994) and Roncoli and Medoff-Cooper (1992), rates of brown fat metabolism and heat production are reduced in preterm infants and, furthermore, are minimal in the VLBW infant.

Another response made by term infants when experiencing heat loss is to change body posture (LeBlanc, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). The term infant will assume either the fetal or a more compact body position to reduce the surface area available for heat loss. In addition, when these infants become extremely cold they begin to shiver. The shivering action utilises muscle exertion to generate heat (Bruck, 1978; Thomas, 1994). LeBlanc (1991) indicates that as term infants become warmer, blood vessels in the skin dilate and increase the environment to skin temperature gradient, leading to increased heat loss. The infant responds by assuming a more extended posture. Extended posture increases the available surface area for heat loss and, subsequently, increases evaporative heat loss caused by sweating (LeBlanc, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994).

In contrast, VLBW infants are unable to maintain their body temperature at a level above that of the environment. It is has been frequently reported that these infants behave like poikilotherms when heat loss occurs (Mok et al., 1991; Okken, 1991; Perlstein, 1995). Consequently, their metabolic rate does not increase and they become colder as their temperature follows that of the cooler environment (Mok et al., 1991; Okken, 1991; Wheldon & Hull, 1983). In addition, heart, respiratory and physical rates may also decrease.

The use of strategies that safeguard these vulnerable infants from heat loss is of primary importance to nurses, because VLBW infants lack the ability to invoke automatic self protective measures against thermal stress.

Such infants are dependent on environmental temperature to maintain thermal stability until they reach term conceptional age (Okken, 1991; Thomas, 1994). It is thought that during the last trimester of pregnancy, the thermoregulatory system matures and is able to function adequately near to, or at the time of term birth (Okken, 1991).

Recent studies suggest that thermal regulation and the maintenance of neutral temperature is dependent more on gestational age at birth, than on birth weight (Sauer et al., 1984; Sauer & Visser, 1984; Wheldon & Hull, 1983). Neutral temperature is defined by Sauer and colleagues (1984) as "... the ambient temperature at which the core temperature of the infant at rest is between 36.7°C and 37.3°C, and the core and mean skin temperatures are changing less than 0.2°C and 0.3°C per hour respectively" (p. 19). The issue of neutral temperature will be discussed in more detail in subsequent paragraphs.

# Hyperthermia.

A preterm infant is predisposed to hyperthermia because of a large surface area to body mass ratio, limited insulation, and a limited or possibly absent sweating ability (Thomas, 1994; Wheldon & Hull, 1983). These infants respond to a cool environment by increasing heat production. Unfortunately, this leads to overheating because such infants are unable to reduce their basal metabolic rate through the action of sweating (i.e., the sole means of decreasing body heat in response to high environmental temperatures). As a result fluid loss occurs, and respiratory and metabolic rates may increase to potentially fatal levels (Thomas, 1994). Sweating is considered to be the only means of decreasing body heat in this situation. The ability to sweat increases with gestational age and is triggered when an infant's skin temperature reaches a level of 0.5°C less than core temperature (Okken, 1991; Thomas, 1994).

Immaturity, therefore, prevents preterm infants from mounting a sweating response. This evidence supports the theoretical assumption that thermoregulation is a progressive process that matures *in utero* to function adequately at the time of term birth. The evidence supports the view that VLBW infants are at particular risk because they are most likely to suffer heat loss.

# Mechanisms of Heat Loss and Heat Gain in VLBW Infants

As explained by Swyer (1978), heat loss in infants can be conceptualised as either the transfer of heat from the skin surface to the environment (i.e., external gradient) or, the transfer of heat from the body to the skin surface (i.e., internal gradient). There are four physical methods of heat loss and gain, and the VLBW infant is at risk for losing heat by each one of these methods.

#### Convection.

Convection is the transfer of heat from a solid surface to surrounding air or liquid (Roncoli & Medoff-Cooper, 1992). The greater the difference between the infant's skin temperature and surrounding air temperature, the greater the heat loss or gain. If the VLBW infant's skin temperature is higher than that of the surrounding air, heat loss will occur as the blood travels through the body to the thin skin surface where heat is given off to the environment. Convective heat losses also occur in the respiratory tract as air and heat are expired.

The VLBW infant is also vulnerable to convective heat loss due to a lack of external insulation (Roncoli & Medoff-Cooper, 1992; Thomas, 1994). Insulation can be classified as either internal or external. Internal insulation refers to body tissues that separate internal organs from the skin surface and includes the skin, musculoskeletal structures, and subcutaneous body tissues such as fat (Thomas, 1994). Thomas (1994) further explains that subcutaneous fat in particular, is a highly effective insulator and a poor conductor of heat.

The thickness of the subcutaneous fat layer contributes to its effectiveness. Subcutaneous fat appears at approximately 26 to 29 weeks gestation which means this layer can either be absent, or extremely thin in VLBW infants.

External insulation modifies the heat transfer at the body surface and consists of two forms (Roncoli & Medoff-Cooper, 1992; Thomas, 1994). The first is the very thin layer of air that surrounds the body. The thickness of this air layer (i.e., insulation) is inversely related to the diameter of the body or an extremity. Increased air flow reduces the air layer. The smaller the diameter, the thinner the air insulation layer (Thomas, 1994). As the diameters of VLBW infants' limbs are small and tissue insulation is minimal, they are at great risk and consideration should be given to nursery air flows and drafts. External insulation also reduces radiant and conductive heat transfer and can be provided for VLBW infants in the form of clothing and other coverings. Evaporative heat loss can also be reduced by trapping moist air near the body surface through the use of external insulation (i.e., in the form of clothing) (Thomas, 1994).

It is widely agreed that the large surface area to body mass ratio of the VLBW infant increases convective heat loss (Brueggemeyer, 1995; LeBlanc, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). The head of a VLBW infant is one of the major sources of heat loss, due to its large surface area and vascularisation, when compared with size. Heat loss can effectively be lessened by reducing the exposed surface area (i.e., placing a bonnet on the infant's head). Minimising air flow such as drafts created by ventilation systems, traffic and the opening and closing of doors associated with infant handling, can decrease convective heat loss (Mok et al., 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). As a reduction in the velocity of air flow lessens convective heat loss, it should be a primary aim of nursing care related to the VLBW infant.

Of interest, the concept of convection can also be used to promote heat gain in VLBW infants (Thomas, 1994). This is demonstrated by the routine use of convection incubators that rely on the continuous flow of warmed air. Again, caution must be used as the VLBW infant is unable to regulate heat gain and can easily become overheated.

#### Conduction.

Conduction is the transfer of heat from one solid object to another solid object by direct contact, and refers to heat flow between the infant's body surface and other solid surfaces (LeBlanc, 1991; Thomas, 1994). Thermal conductance, or the conductivity coefficient, is a measure of the ability of a surface to conduct heat; therefore, the higher the conductivity of a surface the greater the potential heat loss. According to LeBlanc (1991), the flow of heat is proportional to the temperature difference or gradient between the two objects and the thermal conductance of the solid surface upon which the infant is in contact. Conductive heat loss from metal can be considerably greater when compared with plastic and wood.

Thomas (1994) explains that conductive heat loss is also influenced by the size of an infant's surface area in contact with a solid surface (e.g., when nursed in the supine position approximately 10% of an infant's surface area is in contact with the mattress). An example of conductive heat loss that occurs frequently in VLBW infants is the cooling of infant's skin when handled by carers during procedures such as nappy changing and medical examinations (Mok et al., 1991; Thomas, 1994).

Conduction contributes little to heat gain in VLBW infants. Surfaces that are covered with prewarmed linen will prevent heat loss, but are not efficient in providing heat. Although prewarmed surfaces may prevent heat loss, they should be used with caution because the skin of VLBW infants is extremely permeable and at increased risk for burns (Brueggemeyer, 1995).

### Radiation.

Radiation is the transfer of heat from solid surfaces that have no direct contact. Heat energy is transferred by electromagnetic infra-red wavelengths from an object of higher temperature (e.g., an infant), to a an object of cooler temperature (e.g., the cool inner wall of an incubator) (LeBlanc, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994).

Heat loss by radiation can be affected by emissivity (i.e., the power of an object to emit heat by radiation). Emissivity in humans is similar to the radiant capability of a black surface that reflects little radiant heat (Thomas, 1994). Emissivity of the skin in VLBW infants is reported by Baumgart (1986) to be relatively constant. As a general rule, methods of reducing heat loss by radiation, such as the use of clothing and blankets, is of prime importance in nursing care.

The temperature gradient present between two solid surfaces ultimately controls the rate of radiant heat transfer (LeBlanc, 1991; Thomas, 1994).

Typically, the VLBW infant's skin temperature is greater than the surrounding surfaces; therefore, the direction of heat transfer is from infant to these surrounding surfaces. Conversely, heat gain will occur when a radiant heat source is warmer than an infant's skin temperature (Thomas, 1994).

It is well reported that the size of an infant's body surface area can also directly affect radiant heat loss (LeBlanc, 1991; Perlstein, 1995; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). The large surface area to body mass ratio of the VLBW infant potentiates radiant heat loss. In comparison to the infant's large surface area, surrounding surfaces such as incubator walls are much larger in size. Potentially, this contributes to even greater rates of heat loss (e.g., when a VLBW infant is lying supine the surface area of the incubator wall directly above and to the side of the infant accounts for a total of 47% of all radiant heat loss) (Thomas, 1994).

The distance between the solid surfaces is also a contributing radiant heat loss factor because the closer two surfaces, the greater the heat loss (Thomas, 1994). This is an important consideration in radiant heat loss and gain. Ambient air temperature does not affect radiant temperature.

As described by Thomas (1994), radiant temperature in a nursery is generally lower than air temperature unless a radiant temperature source is present (e.g., sunlight or radiant overhead warmers). These radiant temperature sources create temperatures that are higher than the nursery air temperature (e.g., when exposed to sunlight the plexiglass of the incubator walls can transmit almost 100% of the sun's short wave radiation which will in turn heat the infant). Conversely, almost none of the infant's long wave radiation is transmitted through the plexiglass; therefore, there is great potential for overheating and caution must be exercised by not exposing the incubators to sunlight (Thomas, 1994). This problem is also observed when phototherapy units or heat lamps are used with incubators. Again, because air temperature is not a measure of radiant temperature, the temperature within the incubator will not accurately reflect the degree of infant heating.

### Evaporation.

Evaporation is the transfer of heat through energy used in the conversion of water to its gaseous state (Thomas, 1994). Evaporative heat loss may occur in two forms. Insensible loss occurs from evaporation of water from the skin or respiratory tract; whereas, sensible loss occurs from sweating. Hammarlund and colleagues (1983) reported that evaporative heat loss is the principal form of heat loss in small preterm infants, and accounts for most of the differences in temperature requirements between VLBW and term infants.

Evaporative heat loss in infants is exponentially related to gestational age during the first four weeks of life, with highest losses recorded in preterm infants (Doty, McCormack, & Seagrave, 1994; Hammarlund et al., 1983; Sauer et al., 1984). Evaporative heat loss is significantly related to the degree of keratinisation of the epidermal stratum corneum (Doty et al., 1994). Keratin forms a layer of tough fibrous protein that protects the underlying epithelium and is relatively impermeable to water (Doty et al., 1994; Thomas, 1994). The formation of keratin is directly related to gestational age, thus placing the VLBW infant at risk because keratinisation begins at 21 weeks gestation and steadily increases in thickness from 24 weeks gestation to term conceptional age. This growth occurs at the same rate in the postnatal period as in the antenatal period (Doty et al., 1994; Hammarlund et al., 1983; Thomas, 1994).

Thus, in VLBW infants body water readily diffuses across the extremely permeable skin layer that lacks keratinisation. The underdeveloped stratum corneum, therefore, contributes to the magnitude of heat and water loss in VLBW infants.

Insensible water loss through the skin is known as transepidermal water loss (TEWL). In VLBW infants TEWL is three to five times higher than in infants born after 31 to 32 weeks gestation. Heat loss that occurs as a result of TEWL in VLBW infants can be equal to, or even higher, than total heat production (Hammarlund et al., 1983; Sauer & Visser, 1984; Thomas, 1994).

Transepidermal heat loss gradually decreases after birth in preterm infants (Brueggemeyer, 1995; Hammarlund et al., 1983).

Evaporative heat loss also occurs as a result of a VLBW infant's exposure to radiant heat. This heat loss, therefore, must be buffered by the use of plexiglass heat shields or plastic blankets (Brueggemeyer, 1995; Roncoli & Medoff-Cooper, 1992; Thomas, 1994).

As with other forms of heat loss, the VLBW infant's large surface area to body mass ratio increases the area of skin susceptible to evaporative heat loss (Doty et al., 1994; Hammarlund et al., 1983; Sauer et al., 1984). Evaporative heat loss is also affected by air vapour pressure, and the greater the ambient air pressure, the less the evaporative heat loss. As temperature and evaporation are directly related, increases in temperature decrease vapour pressure and increase evaporation. Warm air temperatures are associated with heat loss in these infants (Thomas, 1994). The use of humidity increases vapour pressure and decreases evaporative heat loss. Like convective heat loss, the speed and turbulence of air flow potentiates evaporative heat loss (Thomas, 1994). It has been reported that opening of incubator doors, especially in a non humidified incubator environment, can cause significant heat loss through evaporation (Mok et al., 1991).

The most significant cause of evaporative heat loss in VLBW infants is the evaporation of water or urine from the skin (Graham, 1992; Thomas, 1994).

Therefore, skin that is kept moist from wet or damp nappies will contribute to this mechanism of heat loss and lead to fluctuations in temperature. Razi and colleagues (1997) investigated evaporative loss of urine from nappies in premature infants and found that evaporation of urine from nappies was rapid, significant, and could influence hydration requirements of these infants.

Anecdotal evidence suggests that use of disposable nappies reduces temperature instability (Graham, 1992). Attempts to create a more thermally stable environment have led to the widespread use of disposable nappies in place of traditional cloth nappies. The reported benefits of disposable nappies in the maintenance of temperature remain unsubstantiated by empirical research. Furthermore, because of the bulky shape of these nappies, they appear to exaggerate the adverse postural effects seen in VLBW infants described as flattened posture (Graham, 1992). Flattened posture will be discussed in detail in the second section of this literature review. It is apparent that guidelines are required for the use of nappies that ensure optimal temperature maintenance, while providing postural support.

#### The Thermal Neutral Environment.

Transitional events that occur in VLBW infants following birth and the physiological adaptations that occur in the neonatal period have been described. These infants require an environment where heat loss and heat gain can be maintained at an equal level. The provision of this environment by informed nursing care is a primary issue because it is associated with improved morbidity and mortality outcomes. To achieve a neutral temperature in VLBW infants, a neutral thermal environment that balances thermoregulating mechanisms is required (Sauer et al., 1984).

Normal body temperature (i.e., neutral temperature) of infants has been empirically examined and defined by several authors. Unfortunately, this definition cannot be applied to VLBW infants because of their inability to produce heat in response to cooling, and their increased TEWL. Sauer and colleagues (1984) provide the only meaningful definition of neutral temperature for VLBW infants, postulating that a neutral thermal temperature is present when core temperature is between 36.7°C and 37.3°C at rest, and that core and mean skin temperatures change less than 0.2°C and 0.3°C per hour respectively. At this temperature the metabolic rate is at a minimum and temperature regulation is achieved by non-evaporative physical processes (Sauer & Visser, 1984).

## Mechanisms that Contribute to Thermoregulation.

Radiant warmers and incubators are the most important heating systems currently used to provide a neutral thermal environment. Other methods that contribute to a neutral thermal environment (e.g., plexiglass shields, clothing and reduction of air flow) have been previously discussed.

The decision to use either radiant warmers or incubators is dependent on individual NICU guidelines (Brueggemeyer, 1995; LeBlanc, 1991; Roncoli & Medoff-Cooper, 1992; Thomas, 1994). Convection, radiation and evaporative heat losses are high in VLBW infants nursed under radiant warmers; therefore, other methods of heat loss prevention should be incorporated into the care of these infants when placed on radiant warmers (Brueggemeyer, 1995).

Incubators protect against conductive and convective heat losses.

Incubators are heated either by radiation or convection, with heater and humidification systems located beneath the infant compartment (Nobel, 1991).

Additional humidified air is often used within incubators to reduce evaporative heat loss in VLBW infants (LeBlanc, 1991).

Incubators are equipped for two modes of operation: air temperature control or infant servo control (Ducker et al., 1985; LeBlanc, 1991; Nobel, 1991; Wheldon & Hull, 1983). Air temperature control enables the operator to set a desired inner incubator temperature that can be manually altered according to changes in infant body temperature. The infant servo control (ISC) mode functions as an automatic feedback mechanism where the operator sets a predetermined skin temperature. A temperature sensor that is taped to the infant's skin constantly measures skin temperature. The incubator heater responds to changes in skin temperature to maintain the predetermined skin temperature. Another feature of incubators is the use of double inner plexiglass walls. Conventional incubators are manufactured as single walled units (LeBlanc, 1991). Use of a second wall provides a warmed air space that is thought to reduce radiant heat loss.

In the setting for the present study, VLBW infants are routinely nursed on a radiant warmer until their initial condition stabilises. Stabilisation usually occurs within 24 to 48 hours following which infants are nursed in a double-walled incubator. Incubator temperatures greater than 32.0°C are considered to be *high* and indicative of an infant's requirement for additional thermoregulatory support to maintain a stable normal skin temperature. Infants are removed from the incubator when their thermoregulatory abilities have matured and they can maintain a neutral temperature in an open cot. Clinical experience has shown this occurs at approximately 32 weeks conceptional age when the majority of infants maintain constant incubator temperatures below 32.0°C. At this stage (i.e., in the study setting) infants are deemed to have developed a mature thermoregulatory system and are able to maintain normal skin temperatures between 36.5°C - 37.0°C in room air.

## Summary of Section One

It is apparent from the literature discussed that thermoregulation is a significant problem for the VLBW infant. The development of self temperature regulation is progressive and dependent on increasing gestational age. As VLBW infants behave like poikilotherms, maintenance of neutral thermal temperature in these infants is dependent upon the ability of the physical environment to provide a balance between heat loss and heat gain. The provision of a neutral thermal environment is a major concern for neonatal nurses. Advances in technology have led to significant improvements in the manufacture of radiant warmers and incubators that stand alone as the major heat producing sources used in the care of these infants.

Despite these technological advances, constraints faced by VLBW infants because of physical immaturity make them highly susceptible to four major mechanisms of heat loss. Heat loss from conduction is minimal and considered by many as inconsequential. Heat loss from convection and radiation is also minimal. Evaporation, however, accounts for the major source of heat loss in VLBW infants. The majority of this heat loss results from the evaporation of urine from wet nappies. In addition to the significant increase in evaporative heat loss caused by wet nappies, an underestimation of urine output can also occur. This can lead to decisions to increase hydration of infants. The over hydration of infants can lead to a number of undesirable consequences.

Attempts by nurses to create a more thermally stable environment have led to widespread use of disposable nappies in place of traditional cloth nappies. It is thought that disposable nappies improve temperature stability by reducing evaporative heat loss.

These claims are unsubstantiated by empirical research; and furthermore, the bulky shape of disposable nappies may contribute to undesirable effects on the infant's posture described as *flattened* posture.

Monterosso and colleagues (1995) showed that a cloth postural support nappy reduced the features of *flattened* posture at the time of hospital discharge in very low birthweight infants. Use of the nappy was then implemented as routine nursing protocol in the NICU of the study hospital. Anecdotal evidence suggested, however, that infants experienced temperature fluctuations as a result of evaporative heat loss from wet cloth nappies.

This nursing problem provided the rationale for Phase 1 of the present study that tested the use of a cloth postural support nappy in conjunction with a inner absorbent nappy liner (i.e., containing absorbent gelling material similar to that found in the majority of disposable nappies used in NICUs worldwide). In combination, these interventions were designed to meet both temperature and postural needs of VLBW infants.

This section of the literature review has provided substantial evidence to support use of the interventions tested in Phase 1 of this study.

#### Section Two

This section specifically explores neuromotor development and its relationship with postural abnormalities in VLBW infants. The following issues are described: physiological homeostasis, neuromotor development, developmental outcomes, emergence of prone positioning, associated physiological benefits and complications of prone positioning (i.e., *flattened* posture), interventions used to minimise or prevent short and longer term effects of *flattened* posture, and measurement tools used for assessment of neuromotor development and function.

### Physiological Homeostasis

Physiological homeostasis is a prerequisite for the healthy development of all body systems in the fetus and contributes to regulation of behavioural states, activity levels, and organisation (Bregman & Kimberlin, 1993). A disruption of one system may cause disruptions in other systems. In the containing environment of the uterus, homeostasis in the fetus is maintained as it develops into a mature infant. Since VLBW infants are physiologically and neurologically immature, they are at particular risk following admission to a stressful NICU because homeostasis is challenged, and the infant is incapable of effective responses to the demands of life in an extrauterine environment.

At this critical time of development, the VLBW infant has minimal autonomic control and is unable to breathe spontaneously because of central nervous system immaturity (Bregman & Kimberlin, 1993). Consequently, VLBW infants experience alterations in timing and intensity of signals to respiratory neurones that result in an inconsistent respiratory drive. This leads to an increased risk of apnoea (Blackburn, 1992).

These irregularities of the respiratory system can lead to hypotension that can cause injury to the periventricular white matter (i.e., periventricular leukomalacia). Hypotension can place the VLBW infant at risk for fluctuations in cerebral blood flow that can lead to damage of developing parts of the central nervous system, particularly those adjacent to the ventricular system where most neural growth is occurring (Burns, 1980; Skidmore, Rivers, & Hack, 1990).

Decreases in systemic blood pressure can also occur in these infants as a result of conditions such as perinatal asphyxia, infection, patent ductus arteriosus, apnoea, bradycardia and procedures requiring handling of infants (Bregman & Kimberlin, 1993). Alterations in blood flow and oxygenation, therefore, vary in response to an infant's gestational maturity and internal and/or external environments.

Nutrition also plays a vital role in the delicate balance of homeostasis (Bregman & Kimberlin, 1993). Following cessation of the placental nutrient supply, the preterm infant is challenged by the need to digest, absorb and metabolise nutrients through an immature gastrointestinal system. Apart from the effect this has on growth, system development is also affected. The brain undergoes rapid growth and development from 28 weeks gestation, and during this time is susceptible to injury from high levels of phenylalinine, malnutrition, amino acid imbalance and hypothyroidism.

An additional problem related to nutrition can occur in VLBW infants after birth as a result of stress, often experienced by these infants in response to handling. Stress increases the risk of hyperglycaemia by stimulating the release of catecholamines (Amspacher, 1992). This can result in the release of glucagon that will interfere with the action of insulin, leading to hyperglycaemia and poor growth in VLBW infants (Amspacher, 1992).

In summary, the last trimester of pregnancy (i.e., from 28 weeks gestation) is a critical time for brain maturation as the brain undergoes very rapid neural growth and an increase in size (Brown, 1974; Burns, 1980; Palmer, Dubowitz, Verghote, & Dubowitz, 1982; Piper, Kunos, Willis, & Mazer, 1985). Nervous system development and maturation are highly dependent on adequate perfusion and nutrition. A state of physiological stability and homeostasis promotes optimal neurological development and is dependent upon the following conditions: sustained and regular respiration, a stable nutritional status, and a non fluctuating systemic and cerebral blood flow. Physiological instability, in addition to the stress encountered in the NICU, places the VLBW infant at high risk for both minor and major neurological problems.

### Neuromotor Development

Development in the preterm infant is a continuous and dynamic process that is influenced by environmental and genetic factors. Neuromotor development and function during the first year of life is closely linked with maturation of the central nervous system. For the purpose of this literature review, neuromotor development has been defined as the early development of neonatal neurological systems as evidenced by the appearance of normal developmental patterns (Schultz, 1992).

Principles of neuromotor development will be described to highlight differences in motor function between preterm and term infants. These principles are derived from both the neuromaturational and systems theories of motor development, active and passive muscle tone, and correction for gestational age at birth (i.e., conceptional age).

### Theories of Motor Development.

Normal motor development evolves in a predictable fashion. In relation to VLBW infants this raises the question of how motor skills evolve, and what factors influence the rate, pattern, sequence and quality of movement. To address these issues, two theories of motor development will be examined. These theories have been selected because they underpin the theoretical framework of this study.

The neuromaturational theory, the traditional model for motor development, was first advocated by Gesell and Amatruda (1945) and McGraw (1945). This theory provides the framework for many current treatment techniques used in physical and occupational therapies. The neuromaturational theory is characterised by the assumption that development follows a similar progression, whether an infant is in a uterine or extrauterine environment, and proceeds as a function of time since conception. Therefore, development of the central nervous system is dependent solely on processes that are pre-determined in the cerebral cortex, and the progression of motor development should be unaffected by gestational age at birth or the influence of the extrauterine environment (Piper et al., 1989). This hypothesis has been supported by studies that reported sensory, motor, and general developmental progress of preterm infants as comparable to that of term infants (Parmelee & Shulte, 1970; Schulte, Stennert, Wulbrand, Eichorn, & Lenard, 1977).

Touwen (1980), however, reported that environmental influences affect neurological development and contribute to variability of neurological functioning.

Several authors have concurred with Touwen (1980), reporting variations in development of tone, postural reactions, motor milestones, primitive reflexes, and oral development in preterm infants when compared with term infants (Bennett, 1990; Bennett & Scott, 1997; Burns, Gray, & O'Callaghan, 1997; de Groot et al., 1995; Dunn, Crichton, & Grunau, 1980; Hack et al., 1995; Hoy, Bill, & Sykes, 1988; Palmer et al., 1982; Ungerer & Sigman, 1983; Vohr & Msall, 1997). Extrauterine stimulation during the last phase of intrauterine life has been described as both accelerating development, or, resulting in over stimulation that may in turn lead to delayed development (Forslund & Bjerre, 1985; Piper et al., 1985; Touwen, 1980). A low birthweight in combination with prematurity, has been shown to be associated with problems in motor development (de Groot et al., 1995; Hadders-Algra et al., 1988; Piper et al., 1989). In addition, the varying length of exposure to the extrauterine environment may affect motor development by either delaying or enhancing particular aspects of development (Parmelee, 1975; Piper et al., 1989).

Studies documenting the influence of the environment on neuromotor development have raised the question of whether the neuromaturational theory adequately describes neuromotor development in VLBW infants. In view of this information, the systems theory of motor development has been proposed as a more useful theoretical basis with which to examine neuromotor development in VLBW infants.

Systems theory originated from theories of physics, chemistry and mathematics (Piper & Darrah, 1994). Researchers observed that when elements of a system work together, behaviours or properties emerged that were dependent on all factors contributing to the system, and could not be predicted from separate elements (Piper & Darrah, 1994).

This model was applied to motor development by Bernstein (1967) who postulated that the brain controls muscle groups rather than individual units, and that groups of muscle, bones and tendons can regulate muscle behaviour without instructions from the cerebral cortex. In contrast to the neuromaturational theory that recognises only the influence of the cerebral cortex, the systems motor theory takes into consideration the influence of all factors essential to the function of the motor system, including the environment (Piper & Darrah, 1994). It is hypothesised that the motor system is a cooperative unit where all factors contributing to the system are important and able to influence outcomes (Piper & Darrah, 1994). The systems motor theory is judged to be a more fully specified theory that allows testing of care interventions. A shortcoming of systems motor theory, however, is that it does not predict developmental outcome in the way that the neuromaturational theory does, because of the number of variables that can potentially affect development.

Strengths and weaknesses are evident in both models. The neuromaturational model provides a description of the sequence for motor development, but does not provide a theoretical basis for care interventions. In contrast, systems theory considers the influence of all factors, including the central nervous system, on motor development. Use of systems theory encourages clinicians to broaden their treatment and intervention strategies. Systems theory does not, however, predict the emergence of motor milestones in development since appearance of these so called milestones is considered by systems theory to be related to multiple factors. In light of this evidence it was appropriate to use both theories of neuromotor development to guide Phase 2 of this study.

## Correction for Gestational Age at Birth.

Given the general acceptance that neurological maturation occurs at a predetermined rate as a function of time since conception, rather than gestational age at birth, conceptional age is most often used for the first two years of a preterm infant's life when comparing preterm and term infants (Gesell & Amatruda, 1945; Miller, Dubowitz, & Palmer, 1984; Saint-Anne Dargassies, 1979). Corrected age, or as previously described, conceptional age is defined as the gestational age of an infant at birth plus actual age from birth (Howard, Parmelee, Kopp, & Littman, 1976). Use of conceptional age allows for the disadvantage of biological immaturity and the separation of developmental delay associated with prematurity from that caused by neurological damage (Miller et al., 1984). Several studies have supported use of conceptional age when assessing motor development by demonstrating a greater correspondence between preterm and term infant motor development (Forslund & Bjerre, 1985).

In contrast, it has been suggested that use of age correction for prematurity cannot address the complexities associated with documenting preterm development, because there are facets of preterm development that do not run a parallel course to development in term infants (DiPietro & Allen, 1991; Miller et al., 1984). This claim is underpinned by the rationale that, not only are preterm infants born early, they are placed in an environment they have never experienced and to which they are poorly adapted. These authors suggest, therefore, that individual activity and reactivity of the nervous system in relation to neuromotor development may differ (DiPietro & Allen, 1991; Miller et al., 1984).

More recent studies, however, report differences between preterm and term infants related to muscle power and function of both upper and lower extremities when using conceptional ages up to 52 weeks (de Groot et al., 1995; de Groot, de Groot, & Hopkins, 1996). In view of this recent evidence, conceptional age was used when measuring the infants in this study.

#### Active and Passive Muscle Tone.

The impact of early birth on the neuromotor development of preterm infants, therefore, remains unclear. There has been consistent reporting of discrepancies between active and passive muscle tone in preterm infants, particularly those of lower gestation, leading to deviations in motor behaviour patterns. Muscle tone in such infants has been described as a state of contraction of the skeletal muscles, that maintains an infant in a particular antigravity posture and causes return to this posture if it is passively changed (Brown, 1974).

From a clinical perspective passive muscle tone is identified as one element of muscle power, the other being active muscle tone (de Groot, 1993). Total muscle capacity increases with age in a caudocephalic direction (Amiel-Tison, 1987; Hunter, 1996).

In the preterm infant, muscle tone evolves from a state of global hypotonia of the axis (i.e., a line through the centre of the body) and extremities at 28 weeks gestation, to hypertonia and the beginning of flexion in the lower extremities at 30 weeks gestation. Flexion in the lower extremities strengthens by 32 weeks gestation until hip flexion occurs at 34 weeks gestation, with the beginning of flexor tone in the upper extremities. At 36 weeks gestation flexor tone dominates in the trunk and extremities.

At 40 weeks gestation the flexor (i.e., anterior) muscles and extensor (i.e., posterior) muscles have equalised and the upper and lower extremities are held in flexion (Hunter, 1996). In summary, muscle tone increases in a caudocephalic direction with the flexor muscles developing slightly later than the extensor muscles until they equalise at 40 weeks gestation.

Passive tone can be observed by the application of particular movements to an infant who remains passive and at rest. The degree of muscle tone can be measured by estimating the angle a joint or body part makes with a consistent reference point such as a specific anatomical landmark (Amiel-Tison, 1987). Alternately, passive tone can be evaluated as the amplitude of movement of a single joint.

In contrast, active tone is the infant's ability to respond to active motor demands and is evaluated by the degree of vigour expressed in spontaneous movements (Amiel-Tison, 1987). Active muscle tone can also be evaluated by judging an infant's response to a particular manoeuvre. As described by Amiel-Tison (1987), utilisation of these two forms of assessment enables judgement of both activity (i.e., spontaneous movements) and reactivity (i.e., infant reactions) of the nervous system.

In summary, development of posture and motility in newborn infants requires an optimal balance between active and passive muscle tone.

# Preterm Infant Developmental Outcomes.

The majority of VLBW infants have normal developmental outcomes, although as a group they experience more sub-optimal growth patterns, illnesses and neurodevelopmental problems than term born infants (Bennett & Scott, 1997; Hack et al., 1995). It is purported that the rate of these problems increases as gestational age at birth decreases (Bennett & Scott, 1997; Hack et al., 1995).

Other biological factors contributing to risks associated with low birthweight include: birth defects, birth asphyxia, and neonatal complications of prematurity (i.e., periventricular haemorrhage, chronic lung disease, seizures, hypoglycaemia, and jaundice). In addition, there is evidence that male infants are at higher risk than female infants (Bennett & Scott, 1997; Hack et al., 1995). Physiological problems that affect these infants include anaemia of prematurity, retrolental fibroplasia, umbilical and inguinal hernias, chronic pulmonary and gastrointestinal problems (e.g., asthma, bronchiolitis and subnormal weight). From a neurodevelopmental perspective major impairments include: cerebral palsy, mental retardation, sensorineural hearing loss, and visual impairment resulting from retrolental fibroplasia (Bennett & Scott, 1997). Minor neurodevelopmental problems include: mild problems in cognition, attention, and neuromotor functioning.

Phase 2 of this study focused on minor problems of neuromotor functioning related to postural abnormalities of the upper and lower extremities. These postural abnormalities will be examined in the following section.

#### Postural Abnormalities.

In the liquid milieu of uterine environment the effect of gravity on the fetus is minimal. In the extrauterine environment, the VLBW infant has inadequate muscle development and is unable to counteract the forces of gravity as it lies statically on a firm mattress. In addition, general hypotonia and the positions used to nurse infants can restrict mobility (Touwen & Hadders-Algra, 1983).

It has been shown that restricted mobility in association with prone or supine positioning, can result in transient abnormalities of muscle tone that can affect neurologically normal preterm infants (Georgieff et al., 1983; Hack, 1983; Touwen, 1983; de Groot, 1993).

Due to the inability of a preterm infant to correct postural imbalances, muscle imbalances can develop due largely to a more favourable environment being provided for extensor muscles compared with flexor muscles. In addition, the caudocephalic development of muscle tone is affected by the reduction in flexor tone in the lower extremities and a higher active muscle tone in the extensor muscles of the trunk (Touwen, 1983; Bregman & Kimberlin, 1993; de Groot et al., 1995; Piper et al., 1989; Palmer et al., 1982). This can lead to a dominance of trunk extensor activity compared with trunk flexor activity, resulting in extension of the spine with associated scapular retraction produced by elevation and adduction of the scapula induced by positioning routines.

Scapular retraction is associated with hyperextension of the neck and trunk and abduction of the shoulders (Georgieff & Bernbaum, 1986; de Groot et al., 1995; Touwen & Hadders-Algra, 1983). In the lower trunk, external rotation and wide abduction of the hips occurs with a lack of pelvic elevation (Grenier, 1988; Davis et al., 1993; Downs et al., 1991; Monterosso et al., 1995).

These abnormalities should not be regarded as an early sign of neurological impairment in the absence of other neurological symptoms. The next section will explore the rationale supporting current positioning practices in NICUs.

# Physiological Effects of Positioning

# Emergence of Prone Positioning.

For many years the supine position was exclusively used to position preterm infants because it allowed for easy access and observation (Schwartz, Fenner & Wolfsdorf, 1975; Lioy & Manginello, 1987; Wagaman et al., 1979). In response to adult studies that showed an association between position changes and altered respiratory function, the practice of supine positioning was questioned and similar studies were conducted in preterm infants to determine the optimal nursing position (Attinger, Monroe, & Segal, 1956). Many of these studies produced findings that favoured the prone position over the supine position (Table 2.1), and the prone position over supine and lateral positions (Table 2.2). These findings were instrumental in changing positioning practices in NICUs. The prone position is now routinely used worldwide when nursing VLBW infants.

#### Physiological Effects of Positioning.

As shown in Tables 2.1 and 2.2, early studies examined the effect of prone versus supine positioning on respiratory function. More recent studies extended this work by examining the effect of prone positioning compared with supine and lateral positioning in infants on other physiological effects, in addition to respiratory function. Various infant populations have been used, however, for the purpose of this review only studies that focused specifically on preterm infants have been examined and are outlined in Tables 2.1 and 2.2. Several critical findings have emerged.

Studies Related to Physiological Effects of Prone Versus Supine Positioning in Preterm Infants

Table 2.1

Author (Year)	Design	Measures	Findings	Limitations
	Sample ( <u>n</u> )			
Kravitz, Elegant,	Randomised	· respiratory rate	· increased rate of respiration	· limited period of
Block, Babkitis &	crossover.	· respiration amplitude	in prone position	measurement
Lundeen (1958).	Healthy preterm		greater respiratory rate	· ages not given
	infants (119).		irregularity and amplitude in	· visual counting of
			supine position	respirations
Schwartz, Fenner	Crossover.	· respiratory rate	· higher expired PaCO <sub>2</sub>	small sample size
& Wolfsdorf	Healthy low birth	· arterial pH, PaO <sub>2</sub> ,	(p<0.05), lower expired PaO <sub>2</sub>	· no randomisation
(1975).	weight infants (10).	PaCO <sub>2</sub>	(p<0.05) in prone	· GA not reported
Sconyers,	Randomised	· respiratory and heart	· lower respiratory rate in	· no demographic details
Ogden, &	crossover. Infants	rate in either elevated	elevated or flat variation of prone	· no gestational or actual
Goldberg (1987).	with respiratory	(30°) or flat variations of	position	age of infants given
	distress (17).	position		
Martin, Herrell,	Randomised	· PaO <sub>2</sub>	· increased PaO <sub>2</sub> (p<0.001) and	<ul> <li>quiet sleep may have</li> </ul>
Rubin & Fanaroff	crossover. Healthy	· chest wall movement	decreased chest wall asynchrony	influenced findings
(1979).	preterm infants (16).		(p<0.02) in prone position	

Table 2.1 (continued)

Wagaman et al.	Randomised	· lung compliance	· increased PaO <sub>2</sub> , lung	prone positions used not
(1979).	crossover. Preterm	· PaO <sub>2</sub>	compliance and tidal volume	clinically practical
	ventilated infants	· tidal volume	(p<0.05) in two variants of prone	· monitoring time not
	(14).		position	reported
Masterson,	Randomised	energy expenditure	· decreased energy	· metabolic rate of LBW
Zucker, &	crossover. Healthy	· behaviour	expenditure of 2.6 kcal/kg/day	infants higher during physical
Schulze (1987).	preterm infants (42).		(p<0.001), increased quiet sleep	activity
			time (p<0.001), and decreased	· changes in posture
			time spent awake (p<0.001) in	affect surface area and may
			prone	account for metabolic rate
				differences
Lioy &	Crossover.	· PaO <sub>2</sub>	· increased PaO <sub>2</sub>	· no randomisation
Manginello	Preterm infants	· end tidal CO <sub>2</sub>	(p<0.00001) and decreased end	· ages not reported
(1988).	recovering from	· respiratory rate	tidal PaCO <sub>2</sub> (p<0.00001) in the	
	respiratory distress		immediate post extubation period	
	(18).		in prone position	

Table 2.1 (continued)

Fox & Molesky,	Randomised	· PaO <sub>2</sub>	· higher PaO <sub>2</sub> (p=0.005) in	· infants nursed
(1990).	crossover. Preterm		prone position	on water beds that placed
	ventilated infants			less pressure on abdomen
	(25).			
Baird, Paton, &	Crossover. Preterm	· oxygenation	· higher transcutaneous	· no randomisation
Fisher (1991).	infants needing	sleep time	PaO <sub>2</sub> (p<0.05) and time spent	· ages not reported
	ventilator or		asleep (p<0.05) in prone position	
	headbox O <sub>2</sub> (14			
	studies of 7 infants).			
Mendoza,	Randomised	· pulmonary function	·increased oxygen	
Roberts, &	crossover. Preterm	· heart rate	saturation ( <u>p</u> =0.002), decreased	
Cook (1991).	ventilated infants		heart rate (p=0.03) and	
	(33).		pulmonary resistance (p=0.003)	
			in prone position	
Heimler,	Randomised	· breathing patterns	· decreased apnoea ( <u>p</u> =0.01)	
Langlois, Hodel,	crossover. Preterm		and periodic breathing (p=0.015)	
Nelin, &	infants with clinical		in prone position	
Sasidharan	apnoea (14).			
(1992).				

Table 2.1 (continued)

	Landollised	paintolial y lanction		
Greenspan,	crossover. Preterm		wall synchrony (p<0.05) and	
Deoras, Allen, & infants recovering	infants recovering		chest wall distortion (p<0.001) in	
Schaffer (1992).   from respiratory	from respiratory		prone position	
	distress (24).			
Kurlak,	Randomised	· incidence and type	· mixed apnoea accounted for	
Ruggins, &	crossover.	of apnoea	65% of all apnoea less central	
Stephenson	Preterm infants		(p=0.025) and mixed (p=0.012)	
(1994).	with recent clinical		apnoea in prone position	
	apnoea (35).		greater duration of	
			accompanying bradycardia	
			(p=0.0003) and oxygen	
			desaturation (p=0.03) with	
			apnoea when supine	
Martin, Di Fiore,	Crossover.	· O <sub>2</sub> saturation	· lower respiratory rate( <u>p</u> <0.02),	no randomisation
Korenke,	Healthy preterm	· chest wall movement	higher O <sub>2</sub> saturation (p<0.0007),	
Randal, Miller &	infants (19).	· respiratory rate during	and greater rib cage asynchrony	
Brooks (1995).		active and quiet sleep	(p<0.0001) during both sleep	
			states in prone position	

Studies Related to Physiological Effects of Prone Versus Supine Versus Lateral Positioning in Preterm Infants

Table 2.2

Author (Year)	Design	Measures	Findings	Limitations
	Sample ( <u>n</u> )			
Blumental &	Crossover. Healthy	· gastric reflux	· less gastric reflux in prone position	о <b>п</b> .
Lealman (1982).	LBW infants (18).			randomisation
Crane, Snyder,	Randomised	· PaCO <sub>2</sub>	· higher PaCO <sub>2</sub> levels in supine position - not	small sample
Knight, Philips, &	crossover.		statistically significant	size
Cassady (1990).	Ventilated preterm			· ages not
	infants (14).			reported
Hutchison, Ross,	Crossover. Healthy	· ventilation and	improved tidal volume(p<0.01), minute volume	
& Russell (1979).	term and preterm	lung mechanics	(p<0.05) and total work of breathing (p<0.02) in	
	infants (23).		preterm infants nursed prone	
Yu (1979).	Randomised	· gastric	· stomach emptied more rapidly in prone (p<0.05)	
	crossover. Term,	emptying	and right lateral positions (p<0.01) in all infants	
	preterm and small		delayed gastric emptying ( $\underline{p}$ <0.01), more	
	for gestational age		abdominal distension and pooling of feeds in	
	infants with		stomach in preterm infants nursed supine	
	respiratory distress			
	(48)			

Studies examining physiological effects of body position changes in preterm infants first emerged in the late 1950s. A study by Kravitz and colleagues (1958) showed the prone position increased the respiratory rate in healthy preterm infants. This finding is of particular interest because it conflicts with findings from later studies. The findings from this study, however, must be viewed with caution because of potential measurement error and a lack of randomisation. Despite these shortcomings, this study was significant because it stimulated further crucial research at a time when neonatal intensive care was in its infancy and little evidence to support practice existed.

An examination of Table 2.1 reveals that many studies have investigated the effect of positioning on respiratory function in preterm infants who are experiencing varying states of respiratory distress (i.e., healthy infants breathing spontaneously, infants requiring supplemental oxygen and breathing spontaneously, or infants requiring ventilation). Regardless of the infant's state of health, several overriding conclusions can be drawn from these studies. The prone position has consistently been shown to improve gaseous exchange by increasing PaO<sub>2</sub> and end tidal CO<sub>2</sub>, decreasing PaCO<sub>2</sub>, and decreasing respiratory rate (Fox & Molesky, 1990; Martin et al., 1979; Mendoza et al., 1991). Of the studies identified in Table 2.1, findings from these three studies are the most compelling and are strengthened by sound methodology, use of randomisation and sound measurement techniques.

Another widely studied measure of respiratory function is synchrony of the chest wall during respiration. As shown in Table 2.2, findings from three studies have shown that the prone position compared with the supine position results in greater chest wall synchrony and improved respiration (Martin et al., 1995; Martin et al., 1979; Wolfson et al., 1992).

These studies were the most methodologically sound, making use of randomisation techniques and demonstrating minimal measurement error.

Body position has also been shown to affect the incidence and type of apnoea in preterm infants. The strongest and most compelling findings resulted from two recent studies (Heimler et al., 1992; Kurlak et al., 1994). Findings from these studies indicated that the prone position, when compared with the supine position, resulted in decreased episodes of apnoea in infants with a clinical history of recent apnoea.

Energy expenditure and time spent asleep is also of particular significance in preterm infants because it is associated with growth and respiratory status.

Masterson and colleagues (1987) conducted a rigorous study that found preterm infants nursed in the prone position (i.e., compared with the supine position) spent more time asleep and used less energy.

Finally, landmark studies relating to the tolerance of gastric feeds were conducted by Yu (1979) and Blumenthal and Lealman (1982). These authors showed that the prone position compared with the supine and lateral positions, resulted in more rapid gastric emptying and less gastric reflux respectively.

This review of the physiological effects of positioning has shown that the prone position is physiologically more beneficial for the preterm infant than the supine and lateral positions. The prone position, however, can lead to alterations in postural development, in particular *flattened* posture (Davis et al., 1993; Downs et al., 1991; Georgieff & Bernbaum, 1986; Hadders-Algra et al., 1988; Katz et al., 1991; Konishi et al., 1994; Monterosso et al., 1995). Postural complications will be discussed in the following section.

# Postural Complications of Prone Positioning

Early removal from the intrauterine environment impedes mobility of preterm infants as they statically lie on a firm flat surface. In combination with the profound effect of gravity, global hypotonia and the caudocephalic direction of motor development, nursing a preterm infant in the prone position affects postural development resulting in *flattened* posture. As discussed previously several authors have postulated that predominant extensor tone and positioning practices are causative factors in the development of this posture (Georgieff & Bernbaum, 1986; Semmler, 1989)

Flattened posture affects both upper and lower extremities resulting in short and longer term implications for motor development and function (Davis et al., 1993; Downs et al., 1991; Monterosso et al., 1995; Montfort & Case-Smith, 1997). In the upper extremities flattened posture is characterised by elevation and adduction of the scapula causing a retracted appearance (Georgieff & Bernbaum, 1986; Hunter, 1996; Montfort & Case-Smith, 1997, Touwen & Hadders-Algra, 1983). This is often due to the unopposed activity of the trapezius and rhomboid muscle groups that may represent a compensatory mechanism for abnormally increased extensor tone in the upper trunk (Georgieff & Bernbaum, 1986). Shoulder retraction may render an infant unable to see his or her hands and to discover them as instruments. This may cause further extension and abduction of the shoulders that may counteract the functional development of midline behaviour (Touwen & Hadders-Algra, 1983).

Scapular retraction may limit the ability of infants to sit without support.

crawl, reach for objects, bear weight on the forearms in prone, manipulate and transfer objects (Georgieff & Bernbaum, 1986). Without the ability to bear weight in the forearms when prone, creeping and crawling may be delayed (Bly, 1990, Georgieff & Bernbaum, 1986, Hunter, 1996). These developmental tasks are important because they contribute to an infant's ability to achieve important milestones. The delays in achieving milestones can psychologically impact on children and their parents because development differs from the peer group who achieve milestones at an age appropriate rate.

Flexion of the trunk with the arms held forward is advised to prevent the occurrence of this posture. This is difficult to achieve with an infant lying in the prone position. For this study, therefore, a postural support roll (R) was used to support infants in a supported quarter turn from prone position (see Appendix A). This position enabled movement of the upper and lower extremities, including hand to mouth orientation.

In the lower extremities *flattened* posture results in a lack of pelvic elevation, wide abduction and external rotation of the hips to greater than 90° (Downs et al., 1991; Konishi et al., 1994; Monterosso et al., 1995). It has been proposed that the prolonged excessive hip flexion results in shortening of the iliopsoas and adductor brevis muscles because excessive hip flexion brings the origin and insertion of these muscles closer together, and immobilised muscle adapts to the imposed length by shortening of individual sarcomeres (Grenier, 1988). This is a process that can be reversed with a return to normal movement patterns (Grenier, 1988).

The effects of this posture on functional motor development include delays in motor skills such as infants reaching with hands to knees and feet. It may also be disadvantageous for weight-bearing, leading to delays in crawling, walking and sitting (Konishi et al., 1987). Furthermore, this posture may cause infants < 31 weeks gestation to walk with a marked out-toeing gait for up to four to six years or longer (Katz et al., 1991; Davis et al., 1993; Konishi et al., 1994). The posture may also be cosmetically displeasing for parents who would prefer their infants to look like their full term counterparts (Budreau, 1987).

The postural and developmental complications of *flattened* posture are well documented, and several authors have hypothesised that postural abnormalities can be ameliorated through use of nursing interventions that provide postural support (Davis et at., 1993; Grenier, 1988; Schultz, 1992; Turrill, 1992; Updike et al., 1985). Although some of the suggested interventions have been used more recently, they remain untested. Effects of devices used to support an infant's position (i.e., waterbeds, water pillows, rocking water beds, and air mattresses) have specifically investigated the development of bilateral head flattening. Two studies have shown that use of a water pillow reduces bilateral head flattening in preterm infants (Marsden, 1980; Schwirian, Eesley & Cueller, 1986).

Few studies, however, have examined the effect of postural supportive techniques on the development of *flattened* posture. One study investigated the short term effect of a positioning device on scapular retraction. A time series, counterbalanced design examined differences in scapular rotation in preterm infants when positioned on and off individually fabricated *prone positioners* (Montfort & Case-Smith, 1997). A convenience sample of 20 preterm infants was used for this study and infants were not randomised. Infants were each observed during six measurement sessions over a two week period.

Four measures of scapular and spine measurements were used to measure scapular retraction. The *prone positioner* improved scapular retraction in infants while they were being nursed on the positioning device. Clinically, the *prone positioner* was found to facilitate midline orientation of the hands. The findings of this study cannot be generalised because the sample is not representative of preterm infants who are particularly at risk for shoulder retraction (i.e., VLBW infants). Although the *prone positioner* was found to improve shoulder retraction, infants were positioned with the *prone positioner* for a maximum period of 210 minutes only and the longer term effects of such a device were not tested. These findings justify use of the interventions in this study, and the importance of short and longer term infant follow up.

Only two studies have examined the effect of postural supports on the development of *flattened* posture in the lower extremities. Downs and colleagues (1991) reported a randomised controlled study of 45 infants < 33 weeks gestation to investigate effects of rolled sheets or beanbags for prone, lateral and supine placement on development of *flattening* in the lower extremities. Findings demonstrated that *flattening* was virtually abolished in the group of most vulnerable infants (i.e., those between 24 and 28 weeks gestation). Dunn (1991), however, argued that such postural supports may lead to an increase in hip pathology due to adduction of the hips caused by weight-bearing through the anterior rather than the medial knee. In addition, reduced lower limb mobility may impede normal postural development (Saint-Anne Dargassies, 1979). This argument is further supported by Perez-Woods, Malloy & Tse (1992) and Oehler (1993) who recommend that restraints should not be used to maintain position.

A recent randomised, controlled, observer blind study of 68 infants < 31 weeks gestation investigated the short term effect of a postural support nappy (N) on infants nursed in the prone position (Monterosso et al., 1995). This simple intervention promoted movement and flexion of the lower extremities without the associated disadvantages of the postural supports used by Downs and colleagues (1991). Monterosso and colleagues (1995) found that use of the N in the prone position significantly reduced the features of *flattened* posture of the lower extremities at the time of hospital discharge. Specifically, the N increased the angle of pelvic elevation, reduced the angle of external rotation of the hips and the weight-bearing surface of the inner thigh and knee (see Appendix B). Findings from this study resulted in a change to nursing protocol recommending use of the N in infants < 31 weeks gestation. Further research is required to determine longer term effects of the N. The current study was designed to extend the work of Monterosso and colleagues (1995) by evaluating both short and longer term effects of postural supports on upper and lower extremities.

In summary, use of the prone position when compared with supine and lateral positions has many physiological benefits for preterm infants. However, the prone position is associated with short and longer term postural and associated developmental outcomes. Limited nursing research has been undertaken to examine short term effects of postural interventions on the development of *flattened* posture. In addition, no research has been conducted to examine longer term effects of *flattened* posture on developmental outcomes.

Measurement tools that appropriately assessed both anatomical and functional aspects of posture and motor development were required for this study. The following section discusses the rationale used in the selection of the specific measurement tools used.

# Measurement Tools.

The motor assessment of the preterm infant presents a new challenge. Motor skills of the developing preterm infant are not static because they represent many stages of complex evolutionary processes (Piper & Darrah, 1994). Evaluative tests of motor function can be performed to determine change over time or effectiveness of treatment (Westcott, Pax Lowes, & Richardson, 1997). Evaluative techniques are predominantly based on neurological and behavioural studies of full term infants, and on subjective descriptions of the development of premature infants (Robert, 1983). In light of information previously presented indicating that neuromotor development of the preterm infant differs from that of the term infant, use of evaluative measures designed for use in term infants were not considered appropriate for this study.

To date, there has been a paucity of measures that can be used to assess motor function in preterm infants, particularly VLBW infants. Interest in assessment of skills and capabilities of the newborn infant with the possibility of detecting deviations in these skills, has resulted in the development of several instruments to assess the neurological integrity and behavioural repertoire of the newborn infant (Brazelton, 1984; Dubowitz & Dubowitz, 1981; Prechtl, 1977). These measurement systems have primarily been concerned with detecting motor impairment (i.e., deviations from normal). The majority of preterm infants who are assessed will be found to be developing normally, and those infants at risk for neurological impairment in fact represent a new group of infants with different assessment needs. In addition, examination of the newborn infant is limited to a reference period from 38 to 42 weeks conceptional age, rather than measuring motor function over time (Piper & Darrah, 1994).

These scales, therefore, have limited application after this period; furthermore, they are inappropriate for the maturing infant who is born prior to 38 weeks gestation.

Additional measures that have been developed to assess the presence and evolution of primitive motor reflexes are based on the assumption that reflexes and reactions underlie most volitional movement, and, that there is a relationship between functional motor achievement and reflex activity early in life (Capute, Accardo, & Vining, 1978; Milani-Comparetti & Gidoni, 1967). These tests can provide information about early neurological and motor development. However, they lack the precision of measurement which limits their usefulness as measures of motor development over a short time frame. In addition, they also involve arbitrary manipulation of an infant and, therefore, provide little information on functional motor skills (Horak, 1991).

It is now agreed that additional information is required to assess and monitor the ongoing motor development of preterm infants, and that assessment of spontaneous, non reflexive behaviours is a more accurate portrayal of an infant's motor function (de Groot, 1993; Piper & Darrah, 1994; VanSant, 1987). When planning neuromotor testing, consideration must be given to the environment and the physical condition of the infant. It is well documented that measurements should be undertaken midway between feeds and under conditions where there is minimal disturbance to the infant (Lacey, Henderson-Smart, Edwards, & Storey, 1985; Robert, 1983; Westcott et al., 1997). In addition, the infant should be in an optimal state of wellbeing and independent of factors that could affect posture (e.g., infection or crying).

Tests selected for use in measuring neuromotor function were required to meet several significant criteria for inclusion in the assessment process. Tests must have been able to evaluate quality of movement (i.e., including postural alignment and control, balance, and coordination), measure functional skills, capture improvement in VLBW infants over short time frames and, finally, demonstrate adequate reliability and validity (Westcott et al., 1997).

Given the problems associated with the difficulty VLBW infants have in assuming antigravity postures and the propensity to develop a *flattened* posture, measures that provide an indication of the difference a postural intervention made were of particular interest. Of the available tools, measures that provided information about postural alignment of the hips and shoulders, appeared to be most useful to the examination of an intervention designed to overcome those factors that contribute to development of the *flattened* posture in these infants. Consequently, a combination of anatomical and standardised functional measures were examined to determine their usefulness as evaluative markers of postural alignment. Measures were selected because they could provide information on the effect of postural interventions on the progression of motor development over time.

Assessments of spontaneous arm movements (Lacey, Henderson-Smart, Lewis & Edwards, 1991) and early leg postures (Lacey et al., 1990) to determine progressive development of antigravity arm and leg postures in preterm infants have been described. These standardised measures are considered to be age specific, therefore, they are appropriate for longitudinal assessment of motor development and have been used successfully in a number of studies (Downs et al., 1991; Lacey et al., 1990; Lacey et al., 1991; Monterosso et al., 1995).

A significant point in favour of the measures of Lacey and colleagues (1990, 1991) is that in describing arm and leg postures, they provide important information about the capacity of the infant to assume and sustain antigravity postures of the hips and shoulders. While Lacey and colleagues (1990) have described three measures of lower extremity postures, they describe only one relating to the upper extremities (Lacey et al., 1991). Thus, additional ways of evaluating shoulder girdle posture had to be identified.

The scarf sign was selected from a range of measures developed to assess the neurological maturity of the preterm infant (Amiel-Tison, 1968; Ballard, Kazmaier Novak, & Driver, 1979). The scarf sign measures passive muscle tone in the upper extremities, requiring the arm to be passively wrapped across the midline toward the opposite shoulder. The position of the elbow is then observed in relation to the umbilicus in the midline (Robert, 1983)

In addition, one anatomical measurement was devised for the present study in an effort to examine the degree of scapulae retraction. The measure used was the distance from the suprasternal notch to the acromion process. This measurement was selected because it had the capacity to indicate the degree of scapulae retraction (i.e., greater distance between the two points of measurement) and scapulae protraction (i.e., reduced distance between the two points of measurement). Prior to use of this measure in this study, inter-rater and test-retest reliability was established.

To examine the longer term effects of early postural intervention in VLBW infants, it is necessary to undertake repeated measures at significant ages up to the first eight months of adjusted age. The Alberta Infant Motor Scale (AIMS) developed by Piper and Darrah (1994) is ideal for this purpose as it measures functional motor performance at four and eight months conceptional age.

The AIMS is a standardised, observational measurement tool that incorporates the theoretical concepts of neuromotor development previously described. The AIMS is a theoretically sound, performance based, norm referenced, reliable and valid tool used to measure motor maturation of infants from term or 40 weeks conceptional age to the age of independent walking (Piper & Darrah, 1994). Given the AIMS is a standardised tool, risks associated with clinical judgement are minimised. The AIMS uses a testing protocol (i.e., scale) for assessment of sequential development of infant motor milestones in terms of the progressive development and integration of antigravity muscular control in four postural positions (i.e., prone, supine, sitting and standing). Infants are assessed through observation in an unobtrusive environment, with minimal handling and no arbitrary stimulation or facilitation. The protocol prevents errors of omission and guards against biased expectations in the interpretation of observations (Piper & Darrah, 1994).

The foot progression angle (i.e., a measure of structural alignment) was included in Assessment 3. This measure is utilised in gait analysis in children and adults (Staheli, 1987; Staheli, Corbett, Wyss, & King, 1985). Although normal values are not available for infants younger than one year of age, the measure was included in this study for two reasons. Firstly, it was a realistic measure to perform because infants at this developmental stage can maintain a position of supported standing and the foot progression angle could easily be measured. Secondly, if the measure proved sensitive to differences in the foot progression angle in the study population, the findings could provide meaningful information in determining whether the effect of the postural interventions on external rotation of the legs is sustained. This would be of interest because external rotation of the legs contributes to an out-toeing gait (Staheli et al., 1985).

# Summary of the Chapter

Medical technologies have resulted in increased survival rates of extremely low gestation infants over the last three decades. It is only during the last decade that an understanding of the fetus as a competent organism that experiences life in the warm, fluid filled, gently oscillating uterine environment has begun to emerge. Within this secure environment basic physiological, sensory and motor needs are met. The early transition to extrauterine life creates a challenge for the preterm infant who struggles to maintain previously organised patterns of functioning in the face of overwhelming stimuli. Not only are physiological systems immature, but the infant is also required to stabilise and recover from serious illness. The VLBW infant's central nervous system has not yet adapted to the extrauterine environment where oxygen, nutrition, and protection from infection must be provided to maintain life. The VLBW should not be viewed as a deficient full term infant, but as a competent infant who was functioning appropriately for the intrauterine environment for which it was adapted.

The prone position is the nursing position of choice for VLBW infants as it promotes development of pulmonary, cardiovascular, sleep state, organisational and gastrointestinal functions. The prone position has also been shown to facilitate the preterm infant's recovery from respiratory complications associated with immaturity. Despite the physiological benefits of the prone position, the VLBW infant is at risk for postural abnormalities such as *flattened* posture that are known to affect developmental milestones up to the age of six years. Predisposing factors to *flattened* posture other than prone positioning which reduces mobility, are related to immaturity and include hypotonia, immature muscle development and the effects of gravity.

Nurses are in a prime position to provide care that reduces detrimental stimuli and promotes homeostasis. Helping infants regulate physiological and behavioural functioning is an integral part of nursing care. The provision of developmental interventions appropriate for an infant's gestational age, health status, and overall organisational capacity is required. The therapeutic interventions used in this study were designed to promote physiological and motor development, and decrease developmental dysfunction associated with prone positioning in VLBW infants.

#### **CHAPTER 3**

## Frame of Reference

The theoretical framework for this study was based upon postulates from General Systems Theory and the Neuman Systems Model. General Systems Theory (GST) views all forms of animate and inanimate matter as systems composed of related parts that interact and present in different forms (McKay, 1997; von Bertalanffy, 1968). Universal laws are used to describe the structure and functioning of these systems. The development of the GST and its underlying theoretical concepts will initially be described.

As described by von Bertalanffy (1968), preliminary work in the area of GST first emerged when Kohler alluded to the theory in a study of Gestalten in physics in 1924. In 1927, Kohler raised the postulate of a system theory when elaborating general properties of inorganic systems compared with organic systems (cited in von Bertalanffy, 1968). Gestalten theory maintains that the whole (i.e., the system) is surrounded by a perceptual field in dynamic equilibrium. Field theories such as this maintain the system is composed of interrelated and interdependent parts. Gestalten theory is based on concepts of wholeness and nonsummativity, where the whole is greater than the sum of its parts in which there is a degree of inter-relatedness (Braden & Herban, 1976; Campbell & Keller, 1989; von Bertalanffy, 1968).

Lotka first postulated a general concept of systems in 1925 (cited in von Bertalanffy, 1968). Unlike Kohler who restricted the concept of systems to physics, Lotka conceived communities as systems and regarded the individual organism as a sum of cells. Burton (1939) and von Bertalanffy (1940) extended this theory by introducing the concept of viewing the living organism as an open system.

Von Bertalanffy (1968) continued this work and presented the first statement on GST in 1945 that included the following abstract laws: interaction among components determines system behaviour; interaction among components of a system produce uniquely dynamic situations and no system repeats its interaction; regular changes are found in the evolution of systems as they move toward higher states of order, differentiation and probability; evolution proceeds from a less to a more differentiated state, and dynamic interaction between individuals and the environment resulting in increasing complexity for both; and people are living, open systems, exhibiting self-differentiation, providing energy, and having a stored information system to steer the process. General System Theory has continued to evolve and has been applied by scientists in disciplines such as physics, biology, political science, nursing, psychology, economics and sociology (Kenney, 1990; von Bertalanffy, 1968).

Postulates from GST have been incorporated into the development of nursing theory and nursing models since 1964. Several nursing theorists (i.e., Johnson, Neuman and Roy) have specifically based their models on human beings as open living systems. Concepts for the Neuman Systems Model developed by Betty Neuman influenced the theoretical framework for this research study (Neuman, 1989). The key concepts of GST will now be discussed.

# **Systems**

As shown in Figure 3.1, a system consists of a set of interacting components within a boundary that filters the type and rate of exchange with the environment (Riehl & Roy, 1980). A boundary is the line of demarcation between a system and its environment. A boundary may exist either in a physical or less tangible form, and can be operationally defined as the line forming a closed circle around selected variables, where less energy is exchanged across the line of the circle than within the circle (Chin, 1980). An example of a physical boundary is a sealed container; whereas, a less tangible boundary can be thought of as the boundary around a group of people. Boundaries can have different degrees of permeability and may be viewed as very or fairly permeable. The greater the permeability of the boundary, the greater the interchange of energy between the system and its environment (Fawcett, 1984).

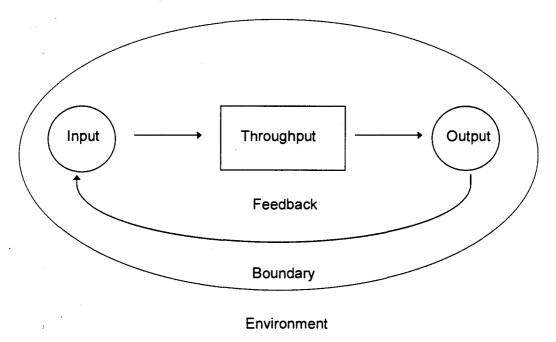


Figure 3.1 Basic Systems Model.

## Open and Closed Systems

Systems can be differentiated as open or closed. An open system is related to, and exchanges matter with its environment. All living organisms are considered to be open systems (von Bertalanffy, 1968). All open systems consist of subsystems, and all but the largest system have suprasystems. A suprasystem consists of the system and its environment.

Open systems have feedback loops (i.e., channels) through which feedback enters and leaves the system. As a result of interaction with the environment, open systems receive input and give back output in the form of energy, matter and information. While affecting the environment, a process known as output, the system gathers information in relation to its progress. This information is fed back into the environment as input that is used to guide system operation (Riehl & Roy, 1980). The system regulates the type and amount of input received from the environment through the process of selection. Closed systems are considered to be isolated from the environment; therefore, no exchange with the environment occurs (Braden & Herban, 1976; von Bertalanffy, 1968). Closed systems exist principally in the field of physical science; however, closed systems can also be applied to social sciences where a system may be viewed as not accepting or using feedback readily (Braden & Herban, 1976).

In summary, both structural and transactional components are required for a system to function. The degree of component interaction can be stated in terms of nonsummativity or wholeness, and the increasing complexity of these interrelations is called equifinality. Feedback loops, in association with the acceptance of positive and negative feedback, are essential for the function of open systems.

The internal operation of systems will now be described.

# Internal System Operation.

Systems are composed of dynamic interactions; therefore, stability over time and space must occur. In order to function, a system requires energy that is transformed either by internal or external forces. Transformed energy is then distributed into the system through channels. Each channel has individual properties including receptiveness and resistance to the flow of energy. Channels have an upper level of energy acceptance (i.e., channel capacity) and when capacity is reached, the channel will no longer accept energy. While some systems are capable of preventing channel damage by diffusing excess energy, other systems lack this capability and can break down as a result of channel damage (Braden & Herban, 1976).

### Equilibrium.

It is postulated that systems have a tendency toward achieving balance between internal and external forces (Chin, 1980; Fawcett, 1984; von Bertalanffy, 1968). Two terms have been used to denote concepts of balance in relation to systems. *Equilibrium* is characteristic of open systems and refers to balance, thought of as a fixed point or level (von Bertalanffy, 1968). In contrast, *steady state* is the term used to describe a balanced relationship where components are not dependent on any fixed *equilibrium* point or level. Von Bertalanffy (1968) further postulated that a *steady state* is maintained by a continuous flow of energy both within the system, and between the system and its environment.

## Entropy, Stability and Organisation.

Energy interaction patterns develop as a result of energy flow. Components of a system act as a knot within energy flow patterns. Components do not contribute to the system process unless there is a degree of interdependence, or nonsummativity. At this point, a degree of instability (or entropy) exists in the system and is accounted for by the Second Law of Thermodynamics (a classic physics law). This law applies to both open and closed systems and defines entropy as a measurable physical quality, based on the tendency of matter to become disorganised (Braden & Herban, 1976). Entropy is characterised by a decrease in energy flow as components utilise the available energy. This creates tension on the flow of energy because there is no other available source of energy input. It would be possible, therefore, for an increase in entropy to occur at this level of system process. Systems that cannot make use of the feedback loop are unable to access outside energy sources and are at risk for death as energy flow becomes insufficient to enable system function. The Second Law of Thermodynamics states that the entropy of a closed system will always increase until a state of equilibrium occurs (McKay, 1997). Closed systems, therefore, are less able to accommodate this law as they move toward a state of extinction (i.e., entropy) where increasing disorganisation, randomness and dissipation of energy occurs.

In contrast, open systems can diminish the effects of entropy and develop toward a state of stability and organisation. Through the process of negative entropy, open systems can achieve a more complex order and heterogeneity by importing matter containing free energy to compensate for the increase in entropy due to irreversible processes within the system.

The composition of the system, therefore, remains constant despite a continual exchange and flow component material.

## System Interface.

The space that exists outside systems is known as the interface and is a medium between boundaries. The interface can transport energy, matter and information between systems from the output boundary of one system to the input boundary of another system. The interface can also accept entropy. In contrast, if systems wish to reduce entropy in the interface, links will be established between other systems that are known to interact together (Braden & Herban, 1976).

# Interaction.

Equifinality is used to describe the progressive complexity of interaction patterns between components in a system (Braden & Herban, 1976). This is an important concept because the final product of a system's interactions may be reached from different initial conditions and in different ways, and different final states may be reached from the same initial condition. For every individual there is a characteristic state that he or she by nature must try to assume. This concept can be extrapolated to VLBW infants as they attempt to maintain a normal state of thermoregulation and motor development, despite the negative forces generated by the NICU environment and immaturity of body systems. Another term used in systems theory to describe interrelationships among components is nonsummativity. Nonsummativity describes the degree of interrelatedness or wholeness among system components, otherwise known as the *Gestalten effect* (Braden & Herban, 1976).

This concept is illustrated when a change in one component of a system effects change in all other parts and in the total system. This concept can be illustrated in the VLBW infant where extended body posture can cause increased temperature loss that in turn affects respiratory, gastrointestinal and neurodevelopmental systems. This problem can potentially disrupt homeostasis and place the infant at risk for increased entropy unless all system requirements are met.

## Tension, Strain and Conflict.

Individual components within a system differ from each other, lack perfect integration, and may be in a state of change or reaction to change. In view of these differences between systems components and the need to adjust to disturbances outside the system, varying degrees of tension can occur within a system (Chin, 1980; Fawcett, 1984). Chin (1980) states that internal tensions arising from structural arrangements of the system may be called stresses and strains of the system. Strain can occur when tensions surface and become opposed along the lines of two or more components, leading to conflict within the system (Chin, 1980). To resolve conflict, change may occur within a system. The process of change involves identification and analysis of tension and conflict. This can serve as a major utility for practitioners by exposing the dynamics of the system and creating the opportunity for change (Chin, 1980).

In summary, the key concepts of GST have been introduced. The GST is considered to be practical and logical. General System Theory and Gestalten Theory underpin the Neuman Systems Model that was used to guide this research study. Key concepts from the Neuman Systems Model will be now outlined and operationalised to create a nursing care system for the VLBW infant.

## Neuman Systems Model

The Neuman Systems Model (NSM) is strongly influenced by General System Theory and Gestalten Theory. The NSM is a comprehensive and dynamic view of individuals, groups or communities that are subject to environmental stressors (Cross, 1980; Fawcett, 1984; Neuman, 1989). Neuman's model views the person as an open and holistic system that interacts with, and adjusts to the environment, and who is at all times in a dynamic state of wellness or ill health in varying degrees (Neuman, 1989). The person is depicted as having a basic structure or core. The focus of the NSM is on the system's (i.e., the person's) response to stress and on factors influencing reconstitution (Fawcett, 1984). Nursing is also a central concept in this model with the focus being on stressors, the person's response to them and the state of the person (Chinn & Kramer, 1991). The aim of the model is to provide a unifying focus for approaching nursing problems and for understanding the phenomena of the person and his/her environment (Neuman, 1989).

Neuman (1989) based the NSM model on several assumptions:

1. Each individual is viewed as unique and a composite of common characteristics within a normal, given range of response.

- 2. There are many known *stressors*, each different and potentially capable of disturbing an individual's equilibrium or *normal line of defence*. The particular relationship of variables (i.e., physiologic, psychologic, sociocultural and developmental) can at any point affect the degree to which an individual is able to use his or her's *flexible line of defence* against possible reaction to a single stressors or range of stressors.
- 3. Each individual over time has evolved a normal range of responses that are referred to as a *normal line of defence*.
- 4. When the cushioning effect of the *flexible line of defence* is no longer capable of protecting the individual against a *stressor*, the *stressor* breaks through the *normal line of defence*. The interrelationship of variables determines the nature and degree of the individual's *reaction* (i.e., outcome) to the *stressor*.
- 5. Each individual has an internal set of resistance factors (*lines of resistance*) that attempt to stabilise and return him or her to a *normal line of defence* should a stressor break through it.
- 6. An individual in a state of wellness or illness is a dynamic composite of the interrelationship of the four variables that are always present.
- 7. Primary prevention relates to general knowledge that is applied to the assessment of an individual in an attempt to identify and allay the possible risk factors associated with stressors.
- 8. Secondary prevention relates to symptomology, appropriate ranking of intervention priorities, and treatment.
- 9. Tertiary prevention relates to the adaptive process as reconstitution begins, and moves back in a circular manner toward primary prevention.

For the purpose of this research study, a nursing care model for the primary prevention of temperature instability and neuromotor dysfunction in VLBW infants was developed. The nursing care model is based on key concepts from the assumptions outlined above, and is conceptualised in Figure 3.2.

The VLBW infant, represented by the inner circle in Figure 3.2, is capable of intake of both intrapersonal and extrapersonal environmental factors. The VLBW infant both adjusts to this intake and adjusts the intake to the system. In operational terms, the VLBW is seen as adjusting to the nursing interventions used in this study (i.e., postural support nappy, absorbent nappy liner and postural support roll) by improved short and longer term outcomes (i.e., findings). These findings will provide feedback that will be returned to the system resulting in changes to the nursing care environment. The lines of resistance surrounding the VLBW infant are internal factors (i.e., nursing interventions) that protect the infant from stressors. The normal line of defence essentially refers to an individual's normal state of wellness. This state of wellness is considered to be dynamic because it relates to the way the system stabilises over time. In this model, the normal line of defence refers to short and longer term outcomes of improved temperature stability and development of normal neuromotor function in the VLBW infant. The flexible line of defence is dynamic, can be altered rapidly over time, and functions in an accordion-like manner. The flexible line of defence can be affected by one or more stressors that can generate varying degrees of response. Neuman (1989) classifies stressors as extrapersonal, interpersonal and intrapersonal.

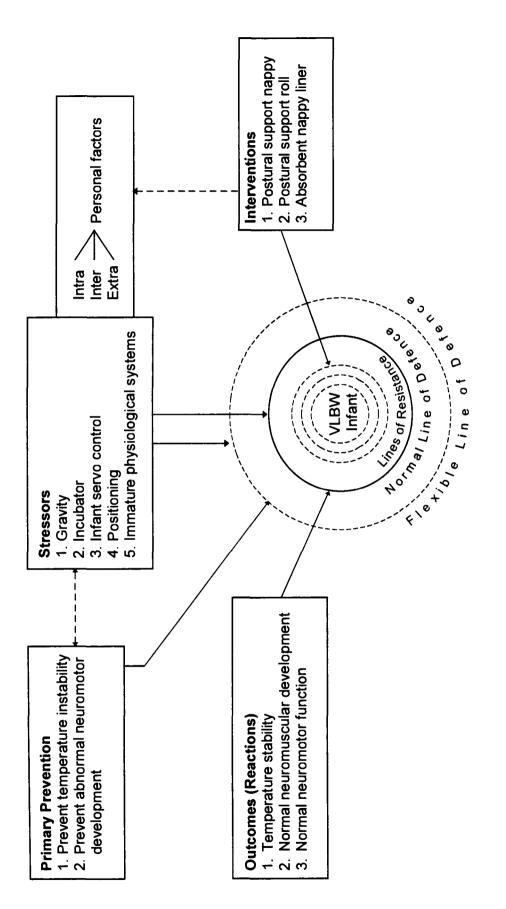


Figure 3.2 Nursing Care Model for the Primary Prevention of Temperature Instability and Neuromotor Problems in VLBW Infants (adapted from Neuman, 1989).

Stressors and their influencing variables have been operationally defined according to evidence provided in the literature review as seen in Table 3.1.

Table 3.1
Stressors Affecting the VLBW Infant

Stressor	Definition	Variable
Extrapersonal	Forces that occur outside the system	Gravity
		Infant servo control
		Incubator
Interpersonal	Forces occurring between one or	Infant positioning
	more individuals (i.e., nursing care)	Nappy use
Intrapersonal	Forces occurring within a person	Immature systems
		• gastrointestinal
		<ul> <li>respiratory</li> </ul>
		cardiovascular
		central nervous
		• skeletal

As described in Neuman's (1989) assumptions, three lines of prevention can be used in Neuman System Models. The focus of the model developed for this study was primary prevention. The literature review provided empirical evidence regarding immature temperature regulation and neuromotor function in VLBW infants. In view of this evidence, potential stressors can be identified by nurses on the admission of a VLBW infant to a NICU.

The goal of this nursing model, therefore, was to prevent these known stressors from penetrating the *normal line of defence*. In addition, this model would lessen the degree of reaction to stressors by reducing the possibility of encounters with identified stressors. Although not explicitly stated in Neuman's assumption regarding primary prevention, nursing intervention can begin at any point at which a stressor is either suspected or identified. In this experimental study nursing interventions were used as a primary prevention strategy to lessen the degree of the VLBW infant's reaction to known stressors. This model also had the potential to strengthen the VLBW infant's line of defence.

In summary, key concepts from the Neuman System Model were used to develop this nursing care model for the primary prevention of temperature instability and neuromotor problems in VLBW infants. Neuman Systems Model is logical and practical and reflects both mechanistic and organismic world views. The mechanistic view is reflected by the person's response to environmental stressors and use of theoretical concepts of stress and adaptation. The organismic view is characterised by use of Gestalten and field theories. The NSM theory is multi-dimensional, reflects interest in the total person from a nursing perspective and was suitable for the experimental nature of this research study. The pragmatic approach of the NSM provided a useful guide for the development of the primary prevention nursing care model as it applies to VLBW infants. The power of this model was heightened because it also added to the organisation and understanding of the underlying processes of development in the VLBW infants.

# Retroductive Theoretical Strategy

The development of the conceptual model used in this research study was influenced by the use of retroductive strategies. Retroduction combines inductive and deductive methods (Fawcett, 1984). In the inductive mode of the theoretical framework development, concepts and propositions from General System Theory and the Neuman Systems Model led to author to the view the VLBW an open living system. In the deductive mode, empirical evidence that emerged from the literature review provided support for the hypotheses of this study. It was concluded that the following variables affect temperature stability and neuromotor development: immature system development, positioning practices, incubators, infant servo control and the effect of gravity.

# Summary of the Chapter

The theoretical framework provided a foundation for explaining the hypothesis that it may be possible to prevent thermoregulation and neuromotor problems in VLBW infants by creating an extrauterine environment that promotes homeostasis. Several testable hypotheses emerged from the framework:

- 1. As a result of preterm birth a combination of physiological immaturity and environmental factors lead to temperature instability in VLBW infants.
- 2. Use of an absorbent nappy liner within a cloth postural support nappy will reduce evaporative heat loss and improve temperature stability.
- 3. As a result of preterm birth a combination of physiological immaturity and environmental factors lead to the development of *flattened* posture in VLBW infants.

- 4. Use of posturally supportive interventions will have a positive influence on the extrauterine environment of the VLBW infant by enabling them to assume positions where there is a balance between flexion and extension of muscle groups.
- As patients of the major neonatal tertiary referral centre of Western
   Australia, infants < 31 weeks gestation are routinely nursed in the prone position.</li>

#### **CHAPTER 4**

#### Method

In this chapter the methods and procedures used to conduct Phase 1 and Phase 2 of this study will be discussed. For clarity, the first component of this chapter will describe the methods and procedures related to Phase 1. Similarly, the second component will describe the methods and procedures related to Phase 2.

# Phase 1

# Design

A randomised, observer blind, crossover study was conducted. Infants were randomly assigned to commence wearing either a postural support nappy with an inner absorbent liner, or a postural support nappy without an inner absorbent liner. Randomisation was controlled by the study's biostatistician using a sealed envelope technique containing group allocation in blocks of 10, five for each group. Following randomisation, infants alternated wearing each type of nappy for a 24 hour time period during the four days of the study. The independent variable was the type of nappy. The dependent variables were skin temperature and incubator temperature.

## Setting

The setting for this study was the neonatal intensive care unit (NICU) of a 260 bed women and infants' hospital in Perth, Western Australia (WA), hereafter known as the NICU. The hospital is the major teaching and tertiary referral centre for obstetrics, gynaecology and neonatology in the state. The NICU cares for 95% of all VLBW infants born in WA.

# Sample

Infants < 31 weeks gestation who were nursed in double-walled Airshields™ incubators on infant servo control (ISC) in the NICU between February 1996 and April 1996 inclusive were eligible for inclusion in the study. Infants were excluded from the study if they were receiving antibiotic or diuretic therapy, phototherapy, or if they had umbilical catheters *in situ*.

Twenty three infants < 31 weeks gestation were enrolled in the study including four sets of twins. Infants were at least one week of age, clinically stable and able to wear a nappy. Following enrolment, three participants were subsequently withdrawn from the study. Of these, two infants commenced diuretic therapy and one infant began phototherapy after commencement of the study.

Of the 23 infants enrolled, 10 infants were randomly assigned to the control group and 13 infants to the treatment group. The attrition rate was 13%; therefore, 20 infants completed the study. Nine infants remained in the control group and 11 infants in the treatment group.

The Fisher's exact test was used to compare the control and treatment groups to determine whether there was any difference in withdrawal rate between the two groups. The p value (0.839) indicates that there was no difference. The outcomes for all infants enrolled in the study are shown in Table 4.1. The Fisher's exact test does not provide a test statistic, therefore, wherever this test is used only p values will be quoted.

Table 4.1

Differences Between Temperature Study Treatment Groups for Outcome

	Control	Treatment		
Outcome	<u>n</u> (%)	<u>n</u> (%)	<u>p</u>	
Completed	9 (39)	11 (48)	0.839	
Withdrawn	1 (4)	2 (9)		

# **Instruments and Materials**

- 1. A data collection form was used to transcribe temperature measurements and selected delivery and postnatal variables from routine nursing observation charts by the researcher (see Appendix C). Delivery and postnatal variables included those identified in the literature that are known to affect temperature regulation, such as gestational age, weight, events or nursing care procedures requiring infant handling (e.g., nappy changing). The face and content validity of the data collection form was assessed by nine selected experts which included nursing and medical staff. This expert panel agreed the data collection form would enable collection of data that was comprehensive and appropriate for the study.
- 2. To facilitate the conduct of the study, instructions regarding the treatment protocol were placed on each study infant's incubator (see Appendix D).
- 3. All infants were nursed inside a double-walled Airshields™ incubator. Infant incubators provide a closed, controlled environment that warm an infant by circulating heated air over the skin. The heat is then absorbed into the body by tissue conduction and blood convection. The infant lies on a mattress in the infant compartment which is enclosed by a clear plastic hood. A heating system is located beneath the infant compartment where a fan circulates air past a heater and temperature measuring device, then up into the infant compartment.

The Airshields™ incubator used in this study had two modes of operation: manual control and ISC mode. In the manual mode, the desired incubator air temperature is set, periodic readings of infant body temperature are made, and incubator air temperature is adjusted accordingly (LeBlanc, 1991; Nobel, 1991). In the ISC mode, an optimal skin temperature is preset on an electronic control panel and a temperature sensor is taped to the skin surface of the infant's lower back. The incubator heater responds to maintain the skin temperature at the preset level. The use of ISC is standard procedure within the study setting. Optimal and actual skin temperatures are displayed on the electronic control panel on the front of the incubator, below the infant compartment.

- 3. An Exergen Ototemp™ infra-red thermometer was used to record temperatures per axilla (PA). This thermometer records skin temperature by reading the temperature of arterial blood below the skin surface.
- 4. The postural support nappy used in this study is described in Appendix B. This nappy was designed to provide elevation of the pelvis, prevent external hip rotation and enhance mobility of the infant's legs (Monterosso et al., 1994). These essential features promote development of normal hip posture in VLBW infants (Saint-Anne Dargassies, 1979). To ensure the correct folding technique was used to fold the N, these nappies were prefolded and available to nursing staff at all times. Periodic checks of infants in both control and treatment groups were made by a research assistant to ensure correct nappy application throughout the study. This guaranteed that nappies were correctly folded and applied, and that no disposable nappies were used during the study (disposable nappies are also available for use in the NICU).

5. The sanitary napkin used in this study was a Whisper Ultrathin Pad with Wings™, secured by means of an adhesive backing to the inner side of the N prior to use. The ultrathin pad contained absorbent gelling material (AGM) and was used to meet temperature needs of the VLBW infant. The AGM contained cross linked sodium polyacrylate which has the ability to absorb and hold up to 80 times its weight in liquid, and form a gel when hydrated (Campbell, Seymour, Stone, & Milligan, 1987). Adhesive *wings* located centrally on either side of the pad were used to secure the pad to the underside of the N. This was an added advantage because the *wings* were useful in reducing the width of nappies when used on very low birthweight infants. At the commencement of the study, sufficient Whisper Ultrathin Pads with Wings™ were placed in the nursery to cover the duration of the study.

### Procedure

The data for this study were collected during a three month period from February 1996 to April 1996. Recordings of PA, skin and incubator temperatures, nappy changes, and any procedures that required infant handling were based on the nursing guidelines used in the NICU. These recordings are routinely documented on infants' observation charts by the nurses responsible for their care.

Hourly recordings of skin and incubator temperature were read from an electronic display located on the temperature control panel on the front of the incubator. As per unit protocol, PA temperatures were taken eight hourly as a validity check to determine whether skin temperature recordings adequately reflected the infant's central body temperature. It was expected that the PA temperature might have been as much as  $0.6^{\circ}$ C greater than the skin temperature because the Ototemp<sup>TM</sup> measured the temperature between the two surfaces of the axilla.

Conversely, the ISC skin probe measured the temperature from one skin surface, (i.e., the skin surface of an infant's lower back).

Nappies were changed four to six hourly. Times of all nappy changes and other procedures requiring infant handling were recorded hourly and at the same time as the temperature readings. The researcher made random checks of ISC temperature probe placement to ensure correct application, and transcribed data from nursing observation charts to the data collection form at the completion of the study. It was not possible from routine observation of infants to determine whether infants were wearing nappies with or without nappy liners. This enabled the researcher to remain blind to infant group allocation,

Infants commenced the study as soon as they were clinically stable and their condition permitted wearing of a nappy. This routinely occurred after at least one week of age when any umbilical catheters and/or intercostal catheters had been removed. Following consent and enrolment of infants to the study, parents were asked by the researcher to select a randomisation envelope. The envelope which contained the infant's group allocation and study protocol instructions (see Appendix D) was then given to the nurse caring for the infant. The nurse was then instructed to open the envelope and place an identification label containing the infant's family name and medical record number on the protocol. Study protocol instructions were attached to infants' incubators to facilitate nursing staff compliance and correct documentation on nursing observation charts. Following randomisation, infants alternated wearing each type of nappy for a 24 hour time period during the four days of the study; therefore, each infant received two days of each treatment over a four day period. Inservice education was provided for all nursing staff.

## **Ethical Considerations**

Approval was initially gained from Unit Management in the Department of Newborn Services at King Edward Memorial Hospital. Permission to conduct the study was given by Edith Cowan University Committee for the Conduct of Ethical Research on 28 November 1995, and the Ethics Committee of the study hospital on 12 December, 1995 (see Appendix L).

There were no risks to infants in either control or treatment groups. Application of a nappy forms a routine part of the normal nursing care of the premature infants, and both cloth and disposable nappies are routinely used with the NICU. The Whisper Ultrathin Pad with Wings™ used in the treatment group contained similar components to those found in the disposable nappies used within the NICU. Infants in the study, therefore, were exposed to no risks. Furthermore, as discussed in the procedures section, all recordings and interventions were performed according to routine nursing practice. The disturbance to infants, therefore, was minimal.

Verbal consent was obtained from parents before the infant's entry into the study. The consultant hospital staff deemed that written consent was inappropriate given that: the proposed intervention fell within normal nursing care boundaries, and enrolment may occur at a stressful period for parents; therefore, a request for written consent to participate in a routine nursing practice could create undue anxiety.

Confidentiality was ensured by number coding participants on a master list (see Appendix E). The master list was kept separately in a locked cabinet. Infants were then identified by number code only on the data collection form and on all computer entries. The data collection forms will be kept for at least five years.

#### Phase 2

# Design

A randomised, observer blind, controlled treatment study was conducted with allocation of infants to one of three treatment groups. Infants were also stratified into one of two gestational age groups (< 29 weeks, and 29 - 30 weeks) to observe for differences in shoulder and hip measurements with different gestational ages at birth. Randomisation was controlled by the study's biostatistician using a sealed envelope technique containing group allocation in blocks of 15, five for each group. The two independent variables were: the presence or absence of the postural support nappy, and the presence or absence of the postural support roll. The dependent variables were: shoulder retraction (i.e., the distance between the acromion process and the suprasternal notch); scarf sign; spontaneous arm movements; weight-bearing surface of the inner surface of the thigh and leg; angle of external rotation of the leg from lateral support; angle of elevation of the pelvis; weight-bearing through shoulders and spontaneous leg movements; reaching with hands to feet; finger-finger play in supine; reaching from prone support; crawling; rolling; sitting; supported standing; and the foot progression angle.

It was not possible to have a true control group in this study (i.e., a group in which neither intervention was used) because use of both a postural support nappy and disposable nappy was routine practice within the NICU. Therefore, the best clinical alternative was chosen and three treatment groups were used. As shown in Figure 4.1, infants in Group N wore a postural support nappy, infants in Group NR wore a postural support nappy and a postural support roll, and infants in Group R wore a disposable nappy and a postural support roll.

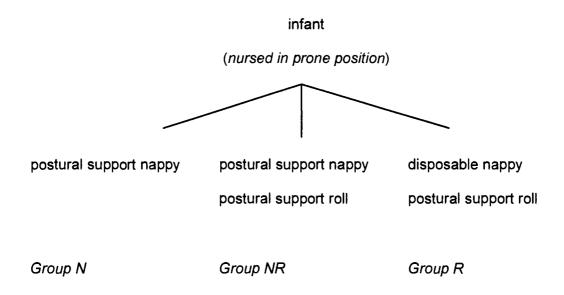


Figure 4.I Postural Support Study Design.

# Setting

The setting for this study was the neonatal intensive care nursery of a 260 bed women and infant's hospital in Perth, Western Australia. As previously described, the hospital is the major teaching and tertiary referral centre for obstetrics, gynaecology and neonatology in the state. The NICU cares for 95% of all VLBW infants born in Western Australia.

## Sample

Infants < 31 weeks gestation who were admitted to the NICU between May 1996 and August 1997 inclusive were eligible for inclusion in this study. Infants were excluded from the study if they suffered from any congenital or postnatally acquired abnormalities or limb deformities that were known to affect muscle tone and development of normal posture.

These conditions included: known congenital abnormalities (e.g., talipes, hydrocephalus, seizures), neonatal ischaemic encephalopathy, grade 3 or 4 intraventricular haemorrhage (IVH), periventricular leukomalacia (PVL) and cerebral palsy (CP).

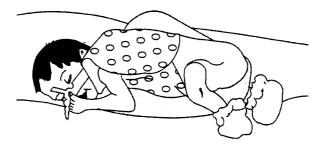
One hundred and three parents were approached for consent to enrol their infants into the study. All parents gave consent and 123 infants < 31 weeks gestation were enrolled. This number included two sets of quadruplets, one set of triplets, and 18 sets of twins. Of the two sets of quadruplets, only six infants were enrolled because one sibling had died prior to enrolment. Similarly, of the 18 sets of twins, only 32 infants were enrolled because in four of the sets of twins, one infant had died prior to enrolment.

Following enrolment, 23 (28%) infants were subsequently withdrawn from the study at different assessment periods (i.e., two infants at Assessment 1, 17 infants at Assessment 2, and four infants at Assessment 3). Of these, three infants died from complications of prematurity, two infants developed PVL, four infants developed Grade 3 IVHs, two infants developed Grade 4 IVHs, one infant developed blindness, one infant developed abnormal neck muscle tone, six infants developed probable CP, one infant was transferred with its sibling who required surgery to another hospital, and three infants were *lost to follow-up*. As the analyses followed an *intention to treat* model, data from all infants were included wherever possible.

In summary, a response rate of 100% was achieved with recruitment of 123 infants to the study. Of the 123 infants enrolled, 41 infants were randomly assigned to the treatment group N, 43 infants to treatment group NR and 39 infants to treatment group R. There was an overall attrition rate of 28%.

# Instruments and Materials

1. The postural support roll (R) is shown in Appendix A. Throughout the study, periodic checks were made by the NICU physiotherapist to ensure correct placement of the R in infants enrolled in either the NR or R treatment groups. As seen in Figure 4.2, the R enabled infants to lie in a quarter turn from prone position that enabled flexion in both upper and lower extremities, and positioned lower extremities so that both knees and feet were facing the same direction.



<u>Figure 4.2</u> Infant Positioned in a Quarter Turn from Prone with a Postural Support Roll.

2. The postural support nappy (N) is described in Appendix B. Throughout the study, periodic checks were made by the NICU physiotherapist to ensure correct application of the N throughout the study. Figure 4.3 demonstrates how an infant nursed in a N achieved flexion in the lower extremities.

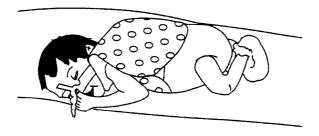


Figure 4.3 Infant Positioned Prone in a Postural Support Nappy.

To ensure the correct technique was used for the folding of the N, these nappies were prefolded by hospital volunteers and available to nursing staff at all times. In addition, periodic checks of infants in all groups were made by two research assistants to ensure correct application of interventions throughout the study.

- 3. A clear plastic universal goniometer with a 180 degree dial, increments of five degrees, and a perspex arm was used to measure the angles of elevation of the pelvis and external rotation of the leg from lateral support. The goniometer is a widely used evaluation tool in physical therapy for the examination of hip motion in neonatology (Forero, Okamura, & Larson, 1989; Gajdosik & Bohannon, 1987; Haas, Epps, & Adams, 1973; Lacey et al., 1990; Phelps, Smith, & Hallum, 1985). The goniometer has been shown by Forero and colleagues (1989) to be reliable with inter-rater reliabilities of r = 0.999 (p < 0.05) and r = 0.977 (p < 0.05). Following recommendations by Monterosso and colleagues (1995) in a previous study, the goniometer was fixed to a perspex board to achieve optimum stability and efficacy. Prior to commencement of this study, the goniometer was calibrated against known angles of 0, 45, 90, 135 and 180 degrees.
- 4. Surgical callipers were used to measure the distance between the acromion process and the suprasternal notch. To ensure that safety of infants during use, plastic protective covers were placed over the two pointed ends of the callipers.
- 5. The data collection form designed for the present study was used to record all measurements for each assessment period and selected antenatal, delivery and postnatal variables (see Appendix F).

The data collection form included strictly standardised criteria for longitudinal assessment of the premature infant that have been empirically tested by Lacey and colleagues (1990), Piper and Darrah (1994) and Monterosso and colleagues (1995). Other variables included those identified in the literature that are known to affect the development of posture, such as chronic oxygen dependency, the number of days infants were nursed on a ventilator, possible neurological impairment (i.e., IVH and PVL) and gestational age (Downs et al., 1991; Grenier, 1988; Lacey et al., 1990). The face and content validity of the data collection form were assessed by nine selected experts which included nursing, medical and physiotherapy staff. This expert panel agreed that the data collection form would enable collection of data that was comprehensive and appropriate for the study.

### **Procedure**

Data for this study were collected during a 26 month period from May 1996 to July 1998. Written permission was granted by Lacey, and Piper and Darrah to use their standardised measures (see Appendix G). Pilot testing was conducted with nine infants randomised into one of the three treatment groups, to determine whether procedures were appropriate. During this pilot study nursing staff suggested that a cotton tie be attached to the R to facilitate maximum stability when placed around infants. This was undertaken and found to be effective. No other problems were encountered, therefore, the nine infants were included in the study. Infants in all treatment groups were enrolled and commenced in the study after parental consent had been obtained, and their condition permitted prone positioning and application of a nappy.

The immediate period following a VLBW infant's admission to the NICU can be stressful for many parents, especially in the first few days until their infant's condition becomes *stable*. Therefore, infants were recruited by the researcher following an initial stabilisation period. This usually occurred after the first week of life when any umbilical or intercostal catheters had been removed, peripheral arterial infusions had been discontinued, and treatment for low blood pressure had ceased. This also ensured that recruitment for this study did not conflict with other research studies that required recruitment of infants during their first week of life.

Following written consent and enrolment of infants to the study, parents were asked by the researcher to select a randomisation envelope. The envelope, which contained the infant's group allocation and study protocol instructions, was then given to the nurse caring for the infant. The nurse was instructed to open the envelope and place an identification label containing the infant's family name and medical record number on the protocol.

The nurse then placed the protocol in the infant's medical and nursing notes for the duration of the study. Nurses were instructed to commence the appropriate treatment protocol when the infant's condition permitted (see Appendix H). The commencement and completion dates of the interventions were recorded on the infant's weight chart. To facilitate collection of this data, the researcher used a self inking stamp to place the following information on each infant's weight chart:

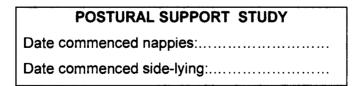


Figure 4.4 Commencement and Completion of Postural Intervention Stamp.

Interventions were ceased when infants commenced routine positioning from side to side (i.e., side-lying). Routine side lying of infants itself can prevent development of *flattened* posture. This occurred in the NICU when the following criteria were met:

- 1. Current weight was greater than 1500g.
- 2. Milk was administered intermittently via gastric tube, breast or bottle.
- 3. Oxygen therapy was not required.

Measurements of shoulder and hip posture were performed at three assessment periods. Assessment 1 included measurement of infants at three time points (i.e., prior to study commencement; five weeks post intervention; and term conceptional age) when measures of upper and lower extremity body alignment and upper extremity neuromotor function were performed. Assessment 2 was performed at four months conceptional age and included measures of upper extremity movement patterns and composite measures of movement patterns in both upper and lower extremities. Assessment 3 occurred at eight months conceptional age and included composite measures of movement patterns in upper and lower extremities, as well as measurement of the foot progression angle. All measures were based on expected developmental milestones of term infants at equivalent conceptional age and are shown in Appendices I, J and K. In addition, other than the measures of the distance between the acromion process and suprasternal notch (see Appendix I), and the foot progression angle (see Appendix K), all measures were standardised. Inter-rater and test-retest reliability was established for all measures prior to the study. For clarity, the measurement schedule is shown in Figure 4.5.

Measurement	Birth	5 weeks <sup>₩</sup>	Term*	4 Months*	8 Months#
Angle of pelvic elevation <sup>†</sup>	<b>√</b>	<b>V</b>	√		
Angle of external rotation <sup>†</sup>	$\checkmark$	$\checkmark$	$\checkmark$		
Distance from acromion process to suprasternal notch	√	$\checkmark$	√		
Weight-bearing of surface of the inner thigh and knee <sup>†</sup>	√	√	√		
Scarf sign <sup>§</sup>	$\checkmark$	√	√		
Spontaneous arm movements <sup>†</sup>	√	<b>√</b>	√		
Reaching with hands to feet <sup>‡</sup>				<b>√</b>	
Finger-finger play <sup>‡</sup>				$\checkmark$	
Weight-bearing on forearms <sup>‡</sup>				$\checkmark$	
Reaching <sup>‡</sup>				$\checkmark$	
Crawling <sup>‡</sup>					√
Rolling <sup>‡</sup>					$\checkmark$
Sitting <sup>‡</sup>					$\checkmark$
Supported standing <sup>‡</sup>					$\checkmark$
Foot progression angle*					<b>√</b>

Note.  $^{\#}$  = conceptional age;  $^{\Psi}$  = post commencement of intervention;  $^{\dagger}$  = (Lacey et al., 1990);  $^{\$}$  = (Ballard et al., 1979);  $^{\ddagger}$  = (Piper & Darrah, 1994);  $^{*}$  = (Downs et al., 1991).

<u>Figure 4.5</u> Schematic View of Postural Support Study Measurement Schedule.

# Assessment 1 Measurements.

As previously described, measurements during this assessment period were performed at three time points (i.e., prior to commencement of interventions, five weeks post intervention, and at term conceptional age). Apart from the term conceptional age measurements, all measurements were performed while infants were in the NICU. The measurements are described in detail in Appendix I. Each measurement was repeated three times with the mean value recorded for the distance between the right acromion process and suprasternal notch (ACSS), the angle of external rotation of the leg from lateral support (ERL), and the angle of elevation of the pelvis (EP). The lowest score was recorded for the weight-bearing surface of the inner thigh and knee (WBS), scarf sign (SS), and spontaneous arm movements (SAM).

The ERL, ACSS, SS and SAM measurements were performed while the infant was in the supine position. The WBS and EP measurements were performed with the infant in the prone position. Accurate examination of infants was dependent on muscle tone; therefore, it was important to perform measurements when infants were neither too hungry nor too sleepy (Avery, 1987; Lacey et al., 1990). Hence, they were examined midway between feeds and independent of other factors which may have influenced posture (e.g., severe infection). As recommended by Lacey and colleagues (1990), if unstable breathing patterns and/or sternal recession were observed when the infant was placed in the supine position, observation was postponed until the infant's posture was stable again for two minutes. In addition, when the infant was placed supine, the head was stabilised in a midline position to prevent rotation.

Positioning the infant in the midline prevented the possible influence of asymmetrical tonic neck reflex (Phelps et al., 1985). If the infant varied the position during the observation period, the highest grade observed was recorded. The right upper and lower extremities were used for all measurements (i.e., excluding scores of movement) because there is no reported difference in the range of motion between either right or left upper or lower extremities (Haas et al., 1973; Phelps et al., 1985).

To minimise infant handling, all measurements were made while the infant was naked and awake throughout a 20 minute observation period (10 minutes in prone and 10 minutes in supine). For the researcher to remain blind to group allocation, the following precaution was taken. If an infant had not commenced routine sidelying (i.e., interventions were still in progress and the infant was being nursed prone), the nurse caring for the infant was asked to remove all clothing and postural support rolls from the infant prior to the researcher's arrival to perform measurements. If the infant had already commenced routine side-lying, the researcher removed infant clothing.

# Assessment 2 and 3 Measurements.

Assessments 2 and 3 were performed following discharge at four and eight months conceptional age respectively. Piper & Darrah (1994) recommend that AIMS assessments be performed in a clinic or in the home. For parental convenience, these assessments were performed when infants attended their routine four and eight month follow-up clinic appointments at the paediatric clinic. Appointments were arranged by the co-ordinator of the Preterm Infant Follow-up Programme who also designated a room in which to conduct measurements.

Where possible, assessments were performed on infants before they had been seen by the neonatal paediatrician in the paediatric clinic. This ensured that infants were not too tired or too restless before measurements were performed (Lacey et al., 1985; Robert, 1983; Westcott et al., 1997). The room designated for the purpose of performing measurements ensured privacy for parents and minimised potential distractions that could affect measurements (Piper & Darrah, 1994; Westcott et al., 1997).

The Alberta Infant Motor Scale (Piper & Darrah, 1994) was used to develop measurements for the four and eight month conceptional age measurement periods. This tool was chosen because it represents a carefully constructed, theoretically sound, performance based, and norm referenced observational tool. It was designed specifically for the motor assessment of the developing infant and is sensitive to changes in motor behaviour over time. An added strength of the AIMS is the observational nature of the tool, therefore, minimal handling of an infant is required by the examiner. The infant is encouraged to demonstrate the skills he or she can accomplish spontaneously. Furthermore, the AIMS may be performed by any health professional with a background in infant motor development and an understanding of the essential components of movements as described for each AIMS item.

It is not necessary to administer the entire AIMS scale to each infant. Infants should only be tested on those items in the range that are most appropriate for the infant's developmental level (Piper & Darrah, 1994). Assessment items were, therefore, selected by the researcher and a panel of experts including the NICU physiotherapist, the Head of the School of Physiotherapy at Curtin University, and the neonatal paediatricians in the NICU.

At four months conceptional age, the following measurements were taken: weight-bearing through the shoulders in prone, reaching from prone, reaching with hands to feet in supine, and finger-finger play in supine (see Appendix J). At eight months conceptional age the following measurements were taken: crawling, rolling, sitting, supported standing, and the angle of foot progression (see Appendix K).

The researcher who was blind to group allocation performed all measurements.

#### Inter-rater Reliability.

To ensure the researcher's consistency in measurement techniques several steps were taken to increase the rigour of the study prior to its commencement, and throughout its duration. The researcher was trained in measurement techniques by the NICU physiotherapist prior to commencement of the study. Test-retest reliability was then established by the researcher and the NICU physiotherapist by scoring and re-scoring a group of infants within a 24 hour period. This was conducted under the supervision of an independent physiotherapist.

To ensure consistency, the same format utilised during the study was used for recording of all measurements (i.e., each measurement was performed on three consecutive occasions with the mean score recorded). Prior to commencement of the study, three infants were rated independently by the researcher and NICU physiotherapist on four occasions.

In addition, inter-rater consistency was assessed throughout the study on randomly selected infants at two to four weekly intervals, following which the reliability co-efficient was calculated.

During the study inter-rater consistency was assessed on 18 occasions during the Assessment 1 phase; on 17 occasions during the Assessment 2 phase; and on 14 occasions during the Assessment 3 phase.

A mixed linear model with the rating pairs as the random intercept was modelled to identify the sources of variation as those between babies and those between observers. Inter-rater reliability was expressed as the percentage of the measurement of variation that was attributable to the differences between the observers. Inter-rater reliability was calculated as 100% minus the inter-rater variation. As shown in Table 4.2 pre-study reliability coefficients for Assessment 1 measures ranged from 0.99 - 1.00, and, reliability coefficients ranged from 0.997 - 1.00 during the study.

Table 4.2

Inter-rater Reliability for Assessment 1 Measures

Measure	Pre-study	Study
Scarf sign	1.000	1.000
Spontaneous arm movements	1.000	1.000
Acromion suprasternal notch	0.999	0.997
Angle of elevation of the pelvis	0.999	0.997
Angle of external rotation	0.999	0.997
Weight-bearing surface of the inner thigh and knee	1.000	1.000

As shown in Table 4.3 pre-study reliability coefficients for Assessment 2 measures ranged from 0.952 - 0.984, and, reliability coefficients ranged from 0.890 - 1.00 during the study.

Table 4.3

Inter-rater Reliability for Assessment 2 Measures

Measure	Pre-study	Study
Reaching from prone	0.944	0.890
Weight-bearing through shoulders	0.984	1.000
Reaching with hands to feet	0.954	0.958
Finger-finger play in supine	0.952	0.973

As shown in Table 4.4 pre-study reliability coefficients for Assessment 3 measures ranged from 0.909 - 0.978, and, reliability coefficients ranged from 0.898 - 1.00 during the study.

Table 4.4

Inter-rater Reliability for Assessment 3 Measures

Measure	Pre-study	Study
Sitting	0.955	1.000
Crawling	0.940	0.951
Supported standing	0.909	0.947
Rolling	0.966	0.898
Foot progression angle	0.978	0.998

In conclusion, reliability coefficients ranged from 0.9 to 1.0 for all measurements throughout the study. These results indicate a high level of consistency in measurement techniques between the researcher and the NICU physiotherapist.

### **Ethical Considerations**

Approval was initially gained from Unit Management in the Department of Newborn Services at King Edward Memorial Hospital. Permission to conduct the study was given by Edith Cowan University Committee for the Conduct of Ethical Research on 28 November 1995, and the Ethics Committee of the study hospital on 12 December, 1995 (see Appendix L).

### Risks and Benefits.

There were no risks to infants in any of the treatment groups. Application of both the postural support nappy and disposable nappy forms a routine part of the normal nursing care of the premature infant in the NICU. In addition, prior to implementation of the study the postural support roll was used to support infants during chest physiotherapy with no adverse effects. No parent refused entry of their infant to the study. Many parents expressed willingness and gratitude for their infant's involvement in the study because they had observed VLBW infants with flattened posture (i.e., through previous personal experience of having a preterm infant, or, observation of other VLBW infants in the NICU). Furthermore, as discussed in the procedures section, all measurements were performed in such a way so as to minimise disturbance to the infant. Particular attention was paid to the clinical status of the infants and attached equipment used to monitor the physiological status of each infant.

## Consent.

Parents received a schedule of Information for Parents of Potential Participants detailing the purpose and nature of the study and informing them of their rights as advocates for their infants (see Appendix M). Telephone numbers were included to provide ongoing opportunity for participants to ask questions or exercise their right to withdraw their infants from the study. Written consent was obtained from parents before their infant's entry into the study (see Appendix M).

Number coding on a master list ensured confidentiality of name-related data (see Appendix N). Infants were then identified by number code only on the data collection form and on all computer data entries. The master list and data collections forms were kept separately in a locked cabinet. The data collection forms will be kept for at least five years.

#### **CHAPTER 5**

#### Results

This chapter will describe the statistical techniques applied to the data for Phase 1 and Phase 2 of this study. The results will then be presented. For clarity, the first component of this chapter will describe statistical techniques and results related to Phase 1. Similarly, the second component will describe statistical techniques and results related to Phase 2.

# Data Analysis - Phase 1

The data were analysed using univariate and multivariate statistical techniques within the Statistical Analysis System (SAS), Release 6.12. Analyses were two-tailed with the significance level set at 0.05 for all tests. As recommended by Gore (1981), exact <u>p</u> values have been quoted in tables throughout this chapter to enable the reader to interpret the closeness of the decisions.

When the data were normally distributed, the differences between the two commencement protocol groups were assessed using a paired <u>t</u> test. When the differences were not normally distributed the Wilcoxon ranks sum test for non parametric data was used. For categorical variables with two levels, a Fisher's exact test was used.

# Statistical Model for Multivariate Statistical Techniques

A statistical model is a mathematical description of how the data may have been generated. The standard linear model as follows is one of the most common statistical models:  $y = X\beta + \varepsilon$ . In this model, y represents a vector of observed data,  $\beta$  is an unknown vector of fixed-effects parameters with known design matrix X, and  $\varepsilon$  is an unknown random error vector modeling the statistical noise around  $X\beta$ .

The focus of the standard linear model is to model the mean of y by using the fixed effects parameters  $\beta$ . The residual errors  $\varepsilon$  are assumed to be independent and identically distributed random variables with mean 0 and variance  $\sigma^2$ .

The mathematical notation used to describe the mixed linear model used for this study was as follows:  $y = X\beta + Z\gamma + \varepsilon$ . Here  $\gamma$  was an unknown vector of random effects parameters with known design matrix Z, and  $\varepsilon$  was an unknown random error vector whose elements were no longer required to be independent and homogenous.

Repeated measures were made of the dependent variables *Y*, therefore, for the final analysis of the data a mixed linear model was used. This model provided the flexibility of modeling not only the means of the data, but also their variances and covariances.

The model was fitted using residual maximum likelihood (REML) methods (Laird, Donnelly, & Ware, 1992). The covariance structure of the random effects vector was modelled as unstructured specifying a random intercept-slope model that has different variances for the intercept and slope, and a covariance between them.

The crossover design used in Phase 1 was similar to a repeated measures design (i.e., the same subjects were measured under more than one treatment condition). Unlike the repeated measures design, crossover designs generally allow for systematic changes in responses over time, and may incorporate *carryover* variables to account for treatment effects that arise as a result of sequencing (Laird et al., 1992). In this study, therefore, *time-varying* covariates were of three types: period effects (i.e., allowing for time trends), direct treatment effects and carryover treatment effects (i.e., previous treatment protocols).

The main interest in this study was the direct treatment effect. Use of the mixed model for this analysis was based on the assumption that the time periods were equally spaced in a four period crossover study, with repeated measures within periods. The following primary assumptions underlying the analysis model were tested:

- 1. The data were normally distributed.
- 2. The means (i.e., expected values) of the data were linear.
- 3. The variances and covariances of the data were in terms of fixed effect and random effect parameters (SAS, 1996).

The parameters of the mean model were referred to as fixed effects, and the parameters of the variance-covariance model were referred to as random effects.

The need for covariance parameters arose because the repeated measurements performed on each infant were correlated within each infant and treatment period, and could have exhibited variability that changed over time.

The variables that were treated as fixed effects were: treatment protocol, intervention, gender, gestational age at birth, conceptional age, age at study entry (i.e., age in days from birth), weight at birth and at study entry, and birthweight ratio. Birthweight ratio was calculated as the ratio between an infant's weight at birth and the median birthweight for an infant of the same sex and gestational age born to a mother of similar height and parity. Variables treated as random effects were individual infants and time. Variations between nappy treatments were compared by inspection of the coefficients of variation.

# Demographic and Perinatal Data.

Demographic and selected perinatal data related to the participants are shown in Table 5.1. These data were checked for normality using the Wald statistic.

Baseline characteristics were compared for treatment protocol groups using paired tests for birthweight, weight at study entry and birthweight ratio. The Wilcoxon ranks sum test was used for gestational age at birth and conceptional age at study entry. The Fisher's exact test was used to check the variable of gender. The results are shown in Table 5.1.

Table 5.I

Baseline Comparison of Commencement Protocols for Temperature Study

	N without liner	N with liner	р
ū	10	13	
Gestational age at birth (wk) <sup>†</sup>	27.3 (26-29)	26 (24-28)	0.449
Weight at birth (g)§	879 (250)	869 (250)	0.926
Birthweight ratio§	0.9 (0.21)	1.0 (0.23)	0.349
Male gender <sup>‡</sup>	7 (70)	4 (31)	0.100
Conceptional age at entry (wk) <sup>†</sup>	28.9 (27-31)	28.2 (27-28)	0.435
Age at entry (day)	13 (8-19)	9 (7-19)	0.675
Weight at entry (g)§	877 (224)	918 (166)	0.644
Withdrawn	1	2	

Note. † = Median (interquartile range); \$ = Mean (standard deviation); ‡ = n(%).

Analyses indicated there were no differences between the treatment protocol groups at baseline for the birth variables of conceptional age, birthweight, birthweight ratio, and gender. There was also no difference for the variables of weight and conceptional age at study entry. The results for incubator, skin and per axilla follow.

## Crossover Sequence.

Figure 5.1 shows the crossover sequence used in this study. As shown in Figure 5.1 the control group (i.e., infants randomly allocated to commence the study wearing the control nappy) were identified as Group 1, and the treatment group (i.e., infants randomly allocated to commence the study wearing the treatment nappy) were identified as Group 2. For the statistical analysis, the control nappy (i.e., postural support nappy) was labelled as TX1 and the treatment nappy (i.e., postural support nappy with liner) was labelled as TX2.

	Day 1	Day 2	Day 3	Day 4
Group 1	control nappy	treatment nappy	control nappy	treatment nappy
	TX1	TX2	TX1	TX2
Group 2	treatment nappy	control nappy	treatment nappy	control nappy
	TX2	TX1	TX2	TX1

Figure 5.1 Crossover Sequence for Temperature Study.

Use of a crossover design required the testing for possible carryover and crossover effects of the treatment nappy used in this study. Carryover effects occur when the application of a treatment between two control periods affects the baseline for the second control period, that is, the baseline is permanently adjusted. Crossover effects occur when the amount of any effect differs according to the rotation schedule, that is, the treatment in question is different when it is given in a different order. The model used allowed a comparison of nappy treatments by sorting individual periods of treatment according to nappy treatment, group allocation and day of treatment:

The carryover effect was tested by looking at the incubator temperature in successive control nappy periods (i.e., TX1 on day one with TX1 on day three, or, day one versus day three of the control nappy). The crossover effect was tested by looking at incubator and skin temperatures of infants prior to and following a control nappy period (i.e., TX 2 on day one with TX2 on day two, or, day one versus day two of the treatment nappy).

#### Data Related to Measurements of Incubator Temperature

Initially, the data for incubator temperature were checked for any carryover or crossover effect.

### Carryover Effect.

In a design such as that utilised in this study, a carryover effect is tested for by comparing results from control periods before and after a treatment period.

In this study, Group 1 incubator temperatures from day one and day three were compared because they were the control nappy periods that occurred before and after the treatment nappy period. As shown in Table 5.2 there was no carryover effect of the treatment nappy on incubator temperatures measured in the control periods (p = 0.087).

Table 5.2

<u>Carryover Effect of Treatment Nappy on Incubator Temperature</u>

Day	Difference	SE	95% CI	Б
Group 1 (Days 1 and 3)	0.2875	0.16739	-0.042, 0.616	0.087

# Crossover Effect.

A crossover effect is determined by comparing the order in which the treatment is administered. In this study the crossover effect was determined by comparing the incubator temperatures from a treatment nappy period that occurred after a control nappy period, with incubator temperatures from a treatment nappy period that occurred before a control nappy period. Therefore, incubator temperatures from infants in Group 1 on day two were compared with incubator temperatures from infants in Group 2 on day one. As shown in Table 5.3, there was no crossover effect of the treatment nappy on incubator temperatures (p = 0.126).

Table 5.3

Crossover Effect of Treatment Nappy on Incubator Temperature

Nappy treatment intervention	Difference	SE	95% CI	Б
Group 1 - Day 2	0.076	0.366	-0.632, 0.785	0.126
versus				
Group 2 - Day 1				

# Data Related to Hypothesis Testing

The hypothesis posed related to measurements of incubator temperature was as follows:

Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent liner will demonstrate lower incubator temperatures compared with infants nursed in a cloth postural support nappy without a fixed inner absorbent liner on infant servo control.

In the NICU, infant servo control (ISC) is used when nursing infants in incubators. Higher incubator temperatures reflect an infant's inability to regulate body temperature in response to hypothermia. To investigate this hypothesis, repeated measures analysis of variance (ANOVA) was used to analyse the incubator temperatures over the four day study, allowing the intercept and slope of the incubator time curves to be a random effect. Possible covariates were placed in two groups. The first group of covariates consisted of variables pertaining to the VLBW infant (i.e., gestational age at birth, actual age at entry to the study, birthweight ratio, conceptional age at enrolment, and gender of the infant).

To aid interpretation of parameter estimates from the ANOVA, the first three variables were centralised by subtracting the mean value before modelling their effect. The labels applied to these variables following centralisation were as follows: gestational age at birth, actual age at entry to study, and birthweight ratio. The second group of covariates consisted of variables pertaining to the design of the study, consisting of the possible variation of incubator temperatures taken: on individual days, during day time compared with night time, and following the handling of infants by NICU staff for care related procedures. These covariates were adjusted for in the analysis.

The variable known as conceptional age is a composite of gestational age at birth and actual age. If these variables were analysed within the same model, analysis would be difficult due to a high confounding effect between the variables. Therefore, separate models were used for (a) gestational age at birth and actual age, and (b) conceptional age.

As shown in Table 5.4, there were no effects for any of the first group of covariates (i.e., those pertaining to the VLBW infant) on incubator temperature.

Table 5.4

Baseline Estimate for Covariates Related to Incubator Temperature

	Incubator temperature	SE	р
Baseline intercept	34.745	9.352	0.0019
Gestational age at birth	-0.636	0.646	0.325
Conceptional age at entry*	0.114	0.096	0.239
Actual age	-0.016	0.163	0.922
Birthweight ratio	-0.424	0.973	0.663
Gender	-0.189	0.447	0.672
Day 1	0.170	0.170	0.318
Day 2	0.301	0.137	0.279
Day 3	0.174	0.112	0.122
Day 4	0	-	-
Wake	-0.128	0.074	0.083
Infant handling	-0.275	0.082	0.0008
Nappy treatment	0.981	0.078	0.0001

Note. \* = results from separate analysis.

As there was no effect of the first group of covariates, they were removed from the model using the dropping rule (i.e.,  $\underline{p} > 0.20$ ). The model was rerun to analyse effects of the second group of covariates as well as their interactions.

The results of this analysis provided information for the following questions.

1. Was there a difference in incubator temperatures between individual days for nappy treatments?

The overall effect of individual treatment days on incubator temperature was not significant ( $\underline{p} = 0.122$ ). In addition, as shown in Table 5.5 for this analysis, there was no effect of any individual day on incubator temperature (SAS defaults to using the last value as the baseline for comparison).

Table 5.5

Effect of Individual Days on Incubator Temperature

	Estimate	SE	р
Day 1	0.416	0.448	0.354
Day 2	0.173	0.271	0.523
Day 3	0.427	0.471	0.365

In addition, no differences in incubator temperatures were detected as a result of the interaction of individual days of treatment and the covariates of nappy treatment, infant handling or day/night periods (Table 5.6).

Table 5.6

<u>Differences in Incubator Temperatures between Individual Days as a Result of Interactions of Type of Nappy Treatment, Infant Handling and Day/Night Periods</u>

Interaction	Б
day × nappy treatment	0.197
day × infant handling	0.779
day × wake	0.370

As there was no difference in incubator temperatures between individual days of treatment, the variable of day was removed from the model.

2. Were incubator temperatures affected by the time of day that temperature measurements were taken?

Recording incubator temperatures during night periods versus day periods had no significant overall effect on the mean incubator temperature (33.084°C) as incubator temperature was decreased by  $0.06^{\circ}$ C (SE 0.140, p = 0.645). When day versus night temperatures were considered with interaction of infant handling performed in the last hour, there was also no significant effect on the mean incubator temperature (estimate -0.0645°C, SE 0.140, p = 0.658). As the time of day that incubator temperatures were taken had no effect on incubator temperature, the model was rerun without the variable of wake as a fixed effect.

3. Did the handling of infants for NICU procedures have an effect on incubator temperatures?

The handling of infants in the hour preceding the recording of an incubator temperature significantly decreased incubator temperature by  $0.277^{\circ}$ C (SE 0.081, p = 0.0007).

Final model used for hypothesis testing.

The original hypothesis was:

Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent liner will demonstrate lower incubator temperatures compared with infants nursed in a cloth postural support nappy without a fixed inner absorbent liner on infant servo control

Results from this analysis showed that: (a) when infants were nursed in a postural support nappy with an inner absorbent liner there was a significant decrease in incubator temperature of  $0.980^{\circ}$ C (SE 0.077,  $\underline{p} = 0.0001$ ), and (b) the handling of an infant in the hour preceding the recording of incubator temperature caused an increase in incubator temperature of  $0.280^{\circ}$ C.

In summary, covariates pertaining to the VLBW infant had no effect on incubator temperature. Of the covariates pertaining to the nature of the crossover design used in this study, only the handling of infants for procedures caused both a statistically and clinically significant increase in incubator temperature. This was an expected finding because the handling of infants nursed in incubators usually results in hypothermic episodes for a number of reasons (e.g., flow of cool air into incubator from the opening of doors and cooling of the infants' skin when handled by carers).

The decrease in incubator temperature of approximately 1.0°C caused by the postural support nappy with a fixed inner absorbent liner, was of great clinical interest because one of the prime objectives of nursing care is to maintain a stable thermal environment. Therefore, these results support a nursing practice recommendation that a cloth postural support nappy with a fixed inner absorbent liner should be used for VLBW infants.

# Data Related to Measurements of Skin Temperature

As with the analyses related to incubator temperature, skin temperature values were initially checked for any carryover and crossover effects.

# Carryover Effect.

As shown in Table 5.7, there was no carryover effect of the nappy treatment on skin temperatures measured in the control periods (p = 0.599).

Table 5.7

Carryover Effect of Treatment Nappy on Skin Temperature

Day	Difference	SE	95% CI	Б
Group 1 (Days 1 and 3)	0.009	0.016	-0.0239,0.041	0.599

# Crossover Effect.

As shown in Table 5.8, there was no crossover effect of the treatment nappy on skin temperatures (p = 0.612).

Table 5.8

<u>Crossover Effect of Treatment Nappy on Skin Temperature</u>

Nappy treatment intervention	Difference	SE	95% CI	р
Group 1 - Day 2	0.011	0.021	-0.031, 0.053	0.612
versus				
Group 2 - Day 1				

# Data Related to Hypothesis Testing

The hypothesis posed related to measurements of skin temperature was as follows:

Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent liner will demonstrate higher skin temperatures compared with infants nursed in a cloth postural support nappy without an absorbent liner on infant servo control.

Skin temperature is a reflection of core body temperature. In the NICU, ISC is used when nursing infants in incubators. Skin temperature is measured by a probe attached to the skin on an infant's lower back. The probe forms part of a feedback system within the incubator where the desired skin temperature is preset and incubator temperature adjust accordingly to maintain skin temperature at the preset level. Higher skin temperatures in a well infant reflect the infant's ability to regulate body temperature.

To investigate this hypothesis, the previously described repeated measures ANOVA was used to analyse the skin temperatures over the four days of the study, allowing the intercept and slope of the skin time curves to be a random effect. Possible covariates were placed into two groups and were similar for both incubator and skin temperature analyses. In addition, separate models were used for gestational age at birth and conceptional age because these variables are highly correlated, and analysis of both variables at the same time would be difficult to interpret.

As shown in Table 5.9 the only covariate that affected baseline skin temperature was the variable of infant's actual age. Although this variable caused a statistically significant increase in skin temperature of  $0.019^{\circ}$ C (p = 0.046), the effect was considered to be clinically non significant. The model was rerun with the addition of conceptional age and the removal of gestational age and actual age because of the high confounding of gestational age at birth and conceptional age (i.e., conceptional age is a composite of an infant's gestational age and actual age). This composite variable was not significant possibly due to the magnitude of the gestational age component.

Table 5.9

Baseline Estimate for Covariates Related to Skin Temperature

	Skin temperature	SE	Б
Baseline intercept	36.669	0.024	0.0001
Gestational age at birth	0.002	0.005	0.650
Conceptional age at entry*	0.002	0.005	0.679
Actual age	0.019	0.010	0.046
Birthweight ratio	0.002	0.005	0.665
Male gender	0.002	0.021	0.919
Day 1	0.011	0.017	0.512
Day 2	-0.011	0.014	0.449
Day 3	0.010	0.012	0.382
Day 4	0.011	0.017	0.512
Wake	0.009	0.008	0.275
Infant handling	0.027	0.009	0.002
Nappy treatment	-0.048	0.008	0.0001

Note. \* = results from separate analysis.

The first group of covariates excluding the variable of infants' actual age were removed from the model using the dropping rule (i.e., p > 0.20). The model was rerun to analyse effects of the second group of covariates as well as their interactions. The results of this analysis provided information for the following questions.

1. Was there a difference in skin temperatures between individual days for nappy treatments?

The overall effect of individual treatment days on skin temperature was not significant (p = 0.147). In addition, as shown in Table 5.10 for this analysis, there was no effect of any individual day on skin temperature (SAS defaults to using the last value as the baseline for comparison).

Table 5.10

Effect of Individual Days on Skin Temperature

	Estimate	SE	Б
Day 1	-0.023	0.033	0.481
Day 2	-0.021	0.028	0.503
Day 3	0.062	0.035	0.081

The effect of infants' actual age on skin temperature was also tested and found to be non significant ( $\underline{p} = 0.344$ ). Based on these findings, the variables of day and actual age were removed from the model.

2. Were skin temperatures affected by the time of day that temperature measurements were taken?

Recording skin temperatures during night periods versus day periods did not increase the mean skin temperature (SE 0.015,  $\underline{p}$  = 0.226). Day versus night temperatures were also considered with their interaction with infant handling. The handling of infants in the hour preceding the measurement of skin temperature showed no change in the mean skin temperature (SE 0.018,  $\underline{p}$  = 0.450).

As the time of day that skin temperatures were taken had no effect on skin temperature, the model was rerun without the variable of wake as a fixed effect.

3. Did the handling of infants for NICU procedures have an effect on skin temperatures?

The handling of infants in the hour preceding the recording of skin temperature significantly decreased the mean skin temperature (36.684°C) by  $0.027^{\circ}$ C (SE 0.009, p = 0.002).

### Final model used for hypothesis testing.

The original hypothesis was:

Infants < 31 weeks gestation nursed in a cloth postural support nappy with a fixed inner absorbent nappy liner will demonstrate higher skin temperatures compared with infants nursed in a cloth postural support nappy without an absorbent liner on ISC.

Results from this model showed that when infants were nursed in a cloth postural support nappy with an inner absorbent liner, there was a significant increase in skin temperature of  $0.05^{\circ}$ C (SE 0.008, p = 0.0001).

In summary, of the covariates pertaining to the nature of the crossover design of this study, only the handling of infants for procedures caused both a statistically and clinically significant decrease in skin temperature. This was an expected finding because the handling of an infant who is nursed in an incubator usually results in a hypothermic episode for a number of reasons (e.g., flow of cool air into incubator from the opening of doors, cooling of the infants skin when handled by carers, and removal of clothing for examination).

The increase in skin temperature of approximately 0.05°C caused by use of the postural support nappy with an inner absorbent liner is of great clinical interest because one of the prime objectives of nursing care is to maintain a stable thermal environment. Therefore, these results support a nursing practice recommendation that VLBW infants should be cared for in a cloth postural support nappy with an inner absorbent liner.

### Data Related to Measurements of Per Axilla Temperature

As per unit protocol, per axilla (PA) temperatures were taken eight hourly as a validity check to determine whether skin temperature recordings adequately reflected the infant's body temperature. Within the study setting a difference of as much as 0.6°C between PA and skin temperature is accepted as reasonable (i.e., where PA temperature is higher than skin temperature).

Per axilla temperatures are measured by a thermometer that is placed between the two skin folds of the axilla. In contrast, skin temperatures are measured from the skin surface of the lower back. It is, therefore, accepted that PA temperatures will be higher than skin temperatures because the combined heat radiated from two skin folds will be higher than the degree of heat radiated from one skin surface.

A fitted linear regression model (i.e., rather than one including higher order polynomials) was chosen for this data because the range of skin temperature was small and it was not possible to detect more complex relationships between skin and per axilla temperatures. A value of 36.5°C was used to centre the data. The multiple linear regression equation used was as follows:

PA temperature = 36.5 + 0.289<sup>(intercept)</sup> + 0.568<sup>(gradient)</sup>(skin temperature – 36.5).

Provision was made in the model to account for repeated measures by allowing the estimated intercept in the linear relationship to vary between individuals. The intercept generated in the output from this analysis was the mean intercept for all subjects. There was no evidence of variability in the gradient between subjects in the linear relationship between PA and skin temperatures.

A constant difference between PA and skin temperatures could not be established. Table 5.11 shows a clinically common range of skin temperatures with predicted PA temperatures, the differences and their 95% confidence intervals. Given the protocol within the study setting, differences between predicted PA and skin temperatures are well placed within the accepted level of as much as 0.6°C. The 95% confidence intervals demonstrate the accepted value is reasonable, within rounding error.

Table 5.11

Predicted Per Axilla (PA) Temperatures

Skin temperature	Predicted PA temperature	Δ	95% CI
36.0	36.5	0.5	36.0, 37.0
36.5	36.8	0.3	36.3, 37.3
37.0	37.0	0.0	36.5, 37.5
37.5	37.4	-0.1	36.9, 37.9
38.0	37.6	-0.4	37.1, 38.1

### Data Analysis - Phase 2

This second component of Chapter 5 will describe the statistical techniques and results related to Phase 2 of this study.

### Demographic and Perinatal Data

Demographic and selected perinatal data related to the participants are shown in Tables 5.12 and 5.13. These data were checked for normality using the Wald statistic. When the data were normally distributed the differences between the treatment groups were assessed using analysis of variance (ANOVA). When the differences were not normally distributed the Kruskal-Wallis Chi Square test for non parametric data was used. The Chi Square test was used for categorical variables. Differences between the treatment groups for the variables of birthweight, birthweight ratio, and gestational age were analysed using the Kruskal-Wallis Chi Square test.

The Chi Square test was used for the variables of gestational age group, presentation at delivery, gender and type of delivery. These results are shown in Table 5.12. Analyses indicated that there were no differences between the groups at baseline for the variables of gestational age, presentation at delivery, gender, type of delivery, being part of a multiple birth, order of birth and gestational age. There was a significant difference between groups for birthweight ratio (p = 0.001). This is evident from the median birthweight (1210g) in the disposable nappy and postural roll group (R), compared with the birthweights of the postural support nappy (N) and postural support nappy and postural roll groups (NR) that were 1045g and 1035g respectively. There was, however, no associated difference in gestational age.

Table 5.12

<u>Differences between Postural Treatment Groups for Delivery Variables</u>

Variable	N	NR	R	₽
<u>n</u>	41	43	39	
Gestational age group <sup>†</sup>				0.720
< 29 weeks	24(59)	27(63)	23(59)	
29 - 30 weeks	17(41)	16(37)	16(41)	
Presentation <sup>†</sup>				0.097
vertex	24(59)	24(56)	27(69)	
breech	16(39)	16(37)	12(31)	
transverse	0(0)	2(5)	0(0)	
other	1(2)	1(2)	0(0)	
Gender <sup>†</sup>				0.284
female	20(49)	17(40)	20(51)	
male	21(51)	26(60)	19(49)	
Delivery mode <sup>†</sup>				0.861
vaginal	18(44)	19(44)	18(46)	
caesarean	23(56)	24(56)	21(54)	
Multiple birth (part of) <sup>†</sup>				0.084
singleton	32(78)	22(51)	29(74)	
twin	7(17)	16(37)	8(21)	
triplet/quadruplet	2(5)	5(12)	2(5)	
Birth order (if multiple)				0.594
1	5(12)	4(9)	6(15)	
2	3(7)	5(12)	11(28)	
<b>3</b> <sup>+</sup>	1(2)	0(0)	3(8)	
Gestational age (weeks)§	28 <sup>1</sup> (26 <sup>4</sup> -29 <sup>2</sup> )	28 <sup>6</sup> (27 <sup>5</sup> -29 <sup>5</sup> )	28 <sup>2</sup> (27 <sup>2</sup> -29 <sup>3</sup> )	0.475
Birthweight ratio§	0.99(0.89-1.13)	1.05(0.94-1.15)	0.94(0.77-1.04)	0.001
Birthweight (g)§	1045(830-1400)	1210(1005-1395)	1035(830-1150)	0.050

Note. † = n(%); § = median(interquartile range).

The mean birthweight was marginally different between groups (p = 0.050).

Because of the close association of birthweight and gestational age, birthweight ratio being independent of gestational age, was included with gestational age in the ANOVA and Kruskal-Wallis Chi Square models, to test for any effect of size at birth on baseline postural measurements.

Similar tests were used to examine differences between the treatment groups for possible confounding variables measured during the postnatal period. Differences between treatment groups for the variables of intraventricular haemorrhage (IVH)/periventricular leukomalacia (PVL) and discharge oxygen were analysed using the Chi Square test. Differences for the number of suspected septic episodes, number of proven septic episodes, number of endotracheal tube (ETT) ventilator dependent days, number of double nasal prong (DNP) ventilator dependent days, number of ventilated oxygen dependent days and the number of post ventilation oxygen dependent days were analysed using the Kruskal-Wallis Chi Square test. The one way ANOVA test was used to examine differences between groups for the variables of weight at five weeks post intervention, weight at term conceptional age, weight at four months conceptional age and weight at eight months conceptional age. As seen in Table 5.13 there were no differences detected between treatment groups for any of the variables. Testing for birthweight, birthweight ratio and gestational effects showed no differences between treatment groups. Thus, randomisation was effective.

Table 5.13

<u>Differences Between Postural Treatment Groups for Postnatal Variables</u>

Variable	N	NR	R	p
<u>n</u>	41	43	39	
IVH <sup>†</sup>				
Grade 0-2	37(90)	39(91)	39(100)	0.334
Grade 3-4, PVL	4(10)	4(9)	0(0)	
Discharge O <sub>2</sub> <sup>†</sup>				0.139
Yes	6(15)	3(7)	7(18)	
No	35(85)	40(93)	32(82)	
Oxygen ventilated (days)§	3(1-24)	3(1-19)	3(0-27)	0.921
Oxygen post ventilation (days)§	2(0-32)	0(0-19)	3(0-28)	0.695
Ventilated - ETT (days) <sup>§</sup>	3(1-20)	3(2-9)	2(0-20)	0.671
Ventilated - DNP (days)§	2(0-4)	2(0-12)	1(0-6)	0.369
Proven sepsis episodes§	0(0-0)	0(0-1)	0(0-0)	0.853
Suspected sepsis episodes§	1(0-3)	1(0-2)	1(1-2)	0.321
Days until study commenced§	6(4-8)	5(3-8)	5(3-8)	0.676
Days of intervention <sup>§</sup>	34(21-44)	28(21-37)	33(21-48)	0.525
Weight (g) <sup>‡</sup> - 5 weeks post intervention	1693(57)	1808(58)	1738(58)	0.327
Weight (g) <sup>‡</sup> - term <sup>#</sup>	2901(83)	3310(80)	2946(85)	0.193
Weight (g) <sup>‡</sup> - 4 months <sup>#</sup>	6047(171)	6207(163)	6212(176)	0.735
Weight (g) <sup>‡</sup> - 8 months <sup>#</sup>	7848(203)	8124(200)	8034(209)	0.611

Note.  $^{\dagger}$  = n(%);  $^{\S}$  = median(interquartile range);  $^{\ddagger}$  =  $\underline{M}$ (standard error), #conceptional age.

## Data Related to Measurements of Posture

As described in Chapter 4, a series of measurements relating to posture were performed at three assessment periods (i.e, Assessment 1 - prior to study commencement, five weeks post intervention and term conceptional age;

Assessment 2 - four months conceptional age; and Assessment 3 - eight months conceptional age). For clarity, Figure 5.2 reproduces the original schematic view of the measurement schedule introduced in Chapter 4.

Measurement	Birth	5 weeks <sup>†</sup>	Term <sup>§</sup>	4 months§	8 months§
Angle of pelvic elevation	√	<b>√</b>	<b>√</b>		
Angle of external rotation of leg	√	$\checkmark$	$\checkmark$		
Distance from acromion process to suprasternal notch	1	√	<b>√</b>		
Weight-bearing surface of inner thigh and knee	<b>√</b>	√	√		
Scarf sign	$\checkmark$	$\checkmark$	$\checkmark$		
Spontaneous arm movements	$\checkmark$	$\checkmark$	√		
Hands to face				$\checkmark$	
Finge-finger play				$\checkmark$	
Weight-bearing through shoulders				$\checkmark$	
Reaching				$\checkmark$	
Crawling					$\checkmark$
Rolling					$\checkmark$
Sitting					$\checkmark$
Standing					$\checkmark$
Foot progression					√

Note. † = post intervention; § = conceptional age.

Figure 5.2 Schematic View of Postural Support Study Measurement Schedule.

#### Baseline Measurements.

Any differences between the treatment groups for distribution of baseline measurements for the distance between the acromion process and suprasternal notch (ACSS), and the angles of elevation of the pelvis (EP) and external rotation of the leg (ERL) were analysed using a one way ANOVA test. The measurements of the weight-bearing surface of the inner thigh and knee (WBS), scarf sign (SS), and spontaneous arm movements (SAM) were not normally distributed. The measurements were ordinal and took the values of one, two, three, four or five only. Therefore, one way ANOVA was inappropriate and non parametric tests were used. The Kruskal-Wallis Chi Square test was used to examine differences between groups for WBS, SS and SAM.

At baseline, data from 123 infants were available for analysis. As shown in Table 5.14, there were no differences in the distribution of baseline measurements between the treatment groups for any of the baseline measurements. Testing for birthweight and birthweight ratio with gestational age, showed no additional effect between treatment groups. These variables, therefore, were not considered in further analyses.

Table 5.14

Distribution of Baseline Postural Measurements for Treatment Groups

Variable	N	NR	R	р
<u>n</u>	41	43	39	
WBS <sup>†</sup>	4(3-4)	3(3-4)	3(2-4)	0.517
SAM <sup>†</sup>	2(2-3)	3(2-3)	3(2-3)	0.571
SS <sup>†</sup>	2(2-2)	3(2-3)	2(2-2)	0.678
EP <sup>§</sup>	40(0.976)	40(0.953)	42(1.000)	0.245
ERL <sup>§</sup>	40(0.951)	41(0.929)	41(0.975)	0.756
ACSS§	4.8(0.065)	4.9(0.064)	4.8(0.066)	0.616

Note.  $^{\dagger}$  = median(interquartile range);  $^{\$}$  =  $\underline{M}(SE)$ .

In summary, as shown in Tables 5.12, 5.13 and 5.14, randomisation was effective. With the exception of birthweight ratio there were no differences detected between the three treatment groups for delivery and postnatal variables, or baseline postural measurements.

## **Hypothesis Testing**

#### Data Related to Postural Measurements at Assessment 1

## Assessment 1 - Secondary Hypotheses.

1. At five weeks post intervention and term conceptional age, infants < 31 weeks gestation nursed prone with a postural support nappy and a postural support roll, will demonstrate a reduced area of weight-bearing surface of the inner thigh and knee, a decreased angle of external rotation of the leg from lateral support, and an increased angle of pelvic elevation compared with infants nursed with a postural support nappy or a disposable nappy and a postural support roll.

2. At five weeks post intervention and at term conceptional age, infants < 31 weeks gestation nursed prone with a postural support nappy or a disposable nappy and a postural support roll will demonstrate a lower scarf sign score, decreased shoulder retraction and increased spontaneous arm movements, compared with infants < 31 weeks gestation nursed prone in a postural support nappy without a postural support roll.

To test these hypotheses for the ACSS, EP and ERL measurements within each treatment group, ANOVA comparisons were made between the measurements at each time point (five weeks post intervention and term conceptional age). The measurements were then adjusted for differences from baseline within and between each treatment group.

To test these hypotheses for the WBS, SS and SAM measurements within each treatment group, the medians of the scores at each time point were compared among groups using the Kruskal-Wallis Chi Square test. The differences between scores at each time point and baseline were then compared within each treatment group using the Kruskal-Wallis Chi Square test. The type 1 error rate was set at 1% for all multiple comparisons for these secondary hypotheses.

## Data Related to Testing of Secondary Hypothesis 1

One infant died at nine days of age and one infant was transferred with its sibling who required surgery to another hospital at 17 days of age. Thus, 121 infants were available for analysis at the five week post intervention and term conceptional age time points during assessment one. There were no differences in baseline measurements between infants who were available at five weeks post intervention and those who were not available.

# Weight-bearing Surface of the Inner Thigh and Knee (WBS).

Overall, there was a significant difference among treatment groups in the WBS at five weeks post intervention ( $\underline{p}=0.0001$ ). This significance was maintained at term conceptional age ( $\underline{p}=0.0001$ ). In particular, there was a significant increase in the WBS in the NR group when compared with the R and N groups at five weeks post intervention ( $\underline{p}=0.005$ ,  $\underline{p}=0.0001$ ) and at term conceptional age ( $\underline{p}=0.0001$ ,  $\underline{p}=0.0001$ ). There was no difference in the WBS between the N or R groups at five weeks post intervention or term conceptional age ( $\underline{p}=0.665$ ,  $\underline{p}=0.640$ ). The results are shown in Table 5.15.

When the median scores for differences from baseline were compared there was a significant difference among treatment groups at five weeks post intervention (p = 0.0002). This significance was maintained at term conceptional age (p = 0.0008). In particular, there was a significant increase in the WBS in the NR group when compared with the R and N groups at five weeks post intervention (p = 0.001, p = 0.0002) and at term conceptional age (p = 0.001, p = 0.001). There was no difference between in the WBS between the N or R groups at five weeks post intervention or term conceptional age (p = 0.540, p = 0.905). The results are shown in Table 5.15.

A high score for WBS indicated a reduced weight-bearing surface of the inner thigh and knee. The secondary hypothesis was supported because use of a N and R resulted in a significant decrease in the weight-bearing surface of the inner thigh and knee from baseline measurements in the NR group. This decrease was evident at five weeks post intervention and maintained at term conceptional age.

**Table 5.15** 

Overall Group Effect and Differences from Baseline for Weight-bearing Surface of Inner Thigh and Knee at Assessment 1 Time 0.0001 NR>R 0.0001 NR>N 0.001 NR>R 0.001 NR>N 0.905 NS 0.640 0.0008 Term conceptional age Median (IQ range) Median (IQ range) p(NR vs N) p(NR vs R) p(NR vs R) Overall p value Overall p value D(NR vs N) p(R vs N) p(R vs N) 4(4-5) 5(5-5) 4(4-5) 1(0-2) 2(1-2) 1(0-2) **4** € 38 NR NR NV N NR>R NR>N SS SS 0.005 0.0002 0.001 0.0002 0.0001 0.665 0.540 Median (IQ range) Overall <u>p</u> value <u>p</u>(NR vs R) <u>p</u>(NR vs N) Median (IQ range) p(NR vs N) p(R vs N) p(NR vs R) Overall p value p(R vs N) Five weeks 2(1-2) 0.5(0-1) 0(0-1) 4(3-4) 5(4-5) 4(3-5) 4 4 3 8 8 Overall p value 0.517 Median (IQ range) Baseline 3(3-4) 4(3-4) 3(2-4) Group zæz zĸ ZEZ Median Scores for Differences Overall Group from Baseline Points ⊏ا

## Angle of External Rotation of the Leg from Lateral Support (ERL).

Overall, there was a significant difference among treatment groups in the ERL at five weeks post intervention ( $\underline{p}$  = 0.029). This significance was maintained at term conceptional age ( $\underline{p}$  = 0.0001). In particular, there was a significant increase in the ERL angle in the NR group when compared with the N group at five weeks post intervention ( $\underline{p}$  = 0.010) and at term conceptional age ( $\underline{p}$  = 0.0001). There was also a significant increase in the ERL angle at term in the NR group when compared with the R group ( $\underline{p}$  = 0.0002). There was no difference in the ERL between the N or R groups at five weeks post intervention or term conceptional age ( $\underline{p}$  = 0.474,  $\underline{p}$  = 0.542). The results are shown in Table 5.16.

When the mean scores adjusted for differences from baseline were compared, there was a significant difference among treatment groups in the SS at five weeks post intervention (p = 0.0001). This significance was maintained at term conceptional age (p = 0.0007). In particular, there was a significant increase in the ERL angle in the NR group when compared with the N group at five weeks post intervention (p = 0.007) and at term conceptional age p = 0.0001). In addition, there was a trend towards an increase in the ERL angle in the NR group when compared with the R group at five weeks post intervention (p = 0.025). This trend reached significance at term conceptional age (p = 0.0001). There was no difference in the ERL angle between the N or R groups at five weeks post intervention or term conceptional age (p = 0.676, p = 0.685). The results are shown in Table 5.16.

Table 5.16

Overall Group Effect and Differences from Baseline for Angle of External Rotation of the Leg from Lateral Support at Assessment 1 Time Points

	Group	Baseline	Five weeks	Term conceptional age	
<b>C</b> I	z z z	41 43 39	40 43 38	40 43 38	
Overall Group Effect	ZZZ	Mean (95% CI) 40.463(38.599,42.328) 41.070(39.249,42.890) 41.462(39.550,43.374)	Mean (95% CI) 51.050(49.021,53.080) 54.767(52.810,56.724) 52.105(50.024,54.187)	Mean (95% CI) 53.975(52.253,55.697) 59.419(57.758,61.079) 54.737(52.971,56.503)	
		Overall <u>p</u> value 0.757	Overall <u>p</u> value 0.029 <u>p</u> (NR vs R) 0.068 NS <u>p</u> (NR vs N) 0.010 NR>N <u>p</u> (R vs N) 0.474 NS	Overall <u>p</u> value 0.0001 <u>p</u> (NR vs R) 0.0002 <u>p</u> (NR vs N) 0.0001 <u>p</u> (R vs N) 0.542	NR>R NR>N NS
Mean Scores for Differences from Baseline	ZZX		Mean(95% CI) 51.310(49.518,53.101) 54.749(53.023,56.474) 51.853(50.016,53.691)	Mean(95% CI) 54.115(52.470,55.764) 59.408(57.820,61.000) 54.601(52.910,56.292)	
			Overall p value 0.0001 p(NR vs R) 0.025 NS p(NR vs N) 0.007 NR>N p(R vs N) 0.676 NS	Overall p value 0.0007 p(NR vs R) 0.0001 p(NR vs N) 0.0001 p(R vs N) 0.685	NR>R NS NS

In the scoring system used for the measurement of the ERL angle, high scores indicated a reduced angle of external rotation of the legs from lateral support. As hypothesised, there was a significant decrease in the ERL angle from baseline measurements in the NR group. This decrease was evident at five weeks post intervention and maintained at term conceptional age. There was no significant change in the ERL angle from baseline measurements in the R or N groups.

Therefore, the secondary hypothesis was supported for the ERL angle, showing infants nursed prone with a postural support nappy and postural support roll demonstrated a decreased angle of external rotation of the hips (i.e., reflected by higher scores for the ERL angle).

## Angle of Elevation of the Hips (EP).

Overall, there was a significant difference among treatment groups in the EP at five weeks post intervention ( $\underline{p}=0.018$ ). This significance was maintained at term conceptional age ( $\underline{p}=0.0001$ ). In particular, there was a significant increase in the EP angle in the NR group when compared with the N group at five weeks post intervention ( $\underline{p}=0.005$ ) and at term conceptional age ( $\underline{p}=0.0001$ ). There was a trend toward an increase in the EP angle at five weeks post intervention in the NR group when compared with the R group ( $\underline{p}=0.072$ ) that reached significance at term conceptional age ( $\underline{p}=0.0008$ ). There was no difference between in the EP between the N or R groups at five weeks post intervention or term conceptional age ( $\underline{p}=0.434$ ). The results are shown in Table 5.17.

Table 5.17

Overall Group Effect and Differences from Baseline for Angle of Pelvic Elevation at Assessment 1 Time Points

	Group	Baseline	Five weeks	Term conceptional age
<b>⊆</b> I	z z c	41 43 39	40 43 38	40 43 38
Overall Group Effect	zzα	Mean (95% CI) 40.415(38.501,42.328) 40.465(38.597,42.333) 42.461(40.500,44.42)	Mean (95% CI) 51.050(48.967,53.133) 55.186(53.177,57.195) 52.500(50.362,54.637)	Mean (95% CI) 54.000(52.056,55.944) 59.860(57.985,61.735) 55.105(53.112,57.100)
		Overall <u>p</u> value 0.245	Overall <u>p</u> value 0.018 <u>p(NR vs R)</u> 0.072 NS <u>p(NR vs N)</u> 0.005 NR>N <u>p(R vs N)</u> 0.338 NS	Overall <u>p</u> value 0.0001 <u>p</u> (NR vs R) 0.0008 NR>R <u>p</u> (NR vs N) 0.0001 NR>N <u>p</u> (R vs N) 0.434 NS
Mean Scores for Differences from Baseline	zzα		Mean(95% CI) 53.305(49.364,53.246) 55.445(53.572,57.317) 51.939(49.935,53.943)	Mean(95% CI) 54.199(52.343,56.055) 60.063(58.273,61.852) 54.667(52.751,56.582)
			Overall <u>p</u> value 0.0001 <u>p(NR vs R) 0.013 NR&gt;R</u> <u>p(NR vs N) 0.003 NR&gt;N</u> <u>p(R vs N) 0.654 NS</u>	Overall <u>p</u> value 0.0001 <u>p</u> (NR vs R) 0.0001 NR>R <u>p</u> (NR vs N) 0.0001 NR>R <u>p</u> (R vs N) 0.730 NS

When the mean scores for differences from baseline were compared, there was a significant difference among treatment groups in the EP angle at five weeks post intervention (p = 0.0001). This significance was maintained at term conceptional age (p = 0.0001). In particular, there was a significant increase in the EP angle in the NR group when compared with the R and N groups at five weeks post intervention (p = 0.013, p = 0.003) and at term conceptional age (p = 0.0001, p = 0.0001). There was no difference between in the EP angle between the N or R groups at five weeks post intervention or term conceptional age (p = 0.654, p = 0.730). The results are shown in Table 5.17.

As hypothesised, there was a significant increase in the angle of pelvic elevation from baseline measurements in the NR group. This increase was evident at five weeks post intervention and maintained at term conceptional age. There was no significant change in the angle of pelvic elevation from baseline measurements in the R or N groups. Therefore, the secondary hypothesis was supported for the EP angle showing infants nursed prone with a postural support nappy and postural support roll demonstrated an increased angle of pelvic elevation.

Data Related to Testing of Secondary Hypothesis 2
Scarf Sign (SS).

Overall, there was a significant difference among treatment groups in the SS at five weeks post intervention ( $\underline{p} = 0.0001$ ). This significance was maintained at term conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant decrease in the SS in the NR and R groups when compared with the N groups at five weeks post intervention ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0004$ ) and at term conceptional age ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0001$ ). The results are shown in Table 5.18.

Table 5.18

Overall Group Effect and Differences from Baseline for Scarf Sign at Assessment 1 Time Points

	Group	Baseline	Five weeks	Term conceptional age	
<b>C</b> I	ZZZ	41 43 39	40 43 38	40 43 38	
Overall Group Effect	ZZX	Median (IQ range) 2(2-2) 2(2-2) 2(2-2)	Median (IQ range) 3(3-4) 3(2-3) 3(2-3)	Median (IQ range) 4(4-4) 3(3-3) 3(3-4)	
Median Scores Adjusted for Differences from Baseline	ZZZ	Overall <u>p</u> value 0.678	Overall p value 0.0001  p(NR vs R) 0.268 NS p(NR vs N) 0.0001 N>NR p(R vs N) 0.0004 N>R Median (IQ range) 1(1-2) 1(0-1)	Overall p value 0.0001 p(NR vs R) 0.056 p(NR vs N) 0.0001 p(R vs N) 0.0001 Median (IQ range) 1(1-2) 1(0-1)	01 56 NS 001 N>NR 001 N>R
			Overall p value 0.0001  p(NR vs R) 0.571 NS  p(NR vs N) 0.0001 N>NR  p(R vs N) 0.0006 N>R	Overall p value 0.0001 p(NR vs R) 0.275 p(NR vs N) 0.0001 p(R vs N) 0.0001	01 75 NS 001 N>NR

When the median scores for differences from baseline were compared, there was a significant difference among treatment groups in the SS at five weeks post intervention (p = 0.0001). This significance was maintained at term conceptional age (p = 0.0001). In particular, there was a significant decrease in the SS in the NR and R groups when compared with the N group at five weeks post intervention (p = 0.0001, p = 0.0006) and at term conceptional age (p = 0.0001, p = 0.0001). The results are shown in Table 5.18.

In the scoring system used for the measurement of SS, high scores indicated reduced passive muscle tone of the shoulder. As hypothesised, there was a significant decrease in the scarf sign from baseline measurements in the NR and the R groups. This decrease was evident at five weeks post intervention and maintained at term conceptional age. There was no significant change in scarf sign from baseline measurements in the N group. Therefore, the secondary hypothesis was supported for the scarf sign showing that infants nursed with a postural support roll demonstrated a lower scarf sign.

# Acromion Process to Supra Sternal Notch Distance (ACSS)

Overall, there was a significant difference among treatment groups in the ACSS distance at five weeks post intervention ( $\underline{p} = 0.0001$ ). This significance was maintained at term conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant decrease in the ACSS distance in the NR and R groups when compared with the N group at five weeks post intervention ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0001$ ) and at term conceptional age ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0001$ ). The results are shown in Table 5.19.

When the mean scores adjusted for differences from baseline were compared, there was a significant difference among treatment groups in the ACSS distance at five weeks post intervention (p = 0.0001). This significance was maintained at term conceptional age (p = 0.0001). In particular, there was a significant decrease in the ACSS distance in the NR and R groups when compared with the N group at five weeks post intervention (p = 0.0001, p = 0.0001) and at term conceptional age (p = 0.0001, p = 0.0001). The results are shown in Table 5.19.

In the scoring system used for the measurement of the ACSS distance, lower scores reflected reduced shoulder retraction. As hypothesised, there was a significant decrease in the distance between the acromion process and the suprasternal notch, from baseline measurements in the NR and R groups. This decrease was evident at five weeks post intervention and maintained at term conceptional age. There was no significant change in the distance between the acromion process and the suprasternal notch from baseline measurements in the N groups. Therefore, the secondary hypothesis was supported for the distance between the acromion process and the suprasternal notch, showing infants nursed with a postural support roll demonstrated decreased shoulder retraction.

Table 5.19

Overall Group Effect and Differences from Baseline for the Distance from the Acromion Process to Suprasternal Notch Distance at Assessment 1 Time Points

	Group	Baseline	Five weeks			Term conceptional age	al age	
디	2 Z Z	41 43 39	40 43 38			40 43 38		
Overall Group Effect	ZZW	Mean (95% CI) 4.824(4.696,4.952) 4.895(4.770,5.020) 4.813(4.682,4.944)	Mean (95% CI) 6.152(5.997,6.309) 5.591(5.440,5.741) 5.660(5.500,5.821)			Mean (95% CI) 6.945(6.769,7.121) 6.167(5.998,6.334) 6.321(6.141,6.501)	£ <del>\$</del> £	
		Overall <u>p</u> value 0.616	Overall <u>p</u> value <u>p</u> (NR vs R) <u>p</u> (NR vs N) <u>p</u> (R vs N)	0.0001 0.531 0.0001 0.0001	NS N > N N > N N > N	Overall p value p(NR vs R) p(NR vs N) p(R vs N)	0.0001 0.221 0.0001 0.0001	NS N>NR N>R
Mean Scores for Differences from Baseline	ZZZ		Mean (95% CI) 6.174(6.034,6.314) 5.564(5.429,5.699) 5.668(5.525,5.817)			Mean(95% CI) 6.958(6.787,7.130) 6.151(5.986,6.316) 6.326(6.151,6.501)	<del>(</del> )	
			Overall p value <u>p</u> (NR vs R) <u>p</u> (NR vs N) <u>p</u> (R vs N)	0.0001 0.299 0.0001 0.0001	NS NV NV NV	Overall p value p(NR vs R) p(NR vs N) p(R vs N)	0.0001 0.153 0.0001 0.0001	NS N>NS N>R

## Spontaneous Arm Movements (SAM).

Overall, there was a significant difference among treatment groups in SAM at five weeks post intervention ( $\underline{p} = 0.0001$ ). This significance was maintained at term conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant increase in the SAM in the NR and R groups when compared with the N groups at five weeks post intervention ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0001$ ) and at term conceptional age ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.0001$ ). The results are shown in Table 5.20.

When the median scores from baseline were compared for differences, there was a significant difference among treatment groups in the SAM at five weeks post intervention (p = 0.0001). This significance was maintained at term conceptional age (p = 0.0001). In particular, there was a significant increase in the SAM in the NR and R groups when compared with the N group at five weeks post intervention (p = 0.0001, p = 0.0001) and at term conceptional age (p = 0.0001, p = 0.0001). The results are shown in Table 5.20.

In the scoring system used for the measurement of SAM, high scores indicated a high level of antigravity control of arm movements. As hypothesised, there was a significant increase in spontaneous arm movements from baseline measurements in the NR and the R groups. This increase was evident at five weeks post intervention and maintained at term conceptional age. There was no significant change in spontaneous arm movements from baseline measurements in the N group. Therefore, the secondary hypothesis was supported for spontaneous arm movements showing that antigravity control of arm movements increased in those infants nursed with a postural support roll.

**Table 5.20** 

Overall Group Effect and Differences from Baseline for Spontaneous Arm Movements at Assessment 1 Time Points

	Group	Baseline	Five weeks		Term conceptional age	<u>a</u>
디	2 Z X	41 43 39	40 43 38		40 43 38	
Overall Group Effect	zΣα	Median (IQ range) 2(2-3) 2(2-3) 2(2-3)	Median (IQ range) 3(3-3) 5(4-5) 4(4-5)		Median (IQ range) 3(3-4) 5(5-5) 5(4-5)	
		Overall <u>p</u> value 0.571	Overall <u>p</u> value 0.0001 <u>p</u> (NR vs R) 0.228 <u>p</u> (NR vs N) 0.0001 <u>p</u> (R vs N) 0.0001	NS NR>N N>N	Overall <u>p</u> value 0.0 <u>p(NR vs R) 0.0</u> <u>p(NR vs N) 0.0</u> <u>p(R vs N) 0.0</u>	0.0001 0.019 NR>R 0.0001 NR>N 0.0001 R>N
Mean Scores for Differences from Baseline	zχα		Median (IQ range) 1(0-1) 2(1-2) 2(1-2)		Median (IQ range) 1(0.5-2) 2(2-3) 2(2-3)	
			Overall p value 0.0001 p(NR vs N) 0.533 p(NR vs N) 0.0001 p(R vs N) 0.0001	NS NR>N N N	Overall <u>p</u> value 0.0001 <u>p</u> (NR vs R) 0.31 <u>p</u> (NR vs N) 0.00 <u>p</u> (R vs N) 0.00	0001 0.313 NS 0.0001 NR>N 0.0001 R>N

### Data Related to Postural Measurements at Assessment 2

#### Primary Hypotheses.

- Infants < 31 weeks gestation nursed prone with a postural support roll,</li>
   either with or without a postural support nappy, will achieve higher shoulder
   dependent motor scores at four months conceptional age compared with infants
   < 31 weeks gestation nursed prone with a postural support nappy only.</li>
- 2. Infants < 31 weeks gestation nursed prone with a postural support roll, either with or without a postural support nappy, will achieve higher combined shoulder and hip dependent motor scores at four months conceptional age compared with infants nursed prone in a postural support nappy without a postural support roll.</p>

#### Data Related to Testing of Hypotheses

Following the death of two infants from severe respiratory disease at four and five weeks of age respectively, the exclusion of two infants who were *lost to follow-up*, one infant who was diagnosed as blind, one infant with severe torticollis, and seven infants who presented with abnormal tone and thought to be at high risk for cerebral palsy, data from 104 infants was available for analysis. There were no differences in baseline measurements between infants who were available at four months conceptional age and those who were not available.

## Finger-finger Play (FF).

The FF measure tested the infant's motor function in the upper extremities. There was a significant difference among treatment groups for FF at four months conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant increase in the FF in the NR and R groups when compared with the N groups ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.004$ ). The results are shown in Table 5.21.

As hypothesised, there was a significant increase in finger-finger play for the NR and the R groups. Therefore, the first primary hypothesis was supported demonstrating improved scores for finger-finger play in infants that were nursed with a postural support roll, either with or without a postural support nappy.

Table 5.21

Overall Group Effect and Group Comparisons of Finger-Finger Play at

Assessment 2

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	<u>p</u> value
		(IQ range)		comparison	
N	34	3(2-3)	0.0003	(NR vs R)	0.297 NS
NR	36	4(3-4)		(NR vs N)	0.0001 NR>R
R	34	3.5(3-4)		(R vs N)	0.004 R>N

## Reaching (REACH).

The REACH measurement also tested the infant's motor function in the upper extremities. There was a significant difference among treatment groups for REACH at four months conceptional age ( $\underline{p} = 0.0006$ ). In particular, there was a significant increase in the REACH in the NR and R groups when compared with the N groups ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.007$ ). The results are shown in Table 5.22.

As hypothesised, there was a significant increase in the ability of an infant to reach in NR and the R groups. Thus, the first primary hypothesis was supported, confirmed by improved scores for reaching ability in those infants nursed with a postural support roll, either with or without a postural support nappy.

Table 5.22

Overall Group Effect and Group Comparisons of Reaching Ability at Assessment 2

Group	<u>n</u>	Median	Overall p value	Group	p value
·	_	(IQ range)	-	comparison	_
N	34	1(1-1)	0.0006	(NR vs R)	0.229 NS
NR	36	2(1-3)		(NR vs N)	0.0001 NR>N
R	34	2(1-3)		(R vs N)	0.007 R>N

## Weight-bearing through Forearms and Spontaneous Leg Movements (WTB).

The WTB measurement was a composite measure of both shoulder and hip motor function. There was a significant difference among treatment groups for WTB at four months conceptional age ( $\underline{p} = 0.0002$ ). In particular, there was a significant increase in the WTB in the NR and R groups when compared with the N groups ( $\underline{p} = 0.0003$ ,  $\underline{p} = 0.001$ ). There was no difference in WTB between the NR and R groups. The results are shown in Table 5.23.

Therefore, the second primary hypothesis was supported for weight-bearing demonstrated by those infants nursed with a postural support roll, either with or without a postural support nappy, showing a greater ability to bear weight on the forearms and make spontaneous movements of their legs.

Table 5.23

Overall Group Effect and Group Comparisons of Weight-bearing through the

Forearms and Spontaneous Leg Movements at Assessment 2

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	p value
		(IQ range)		comparison	
N	34	3(2-4)	0.0002	(NR vs R)	0.293 NS
NR	36	5(3-5)		(NR vs N)	0.0003 NR>N
R	34	4(3-5)		(R vs N)	0.001 R>N

## Hands to Feet (HTOF).

The HTOF measurement was a composite measure of both shoulder and hip motor function. There was a significant difference among treatment groups for HTOF at four months conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant increase in the HTOF in the NR and R groups when compared with the N groups ( $\underline{p} = 0.000$ ,  $\underline{p} = 0.013$ ). There was no difference in HTOF between the NR and R groups. The results are shown in Table 5.24.

The second primary hypothesis was supported for the variable of reaching with hands to feet, demonstrated by infants nursed with a postural support roll, either with or without a postural support nappy, showing a greater ability to reach their feet with their hands.

Table 5.24

Overall Group Effect and Group Comparisons of Ability to Reach Feet with Hands at

Assessment 2

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	<u>p</u> value
		(IQ range)		comparison	
N	34	2(2-3)	0.0001	(NR vs R)	0.058 NS
NR	36	5(3-5)		(NR vs N)	0.0001 NR>N
R	34	3(3-5)		(R vs N)	0.013 R>N

#### Data Related to Postural Measurements at Assessment 3

#### Primary Hypothesis.

Infants < 31 weeks gestation nursed prone with a postural support roll, either with or without postural support nappy, will achieve higher shoulder and hip dependent motor scores at eight months conceptional age compared with infants < 31 weeks gestation nursed prone with a postural support nappy without a postural support roll.

#### Secondary Hypothesis.

Infants < 31 weeks gestation nursed prone with a postural support roll and a postural support nappy will achieve a higher foot progression angle at eight months conceptional age, compared with infants nursed prone in a postural support nappy without a postural support roll, or a postural support roll without a postural support nappy.

### Data Related to Testing of Hypotheses

Following the further exclusion of two infants who were *lost to follow-up* at eight months and the diagnosis of probable CP in two infants, data from 100 infants was available for analysis. There were no differences in baseline measurements between infants who were available at eight months conceptional age and those who were not available.

## Rolling (ROLL).

The ROLL measurement was a composite measure of both shoulder and hip motor function. There was a significant difference among treatment groups for ROLL at eight months conceptional age ( $\underline{p} = 0.0001$ ). In particular, there was a significant increase in ROLL in the NR and R groups when compared with the N groups ( $\underline{p} = 0.0001$ ,  $\underline{p} = 0.013$ ). In addition, the NR group had a higher median score for ROLL when compared with the R group. The results are shown in Table 5.25.

There was a significant increase in infants' ability to roll in the NR and the R groups. In addition the NR group had a higher score for rolling than the R group.

Nursing an infant with a postural support roll, either with or without a postural support nappy, improved the infant's ability to roll at eight months conceptional age.

The primary hypothesis for rolling was, therefore, supported.

Table 5.25

Overall Group Effect and Group Comparisons of Ability to Roll at Assessment 3

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	<u>p</u> value
		(IQ range)		comparison	
N	34	4(3-5)	0.0001	(NR vs R)	0.013 NR>R
NR	35	5(5-5)		(NR vs N)	0.0001 NR>N
R	34	5(4-5)		(R vs N)	0.011 R>N

# Crawling (CRAWL).

The CRAWL measurement was a composite measure of both shoulder and hip motor function. There was a significant difference among treatment groups for CRAWL at eight months conceptional age ( $\underline{p} = 0.035$ ). In particular, there was a significant increase in the CRAWL in the NR and R groups when compared with the N groups ( $\underline{p} = 0.017$ ,  $\underline{p} = 0.042$ ). There was no significant difference in CRAWL between the NR and R groups. The results are shown in Table 5.26.

The primary hypothesis was, therefore, supported as there was a significant increase in the ability to crawl demonstrated in those infants nursed with a postural support roll, either with or without a postural support nappy.

Table 5.26

Overall Group Effect and Group Comparisons of Crawling Ability at Assessment 3

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	Б	
		(IQ range)		comparison		
N	34	2(2-3)	0.035	(NR vs R)	0.678 NS	
NR	35	3(2-5)		(NR vs N)	0.017 NR	>N
R	34	3(2-5)		(R vs N)	0.042 R>1	N

### Sitting (SIT).

The SIT measurement was a composite measure of both shoulder and hip motor function. There was a significant difference among groups for SIT at eight months conceptional age ( $\underline{p} = 0.012$ ). Of particular note was the significant difference for SIT between the R and N groups ( $\underline{p} = 0.026$ ). There was no difference in SIT between the NR and R groups ( $\underline{p} = 0.196$ ). When the NR and the R groups were combined for analysis and compared with the N group, there was a significant difference between groups ( $\underline{p} = 0.007$ ). The results are shown in Table 5.27.

Although the primary hypothesis for sitting was not supported, the results reflect improved shoulder posture associated with use of the postural support roll on upper extremities, and the unexpected benefit of hip abduction associated with flattened posture.

Table 5.27

Overall Group Effect and Group Comparisons of Sitting Ability at Assessment 3

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	<u>p</u> value
		(IQ range)		comparison	
N	34	3(2-5)	0.012	(NR vs R)	0.197 NS
NR	35	5(3-5)		(NR vs N)	0.123 NS
R	34	5(4-5)		(R vs N)	0.003 R>N

### Standing (STAND).

The STAND measurement was a composite measure of both shoulder and hip motor function. There was a trend toward a difference among treatment groups for STAND at eight months conceptional ( $\underline{p} = 0.049$ ). In particular, STAND in the NR and R groups when compared with the N groups showed this trend ( $\underline{p} = 0.022$ ,  $\underline{p} = 0.013$ ). There was no difference in STAND between the NR and R and between the NR and N groups. The results are shown in Table 5.28.

No clear increase in the infant's ability to stand was shown. The primary hypothesis for standing was, therefore, not supported. The results do, however, suggest that this measure may be highly correlated with the measure of the foot progression angle (FOOT). Results for the FOOT measure follow.

Table 5.28

Overall Group Effect and Group Comparisons of Standing Ability at Assessment 3

Group	<u>n</u>	Median	Overall <u>p</u> value	Group	p value
		(IQ range)		comparison	
N	34	3(2-4)	0.049	(NR vs R)	0.196 NS
NR	35	3(2-4)		(NR vs N)	0.022 NR>N
R	34	4(3-5)		(R vs N)	0.013 R>N

# Foot Progression Angle (FOOT).

The FOOT measurement estimated the angle of deviation from neutral rotation in infant's at eight months conceptional age. There were no differences among the treatment groups for this measure (p = 0.768).

The secondary hypothesis, therefore, for the angle of foot progression was not supported. The results are shown in Table 5.29. It is interesting to note that these results may indicate a correlation between the Stand and Foot measures.

Table 5.29

Overall Group Effect and Group Comparisons of the Foot Progression Angle at

Assessment 3

Group	<u>n</u>	Mean (95% Ci)	Overall <u>p</u> value	Group comparison	ը value
N	34	22.455(24.916,19.994)	0.768	(R vs NR)	0.486 NS
NR	35	23.061(25.450,20.672)		(N vs NR)	0.860 NS
R	34	20.677(23.101,18.253)		(R vs N)	0.603 NS

#### Summary of the Chapter

This chapter has documented the analysis and findings of data collected on the two phases of this study. The first component of the chapter described data related to Phase 1 (i.e., the effect of absorbent nappy liners on temperature stability in 23 infants < 31 weeks gestation). Randomisation was found to be effective as both groups were well matched for birth and postnatal details.

Results from Phase 1 showed the theoretical relationships posed in the theoretical model could be demonstrated empirically through univariate and multivariate analysis. It was shown that use of an intervention such as an absorbent nappy liner, could provide primary prevention for temperature instability in very low birthweight infants by reducing the effects of stressors (i.e., immature thermoregulation mechanisms and an incubator environment) and improving temperature stability. A prediction model for predicting per axilla temperatures in very low birthweight infants nursed in incubators on infant servo control was also constructed.

The second component of the chapter described data related to Phase 2 (i.e., the effect of postural nursing interventions on the short and longer term postural and developmental outcomes in 123 infants < 31 weeks gestation).

Randomisation was shown to be effective with each of the three treatment groups well matched for birth, postnatal and baseline postural variables. The accuracy of the researcher's consistency of scoring throughout Phase 2 was demonstrated. Comparison between the researcher's scoring and that of the NICU physiotherapist indicated a high level of reliability.

Findings from Phase 2 showed the theoretical relationships posed in the theoretical model could be demonstrated empirically. The principal finding was that use of a postural support roll when VLBW infants must be nursed prone, was most effective in the primary prevention of abnormal postural alignment and neuromuscular development in VLBW infants up until eight months conceptional age. Findings also showed that combined use of a postural support nappy and a postural support roll promotes normal postural alignment and neuromotor development of upper and lower extremities until term conceptional age. In addition, use of either a postural support nappy or a postural support roll had an equivalent effect on postural alignment and neuromotor development of the lower extremities up until eight months conceptional age.

#### **CHAPTER 6**

#### Discussion

The following discussion will present and explore the relevance of the major findings from this study in relation to methodological, theoretical and clinical issues. This will be followed by an investigation of the strengths and limitations of the study. The final chapter will present the conclusions from this study in addition to implications for nursing practice, education and future research.

The principal hypothesis developed and tested in this study was that it may be possible to prevent thermoregulation and neuromotor problems in very low birthweight infants (VLBW) by creating an extrauterine environment that promotes homeostasis. The purpose of this study was to demonstrate the effect of a nursing care model designed for the primary prevention of temperature instability and neuromotor problems in VLBW infants. The development and implementation of the primary prevention model was reported in detail in this thesis. The research focused on VLBW infants admitted to the neonatal intensive care (NICU) unit at the sole perinatal tertiary referral centre in the state of Western Australia (WA). The NICU cares for 95% of all VLBW infants born in the state. The sample of infants, therefore, was representative of the general population in WA.

This study originated from the researcher's interest in the development and complications of *flattened* posture in VLBW infants. Previous work by the researcher revealed that use of a cloth postural support nappy (N) in VLBW infants while they are nursed prone, reduced the features of *flattened* posture in the lower extremities until infants were discharged from hospital (Monterosso et al., 1995).

Findings from this earlier study resulted in a change to nursing practice in the NICU, and application of a N was implemented as routine practice for VLBW infants when nursed in the prone position. The unique qualities of this study, in addition to the significance of the findings, prompted the researcher to further explore this largely untested area by undertaking a two phase study. Prevention of temperature instability and the short and longer term structural and functional limitations associated with *flattened* posture in VLBW infants, were explored through use of three nursing interventions.

The rationale for Phase 1 of this study evolved from anecdotal reports by nurses following the implementation of routine application of the N in the NICU of the study hospital. Nurses claimed that wetness produced from the absorption of urine by the cloth N led to hypothermia in VLBW infants. It was logical to assume that infants experienced heat loss from the evaporation of urine from the wet N. Although the N provided valuable postural support, the researcher recognised the immediate need to resolve the associated thermoregulation problem resulting from use of the N. Phase 1 of this study, therefore, examined the effect of an absorbent nappy liner within a cloth N on temperature stability in VLBW infants. Phase 2 of this study extended the researcher's previous work on *flattened* posture by examining the effects of two postural supports on the structure and function of both upper and lower extremities during hospitalisation and up to the age of eight months postconception.

## Summary of Findings

#### Phase 1

Data were collected from a sample of 23 infants < 31 weeks gestation. A randomised, observer blind, crossover study was conducted over a four day period to determine the effect of absorbent nappy liners on incubator and skin temperature in these infants when nursed in double-walled Airshields™ incubators on infant servo control (ISC). Infants alternated wearing either a N with an inner absorbent nappy liner or a N without an inner absorbent liner, for a 24 hour time period during the four days of the study. The sample was representative of the general population of VLBW infants in WA and infants in each group were well matched for birth and postnatal variables (i.e., gestational age and weight at birth; birthweight ratio; gender; conceptional age and actual age at study entry; and weight at study entry).

### Data Related to Measures of Incubator and Skin Temperature

As discussed in Chapter 2, lower incubator temperatures reflect an infant's ability to maintain normal skin temperature (i.e., when nursed on ISC mode in an incubator). Incubator temperatures greater than 32.0°C indicate an infant's inability to respond to hypothermia because he or she requires higher environmental temperatures to maintain a normal skin temperature.

## Crossover and Carryover Effects.

As a crossover design was used for this phase of the study, the data were initially tested for possible carryover and crossover effects of the treatment nappy (i.e., N with inner absorbent liner). It is significant to note that analyses revealed no evidence of any carryover or crossover effect from the treatment nappy on either incubator or skin temperature.

## Covariates Pertaining to Very Low Birthweight Infants (VLBW).

As expected, there were no effects of any of the covariates pertaining to VLBW infants (i.e., gestational age at birth, age at study entry, birthweight ratio, and gender of the infant). In addition, there was no overall effect of individual treatment days on either incubator or skin temperature.

## Effect of Day Versus Night Periods.

Literature relating to circadian rhythms suggests that circadian rhythmicity is present during the early neonatal period in certain physiologic variables including body temperature (Miriman et al., 1990; Thomas, 1991; Updike et al., 1985).

Contrary to emerging evidence regarding the presence of circadian rhythms in preterm infants, this study showed no significant differences in incubator temperature were detected between day (i.e., 0600 - 2100 hr) and night (i.e., 2100 - 0600 hr) periods. The period of subjective night used for this study compared favourably with that used by Mirimar and colleagues (1990) who used 1900 - 0700 hr as the night period. As discussed in Chapter 2, it is probable that ISC masked or altered the expression of a temperature biorhythm in the infants because incubator temperature is controlled by a feedback mechanism in order to maintain a pre-set normal skin temperature. This interpretation is supported by previous studies that examined circadian rhythm using the air control mode, rather than the ISC mode in incubators (Miriman et al., 1990; Thomas, 1991; Updike et al., 1985).

## Effect of Infant Handling.

Infant handling for nursing and medical procedures had the expected effect as described in Chapter 2. Infant handling caused a significant increase of 0.3°C in mean incubator temperature, and a significant decrease of 0.03°C in mean skin temperature.

Both results were clinically significant and concur with findings by Mok and colleagues (1991) who also showed significant core and skin temperature instability during nursing procedures with slow recovery to normal temperatures. The finding from this study of a reduction in skin temperature of  $0.03^{\circ}$ C may be viewed as too marginal to be of any clinical significance. However, as explained in Chapter 2, the heating requirements of the preterm infant are exact because the thermal neutral zone is extremely narrow. Consequently, any increase in heat production arising from hypothermic episodes increases oxygen consumption, energy requirements and hypoglycaemia. Ultimately, this results in poor weight gain and growth (Thomas, 1991).

#### Effect of Treatment Nappy on Incubator and Skin Temperature.

As expected, infants nursed in a N with an inner absorbent liner demonstrated a significant decrease in mean incubator temperature of 1.0°C and a significantly higher mean skin temperature of 0.05°C. This is the first study to test the effect of an absorbent material contained within nappies on evaporative heat loss in VLBW infants. These results are highly significant. The findings provide the empirical evidence to support the long held belief that absorbent qualities of cross linked sodium polyacrylate, such as that contained in most commonly used disposable nappies, prevents temperature instability in VLBW infants (Graham, 1992).

Although not empirically proven due to the constraints of this study, it can be anticipated that VLBW infants nursed in a N with an absorbent liner will experience less temperature instability and will, therefore, be more physiologically stable than infants nursed in a N without an absorbent liner. In addition, these infants should benefit from improved weight gain and growth.

### Per Axilla (PA) Temperature.

As expected, PA temperatures (i.e., measured eight hourly as a validity check for skin temperatures) fell within the acceptable range of being within 0.6°C higher than skin temperatures. As discussed in Chapter 4, this can be explained because PA temperatures are a measurement of the temperature between the two skin folds of the axilla; whereas, skin temperatures measure the temperature of the skin surface on the lower back. These results confirm the long held beliefs of nursing staff in the NICU that an infant's PA temperature can be expected to be as much as 0.6°C higher than the skin temperature shown on the incubator control panel. The prediction model for PA temperatures developed from the analysis has provided a useful tool for the prediction PA temperatures and the management of thermoregulation in VLBW infants. Previously, this has not been possible due to a lack of empirical evidence.

Findings from Phase 1 resulted in the addition of nappy liners to the postural support nappy used in the N and NR groups during Phase 2. The disposable nappy used on infants in the R group contained the same absorbent material as that found within the nappy liners used in Phase 1. Infants in all treatment groups of Phase 2, therefore, benefited from improved temperature stability.

#### Summary of Findings

## Phase 2

Data were collected from a sample of 123 infants < 31 weeks gestation. A randomised, controlled, observer blind study was used to determine the effects of two postural supports on development of *flattened* posture in the upper and lower extremities. Interventions commenced when infants were clinically stable and ceased when routine side-lying commenced. The mean number of days prior to commencement of interventions was five days and the mean duration of interventions was 32 days. *Flattened* posture contrasts with normal posture seen in term infants who benefit from prolonged flexion and extension in utero. Development of flexion and extension, balanced with support, stability and a mature musculoskeletal system, are vital for the development of normal body posture and subsequent normal movement patterns throughout infancy (Fay, 1988; Semmler, 1989).

During this observation period measures of posture (i.e., body alignment) and neuromotor development were performed at three assessment periods. Assessment 1 involved measurement of infants at three time points (i.e., prior to study commencement, five weeks post intervention, and term conceptional age) where measures of upper and lower extremity body alignment and upper extremity neuromotor function were performed). Assessment 2 occurred at four months conceptional age and measures of upper extremity movement patterns and composite measures of both upper and lower extremity movement patterns were performed. Assessment 3 occurred at eight months conceptional age. Measures of movement patterns of upper and lower extremities were performed. In addition the foot progression angle was measured.

All measures were based on the expected developmental milestones of term infants at equivalent conceptional age.

The nursing interventions used in this study were a postural support roll (R) and a N. The R supported and maintained infants in a quarter turn position while nursed prone, thereby, facilitating movement of both upper and lower extremities and midline hand to mouth orientation. The N, previously tested by the researcher, provided pelvic elevation and prevented external rotation and wide abduction of the lower extremities (Monterosso et al., 1995). This in turn, promoted flexion and mobility of the lower limbs, vital in the development of normal posture and movement in the lower extremities. It was anticipated that flexion and mobility in both upper and lower extremities would be achieved resulting in the development of normal posture and neuromotor development in VLBW infants up to eight months conceptional age. The researcher, therefore, sought to explore whether combined use of both a R and a N would achieve this aim, or, if sole use of a R would be sufficient. Therefore, three treatment groups were used in this study and, for clarity, Figure 6.1 reproduces the study design introduced in Chapter 4.

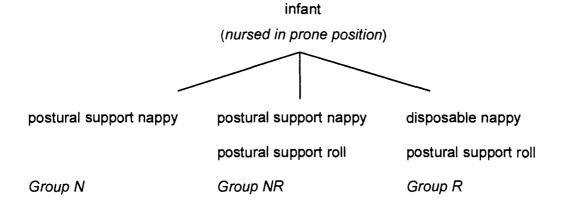


Figure 6.1 Postural Support Study Design.

As previously described, the sample was representative of the general population of VLBW infants in WA. Infants in each of the three treatment groups were well matched for birth and postnatal variables. The sample was also similar to populations of VLBW infants included in other studies that have explored *flattened* posture (Downs et al., 1991; Konishi et al., 1987; Konishi et al., 1994; Monterosso et al., 1995; Montfort & Case-Smith, 1997).

## Assessment 1

#### Baseline Measures.

Three measures of lower extremity body alignment were used (i.e., the angles of elevation of the pelvis and external rotation of the leg, and the weight-bearing surface of the inner surface and knee). In addition, an anatomical measure of the distance between the acromion process and the suprasternal notch, a measure of antigravity movements of the upper extremities (i.e., scarf sign), and a measure of midline hand to mouth orientation were used (i.e., hand to mouth). The measures were performed at baseline (i.e., prior to study commencement), and then repeated at five weeks post intervention and again at term conceptional age.

All 123 infants were available for baseline measures. Analyses showed no differences between the three treatment groups for any measure. These results were used for subsequent measures at five weeks post intervention and term conceptional age as a comparison for differences from baseline. Other than previous work conducted by the researcher, this is the only study to perform baseline measures of body alignment and, furthermore, to compare measures at subsequent time points for differences from baseline measures (Monterosso et al., 1995).

## Five Weeks Post Intervention and Term Conceptional Age Measures.

Of the original sample of 123 infants, 121 infants were available for assessment at five weeks post intervention and term conceptional age.

Findings from a previous study by Monterosso and colleagues (1995) showed a treatment effect in lower extremity posture occurred at approximately 4-6 weeks post implementation of a postural intervention. Therefore, measures in this study were initially performed at approximately five weeks post intervention to determine a treatment effect, and then again at term conceptional age to ascertain if the treatment effect was sustained. Findings confirmed the hypothesis that *flattened* posture leads to increased extensor tone in upper and lower extremities, causing scapular retraction and external rotation and abduction of the hips, and a reduction in midline behavioural ability (Georgieff & Bernabum, 1986). Findings also confirmed that use of appropriate postural interventions could prevent *flattened* posture.

## Measures Related to Upper Extremities.

As postulated in the conceptual model, there was a significant improvement in body alignment and neuromotor function related to upper extremities in the NR and R groups at five weeks post intervention. In addition, the treatment effect was sustained to term conceptional age. Details of individual measures will be described.

#### Scarf Sign.

Since its introduction, the scarf sign has principally been used as a measure of neurological maturity in newborn infants and has been incorporated in a number of assessment tools for determining gestational age (Amiel-Tison, 1968; Ballard et al., 1979; Dubowitz & Dubowitz, 1981). The scarf sign was sensitive to changes in shoulder posture.

As anticipated, differences were shown in passive muscle tone between infants in the R and NR groups, compared with infants in the N group. Reduced scarf sign scores indicate improved passive muscle tone of the shoulder. Infants in the NR and R groups showed a reduction in median scarf sign scores. In addition, when median scores for differences from baseline were compared, similar findings were shown. The most significant finding was that median scores for infants in the R and NR groups were equivalent to those seen in a newborn term infant (Amiel-Tison, 1968). In these infants it was possible to bring the elbow to the midline. In contrast, infants nursed without a R had lower median scores for the scarf sign, demonstrated by the inability of the examiner to bring the elbow to the midline. This is probably explained by the presence of shoulder retraction known to be associated with *flattened* posture, and that can restrict movement and create a greater degree of resistance to the manoeuvre (Georgieff, 1986).

It can be concluded that the scarf sign is an effective measure of upper extremity movement, and that infants nursed with a R developed passive shoulder tone equivalent to that seen newborn term infants.

Distance between Acromion Process and Suprasternal Notch (ACSS).

As described in Chapter 2, *flattened* posture of the upper extremities is characterised by elevation and adduction of the scapulae causing a retracted appearance and resulting in extension and abduction of the shoulders (Georgieff & Bernbaum, 1986; Montfort & Case-Smith, 1997). It was, therefore, considered desirable to include an anatomical measurement of scapular retraction as a measure of shoulder posture. A measure was devised that had the capacity to measure the degree of scapulae retraction protraction in VLBW infants.

As previously described in Chapter 2, the ACSS was measured as the distance between the suprasternal notch and the acromion process. As anticipated, this measure was sensitive to the presence of changes in shoulder posture. The measure was also sensitive to growth as demonstrated by differences between mean measures at five weeks post intervention and term conceptional age. Infants nursed in either the R or the NR groups demonstrated scapular *protraction* (reduced distance between the two points of measurement). In contrast, infants nursed in the N group (i.e., without a R) demonstrated scapular *retraction* (greater distance between the two points of measurement). It can also be concluded that the ACSS is a reliable measure of shoulder posture in VLBW infants.

## Spontaneous Arm Movements.

As described in Chapter 2, this measure was chosen because it could provide useful information about the capacity of infants to assume and sustain antigravity movements of the shoulders. This measure was originally devised and incorporated into a preterm motor score to quantify development and the influence of intrauterine growth retardation in preterm infants (Lacey et al., 1991). To date, there has been no indication in the literature that this measure has been used in the evaluation of shoulder posture in VLBW infants. The present study showed that infants in either the R or NR group had higher scores for spontaneous arm movements, compared with infants nursed in the N group.

Clinically, these findings indicate that infants nursed with a R demonstrated improved hand to mouth orientation (i.e., the ability to assume and sustain antigravity posture of the shoulder and arms) equivalent to that seen in term infants.

These findings were expected and confirm the hypothesis that shoulder retraction may counteract the functional development of midline behaviour and probably explains why infants nursed without a R demonstrated a reduced level of midline orientation (Georgieff, 1986; Touwen & Hadders-Algra, 1983).

#### Measures Related to Lower Extremities.

As postulated in the conceptual model, there was a significant improvement in body alignment and neuromotor function related to lower extremities in the NR group at five weeks post intervention. In addition, the treatment effect was sustained to term conceptional age. This agrees with similar findings by Monterosso and colleagues (1995) who showed a treatment effect of the N at 4-6 weeks post intervention. Also as postulated, infants nursed with either a R or N showed similar treatment effects for each of the lower extremity measures. Previous research has shown that the N reduces the features of *flattened* posture in the lower extremities (Monterosso et al., 1995). The findings from the present study confirm the R has similar effects as the N on lower extremity posture. In addition, and of significance, findings from this study also show that combined use of a R and a N results in additional improvements of lower extremity posture. Details of individual measures will be described.

## Weight-bearing Surface of the Inner Surface of the Thigh and Knee.

A feature of normal posture is a greater degree of flexion in the lower extremities, therefore, the area of weight-bearing of the inner surface of the thigh and knee is reduced so that only the anterior surface of the knee rests on the mattress. In contrast, in infants with *flattened* posture, the medial aspect of the thigh, lower limb and foot may rest on the mattress as the infant lies in a *frog-like* posture.

According to the scoring system of this measure, higher scores for the weight-bearing surface indicated a reduced area of weight-bearing surface in the inner thigh and knee. The measure of the weight-bearing surface, as previously reported in the literature, used a scale measurement that varied from one to three. This was found to be limiting by Monterosso and colleagues (1995) because there was insufficient range in the measurement tool to allow differences to be detected. A strength of this study was modification of the scale to a range of one to five. This revised scale produced the desired sensitivity of the measurement to changes in leg posture.

As anticipated, infants nursed in the NR group showed a median score of five for this measure at both five weeks post intervention and term conceptional age, compared with infants nursed with either a R or N. This score was similar to that seen in normal term infants indicating that when lying in the prone position, flexion of the lower extremities was present because only the medial aspect of the infant's knee rested on the mattress (Lacey et al., 1990).

## Angle of External Rotation of the Leg from Lateral Support.

Unlike newborn term infants with normal posture, infants with *flattened* posture develop wide abduction and external rotation of the hips, and lie in a *frog-like* position (Grenier, 1988). This results in a reduced angle of external rotation from lateral support. Infants in the NR group showed a lower mean angle of external rotation of the leg from lateral support, compared with infants in the N group at five weeks post intervention and term conceptional age.

In contrast to findings for the weight-bearing surface, there was a trend for infants the NR group to have a greater mean angle of external rotation than infants nursed with a R only, however, this reached significance at term conceptional age.

Therefore, it is concluded that nursing infants with both a R and a N increases the angle of external rotation of the leg from lateral support. This finding confirms the hypothesis that use of appropriate postural supports can prevent some or all of the features of flattened posture (Grenier, 1988; Turrill, 1992; Updike et al., 1985).

Use of this particular measurement added rigour to this study because it was not affected by congenital abnormalities of the lower limbs that can often result from fetal positioning in utero. Tibial torsion is one such abnormality that may cause infants to walk with an in-toeing gait. This directly contrasts with the out-toeing gait that may result from *flattened* posture. Consequently, tibial torsion has the potential to mask the effect of *flattened* posture unless correct measurement techniques are used to prevent this potential problem (Monterosso et al., 1995). Because the technique used for determining the angle of external rotation from lateral support in the present study was to measure the distance from the anterior surface of the patella to the mattress (i.e., with the head in midline), the presence of tibial torsion would not have influenced the measurement.

## Angle of Pelvic Elevation.

This angle was assessed as the angle between the mattress and a line from the xyphisternum to the centre of the hip joint. As previously described, infants with flattened posture lack pelvic elevation because of wide hip abduction and external rotation. Of particular interest, findings for this measure were similar to those for the angle of external rotation of the leg from lateral support. Infants in the NR group showed a greater mean angle of pelvic elevation, compared with infants nursed in the N group at five weeks post intervention and at term conceptional age.

There was a trend for infants nursed with a R and a N to have a greater mean angle of pelvic elevation than infants nursed with a R only. However, this reached significance at term conceptional age. Infants nursed with either a R or a N showed equivalent mean scores for the angle of pelvic elevation.

These findings indicate that infants nursed with either a R or a N developed greater flexion in the lower extremities. Monterosso and colleagues (1995) and Downs and colleagues (1991), also reported that postural supports used in their study promoted elevation of the pelvis. Unfortunately, the postural supports used by Downs and colleagues (1991) may have impeded mobility of the legs as the knees and lower legs of infants were actually held in position by the postural support (Dunn, 1991). These findings also confirm the hypothesis that it is possible to ameliorate postural abnormalities through use of nursing interventions that provide postural support (Davis et al., 1993; Grenier, 1988; Turrill, 1992; Schultz). It is also noteworthy that according to anecdotal nursing and parental reports, both the R and N promoted mobility by allowing infants to move their legs freely. These reports indicate the R and N probably produced a balance between flexion and extension, a known requirement for mobility and development of normal posture in infants (de Groot, 1993; Hunter, 1996; Touwen & Hadders-Algra, 1983).

#### Assessment 2

Assessment 2 measures were performed at four months conceptional age. Of the original sample of 123 infants, 104 infants were available for analysis. As postulated in the conceptual model, it was considered appropriate to include measures that assessed motor skills in the longer term (i.e., at four and eight months conceptional age). This postulate is supported by McGraw (1945) who first described that motor development consists of sequential change in specific motor activities with maturation.

To date, no study has investigated longer term effects postural supports on developmental milestones beyond term conceptional age. Measures used during Assessment 2 included measurements of motor function related to specifically to the upper extremities, in addition to composite measures of both upper and lower extremity motor function. As hypothesised, infants nursed with a R (i.e., with or without a N) achieved significantly higher median scores for measures related specifically to upper extremity motor function than infants nursed with a N. Group comparisons showed infants nursed with a R and N achieved a higher median score than infants nursed with only a R. Findings from measures of movement in upper and lower extremities confirmed the hypothesis that *flattened* posture increases extensor muscle tone in all extremities, producing retraction and external rotation of the shoulders, hips and legs (de Groot, 1993; Touwen & Hadders-Algra, 1983). Reduced midline functional ability and lower weightbearing scores were noted in infants in the N group (de Groot, 1993). Details of individual measures will be described.

#### Finger-Finger Play.

This measure was observed with infants positioned under a toy frame in the supine position where finger-finger play (i.e., a specific feature of midline behaviour) was observed. Findings from this study showed that VLBW infants nursed with a R were able to swipe and hold a toy with upper arms level with the body, and infants nursed with both a R and N could reach for and hold a toy by lifting their upper arm away from their body. At four months conceptional age the majority of term infants can swipe and hold a toy under a frame, and at five months can reach for and hold a toy by lifting their upper arm away from their body. These findings were better than expected as infants nursed with a R achieved equivalent scores to those observed in term infants at four or five months conceptional age (Piper & Darrah, 1994).

#### Reaching with Hands to Feet.

This measure also assessed midline behaviour and was observed with infants lying in the supine position. Infants nursed with a R were able to reach with their hands to their knees, and infants nursed with a R and N were able to reach their hands to their feet and push into extension with their legs.

These results were also better than anticipated because 90% of term infants at five months conceptional age are able to reach with their hands to their knees, and 90% of term infants at approximately six months conceptional age can reach with their hands to their feet and push into extension with their legs (Piper & Darrah, 1994).

# Weight-bearing through Shoulders and Spontaneous Leg Movements.

This measure was observed with infants in the prone position where, both the ability to weight-bear through the shoulders, and spontaneous leg movements were measured. The median score for infants nursed with a R indicated infants were able to bear weight on their forearms, abdomen and thighs with abducted hips and uncontrolled weight shifts onto one arm. This score is observed in 90% of term infants at four months conceptional age (Piper & Darrah, 1994). Infants nursed with a R and N were able to bear weight on their forearms, hands and abdomen. In addition, infants' elbows were placed in front of their shoulders and hips were abducted and externally rotated. This score is observed in 90% of term infants at five months conceptional age (Piper & Darrah, 1994). These findings also exceeded expectations and were highly significant because they demonstrated the developmental advantage of nursing VLBW infants with a R and a N.

## Reaching from Forearm Support.

This measure was observed with infants lying prone in the forearm support position, where the ability of an infant to reach for a toy was measured. Infants in either the N or NR groups were able to perform a *controlled* reach where they could actively weight shift to one side and reach for a toy with their free arm. This score is observed in 90% of term infants at seven months conceptional age, and 50% of term infants at five months conceptional age (Piper & Darrah, 1994). Again, these findings were surprising and indicated a developmental advantage equivalent to normal milestones seen in term infants.

## Assessment 3

Assessment 3 measures were performed at eight months conceptional age.

One hundred infants from the original sample of 123 infants were available for analysis. Composite measures of motor function related to upper and lower extremities and a structural measure the foot progression angle were included.

The most consistent finding at this assessment period was the therapeutic effect of the roll for all measures with the exception of the foot progression angle. The measure of the foot progression angle showed no difference between groups; however, results indicated the advantageous effect of both postural supports on the development of foot progression. This measure is used routinely in the measurement of gait in children and adults; however, to date this is only the second study to use the measure in infants that are not yet walking (Downs et al., 1991).

Findings from measures of movement in upper and lower extremities also confirmed the hypothesis that *flattened* posture increases extensor muscle tone in all extremities, causing reduced midline functional ability (de Groot, 1993).

#### Foot Progression Angle.

This measure was performed with the infant in a supported standing position. The line joining the tip of the first toe and the posterior aspect of the heel was defined and deviation from neutral position was measured. The mean foot progression angle was 21°, with no significant difference between any of the three groups shown for this measure. Although this was an unexpected finding, it is of particular interest because Downs and colleagues (1991) reported a mean foot progression angle of 33° in infants nursed prone with postural supports, and a mean angle of 40° in infants nursed prone without postural supports. The population of infants sampled in the Downs and colleagues (1991) study was similar to those included in the present study. As well, the postural supports used by Downs and colleagues (1991) produced similar benefits to the N used in the present study. It is postulated that use of either a N or R improves the foot progression angle in VLBW infants nursed prone, compared to that previously observed in infants with or without flattened posture. In addition, use of the R produces no additional benefit to the foot progression angle in these infants when used in combination with a N.

## Crawling.

This measure was observed by placing infants in the prone position and prompting them with a toy midline or laterally, to observe antigravity movements. The median score achieved by infants nursed with a R, with or without a N, demonstrated infants' ability to creep in a reciprocal fashion (i.e., creep using reciprocal arm and leg movements with trunk rotation and chest and abdomen in contact with supporting surface).

This score is observed in 50% of term infants at seven and a half months conceptional age and 90% of term infants at approximately nine months of age.

These findings indicate that use of the R resulted in achievement of this milestone.

There appears to be no additional benefit from use of the N.

## Rolling.

This measure was observed by placing infants in the supine position and offering them a toy to prompt the infants to roll into the prone position. Once in the prone position, the infants were once again prompted with a toy to encourage them to roll back to the supine position. Infants nursed with a R and a N achieved the highest median scores and were able to roll with trunk rotation from supine to prone and from prone to supine. This score is observed in 50% of term infants at approximately seven months conceptional age and 90% of term infants at approximately nine months of age (Piper & Darrah, 1994). As anticipated, combined use of a R and a N enables VLBW infants to achieve an equivalent developmental milestone to term infants at eight months conceptional age.

#### Sitting.

This measure was observed by placing the infant in a sitting position and offering them a toy to prompt a reaching movement. Findings were again unexpected. Infants nursed with a R achieved significantly higher median scores than infants nursed with a N alone, or with a N and a R. Although infants in both R and NR groups had the same median score, the range was greater for infants in the R group. The median score indicated that infants were able to reach with rotation in the sitting position. This score is observed in 90% of term infants at eight months conceptional age, and 50% of term infants at seven months conceptional age.

This result is possibly explained by a number of factors. Infants in the N and R groups had lower scores for pelvic elevation and weight-bearing surface of the inner thigh and knee, and higher scores for external rotation of the hips. These results indicate the presence of hip abduction in these two groups of infants (i.e., a major feature of *flattened* posture in the lower extremities). In addition, results of the measures specifically related to shoulder posture have shown that infants nursed with a R had improved shoulder posture. Infants with abducted hips are more likely to maintain a sitting position because of the stability produced by hip abduction. Infants with normal shoulder posture are more likely to be able to rotate their trunk while in the sitting position. Therefore, infants in the R group benefited from both greater hip stability and the ability to rotate their upper extremities in the sitting position. These findings reflect both improved shoulder posture (i.e., associated with use of the N on upper extremities) and the unexpected benefit of hip abduction associated with *flattened* posture.

#### Standing.

Although no clear increase in infants' ability to stand was shown, a trend toward a difference in treatment groups was demonstrated. In particular this trend was seen in the NR and R groups compared with the N group. Although this finding was unexpected, it possibly reflects the effect of a high sitting score in the R group, as these infants may have experienced difficulty in progressing from sitting to standing. For infants to assume a supported standing position, they must be able to move easily out of the sitting position. The median score for supported standing indicated that infants were able to pull to stand with support, and pull to a stand position and shift weight from side to side.

These scores equate to those observed in 50% of term infants at eight months conceptional age (Piper & Darrah, 1994). This finding indicates that nursing an infant with either a R or a N, or a combination of both, results in an appropriate developmental advantage for this milestone.

The most striking feature of findings from Phase 2 was that it was possible to ameliorate postural abnormalities associated with *flattened* posture in both the short and longer term. Of further significance, this is the first study to report that VLBW infants can achieve developmental milestones equivalent to those of infants born at term conceptional age by using a simple postural nursing intervention such as the postural support roll.

## Comparing the Conceptual Framework with the Empirical Evidence

Substantive evidence emerged to support the hypothesis generated from the conceptual model. As hypothesised, findings from Phase 1 demonstrated the absorbent qualities of the nappy liner to be an effective primary prevention tool against temperature instability in VLBW infants nursed in incubators on infant servo control (ISC). Specifically, the nappy liner penetrated the infant's *normal line of defence* and compensated for infants' immature thermoregulation system by reducing evaporative heat loss. This was manifested by reduced incubator temperatures and higher skin temperatures. In addition, an unexpected and positive outcome from the conceptual model was the formulation of a prediction model for per axilla temperature. This prediction model can now be used as an intervention for the primary prevention of temperature instability.

As described earlier in this chapter, empirical findings from Phase 1 resulted in a change of nursing practice in the NICU that enabled nappy liners to be added to all postural support nappies, including those used in Phase 2 of the study.

This demonstrates the contribution of empirical findings from Phase 1 to the strengthening of the VLBW infants' lines of defence. Empirical findings from Phase 2 confirmed it was possible for VLBW infants, who must be nursed prone for physiological reasons, to develop normal postural related outcomes. Combined use of a R and a N were shown to be effective primary prevention tools.

These nursing interventions, or internal factors, protected the infant from the stressors (i.e., gravity, prone positioning and immature physiological systems) and promoted outcomes of normal neuromuscular function and neuromotor development until the age of eight months postconception (i.e., feedback).

The state of *wellness* achieved by the study infants reflected not only physiological stability, but more importantly, neuromotor stability for as long as eight months conceptional age. The primary prevention nursing model, therefore, showed that it was possible to promote a degree of homeostasis in VLBW infants nursed in a NICU environment comparable to that experienced by a fetus in utero.

#### Measurement Issues

The research process required use of several measurement tools to determine the outcomes (i.e., reactions) in response to interventions used in this study. Tests selected for assessment of neuromotor function were required to demonstrate reliability and validity, measure quality of movement, measure functional skills, and capture improvement in VLBW infants over a short period of time (Westcott, 1997). Consequently, this complexity of measuring neuromuscular and neuromotor development in VLBW infants required the development of a new measurement tool. In addition, tools traditionally used to either determine gestational age in newborn infants, or to quantify motor development in preterm infants, were also utilised.

The process of choosing, modifying and developing measures that met the above criteria was a focal point in the developmental stage of this study. The results of content validity, test-retest and inter-rater reliability as discussed in Chapter 4, indicate the instruments were reliable measures of the neuromuscular and neuromotor and concepts under investigation.

All measures were simple, inexpensive and easy to use and interpret. Of note, assessment of spontaneous, non-reflexive behaviours is reported as a more accurate portrayal of an infant's motor function (de Groot, 1993; Piper & Darrah, 1994; VanSant, 1987). Consequently, other than the measurement of the foot progression angle, measures used during Assessments 2 and 3 were observational, did not involve handling, or elicit responses from infants. It is also important to note this study has shown the scarf sign used during Assessment 1 to be a sensitive measure, demonstrated by its ability to capture changes in shoulder posture over time. In addition, leg and shoulder posture measures (Lacey et al., 1990; Lacey et al., 1991) used during Assessment 1 were also shown to be sensitive to effects of interventions on posture over time. This study has also confirmed the usefulness of the Alberta Infant Motor Score (Piper & Darrah, 1994) for determining neuromotor function in VLBW infants during the first eight months (i.e., conceptional age) of infancy.

To date, other than two previous studies that utilised the leg posture measures developed by Lacey and colleagues (1991), there is no indication in the literature that any of the other measures chosen for this study have previously been utilised for the measurement of postural development in VLBW infants (Downs et al., 1991; Monterosso et al., 1995).

## Movement and Flexion

As previously discussed, increased movement in the lower extremities was noted in those infants nursed in the N. Although this finding is not supported by empirical evidence, it was noted by the physiotherapist, parents and nursing staff in the NICU throughout the study. These observations agree with reports by Monterosso (1994) from a previous study of the effects of the N on movement in the lower extremities. In addition, it was also noted by the physiotherapist and nursing staff of the NICU that the R promoted flexion and movement of both upper and lower extremities. Furthermore, it was observed by parents and nursing staff that infants nursed with a R appeared to be more stable and comfortable and settled in the quarter turn position.

## Limitations and Strengths

#### Limitations

The limitations of this study relate to three issues. Firstly a convenience sample was used. However, WA has only one perinatal tertiary referral centre that cares for 95% of all preterm infants born within the state. The sample used, therefore, was representative of the total population of VLBW infants in WA. As well, results demonstrated that there were no differences in birth and postnatal variables among groups in either Phase of this study.

Secondly, the limitations of one measure must be considered (i.e., the distance between the acromion process and the suprasternal notch). This measure was confirmed by inter-rater and test-retest reliability testing. Further testing will determine the utility of this measure for assessment of shoulder posture in VLBW infants in the clinical setting.

Thirdly, it would have been preferable to have used a control group in which neither a R or N were applied to infants in Phase 2. Unfortunately, this was not possible for ethical reasons because use of the N was routine practice in the NICU. However, as previously discussed in Chapter 4, the best clinical alternative was used (i.e., three treatment groups). This assured a control (i.e., N group) for infants nursed with a R in relation to upper extremity posture. As all three treatment groups provided some form of postural support for the lower extremities, it was not possible to provide a control for lower extremity posture. However, findings from this study confirmed those of the researcher's previous work on the N demonstrating the short and longer term advantage on lower extremity posture.

## Strengths

The study limitations were balanced by several strengths. The study was based upon a sound theoretical foundation. Only one observer performed all measurements and collected all data throughout both phases of the study. This ensured consistency and accuracy of all data. A further strength of the study was that with the exception of the foot progression angle and the distance between the acromion process and suprasternal notch, measures used were standardised. In addition, inter-rater and test-retest reliability were established in a rigorous manner prior to, and throughout the course of Phase 2. In addition, the observer remained blind to the group allocation of infants throughout the duration of the study. Furthermore, effective randomisation was achieved, controlling for possible confounding variables. Use of baseline measurements for Assessment 1 added further rigour to Phase 2 of the present study. Only one previous study has used baseline measurements.

# Infant Posture Assessment Tool

It was possible, from the findings that confirmed the sensitivity of the measures and the ability to establish test-retest and inter-rater reliability, to develop a rudimentary Infant Posture Assessment Tool (IPAT) for use in VLBW infants up to eight months conceptional age (see Appendix O). The tool is not intended for immediate clinical use; however, following further testing the tool may be useful to both nursing, medical and physical therapy practices in the future.

Application of the Primary Prevention Model for the Prevention of Temperature

Instability and Neuromotor Problems in VLBW Infants to Clinical Practice

The interdisciplinary focus of this study facilitated the transfer of clinically meaningful knowledge between health disciplines involved in the care of VLBW infants. Underpinning this research was the aim of developing an empirical base for the prevention of temperature instability and neuromotor problems in VLBW infants nursed in a NICU environment. This study was guided by a sound theoretical base and provided empirical evidence that is clinically meaningful to support this aim. This knowledge can easily be applied by nurses and other health professionals involved in the care of VLBW infants by improving the NICU environment for VLBW infants. In addition, the knowledge provided by Phase 2 findings can be utilised in the assessment of posture as well as the development of future postural interventions for VLBW infants.

Findings from Phase 1 have already resulted in a change to nursing practice, and routine use of absorbent nappy liners within postural support nappies has been implemented in the NICU.

Although findings from Phase 1 related to infants nursed in incubators on ISC, it was considered logical to extend use of the nappy liner to all infants nursed in a postural support nappy (i.e., nursed either in an incubator or a cot). Nursing staff and parents have reported satisfaction with this outcome and consider use of the postural support nappy as preferable to that of the current alternative (i.e., the disposable nappy). The disposable nappy is bulky and does not offer the postural or aesthetic benefits of the postural support nappy.

Nursing, physical and occupational therapy staff can incorporate use of a postural support roll, with or without a postural support nappy, when positioning VLBW infants prone. In addition, physical therapists, nurses and medical staff can utilise the IPAT to assess VLBW infant posture in the short and longer term. Information gained from this practice could be used to develop treatment plans for both clinical and home use by parents. Future use of the IPAT will confirm its meaningfulness and utility as an assessment tool, and facilitate further clinical research in the area of posture and neuromotor development.

## Summary of the Chapter

Given the limitations of this study, the findings contribute to neonatal nursing knowledge and practice. The findings have contributed to theory development that links empirical knowledge of thermoregulation, physiological and postural development in VLBW infants. Testing of the theoretical relationships of the primary prevention nursing model provided the empirical evidence to recommend implementation of the model in the clinical setting. In addition, it is anticipated that the IPAT will evolve with further research and development, and facilitate valuable research in preterm infant posture and use of postural interventions.

#### **CHAPTER 7**

Conclusions, Implications and Recommendations

This unique study produced findings of theoretical and clinical significance.

The study was comprehensive and although firmly placed within nursing, reflected an interdisciplinary focus. The assumption that underpinned the primary prevention nursing model and guided the research process, was that an extrauterine environment that promoted homeostasis could prevent temperature instability and abnormal neuromotor development in VLBW infants.

The research consisted of two phases reflecting the overall aims of the research. Phase 1 showed that use of an absorbent nappy liner within a cloth postural support nappy (N) in VLBW infants nursed in incubators on infant servo control (ISC) improved temperature stability. As a result of the implementation of empirical findings from this study, infants now benefit from the postural and thermoregulation advantage of the N in the NICU.

Phase 2 confirmed that use of a N improves hip posture up to term conceptional age. In addition, it was shown that use of a postural support roll (R) improved hip and shoulder posture in VLBW infants up to the age of eight months postconception. All measures met the required selection criteria, were simple to use and sensitive to postural changes over time. Test-retest and inter-rater reliability was established prior to and throughout the duration of the study. The researcher who was blind to infant group allocation performed all measures. The sample of 23 VLBW infants for Phase 1, and 123 VLBW infants for Phase 2, were recruited over a three and 15 month period respectively. The sample was representative of the general VLBW infant population in WA.

As shown in the findings, the majority of hypotheses were supported. Combined use of the N and the R significantly improved hip posture up to term conceptional age; however, this advantage was not observed in all measures at four and eight months conceptional age. This can be possible be explained because measures specifically related to hip posture could not be included at these time points because hip posture at these developmental stages is closely interrelated with shoulder posture. Therefore, it was not possible to measure hip posture in isolation. In contrast, it was still possible to measure two specific shoulder related milestones at four months conceptional age. The overwhelming conclusion from Phase 2 was that as a result of use of the R when infants are nursed prone in a NICU, shoulder and hip posture significantly improved in the short and longer term. Although the importance of the R has been identified, use of a nappy that provides thermal stability, produces minimal bulk between the legs and some form of pelvic elevation is also recommended. This should take the form of either a cloth N or a disposable nappy incorporating the beneficial features of the N.

The findings contribute to the theoretical knowledge base and practice of neonatal nursing. The theory base was developed by drawing together literature related to thermoregulation and postural development. Testing the theoretical relationships between use of nursing interventions and their effects on thermoregulation and posture, provided the empirical evidence required to improve nursing practice and develop an infant posture assessment tool (IPAT) for the assessment of posture over time in VLBW infants. The assessment tool will evolve with further refinement and research, and will add to the clinical skills of nurses, doctors, physical and occupational therapists.

#### **Future Research Directions**

The empirical evidence provided by this nursing study is unique in the area of preterm infant thermoregulation and posture development. This research has also highlighted the need for nurses to consider not only the immediate survival needs of infants, but also the short and longer term outcomes of these infants. Furthermore, this study has finally confirmed a number of long held beliefs that in the past were based on anecdotal evidence.

This study explored and tested the effect of thermoregulation and postural interventions in VLBW infants. Although well described and hypothesised in nursing texts and other literature, these relationships have not yet been tested in a prospective study. Having considered the limitations and strengths of this research it would be appropriate to continue research that promotes homeostasis in preterm infants and adds to the primary prevention model used in this study.

The first line of future research would be to replicate Phase 2 in other populations to confirm the findings. Replication of this research would further test the reliability and sensitivity of measures used in this study.

The second line of research is to extend this study by examining the effects of the postural interventions on the development of gait and the angle of foot progression at one and two years of age respectively. This research will establish whether use of the R improves the mean age that VLBW infants commence walking. In addition, this research should incorporate examination of the movement and flexion of infants to confirm reported observations from parents and nursing staff as previously described in Chapter 6.

## Summary of Recommendations

## Clinical Nursing

- Nursing protocols should include use of postural support nappies with inner absorbent liners, or, disposable nappies with the postural advantages of the postural support nappy.
- Nursing protocols for the positioning of infants should include use of postural support rolls in VLBW infants nursed in the prone position.

### **Future Research**

- A longer term follow-up study should be undertaken of all infants studied in Phase
   until the infants reach two years conceptional age, to determine the effects of
   postural supports on gait patterns and the foot progression angle
- 2. Use of postural supports in VLBW infants nursed in the prone position should be further investigated to validate the findings of this study.
- 3. The measure for shoulder retraction (i.e., the distance between the acromion process to the suprasternal notch) requires further testing and validation.
- 4. The IPAT requires further testing and validation.

### **Education**

- Findings from this study should be incorporated into neonatal, paediatric, maternal and child health nursing education programmes.
- 2. Findings from Phase 2 of this study should be incorporated into medical, physical and occupational therapy education programmes.

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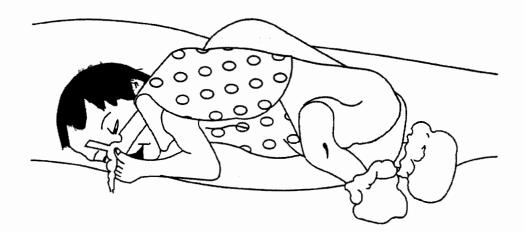
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Appendix A
Quarter Turn Position Using Postural Support Roll

### **Quarter Turn Position Using Postural Support Roll**

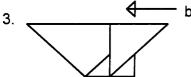


Appendix B
Postural Support Nappy Folding Instructions

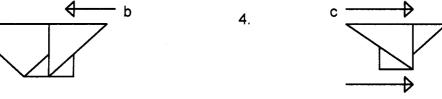
#### **Postural Support Nappy Folding Instructions**



Place triangular nappy on a flat surface

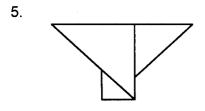


Fold (b) to the left along dotted line

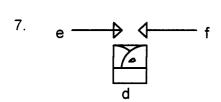


Fold (c) to the right along dotted line

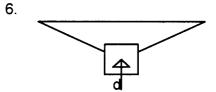
Fold lower point (a) upward



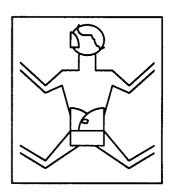
Fold top edge under nappy



Fasten (e) and (f) to (d), allowing infant room for leg movement



Place nappy under prone infant and fold (d) upward between infant's legs



Appendix C	
Data Collection Form - Temperature Study	

#### **Data Collection Form - Temperature Study**

Code Gestat	ion _	<del></del>		Sex Birthw	eight _				
Day 1					Day 2				
Date:					Date:				
Weigh	t:				Weight	t:			
Time	ISC TO	INC TO	PA T <sup>o</sup>	Rx	Time	ISC T <sup>o</sup>	INC TO	PA T <sup>o</sup>	Rx
									-

Day 3

Day 4

Date:					Date:				
Weight:				Weight:					
Time	ISC T <sup>o</sup>	INC T <sup>o</sup>	PA T <sup>o</sup>	Rx	Time	ISC T°	INC TO	PA T <sup>o</sup>	Rx

Appendix D
Temperature Study Instructions

#### **Temperature Study Instructions**

## Please Attach These Instructions to Incubator if Infant Commences Study Wearing a Cloth Nappy with a Liner

NB Please record:

- (a) the date and time each nappy period commences
- (b) the date and time the study is completed

Date	Time	<b>Nappy Type</b>
		Cloth with nappy liner
		Cloth (no liner)
		Cloth with nappy liner
		Cloth (no liner)
		Completed

<ul> <li>change nappy type at the same time each day of the f</li> </ul>	trial	•	change nappy	type at the s	same time	each day	of the tria
--	-------	---	--------------	---------------	-----------	----------	-------------

- change nappy 4 hourly ensuring ISC temperature probe is clear of nappy
- record ISC and incubator temperature hourly (Ototemp 8 hourly)

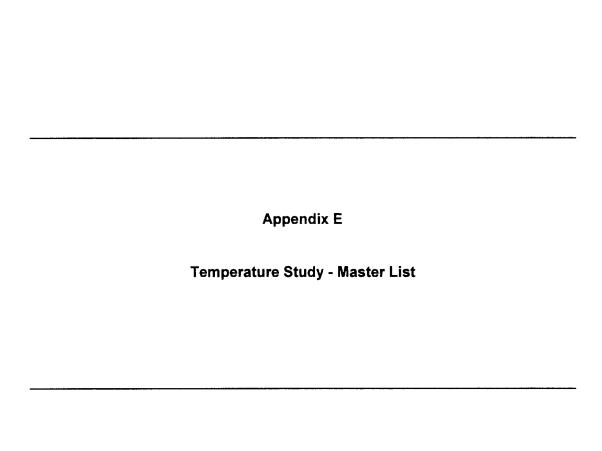
## Please Attach these Instructions to Incubator if Infant Commences Study Wearing a Cloth Nappy without a Liner

NB Please record:

- (a) the date and time each nappy period commences
- (b) the date and time the study is completed

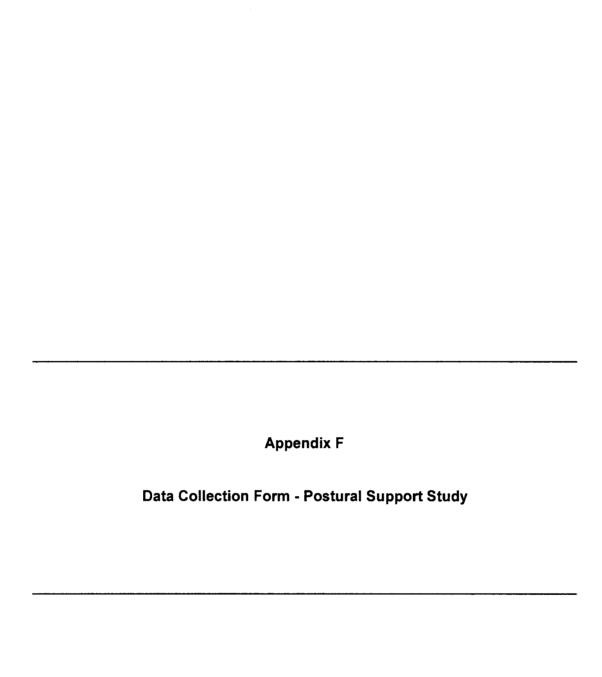
Date	Time	<b>Nappy Type</b>
		Cloth (no liner)
		Cloth with nappy liner
		Cloth (no liner)
		Cloth with nappy liner
		Completed

- change nappy type at the same time each day of the trial
- change nappy 4 hourly ensuring ISC temperature probe is clear of nappy
- record ISC and incubator temperature hourly (Ototemp 8 hourly)



### Temperature Study - Master List

Code	Unit Medical Record Number Label
·	



#### **Data Collection Form - Postural Support Study**

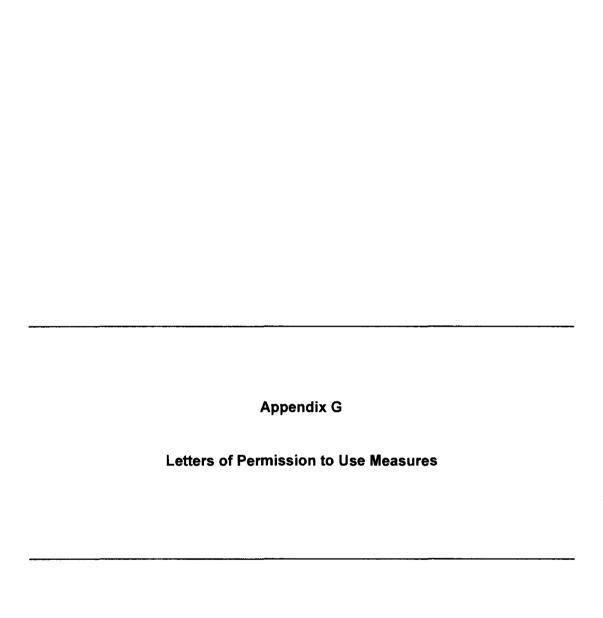
1	Code		
2	Sex	Female Male	1 2
3	Gestation (wks)		
4	Gestation age group	<29 29 - 30	1 2
5	Weight	Birth 4-6 wks Term 4 months	
		8 months	
6	Birthweight ratio		
7	Delivery type	Vaginal LUSCS	1 2
8	Presentation	Vertex Breech Transverse Other	1 2 3 4
9	IVH	Grade 1 Grade 2 Grade 3 Grade 4	1 2 3 4
10	PVL	Yes No	1 2
11	Suspected septic episodes Proven septic episodes		
12	Ventilated days	ETT DNP	
13	Oxygen days	Ventilated Post/non vent	=
14	Discharge oxygen	Yes No	1 2
15	Outcome	Alive Dead Withdrawn Abnormality	A D W ABN

#### <u>Assessment 1</u> 16 ERL 1 ERL 2 ERL 3 EP 1 17 EP 2 EP 3 **WBS 1** 18 **WBS 2 WBS 3** SS<sub>1</sub> 19 SS 2 **SS 3** 20 ACSS<sub>1</sub> ACSS 2 ACSS 3 21 SAM 1 SAM 2 SAM 3 Assessment 2 Hands to feet (4 months) 1 22 2 3 4 5 1 Finger-finger (4 months) 23 2 3 4 1 Reaching (4 months) 24 2 3 4 1 Weightbearing - shoulders (4 months) 25 2 3

4 5

#### Assessment 3

26	Crawling (8 months)	1 2 3 4 5
27	Rolling (8 months)	1 2 3 4 5
28	Combined sitting (8 months)	1 2 3 4 5
29	Supported standing (8 months)	1 2 3 4 5
30	Foot progression angle (8 months)	
31	Days until intervention commenced	-
32	Days spent on intervention	





PRINCE ALFRED HOSPITAL

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Missenden Road Camperdown NSW 2050 Sydney, Australia

Telephone: 595

Facsimile: 02 95159451

Reference: Peddished Karand

PERMISSIONO

Leanne Montertosso

16 September 1995

W. B. Saunders Company The Curtis Center Independence Square West Philadelphia Pennsylvania 19106

Dear Sir/Madam

Re: Motor Assessment of the Developing Infant. Martha C. Piper, Johanna Darrah. (1994). W. B. Saunders Company.

I am writing to seek permission to use and reproduce the Alberta Motor Scale which is published in the above book.

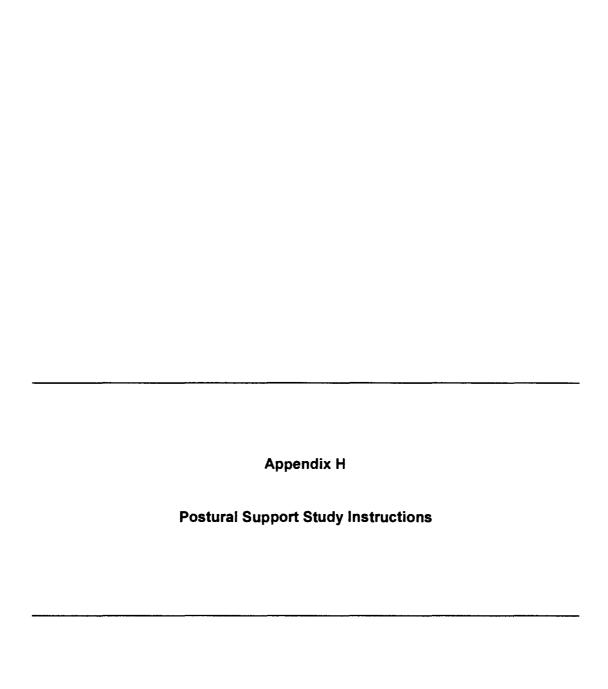
I am currently undertaking a PhD in Nursing - part of which involves the investigation of the long term motor and postural outcomes of infants born at less than 31 weeks gestation. I have found that the above motor scale would be particularly suitable for my purposes. I would be most grateful for your permission to reproduce (with appropriate acknowledgement) the relevant sections of the Alberta Motor Scale in my research study proposal, and also in my thesis upon completion of the study.

I look forward to your early response which will enable me to complete my research proposal. I may also be contacted by facsimile if this is convenient for you - 0011 1 9 381 7559

Your Sincerely

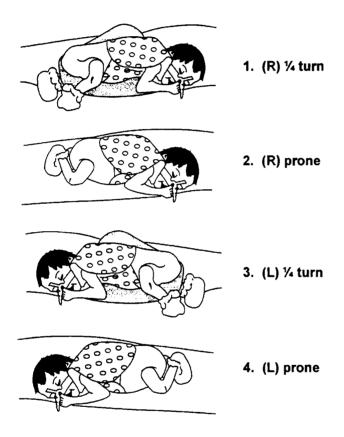
Permission granted, provided no other source is credited. Permission is contingent upon the consent of the author, and complete credit to original source must be given.

W. B. Saunders Company Date



#### **CLOTH POSTURAL SUPPORT NAPPY & POSTURAL SUPPORT ROLL**

- 1. Please use a **CLOTH POSTURAL SUPPORT NAPPY** until the baby commences routine side-lying.
- 2. Please change the baby's position with each nappy change/ETT suction (if suction coincides with nappy change) using the following sequence.



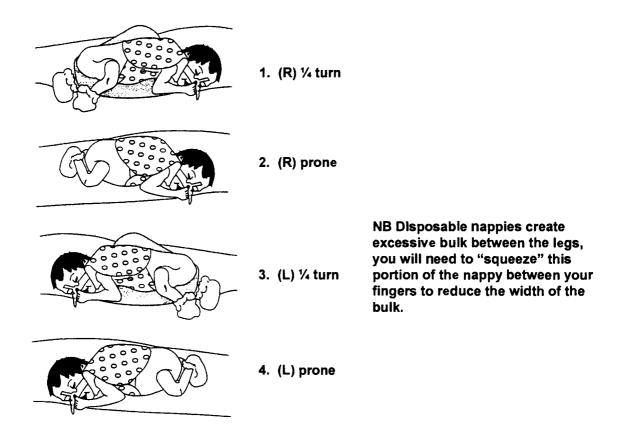
#### AIM

To support the whole trunk from shoulder to hip on one side of body at a time. **METHOD** 

- 1. Place then end of the postural support roll (with attached ties) between the upper boarder of the sternum and shoulder tip. Place the ties underneath the baby's body and pull them through to the opposite hip. Position the remainder of the roll so that it elevates the rest of the trunk and hip, and then it between the legs to the other side. Fasten the ties around the roll to ensure that it remains in place if the baby becomes active. Tuck the remainder of the roll under the mattress. Ensure that the legs are flexed, and that the knees and feet are pointing in the same direction.
- 2. Flex the arm on the elevated side so that the hand is at eye level, ensuring that the elbow is in line with the shoulder. Position the other arm straight down and in alignment with the baby's body.

#### **DISPOSABLE NAPPY & POSTURAL SUPPORT ROLL**

- Please use a DISPOSABLE NAPPY until the baby commences routine side-lying.
- 2. Please change the baby's position with each nappy change/ETT suction (if suction coincides with nappy change) using the following sequence.



#### **AIM**

To support the whole trunk from shoulder to hip on one side of body at a time.

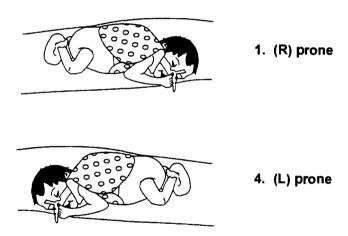
#### **METHOD**

1. Place then end of the postural support roll (with attached ties) between the upper boarder of the sternum and shoulder tip. Place the ties underneath the baby's body and pull them through to the opposite hip. Position the remainder of the roll so that it elevates the rest of the trunk and hip, and then it between the legs to the other side. Fasten the ties around the roll to ensure that it remains in place if the baby becomes active. Tuck the remainder of the roll under the mattress. Ensure that the legs are flexed, and that the knees and feet are pointing in the same direction.

Flex the arm on the elevated side so that the hand is at eye level, ensuring that the elbow is in line with the shoulder. Position the other arm straight down and in alignment with the baby's body.

#### **CLOTH POSTURAL SUPPORT NAPPY**

- 1. Please use a **CLOTH POSTURAL SUPPORT NAPPY** until the baby commences routine side lying.
- 2. Place infant in the PRONE POSITION ONLY at all times.
- 3. PLEASE DO NOT USE A POSTURAL SUPPORT ROLL.
- 4. Please change the baby's position with each nappy change/ETT suction (if suction coincides with nappy change) using the following sequence.



# Appendix I Postural Support Study Assessment 1 - Measures

#### Assessment 1 Measures

#### 1. Weightbearing Surface of the Leg in Prone (Lacey et al., 1990)

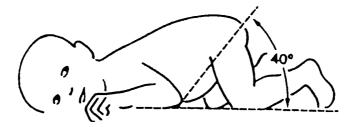
(examiner to indicate which posture infant achieves)

This posture will be divided into 5 grades according to the surface of the leg resting on the mattress while the infant is lying prone as follows:

- Legs in widest abduction and external rotation, with the whole length
  of the medial aspect of the thigh, lower limb and foot resting on the
  mattress (everted).
- Medial aspect of the knee, lower limb and foot resting on the mattress, slight elevation of the pelvis.
- Medio-anterior aspect of the knee, part of the thigh raised above the mattress, heels elevated <45<sup>0</sup> from the mattress.
- Anterio-medial aspect of the knee, thigh raised above the mattress,
   heels elevated >45<sup>0</sup> from the mattress.
- 5. The anterior surface of the knee rests on the mattress, the thigh raised above the mattress, feet in line with lower limb, or, inverted.

#### 2. Angle of Elevation of the Pelvis in Prone (Lacey et al., 1990)

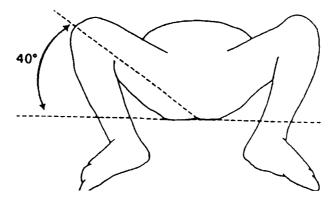
The infant's head can be rotated to either the left or right, but the pelvis must not be rotated. Using a goniometer, elevation of the pelvis will be assessed as the angle between the mattress and a line from the xyphisternum to the centre of the hip joint.



Angle of pelvic elevation in prone = angle between mattress and line from xyphisternum to centre of hip joint.

# 3. Angle of External Rotation of the Leg from Lateral Support (Lacey et al., 1990)

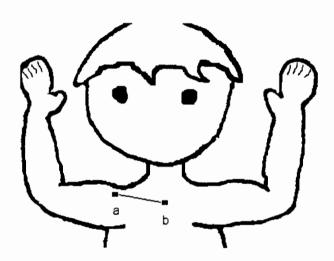
The examiner will gently roll the infant to supine, starting the movement by raising one side of the infant's body in the hand. The infant must be in the midsupine position, with the buttocks resting equally on the mattress and the head in mid-line to minimise any possible influence of the asymmetrical tonic neck reflex (Phelps et al., 1985). A goniometer will be used to measure the angle of external rotation of the leg which is defined as the angle between the mattress and the anterior surface of the patella.



Angle of leg rotation from lateral support in supine = angle between mattress and end of anterior surface of the patella.

#### 4. Shoulder Retraction

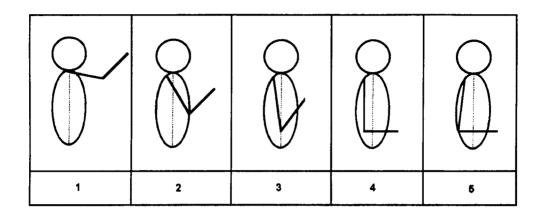
Surgical callipers will be used to measure the distance between the acromion process and the suprasternal notch in centimetres. The infant will be placed in the supine position with the head supported in the midline.



Shoulder retraction = distance from the acromion process (a), to the suprasternal notch (b), measured in centimetres.

#### 5. Scarf Sign (Ballard et al., 1979)

This will be assessed with the infant in the supine position as shown below.



Score

#### 6. Quality of Spontaneous Arm Movements (Lacey et al., 1990)

To measure antigravity control of arm movements, the infant's head will be supported in the midline position while lying supine.

#### Score

- 1. Global movements without elbow flexion (i.e., arms straight).
- 2. Wide arc shoulder movements in body plane (i.e., "windmilling").
- 3. Hands to midline across chest, or, brings dorsum of hand to face.
- 4. Hands to face not central (i.e., brings palm to face only).
- 5. Goal directed hand to mouth movements.

# Appendix J Postural Support Study Assessment 2 - Measures

#### **Assessment 2 Measures**

#### (examiner to indicate which posture infant achieves)

#### 1. Finger-Finger Play in Supine

- 1. Does not bring hands together in the midline.
- 2. Brings hands together in the midline but does not swipe or grasp.
- Swipes and may hold a toy while positioned underneath a frame.
   Arms are resting on the chest. Toy is positioned within reaching distance.
- 4. Reaches for and holds a toy while positioned underneath a frame.
  Arms are lifted away from the body. Infant completes a full reaching distance. Toy is placed slightly higher than above reaching distance.

#### 2. Reaching from Prone Forearm Support

- Does not reach for a toy when prompted in the prone forearm support position.
- Leans into toy when prompted. Does not actively weight shift with elbows or forearms.
- Controlled reach active weight shift onto one elbow to enable an active reach for a toy with other arm.

# 3. Weightbearing through Shoulders with Spontaneous Leg Movements (Piper & Darrah, 1994)

- · examiner to indicate which posture infant achieves
- · full description of each posture overleaf

Prone lying (2)	1
Prone prop	2
Forearm support (1)	3
Prone mobility	4
Forearm support (2)	5

# 3. Weightbearing through Shoulders with Spontaneous Leg Movements (Piper & Darrah, 1994)

1. Prone lying (1)

Weightbearing	Weight on hands, forearms, and chest
Posture	Elbows behind shoulders and close to body Hips and knees flexed
Antigravity Movement	Raises head to 45 <sup>o</sup> Turns head

The infant is able to lift head to 45° in the midline; this position may not be maintained indefinitely.

2. Prone prop

Weightbearing	Weight on hands, forearms, and chest
Posture	Shoulders slightly abducted
	Elbows behind shoulders
	Hips and knees flexed
Antigravity Movement	Raises head to 45 <sup>0</sup>
	Turns head

The infant is able to lift head to 45° in the midline; this position may not be maintained indefinitely.

3. Forearm support (1)

o. roroarm capport (1)	
Weightbearing	Weight symmetrically distributed on forearms and trunk
Posture	Shoulders abducted Elbows in line with shoulders Hips abducted and externally rotated Knees flexed
Antigravity Movement	Pushes against surface to raise head Lifts and maintains head past 45 <sup>0</sup> Chest elevated

To pass this item the elbows must not be behind the shoulders; they may be beyond the shoulders. The infant may play with the feet together in this position. The head does not have to be maintained at 90°. Active chin tuck is not present.

4. Prone mobility

Weightbearing	Weight on forearms, abdomen, and thighs
Posture	Head to 90 <sup>0</sup> Forearm support or immature extended arm support Hips abducted
Antigravity Movement	Uncontrolled weight shift onto one arm; there may or may not be any displacement of the trunk

This item represents the infant's early attempt to observe antigravity movements. **Prompt**: May place toys appropriately to observe antigravity movements.

5. Forearm support (2)

Weightbearing	Weight on forearms, hands, and abdomen
Posture	Elbows in front of shoulders
	Hips abducted and externally rotated
Antigravity Movement	Raises and maintains head in midline Active chin tuck and neck elongation Chest elevated

The elbows must be in front of the shoulders to pass this item. The shoulders may be either abducted or in a more neutral position. The infant will often actively flex and extend the knees in this position. This item represents more mature head control than does the previous forearm support.

### 4. Hands to feet (Piper & Darrah, 1994)

- examiner to indicate which posture infant achieves
- full description of each posture overleaf

# Supine lying (4) 2 Hands to knees 4 Active extension 5

### 4. Hands to Feet (Piper & Darrah, 1994)

Supine lying (3)

Weightbearing	Weight symmetrically distributed on head, trunk and buttocks
Posture	Head in midline Arms flexed and abducted or positioned at side of body Legs flexed or extended
Antigravity Movement	Bilateral or reciprocal kicking  Moves arms but unable to bring hands to  midline

The posture of the legs may vary between flexion and extension. The infant is still moving the arms at the side rather than playing in the midline.

Supine lying (4)

Weightbearing	Weight symmetrically distributed on head, trunk and buttocks
Posture	Head in midline with chin tuck Arms resting on chest Legs flexed or extended
Antigravity Movement	Neck flexors active-chin tuck Brings hands to midline Bilateral or reciprocal kicking

The infant is easily able to bring the hands together in the midline but does not have to successfully grasp a toy to pass this item

Prompt. May use toy to observe progression of hands to midline

### Hands to knees

Harida to Kricea	
Weightbearing	Weight symmetrically distributed on head, trunk, and pelvis
Posture	Hips abducted and externally rotated and knees flexed
Antigravity Movement	Turns head easily side to side Chin tuck Reaches hand or hands to knees Abdominal muscles active May fall to side by lifting legs

It is important to observe active abdominal muscles. If the legs are widely abducted and resting on the abdomen passively, the infant will not pass this item. Hypotonic infants often display this passive position.

### Hands to feet

Weightbearing	Weight on head and trunk
Posture	Hand contact with one or both feet
	Hips flexed greater than 90°
	Knees semiflexed or extended
Antigravity Movement	Chin tuck
	Lifts legs and brings feet to hands
	Can maintain legs in midrange
	Pelvic mobility present
	Rocks from side to side; may roll to side

### Active extension

Weightbearing	Weight on one side of body
Posture	Hyperextension of neck and spine
Antigravity Movement	Shoulders protracted Pushes into extension with one or both legs May roll to side accidentally

During this movement, one buttock usually remains on the supporting surface. There is a movement that the infant plays with, distinguishing it from the 'arching' of hypertonic infants.

# Appendix K Postural Support Study

Assessment 3 - Measures

### **Assessment 3 Measures**

### 1. Crawling (Piper & Darrah, 1994)

- · examiner to indicate which posture infant achieves
- full description of each posture overleaf

# Reaching from forearm support **Pivoting** 2 **Rocking** 3 Reciprocal creeping Four point kneeling (1) 5

### 1. Crawling (Piper & Darrah, 1994)

**Reaching From forearm Support** 

Weightbearing	Weight on one forearm, hand and abdomen
Posture	Forearm support
1	Legs approaching neutral position
Antigravity Movement	Active weight shift to one side
	Controlled reach with free arm

This item represents a controlled reach; the infant does not lose his or her balance as the arm reaches

Prompt: Object placed in midline to laterally to observe antigravity movements.

**Pivoting** 

Weightbearing	Weight on trunk, arms and hands
Posture	Head to 90 <sup>0</sup>
Antigravity Movement	Pivots  Movement in arms and legs  Lateral trunk flexion

To pass this item, the infant must use both arms and kegs to pivot. **Prompt**: Place toy laterally to initiate movement.

Rocking

Weightbearing	Weight on hands and knees
Posture	Legs flexed, hips aligned under pelvis
	Flattening of lumbar spine
Antigravity Movement	Abdominal muscles active
	Rocks back and forth diagonally
	May propel self forward

This item is characterised by the mature posture of the hips aligned under the pelvis. The infant should rock to pass this item.

Reciprocal crawling

resipresur oratting	
Weightbearing	Weight on opposite arm and leg
Posture	Flexion of one hip, extension of the other
	Arm flexion
	Head to 90 <sup>0</sup>
	Rotation in trunk
Antigravity Movement	Reciprocal arm and leg movements with trunk
	rotation

Movement in both arms and legs must be observed.

Four point kneeling (1)

Weightbearing	Weight on hands and knees
Posture	Legs flexed, abducted, and externally rotated
	Lumbar lordosis
Antigravity Movement	Maintains position
	May rock back and forth or diagonally
	May propel self forward by falling

This item is characterised by the immature position of hip abduction. The shoulders may be internally rotated or in a neutral position. The infant need not be observed rocking to pass this item.

### 2. Rolling (Piper & Darrah, 1994)

- examiner to indicate which posture infant achieves
- full description of each posture overleaf

# Hands to feet Rolling supine to prone 2 without rotation Rolling prone to supine without rotation 3 **Rolling supine** to prone with rotation Rolling prone to supine with rotation 5

### 2. Rolling (Piper & Darrah, 1994)

### Hands to feet

Weightbearing	Weight on head and trunk
Posture	Hand contact with one or both feet Hips flexed greater than 90°
	Knees semiflexed or extended
Antigravity Movement	Chin tuck
	Lifts legs and brings feet to hands
	Can maintain legs in midrange
	Pelvic mobility present
	Rocks from side to side; may roll to side

Rolling supine to prone without rotation

Weightbearing	Weight on one side of body
Posture	Head up
	Trunk elongated on Weightbearing side
	Shoulder in line with pelvis
Antigravity Movement	Lateral head righting
	Rolling initiated from head, shoulder or hip
	Trunk moves as one unit

Rolling prone to supine without rotation

Weightbearing	Weight on one side of body
Posture	Shoulder in line with pelvis
	Trunk extension
Antigravity Movement	Movement initiated by head
	Rolls prone to supine without trunk rotation

Rolling supine to prone with rotation

Weightbearing	Weight on one side of body
Posture	Head up Trunk elongated on Weightbearing side Shoulder and pelvis not aligned
Antigravity Movement	Lateral head righting Dissociated movement in legs Rolling initiated from head, shoulder or hip Trunk rotation

Rolling prone to supine with rotation

Rolling prono to supino with roution		
Weightbearing	Weight on one side of body	
Posture	Shoulder not in line with pelvis Trunk rotation	
Antigravity Movement	Movement initiated by shoulder, pelvis or head Trunk rotation	

### 3. Sitting (Piper & Darrah, 1994)

- examiner to indicate which posture infant achieves
- full description of each posture overleaf

Sitting with arm support		1
Unsustained sitting with arm support		2
Weight shift in unsustained sitting	(a)	3
Sitting without arm support (1)	C. M.	4
Reaching with rotation in sitting		5

### 3. Sitting (Piper & Darrah, 1994)

Sitting with arm support

Weightbearing	Weight on buttocks, legs and hands
Posture	Head up Lumbar spine rounded, thoracic spine extended Extended arm support Hips flexed, externally rotated, and abducted Knees flexed
Antigravity Movement	Head movements free from trunk Propped on extended arms Cannot move in and out of position

Prompt: Examiner places the infant in sitting position

Unsustained sitting without arm support

Weightbearing	Weight on buttocks and legs
Posture	Elbows flexed Thoracic spine extended Hips flexed, externally rotated, and abducted with wide base of support Knees flexed
Antigravity Movement	Cannot be left alone in sitting position indefinitely

To pass this item the infant must be able to maintain sitting alone for a brief period but still may require supervision.

Weight shift in unsustained sitting

Weightbearing	Weight on buttocks and legs
Posture	Hips flexed, abducted, and externally rotated
	Arms free
Antigravity Movement	Weight shift forward, backward, or sideways
	Beginning to right body back to midline
	Cannot be left alone in sitting position

This item represents a stage in sitting in which an infant loses balance easily, especially when experimenting with weight shift.

Prompt: Examiner places the infant in sitting position. May use toys to elicit weight shift.

Sitting without arm support (1)

Ortang without ann support (1)			
Weightbearing	Weight on buttocks and legs		
Posture	Shoulders aligned over hips		
	Arms free		
	Wide base of support		
Antigravity Movement	Arms move away from body		
	Can play with a toy		
	Can be left alone in sitting position		

To pass this item, an infant must be able to maintain sitting well. The caregiver is comfortable leaving the infant in sitting position. Rotation within the trunk does not need to be present to pass this item.

Reach with rotation in sitting

Access with total of the ording		
Weightbearing Weight on buttocks and legs		
Posture	Trunk rotated	
	Elongation of trunk on reaching side	
Antigravity Movement	Sits independently	
	Reaches for toy with trunk rotation	

To pass this item, an infant must be able to easily reach for a toy, and rotation must be seen within the trunk. The infant may reach in any direction as long as trunk rotation is observed. *Prompt*: Examiner may place infant in sitting position. May use toys to encourage infant to reach.

### 4. Supported Standing (Piper & Darrah, 1994)

- examiner to indicate which posture infant achieves
- full description of each posture overleaf

# Supported standing (1) Supported standing (3) 2 Pulls to stand with support 3 Pulls to stand/stands Supported standing with 5 rotation

### 4. Supported Standing (Piper & Darrah, 1994)

Supported standing (1)

Weightbearing	Bears weight intermittently
Posture	Head flexed forward Hips behind shoulders
	Hips and knees flexed
	Feet may be close together Infant does not slip through examiner's hands
Antigravity Movement	There may be intermittent hip and knee flexion

**Prompt**: Supported by examiner under axillae.

Supported standing (3)

Weightbearing	Weight on feet
Posture	Head in midline Hips in line with shoulders
	Hips abducted and externally rotated
Antigravity Movement	Active control of trunk Variable movements of legs: may bounce up and down, lift one leg, or hyperextend the
	knees

The antigravity movements are extremely variable. To pass this item, the infant must have the heels down at some point during the observation period and demonstrate spontaneous movement in the legs.

**Prompt**: Infant is supported by examiner at chest level.

Pulls to stand with support

Weightbearing	Weight on arms and feet		
Posture	Arms on support Hips abducted and externally rotated Leans on support Lumbar lordosis		
Antigravity Movement	Pushes down with arms and extends knees to achieve standing		

The legs do not have to be completely symmetrical during this manoeuvre, and the infant may push with the legs to assume the position. The posture of the feet is variable; Weightbearing may be observed on the toes or medial border of the feet

**Prompt**: May use toys to encourage infant to get to standing position. Do not place in standing position

### Pulls to stand/stands

Weightbearing	Weight on feet		
	Some arm support		
Posture	Hips flexed, abducted, and externally rotated		
	Lumbar lordosis		
	Broad stance		
Antigravity Movement	Pulls to stand		
	Shifts weight from side to side		
	May lift one leg off surface		
	No rotation in trunk		

The examiner must observe the infant independently assume the standing position. The infant may pull to stand through postures other than half-kneeling. **Prompt**: May use toys to encourage infant to stand.

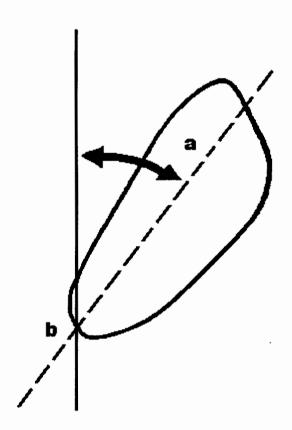
Supported standing with rotation

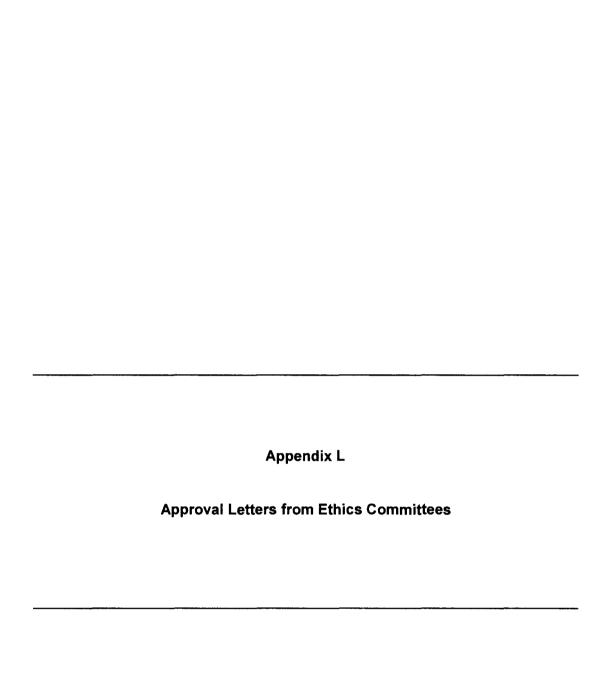
Capported during with rotation			
Weightbearing	Weight on feet		
	One arm support		
Posture	Hips abducted		
	Trunk rotated		
Antigravity Movement	Able to release one hand and reach with		
	rotation of trunk and pelvis		

If the infant is not observed to pull to stand independently, he or she should not pass this item. The infant's base of support may still be wide.

### 5. Foot Progression Angle (Downs et al., 1991)

Infant to be supported in a standing position with the pelvic girdle parallel to a vinyl covered square foam support. The line joining the tip of the first toe (a), and the posterior aspect of the heel (b), will be defined. Deviation from the position of neutral rotation will be measured.







### OFFICE OF RESEARCH AND DEVELOPMENT

Pearson Street. Churchlands Western Australia 6018 Telephone (09) 273 8170 Facsimile (09) 273 8046

### Committee for the Conduct of Ethical Research

Ms Leanne Monterosso

Dear Ms Monterosso

Re:

**Ethics Approval** 

Code:

95-157

**Project Title:** 

The effects of postural support on 'flattened posture', thermoregulation

and physiological outcomes in babies less than 31 weeks gestation.

This project was reviewed by the Committee for the Conduct of Ethical Research at its meeting on 24 November 1995.

I am pleased to advise that the project complies with the provisions contained in the University's policy for the conduct of ethical research, and has been cleared for implementation.

Period of approval is from 1 January 1996 to 31 January 1999.

Yours sincerely

ROD CROTHERS
Executive Officer

28 November 1995

Please note: Students conducting approved research are required to submit an ethics report as an addendum to that which they submit to their Faculty's Higher Degrees Committee.

cc:

Dr Patricia Percival, Supervisor

A/Professor Steve Barrie, Academic Registrar

Mrs Gerrie Sherratt, Secretary H.D.C.

Princess Margaret Hospital For Children Perth, Western Australia

Herer Enguir et to

2037:Monterosso

Dr J Andrew Cumming

340 8245

Telephone

12 December 1995

Ms Leanne Monterosso Clinical Nurse Special Care Nursery King Edward Memorial Hospital SUBIACO WA 6008 Princess
Margaret
Hospital for
Children

Roberts Road Subiaco WA 6008 GPO Box D184 Perth WA 6001 Telephone (09) 340 8222 Facsimile (09) 340 8111 Facsimile (09) 340 8115

Dear Ms Monterosso

**REGISTRATION NUMBER:** 

035/EW

TITLE:

The effects of postural supports on 'flattened posture', thermo-regulation and physiological outcomes in infants under 31

weeks gestation.

REFERENCE NUMBER:

EC95-29.5 16 November 1995

The Ethics Committee has recommended and the Board of Management has ratified that provisional approval be given for you to undertake the abovenamed research study

Approval is given subject to:

Clarification of who would be recruiting the subjects. This information is to also be including in the documentation.

Appendix D - Schedule of information to be amended. Third paragraph to be altered to state "one in three groups" in line with the study design. The wording of the letter needs to be standardised. e.g. to be first or second person through the letter. There is also no indication that the baby is only to use the product while in an intensive nursing situation.

Clarification is also required of the financial aspects of the project.

The above conditions and amended documentation need to be approved by Professor Michael, Chairman of the Scientific Advisory Sub-committee at KEMH.

The Ethics Committee does however wish to be informed immediately of:

I. any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these.

- II. substantial changes in the research protocol together with an indication of ethical implications, and
- III. other unforeseen events.

The Ethics Committee has been charged with the responsibility of keeping the progress of all approved research under surveillance. A copy of the final result must be forwarded to the Committee upon completion of the research or if the research is not completed within six months you are asked to submit a progress report and annually thereafter. This information should include:

- a) The status of the project (completed/in progress/abandoned/not commenced).
- b) Compliance with conditions of ethical approval, including security of records and procedures for consent.
- c) Compliance with any special conditions stated by the Ethics Committee as a condition of approval.
- d) Results from the study to date, including outcome.

Please note that approval for studies is for three years and the research should be commenced and completed within that period of time. Projects must be resubmitted if an extension of time is required.

Please quote the above registration number on all correspondence.

Yours sincerely

### Dr J/Andrew Cumming Director Medical Services

- cc: Professor Michael, Chairman Scientific Advisory Sub-committee
- \* The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's Statement on Human Experimentation and Supplementary Notes.

### Appendix M

### **Postural Support Study**

Information for Parents of Potential Participants
Consent Form

# INFORMATION FOR PARENTS OF POTENTIAL PARTICIPANTS Postural Support Study

A study of the development of "flattened posture" in the premature baby is being conducted by myself, Leanne Monterosso, a PhD Nursing student at Edith Cowan University. I may be contacted by telephone on 340 2099 (work) or 276 2840 (home). The School of Nursing at Edith Cowan University may be contacted if you have any further questions on this number - 273 8333. The participation of both you and your baby in the study would be appreciated.

Initially, all babies are usually be nursed prone (lying face downward) because it helps with their breathing and feeding. The prone position is very different to that in the uterus where babies lie in a curled position which contributes to the development of posture. Babies that are born premature do not experience the full benefit of this curled position, therefore, I would like to provide an environment which has similar postural benefits to that of the uterus.

I wish to study whether the use of postural supports may provide a similar degree of flexion to that which they receive in the uterus as babies grow to full term. This will involve random allocation of babies to one of three groups which means that your baby will be nursed with: a) a cloth postural support nappy and a postural support roll, b) a disposable nappy and a postural support roll, or c) a cloth postural support nappy which is the current practice in all areas of Special Care Nursery. This means that your baby will receive at least one of two postural supports.

Measurements of hip and shoulder posture will be taken before your baby commences in the study. Thereafter, the measurements will be repeated after four to six weeks, then at term and at 4 and 8 months corrected age. The term, 4 and 8 months corrected age measurements will coincide with your baby's follow-up assessment appointments.

This study involves no risks for your baby. The study will take place while your baby is being nursed in the prone position which may occur in all areas of Special Care Nursery. Eventually, your baby will be nursed on its side unless there is any medical reason for continuing prone posturing.

### CONSENT FORM

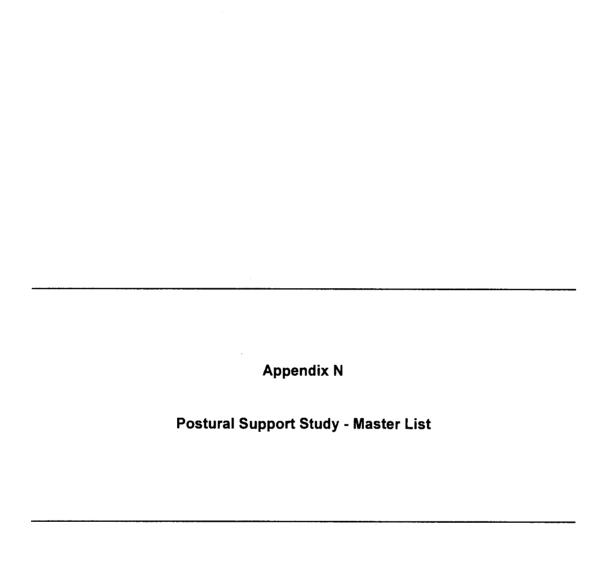
### **Postural Support Study**

I have read and understood the Schedule of Information for Parents of Potential Participants and any questions I have asked about the study have been answered to my satisfaction.

I have been informed that:

- a) The study will be carried out in a manner conforming to the principles set out by the National Health and Medical Research Council.
- b) I give consent for my baby to participate in the study and providing our identity is not disclosed.
- c) The research data obtained from this project may be published in scientific journals.
- d) My baby's participation in this study is voluntary and without financial involvement. No risk to my baby will occur as a result of the proposed treatment. I may withdraw my baby from the study at any time, and the care of my baby or my relationship with the health team will not be affected.

I, have been asked to participate in the abo						
research study, which has been e	explained to me					
by I understand its aims and how I will be						
involved and hereby give my writing	ten consent.					
Baby						
Family Name	Given Name					
Parent Name						
Signature of Parent						
Date						
Witnessed by						
Signature of Witness						
D - 1 -						



### Postural Support Study - Master List

Code	Unit Medical Record Number Label				

•	Appendix O	
	Infant Posture Assessment Tool (IPAT)	
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Infant Posture Assessment Tool (IPAT) - Birth to Term Conceptional Age	Score			
<ol> <li>Weightbearing Surface of Inner Thigh and Knee (Lacey et al., 1990)</li> <li>Legs in widest abduction and external rotation, whole length of medial aspect of thigh, lower limb and foot resting on mattress, feet everted.</li> <li>Medial aspect of knee, lower limb and foot resting on mattress, slight elevation of pelvis.</li> <li>Medio-anterior aspect of knee, part of thigh raised above mattress, heels elevated &lt;45° from mattress.</li> <li>Anterio-medial aspect of knee, thigh raised above the mattress, heels elevated &gt;45° from the mattress.</li> <li>Anterior surface of knee rests on the mattress, thigh raised above mattress, feet in line with lower limb, or, inverted.</li> </ol>				
Angle of Pelvic Elevation (Lacey et al., 1990)	<b> </b>			
Angle of External Rotation of Leg from Lateral Support (Lacey et al., 1990)				
40"				
Distance between Acromion Process and Suprasternal Notch				
Scarf Sign (Ballard et al., 1979)				
1 2 3 4 6				
Spontangous Arm Movements (Lacey et al. 1990)				
Spontaneous Arm Movements (Lacey et al., 1990)  1. Global movements without elbow flexion (i.e., arms straight).  2. Wide arc shoulder movements in body plane (i.e., arms "windmilling").  3. Hands to midline across chest, or, brings dorsum of hand to face.  4. Hands to face - not central (i.e., brings palm of hand only to face).  5. Goal directed hand to mouth movements.				

	Infant Po	sture Assessme	ent Tool (IPAT)	- 4 Months Co	onceptional Age	Score
2. 3.	Finger-Finger Play in Supine  1. Does not bring hands together in the midline.  2. Brings hands together in the midline but does not swipe or grasp.  3. Swipes and may hold a toy while positioned underneath a frame. Arms resting on the chest. Toy positioned within reaching distance.  4. Reaches for and holds a toy while positioned underneath a frame. Arms lifted away from the body. Infant completes a full reaching distance. Toy is placed slightly higher than above reaching distance.					
2.	Reaching from Prone Forearm Support  1. Does not reach for a toy when prompted in the prone forearm support position.  2. Leans into toy when prompted. Does not actively weight shift with elbows or forearms.  3. Controlled reach - active weight shift onto one elbow to enable an active reach for a toy with other arm.					
W	eightbearing	through Shoulder	s & Spontaneous	Leg Movements	(Piper & Darrah, 1994)	
ئ			25			
	1 2 3 4 5 Hands to Feet (Piper & Darrah, 1994)					
\$ E					ezizeo	
	1	2	3	4	5	

Infant Posture Assessment Tool (IPAT) - 8 Months Conceptional Age					Score
Crawling (Piper & Darrah, 1994)					
1	2	3	4	5	
Rolling (Piper & Darrah, 1994)					
A Committee of the Comm				25	
1	2	3	4	5	
Sitting (Piper & Darrah, 1994)					
G.		1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -			
. 1	2	3	4	5	
Supported Standing (Piper & Darrah, 1994)					
Sing.					
1	2	3	4	5	
Foot Progression Angle (Downs et al., 1991)					